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

FRIDAY, JULY 16, 2021

10:00 A.M.

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APPEARANCES

PANEL MEMBERS:

Megan R. Schwarzman, MD, MPH, Chair

Carl Cranor, PhD, MSL

Oliver Fiehn, PhD

Ulrike Luderer, MD, PhD

Thomas McKone, PhD

Penelope (Jenny) Quintana, PhD, MPH

Veena Singla, PhD

OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT:

Vince Cogliano, PhD, Deputy Director, Scientific Programs

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

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

Shoba Iyer, PhD, Staff Toxicologist, 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

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APPEARANCES CONTINUED

CALIFORNIA DEPARTMENT OF PUBLIC HEALTH:

Jianwen She, PhD, Chief, Biochemistry Section, Environmental Health Laboratory Branch

Nerissa Wu, MPH, PhD, Chief, Exposure Assessment Section, environmental Health Investigations Branch

DEPARTMENT OF TOXIC SUBSTANCES CONTROL

June-Soo Park, PhD, Chief, Environmental Chemistry Laboratory

PRESENTERS:

Ryan Allen, PhD, Simon Fraser University

John Balms, MD, University of California Berkeley, University of California, San Francisco

Maggie Clark, PhD, Colorado State University

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PROCEEDINGS

MS. JARMUL: Okay. And now I'd like to go ahead and introduce Vince Cogliano, who is the Deputy Director for Scientific Programs of the Office of Environmental Health Hazard Assessment, or OEHHA. Vince is stepping in today to give the welcome on behalf of Lauren Zeise, OEHHA's Director.

DR. COGLIANO: Good morning, everybody. I'd like to welcome the Panel and the audience to this meeting of the Scientific Guidance Panel for the California Environmental Contaminant Biomonitoring Program, better known as Biomonitoring California. I want to thank you all for participating and for sharing your expertise.

The Panel last met on March 8th, 2021 and here's a brief summary of the meeting. After the Program update, the Panel provided input on options for statewide biomonitoring surveillance. The remainder of the meeting focused on the Panel's consideration of the class of quaternary ammonium compounds, also known as QACs, as potential priority chemicals. The Panel's deliberations were informed by guest presentations on increased exposure to QACs during the COVID-19 pandemic, by environmental detections, biomonitoring analytical methods, and safety evaluations, as well as public comment.

The Panel voted unanimously to recommend that the

class of QACs be added to the list of priority chemicals for Biomonitoring California. In making this recommendation, Panel members highlighted the following items: significant data gaps in exposure information and the high potential for exposure in California; detections of QACs in human blood and urine samples; known and suspected human health effects; and the importance of adding the class of QACs to the list of priority chemicals as production is rising, so we wanted to capture the trends in exposures.

Panel members requested that OEHHA implement a conflict of interest procedure for guest speakers and we've done so. So guest speakers are now advised that for purposes of preparing presentations to the Scientific Guidance Panel, conflict of interest should be disclosed if they, or their employer or sponsor, have a financial, commercial, legal, or professional relationship with other organizations, or with the people working at them that could influence their research. They're asked to include a slide at the beginning of their talk either to state that they have no conflict of interest to disclose or to describe any conflict of interest that they have.

A summary of input from the March meeting, along with the complete transcript, is posted on the March Panel meeting page at biomonitoring.ca.gov.

Because we're meeting virtually today, I would like to have the Panel members introduce themselves. I will call on each member and ask you to unmute yourself and state your name and affiliation.

So I'll begin in alphabetical with Carl Cranor.

MS. JARMUL: Carl, I think you're muted.

DR. COGLIANO: Okay. We'll come back. Carl, you're still on mute, but we'll come back to you.

Oliver Fiehn.

PANEL MEMBER FIEHN: My name is Oliver Fiehn. I'm a professor at the UC Davis Genome Center. I'm an analytical chemist and like to look at both low abundant molecules as well as complex mixtures of molecules.

DR. COGLIANO: Thank you.

Ulrike Luderer.

PANEL MEMBER LUDERER: Hi. My name is Ulrike Luderer. And I am the Director of the Center for Occupational and Environmental Health at UC Irvine, and my research area is reproductive toxicology.

DR. COGLIANO: Okay. Thank you.

Tom McKone.

PANEL MEMBER McKONE: Hi. I'm Tom McKone. I'm a Professor Emeritus at the University of California, Berkeley School of Public Health. And I'm also an affiliate at the Lawrence Berkeley National Laboratory.

These are both institutions that I've spent more than 25 years working at, but now I'm in retirement, but still active in some areas.

DR. COGLIANO: Thank you. Jenny Quintana.

PANEL MEMBER QUINTANA: Hi. My name is Penelope, or Jenny, Quintana. I'm a Professor in the School of Public Health at San Diego State University in the area of environmental health. And my area is environmental justice in communities at the U.S.-Mexico border and exposures to children.

DR. COGLIANO: Okay. Thank you.

Veena Singla.

PANEL MEMBER SINGLA: Good morning. I'm Veena Singla. I'm a Senior Scientist with the Natural Resources Defense Council in the Healthy People and Thriving Communities Program. And I work on healthier indoor environments and bringing the most current scientific principles and data to inform policy.

DR. COGLIANO: Okay. Thank you.

Let me come back to Carl Cranor. I see you're still muted, it looks like.

MS. JARMUL: Carl, you need to click the red -- I sent an unmute request, if you could click the red microphone button.

PANEL MEMBER QUINTANA: I had the same thing

happen to me, Carl. The button disappeared, but at the very top of the line, you can go to audio at the very top of your screen on the menu option, and then under audio, you can do unmute.

DR. COGLIANO: Well, it looks like there is a difficulty there. Anyway, that's Carl Cranor from the University of California, Riverside.

MS. HOOVER: Yeah. And Vince, this is Sara Hoover. I'm just going to chime in to tell Carl, Carl, if you have -- you know, we'll try to troubleshoot on a break. And if you have questions, in the meantime, you can put them in the chat or email them to the Biomonitoring California email address and we'll read them aloud.

DR. COGLIANO: Thank you very much. And now, I'd like to turn the meeting over to Meg Schwarzman who's our Panel Chair.

Meg, it's up to you.

CHAIRPERSON SCHWARZMAN: Thanks. I think I'm unmuted. You can hear me okay?

DR. COGLIANO: Yes, we can.

CHAIRPERSON SCHWARZMAN: Great.

I am Meg Schwarzman. I am at the UC Berkeley School of Public Health in the area of environmental health sciences.

And I as Chair of the Panel and today's meeting want to start by announcing the goals for today's meeting. The first item of the day, as usual, we'll receive a Program update and a little less as usual provide input on the recommendations for Biomonitoring California's Seventh Report to the Legislature.

We'll next hear a detailed update on the targeted biomonitoring study in an AB 617 community and will provide comments on their current plan -- on that current plan.

And the remaining -- remainder of the meeting, we'll focus on the use of biomarkers of effect in air pollution studies, including intervention studies that use air filtration. We'll start with presentations by guest speakers from University of California, Simon Fraser University, and Colorado State University.

And after those presentations, we will have -- excuse me -- an open discussion with the guest speakers and the audience. And that will focus on topics including study design issues in air pollution biomonitoring studies, timing of urine sample collection, given whichever biomarkers are being used -- measured, which factors should be included in questionnaires to participants, and interpreting results for biomarkers of oxidative stress and inflammation as indicators of

exposure. So we'll be having an open discussion about that and hopefully providing some input.

There will be time for questions from the Panel and the audience as usual after each presentation. And during the question periods after each talk, speakers should remain unmuted with their webcam showing, so that they can respond to questions from the Panel and from the audience.

For Panel members, if you want to speak or ask a question, please just physically raise your hand, not in the interface in the GoToMeeting. And I will call on you at the appropriate time. You can then unmute yourself to ask your question or provide your comment.

Attendees of the webinar, if you have questions or comments during the question periods after each talk, you can submit them, as Stephanie said earlier, via the question feature of GoToWebinar or by email to biomonitoring@oehha.ca.gov. Please keep your comments brief and focused on the items under discussion and we'll read aloud relevant comments. We'll paraphrase them, if necessary.

During the public comment periods in both the morning, and the afternoon, and during the afternoon discussion session, we also welcome oral comments live from webinar attendees. And if you want to speak, please

use the raise hand or question feature in the GoToWebinar platform and we'll call on you at the appropriate time.

So I want to start by introducing for our first agenda item, Nerissa Wu. Nerissa Wu is Acting Chief of the Environmental Health Investigations Branch at the California Department of Public Health. And she is overall lead for Biomonitoring California.

She'll provide an update on current Program activities and request Panel input on recommendations for the Seventh Report to the Legislature.

DR. WU: All right. Good morning.

(Thereupon a slide presentation.)

DR. WU: Let me show my screen here.

Woops. Do you see my slides?

CHAIRPERSON SCHWARZMAN: (Nods head.)

MS. JARMUL: Yes, but not in presenter mode.

DR. WU: Yeah. And I'm having trouble kind of getting into minimizing my GoToMeeting so that I can change them into presenter mode.

Here we go.

MS. JARMUL: There we go.

DR. WU: Okay. All right. And I just want to make ond correction. I'm no longer the Acting Branch Chief at EHIB. We do have a permanent Branch Chief at this point, but I am still a Program lead. Good morning,

everybody.

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DR. WU: I have 15 minutes to update you on a number of activities, so I am going to crank through these fairly fast.

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DR. WU: I want to start off by talking about the budget. And this is a slide that's familiar to many of you depicting the Program's budget over the past five years. But I have the great pleasure of bringing some good news to this Panel. We have a new State budget that has just recently been signed that includes an additional $2 million appropriation for the Program. So given our -- I know, yay. Given our baseline funding of about 2.2 million, this represents a really significant increase to the Program. So 14 years after the formation of the Program, this is our first permanent State budget increase.

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DR. WU: It's very recent news. So it's pretty premature to be talking about how this money will be spent within the Program. But in general, the funding is intended to support surveillance to track temporal trends and to help us interpret the results of community-focused exposure studies. The funds will be used to hire more

staff, laboratory analysts, epidemiologists, health program specialists, basically all the people that are needed for the different aspects of biomonitoring.

And there's also, for the first time in our Program's history, State funding to support the operations of the Program, purchase of supplies and so on. So really grateful for this. Big thank you to our supporters, who have worked so hard over the years to raise awareness of the importance of biomonitoring.

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DR. WU: We do have some staff changes to announce. We have a new Research Scientist III in our epi group, Dina Dobraca, who was actually with the Program, 2010 to 2012, so she's not entirely new. Welcome back, Dina. We're very excited to have you in the Program.

We also have a couple of departures shown here in red. Julia Varshavsky who has been with OEHHA for the past year, has taken a position at Northeastern University, where she'll be an awesome addition to their faculty. And Jennifer Mann retired in May. Both super talented epidemiologists who made enormous contributions to the Program. So we very much appreciate their work and we miss them.

CDPH staff continue to be redirected for COVID work, although to a lesser extent than before. But

between staff changes, and redirections, and we're all still mostly teleworking, it has not been an easy time for us to work as a team and to maintain a sense of continuity. So kudos to everyone who has worked really hard to remain productive and to take on all these extra burdens.

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DR. WU: One example of a task that's made much harder by teleworking is results return. When we create the results return packets, it's really an all-hands-on-deck kind of situation, which was made a lot harder by not being able to assemble and physically work on the packets together. But results for CARE-3, our 90 participants, have been sent out. These bound packets have been a standard of the Program for many years, so those of us who are not in the weeds of producing those packets might not -- might not know what goes into them. So I just want to acknowledge the hard work that goes into producing these packets. It's many hours of writing up fact sheets, data management and analysis, formatting, making sure all the data ends up in the right place for the right person, and then gets bound up in this nice packet.

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DR. WU: And we did get some positive feedback

from our CARE-3 participants with a couple people noting how impressed they were with the information provided. It's also really great to get feedback and suggestions from participants to help us understand how we can be useful to our participants.

So, for example, one participant noted that it would be helpful to get a summary of results, so they could give it easily to their medical provider. This kind of feedback is great, because we're always trying to tweak and improve our results material. And our goal is always to be as useful as we can be to our participants.

So now that results are out to participants, we can turn to conducting our demographic analyses and getting summarized data posted. There are many different ways we try to distribute our findings, both to individual participants, but also to a broader public. And this was -- I'm going to go back a couple slides. I did not have an X here to indicate that we have another product coming out, because it's just been finalized this week. But we've just finalized a four-page newsletter style publication on the CARE-LA results that we'll be able to post and otherwise disseminate. So that will be coming out in the next couple weeks. And this is a format we hope to use to broaden our distribution of study findings.

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DR. WU: So as we've discussed in the last couple meetings, we are continuing to explore options for surveillance to determine the best study design to implement in the coming years. As part of that, we're putting significant effort into looking back, documenting and evaluating CARE. And we're doing a similar effort with BEST, taking a look at the methodology and the data that was collected. I think it's really important to look back in order to move forward. It helps us identify lessons learned and to weigh some of the different design choices that we've made in the past.

One of the issues we've been discussing is weighting both for BEST and CARE data. We want to compare our data between regions, between California and NHANES. And actually external researchers use our data as a basis for comparison for their own studies. The data that we have posted and that we've presented here and other forums has been unweighted, which is fine as a reflection of study statistics. But if we're going to use this data as population -- population tendencies, we need to be able to weight the data so that it reflects the underlying population.

For a number of our analytes, such as PFAS, there are associations with sex, or age, or race. And so using data that's unweighted for those parameters to calculate

central tendencies can give us a skewed geometric mean, for example. So we're putting some effort now into weighting the previously collected data. And it's also helping us think about when we go to design a future study, how do we generate the most useful data possible.

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DR. WU: We're also in the process of producing a report on the CARE study, which is something that we haven't done for projects in the past. It's a significant task, given the scope and complexity of CARE, but it's another opportunity for us to really evaluate how we did and also share the methodologies and findings with a wider audience.

So the report will include information on field and lab methods, and study results, summaries per region, participant demographics, as well comparisons between regions. And this is data that has been presented in this forum to an extent, but this will be a more detailed version of that.

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DR. WU: We're also continuing to look ahead to explore potential collaborations. For example, we've met with the Childhood Lead Poisoning Prevention Branch within CDPH to talk about how we might work together to conduct surveillance of pregnant women to identify women with

elevated lead and mercury levels, so that we can target intervention and reduce exposures among pregnant women and newborns. This is similar to what Minnesota and New Jersey programs have done.

And we're continuing to talk to colleagues from other states. New Jersey has come up with a temporal comparison for their PFAS data using weighted data. New Hampshire and Massachusetts are coming out with reports on their first round of surveillance. And we have the current CDC grantees, New Jersey, New Hampshire, Minnesota, Michigan, and Iowa starting up their field work. So we're following their progress, watching their study designs to help inform our path forward.

So we're going to continue this exploration of different surveillance methods over the next year. With our recent budget news, we're more hopeful that we'll be able to implement some of the ideas we've discussed and we'll continue to report back to you to get feedback.

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DR. WU: So I just want to turn to laboratory activities. We haven't been in the field this last year, but the labs have been very busy with collaborations. EHLB has been working on the PRECATO study to measure tobacco and cannabis exposure among pregnant women. They're also working with the Women Workers Biomonitoring

Collaborative to look at PAH levels in firefighters at multiple time points following participation in a fire response.

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DR. WU: ECL has been working on the Discovery of Novel Environmental Chemicals in Maternal-Infant pairs doing non-targeted screening on 300 paired maternal and cord blood samples. They're also involved with the Women Worker Biomonitoring Collaborative using non-targeted screening to compare chemical exposures between firefighters, office workers, and nurses; the PFAS and Maternal Cardiovascular Disease Risk, looking at PFAS levels in 250 study participants; the EaRTH Center, measuring POPs, and flame retardants, and non-targeted screening. And the N of that is still to be determined. And finally, there's the Environmental Influences on Child Health Outcomes, or ECHO, Pediatric Cohorts for which they're looking at PFASs in mothers, both in California and Illinois with a total N of about a thousand.

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DR. WU: Both labs are also actively working on developing or improving methods, mercury speciation, a method to measure stable VOC metabolites in urine, expanding -- or automating the expanded PFAS panel, as well as developing a new QC -- GC-QTOF non-targeted method

to screen for volatile and semi-volatile chemicals.

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DR. WU: And finally, I want to talk about the legislative reports. Just a reminder that our founding legislation calls for the submittal of legislative reports every two years. So Report 7, which covers July 2019 to June 2021 is due at the end of this calendar year. So we're working on that now. As you might remember from our last Leg Report, Leg. 6, we include program recommendations from this Panel. And for Leg. 6, there was a discussion at the July 2019 meeting about what this would include. And you can see the recommendations as they -- as they ended up in Leg. Report 6.

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DR. WU: So things like maintain core laboratory capabilities and develop innovative and efficient laboratory methods, improve the CARE study, conduct biomonitoring studies that seek to better understand and mitigate environmental health inequities, expand assistance to local agencies, expand and improve health education, conduct biomonitoring studies that seek to better understand and mitigate environmental health inequities, and --

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DR. WU: Woops. Did I already say that one?

And conduct biomonitoring studies to evaluate the effectiveness of regulatory programs.

Sorry I went a little out of order.

So we'd like to have a similar list of Panel recommendations to include with Leg. 7.

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DR. WU: And over the past couple of years, we've had a lot of discussion about the directions of the Program, what to prioritize and where to focus our surveillance efforts. So in these next couple of slides, there are things that we have captured from those meetings. Some of them are similar to Leg. 6. They're recommendations that are kind of eternal for the Program, I guess. But this list is not exhaustive and it's certainly not a closed list. You can continue to add or delete from this list or elucidate on an idea that's on here.

I will say that it's most helpful to us if the recommendations are specific. All the ideas are important, but it's helpful if not everything is a priority. And I guess the other thing I'd say is it's helpful if the recommendations are feasible, given our program limits. Because even with our new expanded budget, we clearly can't do everything. So it's good to be aspirational, but it's helpful for us to get a sense of

recommendations are within our -- within a feasibility.

So some of the recommendations are about general program directions, things like conducting studies that seek to better understand and mitigate environmental health inequities, design studies to focus on differences across demographics and types of communities like rural versus urban, conduct intervention studies to link community needs with biomonitoring, prioritize studies of exposures among children, study impact of wildfires not only among firefighters, but also clean-up crews and field workers.

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DR. WU: Promote fee-for-service laboratory capabilities to help us support the Program, maintain core lab capabilities, develop innovative and efficient lab methods, and ensure that study results are distributed to the broader public.

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DR. WU: Some of the feedback we've heard has been more specifically related to surveillance from our last couple of meetings and we've heard the following, that we should consider less expensive ways to collect samples, things like in-home self-collected samples or using banked samples, or perhaps even turning to using wastewater treatment samples that is an indicator of

exposure as compared with our current urine and blood collection.

We've heard that we should collaborate with others on participant recruitment, interpretation of non-targeted screening data, and data analysis, helping bring in some expertise perhaps from doctoral students, ensure that surveillance studies reflect the population with respect to education and income level.

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DR. WU: We should recognize that studies can't address all questions and so we should prioritize temporal trends over geographic trends, conduct studies that can help evaluate the effectiveness of regulatory programs, publicize policy-relevant studies, and we should focus on what makes California different, so we're not replicating work that exists in other forums.

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DR. WU: So those are some of the recommendations that we've heard over the past couple of years. And again, this is not a final list, but we would able to be -- we would like to be able to include formal Panel recommendations in our next Leg Report. So perhaps in the discussion, we can talk both about what should be retained in this list, further things to add or delete, but also discuss a process by which this list is finalized and

provided to us.

So I want to stop there. I want to thank the Panel for your attention and support. Thank our stakeholders again for the amazing work you've done over the years for the Program, and, of course, thank the staff of Biomonitoring without whom none of this would be possible.

CHAIRPERSON SCHWARZMAN: Thank you so much for that, Nerissa. And it's so great to have the good news. Congratulations to you, and to the staff, and to everyone who has advocated for that change over the years. I think it's a pretty wide community.

I want to open it up to questions from the Panel for Nerissa. And we'll have a Panel discussion about those legislative -- the legislative report priorities in a minute, so this is just a moment for questions to Nerissa.

Yeah, Jenny.

PANEL MEMBER QUINTANA: Hi. I was happy to hear the good news. But the question I have is over the years we've talked about that this Program has not been funded to do the initial intent of the Program, which was to provide a population-weighted snapshot of all of California, similar to the NHANES, CDC Environmental Health study. And so I guess my question is how much does

doubling your budget bring you to being able to do it quote unquote right, to do the study that was envisioned when this Program started? Like I think it's still short is my gut feeling.

DR. WU: Yeah, that's a really good question. And I don't want to stand up here and say give us more money. But the initial assessment of what this Program was initially envisioned to do was 10 to 12 million dollars and that was in 2006-2007. And when we've done sort of updated assessments of what it would take using the CARE template to do sort of a two- or three-year cycle around the state, it was similarly 12 to 14 million dollars.

So clearly a $4 million budget is not going to accomplish that. I think we need to continue down the path of finding alternatives to that full State probabilistic model, but I think there's a lot more we can do. I think we have some really good potential study designs that will help us have the most public health impact we can, perhaps not the all-encompassing surveillance we'd like to do, but it will help us accomplish those goals. And it's still -- you know, it's still a doubling of our budget.

CHAIRPERSON SCHWARZMAN: Tom.

PANEL MEMBER McKONE: Thank you for the

presentation. Very informative. I'd like to add another question on a similar line, but more about the stability of the two million. You indicated that it would be lasting, but I guess the question -- you know, a lot of different organizations, agencies of the State got additional money this year, because there was a big surplus and they really wanted to get the surplus out. But we don't -- I mean, is there any sense of how stable that might be or when we'll get to a point where all of that added money is going to be pulled back?

DR. WU: The allocation as described is it's general fund and it's described as ongoing annual funding, which is awesome news. Budgets change though, so it's not -- nothing is guaranteed, but it is currently in our budget as ongoing.

PANEL MEMBER McKONE: Thank you.

CHAIRPERSON SCHWARZMAN: We have 10 minutes for public comment now before we go onto the discussion and provide the Program with some input about the Leg Report. So I want to check with Shoba if there's any comments on the public, and Stephanie I guess, on the webinar or the email.

DR. IYER: I'm -- this is Shoba. I'm checking and I'm not seeing any hands raised or comments in the chat or questions.

CHAIRPERSON SCHWARZMAN: I'm actually just going to give it a minute, since I just announced that and we're a little bit ahead of schedule. So why don't we just give it a minute in case there's somebody who wants to participate at this moment for the discussion of the Program update and the legislative report, and then we'll turn to that discussion.

DR. IYER: That is a great idea, because we did just get a question coming in, so I'll read it allowed. This is from Ahimsa Porter Sumchai. And I think it's a comment saying I would like to encourage Biomonitoring California to include in its recommendations the use of geospatial mapping in survey work to identify patterns and distribution of exposure and to promote the use of advanced environmental justice and screening tools, including the EPA EJ screen that allows mapping of 11 environmental indicators, including PM2.5, lead based paint proximity, traffic volume and proximity, hazardous waste and Superfund proximity, and diesel particulates.

And so that was one comment.

We have another comment from Nancy Buermeyer about groups that supported the budget augmentation. So I can go ahead and read the list that she's provided here, which is quite extensive. Shall I read it aloud?

MS. HOOVER: Hi, Shoba. This is Sara. No, I

don't think that's necessary.

DR. IYER: Okay.

MS. HOOVER: We can just have it as part of our record and just note that we have that information.

DR. IYER: Great. And thank you for the information, Nancy.

And those are -- those are the only written questions I'm seeing come in.

CHAIRPERSON SCHWARZMAN: Great. Thank you so much, Shoba. And we will continue to have opportunities for public comment after each presentation. So just keep that in mind if you're listening and you can tee up your questions and we'll try to -- since it follows the Panel question session, folks can just kind of know that if they -- while the Panel is asking clarifying questions, they could submit questions or indicate on GoToWebinar that they have a question and we'll make sure to get it into that -- into that moment in the agenda.

So thanks, Shoba, for doing that on the fly.

Let's see, Sara, I guess -- so we're going to start the Panel discussion now about the recommendations for the legislative report, and -- but I had a question to start us off that's kind of for Sara Hoover, which is responding to the public comment that we just received about encouraging the use of geospatial mapping and

specifically the EPA EJ screen. And I'm wondering if you could say anything about the Program's use of that versus the CalEnviroScreen indicators that's specific to California. Do you have anything to --

MS. HOOVER: I don't --

CHAIRPERSON SCHWARZMAN: Okay.

MS. HOOVER: No, I don't have anything to say, but we'll -- you know, this will be in the transcript and it's something we can follow up on. I will also invite Nerissa. I don't know if you wanted to say anything about that particular comment, but I think we'll just --

DR. WU: No, thanks, Sara.

MS. HOOVER: Sorry?

DR. WU: No, I do not have a comment.

MS. HOOVER: Yeah. Okay. Yeah. And also, Meg, feel free, in addition to discussing the Leg Report recommendations, you can feel free to provide input on other elements of Nerissa's update.

CHAIRPERSON SCHWARZMAN: Okay. Great. And by that, I assume you mean basically sort of program priorities and next steps on the various projects that Nerissa updated us on.

MS. HOOVER: Yeah. Yeah.

CHAIRPERSON SCHWARZMAN: Great. Okay. I guess just to close out that topic that I just raised, and then

I want to open it up to the Panel for discussion of the Program priorities and discussion of the recommendations for the legislative report, is, you know, I hear -- I hear that comment as being very much in line with the priorities that we'd expressed in the -- to the Program for -- at the timing for Leg. Report 6 and also in the comments that Nerissa highlighted about things that have sort of come up over the last couple of years that could feed into Leg. Report 7, if we want to, about making sure that we are looking at uneven distributions of exposures among populations and specifically with an eye toward environmental injustices and inequities.

And so I think I support those comments and then just have that open question about how the Program has used the EPA EJ screen, and whether it feels like a useful addition, since in California we do have the much more California specific CalEnviroScreen that lets us draw on those metrics of California communities. I think that's all I wanted to say about that.

Tom.

PANEL MEMBER McKONE: Yeah. So we do have a special tool that's quite impressive in CalEnviroScreen. But, you know, in terms of the comment about making better use of satellite data and other kinds of surveillance, I think it might be -- you know, I don't know who's around

on this that's into it. It might really be more of an OEHHA broader agenda to consider integration of CalEnviroScreen results or some sort of augmentation of those results.

With all of the emerging GIS, all of the mapping data, all of the things that people are doing for that also. And I don't know, I mean, it could be a small effort, but there is -- there is a lot of new information coming out of these mapping tools. And I think rather than say CalEnviroScreen does everything we need at this point, it might be useful to say, well, let's just check into this and see if it could be enhanced with some of that information.

But, you know, I don't know if -- I don't know if that's necessarily a recommendation that's biomonitoring specific. I think that's more specific to the whole agenda of trying to understand the distribution, inequities, time, history, the interaction of social and environmental factors. That's a much broader agenda than biomonitoring. So we might say something on that, but I actually think it's something that's a little bit odd about our realm of recommendations.

MS. HOOVER: So, Tom and Meg, I will chime in to say a little bit about this now. We actually are doing that sort of work in terms for analyzing the East Bay

Diesel Exposure Project results. We'll also be doing that type of work in our AB 617 biomonitoring study. And obviously, CalEnviroScreen has played a big part both in identifying locations for the diesel project and also for AB 617 communities. So it's definitely integrated. In fact, you know, sort of that whole concept of environmental justice is a founding principle in the enabling legislation.

We take your point though, Tom and Meg, about just focusing on tracking new tools for GIS mapping and taking those into account. That's definitely something that our analysts are aware of.

PANEL MEMBER McKONE: Thank you. That's good to hear.

CHAIRPERSON SCHWARZMAN: Thanks, Sara.

Other comments from the Panel?

It's kind of an open discussion opportunity.

Jenny.

PANEL MEMBER QUINTANA: I just want to briefly add to the past point that I think that it would be enough to say that we would try to add GIS layers as they become available that inform our biomonitoring plans, but also to use them to make sure we are addressing disadvantaged communities and populations. So maybe in using them in two ways, I think we can make a positive statement,

because CalEnviroScreen does lag a little bit behind data that's available, because they have to make a decision about which to apply to which, you know, variable.

So I think it is good to make a statement that we want to incorporate them and also use them to evaluate our programs. But is this the open discussion part? I can say something else to you?

CHAIRPERSON SCHWARZMAN: (Nods head.)

PANEL MEMBER QUINTANA: All right, I just wanted to make sure.

Just looking at the list of priorities, the -- a couple that came to mind is that breast cancer concerns were very foundational to passing this legislation in the beginning, and activists in that area, and I just feel like we haven't, as a Program, really specifically said we'd like to address that. And it would be interesting, especially given the new capabilities and focus on non-targeted analysis, which has the potential to discover important chemicals, especially thinking of things that might inform breast cancer biomonitoring perhaps by using nested data from ongoing studies, because, of course, cancer takes a long time to develop.

But I just think that I'd like to see that in our priorities somewhere. I think that given a lot of chemicals that are endocrine disruptors and maybe ones we

don't know about, I think that would be something that our program should look at.

And then the second area I haven't seen in this list, unlike pretty much every other list I've seen for other efforts I'm involved in is explicitly mentioning climate change. And certainly that's implied in the wildfires bullet point, as we all know that wildfires are increasing in severity and number. But I think I would like to see that maybe explicitly said, that look at exposures that may increase with climate change for -- you know, as example wildfires.

Thank you.

CHAIRPERSON SCHWARZMAN: Jenny, are there any other exposures that you have in mind associated with climate change?

PANEL MEMBER QUINTANA: I was just thinking that. And I was not actually sure. I was just thinking, you know, what chemicals, the increased heat might be more -- like volatile chemicals might be higher concentrations, for example, from air pollution emitted directly from vehicles. And I don't have an answer to that. I was actually thinking of that exact question as Nerissa was speaking, so -- but I think maybe thinking about that explicitly in the future would be good. Yeah.

CHAIRPERSON SCHWARZMAN: And it sounds like even

explicitly making the connection between the interest in wildfires and climate change.

PANEL MEMBER QUINTANA: Yes, that would be --

CHAIRPERSON SCHWARZMAN: Even adding a recommendation for other things to analyze.

Tom, I see your hand. I just wanted to add on one thing to what Jenny said, and then I'll have you speak, which is on the breast cancer related chemicals, I can share with the Program very soon a draft that I'm currently reviewing that's from my research group that's a new -- in concert with Silent Spring that's sort of an updated mammary gland carcinogen paper that includes a lot more hormonally active compounds. And so just to offer that as a resource in the coming months. It's not ready today, but thank you for that.

PANEL MEMBER QUINTANA: Thank you.

CHAIRPERSON SCHWARZMAN: Tom.

PANEL MEMBER McKONE: Yeah. I just wanted to -- I mean, to follow up to that. There are studies that have indicated that climate change can augment enhance exposures through existing pollutants by changing, you know, climate conditions, hotter, drier, more or less wind. So I do think that -- I mean, I actually have been -- I did a paper on this 20 years ago about how a changing climate would affect the transport distribution

of volatile and then persistent chemicals. So there is some -- there's been more work since then, but there is -- there is work going on. So I do like the idea of making it climate related, because climate basically alters a lot of the conditions, the vulnerability of populations, and the level of exposure.

Also, I mean, just to follow up on the issue of wildfires, and I think John Balmes may bring this up, or I've talked with him about it, the, you know, wildfire particulate matter and wildfire emissions are different from PM associated with roadways and other sources. So it is a different kind of exposure. So it is -- and again, it's something we've always had, but the distribution is much wider more intense. So it is a climate-related issue and it really deserves collecting more data, because it's a new -- in a way, kind of new kind of exposure to something that was historical that is now made different by the conditions of fires and the changing climate.

So again, I do second that recommendation to kind of tie this into climate as a key part.

CHAIRPERSON SCHWARZMAN: Thanks for that, Tom.

One thing that I want to add too is that, of course, when we're looking at exposures due to wildfires, it's not just PM that's different, right? It's also because of the fires at the urban interface. Essentially,

it's exposure potentially to lots and lots of other compounds associated with what we're calling wildfires, but that actually involve a lot of built environment, and their components.

Veena, you had a comment.

PANEL MEMBER SINGLA: Thank you, yes. I third the suggestion to draw the explicit connection to climate change. And, you know, this is I'd say not necessarily a recommendation or a priority for the Program but just to note that another area of connection to climate change, something that I'm focused a lot on these days is thinking about building decarbonization, which encompasses electrifying buildings, removing fossil fuel combustion from buildings as well as building energy efficiency improvements and the effect of those on indoor environmental quality. So I'd say that's another really important area of connection between actions the state is taking on climate change and potential exposures to people in the indoor environment.

And the other comment I had is I wanted to express continued strong support on the first bullet on this slide, the studies to better understand and mitigate environmental health inequities. I think as Nerissa said, that's a ongoing important priority. And I think a couple other pieces on these slides are connected to that. In

terms of the mitigation piece -- mitigating environmental health inequities, I think the intervention studies linking community needs as something that can really help inform the mitigation question for kind of individual and community level actions. And then I believe on the next slide, there was a bullet about policy relevant studies in science and the sort of assessing the effectiveness of policy interventions.

And I think both of those are also connected to the -- this question of mitigating environmental health inequities. So I think again the environmental health inequities piece remains a priority and that there is other types of science and studies that can help inform the question of how to mitigate some of those inequities.

CHAIRPERSON SCHWARZMAN: And when you say that other sorts of studies, Veena, you're circling back to what you said about intervention studies that sort of meet the needs of a community at the same time as we're gathering data and also ones that assess the impact of policy.

PANEL MEMBER SINGLA: (Nods head). Yes, you got it.

CHAIRPERSON SCHWARZMAN: Thank you. I just want to make sure I understand.

One of the places that I'm going with this, just

to foreshadow a request that we have to -- I want to make -- I will make of you is that we, as a Panel, need to summarize these recommendations in a letter to the Program. And so I will be asking for a volunteer to help write that letter, but that's why I'm clarifying ideas and making sure I get it right.

So what other comments do panelists have about these recommendations that you see on the slides or other recommendations that you either want to highlight or make sure get in for the next round?

Is there anything on this list that you either want to disavow or, like Veena did, kind of reiterate and expand on?

Jenny, you had something.

PANEL MEMBER QUINTANA: Hi. I just wanted -- if you could toggle through again. I feel like the non-targeted analysis is not specific. Oh, here it is. There is an item that's kind of vague that this third -- the second bullet point that we're looking at right now, I think that's the only bullet point that mentions non-targeted analysis, is that correct?

DR. WU: I think that's correct. And these are sort of harvested from discussions we've had in the past, so they weren't specifically phrased as program recommendations. So certainly you can elucidate on the

point now.

PANEL MEMBER QUINTANA: Well, I think -- I just -- I think we should talk about why we want to use non-targeted analysis. And the reason I'm bringing that up is because we're just -- I'm just sort of writing a paper on non-targeted analysis in house dust. And some of what we get is drugs of abuse, for example, in the dust, which may have been left by our current participants or maybe past participants.

But I think when you have non-targeted analysis, you have such a wide net that I'd like to kind of explicitly say that what we're looking for is industrial or commercial chemicals that we didn't know, you know, were in the environment. And there's certainly many examples of those. I'm not sure if you're familiar with that story about the tire component that turned out to be killing all the salmon that was found by non-targeted analysis. I mean, that's a home run for non-targeted analysis.

So I think I'd just like to really kind of make it explicit that we're looking to see what chemicals, but we're not -- and that -- and it also brings up an issue of how we handle data like that in terms of results return to participants. So I guess I would -- what I'm saying is I think of using that as kind of a pooled -- pooling samples

to look at results rather than individual results for the IRB, the human subjects reasons, and to make it more explicit. I think this is an issue when you use non-targeted analysis.

And I know there's experts on the Panel more expert than I, but just I was thinking maybe of having a bullet point a little more targeted towards that, no pun intended.

Thank you.

CHAIRPERSON SCHWARZMAN: Okay. So that's helpful. That's suggesting that we call out as a separate point the value that we see in non-targeted analysis, not just like this as a subset of -- you know, this is obviously a comment that we were making in response to how to help with participant recruitment or how to help the staff get done all the work that needs to get done. And one of that was like this heavy burden of interpreting non-targeted screening data, but it's not actually saying we really recommend -- or we see the value of and recommend the use of non-targeted screening.

Okay. Carl.

Carl, we so far can't hear you.

MS. JARMUL: You are unmuted, but perhaps your microphone isn't working now.

PANEL MEMBER FIEHN: What sometimes helps if you

take off the earphones and just directly use the microphone of the computer and de-plug your microphone, the --

MS. JARMUL: Sorry, Carl. If you want to email your comments. We can troubleshoot during lunch.

CHAIRPERSON SCHWARZMAN: Okay. So we'll await an emailed comment from Carl. We have Ulrike and Veena and I think we also have one emailed comment about a legislative report recommendation.

MS. HOOVER: And, Meg, I will say real quick -- sorry Ulrike -- for Carl, if you -- Carl, if you want to try, I have had this experience with GoToWebinar that audio starts working again if you leave the meeting and rejoin. That will mean you're briefly out of the meeting, but if you want to try that, so that you can actually speak before lunch, you could give that a shot, and we'll just know that you'll be back.

MS. JARMUL: He did restart. Sorry, this is Stephanie, he just has another issue --

MS. HOOVER: Oh, well. Okay. Thanks, Stephanie.

(Laughter.)

MS. HOOVER: Back to troubleshooting during lunch. Apologies. Please continue.

CHAIRPERSON SCHWARZMAN: Over to you, Ulrike.

PANEL MEMBER LUDERER: Okay. Thank you. I just

wanted to say that, you know, these -- there are -- there are quite a few different, you know, items on these lists here of things that -- you know, that we would like the Program to do. And I just think, you know, maybe we should focus on maybe separating them into things that we believe, you know, are the top priorities and that are doable within the current budget versus things that we would love to see happen, like a -- you know, like what the Program was originally legislatively mandated to do, which is a population-based sample of the whole state, which we don't -- we know is not feasible currently, sort of not forgetting that that was the original idea, but then focusing on, well, what can be done, you know, which of these recommendations can be done within the budget.

And so, you know, a lot of the -- let's see -- you know, for example, you know, the one that you had -- the slide that is currently up, you know, considering less expensive ways to collect samples obviously addresses that, but also some of the other suggestion types of studies. So, you know, studies that focus on a particular community that also addresses the need to understand and mitigate environmental health equities, so, you know, focusing on environmental justice communities. And I think there's several bullets that relate to that.

You know, studying the impact of wildfires is

another one. So more focused studies, but then also say that -- you know, that ideally in the future, it would be great if the funding were available to also do, you know, a more NHANES like, you know, ongoing study that's a population based sam -- biomonitoring study that can assess temporal trends across the whole state over time.

CHAIRPERSON SCHWARZMAN: Thank you, Ulrike.

Veena, you had another comment?

PANEL MEMBER SINGLA: Ulrike said exactly what I was going to say, so that's it.

CHAIRPERSON SCHWARZMAN: Great. Thank you. And Shoba, would you read the comment that was submitted, please.

DR. IYER: Sure thing. So this is a comment that Nancy Buermeyer sent over the questions feature. She has a legislative report recommendation and that's to include a clear section that could be used as a pull-out explaining what the budget augmentation has been used for and allowed the Program to do that would not have been possible without the additional funding. This would be very useful to advocates to continue to build and expand support for the Program.

CHAIRPERSON SCHWARZMAN: Great. Thank you. So that sounds like a recommendation to the Program in preparing the legislative update and not -- we can echo

that, but it's not something that the Panel will do.

Thank you for that comment.

Anything else? We have about two more minutes, if anyone else wants to make a comment?

And, Jenny, if you have a quick thing. Great.

PANEL MEMBER QUINTANA: I just wonder if you could toggle through again -- through the list. I just wanted to think -- maybe over the break, we could number them to help order them, if the Panel is actually going to follow up on Ulrike's suggestion to perhaps prioritize them. And I also wanted to see if we had -- I don't think we have a specific bullet point that says we want to explicitly link to promoting policy. Like, we have publicize policy studies, but I feel like -- I feel like the power of biomonitoring is very strong in terms of intervention studies to show that people got an air cleaner and their body burden dropped, or they changed their cosmetics and their -- it's a very -- it's a very -- it's a very powerful tool for advocating certain changes.

And I'm just wondering if we should more explicitly say that. I think we talk about intervention studies, but it's kind of very modest language, I guess. So I'm just wondering if that is a priority for the Program and we should be maybe call it out.

Thank you. I hope that wasn't too long.

MS. HOOVER: Hi, Jenny and Meg. Sorry, I know we have one minute. Meg, I think if you go back to the Leg. 6 recommendations, there was a recommendation about linking to -- connecting to evaluate the effectiveness of regulatory programs. I think that might be sort of along the lines you're talking about, Jenny. Is that -- or you can -- you can think about a rephrase, if you'd like to get more of your concept.

PANEL MEMBER QUINTANA: Well, I think that would be great for say CARB's clean diesel projects, that bullet point, but even things that are not linked to regulatory. Yeah, so like just maybe --

MS. HOOVER: Yeah. Like shifting market -- you know, market shift.

PANEL MEMBER QUINTANA: Yeah, like green --

MS. HOOVER: Yes.

PANEL MEMBER QUINTANA: -- using greener cleaners on something like that to put in there.

MS. HOOVER: Yeah, yeah, yeah.

PANEL MEMBER QUINTANA: Yeah, that's what I mean, I guess, as well.

MS. HOOVER: Yeah, that makes total sense. So what I -- I'm going to just chime in and say that Jenny's comment about oh, is the Panel going to work on this during the break? Not exactly. However, what we could

consider, since we're almost out of time, Meg needs a volunteer to help her work on the letter. We also could consider, if we have time at the end with the open public comment period, to let you guys look at this more, and then we could come back to that, just so you can say, okay, here are our favorite top 10 priorities, if you want to do that, because we need to do that in a public meeting. We can't do that off-line and you can't like --

PANEL MEMBER QUINTANA: I actually just -- all I recommended that you guys put numbers on these during the break, so we could vote for our numbers, that's what I was saying just to be clear.

MS. HOOVER: Well, I was talking about the vote. The vote, that would happen --

PANEL MEMBER QUINTANA: Because these -- well these are -- these are not -- not vote, but these are not numbered, so we can't say I really like number 6 and number 9. It's hard for us to --

MS. HOOVER: Yeah, these were not intended to be -- these are just --

PANEL MEMBER QUINTANA: Yeah.

MS. HOOVER: -- summarizing what you guys have told us before. They're not intended to be the official recommendations that we're saying we would include. They're just food for thought, which I emailed -- you

know, we emailed to you ahead of time a lot of your past input. Anyway, I'm going to pass it back to Meg and Meg you can decide how you want to proceed.

DR. WU: I was also going to suggest -- this is Nerissa -- that we can create a slide that has these more clustered onto fewer slides, so that you have something that's a little more easily viewed for the next discussion.

CHAIRPERSON SCHWARZMAN: Yes. And as I understand Jenny's comment, which I would support, the request for numbering isn't to order them or prioritize them, it's simply to give us a way to communicate over this thing to point to. Instead of saying the middle bullet, we can say idea number 7. So it's just (inaudible)

MS. HOOVER: Yes, I understood that. I'm just trying to figure out the mechanisms of how you're going to communicate that information to us, because we're moving on to our next item now, so that's my point. It needs to be in the meeting. So why don't we say, yes, we will -- like Nerissa said, she'll create a consolidated slide with all of these numbered. You know, maybe what we can do is in the lunch period, we'll put it up on screen, along with the other advice about we're on lunch and then you guys can view it. We can also email it to you, but we need to

provide it to the public as well. And then we can circle back in the open public comment period, if there's time, to say -- to have last comments from the Panel. Does that sound like a reasonable plan?

PANEL MEMBER QUINTANA: (Nods head).

CHAIRPERSON SCHWARZMAN: That sounds fine.

MS. HOOVER: Okay.

CHAIRPERSON SCHWARZMAN: I need a -- I need a volunteer, and it's just one, because of Bagley-Keene, to work with me doing this summary once we feel like we have an indication from the Panel. Is there somebody who would work with me on doing that basic summary to the Program?

And we don't get to go on to our next agenda item until I have a volunteer.

PANEL MEMBER QUINTANA: (Hand raised).

CHAIRPERSON SCHWARZMAN: Jenny, thank you very much.

Okay. So we will take what we can from today from later discussion, and Jenny and I will work with it, and then, you know, we will pass -- I assume -- we'll work with staff on how to pass it back by the Panel for sort of approval.

So thank you all for that discussion. And I want to go on. We're going to go on and have our update on a biomonitoring study in an AB 617 community. So I want to

introduce Susan Hurley. Susan is a Research Scientist in the Safer Alternatives Assessment and Biomonitoring Section of the Office of Environmental Health Hazard and -- Hazard Assessment. Susan will be providing an update on the targeted biomonitoring study that's being planned in an AB 617 community. And I'll let her describe the rest.

MS. HURLEY: Okay. Thank you, Meg. Let me just get my slides up here.

(Thereupon a slide presentation.)

MS. HURLEY: Can you all see that?

CHAIRPERSON SCHWARZMAN: (Thumbs up).

MS. HOOVER: Yes.

MS. HURLEY: No. Yes. Okay. All right. Now, I've just got to get rid of this. Just give me a second.

Sorry. Okay. So good morning, everyone. Before I start talking about the plans for our study, I just wanted to start my presentation with a little bit of background about how this study fits in with AB 617 activities.

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MS. HURLEY: And then I'll give a brief update on what we've been up to since the last time we presented on this project, which was back in November -- last November. Then I'll go through some of the specific plans we've got

for our targeted biomonitoring study, and finish up with some challenges that we're still grappling with and hope to get some input from all of you on today.

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MS. HURLEY: So AB 617 was passed in 2017. It's goal is -- it's overarching goal is to reduce exposures in communities that are disproportionately impacted by air pollution. So it requires engagement with communities to develop and implement air monitoring plans, as well as exposure reduction strategies. And to help implement AB 617, the California Air Resources Board, or CARB, established the Community Air Protection Program.

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MS. HURLEY: Now, OEHHA is providing support to CARB, as well as the air districts, and communities in a number of ways, including evaluating and interpreting potential health effects from air exposures, as well as evaluating health benefits from reducing those exposures. We're also identifying and tracking community air pollution concerns. And then we are designing and implementing targeted biomonitoring studies in AB 617 communities.

And so the goals of these biomonitoring studies are first to increase our understanding of air pollution exposures that are faced by people living in these

communities and also to evaluate specific emission and exposure reduction measures that these communities are pursuing.

So we're currently planning our first AB 617 biomonitoring study and that will be the topic of the rest of my talk today.

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MS. HURLEY: So we've been busy from -- really from the very early stages of our planning process, we've been engaging with AB 617 communities. We've done this through regularly attending community steering committee meetings, which has helped us learn a lot about the community's concerns, as well as some of the exposure mitigation strategies that they're pursuing.

We've also been meeting with community organizations within these communities. And this has really helped us to identify possible sites for our study.

We also have been developing or we have developed a study protocol and we've drafted the study materials. We've submitted those to the California Committee for the Protection of Human Subjects, which is the State IRB, and have obtained deferred approval, pending just some minor revisions, which we did submit a few weeks ago. So we anticipate having full approval soon, so that was -- that was a big accomplishment.

And now we are currently seeking school district approval to conduct the study in a public elementary school in Stockton.

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MS. HURLEY: So like all AB 617 communities, Stockton shoulders a disproportionate burden of air pollution exposures, as well as adverse health outcomes. For example, it ranks in the 94th percentile in the state for PM2.5. It also ranks at or above the 95th percentile for indicators of asthma, cardiovascular disease, and low birth weight.

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MS. HURLEY: The exposure concerns in Stockton, these are the ones highlighted in Stockton's Community Emissions Reduction Plan, include mobile sources, industrial processes, and port operations. Most of these exposure concerns are pretty similar to those expressed in many of the other AB 617 communities throughout the state.

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MS. HURLEY: So the main objectives of our biomonitoring study are first just to learn more about air pollution exposures to children who are living in disproportionately impacted communities and to evaluate the effectiveness of school air filtration at reducing children's air pollution exposures.

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MS. HURLEY: So we're planning to conduct our study in a public elementary school located within an AB 617 community. As I previously mentioned, we're currently targeting a school in Stockton, which is in the northern part of the San Joaquin Valley. We -- as we researched potential sites for our study, we concluded that the best option would be to do it at a school that already has advanced air filtration installed in its HVAC system. And this was really for reasons of both feasibility and timing.

And, excuse me, MERV 16 filters provide the most effective filtration or fine and ultrafine particles. So we're hoping to do it in a school that has that installed.

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MS. HURLEY: We are -- our target is to recruit from one school 60 children who are between the ages of 7 and 13 and who are in grades 2 through 6. We will be allowing only one child per household. And we also will be enrolling one parent or guardian for each child who will help with the urine collection and also will be completing questionnaires. And all participants will need to speak either English or Spanish.

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MS. HURLEY: So before going into the specific

details, I thought it would be useful just to provide a broad overview of our study design, so you can get a feel for the general picture of what we're doing.

As I mentioned previously, we are hoping to conduct the study at a school that already has MERV 16 filters installed in its HVAC system. And then as part of the study, we will also be providing additional stand-alone air filtration units in the classrooms for half the children who are in the study. And these stand-alone units not only filter for particulate matter, but they also will filter for VOCs.

And then we'll be collecting urine from the kids in the study. And then we'll be conducting biomonitoring for metabolites of PAHs and VOCs. And we'll also be measuring levels of biomarkers for oxidative stress and inflammation. We'll also be conducting some complementary air monitoring and sampling. And to help inform and interpret the biomonitoring results, we'll also be collecting additional information in other ways, such as through questionnaires and by doing walk-throughs of the classrooms, and the school, and the surrounding neighborhood.

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MS. HURLEY: So for the urine collection, we're planning to collect four urine samples from each child in

this study. So the urine will be collected on two separate days over a two-week time period. So the first two samples will be collected on one day during the first week. And then the second set of urine samples will be collected on another day the following week.

So at the start of this study, our 60 children will be drawn from a minimum of two classrooms and split into two groups. So for the first day of urine collection, all children in both groups will be in classrooms with only the MERV 16 already installed. So during this first week there actually will be no difference in the two groups. And then the first day of -- the first sample of the day will be collected before school. So immediately -- ideally a first-morning void. And then the second sample will be collected after school, so after the child has spent the day breathing the filtered air at school.

Then after this first week when we've got all the urine collected and before the second week, we will install stand-alone air filtration units in the classrooms of half the children in the study.

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MS. HURLEY: So in this schematic here, we're talking about group two. Those will be the children with the stand-alone air filtration units.

And then during this week, we will repeat the same urine collection protocol that we did during the first week. So, you know, on one day, we'll collect one sample before school, and then the other sample after school.

And for this week, the before and after biomarkers for group one and group two will allow us to evaluate the effectiveness of MERV 16 filtration alone, compared to MERV 16 combined with the additional stand-alone filtration.

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MS. HURLEY: So for the biomarkers of exposure that we'll be measuring, we'll include urinary metabolites for specific air pollutants, including these four -- metabolites of these four PAHs, as well as the stable metabolites of these six VOCs that are listed here. And the analyses will be done at UCSF under the direction of Peyton Jacob.

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MS. HURLEY: Then we also will be with measuring 8-isoprostane and 8-hydroxy-2´-deoxyguanosine, which are both biomarkers of oxidative stress. We also will be measuring biomarkers of inflammation, including CC-16 and Leukotriene E4. And these analyses will be conducted by Nina Holland's lab at UC Berkeley.

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MS. HURLEY: So to help inform the biomonitoring results, we will be administering questionnaires to gather information on factors that either influence the air pollution exposures or might impact the biomarkers of oxidative stress and inflammation.

But parents will have the opportunity of completing the questionnaire online or on paper. We will ask them to complete the questionnaire on each collection day after they give us their child's urine samples, and this is so that we can capture the relevant time frame of exposure.

The topics that we are currently considering for the questionnaires include information on demographics, some household characteristics and recent household activities. We are looking at including information about the child's diet, recent activities, and indicators for certain health conditions and medication use.

And, you know, given our small sample size, we won't be able to account for a whole lot of factors in our statistical analysis, so we really want to be very thoughtful about which factors we include on this questionnaire -- on the questionnaires to really make sure we're capturing the factors that are most important for interpreting the biomonitoring results.

We also obviously want to keep the questionnaire short just to minimize the burden on our participants.

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MS. HURLEY: So as is mandated by Biomonitoring California's enabling legislation, the individual biomonitoring results will be returned to parents who ask for them. We did get IRB approval to send the results packets electronically, so that actually will save us quite a bit of work, so that's -- that was good news. The packets will include fact sheets on the measured biomarkers, as well as possible ways to reduce air pollution exposures.

We already have a fact sheet for PAHs as a class, but -- and so now we are starting to develop fact sheets for the VOCs as well as for the biomarkers of oxidative stress and inflammation. An important part of returning results for the biomarkers of oxidative stress and inflammation will be to develop the right language for explaining these as additional indicators of exposure. We're not going to be giving health interpretations for these biomarkers.

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MS. HURLEY: So to support the interpretation of our biomonitoring results, we also will be conducting complementary air monitoring and sampling. This will

include real-time air monitoring for particulate matter and black carbon. We also will be collecting air samples, which will be analyzed for PAHs and VOCs. And the monitoring and sampling will be done both inside and outside the classroom at participating classrooms, some selected indoor common areas, and some other locations outside the school on school grounds.

So all of these pollutants have been previously linked at least to some of the biomarkers that we're measuring and we think these data will be really essential to interpreting our biomonitoring results.

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MS. HURLEY: Our -- pending school district approval we are planning to start recruitment in September. We need to get out in the field by early November, so that we can get all of our urine samples to the labs by Thanksgiving. Then the laboratory assays and data analyses will happen over the winter and spring, and -- so that we can return results to participants next summer, so the summer of 2022. And then we will be presenting the, you know, main findings of the study to the community in the fall, so fall 2022.

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MS. HURLEY: And our most immediate next step is to get school district approval to conduct the study.

Once we get that approval, we need to do a site visit and talk to school officials to get more information about the school, so we can plan some of the final details of our study protocol. This information -- you know, we need to get information about some of the physical characteristics of the school, like what type of HVAC and air filtration systems, you know, the details of that, details of the classroom, and of the children's schedule. It would also be useful to get some more information about the meal programs at the school.

We also are continuing to develop and refine the study protocol. For instance, you know, we're still trying to nail down the best timing for our afternoon sample collection. We need to identify specific recruitment events or school events for which -- you know, that we could use to recruit families into the study. And as I said, we are working to develop and refine the content of the questionnaires.

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MS. HURLEY: So as we're trying to tie up the final details of our study protocol, there remain a few challenges that we're still grappling with. First is our limited ability to restrict diet. This is probably most problematic for interpreting our PAH results, since dietary sources can be a significant contributor. And

while we can't prescribe a specific diet, we are planning to offer guidance on recommended foods. Since many of the kids who attend schools in AB 617 communities do receive food through the subsidized meal program at school, we will obtain school menus in advance, so that we can point to specific foods to avoid on the days of urine collection.

In terms of our screening criteria for the study, you know, we considered prescreening for asthma and household smoking, but ultimately ended up not including these factors in our inclusion criteria. This was partly because we were concerned about being able to enroll a sufficient number of participants. We also want the study -- this is a community-based study. We really want it to be inclusive, so that any students or families or all students and families that are interested have the opportunity to participate. But, you know, we do recognize these are important factors. And given that we thought it might -- it's worth raising as a -- this is a topic for possible discussion today.

Let's see, as I mentioned earlier, we are in the process of developing and refining questionnaires to make them as -- you know, as parsimonious as possible, but also making sure that we do capture the most important factors that we need to interpret the biomonitoring results.

Another issue that -- you know, challenging issue we're facing is figuring out how to best interpret and explain the biomarkers of oxidative stress and inflammation as indicators of exposure.

And then finally, we are trying to make some contingency plans for potential issues that might arise like delays in school approval, and the occurrence of wildfires during our sample collection. So we welcome comments and input on these challenges, as well as anything else that I've presented this morning. After hearing from our guest speakers, we will have an opportunity this afternoon to delve further into some of these issues here, as well as other study design and interpretation issues that anyone in the Panel, or audience, or any of our guest speakers would like to raise.

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MS. HURLEY: Before though I -- before we go to questions and discussion, I would like to take a moment to acknowledge our study team. This is a multi-institutional collaborative effort, including researchers from OEHHA, from the California Department of Public Health, as well as UC Berkeley, UC Merced, and UCSF.

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MS. HURLEY: And then finally, I'd like to give a

shout-out to our community partner Matt Holmes of Little Manila Rising, who has provided invaluable support to us. Early on, he helped us brainstorm ideas for study sites within Stockton. He's also served as a liaison in our talks with school district staff. So we're very appreciative of his help so far and are really looking forward to continuing to work with Matt as we launch and conduct this study.

So with that, I will open it up to questions and discussion. Thank you.

CHAIRPERSON SCHWARZMAN: Thank you, Susan. We have just a couple minutes for clarifying questions only from the Panel, and then we'll have public comment, and then we'll have public -- the Panel discussion. So just any clarifying questions for Susan at this point.

Jenny.

We're not hearing you, Jenny.

PANEL MEMBER QUINTANA: Sorry. I don't have the slides in front of me. I can't seem to bring them up, but can you remind me when you're planning to collect the samples, the timeline slide went by pretty quickly.

MS. HURLEY: Oh, yeah, sure.

PANEL MEMBER QUINTANA: Can you tell me what time of year?

MS. HURLEY: Yeah. Early November.

PANEL MEMBER QUINTANA: Okay. And was that selected because that was the most polluted month?

MS. HURLEY: Well, it is one of the more polluted months. It was -- you know, winter is the best time to do it. We didn't want to do it too early, because, you know, ideally it would be good not to do it during wildfire season. We -- and then we couldn't do it too late in the winter, because we need to get our -- with our timeline for getting the samples to the lab. We, you know, couldn't push it too far back. So we think November is a good window.

PANEL MEMBER QUINTANA: Then I guess my second question, sorry, was you were saying you'd want to avoid wildfires, but it seems like it's such a difficult thing to get this whole study set up, that it seems like you might want to ask for additional funding if there were a fire to quickly roll out your protocol and see the effect of the filtration on the fires as well, because that's obviously a huge interest to people. And I was just curious if you thought about trying to augment the study. That way given that the logistics are the hardest part of getting all this stuff ready to roll or augment your IRB, I guess.

MS. HURLEY: Yeah. Well, I don't know that that type of modification would require us to modify our IRB.

Sara, I don't know if you want to chime in here and --

CHAIRPERSON SCHWARZMAN: Let me butt in for a sec just to suggest that we leave this for the discussion portion.

MS. HURLEY: Okay.

CHAIRPERSON SCHWARZMAN: I think Tom has a clarifying question and we'll return to this.

PANEL MEMBER McKONE: Yeah. This is -- I had a clarifying question and I think it should probably rollover to discussion too, but my question is what was the basis for choosing MERV 16?

MS. HURLEY: Well, actually, this -- it's sort of -- that wasn't the -- at the forefront of our criteria for where we do this study. We really -- because of our timeline and what's going on in the schools right now, we found a school that we think is a great site, which already has MERV 16 filtration. And that is actually a benefit, because it is, you know, the most effective filtration that's out there, but it -- that was sort of a bonus of the school that we were looking at. Yeah.

PANEL MEMBER McKONE: Right. Well, I'll save this for discussion, but the concern I raise is that the Air Resources Board says MERV 13 or above. And the risk of going higher is that it increases the -- as you go up, you get more filtration, but you get most of the benefits

starting at 13. And when you get to 16, you're putting a higher load on the HVAC system, so you're using more energy. So my concern is that if this study establishes 16 as the benchmark instead of 13, then we're going to have this -- all these schools wanting to go out and buy MERV 16. And then their energy costs are going to go up and that may not be necessary.

I mean, it's kind of subtle, but we can discuss this more, but I do think one has to be careful in realizing that if this study uses 16, it will set a benchmark, instead of Air Resources Board Lawrence Berkeley Lab say 13 and above.

MS. HOOVER: Yeah. I'll just chime in here real quick, Tom. I know we need to move on to the discussion or public comment, Meg. So ideally I think CARB did want MERV 16. They actually had to change their regulations to allow MERV 13, so I think we can take that into account in messaging. And this school, that would be part of the evaluation of their HVAC system, if it could handle MERV 16. At least that's what we believe occurred.

So we're not calling it a benchmark. As Susan said, we have an opportunity for a really important site to study and they already have this installed.

CHAIRPERSON SCHWARZMAN: I need to call for public comment and let's return to these issues in

discussion.

Shoba, is there any public comment that we should bring in at this point?

DR. IYER: Let's see. I'm not seeing anything in the -- anything new in the chat or questions. We do have a hand that was raised from earlier. Should I go ahead and see if the person can ask the question now?

CHAIRPERSON SCHWARZMAN: Yes. Let's see what that is.

DR. IYER: Great. So LeVonne Stone, I see you have your hand up. I'm going to unmute you and then you'll need to unmute yourself to share your comment or question.

LeVonne Stone, I've unmuted you. If you have a comment or question, you can unmute yourself and ask it.

MS. HOOVER: Shoba, I'm going to suggest that we recommend that she email her comment and we can move on, if there are any questions or comments.

DR. IYER: Yeah. Sure. That sounds good.

So LeVonne, please email us your comment or send it in via the chat or question feature. I also see that we have a hand up from Matt Holmes. So I'm going to unmute you now and that should give you permission to unmute yourself and ask your question.

MS. HOOVER: Shoba, maybe you do need to promote

them to panelists. Why don't you just go ahead and do that for Matt, or Stephanie.

MS. JARMUL: Yes, just did.

MS. HOOVER: Okay.

MS. JARMUL: Matt, can you unmute yourself by clicking the red button?

MS. HOOVER: Oh, boy. We're having the same problem that Carl had.

Matt, if you wouldn't mind emailing us your comment. You can send it to any one of us or the Biomonitoring email or you can post it in the GoToWebinar. I'm really sorry about these audio issues. I will --

MS. HOLMES: How about now?

MS. HOOVER: Oh, fantastic. Go for it.

MS. HOLMES: Yeah. Hallelujah. I'm glad it was my fault and not your fault.

I just wanted to say really quickly that I'm super grateful for Susan for really getting out in front of this. We've been talking since I think January. And that that's really like a prerequisite for working in a community like ours. It takes a very long time to develop these conversations. And, you know, it was really fortunate that this aligned with our community's priorities to protect schools, particularly this school that's in a cluster of emissions sources. And so that's

just my little soapbox to all the scientists out there, be sure to talk to communities early and often. Sometimes you all do research that isn't relevant to us. But this certainly is and so I think this is a special study and we're grateful for the attention.

And then the other comment I would make is about the MERV 16 versus MERV 13. I think a lot of those -- the horse trading around whether or not we need to have a high enough filter is really based on economics that don't concern me. And I think part -- you know, just simply, you know, spending less at a school because of energy costs is not what I think about when I think about protecting my students.

And I'll just also point out that most of these schools have used, you know, their ability to borrow to build up significant solar capacity on campus. And so that they -- they're pretty flush with electricity. And so I would hope to set the highest benchmark possible for our most valuable resource, you know, young human brain tissue. So I'm glad that there was already a SEP in place and that this system was already upgraded. And it's absolutely my hope to upgrade as many systems to the highest grade possible as a community advocate.

But look forward to learning more from you all. Thanks so much for bringing first rate science to a part

of California that doesn't always enjoy that kind of attention.

CHAIRPERSON SCHWARZMAN: Thanks so much for the comment, Matt, and for your involvement.

Sorry.

I appreciate the comment, Matt, and also your involvement in the program.

We have time now until -- we have 20 minutes for Panel discussion of this. And there is also there's some overlap here, because we have a discussion on the questions that Susan has put forth wanting feedback on. We have time for that this afternoon. And so I just want to continue kind of open back up these two issues that were raised by Jenny and by Tom for further discussion.

MS. HOOVER: I'm going to suggest to Susan why don't you put the challenges slide back up as well right now.

MS. HURLEY: Okay. There we go.

CHAIRPERSON SCHWARZMAN: So anything more to say about the MERV 13, MERV 16? I mean, I appreciate, Tom, your comment that there are significant -- you know, that the significant gains start at 13, as well as appreciating Matt's comment about like let's put in place the highest possible protection. So any reflections on that?

PANEL MEMBER McKONE: No. That's a -- yeah,

that's a good point, and especially -- I mean, it's really encouraging to hear that the schools are electrified, because that means you're not -- you know, our concern is always that somebody puts in a MERV filter -- I mean, I do this. I collect a lot of data from my own home. And we spend -- we ran a 600-watt motor day and night through a MERV filter when the wildfires were there. And it's effective, but you know, it's a cost. But we do have solar energy, so we were making up most of it for that, so that -- that does make a difference.

I actually wanted to raise another filtration point, which is on the -- on the additional filters, which would be the stand-alone filters. Now the one thing about a MERV 13 or 16 is it's not going to get the volatile chemicals. It's really only going to get particle-bound chemicals.

But in the market for stand-alone units, there are several units out there that are available, the higher quality unit, for example Austin Air, I think -- I shouldn't name brands, but there are brands -- there's five or six brands that actually have particle filtration, but they also include activated carbon or permanganate or other layers that will take out chemicals as well as taking out fine particles.

So you can remove -- the MERV filters really

won't remove volatiles to any significant extent unless the volatiles are particle bound. But the stand-alone units, if you buy the right kind, particularly with activated carbon, they're going to be much more effective. So I don't know if this is an issue you're looking into, but it is -- and again, it gets into they do -- you know, there's a lot of studies that show those can make a big difference in air quality for chemicals, other than particles.

MS. HURLEY: Okay. Do I need to raise my hand to --

CHAIRPERSON SCHWARZMAN: Go ahead, Susan.

MS. HURLEY: Okay. Yes, we are looking into that. We have identified -- you know, when we were putting out budget together, we identified a stand-alone filtration unit that does target not just particulates, but also VOCs. But we are now, you know, as we're getting ready to actually gear up to do this study, we are continuing to look to make sure that we get the best stand-alone to address VOCs, because we would like to do that. So if you have any, you know, advice on that, we'd love to hear it.

PANEL MEMBER McKONE: Well, I mean, just a quick suggestion, and I think -- and I can help you with this, is the people at Lawrence Berkeley Lab who analyze these

filters --

MS. HURLEY: Um-hmm.

PANEL MEMBER McKONE: -- and their effectiveness -- and again, I think -- you know, I have a brand, my favorite, but there's probably four or five that are really well rated in removing a much broader spectrum of pollutant.

MS. HURLEY: Um-hmm.

MS. HOOVER: Great, Tom, and we can connect with you one-on-one off line. So, Meg, back to you to keep going on the discussion.

CHAIRPERSON SCHWARZMAN: I think Jenny had her hand up.

PANEL MEMBER QUINTANA: I had kind of a broader question or comment. One is that I'm thinking about what you really are trying to learn with biomonitoring, because if you're just looking to see if the air filters are effective, you can do that by measuring air quality and VOCs in the air when they're running and when they're not running. So you could use air monitoring alone to answer the question if the filters are effective.

But what you're really asking with biomonitoring is does that make a difference to their overall day? You know, does -- do you -- given everything else, the other 16 hours when they're not a school, et cetera, is this

intervention effective in reducing their actual burden day-to-day? So that seems to me that's what biomonitoring is asking for this study.

So -- and I'm just thinking of -- and I don't know about this school, and maybe schools don't have this, but a lot of exposure is going to happen on the playground, not only that it's the time that they spend during recess, but the time that they're breathing much harder running around than they are sitting in the classroom. So that's going to represent -- a large part of their exposure is going to be outside on the playground.

And so I guess one question is -- and I don't know the timing of the recess, but -- and the half-lives of the biomarkers exactly, but you may wish to look at the biomarkers when they have -- you know, after they've finished running around, or some time where they're not affected by this, or how have -- if they have an air-conditioned gym that they do recess in the gym, because what you might find out that there's -- that a lot of their exposure does come from outside when you do look at the air concentrations and model their activity. And so -- but you don't want to overlook the benefits perhaps of doing recess in clean air.

So I'm just -- I just want to bring that up and I

don't know -- our schools that I work with do not have air conditioned gyms that they can use for recess, and elementary schools typically don't have gyms. So it's just something to think about, because there's exposures at school that are not, you know inside the classroom, I guess. And I have other recommendations for the study, but I guess it sounds like we have another time later. I can also make them later. If we have more time now, I can come back and make those other recommendations, but I'll stop with that right now.

CHAIRPERSON SCHWARZMAN: Yeah. Why don't you hang on to that for the moment. We may well have time for them now, but we definitely have more time later also. And I'll just see what else there is out there for the moment.

Veena.

PANEL MEMBER SINGLA: Thank you. My comment and question is about the kind of additional information to be collected about the school and the building. And, you know, I would just say it's really important to try to document as much information as possible about the building characteristics like air infiltration rate, has the school had kind of energy efficiency upgrades or retrofits that might have addressed kind of air sealing and other aspects of the building that could affect air

infiltration.

And, you know, related to that, VOCs indoors can reflect infiltration of VOCs from the outdoors to the indoors and can also reflect indoor sources. So to the extent there's any information available on potential indoor sources of VOCs, like recent painting, or sealing, or caulking like kind of building improvements, that could affect indoor levels of VOCs. It would be helpful to collect that information as well.

And then my other comment was -- a comment and a question is if there's any plan for activities that might involve the participants, the children in kind of engagement with this topic or the science -- I'd noticed Asa Bradman is on the study team and he has a lot of experience with this -- with CHAMACOS, so I wondered if you could comment on that?

MS. HURLEY: Yeah, that's a great question. We are very much hopeful that we can involve the students, you know, in the -- actively engage them in this study. Because we actually don't have permission yet to get into the schools, we haven't started, you know, planning that. But it's certainly on our wish list. And you're right, Asa has got great experience in that, so we're hoping to do that.

CHAIRPERSON SCHWARZMAN: Ulrike.

PANEL MEMBER LUDERER: Turn my audio on. Thanks for that really interesting presentation. And it sounds like I think it's going to be very exciting study. I had some questions about the PAHs and the diet. You know, you mentioned that you were going to try to look at the menus for the school meals. But I was wondering -- I hope that you're also planning in your questionnaire to ask about barbecued or grilled food consumption, you know, during the day before, because that -- it could be at home as well. So that's an important thing when you're looking -- if you're looking at PAHs.

And then other question was, maybe you said this, but the air monitoring and sampling, is it -- is it going to be indoor and outdoor all the sampling? You know, between --

MS. HURLEY: Yes

PANEL MEMBER LUDERER: -- the different things that you're looking at, you know the Purple Air, black carbon, VOCs, PAHs.

MS. HURLEY: Yeah. We're going to -- we're going to do everything indoor and out. And with respect to the PAHs, yes, we definitely will have on our questionnaire questions regarding what they've eaten in the last 24 hours or so. But we're also hoping to try to, as much as we can, advise them to avoid the PAH-ladened foods, so

that we don't have as much adjustment that we have to do in our analyses.

PANEL MEMBER LUDERER: Yeah. And just to comment, I mean, it's great that you're doing -- you know, the PAHs -- the biomonitoring that you're doing is really going to give you the metabolites of the lower molecular weight PAHs. And a lot of the higher molecular weight ones that we're concerned about that are mutagenic, et cetera, you can't measure really in urine those metabolites, so --

MS. HURLEY: Yeah.

PANEL MEMBER LUDERER: So I -- your monitors, are they going to be able to speciate, you know, look at the different PAHs individually when you're doing the air monitoring?

MS. HURLEY: Yes, they will. I'm wondering, Asa, if you can talk a little bit more -- I don't know if you want to comment on that a little further. I don't have all the details of specifically what we're, you know, capturing.

MS. HOOVER: That's okay. I don't think we need to --

MS. HURLEY: Okay.

MS. HOOVER: We're almost out of time.

MS. HURLEY: Okay.

MS. HOOVER: And we can share the full list. It's a -- the full list of PAHs that we'll be speciating. We could do that for the VOCs as well.

PANEL MEMBER LUDERER: Great. Thanks.

CHAIRPERSON SCHWARZMAN: In a few minutes, we're going to transition to a talk by John Balmes. But as I understand it, he had a comment on this topic and presentation. I want to invite you to give that comment now, John, if you can manage to with the various audio (inaudible) that we have.

DR. BALMES: Well, can you see and hear me?

CHAIRPERSON SCHWARZMAN: Yes.

DR. BALMES: Amazing. Well, just -- I'll talk about CC16 in my talk, but the comment relates to Matt Holmes actually, because he has also been partnering with a group from UC Berkeley and UCSF that I'm part of. We put in for funding for the Attorney General's office for VW settlement money. It's called, you know, vehicular emissions whatever. And we will be planning to get (inaudible) -- we'll be doing if we funded. You know, we don't think we're going to be.

CHAIRPERSON SCHWARZMAN: John. I'm sorry to interrupt you.

DR. BALMES: We've been working with Little Manila (inaudible).

CHAIRPERSON SCHWARZMAN: John, (inaudible)

DR. BALMES: Yes.

CHAIRPERSON SCHWARZMAN: Oh, your audio and video froze for a minute and it got garbled. Do you mind restating that. You said -- the last we heard was about the vehicle -- vehicular settlement.

DR. BALMES: Yeah. Yeah. So if our group from UC Berkeley and UCSF is lucky enough to get funded, we'd be working with Matt Holmes and Little Manila Rising to put in a network of black carbon monitors at homes of children and adults with asthma. And I think it's in the same area that the school is in. Matt could correct me if I'm wrong, but that could be of interest to this study.

MS. HOLMES: Yeah. Can I chime in real quick and just affirm that, that this is the focus area of all of our study work, because of the cluster of stationary sources at the port and transportation sources all tangled around it.

And then I'll just also add that we had a similar -- not a similar, another proposal to the same fund with Dr. Bradman out of Merced to really characterize ambient air quality across the region with particulate matter and weather specificity, because we really want to model where the pollution is coming from. And we have -- you know, we have ocean-going vessels that visit, you

know, several hundred feet upwind from the school. And no doubt diesel boilers are impacting the type of air they're breathing here at the school. So we'll be -- we should be able to get it -- if we -- we need to get these awards, so we can give you a really clear picture of the air around this school, so that Susan's study can help us corroborate that it's penetrating the school.

And then I'll just do a final plug. You know, the California Air Resources Board community air grants are out. We're currently formulating a proposal to address the gaps in between these studies. And so I loved the conversation that I heard about understanding programming at the school and time outside versus time inside, and the idea of, you know, issuing stay indoor alerts to principals. They could be based on preliminary data not regulatory action just led by a community partner. So if anybody wants to connect with me on that proposal, it will modify significantly depending on whether or not we get either of these justice department awards. So really excited to have all these things complement each other.

MS. JARMUL: This is Stephanie. Just confirming that was Matt Holmes who was speaking.

MS. HOLMES: Correct. Sorry.

CHAIRPERSON SCHWARZMAN: Great. Thank you, all.

We have just two minutes or so before we transition over to John Balmes' talk and a chance to circle back to these challenges that Susan has raised later this afternoon. But I just want to invite any final comments from the panelists or if you want to just mention something to kind of get on the agenda for the afternoon's discussion, so that we all have that in the backs of our minds as we move on.

Veena.

PANEL MEMBER SINGLA: Thank you. One other thought on some of the kind of building level characteristics that would be helpful to document, I'd say cleaning and disinfection protocols. And if it's possible to document some of the products used, so -- again speaking to potential sources of VOCs and the indoor environment.

CHAIRPERSON SCHWARZMAN: Great. Noted. Thank you. Any other -- Jenny, was that a hand? Yes.

PANEL MEMBER QUINTANA: Only if there's no other people. No?

I just wanted to put on the agenda for the afternoon two things. One is additional sampling measures that might be recommended and also questionnaire items that would be important, including how the kid gets to school, you know, do they walk to school, do they ride a

school bus? So some of -- you know, just some really important questions, I have some recommendations for.

And also I want to just say I'm not sure I would tell people what to eat, because you're trying to see if a recommendation works in the real world, you know. And even though it might help you find a signal, it -- again, what biomonitoring is telling you is how does this reduce exposure as assessed by these biomarkers under real-world conditions.

MS. HOOVER: And I'll just quickly chime in to say, Jenny, we have slides with the complete list of questionnaire topics that we'll be showing for the afternoon session. So, yeah, definitely, we have a comprehensive list for you guys to review and add to.

CHAIRPERSON SCHWARZMAN: Great. Thank you, Susan. And thank you to everybody who weighed in on that conversation. It's an exciting study to be launching and we'll have more chance to talk about it this afternoon.

As we get John's presentation teed up here, I want to introduce him as our first guest speaker. John Balmes is a professor of medicine Emeritus at UCSF and a professor of environmental health sciences Emeritus in the School of Public Health at UC Berkeley.

At UC Berkeley, he's also the Director of the Northern California Center for Occupational and

Environmental Health. He is also one of the principal investigators of the Children's Health and Air Pollution Study, CHAPS, in Fresno, which is what he'll be talking about today. And John has been studying the effects of occupational and environmental agents on respiratory, cardiovascular, and metabolic health for over 40 years.

He'll be discussing results from his recent study on traffic-related air pollution and biomarkers of effect in children in Fresno.

(Thereupon a slide presentation.)

DR. BALMES: So can you all see my slides?

CHAIRPERSON SCHWARZMAN: (Nods head.)

DR. BALMES: Okay. So -- and you can all see and hear me still?

CHAIRPERSON SCHWARZMAN: Yes, we can.

MS. JARMUL: Yes.

DR. BALMES: I'm in -- I'm in Tahoe and I think the internet connection is pretty good, but I guess it --

MS. JARMUL: There might be a slight delay, but we can see you, just so everyone is aware.

DR. BALMES: Okay. Can I just have some GoToWebinar assistance in terms of -- so right now, I have a -- well, I'm just going to go ahead. Anyway. Thank you for inviting me to speak on our work in Fresno with regard to traffic-related air pollution and biomarkers of effect

in children.

Okay. So advancing slides -- I'm used to advancing slides in Zoom.

MS. JARMUL: Did you just try clicking on the PowerPoint perhaps.

--o0o--

DR. BALMES: There it is. Click on the PowerPoint. Thank you.

Okay. So I don't have any financial conflict of interest, but I am the Physician Member of the California Air Resources Board. And I did actually have -- my ears perked up when CARB was discussed about AB 617 and MERV filters. No comment about those right now.

--o0o--

DR. BALMES: So I don't think it's a surprise to anybody, either panelists or the public, listening in that there's an epidemic of obesity in the U.S. And I didn't actually update this slide, but I think it's roughly accurate that up to 30 percent -- 38 percent of Americans are overweight and 35 percent are obese. It's really a huge problem. Seventeen percent of children ages to 2 to 19 are obese.

And there is like many health disparities in our country, there are disparities with -- based on people of color, with Latinx and African Americans having a greater

prevalence of obesity in terms of children than other racial ethnic groups. And this is an old slide. It only goes up through 2013, 2014, but it has continued to rise.

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DR. BALMES: So it's thought to be primarily due to increased caloric intake from high consumption of sugar-containing drinks and high-caloric fast food, but also decreased energy expenditure from a sedentary lifestyle, basically, calories in versus calories out.

And there's increasing animal evidence that suggests that chemicals in the environment may be obesogens that contribute to risk of obesity, organochlorines, bisphenol A. This group expert in biomonitoring, you know, is aware of this.

--o0o--

DR. BALMES: Other environmental exposures that have been associated with obesity. Of course, I've already mentioned dietary composition. The gut microbiome is certainly a hot area of research. The built environment, through its role in either decrease -- inhibiting or enhancing exercise, and then food consumption.

You know, how -- do you live in a food desert where you can't get healthy foods, and the only food options are not healthy. And then exposure to ambient air

pollutants, which is what the topic of my presentation is today. And there's a particular interest in whether early exposures in utero and early childhood lead to overweight and obesity in childhood -- later in childhood and then in adulthood.

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DR. BALMES: So we know a little bit about air pollution obesity. There's actually a fairly robust literature now. And I don't have time to go into details of studies, but studies from the Children's Health Study group in Los Angeles, USC, and at Columbia, New York City have shown associations with traffic-related air pollution and overweight in children.

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DR. BALMES: There's also a linkage of diabetes and obesity, type 2 diabetes a disorder of glucose metabolism I think as everybody knows. Basically, the body cells fail to take up glucose from the blood due to insulin resistance. This cartoon shows a normal cell with glucose being brought into a cell because the insulin receptor is functional. With an insulin-resistant cell, glucose can't get into the cell and stays in the peripheral circulation.

Eighty percent of those who develop type 2 diabetes are obese. We used to say that was only a

condition of adults. But increasingly type 2 diabetes is being identified in obese children. And it's associated with insulin resistance and beta cell, the cells that produce insulin in the pancreas not functioning properly, because they get overused, because of the insulin resistance.

And then both diabetes and obesity are associated with increased systemic inflammation. And that's one unifying factor with regard to risk in terms of obesity and diabetes that may be related to air pollution.

And here is a cartoon showing that adipose tissue, fat tissue, is not just storage tissue. It actually gets actively involved with body metabolism and can actually generate inflammation. And that's -- this access of inflammation related to the adipose tissue is increasingly being investigated and may play a role in conditions such as diabetes, obesity, cardiovascular disease, et cetera.

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DR. BALMES: So we know a little bit about air pollution and diabetes in children. Several studies have shown associations between diabetes in adults and exposure to traffic-related air pollution, and a smaller number of studies, again the best one is from USC, showing that traffic-related air pollution exposure in children of

color was associated with higher fasting glucose and insulin resistance. They were really quite elegant studies.

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DR. BALMES: So what's the potential mechanism of air pollution affecting both obesity and diabetes?

Well, oxidative stress, which is one of the areas that the proposed AB 617 study that Susan was talking about will be looking at. And oxidative stress can, in the lungs, from inhalation of air pollution, can spill over into the systemic circulation and lead to inflammation. And then local inflammation in the lungs from air pollution exposure can also spill over into the systemic circulation, and potentially reach fat tissue and contribute to fat tissue inflammation and insulin resistance.

And there's mouse models that have diet-induced obesity that show that co-exposure of PM2.5 with the -- with a high fat diet can lead to really fat mice. This actually is a photo from mice from this study. And based on what I've covered, our hypothesis, and a hypothesis shared by others, is exposure to air pollution in utero and early childhood increases risk of abnormal glucose metabolism and obesity in later childhood.

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DR. BALMES: So Fresno where I've been working with colleagues for over 20 years. Why Fresno? Here is a picture of Fresno on a particularly polluted day. I don't think this was a wildfire exposure day either. And Fresno ranks in the top three to five cities in the country with regard to both PM -- well, PM2.5. I'll leave it at that.

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DR. BALMES: So our specific study that I'll be talking about today is a component study of the Children's Health and Air Pollution Study Center that was a joint UC Berkeley, UC -- Stanford project until a couple years ago. Our current funding is just through UC Berkeley, but this work was collaborative with Stanford.

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DR. BALMES: And, you know, polycyclic aromatic hydrocarbons have already been mentioned. We -- that's part of our special sauce. Kathie Hammond and Betsey Noth, my colleagues at Environmental Sciences at UC Berkeley School of Public Health have been studying ambient PAHs in Fresno for a long time. You know, there are other sources of PAHs that have already been brought up today, but we're -- we're interested in ambient PAH.

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DR. BALMES: And this is a map that Betsey made of PAH cumulative exposure in Fresno with the circles

showing -- the larger the circle, the greater the exposure. And you can see that ambient PAHs somewhat tend to follow the roadways in Fresno. Wildfires, ag burning, and then burning of solid fuel in homes also contribute to ambient PAH in Fresno. But over the course of most of the year, it's traffic that's the biggest component.

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DR. BALMES: So our research question was are exposures ambient air pollutants, especially PAHs, associated with increased body mass index, biomarkers of oxidative stress, systemic inflammation, abnormal fat and glucose metabolism? We -- well, I'll just -- I'll go into systemic inflammation later. Increased blood pressure.

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DR. BALMES: And our study design involved a birth cohort, a child cohort. I'm going to report data from our child cohort from enrollment ages seven to eight today. We're continuing to follow this cohort, or I should say, we're funded to continue to follow both of these cohorts, but we have been limited by the pandemic -- actually, inhibited by the pandemic from doing more recent follow-up, but we're hoping to start soon.

So for all participants, we do anthropom -- anthropometry and biomarker measurements. And we have estimated air pollution exposure to elemental carbon. I

think the slides are going to call it black carbon. Betsey and I argue about whether -- what we should call it. Nitrogen dioxide, which is a good marker of traffic exposure, nitrogen oxides in general, not just NO2. And then we have this special PAH456, so this -- these are polycyclic aromatic hydrocarbons with four, five, or six rings, and then fine particulate matter and carbon monoxide.

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DR. BALMES: Here's the description of our child cohort. Recruited at ages seven to eight. You see the mean in months is closer to eight. You can see the weight. We'll be talking about BMI later. Pretty equally split between boys and girls. And what's remarkable for -- we recruited through the Fresno public schools, and we had 80 percent Latinx, 11 percent Black. So, of color, we had, you know, 91 percent of our child participants.

And also striking is the annual household income. So 28 percent of our families had income less than 15,000. So this is a very poor group. And you can see that there's also a fairly high percentage of obesity and overweight.

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DR. BALMES: So I'm going to start showing data now. Hopefully, these slides aren't too confusing. These

are slides -- or graphs from our published paper in Environmental Research that came out earlier this year. And we have four pollutants below, black carbon, NO2, PAH456, and PM2.5. And there's various exposure windows. These are three months, six months, one year average exposures. And then the outcome here is estimated percent change in BMI using a CDC recommended approach.

And there was only one statistically significant -- borderline statistically significant exposure BMI percentile association, six-month NO2, but I would like to suggest that most of the point estimates show that there is a potential trend towards an increase.

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DR. BALMES: Now, I have hemoglobin A1c percent glycosylated hemoglobin, which is a good marker of glucose regulation. And again, same black carbon, NO2, PAH456, PM2.5. And here we have some statistically significant associations with six-month black carbon, three-month NO2, and borderline for six-month. And then with PAH456, three- and six-month, and PM2.5 three- and six-month average exposures.

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DR. BALMES: Systolic blood pressure, we have -- because systolic blood pressure has a shorter exposure response time, we're looking at one day, and one week, and

one month average exposures, as well as the three, six and -- three- and six-month and one-year exposure averages that I showed in a previous slide. And here again, most of the point estimates are above the line, but we have statistically significant associations for three- and six-month, and one-year exposures for NO2. Again, a very good marker of traffic exposure.

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DR. BALMES: Diastolic blood pressure, a little less dramatic. I think there is only one statistically significant association with one-month black carbon. But you can see that again most of the point estimates are above the line, showing that trend towards an effect.

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DR. BALMES: Urinary 8-isoprostane, which is going to be one of the biomarkers that the proposal -- proposed study in Stockton will use. Again, it has a short time exposure response and basically all of the pollutants at shorter time averages especially are associated with increases in urinary 8-isoprostane. So that's a marker of lipid peroxidation. It's actually quite a good marker of systemic oxidative stress.

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DR. BALMES: Now, the data I showed you so far have been from our child cohort ages seven to eight, but

we did a follow-up at ages nine to 10. And I have some unpublished data that I'm showing here for 182 of our child participants, so a subcohort. We have high-density lipoprotein, which is the good lipoprotein in terms of cardiovascular risk. So a decrease in HDL is not good, and -- so you can see that with NO2 and NOx, we have some statistically significant decreases of the good lipoprotein here and not much for the other pollutants.

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DR. BALMES: And then because you're also going -- well, the AB 617 Stockton study is considering urinary club cell protein-16. We have, I think, no statistically significant decreases, but again, a trend towards decreases and club cell protein-16 with most of the pollutants. Now, just a little comment in terms of the use of this biomarker, it's not really a marker of systemic inflammation. It's a marker that Nina and I have used in multiple studies - Nina Holland - who's going to be measuring it for the AB 617 study team. It's a marker of airway injury. Very sensitive to pollutant airway injury that initially goes up with exposure to air -- an airway toxicant and then goes down over time. And the lower -- a lower level of CC16 is actually associated with increased risk for chronic respiratory outcomes, such as chronic obstructive pulmonary disease.

So you have to be careful in the interpretation of CC16. It's really not a marker of systemic inflammation. The leukotriene 4 that Nina will be obtaining is a marker of inflammation, but CC16 is -- inflammation is involved in the pathway by which CC16 is released from club cells and the airway epithelium, but I wouldn't call it a marker of systemic inflammation.

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DR. BALMES: So in summary, the prevalence of both obesity and pre-diabetes -- you know, we didn't diagnose diabetes in any of these kids. The increase in hemoglobin A1c is just a marker of glucose dis-regulation. Anyway, both obesity and pre-diabetes are high in Latinx youth in the San Joaquin Valley. Air pollution may increase the risk of both conditions by inducing oxidative stress airway inflammation and possibly systemic inflammation, which we didn't actually measure.

Childhood exposure to traffic-related air pollution is associated with outcomes consistent with increased risk of metabolic syndrome. You can't properly diagnose metabolic syndrome in children, but the trend towards increased BMI, the increased hemoglobin A1c, the decreased HDL and the increased blood pressure all are consistent with signs of metabolic syndrome. So we're worried about these kids developing metabolic syndrome as

they get older and we're hoping to continue to be able to follow them over time. And we do have a -- we will be able to follow them over the next few years thanks to increased funding from the NIHS.

And I can't go through the participation of every member of our study group. I've already mentioned Betsey Noth and Kathie Hammond, but I particularly want to make a shout -- give a shout-out to Jennifer Mann, who should be giving this talk, but because she retired, as was mentioned earlier, she stuck me with the job, because Jennifer was really the lead investigator for this project over multiple years.

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DR. BALMES: And then I want to end with acknowledging both our collaborators at Sonoma Technology, who helped us with the air pollution exposure assessment, as did colleagues at Cal State Fresno. We did the visits for our child participants at UC -- UCSF Fresno, and then our funding for this project was from the U.S. EPA and the NIH.

So with that, I think I'm on time.

CHAIRPERSON SCHWARZMAN: You are perfectly on time, John. Thank you so much for the presentation.

We have 15 minutes now before we break for lunch that is devoted to questions and discussion from both the

panelists and any audience members. So I just want to particularly flag in terms of public comment or audience questions, earlier in the day, we -- these were all broken out. And now it's sort of combined. So if you want to submit a question or a comment, please do that as we proceed with the discussion.

And I also just want to flag that while John has been generous to join us, today he can't stay through to the afternoon discussion. So any questions about indicators of systemic inflammation as we'll be discussing later in the afternoon relevant to the AB 617 study, if you have any questions about that to John, now is the time to do that.

Yes, Jenny.

PANEL MEMBER QUINTANA: Hi. Thank you for that fascinating presentation and really impressive cohort. I just wanted to know, if you wouldn't mind expanding a little bit more about some of the biomarkers like 8-isoprostane in terms of -- is there a circadian rhythm to these biomarkers, because I guess that might come up later with timing of collections within a day?

Thank you.

DR. BALMES: Well, that's a good question, Jenny. I actually don't know about 8-isoprostane and circadian rhythm. I suspect that there probably is. And I can

certainly look that up for you and get back to you.

And Nina Holland who I think Susan mentioned is going to be doing the 8-isoprostane, she has measured urinary 8-isoprostane in multiple studies that I've been involved with and maybe other ones as well, so she may have the answer to your question about circadian rhythm.

I do think it's a good marker of oxidative stress. And I'm glad that she's now also willing to do 8-hydroxy de -- I'm going to murder it -- 8-OHdG, because I would have been trying to get her to do that for years. And I think in part because the AB 617 study team reached out to her, she's willing to do it for me in our Fresno work now too, because for years she wouldn't, because she didn't think it was a particularly good marker. But it particularly, as you probably know, is a marker of DNA oxidative damage, whereas the 8-isoprostane is a lipid peroxidation. So having both of those markers I think is a good way to assess oxidative stress.

PANEL MEMBER QUINTANA: Now, maybe taking a step back, I forgot to ask you to comment also on the half-life what's known in children in urinary half-life and --

DR. BALMES: Yeah, the half-life, I actually had to look that up for that paper that we're -- is in review with the Journal of Exposure Science and Environmental Epidemiology with our nine year old data. And now I can't

remember exactly, because one of the reviewers asked about the half-life. But it's definitely -- it sticks around for long enough to be useful.

PANEL MEMBER QUINTANA: Thank you so much.

DR. BALMES: It's a matter of -- it's a good part of the day the half-life.

CHAIRPERSON SCHWARZMAN: Thanks for that.

Other questions?

Ulrike.

PANEL MEMBER LUDERER: Thank you. That was a really interesting talk, John. I really appreciate your presenting that -- those data. I had a question just to make sure that I understood the graphs. So is it the estimated change from the individual's baseline or is it relative to a normal value.

DR. BALMES: It's to the individual's baseline.

PANEL MEMBER LUDERER: Baseline. Okay. So then one day would be one day into -- basically --

DR. BALMES: Yes.

PANEL MEMBER LUDERER: -- One day from when the urinary isoprostane was measured. Okay. Great. Thank you.

CHAIRPERSON SCHWARZMAN: And just to finish that. That's one day into high smoke -- or a high pollution exposure event?

DR. BALMES: No. It's just that one day average exposure. I mean, one day -- one day prior to when their testing was done versus -- and then there was one week, one month, three months, six months, one year average exposure prior to the date of the test.

CHAIRPERSON SCHWARZMAN: So you're essentially looking at cumulative exposure based on the age?

DR. BALMES: Well, it's cumulative exposure for the longer averages, but, you know, one day, one week, not that cumulative. And we only -- we did the one day and one week for the like blood pressure and urinary 8-isoprostane that do respond to acute air pollution events. But hemoglobin A1c, you know, has a half-life of several months, so that's why we didn't look at one day exposures for hemoglobin A1c.

I think Carl had his hand up. Maybe he can actually be heard.

PANEL MEMBER CRANOR: Yes.

DR. BALMES: Hey.

PANEL MEMBER CRANOR: Let's try. Did it work?

CHAIRPERSON SCHWARZMAN: Yes.

DR. BALMES: Yes.

PANEL MEMBER CRANOR: Okay. Can you say a little bit more about the air pollution being in the lungs causing the inflammation in the airways and then how the

pathway from air pollution in the lungs to systemic inflammation. It might be very -- I don't know the field. I might be very interested in that.

DR. BALMES: Well, thank you, Carl. I'm happy to do that, because I kind of whizzed through that. So the air pollutants that we studied, NO2 and other nitric ox -- nitrogen oxides, ambient PAHs, and then both black carbon and PM2.5 all can cause airway inflammation. So when they're breathed in at high enough concentration, they will damage airway cells -- the cells lining the airway, and then those cells will release signals that cause an inflammatory response. And by inflammatory response, I mean immune cells, both resident in the airway, like alveolar macrophages and then potentially cells recruited from the systemic circulation in the bone marrow. This has all been shown actually with PM2.5 in particular.

So you get a local airway inflammatory response to the oxidative stress. I left that out. The oxidative stress that the pollutants cause is what leads to the airway injury. And then there's an inflammatory response to the airway injury. That can just be local in the airways. But if it's severe enough or chronic enough, I think either way, you can have spillover into the systemic inflammation -- the systemic circulation, which can actually lead to extra pulmonary effects.

This has been shown with regard to blood vessel response. Endothelial function is inhibited by exposure to air pollution. And at least in animal models, inflammation of adipose tissue has been shown to occur with exposure to PM2.5, for example. So -- and actually ultrafine particles have been shown to be deposited in the brain of animals exposed to traffic-related air pollution.

So there definitely are systemic ramifications to the airway injury from oxidative stress from air pollutants and then the subsequent inflammatory response. I hope that was somewhat clear, Carl.

PANEL MEMBER CRANOR: Yes. Thank you. It just adds to the picture that air pollution is really nasty. It does other things -- it does things to the brain. It does things to the coronary artery system. And now you've pointed out other areas.

DR. BALMES: And actually that's why I moved -- I'm a pulmonary physician by training and I started with respiratory health effects, moved to cardiovascular, and now I'm doing metabolic effects in kids.

And if I could just throw in something that Tom teed up about wildfire smoke, PM2.5. There's increasing evidence that wildfire smoke PM2.5 may be more toxic than non-wildfire PM2.5 with regard to respiratory outcomes. I wouldn't say that that's clear for the other outcomes like

cardiovascular outcomes or metabolic outcomes. We don't have those data. But with -- in terms of respiratory outcomes, there are data especially with kids with asthma that suggest that PM2.5 from wildfire smoke is more toxic. So I think he was kind of teeing up that comment.

PANEL MEMBER McKONE: I was going to ask that question. You saved me the time or the effort.

DR. BALMES: Well, you hinted earlier, Tom. And Tom and I worked together for years, so he knows how I think.

CHAIRPERSON SCHWARZMAN: Thank you for that. I -- as I understand, we have a public commenter question. Shoba, I think there might be some connectivity issue. Are we able to do that now?

DR. IYER: Yeah. Let's give it a shot. LeVonne Stone, I see you have your hand raised. I'm unmuting you now. So if you unmute yourself, there should be a microphone icon you might see that's red. You can click it and unmute yourself and share your comment.

MS. STONE: Hello.

DR. IYER: Hi. We can hear you.

MS. STONE: Okay. I don't want to take a lot of your time. I'm the Director of the Fort Ord Environmental Justice Network, a community-based organization that has conducted a lot of research in this area, because of

the -- we've been subject to all these prescribed burns, a substance called alumagel, which is a derivative of napalm. And we find out that the State of California when it comes to the biomonitoring, when it comes to the map in OEHHA and the air district, they all pass us by. And we have had -- our children have been affected by all this toxic smoke along with all the other stuff in the air. And it's -- we find it very hard to bring attention to what's going on down here.

And I don't understand that, because -- and just like I heard that, you know, air pollution causes a lot of damage even to the eye, the retina, and all that, because it happened to me during one of the burns on Fort Ord. I just had a corneal eye implant at Stanford, and nobody in my family has any eye problems. And it happened because during a burn, one of the little cinders or something got in my eye. I thought it was just a speck of dust. And we have a big veteran community here. My husband is a veteran. And so we are being ignored by the State of California. I have traveled all over the United States and have gotten more attention from those people than I do here.

And it seems as though there is a contest between community organizations that do this kind of work and the agencies, because once they find out how much you know and

how much research you've done, because we can't even get the grant, we have to do everything ourselves. So I'm just trying to understand why it's continuing. The studies -- the studies, what are the results of the studies and how come the studies are only for some schools and not for all of the schools. And we need air monitors. I have a small tiny air monitor that was given to me by our local air district. And nobody is saying anything about how COVID gets connected to all of this, and it's not, because COVID is saying we're breathing on each other and we are making each other sick. And it's like it's been a cover-up all this whole year of all the other stuff that's been going on in our communities.

So I'm sorry to have to make such a long comment, but I was hoping that the participation process had changed to make it more inclusive. And it seems like to me, you haven't changed that much at all. So I'll stop right there. And I hope I can get some kind of feedback that would be helpful.

CHAIRPERSON SCHWARZMAN: Thank you for your comment, LeVonne. I think Program staff take note of public comment and understanding the community that you're advocating for can help them identify places that are under targeted. I don't know if staff wants to add anything to a response to that.

MS. STONE: I hope so.

CHAIRPERSON SCHWARZMAN: And, if not, Jenny has something to say.

PANEL MEMBER QUINTANA: I just had a question for the commenter. I just -- I missed where you were located, I'm sorry, at the very beginning.

MS. STONE: We're in Monterey, California --

PANEL MEMBER QUINTANA: Thank you.

MS. STONE: -- where there's a huge military base closed down and it's attached to all these communities.

PANEL MEMBER QUINTANA: And there's also agricultural burning you're saying?

MS. STONE: Oh, yes, ma'am, agriculture. You're talking about pesticide of the.... And everything else that you all have talked about, we have it, and it's been here a long time.

PANEL MEMBER QUINTANA: So why don't --

MS. HOOVER: So, Meg, I'll just chime in to say thank you to the public commenter. And we need to move on to our next item, which is lunch. So we have taken note. We will have the full transcript of the comment and we can be in touch to follow up on this comment further.

MS. STONE: I hope so.

CHAIRPERSON SCHWARZMAN: Thank you for joining the meeting and contributing.

So that's Sara prompting us that it's time for lunch and we need to break.

Excuse me.

We have an hour for lunch and it's requested that everybody return no later than 1:30, so that we can begin the afternoon session on time. And I will just provide the following informal Bagley-Keene reminder that to comply as usual with Bagley-Keene requirements and refrain from discussing Panel business during lunch and during the afternoon break, which comes later.

So I'm going to adjourn the -- not adjourning the meeting, but adjourn for lunch and we will return here at 1:30. Thank you so much to everybody who has provided presentations, and comments, and additions to the meeting this morning.

MS. HOOVER: Hey, Meg, I just wanted to let Panel members know that through your -- your, Nerissa's, and Stephanie's efforts, we do have a set of recommendations that are going to be shown during the lunch break. So Panel members and public, feel free to take a look at these and we can circle back during the open public comment period on this -- that topic.

CHAIRPERSON SCHWARZMAN: Great.

(Off record: 12:36 p.m.)

(Thereupon a lunch break was taken.)

AFTERNOON SESSION

(On record: 1:35 p.m.)

CHAIRPERSON SCHWARZMAN: Okay. I want to welcome everybody back from the break and start the afternoon session of the meeting. The first thing is we're going to have a presentation on challenges and opportunities in air filtration intervention studies. And to do that, I want to introduce Ryan Allen. He's a professor in the faculty of Health Sciences at Simon Fraser University in Vancouver, Canada. His research program bridges air pollution exposure assessment and epidemiology with interests in the evaluation of interventions to reduce air pollution-related health effects and the impacts of air pollution exposure in early life on growth and development.

He'll be discussing the challenges and opportunities offered by air filtration intervention studies. Thanks, Ryan.

(Thereupon a slide presentation.)

DR. ALLEN: Great. Thanks for the introduction and for the invitation to participate in this meeting. So I was asked to talk about kind of our research group's experiences conducting air filtration intervention studies over the last 10 years or so. So this really isn't a biomonitoring talk. I'll mention biomarkers very briefly.

And we've used biomarkers of exposure and of effect in our studies. But this really isn't a biomonitoring talk. It's really just a kind of a show-and-tell of our experiences, including some things that worked and some things that didn't.

And I want to make clear that this is not -- I don't claim that we're the experts on doing these studies or that we've, you know, figured it all out. The idea here is just to not so much tell research -- researchers what they should do, but just give researchers some thoughts on things maybe to consider, if you were going to do one of these studies. Certainly things I would consider if I were to do another one of these studies.

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DR. ALLEN: So to start, I'll just disclose that I -- for the most recent study, which I'll tell you about, we received some in-kind support in the form of discounted air purifiers from Coway who is a Korean manufacturer. But they had no role in any of the research that we've conducted. And I'll also just make clear that this presentation is not meant to be an endorsement of any air cleaner manufacturer or model. So I'm not trying to sell you air cleaners.

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DR. ALLEN: So the three studies that I'm going

to draw from in describing our experiences all used HEPA filter -- portable HEPA filter air cleaners to try to understand relationships between air pollution and health. The first study was conducted in a small town in western Canada in British Columbia. And that was focused on wood smoke and cardiovascular outcomes. The second study was conducted -- it was a very similar study in many ways, was conducted in Vancouver. And the third study, which is actually still ongoing, is a longer term study, actually in Ulaanbaatar the Capital City of Mongolia, focused on -- that's a city that's impacted heavily by coal smoke. And the goals of that study were to look at fetal growth and early childhood development as health outcomes.

So I've structured this talk as kind of a list of six considerations or groups of considerations, as I said, that I would -- that I would kind of recommend thinking about if you're going to design and conduct one of these studies. And this is not kind of a typical research talk. I'm really focusing on the methods and our experiences. And I won't say a whole lot about results, but I'll mention results in a few cases, when they're relevant to one of the considerations that I'm describing.

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DR. ALLEN: So the first study that we conducted used a randomized cross-over design. So each participant

underwent two weeks of -- or two seven-day periods of air pollution monitoring. And at the end of each seven-day period, we made measures of markers of health, sort of cardiovascular-related health outcomes including some measures of oxidative stress, inflammation, and endothelial function, things we've already heard quite a lot about today.

And during one of the sessions, the HEPA filter was operating normally. During the other session, the HEPA filter was operating, but the filter was actually removed, so it was sort of, what we call, placebo or sham filtration. And importantly, the order of filtration and sham filtration was randomly assigned. And this was a group of relatively healthy kind of middle-aged adults. And we measured exposures including PM2.5 and levoglucosan, which is a marker of wood smoke, both inside and outside of homes.

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DR. ALLEN: The second study was very similar to the first. This one was conducted in Vancouver. Same study design. Many of the same outcomes. Many of the same exposure measures. The key difference here was that we used some modeling work that had previously be done -- been done in greater Vancouver to identify neighborhoods and areas of the city that were impacted by one but not

both of the pollution sources of interest. And those were traffic-related air pollution, TRAP, and wood smoke.

And so you can see in the map the areas in red are postal codes that are -- have relatively high traffic-related air pollution concentrations and relatively low wood smoke. And then the areas in green are the reverse of that.

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DR. ALLEN: And then the third study that I'm going to draw from is the one that we're actually still working on and this was a -- this was a very different study in many ways. Rather than using that randomized cross-over design, this was a parallel group randomized control trial, like -- very much like a drug trial or a vaccine trial.

We enrolled a group of non-smoking pregnant women living in the capital city of Mongolia, and we randomly allocated them into either an intervention or a control group, where the intervention group received the air cleaners, the control group did not. They used them from enrollment in the study until the end of their pregnancy.

The study was initially designed to look at birth weight as a measure of fetal growth. And then we subsequently got funding to continue to follow these kids and look at indicators of early childhood development,

things like cognitive performance, behavior, measures of obesity, measures of respiratory symptoms, those kinds of things.

And like John said in his work in Fresno, we actually have money to continue to follow this cohort, but COVID has obviously made things a little more challenging.

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DR. ALLEN: So I guess the first consideration when you're thinking about one of these studies is how do -- how do your plans fit in with what's already been done and what we already know? And I would say that this kind of landscape has changed a lot in the -- over the ten years since we started doing these studies.

That first study was published in 2011. And at that time, there was -- there was some evidence that air cleaners -- portable air cleaners improved -- or reduced particulate matter concentrations particularly in residences. But over the last 10 years, there's been quite a lot of research in this area to the point that we're now getting some review papers. And I've included some screenshots here of different review papers try -- kind of summarizing this literature.

I would say now there's pretty strong evidence that these devices reduced PM concentrations in residences, as well as some evidence that these devices or

enhanced filtration in HVAC systems can reduce concentrations in public buildings like schools. These are mostly short-term studies, not entirely, but most of them are short-term studies looking at kind of days or weeks. And there is now some evidence of health benefits from filtration, but there's less health evidence than evidence of exposure benefits.

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DR. ALLEN: And then sort of once you've situated the proposed study in the -- in kind of what we know and what we don't know, I guess the next sort of consideration is what is the goal?

And what I mean by that is, is the goal to actually evaluate the intervention because you're interested in the intervention or is the intervention simply being used as a research tool to reduce exposure and introduce an exposure gradient.

So since we've started doing this work in Mongolia, and I've given talks about it, and I've had people sort of ask, you know, do you think air cleaners are the solution? And my answer is always well no air cleaners aren't the solution to air pollution. The solution to air pollution is to produce less air pollution in the first place.

So these air cleaners might be useful in

particular settings for particular populations. But really my interest in these studies is -- with these air cleaners is that they allow us to ask the question what happens to health when air -- when air pollution goes down, when air quality improves?

And so I think it's worth -- as you're thinking about these studies, it's worth thinking about whether you're interested in the intervention per se or whether you're just simply interested in exposure reductions and air cleaners are one way to kind of manufacture an exposure reduction in your study.

There are a lot of advantages to these kinds of studies, as most of you probably know. Certainly, by randomizing exposure in some way, we reduce the potential for confounding bias, which is always a challenge in this -- in these kind of studies. We can -- we can enhance or increase that exposure gradient. And that's where a lot of the statistical power in these studies comes from. The more kind of -- the larger the difference in exposure within your study population, the more likely you are to see associations with health.

And one of the things I really like about these studies is that they're fairly intuitive. You know, so to try to control -- to try to describe a case control study to someone who doesn't -- who isn't trained in this area

can be challenging, but there's sort of an intuitive element to the idea that you have, you know, health measures when air filters are used and health measures when air filters aren't used and you're comparing those. So that can be useful for trying to kind of communicate and disseminate your results.

Of course, disadvantages, these are difficult studies to do. They take a lot of effort. And as a result, we typically have relatively small study populations. There are concerns about external validity. That is people who participate in these studies may differ in important ways from people who don't participate in these studies.

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DR. ALLEN: Another sort of exposure-related challenge with these studies is one that I'll describe next, and that is this idea that in these studies when you evaluate the health benefits of the intervention, you're effectively using intervention status, that is intervention versus control, as a surrogate for exposure. You're kind of using a binary surrogate in place of a continuous exposure.

And I'll use some results from our studies to try to illustrate this point. So in the Mongolia work, we measured PM2.5 inside residences at two points in -- two

points in each woman's pregnancy, right after enrollment and then a few months later in pregnancy.

And so we had these kind of two discrete measurements of pollution concentration and we wanted to try to model what was happening in all the other weeks of pregnancy. And so we looked at predictors like outdoor pollution concentrations, and whether there was smoking in the home, and window opening, and season and various things. And we were able to develop a pretty good model for explaining -- or for predicting pollution concentrations. The model explained about 80 percent of the variability.

But intervention status alone only explained about six percent of the variation in pollution concentration. So the situation in these intervention studies, even though these interventions are effective, these air filters are effective, the exposure distributions of your groups don't really look like this what I'm showing here. They look more like this figure on the right, where you have these exposure distributions and the intervention is shifting the distribution down, because the inter -- you know, the air cleaners do work. They do reduce concentrations, but there are a lot of sources of variability in your population that will have nothing to do with the air cleaner.

And so -- and so you're essentially using a fairly crude indicator of exposure when your analysis focuses on intervention versus control.

And as -- and as -- the reason I'm kind of going on and on about this is that we've seen what we think are the effects of this. So this figure shows results from our Vancouver study, where we're looking at associations between various measures of exposure and C-reactive protein as an indicator of systemic inflammation. And you can see that for HEPA filter status, or intervention status, intervention versus control, we really saw no evidence of associations. Whereas, for PM2.5, we saw some evidence that when PM2.5 went up C-reactive protein went up. And one explanation for this is this idea that air cleaner status intervention control is really introducing a lot of exposure misclassification.

And so one approach might be when you're doing these studies is to think about analyzing exposure both ways. You can look at whether the intervention is beneficial using kind of a binary approach or you can actually look at measures of exposure, which may give you a more refined exposure estimate.

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DR. ALLEN: Excuse me. Another consideration here, and this actually came up a little bit in the

discussion earlier, is the idea that these air cleaners are only doing any good in terms of exposure when the participants are in the location where the air is being filtered. And we didn't measure personal exposure in our studies, but other studies have demonstrated this very clearly.

For example, there was a study in Beijing that found that HEPA filtration reduced concentrations in homes by 82 percent, but personal exposures actually -- were actually a bit higher when the filters were on. The filters did essentially no good for personal exposure. And the authors attributed this to time spent in other settings.

Similar results from a study in Shanghai where the reduction in concentration was about 68 percent, but the reduction in personal exposure was only about 27 percent. And obviously, this will depend on how much time people are spending away from home. But for age groups and populations that do spend a significant amount of time away from the environment that is being filtered, this can be an important consideration.

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DR. ALLEN: And a third exposure related consideration that I would -- that I would highlight is the importance of the baseline concentrations. So the

exposure gradient that you get in your study, which really drives a lot of your statistical power comes really from two things. It comes from how effective the air cleaners are, but it also comes from what the baseline concentration is. This is probably obvious to most of you, but I just wanted to emphasize it.

So in our study, number one, we saw about a 60 percent reduction in mean PM2.5 concentrations when the air filters were on. And that corresponded to about a six and a half microgram per cubic meter contrast in PM2.5.

Study 2, the air cleaners were less effective and the baseline levels were lower, so there was a much smaller exposure gradient.

And then in study 3, we saw about a 30 percent reduction, which corresponded to about a seven microgram per cubic meter contrast between the intervention and the control group. And so study 3 is a useful example. The air cleaners for various reasons weren't as effective, but because we conducted that study in a place with high baseline concentrations, that 29 percent reduction still corresponded to a relatively large contrast in exposure. And this again has implications for, you know, how much power you have to detect associations with health.

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DR. ALLEN: Study design is obviously an

important consideration. As I said, we've relied largely on this randomized cross-over design, which is a very useful design, because effectively participants serve as their own controls. You're basically comparing each individual to him or herself. And by randomizing the treatment order with some people getting the real filtration first and others getting the placebo filtration first, you reduce the potential for confounding by things that are varying in time.

One of the things we have had to sort of puzzle with when we do these studies is whether or not to include a washout period. So often in these studies, there will be a gap between session one and session two that is meant to prevent any effects from session one from bleeding into or sort of carrying over and contaminating session two, so to speak.

And there was a review paper published just a few weeks ago that looked at these studies and they really highlighted the lack of these washout periods as an important limitation, including in some of our studies. We have not used washout periods in our studies and I would argue that that criticism is maybe a little bit overblown. And the reason we've not used washout periods in our studies is that we thought that the exposure response relationship for the outcomes we were looking at

was relatively short compared to the duration of the monitoring sessions. So for example, we thought that it was probably only about the 48 hours or so of exposure prior to the health measurements that was really driving those measurements.

As a result, with seven-day monitoring sessions, we thought that the first sort of half of the monitoring session was effectively acting like a washout period. So I would argue that the need for a washout period probably depends on the time scale of that exposure response relationship relative to the duration of the monitoring sessions or the duration of the intervention.

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DR. ALLEN: I mentioned, you know, that we'd focused on healthy populations in our studies. And, you know, I'm sort of using -- I'm kind of oversimplifying here talking about healthy people versus susceptible people. When I say susceptible individuals, I mean, for example, maybe people with asthma or some other morbidity that may make them more susceptible to the health effects of air pollution.

And there may be valid reasons for focusing on one or the other. For example, susceptible individuals may be more responsive to air pollution. You may be more likely to see a response in that group. Whereas healthy

individuals may allow for a simpler analysis. So, for example, they may be on fewer medications that may mask the effects of air pollution.

But these studies tend to be pretty small and often you're not able to look at sort of a bunch of subgroups. You kind of end up analyzing the cohort as a whole. And so the approach that we've taken is that because of the way our studies were conducted and the places our studies were conducted, we thought it was going to be difficult to recruit a sufficient number of susceptible individuals to make for a meaningful analysis.

And so we were worried that having just a few susceptible individuals would make the analysis more complicated and, you know, more challenging. And so we sort of took an all-or-nothing approach, the idea being if you can't get enough susceptible individuals into your study population to do a meaningful analysis on that group, it's best to try to -- to try to actually not enroll those people into your study. And so that's why we ended up with these cohorts where we intentionally tried to recruit healthy individuals.

And that's not to suggest that's the only approach, but -- or -- and it won't be appropriate or feasible in every situation, but it seemed to be the right approach for to us.

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DR. ALLEN: As far as the air cleaners go, you know, the first decision is obviously -- or maybe not obviously, but one of the first decisions is whether you're going to do filtration in the HVAC system, or use portable units, or both, as is the case in the proposed schools study.

There is this concern that I think was mentioned earlier about the use of really high efficiency filters in older HVAC systems where the system may not be able to handle that high level of filtration. And I'm not an expert on HVAC systems, but you hear this kind of anecdotally sometimes.

In our studies, as I said, we used -- we used portable air cleaners. We used HEPA filter air cleaners, but there are other technologies available, for example, electrostatic precipitators. A really important consideration, of course, is the amount of filtration that you're achieving relative to the volume of air that needs to be filtered to the -- to the size of the room or the building where you're conducting your study. And that's a function of having either right -- either the right size air cleaners or the right number of air cleaners operating them on a high enough fan setting to do the job. But all of those things have implications for noise.

And then you can think about compliance monitoring, trying to determine how much your participants are actually using these devices. That could be done via self-report using some built-in timer or using some external measure to -- of electricity, for example -- or sorry, external measure of compliance, like measuring how much electricity the unit is using and then converting that into a measure of air cleaner use and intensity.

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DR. ALLEN: I'm going to -- I'm going to skip over some of the more nitty-gritty details of what we've done with the air cleaners in our studies. I'm happy to tell folks about that, if there's interest.

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DR. ALLEN: But I mentioned noise, I just want to highlight this as an important issue. So these are results from our Mongolia study showing concentrations in intervention and control groups after the air cleaners were first deployed and then after about five months of use. And you can see when the air cleaners were first deployed, they were pretty effective. They reduced PM2.5 concentrations by about 40 percent.

After five months of use, the effectiveness had dropped to about 15 percent. And there are a few reasons that we think that happened, but one of them -- again,

this is sort of anecdotal, but one of them is that we heard from a number of participants that they were concerned about the noise, particularly in the bedroom units and so they would just turn the unit off.

And that sort of level of annoyance with the noise kind of increased over time. And so this noise issue I think becomes very important in these studies. The air cleaner is obviously knowing -- doing no good if participants are turing it off, so I think it's really important to try to select air cleaners that work and are appropriately sized, but are also not so noisy that they're going to drive participants crazy and make them turn off the air cleaners.

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DR. ALLEN: I just want to say a few words about kind of how we've selected outcomes, not so much which outcomes we've selected, but our sort of how we thought about selecting outcomes. And John highlighted this -- John highlighted this earlier. This is a very complicated figure showing kind of the different pathways through which air pollution can ultimately affect cardiovascular health in this case.

And the details aren't important for the point I'm trying to make here, which is just that I tend to think of these as kind of a chain of events, this happens,

then this happens, then this happens, then this happens. And I think of that chain as moving from sort of indicators of mechanism all the way ultimately to some disease or some clinically relevant outcome, like maybe it's a heart attack or a stroke.

And this is -- this is a little bit sort of simplified, but you can sort of think of this chain of events. And so the way that we've thought about outcomes is to think about kind of where in this chain of events we want to be when we're doing our study and the trade-offs involved in being at different parts of this chain.

So for example, as you move further to the left in this figure, you may have measures that are more sensitive to air pollution, more temporally variable, but also less -- probably less clinically relevant and potentially more difficult to interpret and to communicate. Whereas, you move to the right, you sort of trade off some of those considerations.

And so we've done -- we're less interested in kind of the mechanisms of how air pollution has its effects. And so our focus was really on what we call intermediate outcomes, outcomes that are -- that are changing on a time scale that we can measure, but that are also predictive of more clinically-relevant outcomes. So this is just sort of how we've thought about how these

outcomes fit together and how to select one way that you might select outcomes in your study.

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DR. ALLEN: So just to summarize, I've been, over the last several years, a real proponent of these intervention studies for a number of reasons. I think they provide several advantages beyond just the one you typically hear, which is that they minimize confounding bias. You can use them to actually evaluate the benefits of air cleaners or the air cleaners can simply be a tool to introduce an exposure gradient, which can be useful to study.

You get a lot of statistical power in these studies, or you can, if you have a sufficiently high baseline pollution concentration and if the air pollution effectiveness is sufficiently high. It's probably obvious to all of you, but you really need to carefully consider the size, number, location of the air cleaners and the amount of noise that they produce.

And, of course, I just wanted to kind of finish by making the point that this is -- this is not meant to be kind of a comprehensive list of considerations. There are a lot of things I didn't talk about, including the ethical implications of these studies, issues around participant burden, which is -- which you all obviously

know about having done a lot of biomonitoring work, and then a lot of analysis consideration.

So, for example, in these studies, you're going to have a lot of missing data typically and how are you going to handle that at the -- in the analysis phase?

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DR. ALLEN: So with that, I'll just acknowledge that the work that we've done that I talked about today was funded by the Canadian Institutes of Health Research. And there were a lot of people involved in a lot of different institutions, too many for me to name. And I've included here for your -- in case it's of interest, I've included all of the references for the studies that I mentioned.

So with that, I will finish up and thanks for your attention. And I'm happy to chat or try to answer any questions.

CHAIRPERSON SCHWARZMAN: Thanks so much, Ryan. I really appreciate that. You elucidated for me some of the advantages that I hadn't -- or anyway, some of the -- all of the situations around these kinds of intervention studies that are helpful here. We have 15 minutes now for questions and discussion from both Panel and the audience. So a heads up to participants and public who would like to ask questions or provide comments, you can do that by

email or through GoToWebinar. And I'll open it up to panelists who have questions.

Tom.

PANEL MEMBER McKONE: Hi. Thanks. That was really interesting. I think it's very useful to do these studies. I guess the question -- I just was interested in a little bit more information about compliance. I mean, you talked about compliance as an issue in Ulaanbaatar, or Baatar, and -- but in the British Columbia studies, in the chart, as I recall, it said the compliance -- the devices were not pre-set, so they could control the fan speed. And the fan speed, of course, is really important in the amount of air volume that's clean.

Did you have some opportunities to look at compliance in those studies and how it affected results, where it was kind of open to the individuals how much they turned up the --

DR. ALLEN: Yeah. Yeah. Yeah. I kind of -- I kind of glossed over that very quickly. We didn't -- we didn't really do much with compliance in the two studies in British Columbia. We never really settled on a method of measuring compliance that we were very happy with. And you mentioned that we didn't do really anything in terms of trying to control how people used it. We basically asked them -- when the study started, we asked them to use

the air cleaner at the highest setting that they were comfortable with. But obviously, that will vary from person to person.

And so that is a source -- that is a -- that is a source of variability in the study with some people using it on high and some people using it on low. And that's part what we were trying to address in the Mongolia study. So I mentioned that we bought the air purifiers from the manufacturer. And when we did, we actually had the manufacturer lock the air cleaner on a particular setting, so it would only operate on one setting. You couldn't -- it was either on or it was off, but there was no adjusting the fan.

In hindsight, that was probably a mistake. And the reason is, you know, letting the participants turn it up and down has its own set of problems, but at least if they're worried about the noise for example, they can turn it down. In Mongolia, what happened is they were concerned about the noise and they couldn't turn it down, so they just turned it off.

So having done it both ways, I would -- I would probably -- my sense is that the way we did it in the first two studies was probably better. It wasn't perfect, but it was better, because then at least you're -- it's better that they use it on low than that they don't use it

at all.

But, no, we don't have any really good data on how those -- how those -- you know, turning it up and down, how that influenced our results. We didn't really have much in terms of compliance monitoring in those first two studies.

PANEL MEMBER McKONE: Thank you.

CHAIRPERSON SCHWARZMAN: Jenny.

PANEL MEMBER QUINTANA: Thank you for that really thoughtful description of pluses and minuses of different approaches. I just have a vague memory of a study that was done in Las Vegas looking at black carbon inside and out in schools, and an air filtration intervention that was performed. I just remember reading it and they just remarked that they had this whole system of air cleaning, but it was completely foiled by the teacher propping the door open. And I'm just wondering how much like people opening doors or what instructions -- what's your experience with instructions about doors and windows open or not, or -- and how that might affect results?

DR. ALLEN: It has a huge effect, because it -- essentially when you open the door, open the window, you're dramatically increasing the amount of polluted air that needs to be filtered, right? And so it has a huge effect.

I didn't -- I didn't show it, because, you know, I couldn't show you everything, but in Mongolia, we looked at filter effectiveness by season. And the effectiveness in the summer was basically zero. And we think that's for two reasons. One is pollution there is very seasonal. And then in the summer pollution levels are lower and so people are just less worried about it. And so we think they use the air cleaners a bit less in the summer, because they just weren't as worried about it. But the real driver we think is that people were opening the windows all the time. Nobody there has air conditioning, so when it gets hot, you just open your windows, and the air cleaner just can't keep up. So that's a huge -- that's a hugely important factor. You can basically make the effectiveness go to zero if you open enough windows.

PANEL MEMBER QUINTANA: Thank you.

CHAIRPERSON SCHWARZMAN: Are there questions or comments for Ryan?

Shoba, I want to check in about other comments or questions that are from anyone other than the panelists?

DR. IYER: Yeah. Thanks. I see none at this time.

CHAIRPERSON SCHWARZMAN: Okay. Great.

Jenny has a question and then I have one after that. Go ahead, Jenny.

PANEL MEMBER QUINTANA: You should go ahead with yours.

CHAIRPERSON SCHWARZMAN: I appreciated your slide showing the range of looking at sort of indicators of mechanism versus health outcomes and the pluses and minuses of each. And I wondered, given that the intervention study that Biomonitoring California is contemplating, where we're really looking at -- the design is to look at biomarkers of exposure, really more than biomarkers of effect, and whether you have any input for the Program given some of the liabilities of the biomarkers that are at that end of the continuum, if you have any recommendations or suggestions relevant to that -- this study that they're working.

DR. ALLEN: You know, I have to admit I don't -- I don't have a lot of experience with biomarkers of exposure. We -- you know, we -- in our studies, to measure exposure, we have kind of done it the old fashioned way so to speak, which is to measure, you know, what's in the air, you know, inside people's homes and outside of people's homes. So I don't have a lot of experience with biomarkers of exposure.

You know, I will say some of the -- some of the biomarkers that are being proposed in that study, you know, I would argue are probably more effect biomarkers

than exposure biomarkers. You know, certainly the PAHs and that sort of thing are obviously exposure markers. But there was some talk of sort of inflammatory markers and those sorts of things. And I think trying to use those as biomarkers of exposure is going to be really difficult to interpret, because they're so non-specific, right? There are lots of things that cause inflammation. There are lots of things that cause oxidative stress.

And so trying to interpret those as telling you about exposure I think may be a little bit challenging. I mean, I guess -- I guess the line between a biomarker of exposure and a biomarker of effect starts to get a little bit fuzzy. But that's real the only comment that I -- that I would make is that some of those, I think, you know, the interpretation may become difficult. Again, just because they're so non-specific.

But as I said, take all this with a grain of salt, because I have much less experience with biomarkers of exposure. We've done some work in our studies with metals, for example. You know, we've looked at cadmium, and lead, and mercury, and those kinds of things. But again, my experience with those biomarkers is fairly limited.

CHAIRPERSON SCHWARZMAN: Thank you. And I think part of the question is how that's being framed in results

return --

DR. ALLEN: Yeah. Yeah.

CHAIRPERSON SCHWARZMAN: -- because participants tend to just lean so much toward wanting to hear and therefore hearing conclusions about health impact that maybe that's part of the balance.

But Sara, it looks like you have something to add here.

MS. HOOVER: Yeah, I just wanted to thank you, Meg, for raising that and note that that's actually one -- one of the challenges we listed and also a particular discussion question we want to go into. But I did want to clarify that, yes, it's true we're planning to use them as biomarkers of exposure, in part because of all the past SGP input about, you know, this is an exposure program. Our goals are about exposure. It doesn't really seem feasible to me and others, my colleagues, to provide a health interpretation of those biomarkers.

And, in fact, we're really using them as complementary, so we were very aware that even just trying to use PAHs and VOCs, you know, there's a lot of difficulty interpreting those. So based on all the research that Susan, Stephanie, and Julia did, you know, we're kind of going at it with multiple lines of evidence, including air measurements, biomarkers of exposure, and

biomarkers of effect. Although, we're using them as another form of biomarkers of exposure. So really the idea is to give us -- give us a nice suite of information to try to interpret our results the best as we can. But we're very aware of the challenges in what we're trying to do. And we definitely appreciate any -- any ideas on how to do that better.

CHAIRPERSON SCHWARZMAN: Jenny, you had a thought?

PANEL MEMBER QUINTANA: I just had a question, because I assume that your participants in Mongolia were possibly lower income than in Vancouver, and -- because we were working with some homes and schools in Tijuana and we were -- I was kind of wondering about trying to raise money for getting air cleaners and wondering if participants would think the electricity required to keep them running would be a burden?

And I'm just wondering how that came up. Did you pay for the electricity in Mongolia or did they pay for it and did they complain or how did that go down?

DR. ALLEN: Yeah. It's a good -- it's a question. Certainly, in kind of a global context, our cohort in Mongolia was relatively low income. But in the Mongolian context, they were actually quite wealthy. This was an urban pop -- apartment-dwelling population. But

yeah, so participants received an honorarium for participating. And part of the intention of the honorarium was to offset electricity costs. So we didn't -- we didn't pay the electricity per se, but they received an honorarium that was sort of intended to cover that.

And we did hear -- again, it was anecdotal, but, you know, I mentioned complaints about the noise. The other reason that we heard that participants turned off the air cleaner or used it less was -- was exactly that. It was concern about the electricity costs. So, yeah, we did -- we heard that from a number of participants.

CHAIRPERSON SCHWARZMAN: I think that is the end of our time. And I really want to thank you, Ryan, both for the thoughtful presentation and sticking around to respond to questions. And we'll also look forward to your contributions to the afternoon discussion.

With that, I want to move on to our next speaker, and introduce Maggie Clark, who is an associate professor in the Department of Environmental and Radiological Health Sciences at Colorado State University. Maggie's research has focused on the health effects of exposure to air pollution, primarily from cooking-related biomass burning and from secondhand smoke, identifying and interpreting appropriate measures of exposure, and indicators of future

disease risk, as well as elucidating factors that may confer increased susceptibility to the adverse effects of air pollution exposures.

She's committed to conducting studies within a community-engaged framework and she will discuss for us issues around study design, including timing the measurement of biomarkers of exposure and effect in relation to air pollution intervention research.

Thank you so much, Maggie.

(Thereupon a slide presentation.)

DR. CLARK: Thank you, Meg.

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DR. CLARK: I also want to take the opportunity to thank Sara, and Susan, and Stephanie for the invitation to speak with you all today. It's been enlightening to see how this process works in California. I'll also start by saying I have no conflict interest to declare.

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DR. CLARK: So for a quick outline, I'll start my presentation by talking a bit about the general perspective about how we approach choosing biomarkers. And these are primarily being conducted within an environmental health focused framework for research. As Meg mentioned, most of my research has focused on the impacts of household air pollution globally, which I may

use the HAP acronym and I know that stands for a couple other things as well. But when I use it, I'm referring to household air pollution and I'll describe that in a little more detail.

And I'll specifically use the example of the HAPIN randomized control trial. And HAPIN stands for Household Air Pollution Intervention Network, as an example of a study that has used a lot of biomarkers. In fact, it represents the largest -- the study that has the largest set of biomarkers in a household air pollution study to date.

We're targeting both biomarkers of exposure and effect in three distinct study population groups. So we're evaluating pregnant women. And then once the child is born, we're evaluating the children from birth to one year of age. And then we're also studying women that live in the same houses. We refer to them as older adult women that are 40 years and older.

And so given the features of this study, you know, I hope this example will provide, you know, a nice opportunity to discuss some of the design decisions that we made in that study that might apply to the California Biomonitoring study as well.

So I'll end my part briefly -- my part of the presentation by briefly going over some study design

considerations, again placed more in sort of a general environmental health research context.

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DR. CLARK: So in our studies, for the most part, we tended to simplify sort of this quest for choosing appropriate biomarkers, again with an environmental health context into these three questions I have on the slide. So when thinking about biomarkers of effect, how informative is the marker regarding disease prediction? I'll talk a bit more of this -- about this in the next slide. But I will say that there are plenty of times when I think understanding more about the mechanism of action is the goal of research. But today, I'm going to focus more on instances when biomarker discovery is not the primary goal of the study.

The second point here is how stable is the marker as it relates to the hypothesized time course of the modifiable effect. And this is something that Ryan talked quite a bit about in his talk as well. You know, in other words, does what we know about a particular biomarker's ability to change within a person lineup with how long we've designed our study to last, you know, and are we targeting the appropriate windows?

So the first window being kind of this -- you know, how long does a participant need to be exposed or

alternatively in a lot of the cases we're talking about today, how long does that exposure need to be removed or reduced in order to see an observable impact. And the second window considers how long it might take for the biomarker to change. So sort of once this process is sort of set in motion, how long does it take for that biomarker response to be observable? So this is the case where there might be a latent period to consider.

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DR. CLARK: All of this is to say is that often our goal really is to say that if there is a true impact of the exposure on the proposed biomarker that we've designed our study in a way that we'll be able to capture that.

I'll also mention that gaining an understanding from the within and between person variability is really important for sample size consideration as well. And I know Ryan discussed that during his talk as well. And so I think that's complementary with what I'd like to talk about a bit today.

The third point here is about the feasibility of measuring a biomarker in a study setting. And so, of course, that really depends on the type of study that we're talking about. For a lot of the work I do in household air pollution studies that often occur in rural

areas in low and middle income resource settings, it's a big challenge that we have to consider.

It's likely not as big of a challenge in -- you know, in a school setting in California. Although, it is still a challenge, I'm sure. But because of that reason, I won't be spending too much time on that third marker -- third issue. Sorry.

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DR. CLARK: So this probably also looks a bit familiar to what Ryan showed earlier. And I have a feeling I could say that a lot during my presentation, Ryan. But -- so there are various iterations of this figure that have been used to sort of conceptualize the idea of understanding biomarkers and research. And you can see the progression from exposure, often a measure of a pollutant that's external to the participant to then internal dose, which can be estimated by using things like body size, and breathing rates in conjunction with the external exposure, but for which biomarkers of exposure have become quite useful, and on to various stages of biomarkers of effect before actually reaching this onset of clinical disease.

So this particular iteration was adopted from a version that the National Research Council had published in the late eighties. But I like this one, because

DeCaprio adds this top portion here where, in essence, he incorporated this idea that I think is used much more commonly now with the exposomics field of this sort of meet in the middle concept. So for exposomics and for a lot of the non-targeted research that's being conducted, you know, the concept is that you study exposure and then you see, you know, in the non-targeted world what shows up as being associated with the exposure and then you sort of do the opposite, where you have diseased and non-diseased people, and you kind of go backwards and say, well, here are these non-targeted biomarkers that show up as interesting. And so where is the overlap and should we be pursuing that mechanism in more of a targeted approach.

So I do think it also applies in a more targeted realm, which I'll be talking about more today and for which the California Biomonitoring study is using.

And really I think the basis for applying what we do to -- applying this type of figure to what we do is the fact that we very rarely can design a study in the chronic health effects world that actually answers the full picture here, all the way from exposure to clinical disease.

We would need much more time and money than what we're typically given, and, you know, even if we have a five-year study design. So if we are interested in

biomarkers of effect, we can shorten the time frame of our environmental health studies by gleaning knowledge from some of the more clinical epi literature that's out there, some of those long-term studies that have helped us to define this second arrow here. And so we may know a bit before we conduct our studies about what might be good well accepted predictors of the clinical disease that we're interested in.

So if we're able to select, you know, one or a handful of those biomarkers that are commonly accepted as predictors of disease risk, then we can focus on this first arrow here when designing our study. So linking the exposure with those biomarkers then allows us to characterize this association of interest, which really allows us to say something about the likelihood that the exposure will lead to increased risk for some clinical disease in a much shorter time frame than what we would need if we had to study the entire picture.

Again, this is a point where participant burden comes into play here as well, especially when some of the clinical diseases might not be readily reported for something like a secondary data analysis.

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DR. CLARK: So I'll shift focus a little bit now to talk about that Household Air Pollution Intervention

Network study as an example of some of the biomarker work I've been doing. It's a randomized controlled trial of free liquefied petroleum gas fuel, including the stove, for 18 months. And I'll dig into those details a little bit in following slides.

But the trial, which is still ongoing, is among 800 households in each of these four study locations across the globe. I'm not going to go into it -- much justification for the trial itself, but I did want to point out that our protocol papers, one for the main trial, one for the exposure assessment, one for the biomarker approach have been published in Environmental Health Perspectives.

So I, you know, encourage you to take a look at that, if you're interested in some of the justification behind the reason we're conducting household air pollution clean -- or cleaner fuel intervention.

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DR. CLARK: So as I mentioned, the intervention is a locally available LPG stove having at least two burners. We provided the continuous free supply of the gas for 18 months. These photos here show two examples of traditional stoves, one from India and one from Peru. All households had to be using solid fuel burning stoves as their primary stove to be eligible for the trial, along

with a few other eligibility criteria that I'll get into.

The two photos here on the bottom show examples of the LPG stoves in households that were randomized to the intervention arm. And both of these also depict the educational and promotional materials that we use to encourage the safe and exclusive use of LPG. So in Guatemala, there were calendars provided along with some of the behavioral messaging. And in Rwanda there were posters.

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DR. CLARK: Our primary aims were to determine the effect of the LPG stove and fuel intervention on health and in the four LMIC settings. The second aim was to establish an exposure response curve for all of the primary and secondary outcomes.

And then thirdly, the one I'll focus on today, the objective was to determine the relationship between LPG intervention and biomarkers of both exposure and health. And I'll describe a bit more about the overall study design here. But as I mentioned, I will be focusing more on the biomarker aim towards the end of my time.

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DR. CLARK: So as I mentioned earlier, there were 800 households in each of the four country locations. The primary trial endpoints involved outcomes in the children,

for which we hypothesized that that in utero exposure would be relevant. And so the goal was actually to recruit women and randomize them before -- between nine and 20 weeks of gestation. We then also followed the child from birth to age one year.

And then in about 15 percent of the households, there was this older adult women population, which was nice, because it gave us the opportunity to ask questions related to chronic diseases, even though it's a much smaller sample size. But this was important for the biomarker of effect design as well.

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DR. CLARK: So I don't plan to walk through this entire table, but this is the Table 1 from the main trial protocol paper. So please check it out if you're interested in kind of understanding the full gamut of measures that we collected in the study. For this presentation purpose, I just want to point to the scale of the project, first of all, and then point out that there were at least seven visits over the course of the 18 months with measures collected among the pregnant women, the child, and the older adult women.

So I'll come back to this a little bit more with a more specific focus on the biomarkers in a few slides.

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DR. CLARK: Again, without going into too much detail, I wanted to provide the study timeline as a reference to give you a sense of how we've moved through each phase of this study from planning and piloting, all the way to analysis and dissemination. You know, of note, is that even once COVID-19 lock downs -- or COVID-19 related lockdowns started to happen around the world, we were able to continue delivery of the fuel. And so the intervention was pretty much unaffected fortunately.

As you can see here, we anticipate unblinding here after the last child, the youngest child born, turns one. And so we will not be unblinding the health outcomes still for a couple of months.

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DR. CLARK: So I can't talk about the HAPIN trial without mentioning the fact that we have been borrowing from expertise all around the world to conduct this study. The primary PIs are Tom Clasen at Emory, Jen Peel at Colorado State, and Will Checkley at Hopkins. Dana Barr and I co-lead the biomarker core. And Dana is located at Emory University. I'll also say that the trial is funded by the NIH and the Gates Foundation.

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DR. CLARK: Okay. So digging into the biomarkers a bit. Our overarching goal was to characterize a wide

range of the biomarkers in each of the participant groups, so pregnant women, older adult women, and child. For this talk, I'm going to focus here on this bolded third bullet to identify, prioritize, and measure specific biomarkers of household air pollution exposure and effect in urine and dried blood spots.

This fourth bullet is more in line with our biomarker discovery objective. So those are things like metabolomics and microRNA that I won't discuss in detail today but am happy to chat about in the Q&A if there's interest.

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DR. CLARK: I also am not going to spend too much time on the first two bullets, but I did want to just show you kind of the very diverse settings that we were collecting biomarker samples in. So, of course, the QA/QC checks had to be tailored to each location for us to have confidence in them.

We -- in addition to kind of training the local field teams in developing those QA/QC checks, we also had a goal of developing local lab capacity in our India study site. So the heavy lifting there was done by my much more analytically minded colleagues, Dana Barr at Emory University and Naveen Puttaswamy at Sri Ramachandra Institution in Chennai. As the epidemiologist part of the

leadership team, I'll focus more on study design considerations.

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DR. CLARK: So as I hinted at earlier, this is a -- this is a piece of the biomarker collection design that's taken from that much larger table I showed a few slides ago. You can see here that the six -- these six HAPIN visits plus birth incorporated biosampling. And then the table just lays out which participants. If there's an X, that means that participant had a sample collected.

The pregnant women had the same -- had collections during gestation. The child had collections during -- from birth to the first year of life, and then the older adult women had collections at all six visits.

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DR. CLARK: So the actual selection of which biomarkers to measure in the urine and dried blood is fairly established for the biomarkers of exposure here, but we have intentionally built in the ability to remain flexible with many of the biomarkers of effect. So we want to evaluate markers that will allow us to say something about the various pathways that we think are important in regards to air pollution exposure, cardiovascular disease, metabolic, cancer and respiratory

endpoints.

But, you know, as we've already been talking about today, we can also take advantage of the fact that many of these major chronic diseases share early mechanisms, such as inflammation and oxidative stress.

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DR. CLARK: So one of the reasons we actually need to really focus on biomarker prioritization is that in the end of the study we're going to have over 55,000 samples. So it isn't going to be logistically feasible to measure every analyte in every sample, of course, but we also don't think we need to do that in order to answer our study objectives.

So we have a pretty good sense of the types of biomarkers that are most appropriate for each participant subgroup. So as you can see here with this table on the right, while we'll measure exposure biomarkers in all three of the participant groups, we focused a marker of anemia in the pregnant women and the child, but the glycate of the hemoglobin, the HbA1c, measure in the older adult women. So that's something that's fairly well established already, even though we're maintaining some degree of flexibility.

We've also spent a lot of time validating our use of dried blood spots. So if there -- if information

wasn't available before we started this study in the literature, then we used formative samples to understand how well correlated dried blood spot was with venous-drawn blood for example.

We also used those formative research samples to understand what we could about within versus between person variability, which also as Ryan mentioned earlier, you know, is really important when thinking through sample size considerations and statistical power for your study.

One downside of using dried blood spots is that the volume -- the sample volume can be limited. And so the prioritization comes into play more for the blood-specific markers that we're interested in. So to help with that, we do plan to measure all analytes from the baseline samples to learn something about the associations between exposures and outcomes cross-sectionally, which we then hope will inform our intention to treat analysis and the longitudinal exposure response analyses with all of the repeated samples. We'll also have an analysis where we conduct -- where we measure analytes in a five percent subsample of the trial participants and then we'll also use this information to really help us better understand within and between person variability in those markers. And so I'll use C-reactive protein as an example of that one here in a moment.

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DR. CLARK: So I do want to state that while I'm sort of pointing to the factors about this study that highlight the challenges we're facing, I certainly don't want to be remiss in saying that we are -- also recognize that we have a pretty exciting opportunity to answer some of these research questions that have been, you know, sitting in this realm of knowledge gaps for quite some time in our field. So with that said, these next two slides just provide an example of how we've gone about working through prioritization of the biomarkers of -- in the study.

So we just take a Excel spreadsheet and lay out the urine aliquots and the dried blood spots and start filling in the samples with what we think is higher priority. So, for example, we know how much of the urine it takes to measure the PAH metabolites we're interested in. We also have to consider our responsibility to provide some subset of our samples to the NIH's BioLINCC repository. We have the second tier of exposure markers that I'm happy to talk about in the Q&A as well. And then we also have encouraged investigator-initiated proposals to add biomarkers. And this is really just our attempt to stay relevant, particularly with new papers that may have come out since we wrote the grant.

And so an example is Kyle Steenland is leading a study that we're doing measuring COVID-19 antibodies in dried blood spots. And similarly, Miles Kirby is leading a study associated with Malaria risk in Rwanda. And so those are just some of the ways we start to fill in these tables.

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DR. CLARK: So this is that same sort of prioritization scheme. This one was for the child samples. This is the older adult women. So again, we have six repeated measures, for that subgroup of the population. And here I really just wanted to point out the difference in that a lot of the literature seems to suggest that C-reactive protein -- the variability in C-reactive protein seems to be driven by between-person variability instead of within among healthy populations.

And so if that holds to be true in our sort of initial formative analyses, then what we might be able to do with that information is to say okay, well, we only need to measure C-reactive protein once during follow-up instead of using that first spot at every single visit. So this would allow us to answer more research questions.

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DR. CLARK: Okay. So my last slide to wrap-up, and actually a lot of these considerations are ones that

Ryan covered well already. So in my last minute, I'll move quickly through these a bit. But oftentimes, when we want to choose a comparison group in a biomarker study, it's the same really with any health and outcome study. What we really want to understand is the frequency of the outcome in a group of exposed people compared to the frequency of the outcome in the same group of people at the same time if they had not been exposed.

So this latter group represents what we call the counterfactual. In the absence of time machines in various movies, you know, the counterfactual is not observable. So we design studies that we believe are sort of along this continuum as far as ability to approximate the counterfactual.

HAPIN utilized a parallel random -- randomized control design. Some of the work Ryan described used the randomized cross-over design, which are really great at approximating the counterfactual when the exposure of interest is shorter acting.

And we also heard from John Balmes with an observational study design.

So next, we utilized the literature to hypothesize the time course or the speed of the anticipated exposure response mechanism that we're hoping to characterize. So again, this really is the same for

biomarkers as it is for typical health endpoint studies. But the hope here is that if we're utilizing biomarkers, that we actually will be able to learn something about the impact of the exposure or the intervention as we've been talking about a lot today in a shorter time period compared to the need to wait for those clinical outcomes to manifest.

I talked a lot about the anticipated variability in the biomarkers already. So in the interest of time, I'll go ahead and skip over that one, because I think it's repeating a lot of what John and Ryan have discussed already.

And I'll just add to the susceptible populations discussion with the fact that, you know, I agree with everything that Ryan had said already. And when we don't know, you know, this simplified distribution of a continuous outcome here shows the difference between baseline and post-intervention. And the idea here is that if we don't know to describe our population in terms of responders and non-responders, we might end up with just noise in our post-intervention analysis.

So the idea is to really be able to characterize these. And, of course, study design considerations also have to play a big role.

So with that, I will go ahead and turn it over.

CHAIRPERSON SCHWARZMAN: I need to unmute. Thank you so much, Maggie for that presentation. And again, we have 15 minutes here for questions and discussion points from both the Panel and audience members. We'll have a break after that and then we'll have our longer afternoon discussion specifically targeting the intervention study that the Program is designing.

Questions for Maggie?

Maybe it was just so clear --

(Laughter.)

CHAIRPERSON SCHWARZMAN: -- that no one was follow-up questions. Jenny, go ahead.

PANEL MEMBER QUINTANA: Hi. Thank you. I was waiting to see if other people wanted to jump in first, because I thought it was so fascinating. I'm just interested just in your blood spots, because that's such a wonderful approach when you have to have a multi-continent study, because getting blood or serum is a real nightmare, as I'm sure you know. And I just had some practical questions. I mean, are these stable at room temperature or are they just dried, and can they be mailed, and, you know, are they completely robust in that sense, I guess, would be my question?

DR. CLARK: Jenny, as you're probably guessing,

my answer is it depends.

(Laughter.)

DR. CLARK: So some analytes are perfectly fine, as far as degradation goes at room temperature. And there have been lots of more chemistry-focused studies that have shown, you know, how long you can leave a dried blood spot card at room temperature. We -- because we could, we avoided that and so we did end up freezing the samples after they were collected, you know, on the sites from our local partners before getting the cards to Emory.

But, yes, I mean, if you're interested in a particular analyte, there probably is a paper that's been written describing. And it does get more complicated as far as, you know, does it matter if you take a punch towards the end of the spot or in the middle of the spot. And so Dana Barr at Emory has been doing a lot of sort of up-front work to make sure that we can have confidence in the analytes that we're measuring in the end.

One of the other big considerations is blood volume standardization with dried blood. And so that's a little tricky for us, because hemoglobin is often used as a standardizing factor. And we think air pollution is associated with hemoglobin or we're hypothesizing that it is. We want to understand if it is. And so, for us, we're trying to understand if there might be other markers

that would be better. And some analytes are pretty robust, I think, to that blood volume standardization issue. C-reactive protein I think is one, but there are some that I think we do need to be worried about that. And so potassium is an example of something we might end up using.

PANEL MEMBER QUINTANA: Thank you. So did you ship them on dry ice from these centers, or just cold or --

DR. CLARK: Actually, we did not. We just shipped them in cooler boxes that were fairly well contained, but with ice packs.

PANEL MEMBER QUINTANA: I see.

DR. CLARK: So we did not have the luxury of using dry ice in many of the locations. So the number of freeze ball cycles that various analytes are able to withstand is also typically published as part of those feasibility or validation studies, but we felt confident in that approach.

PANEL MEMBER QUINTANA: No, that's great if you don't have to use dry ice, because that's so difficult for your partners, like you're saying, so that's wonderful.

DR. CLARK: Yeah.

PANEL MEMBER QUINTANA: Thank you. So interesting.

CHAIRPERSON SCHWARZMAN: Susan, please go ahead.

MS. HURLEY: Yeah. Thank you, Maggie. That was such an interesting talk. I think one of the most impressive things was you were able to continue through COVID, but --

(Laughter.)

MS. HURLEY: But I just had a specific question about the table that you showed where you showed which biomarkers you were measuring for your various groups. And I noticed for the kids you're measuring markers -- inflammatory markers, but not oxidative stress. And I was just wondering if you could comment on how you came to that decision?

DR. CLARK: So that's a good question. And Susan, yeah, to say one line about COVID seems very inadequate, but yes, that was --

(Laughter.)

DR. CLARK: The ability for the teams to kind of continue that supply of the intervention was pretty remarkable. So I think you might be referring to the dried blood spot list. But if not, then I think I may have made a mistake, because in urine we are measuring 8OHdG in all the participants. We will have that marker in the kids.

But you're right, I mean, we're still -- so what

I would like to do is measure telomere length in the dried blood spots. But this is another issue that I think is important to think about when prioritizing biomarkers, because it's doable. And NIH is actually interested in funding studies that are looking at telomere length. And that really is because we're starting to understand that it really might be this really excellent indicator of cumulative oxidative stress.

And so -- but the problem with what we're doing is that it takes two full blood spots to do it. And so for us that's a lot of real estate, when thinking about how much sample we have. So I think, of course, we owe it to the study as a whole and to our participants that provided these samples to think about whether or not we really can go with that biomarker as kind of that cumulative oxidative stress marker or not. But it would be really interesting to at least get to do it in a subsample.

MS. HURLEY: Oh, yeah. Yeah. Okay. Thanks.

CHAIRPERSON SCHWARZMAN: I want to check in with Shoba if there's anything from the audience and then I see Ulrike.

DR. IYER: Hi. I have one question passed along to me from Duyen Kauffman. And you might have mentioned this, Maggie, but were there incentives or honoraria in

your programs?

DR. CLARK: So great question. And there actually is a publication on that, because it was, as I'm sure the questioner is hinting at, extremely challenging to figure out what an appropriate compensation is for this type of research study. So that study is -- actually, the first author is Ashlinn Quinn. And it's published in -- sorry, I can't -- I don't have the title right here, but it's about control compensation for HAPIN. There was a lot of formative work with our community groups in each of the four locations to figure out what we should do as far as the control groups being compensated, because in one sense, we wanted to understand the impact of the ex -- the intervention itself on these outcomes that we had. We didn't want it to be the fact that there was some socioeconomic status advantage from having received the cleaner stove.

And so there was some consideration of, well, let's try to match the socioeconomic potential gain throughout the 18 months and then there was another conversation that was more like, okay, well, let's just wait. Let's not interfere with the control group at all and let's wait until the end of the study. So the decision ended up being for us, and not saying that it's right across the board, but that there was control

compensation.

Some research sites, based on what their community groups were giving them feedback, gave smaller incentives throughout at each visit in the control group, and a larger one at the end. And some of our countries just waited until the end for that control compensation.

Hopefully that answers the question.

CHAIRPERSON SCHWARZMAN: Ulrike.

PANEL MEMBER LUDERER: Yeah. Hi. Thank you for that really interesting and fascinating talk. My question, and you may have said something about this, is there any plan to return results to the participants? And if there is, you know, I'm sure there's many challenges of these different cultures of all the sites. And if you could talk a little bit about that, I think it would be very interesting to hear about.

DR. CLARK: Thanks for that question, Ulrike. Yeah, I think you hit the nail on the head as far as this being a huge challenge. And I will say personally I think I completely failed at that in the past, as far as really appropriately giving results back. So in -- it is important to think about what is meaningful in the local context for wherever you're conducting a study, right?

And so I will say that the NIH has supported studies focused on the bioethics of conducting this type

of work. And so we do have a supplement to work with local community groups to really figure out if -- what we had proposed was to just conduct a community meeting, where we provide the basic results and allow opportunity for questions. But that just seems so insufficient really when you think about how much -- how -- I mean, even just with the biosamples how many samples that each person was providing. And so we are working with a couple of anthropologists on this supplement to start thinking about what the formative early research results we had from the trial, what is most appreciated by the participants, how is it presented best.

And so some of the work we've done started with exposure monitor -- the exposure results that we have for each person. And so in that context, what we've -- I mean, this is extremely early analysis of the focus groups by our social scientist colleagues, but it really seems to be pointing towards kind of putting the exposure within the context of the entire trial.

But then, you know, I think sometimes the concept that there's another group that got something different than you isn't always easy to understand, because a research realm is not intuitive in all locations. And so, we're -- I guess my long answer to what I really only have a short amount of information on is that we're trying to

understand how to be better about that and try to make sure that we're sort of honoring the commitment that these participants make when they volunteer to be in these studies.

PANEL MEMBER LUDERER: Thanks.

CHAIRPERSON SCHWARZMAN: Thank you so much for that discussion.

That brings us to our afternoon break. We have 15 minutes now for a break. And if folks can be back promptly, we'll start right at 3:10 and move into our afternoon discussion session. So thank you so much to you, Maggie and Ryan, and -- who added so much to our -- the contributions by the other speakers also. And we'll resume at 3:10

(Off record: 2:54 p.m.)

(Thereupon a recess was taken.)

(On record: 3:10 p.m.)

CHAIRPERSON SCHWARZMAN: Okay. I want to welcome everyone back from the break and reintroduce Susan Hurley, who is going to introduce our discussion session. She is a Research Scientist in the Safer Alternatives Assessment and Biomonitoring Section of OEHHA. And she'll provide a brief introduction to the questions that the Program could use input on with regard to this planned study.

I'll turn it over to Susan and then we'll have a

discussion.

(Thereupon a slide presentation.)

MS. HURLEY: Okay. Thanks, Meg.

So I think that the purpose of this afternoon discussion session is really an opportunity to delve deeper into some of the challenges I mentioned earlier, and as well as some other design issues -- other issues around design and interpretation. We came up with some informal discussion questions, which I'll present on the next slides, but we welcome your input on, and any topics you think would be useful to discuss.

Okay. I'm sorry. My slides aren't -- okay. There we go.

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MS. HURLEY: So the first question has to do with timing. As I said in my presentation, the first urine collection will be done in the morning using first morning void, but we're still trying to nail the optimal timing for the after-school collection, so that -- the question is what is that optimal timing for that collection to best reflect the air pollution exposures that are experienced during the school day, given that the biomarkers that we're looking at?

And secondary to that is how should we expect diurnal variations of the various biomarkers to be

considered in evaluating the optimal timing for that afternoon urine collection?

And then to help with the interpretation of laboratory results, we will be administering on-line questionnaires. So, you know, which topics would you consider the highest priority for inclusion on the questionnaires? I'm going to actually show -- on the next slide, I'll give you a list of -- a more detailed list of some of the topics we're currently considering, but we'd like to know if there are other factors that aren't captured on this slide that you think we should consider including. And then also what time frame should we -- should be covered when asking about these factors, so the last two or three days, last week, or something else?

So these are the possible question topics that we're considering for inclusion on the questionnaires. I'm not going to read through all this, but we can bring it back up when we get to this part of the discussion. But it -- overall, we've -- we're considering topics that cover demographics, some of the characteristics of the home, some of the activities in the home, you know, recent activities, as well as the child's activities and some of their health and medication use.

So I won't linger on this too long, because we can bring it back up when we are discussing this.

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MS. HURLEY: Other questions we would love some input on is how can we use biomarkers of oxidative stress and inflammation to support the interpretation of our biomarkers of air pollution exposures? So this is more of a scientific question. But then we also have the question of how to communicate the results from biomarkers of oxidative stress and inflammation to our study participants. So that's, you know, more an issue of results return.

And then because we have a very narrow time window to conduct the study, we may have to proceed even during wildfire. So under this scenario, are there any specific study design modifications we should consider?

So those are some of the questions we have. But as I said, we're welcome for discussion on any topics you all think would be useful. And with that, I will hand it back over to Meg who will facilitate the discussion section.

MS. JARMUL: Meg, I think you're muted.

CHAIRPERSON SCHWARZMAN: Yeah. Sorry. I'm juggling a switch in who is screen presenting and all of that.

So I'm not going to show my -- oops, something is happening here.

Sorry. GoToWebinar is threatening to kick me off. So if that happens, I will log back on. It's to do with the screen sharing and giving it permission to record and things like that. Sorry for that.

So I want to open it up to discussion now. We have an hour for this portion. The Program is asking for lots of very specific input on these questions. And I think my preference for how to do this is that I'll leave it open at first if -- for thoughts and then return -- once people have sort of volunteered whatever thoughts they have, we'll return to the sort of organized presentation of questions to make sure that we've provided input on each of them and see if we can elicit any other responses if there's -- if the Program isn't getting the input that you need.

And so before we do this, I just want to remind everyone we'll stick to the same sort of participation methods that we've been using. Panel members, I can see you, so you can just raise your hand. Guest speakers or Program staff, if you want to speak, just turn on your webcam and you'll show up and I can call on you -- you know, raise your hand and I can call on you.

For attendees, you know, who can't show up on webcam, if you want to speak during the discussion session, please just alert us by using the question or

raise hand feature on GoToWebinar and I will be checking in with Shoba who's monitoring that, and we'll call on you. Then you would have to unmute yourself to ask your question or provide your comment. And then just remember to mute -- remute yourself once you've finished speaking.

Everyone aside from Panel members, you can turn off your webcam and mute yourself once you've finished speaking. So just pop on to speak.

As before, webinar attendees can also submit written comments or questions via GoToWebinar or by email to biomonitoring@oehha.ca.gov and we'll read them -- sorry, read them out loud.

So that's enough of the introduction for the moment. And I want to turn it over to Panel members for input and comments, or raising questions of your own, or whatever is on your mind about these study design questions.

Yeah, Veena.

PANEL MEMBER SINGLA: Thank you.

On the -- on the question of the results return, I wonder if it might be helpful to do like a -- maybe a survey or questionnaire with the parents at the start of the study to understand what's most important for them to know about the results -- the results return and maybe ask some questions getting to this -- you know, their

scientific uncertainty or, you know, kind of framing out the general issue and then asking, you know, what kind of information would be most helpful to you, you know, given scientific uncertainty or kind of other issues related to interpreting these results, so to maybe get a sense from the parents what they most want to know and what kind of information would be helpful to them.

CHAIRPERSON SCHWARZMAN: Oliver.

PANEL MEMBER FIEHN: Yeah. You also had somewhere the point diet. This is an open-ended question or I don't know how you -- what kind of responses you expect there. This is really hard to ask people about their diet. I'm just saying that I don't think you really want to do that. It's difficult, scientifically difficult and open-ended.

CHAIRPERSON SCHWARZMAN: Can I ask just a clarifying question about that, because I think it's probably worth starting a discussion about diet. Jenny had a comment earlier that we sort of deferred to this discussion section to -- session and that was Jenny's comment was more about her view that providing dietary guidance is not helpful and potentially complicating. So that's a little bit different.

But Oliver, could you say more about -- you know, I hear you saying that it's -- I'm just wondering if

you're talking about evidence that it's really hard to get accurate dietary information or is it hard to know what the right things are to ask?

PANEL MEMBER FIEHN: No.

CHAIRPERSON SCHWARZMAN: If you're talking PAH exposures, which I assume is what, Susan, you're mainly interested in with dietary exposure. Just that there's no good kind of measure of -- that bears out about dietary exposure to PAHs. Can you just elaborate a little bit, Oliver.

PANEL MEMBER FIEHN: Oh, okay. So if that's the question, then it's different than I thought. If the -- like do you burn your food? I don't know. But that might be a little easier to ask, of course, right, if that's the -- you know, like do you have your own -- do you often cook on fire and have it like barbecued it in a way. That's, of course, easier to ask and easier to answer, if that's what you want.

MS. HURLEY: Yeah, that --

MS. HOOVER: Yeah, Susan, you want to --

MS. HURLEY: Yeah, that

MS. HOOVER: I was going to say diet is the topic. These are not the questions on our questionnaire. These are just topics we're planning to cover and we already have developed questions related to PAHs, because

of our East Bay Diesel Exposure Project. Basically, we're tying to get at, you know -- and you know, we know about barbecued food. We've seen that effect, where somebody ate a barbecued chicken meal in one study and they had an elevated PAH level. We're just trying to figure out are we missing anything? Are there things that, you know, you would chime in about.

PANEL MEMBER FIEHN: If it's a really targeted question, was it a really targeted answer (inaudible) of course.

MS. HURLEY: Right. Right.

CHAIRPERSON SCHWARZMAN: Yes. Jenny.

PANEL MEMBER QUINTANA: So I had kind of a little laundry list, is that appropriate to -- of comments.

One I guess is that, especially if you're using biomarkers of late exposure, early effect, if I'm remembering right, and I apologize if I got this wrong, but you're splitting the kids into two groups, right?

MS. HURLEY: Yes.

PANEL MEMBER QUINTANA: One getting the intervention, one not? I mean, to me, I think using each person as their own control for the biomarkers would be much --

MS. HURLEY: Yeah.

PANEL MEMBER QUINTANA: You'd get rid of a lot

of -- a lot of variability that comes from their other exposures at home or what have you. It just seems like -- had you thought about that? And you mentioned being really time limited and I don't understand what those limits were. Was it that you only had money to go there for one week or -- I wasn't sure what the limits were that you're saying it was very time limited.

MS. HURLEY: Well, with respect to your first question, we're really -- we are intending -- our main analysis is going to be before and after for all the kids, and not that the -- so that second week where we have the additional stand-alone filtration, that will be sort of like a little mini intervention nested within our major -- within our study.

So the major analysis is going to focus on before and after measurements, before school and after school, so the kids can act as their own controls.

PANEL MEMBER QUINTANA: But, I mean, when I have the same kids, the kids get the -- don't get the intervention and they did get the intervention, right, is that what you're saying?

MS. HURLEY: Well, every -- well, the intervention may not be the best word to use here. So the -- during the first week --

PANEL MEMBER QUINTANA: Yeah.

MS. HURLEY: -- actually all the kids will be in classrooms with the MERV 16 already installed. And so what we're measuring is -- or what we're evaluating is does -- you know, with our biomarkers, do exposures go down after kids have been at school for a day breathing the filtered air? So just do their overall exposures go down? And then during that second week we just have this little add-on where one of the groups has the additional stand-alone air filtration.

So in that part we will also be doing before and after, but we will be comparing the before and after in the kids who only have MERV 16 filtration to the group that has MERV filtration with the additional stand-alone. So there will be, you know, sort of two level -- two different analyses that will be going on there. Does that make sense a little bit?

PANEL MEMBER QUINTANA: It does. I guess -- I guess I'm just -- I'm a little confused. I guess, I'm thinking of schools in San Diego that surround me are very old temporary buildings. They don't have air conditioning a lot of them. And maybe that's not true in the Central Valley, because it's so hot, you have to have air conditioning, but -- and so they weren't -- they don't have -- a lot of them don't have good systems. They could even retrofit, but I -- is this school typical of a

school? Do they usually have the MERV 16 or -- I guess to me -- I guess to me, you don't have a comparison group of a school that didn't have it, this filtration. I kind of worry that you're just going to have this -- I'm not sure what you're measuring exactly. They go to school and they breath filtered air. And it's probably a very low particulate at least, and maybe not as low for the VOCs for the reasons they said earlier.

MS. HURLEY: Yeah.

PANEL MEMBER QUINTANA: And then -- and then you're going to have an even lower, hopefully, for the VOC part with the air filtration. But I guess I'm not sure -- so in my mind I would think, oh, you're -- it would be nice to look at the effect of the MERV 16, but you're really not, right?

MS. HURLEY: Well, what we're looking -- I mean, yes, we can't do a -- we can't -- our results will answer the question does being at school breathing filtered air reduce overall exposures to, say for instance, PAHs, right?

We -- I mean, yes, there could be confounding by other things that are different from them being at school versus, you know, being somewhere else. But I actually thought you said it nicely earlier this morning when you said, well, you know, when you're arguing that maybe we

shouldn't be looking at -- be trying to control diet, you know, or advise them on their dietary choices, because really what we're trying to get at is, is this -- the filtered air at school, does that actually reduce the overall kids' exposure?

You know, it would be nice to have a control group. If we had, you know, a ton of money, then, you know, we could have a control group in another location. Although there's always problems with then finding an appropriate control group that really doesn't have other issues where that group is different, and, you know, there's a lot of confounding there, so...

PANEL MEMBER QUINTANA: So if you're taking a sample before school --

MS. HURLEY: Yeah.

PANEL MEMBER QUINTANA: -- and then after school, let's say --

MS. HURLEY: Right.

PANEL MEMBER QUINTANA: Let's say it's eight -- let's say it's an eight-hour period.

MS. HURLEY: Yeah

PANEL MEMBER QUINTANA: Then you're really looking at -- I'm using that same reasoning, you're looking at the exposures eight hours prior to arriving at school. I mean, you're looking that eight-hour window.

You're measuring the before presumably reflecting the eight hours --

MS. HURLEY: Right. Right.

PANEL MEMBER QUINTANA: -- and then you're measuring again eight hours, right?

MS. HURLEY: Right.

PANEL MEMBER QUINTANA: So you're kind of measuring what they're exposed to between midnight and eight or --

MS. HURLEY: Right, outside of school versus inside school.

PANEL MEMBER QUINTANA: Yeah, but more specifically --

MS. HURLEY: Yes.

PANEL MEMBER QUINTANA: -- you know, within a short window of middle of the night to early morning, right?

MS. HURLEY: Yeah. Yeah

PANEL MEMBER QUINTANA: Unless you look at -- it's possible like you see in the workplace that people's levels might go down over the week, you know. I mean, because they have --

MS. HURLEY: Yes, a cumulative --

PANEL MEMBER QUINTANA: Right, if it has a slightly longer half-life. Yeah, it might have a

cumulative effect.

MS. HURLEY: Yeah.

PANEL MEMBER QUINTANA: I just -- I mean, I was thinking of that relative to your questionnaire you kind of want to know like what happens that morning, I guess, you know, like how they got to school and did they --

MS. HURLEY: Right.

PANEL MEMBER QUINTANA: -- get a ride in a diesel truck or --

MS. HURLEY: Right.

PANEL MEMBER QUINTANA: -- did they walk to school next to a busy road?

MS. HURLEY: Yes.

PANEL MEMBER QUINTANA: You know, I'm just thinking of that specifically. And I think you're right, the timing is difficult. And I was disappointed to see you weren't measuring diesel biomarkers specifically, like 1-nitropyrene metabolites, but I assume that's because the half-life is so long that you wouldn't expect to wash out really through the week I'm assuming is what -- why you didn't choose --

MS. HOOVER: I'll respond to that. No. It would totally be possible in terms of half-life, at least our understanding of 1-NP half-life. It's just feasibility of that particular analysis. It turned out to be technically

very difficult. And the particular situation with the lab, we just couldn't do that again. For example, it takes a hundred mls of sample to do 1-NP. So, yeah, it takes a lot of.... And it's very, very (inaudible) levels.

Sorry. Go ahead, Jenny. You wanted to chime in with something.

PANEL MEMBER QUINTANA: Urine is some -- urine is something, especially with older kids, you can get a hundred ml, but I thought Asa did it on 30 or something, 30 ml for --

MS. HOOVER: We could -- Well, ideally you have a large volume collection, so there's that issue, but there was just other technical issues with that method, including the fact that the levels are so extremely low that it just posed a lot of feasibility issues, so -- and we had to go with -- also the nature of the standard agreement is, you know, the best option for us is to work with UC. So just for a whole bunch of reasons. And, yeah, limited funding, and all the rest we settled on this.

We also do have, you know, in our EBDEP study we have pyrene results, which we're going to be looking at correlations between the pyrene results and the 1-NP. So we'll have some information to illuminate that. But,

yeah, ideally, we would have a additional biomarker specific -- more specific to diesel within the panel, but we just weren't able to do that.

PANEL MEMBER QUINTANA: Okay. So maybe I'll quickly just give you my list, because I don't want to take up too much time, but -- so I guess in terms of the questions, I would definitely talk about commute to the school, how they got there would be quite important. And even if you can, like if it's a diesel vehicle or not or something specific like that, or diesel school bus. I'm not sure how far the kids come, but I think -- and when they came to school. I know a lot of kids get dropped off early for pre -- for daycare before school starts, at least in our community.

I would ask, of course, not just do you have smoking that you're asking about, but also -- sorry -- cannabis smoking. Obviously, it would contribute to PAHs. And vaping, because that would help you interpret the cotinine vaping of nicotine in the home and in the car, especially as well.

And then I think that one thing you talked about fires being a big problem for your big week. But I think what's really going to be a problem is rain in November, you know, because during rain episodes here -- and I really apologize for my dog. It's just out of reach. I

can't get it. During rain episodes, at least in San Diego, it's much less polluted. Typically, I know that sometimes you're offset by people heating in the air, you know, or burning stuff, but that wouldn't be as representative if you had rain for five days as if you didn't. So I think -- to me, I think that's what you should be planning for.

Wildfires are -- would be great in a sense. If they happen, you have some real interesting data. And I think you should ask for a supplement from CARB or something to -- even if wildfires happen before you're going to go out there just -- or even after you went, do it again quickly. Just be ready to roll. It's an unusual opportunity, you know, basically.

And then my last bit of laundry list is that have you thought about other measures that maybe you don't have to -- other measures in the study, and specifically exhaled nitric oxide. And I don't know much about that, except what I've read in studies that has the advantage in schools that you could just do it right there. You don't have to collect a sample. And the correlation with that and other markers that you're collecting might be quite interesting, because it would be more easy for community groups to use that particular measure.

And then the other thing was possibly having the

kids wear silicone wristbands, because they're pretty cheap to make and deploy. They're expensive to analyze, but you could just collect them. And I've got so many studies that I've done where I wish I had collected certain samples. I wish I had, you know, collected dust, or I wish I had -- whatever. So I just -- just be thinking about what else maybe like silicone wristbands you could deploy and archive, you know, depending on what you have.

And I think in terms of dietary questions, again I do feel strongly that you shouldn't play with their diet, if that's -- it's supposed to be a real field study. And what real reduction that you get, it has to -- it should be just what it is, you know.

And it might be difficult to get results back, like to kids with smoking parents, or smoking cannabis, or whatever. But from a public health point of view, it's an opportunity to educate people about exposures besides what you intended to measure, you know, that are important, that -- but in terms of Veena's comment about how to phrase results return, you know, I do think that comparing things to a known exposure like tobacco -- like kids living with a smoker have this much elevation in there oxidative markers. Something like that is -- people can kind of relate to that exposure, or kids exposed to a

wildfire -- it's a couple wildfire studies, you know, had this much elevation. You could kind of compare it, the oxidative damage to some other known exposures, you know, that are worse basically, you know, that are very intense might be a way to go, because people have an intuitive understanding of that.

Thank you for all the time and this exciting study.

CHAIRPERSON SCHWARZMAN: Thank you for those, Jenny. Susan -- so, Tom, I see you have a question. We have someone in the audience who has a question. But first, I just wanted to ask Susan if you have any thoughts about Jenny's suggestion about silicone wristbands and the possibility of collecting them, even if you're not able to analyze them at this time. I think that's a complicated issue in and of itself, but it's -- maybe this is something you've already considered or there's some parameters that wouldn't..... it. But I wonder if you have thoughts about it now. It strikes me as if -- if you could analyze it some day at least, it's an interesting -- it would provide context for the biomarkers of exposure that you are measuring and you're (inaudible). And I'd just be curious for your thoughts about it.

MS. HURLEY: Well, I can say that early on in our planning stages, we did discuss the possibility of

actually using the inhaled or exhaled nitric oxide measure as well as silicone wristbands. And I'm not sure on the wristbands where we landed on that. I mean, I know we ultimately didn't -- or aren't currently considering it. But Sara, I don't know if you have any comments as to...

MS. HOOVER: I -- well, yeah. Basically, in our studies, we've just done blood and urine and we wanted to stick with urine for this study. That's the main reason. But I wonder, Jenny, if you'd say why you think the silicone wristbands would be helpful. I mean, the data that I've seen, I'm not so sure, you know, that some -- I'm curious of your perspective of why you think it would be useful for this study?

PANEL MEMBER QUINTANA: Well, one -- one question is how much they're getting at home versus at the school? And it's something that they could wear one overnight and then at school exchange it for another they wear during school. And so you might have a comparison, so PAHs for example, of the two environments I was thinking, just as a way to collect data without a lot of difficulty, I guess, because they're so simple. So comparing the microenvironments, I guess I was thinking it's a possibility. And I'm not living or dying by this. I'm just suggesting it, because it's --

MS. HOOVER: No.

PANEL MEMBER QUINTANA: -- just something that I had wish I had done in the previous studies.

MS. HOOVER: Yeah, I don't know that much about them. I haven't -- yeah. I haven't looked deeply into them, but I'm just curious about, you know, just accuracy and use for PAHs. I don't know if you have any information on that. I mean --

PANEL MEMBER QUINTANA: I just (inaudible) article for PAHs, so I can send that.

MS. HOOVER: Okay.

PANEL MEMBER QUINTANA: It just got accepted. It's not out in the press.

MS. HOOVER: Okay.

PANEL MEMBER QUINTANA: But a couple days now, it should be out in press.

MS. HOOVER: Okay. Cool. So we will -- yeah, we'll just -- we'll add that to our list of things to consider. I also want to chime in and say definitely rain, we're very well aware of the rain issue. We didn't highlight rain, partially because the Panel had previously highlighted wildfires, so we wanted to acknowledge that.

But we experienced that in the East Bay Diesel Exposure Project, like we could not change our sampling day, and sometimes we had to sample in rain. And, no, we don't want to do that.

So we'll be trying to make -- you know, plan for that as we settle on the exact days that we'll be out working. So, yeah, we know it's sort of -- and with Betsey Noth, you know, we've had that conversation. It wouldn't be wise to do it, if it's pouring rain.

I think the rain fall is actually -- we're trying to pick the bad -- you know, bad air quality period, sort of October -- late October, early November. Yeah, so we're partially going to have to play that by ear, but we are aware of it.

CHAIRPERSON SCHWARZMAN: Great. Thank you for that. I want to ask Shoba to let us know who -- because there is someone who had had their hand up from well before, and then Tom.

DR. IYER: Yeah. June-Soo Park, I see you've got your hand up. I'm going to unmute you now. So now you can unmute yourself and share your question or comment.

June-Soo, are you there?

DR. PARK: Yeah, but I never -- the raised hand, I think is -- sorry about that.

DR. IYER: We can hear you. Go ahead.

DR. PARK: Yeah. No, no. I didn't. I didn't raise my hand to ask a question. Yeah.

DR. IYER: Okay.

CHAIRPERSON SCHWARZMAN: All right. In that

case, Tom, what did you have?

PANEL MEMBER McKONE: All right. Well, just one. I know we've talked a lot about the filtering and the indoor and outdoor. But one thing -- you know, we talk about smokers, but the other thing is cooking and how people cook. And so -- this is not a formal experiment, but for two years I -- two years ago, I bought air monitors and I had one indoors and outdoors. And I won't advertise a certain company, but in the neighborhood I live in, they have a coverage of about 200 households. And I always like to look at this every so often.

And what's really interesting is like during the fires, I particularly watched, because we have a whole house MERV 13, and the reduction is phenomenal in what we get. But that has to do with like the conditions of the house and how careful we are. But one of the things that -- when I looked, one of the things I -- normally, the indoor levels -- so this company, which I don't know if we can mention them, right? They're so common, PurpleAir, right, because it's so standard.

But one of the things they do is they mark indoor air. They mark monitors as being indoors or outdoors and they have a dark circle if they're indoors. So if you look at the map -- and I tend to do this almost every day at different times. If you look at the map, most of the

time like 90 percent of the time, the indoor levels are below the outdoor levels. And I don't even know, this is just something we know that there's a reduction due to the envelope of the building.

In the evening, I see some of the highest indoor concentrations, I mean, up at the levels that are hazardous on the air pollution scale, 150, 180, EPA air quality index, which means the air quality inside these homes is as bad as it was in some of the fire communities. And it's like three or four households in this area. And I think what are they doing? I mean, this is not smoking. This is cooking and cooking -- so anyone who cooks with oils and doesn't use -- I learned this from my air quality work. It's like you can talk to Wayne Ott and he will give you reams of information and -- about how the best way -- if you want to generate fine particles indoors, take a pan, put oil on it, and fry food, because it's just a massive fine particle generator, particularly if you don't have ventilation. And I'm just saying, I mean, this is -- this is kind of anecdotally observed, but it's also been measured.

So what I worry about is if there are households in your study that are frying foods or using some sort of frying, they're going to get these huge two-, three-hour exposures during the evening. And I worry that that may

be so high that, you know, in the integrated daily exposure, there would be significant reduction in the school.

So I guess, you know, the thing is if you knew -- if you -- you can't sample all the households. But if there's someway to learn a little bit more about what happens at home, you could understand some people who don't line up with the school. I mean, the school levels -- you know, based on what I've seen from my own filtering system, a MERV 16 is just going to -- unless they leave windows open or anything, a MERV 16 on a furnace system in a relatively new HVAC system is going to drop the indoor levels phenomenally, particularly in wildfires. They're just going to be way down.

So, there's this question about at home beyond smoking. I mean, you can ask them if there's a smoker in the house. I suppose you could ask them how they cook food, but I don't know if that's going to tease out this huge peak that you're going to get from households that are frying food.

CHAIRPERSON SCHWARZMAN: Susan, I notice that on the list of questions you had about an exhaust fan, you had indoor fuel use. But what you're talking about, Tom, I think is sort of agnostic with regard to the source of the heat. You know, if you're frying oil, it could be

with natural gas or it could be with electricity and you're still going to be generating the particulate matter and that what matters more at that point is filtration is the -- I mean, is -- I'm mean, not filtration, but ventilation from an exhaust fan say. And Susan, I saw that on the list of questionnaire questions. So the follow-up question that I have is just, Tom, if you could choose what you would ask families to try to get at that, what would you do?

PANEL MEMBER McKONE: I think you could ask -- you could ask diet questions. I mean -- you know, I mean, what it is is it's -- people are -- you know, you could ask them how they prepare their food. And particularly, I mean, in some households this is breads, or tortillas, or things like that. People really like to fry them up or it could be fried potatoes. But you've got -- I mean, I think the question about frying is pretty important, because again this is my observation, but there's papers that have been written by this, Lance Wallace, who did a fairly systematic study on different kinds of frying. And he said actually -- you know, he measured it in different households. His own was one of the worst, because he said we just love -- we love making fried potatoes, and fried tortillas, and things like that. And he said, he just couldn't believe how much they generated in terms of fine

particles.

And, of course, he's breathing it. But I mean, it's fascinating, because he's like -- he's a very well-renowned indoor air quality person. He said it's so -- it's short term. I mean, it's going to be during the cooking period, but the levels go way up.

And then so it's two questions. It's really do they -- you know, how do they prepare food? How frequently do they fry it? And, I mean, baking isn't as big a problem. Well, ovens can -- I mean, an unvented oven is also going to be an issue too. You know, it's kind of what were you baking. But the big question is how well ventilated? Do they have a vent fan over their stove? It makes a huge difference.

CHAIRPERSON SCHWARZMAN: Stephanie, did you have a point on that? And then I see Veena and Ulrike.

MS. JARMUL: I'm a bit late. This is actually more to chime in on what Jenny was talking about with the kids potentially wearing the wristbands or collecting samples from them at the school. And I just wanted to mention that we've worked pretty hard to ensure the confidentiality of the students at school, and that includes actually not collecting urine samples from them at the school. We had quite a few conversations around that.

So I think that is probably one of the main reasons we chose not to do the wristbands, since that would identify the students in the study at school.

PANEL MEMBER QUINTANA: I mean, you probably thought about this, but you could give them to all the kids in the classes, all the classes. Hand them out. It helps, but I think that there are some validated cooking questionnaires. Sorry, Meg, to not -- to usurp your right to tell me to speak or not. Sorry.

CHAIRPERSON SCHWARZMAN: Go ahead.

PANEL MEMBER QUINTANA: But I just wanted to answer about the -- there are some validated questions for cooking behaviors, so you don't have to make -- reinvent the wheel. Some of the children studies have already asked those kind of questions. I just want to say that.

Thank you.

CHAIRPERSON SCHWARZMAN: Veena.

PANEL MEMBER SINGLA: Thank you. Yes. Jenny's last comment I was -- I was going to say the same thing and -- because it's also -- it's not just you have the stove fan, but do you use it? This is important as well.

And my other comment is it's a little bit off topic, but just wanted to say, you know, I just really appreciate hearing from the community partner on this study earlier in the meeting. And, you know, thinking

forward, yeah, I'm really excited about this study and the results. And I think it would be really great to have the community partner come back to the Panel to present up on the community perspective. Post-study I would love to see that and think about lessons -- you know, lessons learned to inform future studies.

MS. HURLEY: That's great idea.

CHAIRPERSON SCHWARZMAN: I second that.

Ulrike, you had something.

Oh, you're still muted.

PANEL MEMBER LUDERER: Sorry about that. Thank you.

I was going to say, first of all, that I third that.

(Laughter.)

PANEL MEMBER LUDERER: And then next that, you know, just with the -- with the cooking question, I mean, I think we've already talked about it a lot, but just to -- I think it does -- it really has to be during the prior day. So it doesn't have to be, you know, how do they cook in general, but it's probably easier to answer more specific questions, you know, like how did you cook last night. So that was really the main comment I had about that.

CHAIRPERSON SCHWARZMAN: That gets -- thank you

for that, Ulrike, because that gets to one of the questions on Susan's list, which is about timing for administration of the survey. And I'm sure this is a really tricky issue, because probably the timeline for the -- for administration of the survey is going to differ for the different questions, like the ideal timing is going to differ for the different questions. But I think maybe it would be helpful to put out a little bit of that -- those thoughts now to throw them into the mix. Like you're saying for cooking, you really just want to know about what happened the night before the urine test.

What are other timing questions that would be helpful to have input to throw into the mix? And Susan, if you have a specific question also feel free to just chime in. I see Jenny has an idea.

PANEL MEMBER QUINTANA: I was thinking more again about transportation and maybe how they got to school, but also do they drive a lot for games or who knows what they're playing, you know. And then just if it is ambient -- I mean, outdoor air pollution, then sports activities outside would be very important or our time outside basically, how much time do they spend outside the day before or the evening before after school? Did they have an outside, you know, Little League softball practice, you know, outside. Because if they're running

around outside, they're going to have a big dose to their body, you know. And that would be different than someone that went home to an air conditioned house and didn't go outside, you know. So you may wish to ask that.

But I'm trying to think of the operational aspects of ask -- are you going to ask them every day, or ask the parent every morning, or ask the parent when you pick it up, like just how do operationally do this without being super annoying, are you going to text them a questionnaire?

MS. HURLEY: Yeah. So the way that's going to work is when they -- on each sampling day when they return their urine samples to us, we're going to give them the link to the questionnaire or a paper copy, if they prefer that. And so there will be two questionnaires, one on the first sampling day, one on the second sampling day.

And then we're trying to design the questionnaire to capture -- you know, word it so that it captures the relevant time period. And we've been kind of struggling with that. For the biomarkers of PAHs and VOCs, we have at least a pretty good idea of what the half-lives are, so we know, you know, we want the last 24 to maybe 36 hours. So the way we've worded it or our current version -- we're obviously just playing with this still, but we actually have some of the wording in front of me. We ask -- so for

things that we think affect the air quality, right, because there's going to be different time periods depending on the category of questions.

But the ones that we think are relevant to affecting their air exposures, we're asking about the past two days, so activities -- you know, whether it's cooking, or walking to school, or, you know, being outside, all of that is over the last two days. And then we were thinking of saying something like the last two days refers to the day before you collected your child's urine sample and also the day that you collected your sam -- their sample, but we don't want any information that happened after they collected, you know, their second sample. Because they might not fill out the questionnaire right away, we don't want to hear that they, you know, went and played sports after school that day. So that's -- that's the way we're thinking of wording it.

For the biomarkers of oxidative stress and inflammation, we've got other issues around timing, which I don't know if any of our guest speakers have any input on this. But, you know, for some of the health conditions or the medication use, you know, we're not really sure what's the most relevant time window. Is it the last couple days or is it more like the last week? So, you know, we're still researching that. But if anyone has

ideas on that, we would love to hear them.

PANEL MEMBER QUINTANA: But maybe I'm mistaken, I thought you were talking morning and later that day for more than one day in a row or is it once?

MS. HURLEY: Well, it's not in a row. It will be the -- yeah.

PANEL MEMBER QUINTANA: But, I mean, is it day one, and day two, and day three so -- or is it only -- do they only participate once? I think I'm mixed up.

MS. HURLEY: Okay. They participate the first week -- in the first week, we're going to have one sampling day. It may not all be the same day for all kids, because we logistically may not be able to do -- to get all the samples, you know, on a Monday or whatever.

PANEL MEMBER QUINTANA: There's only one before and after in the first week.

MS. HURLEY: In the first --

PANEL MEMBER QUINTANA: I think I thought -- I thought it was -- I thought it was every day like --

MS. HURLEY: Oh, yeah. No. No. No.

PANEL MEMBER QUINTANA: -- like you were giving them -- okay.

MS. HURLEY: Yeah.

PANEL MEMBER QUINTANA: But I was mixed up. Okay.

MS. HURLEY: Right. And then the second day won't be like back to back -- it won't be consecutive days. So the second sampling day will be the following week, so...

PANEL MEMBER QUINTANA: Okay. Okay.

MS. HURLEY: Yeah.

PANEL MEMBER QUINTANA: All right. That makes sense, because you're asking about two days prior. And I'm like wait, if you do it every day, that doesn't make sense.

MS. HURLEY: Yeah. Yeah. It won't spill over -- it won't, yeah, overlap. Right.

PANEL MEMBER QUINTANA: (Inaudible). Sorry.

MS. HOOVER: Sorry. Go ahead, Jenny.

PANEL MEMBER QUINTANA: I was just going to -- from our own studies, which are mostly tobacco related, you usually try to ask questions that are general like does your kid use asthma medication or whatever? And then if you're doing the daily sampling, just the ones that might change. What did -- what did you have last night to eat. Did you grill or fry? Did you have a sports --

MS. HURLEY: Right.

PANEL MEMBER QUINTANA: You know, so just it's very short, so you don't have data loss, because it's already hard to juggle kids, school, and stuff, you know,

like --

MS. HURLEY: Yeah.

(Laughter.)

MS. HOOVER: And I was just going to chime in that the reason we talk about weeks in the study is because the air sampling and monitoring will occur throughout the week. So we will be collecting the air data throughout each week, but we can only do biomonitoring on one day per week. So we've been working on trying to message that clearly, but obviously it wasn't completely clear.

I also did want to mention to Tom, yeah, it's completely fine to talk about PurpleAir. It was on Susan's slide, we're buying PurpleAir. So, yeah, we're taking advantage of that -- of those.

CHAIRPERSON SCHWARZMAN: I have a note that Ryan Allen has a question. So go ahead and turn on your webcam and unmute yourself. And then I see Veena is up next.

DR. ALLEN: Okay. Yeah, I have one kind of question and then one kind of comment. The comment is in terms of collecting this information about diet and medications, I'm wondering if there's any opportunity to collect it prospectively rather than retrospectively, because in my experience people are pretty bad at remembering what has happened.

But I'm wondering if maybe a few days before, you could give the caregiver, you know, a little -- a little grid to hang on the refrigerator or whatever that says just jot down, you know, what medications. Because in my experience, when you sort of give it to them at the outset and ask them to do it prospectively, you get better information than being like what happened last Wednesday. They're always -- not always so good at remembering. So I don't know if that's feasible, but it's just a -- just a thought.

And then my quest -- I don't know if it's a question or comment, but I was sitting here trying to think both other kind of -- other exposures, not necessarily environmental exposures that might influence some of these biomarkers. And this is not my area of expertise, so I know just enough to be sort of dangerous here. But I know at least -- I know at least chronically that stress can be inflammatory. I don't know about more acute stress. But for some kids, school may be a stressful environment, you know, particularly if you get sent to the principal's office or something. So you could have this -- you could theoretically have a situation where the school air is beneficial, but there's something else about the school environment that is harmful, in terms of stress. And so you don't actually see any

change, because those two effects counteract each other.

So I know for -- in some of our studies for adults, we've used sort of pretty well validated measures of self-reported stress or perceived stress. That's probably a lot more tricky to do with a child. And I also don't know how well it would work for sort of more acute stress. But anyway, just a -- just a thought, if you haven't thought about it, you may want to look into sort of the acute inflammatory and oxidative effects of stress and see if there's any way you can account for that or if you even need to account for that.

MS. HURLEY: Yeah. That's an interesting point. Stress wasn't actually on our radar, so we will look into that. I do know I've -- I have done some stress research, but looking at more sort of chronic levels. And I do know a lot of the -- there's are a lot of validated questionnaires out there. But again, I think they're mostly focused on adults and they can be fairly long, but it's a point well taken. I think we should definitely look into that.

MS. HOOVER: Meg, can I just respond to one thing from Ryan?

Just to clarify, Ryan, we're not doing long recall. We're doing the questionnaire the actual night of the sampling. So they immediately answer questions about

what just happened and then we do another questionnaire the following week. So they're not -- they don't have to think back a week ago what happened. It's like literally the day before. But I understand -- you know, I understand your idea of hanging up a grid to make sure you write it down and you don't forget. We did -- you know, we had an activity diary and those sorts of tools for our East Bay Diesel Exposure Project. So we could think about like a refrigerator reminder, because there are certain reminders, like reminding them, you know, to collect your child's first morning void, to have your child tell you, hey, I need to pee, this kind of thing, so we can have a set of reminders. So that's a good idea.

CHAIRPERSON SCHWARZMAN: I really appreciate that suggestion just thinking about it as a parent, not at all in my -- from a scientific perspective of like I will completely forget that something happened, unless somebody says please note if, you know, there was an incident at home or school in the last 24 hours. You know, we'll be asking you about that or whatever the questions are. Please note, these are the things we're going to ask you about. Track them, you know, in the 48 hours before you collect the sample, or whatever, if it's a grid that goes on the fridge or whatever.

Just as a human and a parent, that kind of

advanced notification of what I'm supposed to be paying attention to I find enormously helpful and of one.

Veena.

PANEL MEMBER SINGLA: Thank you. I agree with that. I can't remember anything, so -- and I'm not even a parent.

(Laughter.)

PANEL MEMBER SINGLA: Well, you know the stress comment made me think about masks and you're probably thinking about this already, but just who knows what the mask situation is going to be at the time you do our study, but -- and especially if there might be wildfires, it would probably be good to collect information on masking. I don't -- I don't -- I just have no idea if any of the kids might be wearing N-95 type masks, but it would -- it would probably -- you'd probably want to know if that is the case.

And my other comment is on the sort of question of, you know, reporting back on things that happen within a certain time. I think a visual depiction could be really helpful in addition to the verbal instructions of just like, you know, these calendar dates up to this time. It can be really helpful for people to see something visually.

MS. HURLEY: I think that's an excellent idea,

because we've been struggling with like how to word it. It's so cumbersome. So to have just like a simple picture, I think it's -- it would really help.

CHAIRPERSON SCHWARZMAN: I think Ulrike had something and then I see Jenny. And then what I'll do is put the slides back up that Susan showed and kind of go through for our last 10 minutes and see if there's things we've missed commenting on.

PANEL MEMBER LUDERER: Yeah, I think Susan had asked about the -- like the half-life of isoprostane and the 8OHdG. And from what I understand they're pretty short. So like in the blood, they could be, you know, less than 15 to 30 minutes or something like that, on that order, or maybe a bit longer in the urine, but relatively short.

CHAIRPERSON SCHWARZMAN: Jenny.

PANEL MEMBER QUINTANA: I think one of your questions is the timing of the collection. So we didn't really answer that for the urine. And I do want to talk about recess again, because I do think that if people --

(Phone ringing)

PANEL MEMBER QUINTANA: Sorry -- if kids are running around either at recess, or at lunch, or right after school, that's going to be an exposure source, you know, to outside air at very high breathing rates, you

know, that's going to be an issue. So I'd almost rather see them -- I mean, depending on the half-life that Ulrike was saying, I remember there was a study by, was it, Sarnat that did the community in Atlanta study, where they took a blood sample, and then they drove around in traffic, and then two hours later took another one. And they could see, you know, increases in these inflammation markers. I forget what now, like IL-6 and something else.

And, you know, so I think that there -- I'd almost rather see collection -- and I'm sure that it couldn't take place at school, or near school, or during lunch, or even like some period of time where they're actually not exposed to outside air running around, you might be better off, rather than having -- like a lot of schools for younger kids, they get out and then they stay at school for a while playing on the playground with their friends and then they go home.

You know, I think as they get older, they quit doing that. They just hang around in groups. But, you know --

(Laughter.)

PANEL MEMBER QUINTANA: -- but you know what I mean, I just feel like that's going to be a real source of confounding if -- as you will, but -- so I almost would like to see a shorter -- a shorter thing. And the other

quick question -- comment is that we've had good luck with text reminders, so --

MS. HURLEY: Um-hmm.

PANEL MEMBER QUINTANA: You know, like, what time do you get up? 6:15. Fine, here's a text at 6:15, remember to get your kid's urine.

(Laughter.)

PANEL MEMBER QUINTANA: And it -- I mean, we can -- you can automate them and people really like that. They like text reminders. They like everything by text. They don't like paper stuff any more. That's our experience.

CHAIRPERSON SCHWARZMAN: I need to just make sure that I'm checking in with Shoba. Can you let me know if there's any -- anyone who's queued up to speak and also we're going to -- formal call for public comment on this segment. So I want to break for sec to do those and then show the slide.

DR. IYER: Thanks, Meg. At this time, I'm not seeing any new comments or hands raised, but maybe we can wait for a little bit and see if anything pops up.

CHAIRPERSON SCHWARZMAN: Maggie.

DR. CLARK: Susan, you may have mentioned this already, but do you know if there are diurnal patterns in ambient air pollutants in this study area and what they

would be?

MS. HURLEY: That's a good question. I'm -- my -- I don't know. My guess is that there are and that's a good point that we should, you know, look at that ahead of time. We are going to be having obviously air measurements, you know, throughout the sampling time, so we will be able to account for those, but I don't -- I don't know what it looks like.

DR. CLARK: Just in case -- in case that those are dominant enough to impact this kind of --

MS. HURLEY: Yeah.

DR. CLARK: You know, it could be more important even than -- you know, you're taking into account the diurnal patterns and the half-lives of the biomarkers, but you know, that could be driving --

MS. HURLEY: Yep.

DR. CLARK: -- if you do see any difference in either direction, yeah.

MS. HURLEY: Yeah.

DR. CLARK: But I think we talked about this before. And there isn't -- is there still no opportunity for a group that kind of follows the same timeline as the kids that are in MERV 16 school, but without that in the HVAC system just to have, you know, if there are those patterns that are just sort of naturally occurring,

because of the diurnal patterns of the air pollution, and you would see that represented in those kids' samples to be able to adjust it out.

MS. HURLEY: Yeah, so -- yeah, we can't really do that for a few reasons. One is that, you know, we have to -- we have to do it in a school that already has the air filtration installed.

And we don't really have the budget to have --

MS. HOOVER: Susan.

MS. HURLEY: -- a comparison somewhere else, and we don't --

MS. HOOVER: Susan.

MS. HURLEY: Yes.

MS. HOOVER: I think Maggie is saying a control group in a location without MERV, like to do a parallel -- isn't that what you're saying, Maggie, to do a parallel collection in a school that's similar without MERV. And what I was going to chime in and say, because something has changed, which is our money is back. Our contract money is back. So before we had -- you know, because the budget has been signed and our contract money was restored.

So we've always been saying we don't have the money, which we did not have the money, because we lost our contract money. It's now back. So I think actually

I'm going to say we'll look into that idea. You know, obviously, we're aware that there's not going to be -- I mean, I think if we could look at patterns, you know, it's not going to be the same, right, because this school site is very specific in terms of the impacts around that school site. So we won't have something comparable, like we -- at last November's meeting, we were talking about trying to find a facility where there's two buildings in the same location -- you know --

MS. HURLEY: Right.

MS. HOOVER: -- we're not going to have anything like that, but I'm not -- I'm not going to rule it out at this point, but it would be tough. But we'll definitely think about it now that we have restored funding. But I am aware that's it's 4:10, so I'm going to pitch it back to...

CHAIRPERSON SCHWARZMAN: Nerissa.

DR. WU: Well, that's interesting about having another school, but I wondered if also you could have -- and this is a whole other can of worms, if the families have a younger child who's not in the school, so they would have the same home exposure, but then they wouldn't be going to the MERV 16 building during the day, if that would be maybe a more controlled comparison.

MS. HOOVER: Yeah, that's an interesting idea.

MS. HURLEY: Yeah, that's interesting.

MS. HOOVER: Yeah, thanks for that idea. And that seems substantially easier in terms of recruitment, and management, and logistics. So that's a great idea. Thanks, Nerissa.

CHAIRPERSON SCHWARZMAN: And I think I heard in the inclusion criteria, Susan, that you're specifically saying not two members of the same household. And so it would just be -- unless I'm remembering that wrong.

MS. HURLEY: No, that --

CHAIRPERSON SCHWARZMAN: I mean, that is not two kids.

MS. HURLEY: Yeah, that's right. But, you know, Nerissa's idea is -- you know, that that other child would be a different -- you know, would be a control group. So, yes --

CHAIRPERSON SCHWARZMAN: Yes.

MS. HURLEY: -- in our intervention group, we are -- you know, we only want one per household.

CHAIRPERSON SCHWARZMAN: Great. Jenny, why don't you go ahead with your next thought.

PANEL MEMBER QUINTANA: Just very quickly, another problem I'm sure that some of our speakers know more about than I do is what if you have all these -- more people that want to participate than you have in your

study? I think that's a very likely possibility at a school where the community group has got people excited about it. You know, how are you going to -- or what can you offer people that you can -- that want to participate, but -- you know, how are you going to handle that situation? I think that's quite a likely such a scenario, if it -- especially at school, it's quite public, the recruitment and people talk to each other, you know.

MS. HURLEY: Yeah. We haven't had any specific discussions about that yet. But, Sara, I don't recall, was that an issue for EBDEP in -- I wasn't involved in that study, so I can't comment on that.

MS. HOOVER: It was not an issue.

MS. HURLEY: It was not. Okay.

MS. HOOVER: It was actually really tough for us to recruit children. And it took us -- we actually couldn't do our study design as we planned, because it took us so long to recruit. However, I think the situation Jenny is pointing to and the situation we're creating is very different, because we're recruiting at one school. Truthfully though, our general experience in our surveys, that has not been the case. I will say in East Bay Diesel, we were surprised at how many people that did volunteer wanted to volunteer for the daily samples. Like that happened really quickly.

So, I mean, I think one of the things we can say is we're still going to let everyone know in the community about what the results are particularly -- you know, at a high level summary results and all the air monitoring results. So we'll still be providing information to the community even if their child can't participate. But yeah, we -- like Susan said, we haven't pinned down the exact thing.

I'm aware that we're just about out of time, so I think -- I think you've covered -- we've covered all the discussion questions pretty well. Susan, is there any last thing before we move on to the next item?

MS. HURLEY: I don't think so, no.

MS. HOOVER: It's been really valuable. A lot of great ideas.

MS. HURLEY: Yeah.

CHAIRPERSON SCHWARZMAN: That was going to be my question also. It turns out it's not permitting me to show my screen, so --

MS. HOOVER: Well, we'll --

CHAIRPERSON SCHWARZMAN: -- (inaudible) do that. And someone else should reclaim the ability to be presenter, because I'd have to restart my computer. So our -- because that might be relevant in this next section.

Let's see, all well -- okay. I just had a little burp in my computer.

It is time for us to move on to the public comment session. And as Sara had said, depending on time, we might also use this session to return to the point about recommendations for the legislative report, the seventh legislative report.

But first, I want to make sure that we have covered any public comment. There is 15 minutes allocated for this open public comment period, which is meant to admit any comments that are on any topic related to Biomonitoring California, not just to each of the sessions that we've covered today.

And the same methods of submission apply as all day -- as all day. You can submit written comments and questions via GoToWebinar question feature or by email to biomonitoring@oehha.ca.gov. We'll read them aloud. You can also raise your hand using the raise hand or question feature on GoToWebinar and we can call on you.

So while Shoba checks to see if there's any public comment, I want to mention that prior to the meeting, Dr. Ahimsa Porter Sumchai submitted a link with information from the Hunters Point Community Biomonitoring Program on several topics, including a case study of a mother and child with detection of metals in urine. And

the link to that comment is available on the meeting page. It's too long to do justice to it by reading it out loud in this public comment period, but that's available on the meeting page.

Shoba, is there anyone teed up for public comment?

DR. IYER: I have two comments that we got earlier in the day, but no new ones I'm seeing come in at this time. Shall I go ahead and share the comments we got earlier in the day and didn't have time for.

CHAIRPERSON SCHWARZMAN: Sure.

DR. IYER: All right. One was from Nancy Buermeyer. And this is a general program suggestion on PFAS. Recent State legislation, including a ban on PFAS in firefighting foam last year, and hopefully food packaging this year, may provide an opportunity to track the effectiveness of these policies. For instance, do we see a reduction in PFAS exposure to the State overall and in specific communities, particularly those close to military facilities and airports, and/or who depend more on fast or other processed food that may contain more PFAS in the packaging? Hopefully, this could be accomplished within the current CARE project perhaps with just the addition of a couple of survey questions.

So that was from Nancy.

And the second brief comment we got was from Yolanda Sanchez earlier this afternoon. And she says thank you for thinking about the most important meaningful ways to provide results to participants.

CHAIRPERSON SCHWARZMAN: Great. Thank you for those comments. We really do all always appreciate hearing from folks who are invested in the Program. I guess here's what I think we should do, and, Sara, you can jump in if you think we need to do something else. I would like to take maybe 10 minutes that we have remaining and show the slide that I put together and with some staff about the -- that outlines the suggestions that were discussed in the earlier session from the Panel --

MS. HOOVER: Yes.

CHAIRPERSON SCHWARZMAN: -- for legislative report. And I also want to just have Shoba alert us if there is an additional public comment, so that we're not closing --

MS. HOOVER: Yeah.

CHAIRPERSON SCHWARZMAN: -- down this 15-minute public comment session prematurely.

MS. HOOVER: Agreed. I had the same thought in mind. So do you want -- I was going to suggest Stephanie share her screen since -- and show that slide, since you were having trouble, was that --

CHAIRPERSON SCHWARZMAN: Yes, please. Yes, please.

MS. HOOVER: Okay. Go for it, Stephanie.

MS. JARMUL: Does that work?

CHAIRPERSON SCHWARZMAN: Yes.

MS. JARMUL: Great.

CHAIRPERSON SCHWARZMAN: So the point of this is just I organized into a rough priority as I felt like I was hearing them from the Panel, the recommendations for the seventh legislative report that we discussed as a Panel today. And let's read through them briefly and have any discussion that you want to have about them. And then I wonder if we could return -- I know that staff kind of consolidated -- numbered that list of comments that were gleaned from previous meetings. And if we could return to those to see if we want to grab any of that information and add it to this list that Jenny and I will then work on writing up.

So I'll just review these so that you're not trying to listen and read at the same time. The first is as a more overarching goal mitigating environmental health inequities. And we could elaborate on this, but there's overlap with these additional recommendations, but that, in general, targeting studies to identify and address disproportionate harms borne by some communities. And it

could be based on geography, or occupation, or any number of race and ethnicity or any number of identifiers.

And the second was highlighting the value of intervention studies and their ability to identify the impact of public policy or non-regulatory interventions. And the examples that Jenny gave were like CARB diesel rules or the non-regulatory actions like foam replacement or air filtration like we've been discussing, that it simultaneously is a way of contributing to the goal of addressing environmental health inequities if we're looking at particularly highly impacted communities. And I think it was Veena who mentioned this notion that one of the beauties of intervention studies is they simultaneously address a community need while gathering data and getting useful information, which I think any time that we hear from community members in the meeting, that's often -- that's an often repeated request is to not just study the population but do something about it.

And that's hard particularly coming from the biomonitoring perspective, since the -- it's in the nature of biomonitoring to be monitoring. But the idea of being able to design studies where we're also doing some intervention is very powerful and resonates with me based on what we hear from -- as community priorities.

The third was evaluate exposures associated with

climate change. And in a sense, that's kind of organizing or framing our previous recommendation about wildfires under the -- kind of through the lens of climate change, but also addressing, you know, the specific chemicals exposures, whether it's particulate matter or other chemicals associated with wildfires and fires at the wildland-urban interface, which I didn't hyphenate correctly, but -- and also Tom mentioned the volatile or percent organic compounds that are -- whose patterns of transport and distribution are changing with climate change.

The fourth is the value of non-targeted analyses and particularly highlighting that and their ability to identify previously unrecognized pollutants. Another idea was returning to the initial sort of program priority of evaluating exposure to breast cancer relevant compounds. And finally, as we discuss these recommendations, acknowledging the gap between what is feasible and really the ultimate goal of meeting the legislative mandate of conducting statewide surveillance.

So that was what I captured from this morning's conversation. And what I'd like to do is invite additions to this. And in service of that, maybe Stephanie or whoever is sharing screens could put up the consolidated slide of previously gleaned recommendations to see if we

want to grab anything from that for this process.

Comments, additions, suggestions from the Panel.

Veena.

PANEL MEMBER SINGLA: Thank you, Meg, for putting this together. I have comments on number five and number six of that slide. On number five, I understand this was kind of a motivation or impetus, you know, around when the Program was formed. But I guess I wonder, you know, the Program generally hasn't had a particularly disease-focused lens, and, you know, has thought more about kind of classes of chemicals or kinds of exposures. So this is just a question. If we're going to call out a particular disease, maybe we should give it a little thought if, you know, why breast can -- not that breast cancer isn't an important priority. Of course, it is. But is -- does that still make sense or, you know, would talking about carcinogens as a class of compounds maybe be a better recommendation? I'm not sure. That one does kind of stand out to me as a little different from kind of how the Program has generally done its approach.

And then on number six, I'm not sure what -- like what the exact wording is. I have -- you know, I haven't had time to kind wordsmith it, but I do feel like acknowledging the sort of additional capacity that the stable funding brings and that that sort of -- you know,

the Program's ability to advance on that goal of surveillance while not meeting it, you know, is some -- we want to just reframe it a little bit and definitely mention the stable additional funding.

CHAIRPERSON SCHWARZMAN: Any other comments on that? I don't remember who proposed the -- returning to the idea of breast cancer relevant compounds. I appreciate the -- Veena, your comment about, you know, one disease over another and how do we pick one over another, but if there's any reflection on that. I mean, one thing that I would say in terms of -- based on my work in terms of environmental contributors to breast cancer is that breast cancer is very much unlike other cancers in terms of the hormonal contributions to the disease. And it is getting to the top of the list, if not the top of the list, for both incidence and mortality, depending on the age group and things like that. So if one wanted to make a case for it, there may be ways of making that case, but I'm not actually advocating for that. And I just wanted to open a moment for the person who suggested it to say anything. It sounded like it was basically on the basis of it being original.

Yes, Jenny.

PANEL MEMBER QUINTANA: That was me. So I think your point is well taken, Veena, and perhaps it could be

expressed as endocrine, you know, affecting compounds -- you know, grouping it on the compound area. You know, carcinogens act through endocrine mechanisms and -- or something like that may be a better way to put it.

But I just wanted to bring it up, because I -- you know, just looking at all the different pilot studies we've had and different groups, we haven't focused on that I think was my main point, but not to phrase it like this. I agree with you.

CHAIRPERSON SCHWARZMAN: So in the two minutes that we have remaining, what has been left off this list, because otherwise Jenny and I will just capture what's on this list. And she and I might just review the old list and see if there's something that we want to pick off. But now is your moment for the rest of the panelists to choose something else that needs to be on this list.

MS. HOOVER: Hey, Meg, I want to invite you to extend, if you -- you know, we don't have to end the meeting at 4:30.

CHAIRPERSON SCHWARZMAN: Okay.

MS. HOOVER: We can go a little bit longer. And it seems it will help you and Jenny quite a bit, if you get a little bit more feedback.

CHAIRPERSON SCHWARZMAN: Thank you for that.

MS. HOOVER: So if that helps you and the Panel,

let's just keep going for, you know, a bit longer.

CHAIRPERSON SCHWARZMAN: Great. Okay. I didn't realize we had that flexibility.

Nerissa.

DR. WU: I just had a couple sort of random thoughts. One is I just wanted to acknowledge the role of surveillance in addressing some of these other goals, that it's not really an either/or that -- in order to look at things like inequities, it's really important for us to have robust surveillance and to look at policy effectiveness. It's important for us to have robust surveillance. I would just -- I'm just cautionary about setting it up as sort of an either/or sort of situation.

And I also just wanted to point out with the augmented funding, that does fall outside of the time period that's covered with this legislative report. The legislative reports also don't usually get into resource discussions. But I think -- I mean, I think Nancy's point was well taken that we should be talking about, you know, what we can and can't do given resources, but we -- since this does have a coverage period that ends in June and funding doesn't start until July, it -- we'll have to think about how we talk about that.

And the final thought I had was with climate change, the other huge impact is water availability, and

well water, and the potential uptake of different pollutants to well water. I know these are your recommendations, not mine, but I thought I would throw it out there.

CHAIRPERSON SCHWARZMAN: Great. Given that we've had a bunch of time looking at this slide, is it possible to change back to the other list to see if there's anything there that panelists want to select to add to this list.

MS. HOOVER: Sure. Stephanie can do that. I think that was in Nerissa's list, right?

DR. WU: Yeah. I think if you go to the second page of the list --

MS. HOOVER: Yeah.

DR. WU: -- I had sent you, it orders the things we've captured over the last two years.

MS. HOOVER: Oh, so this is a single slide, Stephanie.

MS. JARMUL: Yeah, I'll open up Nerissa's original right now.

MS. HOOVER: And I'm -- was climate change on the other list, because I thought that was -- wasn't that a comment that somebody wanted captured?

CHAIRPERSON SCHWARZMAN: Climate change is number three on our list.

MS. HOOVER: Climate is -- oh, gosh. Wow. I looked and looked, but I missed the blue text. My apologies.

(Laughter.)

MS. JARMUL: Is this the right page?

CHAIRPERSON SCHWARZMAN: Thank you, Stephanie.

DR. WU: Yes.

CHAIRPERSON SCHWARZMAN: That's great.

Thank you for doing that on the fly.

(Laughter.)

MS. JARMUL: No problem.

MS. HOOVER: Why don't you put it in full screen, yeah, so that it's more visible.

MS. JARMUL: Yes, if I can.

DR. WU: So these are the points that have been gathered over the past two years, just our recollection and summaries of the previous SGP meetings. Some of them are captured on the other slide. And, of course, some of the numbering is not consistent. But I guess the comparison of the two, if there's things on this list that should be migrated onto the other list --

CHAIRPERSON SCHWARZMAN: Exactly, that was just my point is since this was staff capturing recommendations from the Panel in the past, even if they weren't in response to this question, this allows us to revisit those

points and see if we want to select any of them to add to our main recommendation list. And it looks like Stephanie is trying to get it to go full screen.

(Laughter.)

MS. JARMUL: Yeah, I'm having some technical difficulties, but tried to make it larger. I have to --

CHAIRPERSON SCHWARZMAN: Can you at least slide the slider on the bottom right-hand corner up to be a larger percent and you might have to scroll through it.

MS. JARMUL: Yes. Let's see if this helps.

CHAIRPERSON SCHWARZMAN: Great.

MS. JARMUL: For some reason it's not working for me right now, so -- oh, there we go.

CHAIRPERSON SCHWARZMAN: Great. Thank you. So we essentially capture one, two, and three under environmental inequities. And Jenny and I can check to make sure that we're reflecting sort of the richness of that.

Yes, Veena and then Jenny.

PANEL MEMBER SINGLA: I do think number eight is -- remains important on the effectiveness of regulatory programs.

CHAIRPERSON SCHWARZMAN: And do you think we didn't really capture that? I guess we referred to that, but didn't expand on it in the -- in our current list, but

we'll make sure that we capture that.

CHAIRPERSON SCHWARZMAN: Jenny, you had something.

PANEL MEMBER QUINTANA: I just wanted to reiterate that number four I feel like, you know, that we should use the amazing capacity of the laboratories and use the money for analysis and less on sample collection, if possible. Given funding limitations, I just personally feel that would be a way to continue to explore in terms of surveillance.

CHAIRPERSON SCHWARZMAN: Carl.

PANEL MEMBER CRANOR: Just a quick point. Everybody hear me okay? Everything is working I think.

CHAIRPERSON SCHWARZMAN: (Nods head.)

PANEL MEMBER CRANOR: We mentioned children this morning, I think that's terribly important. If we can protect the children, we can protect the rest of us. When we know what's going on in children, we very -- we'll know what's going on in a lot of the rest of us. So insofar as it's consistent with other things, I do think that it's important to understand what's occurring to children. They're the -- one of the most vulnerable groups anyway.

CHAIRPERSON SCHWARZMAN: And Ulrike, you had something.

PANEL MEMBER LUDERER: Yeah. I think also the

focus on California and things that are specific to California. I mean, I think that is another really important aspect of the Program that we shouldn't forget.

CHAIRPERSON SCHWARZMAN: That's the sort of 11, focus on what makes California different?

PANEL MEMBER LUDERER: Um-hmm.

CHAIRPERSON SCHWARZMAN: Great. Anything else from this list or just from your thoughts before we wrap it up?

In that case, I think we should wrap it up. And I will just say that as Jenny and I work to prepare this, please, individual Panel members can email individual Panel members. So if you want to send me or Jenny --

MS. HOOVER: Meg. Meg.

CHAIRPERSON SCHWARZMAN: Yeah.

MS. HOOVER: No, you can't do that, because it's a serial meeting, because it's the same topic.

CHAIRPERSON SCHWARZMAN: Okay. Never mind.

MS. HOOVER: This is your chance.

CHAIRPERSON SCHWARZMAN: Okay.

MS. HOOVER: And actually before you wrap up, like you said, we should just do one last check that we didn't miss any public comment. I don't think so.

CHAIRPERSON SCHWARZMAN: Thank you. I did with Shoba.

MS. HOOVER: Yeah.

CHAIRPERSON SCHWARZMAN: Yes.

DR. IYER: And no, there is no additional public comment.

CHAIRPERSON SCHWARZMAN: Okay.

MS. HOOVER: Okay. Great. Back to you.

CHAIRPERSON SCHWARZMAN: Veena. You had something.

PANEL MEMBER SINGLA: Thank you. Yes, just a quick question. After the letter is prepared, will we see a draft and have an oppor -- just process-wise, could you say a little more about that?

CHAIRPERSON SCHWARZMAN: So, Sara -- yeah, Sara clarified this for me that because of the timing of when the legislative report is due, because it has to be done publicly, there's no way to do that before the report is due.

MS. HOOVER: Yeah. Unfortunately, you know, because of when it has to get into the CDPH chain in order to have a hope of having it issued by 2022, this is the time that you can provide input. And obviously we've -- you know, Nerissa has gathered your input over the last couple of years. So, yeah, I would say try to -- try to give input now and I think Jenny and Meg will do a good job of reflecting the Panel's views.

CHAIRPERSON SCHWARZMAN: Okay. With that, and with confirmation from Shoba that there was no additional public comment, I will do what I need to do to adjourn the meeting here.

So Nerissa, was there -- did you have something?

DR. WU: Nope. Just popping on to say goodbye.

CHAIRPERSON SCHWARZMAN: Oh, okay. Okay. Great. So I just need to announce that a transcript of the meeting will be posted on the Biomonitoring California website when it's available. And the next SGP meeting is Monday, November 8th of 2021 and will be held via webinar again. I want to thank the staff who puts a tremendous amount of work into organizing these meetings and lining up a really interesting agenda, and also to Panel members, and speakers, and the attendees.

And with that, I'll adjourn the meeting.

Thank you.

(Thereupon the California Environmental Contaminant Biomonitoring Program, Scientific Guidance Panel meeting adjourned at 4:38p.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 28th day of July, 2021.

JAMES F. PETERS, CSR
Certified Shorthand Reporter
License No. 10063