ROUND-TABLE DISCUSSION OF REPORT ENTITLED "THE RELATION OF LEAD-CONTAMINATED HOUSE DUST AND BLOOD LEAD LEVELS AMONG URBAN CHILDREN"

Columbia Inn
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Reported by:
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2 WARREN GALKE: We're ready to begin. I would like to say welcome. My name is Warren Galke. I'm the National Center for Lead-Safe Housing's Director of Research and Evaluation. And I would like to thank all of you for taking your time to help us look at what I think is a very provocative piece of research that has been conducted for the Center by the University of Rochester and was supported by funds from the Department of Housing and Urban Development with technical assistance in the design and implementation from the Centers for Disease Control and the U.S. EPA.

What I would like to do first is introduce our peer review panel members so that everybody sitting around the table knows who everyone is. And what I would like to do is start with Harriotte Hurley, and the reason I'm starting with her is that she is the most easily identifiable person on the peer review panel.

HARRIOTTE HURLEY: Wait a minute. You want to explain that?

WARREN GALKE: I say nothing. Harriotte, why don't you say where you're from and what your

background is.

HARRIOTTE HURLEY: I'm Director of Laboratory Services.

WARREN GALKE: Would you speak up. We are recording this session for posterity's sake, so what we're going to ask is when you start to speak, every time use your name, last name is sufficient, and speak loudly. And if you can't hear us, somebody raise a hand and that will be the signal for everybody to speak more forcefully.

HARRIOTTE HURLEY: Harriotte Hurley. I'm Director of Laboratory Services for Clayton Environmental Consultants. My background is all laboratory industrial hygiene and environmental. I have about 17 years' experience managing industrial environment in laboratories. Also have worked with the American Industrial Hygiene Association, which has recently developed an accreditation program, and the accreditation program is off and running. We have about five accredited labs right now, and I was very involved in that effort.

WARREN GALKE: Steve Rust.

STEVEN RUST: My name is Steve Rust. I'm a

research leader with Battelle, and I'm trained as a statistician, and for the past several years have been working primarily for the EPA. I have been working on modeling and statistical analysis of problems associated with lead.

WARREN GALKE: Okay. Mike Rabinowitz.

MICHAEL RABINOWITZ: Well, my name is Michael Rabinowitz. I'm a geochemist by training. I'm an associate scientist at the Marine Biological Laboratory in Woods Hole, Massachusetts, not to be confused with Woods Hole Oceanographic Institution. Two separate institutions. I've had an interest in lead for, I guess, approximately 20 years. Environmental lead and movement of lead into children and within the body.

WARREN GALKE: Routt Reigart.

ROUTT REIGART: My name is Routt Reigart. I'm a pediatrician from Charleston, South Carolina. I've been working in lead prevention activities since about 1972. Really not much else to say.

WARREN GALKE: Chuck Rohde.

CHARLES ROHDE: I'm Chuck Rohde. I'm

chairman of the Department of Biostatistics at Johns Hopkins. I'm trained as a statistician. In the last half dozen years or so, I've been working in environmental lead problems with Mark Farfel and people at EPA and Battelle and others.

WARREN GALKE: Okay. And one thing he didn't say, when Michael Rabinowitz introduced himself, is that he is the chairman of our peer review panel. The natives are getting restless next door. I was joking. Okay.

Formally I would like to go around the table and have people just say your name and your affiliation, but I will take a second to introduce the executive director of the center, and that's Nick Farr, who is sitting in the pink shirt and the bow tie. And that's what I'll say.

We're keeping this real short so all of you have all the time you need to comment about the study. Bruce, oh, I apologize. One key thing to do is introduce the University of Rochester staff who are here for the presentation, and I'll introduce Dr. Bruce Lanphear, who

is the project leader principal investigator, and I'll let him introduce the rest of his staff. Bruce is a pediatric M.D. Right?

BRUCE LANPHEAR: I'm actually not a pediatrician, but I am in the Department of Pediatrics. my background is in public health and preventive medicine. And with me today are a few of the members of the Lead-In-Dust Group. Michael Weitzman, who is also within the Department of Pediatrics. Mary Emond, who is within the Department of Biostatistics. Shirley Eberly, who is within the Department of Biostatistics. Nancy Winter, who is the program or project director. I've never gotten that right in the last year. And I think that's all of us that are here today.

WARREN GALKE: Okay. And then what we'll do is start with Ron Jones here and just circle around and then we'll begin.

RON JONES: Hi. I'm Ron Jones from the National Center for Lead-Safe Housing.

SCOTT CLARK: Scott Clark, University of Cincinnati.

DAVID JACOBS: Dave Jacobs. I'm also with Lead-Safe Housing.

MARK FARFEL: Mark Farfel.

STEVE WEITZ: Steve Weitz, Department of Housing and Urban Development.

JANET REMMERS: Janet Remmers, EPA.

MARCUS PEACOCK: I'm Marcus Peacock. I'm with the consulting firm of Jellinek, Schwartz and Connelly. I'm here representing the Lead Industry Association.

PAT McLAINE: I'm Pat McLaine for the National Center for Lead-Safe Housing.

HEIDI MOST: Heidi Most with the National Center for Lead-Safe Housing.

WHITNEY LONG: Whitney Long, National Paint and Coatings Association.

NISHKAM ARGARWAL: Nishkam Agarwal, EPA.

KAREN HOGAN: Karen Hogan.

BRION COOK: Brion Cook, EPA.

ROB ELIAS: Rob Elias, EPA.

(Unable to hear individuals identify

themselves.)

ELLEN TOHN: Ellen Tohn, Alliance to Prevent Childhood Lead Poisoning.

JOHN WILSON: John Wilson from the National Center.

WARREN GALKE: Okay. Thank you all. And what we'll do first is have a formal presentation by Bruce regarding the study and then I will take five minutes after that and lay out how the peer review process will work, and then turn the session over to Mike Rabinowitz to actually run the session during the day. Okay.

Bruce?

BRUCE LANPHEAR: Okay. Probably will not be too formal, since I'm doing it. I played with the slide just for a minute beforehand and there's this nice dull clunk that happens when you change slides, but it seemed to work, so we'll see how that happens. Make sure it doesn't cause us problems.

Can everyone hear me pretty well? Please remind me, stick your hand up in the air if I start to mumble.

As all of you that are here today are aware, childhood lead poisoning, which was once considered an acute self-limiting disease, is emerging as an important chronic health condition among children, and in some extent in adults.

The recognition that low-level lead exposure is a significant hazardous prompted the development of standards and intervention aimed as preventing exposure before it happens, which contrasts to the current standard today, or the current practice today, of screening children to identify those who have already been exposed.

Now, this study took place at the University of Rochester in the City of Rochester, and as Warren already pointed out, was funded by the U.S. Department of Housing and Urban Development and was designed very much as a collaborative effort, and that design was modified to some degree at the University, but was largely designed in collaboration with the National Center, EPA, CDC, HUD and other expert reviewers around the country.

As I mentioned, there is an effort towards trying to move towards primary prevention. A few years

ago, there were adopted by HUD and some states postabatement clearance standards for lead-contaminated dust, and these were set using the Wipe Method, which I'll talk to you a little bit about today, and these were set at for floors 200 micrograms per square foot, for window sills, interior window sills, 500 micrograms per square foot, and window wells at 800 micrograms per square foot.

We've looked at both carpeted and noncarpeted floors, and the data I'll show you, I'll just lump those two together in terms of comparing with this, but there was not a standard specifically set for carpeted floors as a part of the postabatement standard.

In 1992, the EPA was mandated to promulgate a health-based dust lead standard for children primarily in residential dwellings. However, the data necessary to develop that type of a standard is currently limited.

Previous studies have clearly shown that lead-contaminated dust is a significant contributor to children's lead intake, but in terms of using that data to develop the standard, there are some problems with simply taking those studies and making some extrapolations. Some

of them were small sample sizes. Some of them included children who only had what we now consider to be moderately or more high blood lead levels. They may have included children who had lead exposure elsewhere and as you'll see in a little bit, we've tried to, as much as possible, reduce children's exposure to other sites than their primary residence.

And they typically only use either a Vacuum Method or a Wipe Method or in some cases a dust pan, so it was hard to compare different methods based upon published literature. So the specific aims of this study were to determine whether the relation of lead loading, that is, micrograms per square foot, and lead concentration, that is, micrograms per gram of dust, or parts per million, in house dust and the blood lead levels among urban preschool children controlling for other potential sources, environmental exposure to lead, to determine a risk of a child developing elevated blood lead levels on the basis of a known level of lead in house dust. And to determine whether a Vacuum Method or a Wipe Method of measuring lead-contaminated house dust are better correlated with

children's blood lead levels.

The inclusion criteria were set up first to identify those children who are in the age group at highest risk, that is, children age 12 to 30 months of age, and to try to minimize the exposure to lead from other sites, again, away from their primary residence, so that these children had to live in the same house since six months of age. They had to spend a limited amount of time away from the house, which we arbitrarily designated as less than 20 hours per week. They could not have a known history of a medical or environmental intervention or an elevated blood lead. They could have a history of an elevated blood lead, but not some medical or environmental intervention for that, and that includes iron therapy in the last two months, oral iron therapy. There could not have been any major home renovation in the past 12 months, which we took about two weeks to define that. We essentially limited it to anything greater than one wall or one wall of windows or one ceiling surface. And there could not be any adults who were employed in an industry that potentially involved exposure to lead or

worked in a hobby that involved lead exposure.

The study design was set up as using a random sampling frame. That is, we took approximately 5,000 live births from three urban hospitals and randomly permuted those to develop a list of all children born between March 1st, 1990 and September 30, 1992. It was a cross-sectional study design that ultimately involved 205 children living in 205 residences. We did a significant sampling of siblings, but that's not going to be included in any of the analysis today.

After families agreed to participate, and were determined to be eligible, an environmental field team visited their home to obtain multiple measures of household dust, water, paint and soil lead and to ascertain family characteristics and children's behaviors and activities that we believed would have an effect on their exposure to lead.

Blood sampling was done by venipuncture and all samples were tested in triplicate for precision of plus or minus one microgram per deciliter of lead, and we also obtained ferritin levels at the same time.

One of the questions that we had to deal with in the comments was what kind of quality assurance did we have for the actual collection of blood. And what we had done was make sure that every phlebotomist had gone through the supervisor of the School for Phlebotomy Technicians at Rochester General Hospital, which entailed at least one full day of observation, and was emphasized in meticulous collection. Beyond that, there was not any specific QA/QC of the phlebotomists in the field.

One of the other questions that I just wanted to make sure I identified too is that in the final report we tentatively said there could be some problem with ferritin, which I'm happy to say there is not any problem with ferritin.

We used, in the first phase of this study, a laboratory that allowed the blood samples for ferritin to sit around for 24 hours or sometimes 48 hours in some cases, which does not affect ferritin. A different laboratory used a different protocol, but they were concerned with transference saturation, which is completely different. So I made that final comment in the

report. You can either ignore it or realize it. It has been resolved.

Dust measurements. We obtained side-by-side dust samples using three different methods. And I'm not trying to highlight the Wipe Method for any particular purpose. I just used that as one presentation a few months ago.

We used the Wipe Method which was first used for sampling lead in Rochester back in the early 1970s. We used the Dust Vacuum Method, which we call DVM. I understand it's also called the Microvac in Cincinnati. That's probably the more appropriate term. We used the Baltimore Repair and Maintenance method, which is a high flow vacuum, and it during the study also changed terminology. It used to be called the HVS in our study. Now it's the BRM. I just couldn't make the changes again, Scott, to update all the different terminology. But these were the three methods that we used to collect dust in each of the residences.

Most of you probably are aware, but with the Wipe Method, you can only collect the density or loading

of lead-contaminated dust, and with the two vacuums, you can measure both loading and concentration.

Eleven interior dust samples were collected with each dust collection method for a total of 33 interior dust samples. In some cases it was a few more. In some cases a few less. Often, for example, the child's play area was the same as the living room, and you obviously couldn't sample -- we could have. We chose not to sample the same room twice.

Let me back up here. The locations where we obtained the samples were from surfaces that we thought were most accessible to children, that is, the floors and the window sills, and surfaces that we thought were most heavily contaminated with lead dust, and that was the window well. Obviously the precedent that HUD had set with their postabatement standard drove that largely.

The specific locations include the window well, interior window sill and floor in the child's play area, those same three surfaces in the child's bedroom, the window well and the floor in the kitchen, the window sill and the floor in the living room, if it was different

than the play area, and the floor in the entryway and the porch, if there was a porch.

The midpoint of the room was selected for sampling floors, unless the child had a specific play area in that room. In that case, the play area designated was sampled.

We defined the exact sampling area using a one square foot disposal cardboard template that was laid out on the floor and kept in place with masking tape. The templates for window sills, interior window sills and window wells, were constructed of masking tape and measured after they were constructed to determine the area of that surface.

The location of each sampling method with respect to the other two methods was randomly assigned using a sheet of adhesive labels that the technician would take off and put on to the environmental collection form so that each method had a similar chance of being measured on an edge surface of a window sill or window well or the center. Presumably, which our concern was, the edge might be less dusty than -- I'm sorry. The edge might be more

dusty than the center, because things seem to gather in cracks. We haven't actually looked at that yet, to look at how the data differs by edge versus center measurement, but we did it in a random fashion.

Paint lead measurements were done using a portable X-ray fluorescence analyzer, and we used the Microlead Warrington, Inc.

Each method was an average of three measurements on each surface. These measurements were taken in the three rooms at least and on any surface that appeared to be damaged, any paint condition that was in poor shape.

Soil sampling. There were two composite core surface soil samples. One from the perimeter of the foundation and one from any bare soil areas where a child played, if there was, in fact, a bare soil area.

We also, halfway through the study, decided to get both a fine and a coarse soil sample, because there was some question that the core sample wouldn't be as well correlated as the fine sample would be, because fine particulates are going to stick to children's hands and

would give you a better indication of children's risk. We'll talk a little bit more about what we found in a bit.

Two water samples were collected from the kitchen faucet. First morning draw or flush, and a one-minute flush by the parents. This was the only environmental sample collected by the parents, but because of the obvious concern of trying to leave the water stagnant for eight hours, we didn't want to spend the night with the families or overspend our welcome, either.

Statistical analyses included Pearson correlation coefficients between the log of blood lead and independent variables were calculated and all environmental lead measurements were log transformed. We log transformed the environmental lead measurements because they were log normal in distribution and because in every previous study, we noticed that that's what researchers had done.

That was one of the comments that one of the reviewers had brought up in the discussion, and we certainly would like to have further discussion on that today.

A multiple regression model was used to identify variables independently associated with children's blood lead, and logistic regression was used to model blood lead for hypothetical dust lead standards, and I'll describe that a little bit more when I get to it, because, if not, we're probably going to forget anyway, but we'll come back to that.

The results, this slide shows the characteristics of the participating children. And maybe before we do that, I can let you know, there were actually 215 children finally enrolled, ten of those, however, we identified as not being eligible for several reasons. One that actually lived right over the border of the city in one case. We decided to exclude that child. A couple of them were actually siblings, and to make sure that we didn't have any problems with clustering, we removed two siblings from that total of 215, and the siblings, if you recall the sampling frame I talked about, you could have two people from one house very easily on that sampling frame, so in some case, we actually enrolled both kids.

In one case we only were allowed to sample

the kitchen, and the family tried to convince us that was the only room they used, but we figured out Dad was sleeping upstairs and we couldn't bother him, so that one was also excluded from the analysis.

So of the 205, 44 percent of these children were twelve to 18 months of age, and 28 percent were 18 to 24 months and 24 to 30 months of age. 42 percent of the children were black and 42 percent were white. And eight percent were Hispanic, and eight percent designated themselves as other race or ethnic background.

The mean blood lead of participating children was 7.7 micrograms per deciliter. 24 percent of these children had a blood lead that was greater than or equal to ten. Of the total, 7.8 percent had a blood lead that was greater than or equal to 15 and three percent had a blood lead that was greater than or equal to 20.

These were some of the mouthing behaviors that were reported to us by the parents, or respondents. In most cases, 95 percent or so that respondent was the mother. 31 percent were reported to suck their thumb or fingers. 27 percent were reported to put soil or dirt in

their mouths. 25 percent were reported to put their mouth on the window sill. And 10 percent were reported to put paint chips in their mouths.

Some of the family characteristics, 64 percent of the families reported that they lived in rental housing. 55 percent had an household income of less than $15,500. 48 percent were single parent households. 17 percent reported that they stored food in cans after the cans had been opened, and nine percent stated that they ate or served using some form of pottery.

This slide shows the dust levels that are in excess of the current HUD postabatement standard of the 205 residences. For the floors, two percent exceeded 200 micrograms per square foot. 17 percent exceeded the 500 micrograms per square foot for interior window sills, and 68 percent exceeded the standard for window wells.

DAVID JACOBS: Is that based on the Wipe Method?

BRUCE LANPHEAR: Yes. Correct. This only is looking at the Wipe Method.

These are correlations of blood lead with

environmental lead. Dust lead had a highly significant correlation of .39 and these are all with the Pearson -- these are all Pearson correlation coefficients. Soil lead .38 and .34 for the foundation and play area. Interior paint lead was significantly correlated, but less so than dust and soil. And water lead using the Pearson correlation was not correlated with children's blood lead levels, however, we found very low lead levels in the water in this study. It may not be the same in Utica, New York.

One of the specific aims that I mentioned was to compare dust collection methods. And that probably has been the most challenging from a statistical standpoint. The first thing we did was -- well, the first thing we did actually was to look at the Pearson correlation coefficient for each of those -- the dust collection methods. The order is very similar to this, so I jumped ahead and wanted to report the adjusted slope, that is, the percentage variation accounted for by each of these dust collection methods for the BRM. The variation accounted for using the average dust lead measure across

the house was 13.7 percent.

We determined the average by taking the sum of each of the surfaces, so we took the sum of the window wells, of the three window wells in each house, took the average of that, and then averaged that with the other three surfaces, so a total of four measurements that were summed and averaged.

The wipe was next best in terms of the percent variation explained, and that was at 10.1 percent. The DVM loading was 5.9 percent. BRM concentration actually explained a little more than the DVM, and then the DVM in concentration was 3.2 percent of the variation explained.

The one comment I want to make about this is that in contrast to what we had expected, loading for both of the vacuum methods was better than concentration. That was one of the things that surprised us a bit.

UNIDENTIFIED VOICE: Better because the R squared is higher?

BRUCE LANPHEAR: That's correct. Thank you. And I should point out that this does not necessarily

suggest that each of these are statistically different than one another, but that we put these in the order of the R squared, the variation explained.

What I would like to do now is, for very obvious reasons, we began to limit our analyses a bit, so that instead of looking at all five dust collection method measures, we chose two, and let me define dust collection method measures. Even though it's a mouthful, we have used it because it sometimes is helpful.

We had three dust collection methods. For both vacuum methods, you could measure concentration as well as loading. So, for example, on this slide, we have three dust collection methods, but five dust collection method measures.

The percent variation explained in the model using the BRM found that dust lead loading explained most of the variation or the highest amount of variation of the variables that were included in the model followed by black race, reported behavior of eating dirt, single parent household, and ferritin levels.

The ferritin levels actually seemed to be in

the wrong direction, that is, we found higher ferritin levels were associated with a higher blood lead, and that contrasts with other studies which seem to suggest that iron deficiency is associated with increased levels of lead.

Some of that may be that this may be a spurious finding, but most of the earlier studies also included children who had very high blood lead levels, so maybe there is a different pattern here. Anyway, not to get too much involved in that.

The only thing I want to point out, however, is that this and the next slide uses covariates that were identified primarily for the purpose of setting up a comparison of the dust collection methods, so that these covariates were identified by forcing all five method measures, dust collection method measures, into one model, so that by comparing these different dust collection methods, they all had an equal playing field in terms of the covariates, if you will.

That was one approach that we took, and I think if I were to be able to suggest another area that I

would like further discussion on, that would be another one. Is this the best way? Is there a different way that could augment the approach that we took?

UNIDENTIFIED VOICE: Bruce, let me ask the definition of percent variation accounted for.

BRUCE LANPHEAR: Yeah.

UNIDENTIFIED VOICE: Is that when that variable is added last to the model? Is that the variation?

BRUCE LANPHEAR: This is -- Shirley, did you look up -- you asked this in the comment, I believe, whether -- it is a Type II rather than Type I.

UNIDENTIFIED VOICE: Okay.

BRUCE LANPHEAR: So it's not -- it's not related to the order which it's put into the model. Does that answer your question?

UNIDENTIFIED VOICE: Yes, it does. Thank you.

BRUCE LANPHEAR: And this is the same kind of model used in the Wipe Method. Dust lead loading 10.1 percent, black race 6.1 percent. Eating dirt 4.5 percent.

Single parenting, single parent household 2.4 percent and ferritin 1.1 percent. Again, some of these covariates are in this particular model not because they were chosen as a part of a wipe regression model, but because of the approach that we took.

Well, let me back up just a minute. We've continued to do some additional analyses to try to answer a few more questions. One of those questions is what surfaces should be measured? Do we need to measure all three surfaces? What do we gain by measuring all three versus two? And we haven't done that by location yet, but what we did was we created a model that was done for the Wipe Method and another one that was done for the BRM method, allowing each of them to identify covariates that were also significantly associated with children's blood levels for each of those specific dust collection methods, so these are two different models, and we get different results than the covariates I mentioned here.

And a couple things I would like to point out about that. For both of those, the two surface types that remained in the model that were significantly

associated with children's blood lead was noncarpeted floors, hard floors, linoleum floors, and the second one was window wells.

There was very little difference using the Wipe Method between the window sill and the window well, but that difference was greater when you compared the window sill and the window well in the BRM model, so you might be able to use -- based upon that type of analysis, if you used the Wipe Method, it may be just as appropriate to use the well and the floor or the sill and the floor. There is not that much difference there, but essentially for both of those two models separately they chose essentially the same two surface types.

Then the next thing we did -- now, would anybody like to hear the covariates that came out for each of those two models? I'm sorry I don't have this on the slide. We were just pulling this together. Would people like to hear those?

All right. For the Wipe Method, in addition to dust lead loading, black race remained in the model, interior paint condition and lead content, eating soil,

soil lead levels, were the covariates that remained in the model, and, again, noncarpeted floors and window wells. It's interesting that we did not seem to pick up the socioeconomic variables using that approach.

For the BRM, black race, eating paint chips, eating soil, serum ferritin levels and washing hands more frequently. That one's a little hard to explain. Again, we expect to find the opposite. We're a little concerned that that's a very subjective response on the part of the respondents.

And the way we ask that question is how frequently does Johnny wash his hands after he comes in from out of doors? How frequently does he wash his hands before he sits down to the dinner table? We haven't yet done this, but we've also asked the question when we go in and take a hand wipe sample for lead, when was the last time Johnny washed their hands?

And if I were to suggest that one might give us a better idea of frequency of hand washing, I might rely on the other one, but in any case, we are going to be comparing those two. I don't know if they are going to be

correlated. If they are, and they are correlated positively, then I don't know quite how to explain why if children wash their hands more frequently, they have a higher blood lead level.

CHARLES ROHDE: You have to remember the fact that you also have eating dirt in this model, and it's quite possible that the two go hand in hand. If a child eats dirt, parents see it and say wash their hands, so, I mean, it's not inexplicable.

BRUCE LANPHEAR: It is a little different than others have found. That's an interesting explanation. I like it.

(Laughter.)

It's always nice if you find something that doesn't make sense, that you have a way to make some sense of it.

The other thing that if I'm helpful and I suppose one can create a story for most anything you find, but in terms of the two surfaces that remained in the model, it appeared that dust on the floor seemed to be most accessible to a child. That seems to make some

intuitive sense, and yet there is this large reservoir over here in the window well, so at least in terms of my understanding, I found that a helpful way to interpret those findings.

Okay. Selection of a dust collection method. This was very -- in response to another comment, I put this together very much sort of sitting at my desk, geez, which one costs more? Which one's better correlated? Which one has less burden on the respondents? Which one is easier to use in the field? These are not quantified in any fashion, but the main thing I wanted to do here, and I borrowed these criteria, if you will, from Nexus, which is a -- let's see if I can get this right -- National Health Examination.

DAVID JACOBS: National Human Exposure.

BRUCE LANPHEAR: National Human Exposure. Thank you, Dave. This is something that EPA is doing, and I borrowed those from some of their criteria they developed, and I thought it was helpful, because it's not -- it's not an easy choice at this point. When we begin to identify the BRM is statistically superior, we

haven't compared them to say they are significantly different, and that's actually another point I think would be very helpful to discuss today.

We have done some statistical comparisons of the Pearson correlation of these different method measures and shown that for the unadjusted correlation, BRM loading and wipe loading are not significantly different, whereas for BRM loading and BRM concentration, they are significantly different, and if you remember, those are the three that were most highly correlated of all five method measures. But that has some problems too. That's a comparison of unadjusted data.

Anyway, correlation of children's blood lead with dust lead or with dust lead as measured by each of these two methods, the BRM was superior. This doesn't quantify how much, but it was based upon the criteria that we set.

Field burden. There is no question that the wipe takes less time to sample on each surface. We are actually gathering some timed series data to quantify that in minutes. For each sample that the environmental

technician obtains, we're asking them to put down in actual minutes how long does it take for each type of dust collection method. And we're doing that in a follow up, which is more closely mimicking what we would expect to happen in the field.

What we did in the first study there -- it doesn't make any sense for anybody to try to duplicate except from a research perspective, but not from a large scale screening perspective. So we'll have a little bit more information on that.

The respondent burden, we linked together here, that is, how much time does it take in the field. What's the noise factor? Or the wipes, they sound quieter than the BRM. It doesn't take electricity, so there were things like that that I somewhat subjectively designated as being better for the wipe than the BRM.

The cost was also somewhat subjective. I didn't quantify it. The start-up cost for the BRM is $800 or more. And the wipes, a box of these things costs two-fifty, $2.50. So that one was relatively easy.

Susceptibility to operator bias. They both

seem to have some susceptibility and if we can talk about that a little bit more later, but the other one I didn't put on here was repeated measures and variation in repeated measures, and for that the Wipe Method had less variation in repeated measured on noncarpeted surfaces, whereas the BRM had less variation for carpeted surfaces compared to the other dust collection method measures.

Trying to find ways to quantify some of these, I think, will also be a helpful exercise. I think, however, with the kind of disparities we're finding that we may need to determine through cost benefit analysis to begin to suggest which of these to use.

With the next -- the next section, I would like to show you -- I don't know if I can focus that or not. Can most people see this okay? It's a little bit light. I'll try it.

This pullout shows the estimated proportion of children who have a blood lead greater than or equal to ten micrograms per deciliter, so on this axis, this is the percent of children to have a blood lead or estimated to have a blood lead equal to or greater than ten. This is

the line you want to follow here. On the bottom axis is the hypothetical dust lead standard.

So that if this hypothetical dust lead standard or cutoff was, let's say, 20, then the way we estimated this is that we assume that all dust lead levels would be below that point. If that were the case, then we would estimate, based upon the Rochester sample of children, that about 15 percent of children would have a blood lead equal to or greater than ten micrograms per deciliter.

Several of your comments alluded to the way we described this increase, and we responded a couple different ways, because I wasn't sure what the comments related to, except I think the way we stated it was a bit vague, but it's somewhat based upon the belief that the levels that we're finding of interest are low. We don't know today what low dust lead loading is as measured with the wipe. We've got some data here and there's some additional data, but it's not quite clear what is a low dust lead loading on a nationally representative sample of houses, for example.

What we did find that's a bit concerning is that the change in estimated proportion of children who would have a blood lead greater than or equal to ten micrograms per deciliter increases rapidly at relatively small incremental changes in dust lead loading. Again what we presume to be small incremental changes.

The two lines here represent the 95 percent confidence spans, and it's important to point out that most of our data falls certainly below 40 micrograms per square foot, and in terms of the percent of children, we don't have very many children who have blood lead levels above 20, so we're somewhat limited in the precision of our estimates beyond a certain point.

These are two tables just to show the same kind of thing. The BRM method plateaus a little bit earlier. Again, based upon our estimate in that curve linear line. And the Wipe Method, again, showing the same thing. So, for example, if a dust lead standard was ten, and all children had a dust lead loading below that, we would estimate that 10 percent of children would have a blood lead greater than ten, greater than or equal to ten.

If that was 20, we would expect at 15 percent, or 14.9 percent of children would have a blood lead equal to or greater than ten.

What are some of the limitations? First, as I just mentioned, there was a limited range of dust lead and blood lead levels in this population. They were primarily including children who had blood leads below 15 and dust lead levels between 40 micrograms per square foot.

All the data that we collected was done between August 29 and November 20, so during essentially one season, or the tail end of one season and the beginning of another, and so we don't know that this kind of a relationship is consistent throughout the year. We do know there are seasonal variations in blood lead levels and so we can't say this is a consistent relationship during the 12 months.

We also can't say it's the same for Kuala Lumpur as it is for Rochester. There are some differences certainly in the climate, in how people keep their windows open or closed during different times of the year. So

some concerns about how generalizable is this for the rest of the United States, for example, is another concern I think also would be of great interest for us to discuss.

Although we used randomized sampling frame, it still may not be representative of children in the United States or even in the City of Rochester.

To the extent that we were able to minimize children's exposure elsewhere, we may have also measured a population that's different than if we had measured the whole City of Rochester or 200 children who didn't stay in the same residence since six months of age.

And then finally the cross-sectional study design used lessens our ability to draw causal inferences.

The conclusions, lead-contaminated house dust is an important contributor to urban children's lead intake, even at what appear to be very low dust lead levels. The importance of lead-contaminated house dust has been shown in several studies. Most of them, again, however, looked at children who had higher blood lead levels, were done during a time when there were significant lead exposures from air, from gasoline, from

dietary intake, both of those which have been reduced significantly, so that even after those kinds of changes have been made, this holds -- and it holds for children who have lower blood level levels.

Soil ingestion appears to be an important risk factor for having low level blood lead elevation. This was one of the covariates that no matter which of the 62 models, however many models we looked at, logistic regression, using various dust collection methods, soil ingestion was consistently significant.

Black race appears to be an independent predictor of blood lead, even after controlling for all the environmental measures that we attempted to measure. And while we can't say much about why this is, it appears to be important for some reason.

Some of the additional analyses I've just begun to allude to today, everyone is looking at surface types and the dust collection methods, but also suggest that if we were to try to choose which surfaces should be measured, this analysis suggests, and the way we approached it, that it's noncarpeted floors and window

wells.

The determination of the best dust collection method I think still is a little uncertain. I think given the disparities in our statistical criteria, and the ease of use and cost and training in the field, I think we need to go beyond what we've presented today to begin to say with certainty which is the dust collection method that might be used on a large scale for sampling residential dust.

Some implications. This also would be another interesting topic for discussion. What are some of the implications? Certainly the association that we found at what appear to be low dust lead loading levels has significant technological and enforcement implications. We are beginning to approach some detection limit levels for lead and dust for many labs in the United States. And we used graphite furnace. In fact, that was a modification we made about halfway through, to go back and do all our undetectable lead samples using graphite furnace, which can get down to quite low levels, even lower levels of lead, whereas the flame atomic absorption

has a detection limit of about six micrograms, so that's one potential implication.

Also, the current postabatement standards may be too high in the face of current concerns for low level blood lead in children. We found very few houses that exceeded certainly the floor lead loading standard. In contrast, quite a few exceeded the window well, even though the window well we found to be important here, and we haven't done some of this analysis, our -- our analysis may suggest that even though the window well is important, it may not need to be as low as 800. I'm saying that without having looked at some of our data.

We found very few -- well, 68 percent of our houses failed the current 800 micrograms per square foot. So there is some indication that may be set too low, even though window wells appear to be an important source for children.

I think it's critical to determine dust lead levels in a nationally representative sample of houses. Even if one assumes that we found what we found is scientifically true, and there should not be any problems

with generalizability, one should look at what is feasible. If we set some standard that 50 percent of the housing units in the United States fail, who are we doing good for? And so we need to ask questions of whether it's feasible, or how many housing units would actually fail a specific standard that was set.

And then finally we need to do studies to demonstrate that dust control measures are efficacious in preventing or certainly at least reducing low level exposure to lead in childhood.

UNIDENTIFIED VOICE: This is the national survey data for your first next step there.

BRUCE LANPHEAR: You talking about with the blue nozzle?

UNIDENTIFIED VOICE: Yes,

BRUCE LANPHEAR: Dave or Warren could probably respond to that a little better, because they have started to look into that.

UNIDENTIFIED VOICE: I'm looking for a yes or no.

UNIDENTIFIED VOICE: Yes, we are doing

further work to look at adjusting those data for one of those methods that is more likely to be a standard method. That is a pilot study. The question is whether we want to adjust the old data or actually launch a new national surface.

UNIDENTIFIED VOICE: We have looked at direct comparison of the blue nozzle with the wipe, and there are substantial differences in terms of the dust.

UNIDENTIFIED VOICE: Yeah.

BRUCE LANPHEAR: The other issue is, I mean, for every different dust collection method and surface type, we found differences in the slope, too, so that's important to consider.

MARK FARFEL: I have a question, that is, can you give us some sense of the overall condition of the 205 houses?

THE REPORTER: Could you all speak up for me, please?

MARK FARFEL: I had asked for some comment or description of the overall condition of the houses and were there variations across the rental versus the owner

occupant?

BRUCE LANPHEAR: Yeah. We will be able to, Mark, but we have not yet done that as yet. We have emphasized more the dust collection method comparisons and the estimation. So we've not looked at that specifically.

MARK FARFEL: Can you give us some sense today of what -- are we talking about housing with substantially deferred maintenance with code violations, or are we talking about a fairly well-maintained set of units?

BRUCE LANPHEAR: I think it's fair to say there is a pretty wide range. As you go into some houses, that they certainly wouldn't be closed by the city, but they were in bad repair. And then you go into others that were immaculate, and inasmuch as it was an accident, I think one of the strengths of this is that we did get a wide range of people of low versus high income, and of different racial and ethnic makeup. So I guess the only way I could generally respond to that is to say there seemed to be a range, but I can't speak to anything more specific to that.

Warren, do you want to proceed or shall we just continue?

WARREN GALKE: No. What I wanted to do -- okay, Rob, if you have one very quick technical-type question, otherwise we'll get into the formal deliberations of the committee.

ROB ELIAS: I'll pass. That's fine.

WARREN GALKE: You'll pass. That's fine.

What I would like to do is kind of lay out a modus operandi for us to work under today, and what our intent is is the following: We are seeking comment on the quality of the work that was done. We are seeking input into additional analyses that need to be undertaken of this data set. We are looking for places where our understanding of what the data are saying could stand improvement, and what we hope to do is allow everybody who is in attendance to have an opportunity to contribute their thoughts on the subject.

In that regard, what we are going to do is start the discussion with the members of our peer panel, peer review panel, and then spread to the federal agencies

for their insights, and, in particular, comments from them regarding additional questions that Bruce and his team need to look at the data set with, and in both the morning session and the afternoon session, there will be opportunity for the rest of the attendees to make their comments.

If during the course of discussion there are points of clarity that anybody has, like a comment is being made and an answer is being made, and there's a major point of clarity, anybody can raise their hand and be recognized so that we have the benefit of clearing up any confusion that may exist. But I would like to follow this kind of sequence of solicitation of information so that we can move through the entire process.

And in the beginning, I would like to suggest that the committee focus their attention to general comments regarding the conduct, analysis and report that you read from University of Rochester, and with that, I would like to turn the meeting and the running of it over to Mike Rabinowitz. He is our chairman for the day. And he has volunteered to take on the task

of coordinating the drafting of a formal report of the committee's deliberations regarding this study with, of course, the able assistance of the other panel members, so we're looking forward to having a product that will be sharable to the general audience at the end of July, I believe, is the contract date; right?

With that, Mike? If you have any other suggestions as to how you want to run things -- oh, one other thing. Remember every time you speak, please say who you are. That's to help our reporter. Did I forget anything else? Okay.

MICHAEL RABINOWITZ: Thank you very much. I guess my task is just to make sure that the court reporter is happy, make sure we all just speak one at a time. I know that won't be hard with this group.

(Laughter)

And also to make sure everybody is heard. And then later help coordinate writing assignments with our small group, and, lastly, make sure everybody is able to get to the airport when they want to, so perhaps we could just go from left to right. Would that be all

right? And start with just perhaps general comments.

HARRIOTTE HURLEY: I thought the study was excellent. I didn't really find any holes in it when I reviewed it, as I mentioned in my comments. One of my concerns when I read the study had to do with prior cleaning of the house, and I think that was mentioned. I would think it would be very useful to include some information on when the house was cleaned previously, and that's the one place in the study that I felt like it would have been nice to have that information, and I wondered what does that say about the study. Can we get around missing that information?

BRUCE LANPHEAR: Would you like me to respond to comments like this or no?

MICHAEL RABINOWITZ: Perhaps now a good time, while it's fresh.

BRUCE LANPHEAR: We agree with you, that that was an important omission. Early on we struggled with how do we present ourselves? Do we call people when we schedule the meeting and say, look, please don't clean. And that became -- the question is how do we make sure

we're not making people suspect.

It was only after we had gotten through maybe half of the course of the study we realized, even though we don't want to allude to cleaning prior to going to the house, we really needed to get a good indication of when the last time they cleaned was, and we did not do that. And it was an important omission potentially. We're doing it for the follow up, but that's not going to help us too much, because these now are quite different people.

DAVID JACOBS: Just one thought on that may be the question is why do we really need that data? Does it bias our results, or can we assume that most of the houses in fact have a random distribution with regard to when they were last cleaned. If it is random, then you wouldn't think there would be much difference in the results. But if for some reason this population had all cleaned their houses the week or the day before the sampling was done, then you would see a difference. So I guess the question for the panel would be how important is the absence of this particular piece of data as a

potential bias.

STEVEN RUST: I have a comment. It may be as important as eats dirt in the sense that maybe it's an important covariate if we knew more about might affect our thinking in the way that a standard might be set up.

BRUCE LANPHEAR: The only question that we did ask that might attempt to get at when was the last time you cleaned is the frequency of cleaning, and that was in a univarate analysis a significant covariate, but it was not in the final model. So there at least is some indication there that we have obtained some measure of that.

WARREN GALKE: Don't forget to speak your name before you speak.

HARRIOTTE HURLEY: I'm Harriotte Hurley. One additional comment that I have is I looked over a lot of the work done by the laboratory that wasn't included in the report, and I thought it was done very well.

MICHAEL RABINOWITZ: Steve, before you start, could I just ask a procedural question? I know each of us has read the review and we made some written

comments, and we've gotten written comments back. I wonder if our comments and the responses have also been circulated to the wider audience.

WARREN GALKE: Not universally. The agency people have -- some of the agency people have seen them. But we do have copies of both the reviewer comments and the Rochester results here, and some extras, and anybody who wants them can get them. We will send them when people leave.

MICHAEL RABINOWITZ: I ask that because -- just because you put a comment in writing, we may still want to bring it up.

STEVEN RUST: I also think the study was well designed and well executed, and also in the materials that I reviewed, I found you documented very well what you have done, so it's very easy to review the material, and I feel fortunate to be able to give a few comments or improvements of what I think was some very good work.

In the way of something that wasn't addressed in the report, you may have data to be able to address, is the issue of measurement error. This is

something that has been coming up lately in terms of an explanation for why do we see such low slopes between dust lead measures and blood lead measures, and I think that measurement error in the dust lead variable may be a partial explanation for that. I think you have some interesting data that may shed some light on that particular question, so I would suggest some further work in that area.

In terms of the material that you didn't present, I think that it's possible that some very important decisions will be made based on perhaps a correlation coefficient here or a slope coefficient there that's presented in this report, and so in those cases, I would like to see some very careful documentation of what were the statistical assumptions that underlie that particular analysis, and here is how we went about verifying those assumptions and making sure that this particular number isn't dependent on a very small percentage of the data points here, because of the way they happened to distribute themselves, and so I'm not suggesting that the numbers in the report are influenced

in any way, but I would just like to see some documentation that you go down that pathway and make sure that there aren't some funny things behind those numbers.

And then I guess finally, the thing I liked about the report was that you took many different looks at the data, you looked at things in different ways. When I reached the end of the report, I felt like I had a hard time sort of piecing them all together in one coherent picture of the data, so it may be possible to tweak some things here and there so the different analyses fall together into one puzzle when we are done at the end.

Those are my general comments.

BRUCE LANPHEAR: Okay.

MICHAEL RABINOWITZ: Routt.

ROUTT REIGART: As a pediatrician, I need to speak to the children. This is wonderful, wonderfully done. I think my comments reflect having a little problem with the sort of behavioral side of it, both on the part of the behavior of the interviewers. It wasn't clear who the interviewers were. How they were trained and how well you knew the data, or how well you could ascertain how

reliable the data they were getting was. That's a bad sentence. Maybe we should erase it. And, you know, in that context, there are a couple of things that specifically troubled me.

One is this unusual relationship of ferritin to blood lead. That doesn't -- it's statistically sound but doesn't make a lot of biologic sense from what we know so far. I wouldn't go by that too quickly.

The other is looking at the age and behavior relationships, which obviously are very important. It's not just how much dust is in what part of the house, whether it's floor or window sill or else, but children of different ages have different behaviors relating to those surfaces. And it was a little troubling, if you look at the behavioral determinations about thumb sucking and putting -- there was no difference across age, even though behaviorally that's an enormous age range. You have got kids from 12 months to 30 months, and children change a great deal over that time, and yet none of the things you did to assess behavior at all. How reliable do you think your assessment of children's behavior is?

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And sort of a secondary question, did you do anything to try to independently assess the children's behavioral state by observations of people going into the household, which had been done, as you know, in other studies of lead in children's environment.

BRUCE LANPHEAR: We were primarily interested in the environmental relationship more than specifically looking at behaviors and actually observing the behaviors, which pushed us in one particular direction.

If we were geared towards primarily interested in behaviors as the focus of the study, obviously we would want to spend several hours observing these children, what the dust lead levels were, where the kids played and actually directly observe them, so I think certainly those kinds of studies would be very important, but it wasn't the objective, primary objective, and therefore we didn't emphasize it, and because of that I have pointed out some of the concerns.

The behaviors not being different across ages doesn't concern me too much. And I even checked that

with my expert developmentalist, and that wasn't a concern at all with her. The one thing we did find is eating dirt did seem to peak at 18 to 24 months of age, for whatever reason. I believe there was -- well, certainly activities out of doors increased with age. And that was --

ROUTT REIGART: That's good. That makes sense. I'll give you that one.

BRUCE LANPHEAR: So overall I think while certainly your concerns about reliability of interviewers was an important comment that you brought up, and one that we had anticipated to deal with, in the course of this study was not able to be dealt with because the accelerated course that we took.

ROUTT REIGART: Could you at least tell us who they were, what their training was, which wasn't in there at all.

BRUCE LANPHEAR: Nancy could probably tell you who that was.

NANCY WINTER: We had 25 interviewers working with us at any given time at peak. They received in the very beginning an overview of the entire project.

ROUTT REIGART: What was their background?

NANCY WINTER: The majority are baccalaureates. There are four Master-prepared individuals on the staff. There is one who only had a high school education. But they received an entire one-day training, including the environmental. The afternoon was broken out to discuss the nature of the question, how to ask a question, how to probe for an answer.

BRUCE LANPHEAR: What we also did was to use one of the interviewers who has an about ten-year history of working in environmental sciences, primarily providing information to people as a part of the Environmental Information Center in Rochester that's recently lost some funding, but what we also did was that she would go in the field for one, two, three, four days working with a specific interviewer before they were allowed to work on their own, so she acted as a training supervisor as well.

NANCY WINTER: One of the team field leaders, one of the fellows from ATSDR, became an employee of ours and started as an interviewer, so she was very

well versed.

BRUCE LANPHEAR: Michael, you wanted to say something.

MICHAEL WEITZMAN: I'm Michael Weitzman. Hi.

ROUTT REIGART: Hi.

MICHAEL WEITZMAN: A couple of comments. One is that this questionnaire is a variation or a very close approximation of the exact same question we used in the Boston Lead-In-Soil Study, and as a result, the results for the behavioral, they are quite similar.

ROUTT REIGART: Okay.

MICHAEL WEITZMAN: That's one point. The second is that if you know a bit of the data set about the national evolution of these behaviors, we would welcome that, because I've not been able to find. I've had the same sorts of problems starting five years ago when we were looking at the Boston data. I've not seen a good data set on these sorts of behaviors, and that relates to a generic issue, if I may, to reviewers. And this, too, grows out of the Boston Lead-In-Soil Study. It would be

more helpful to us rather than comments or criticisms if you have overt suggestions, we would welcome them, or if you see things in a data that we don't see, or if you disagree with what we see, to explicitly let us know.

CHARLES ROHDE: I think that's right. Again, I think your comments are fair to the extent you outline how you came up with the questionnaire, how people are trained. That gives you a lot more confidence in the results. But I think, you know, sort of another step, I know what you said is that not -- obviously not this study, maybe one of the additional steps that need to be taken in the future is to better assess behavioral development with regard to these behaviors that seem to be important, and because setting a standard doesn't just relate to the dust, it relates to the children that are in that household. And I think we need to -- I agree, your study won't do it, but I think that it needs to be done.

I agree with the rest of the panel members. This was a very well-managed study, clearly well done, so I'm going to reserve my comments for some potential suggestions that you might do.

16 First of all, I was intrigued by the measure of exposure, that is, the combination of the measurements across the house. I think this is an area that nobody has had very much luck with. People have tried correlating play area dust lead, bedroom dust lead and so forth, and it seems to me that we really need a concerted effort to select the measure of exposure in the house. You've got a good data set to do that. You have one approach.

I might suggest that you might -- you think about a latent variable model to try to combine these ten or so measurements over the houses in some sort of systematic way. It's an idea. It may not work, but it would certainly have the payoff that if it gets down to a nationwide screening of houses, and you can demonstrate that some overall measure correlates best with blood lead, then that can greatly reduce sampling and beginning to screen hundreds of thousands of houses. That's one idea.

The second is don't discount the siblings. I think there's probably a wealth of information in the siblings, particularly as regards the exposure from a particular house and its effect on the children's blood

lead.

Third, to follow up on Mark Farfel's comments, it might be advantageous, if you can, to think about clustering the houses as to the general condition, bad, moderate, good, and stratifying on that variable and see what kind of results you get. You may be able to tease out a little extra variability if you do that.

And then finally, I think you've got a real wealth of data in terms of looking at your in-house variables as compared to between house variables that will be extraordinarily important in dust lead measurements if you begin to think of the nationwide screening, because if it would be possible to just eyeball a house and say chances are this is not a high lead house, then you can concentrate on houses of other types, and you have some information to get that.

And then finally, it's not for you all to do, but I urge somebody to do something like meta-analysis, which I prefer to call Combining Information, to begin to look at the studies that we have got to date and combine some of this information and come

up with some estimates that maybe EPA or some other groups might be able to use effectively, so, again, congratulations on a good study.

MICHAEL RABINOWITZ: Well, I guess it's in the majority thinking that this is an important topic. That this study was well designed to answer and well executed to answer.

I guess another concern we would have as a group is to what extent any conclusions drawn are really supported by the data. Of course, and we'll have a chance to look at that. But in terms of being designed and able to look at the relationship between household dust and blood lead, it's very well done. It was not, of course, designed to look at the relationship between ferritin and lead. And if you want to look at that question, you might have designed the study a little bit differently. Maybe for that reason I'm not too concerned about this apparent paradox that may be in the study. Maybe we don't understand the metabolism well enough or maybe this study, there is something idiosyncratic about the study. I don't feel I should worry so much about the relationship between

ferritin and lead in this population. But I just have a -- but just a few other questions, though, I could just raise now.

I wonder if instead of having -- taking logarithm lead load variables instead if they were handled just as a variable, would that have changed the conclusion? Would that have changed the conclusion in terms of R squared? So maybe I could leave that question on the table for now and somebody may want to answer it now or later.

MARY EMOND: I could address that partially now. My name is Mary Emond. The relationship between the dust lead variables by any measure and blood lead variables is not linear. So the slope changes over the range of the dust lead variable. It's much more steep at lower levels and much less steep at higher levels, and to capture it, a log transformation seemed appropriate.

There is a table in the report, I believe it's Table 18, that shows that if you truncate just a few of the higher values, for example, in BRM loading, the slope changes from a magnitude of .11 to 45.1, which

indicates that that has to be taken into account in any kind of analysis that we're doing.

STEVEN RUST: Those numbers are based on nonlogged transformed.

MICHAEL RABINOWITZ: Yes. These numbers are based on nonlogged transformed environmental data, so it says the effect of not doing the transformation.

STEVEN RUST: You made an assertion in the very first comment there that the slope of the relationship changes as you move across that horizontal variable. And I don't know if now is the time to get into the details on that, but I would like to discuss that in some detail some time today what the basis of that assertion is.

And one of the plots that I believe you included in your package, where you plot things on a log basis, I don't know that I see the evidence for that there. I'm not saying it's not true, but I don't know there is specific evidence to say it's definitely there.

MARY EMOND: I believe this is strong evidence, this table, as one piece of evidence, and we

could discuss some more evidence later.

MICHAEL WEITZMAN: Can we go through that?

WARREN GALKE: I would make a recommendation, since we started this topic, let's -- and I think we've gotten through most of the general comments, let's finish this one question out so that the discussion is packaged rather than stringing it out over several points.

MICHAEL RABINOWITZ: This question of linearity, nonlinearity, we'll talk a little more about it now.

MARY EMOND: Can you say specifically which plot you were referring to?

STEVEN RUST: First of all, in Table 18, these numbers that are presented in terms of nonlog transformed regressions, I guess I have a real question about whether or not those numbers can be meaningful, because for the most part, I agree with the necessity for a log transformation of the data.

When you look at the blood lead data, it does look more log normally distributed than normally

distributed, and so when I see a regression analysis, where you have not in some way logged transformed the blood lead variable, that immediately throws up a red flag for me that the numbers may be suspect that come out of that analysis.

And so making a comparison then of two numbers done that way, I'm just not sure exactly what that means, except that I suspect that this is an analysis that can be easily affected by just a few data points, and that, as you've shown, if you truncate a few data points out, it changes the slope significantly, and so --

MARY EMOND: Well, even if both your variables have a log normal distribution, the relationship between them might still be linear, or it may be nonlinear, so I think we have to distinguish between those two different things. Nonlinear relationship versus linear relationship and normal distributions versus nonnormal distributions.

STEVEN RUST: In terms of a specific comment, I'll try to be as specific as possible. I guess in order to try to get a middle ground here, I agree with

your log transformation of the data in most cases. I also agree with your need to look at a linear relationship between those variables, and what I might suggest there is that you look at a log-additive model that you can't fit with just a standard statistical regression routine, but if you have a nonlinear regression routine available to you, like SAS PROC NLIN, you could fit log blood lead versus log as an additive model on your independent variables, and therefore you can still maintain that additive model, but yet also log transform the blood lead variable to maintain your assumption of normality or at least symmetry on your dependent variable, and that might be a middle ground that allows more of the assumptions to be valid.

MARY EMOND: I think there is also some interest in just knowing what is the general trend, the general relationship, just look at a scatterplot and try to estimate a slope, what is that slope. And that was one point that was brought up in previous discussions with members of the CDC, and so there are obviously many things we need to do, but Table 18 is an attempt to try to

address a simple question.

MICHAEL RABINOWITZ: It might be helpful just to show the raw data as it was before the scatterplot form. I'm sorry.

BRUCE LANPHEAR: There's two things. One, both of the comments that you had we took very seriously. One was that we should preface any data from this simple linear regression from Table 18 and say that people should use this cautiously, and we tried to do that, and in fact Shirley wouldn't allow anything out without carefully stating that, so we tried to be cautious in how people would interpret and read into that analysis, that simple linear regression.

The second thing is that the log-additive model, based upon your comments, we have already planned to proceed with that. We don't have it today. But we do plan to proceed with it.

MICHAEL RABINOWITZ: I'm greatly relieved to know we have enough statistical resources at hand here to address these things, but I'm just wondering whether or not you find the conclusion you reach is dependent or not

dependent on some particular choice of how you statistically approach the question. In other words, if you chose this statistical model or that statistical model, you wind up with quite different conclusions in terms of using the Wipe Method or Vacuum Method. So perhaps later you can tell us your thoughts about that, or now.

MARY EMOND: Well, so far the indication is that the order of the ability of the methods to correlate blood lead is the same under any kind of analysis.

BRUCE LANPHEAR: That we have done so far.

MARY EMOND: That we've done so far. And certainly the standard that is set would have to depend upon the method used, since the slopes do vary in the models, depending upon the method that is used for dust collection, but the qualitative results tend not to vary from model to model.

MICHAEL WEITZMAN: Is that a satisfying answer? That's a crucial question that you've asked. The two of you are shaking your head yes, and I can't read the others. Are there other analyses? Do you not see the

same thing that we see in terms of that interpretation? Or consistent.

STEVEN RUST: Well, I think that in the report, you've done both types of analyses. You've done the linear model and you've done the log linear model. And so it doesn't seem that you have chosen one or the other of the ways to look at this, and I think my comment would be that we probably do need to look at this in different ways and determine whether or not we would draw different conclusions depending on exactly which way we look at it.

If they all give the same conclusions, that's wonderful, because then you don't have to sort out among different ways of looking at the data, but if they do give different answers, then that raises some serious questions about those different models that you might use.

CHARLES ROHDE: Can I try to lay this tentatively to bed? What you might think about doing, remember that the assumptions of these models as you're using them based essentially on something being normal distribution, when you're all said and done just fit

whatever model you want. Look at the residuals. If they are reasonably normal and well behaved, be done with it.

My guess is that in both these cases, they are not perfectly normal after you look at them, but they are adequate enough and we know the methods are robust enough so you are probably pretty safe. You might want to attenuate the confidence intervals just a bit to compensate for the lack of exact normality, but that's probably fine, so -- and you mentioned this earlier, Steve, about look at the residuals, and I think that's the key to the game, is to really look.

MARY EMOND: We have done some residual examinations on the log log models, and they do look fine.

CHARLES ROHDE: That should be reported and that would make, I think, everyone feel a little more comfortable about what the differences are with respect to the models.

I would like to get back while we're on this interpreting coefficient --

STEVEN RUST: Can I comment on your comment before you go on?

One -- if you're staying well within the range of the data that you've collected, then I think I agree with you that those different models probably will be somewhat close to each other.

One caution is that if we're doing any extrapolation beyond the range of the data that we're using here, a log-additive model and a log-linear model and a linear model can give very different answers in that extrapolation, so it may be more than checking of the assumptions of the analysis. It may also be looking at where the different models go when they leave the scatter of data that we have collected if they are going to be used out there.

DAVID JACOBS: It's not clear to me how it would be used, because most of our blood data levels are above ten, presumably is what EPA will set its standard. It doesn't seem it will be necessary to extrapolate too far out of that range.

CHARLES ROHDE: I wouldn't extrapolate it at all.

The other thing I would like to get back to,

there is a point I would also like to finish up, if we could, this is about the hands always being washed being significantly in the wrong direction.

If you look at Table 19, if you look at the unadjusted coefficient, it is statistically significant value of output, one. However, when you look at it adjusted, it's done to about .02 and not significant. What is probably being picked up there is something like the eating dirt and so forth, so I wouldn't consider that a real finding at all. That's just high correlation with some of the other things that we've got in here.

MICHAEL RABINOWITZ: Warren, I'm looking at my clock, too. I see we're scheduled for a 15-minute break. Even though we haven't finished this portion of it yet, I think we should take that break now.

WARREN GALKE: I think so.

MICHAEL RABINOWITZ: So a 12-minute break.

(A recess was taken.)

WARREN GALKE: It's time to reassemble.

MICHAEL RABINOWITZ: You'll let us know if you're not hearing us, okay?

Why don't we reconvene then. We'll just finish up with the other comments from the peer review panel, and then turn it over to the government agency people.

We just finished discussing the statistical issues for now. And I just wanted to raise a few other general comments. I suppose having learned so much from this study, you could offer some advice perhaps in the final report about how you might design a more perfect wipe if it turns out you want to do wipe samples in the future, if there's any way you could improve just the technology of wipes.

Next topic. I'm still a little confused. I hope we can try and explain it to me more. Maybe other people are too. About one of the graphs you showed earlier about the dust versus blood showing different standards of dust. I think you know that graph I'm talking about.

BRUCE LANPHEAR: Yes.

MICHAEL RABINOWITZ: Perhaps I could just ask, when you talk about at or below a standard, dust

standard, does this mean you generated a distribution of dust values and then truncated it at certain levels and used that to generate -- calculate what blood levels might be? I mean, is it model dependent? Is it empirical? Could you tell us a little bit more about that graph.

MARY EMOND: I'll answer that question. My name is Mary Emond. We -- the particular plot you showed, was that the model plot?

BRUCE LANPHEAR: This is the empirical, I believe.

MARY EMOND: Okay. We actually took two approaches, and they yield extremely similar results. One is we just use -- look at the purely empirical probability that a child's blood lead is above ten, so we would look at all children among those who, say, had BRM loading less than 20 micrograms per square foot, so 20 would be the hypothetical standard at that point, and then we would say what percent of those children have blood leads of above ten, and we use that as an estimate of the probability of being above ten. So the -- totally specific to the population we had, and we did that. That was our

model-independent method.

We also did a logistic regression, which if you're familiar with that, is a type of model which estimates the same thing. The probability of the child's blood lead being above ten. And that was adjusted with some covariates. And then we averaged that probability over the values of the covariates in our sample. So, again, it's a way of arriving at an estimate of the same thing.

One is model dependent. One is model independent. And the fact they are so very close is very reassuring. It answers one of the questions of how dependent are the results in the model, and this shows it is not independent of the model.

ROUTT REIGART: Can I just follow up on that one? Did you by any chance look at, say, the blood lead of 15 as well as the blood lead of ten and see how that would affect the lead standard, dust lead standard?

MARY EMOND: We did look at some models where we used a cutoff 15 micrograms per deciliter for the blood leads, and we felt that we did not have enough

children with blood leads in that range to get estimates for small enough standard errors to really be meaningful in any way.

SHIRLEY EBERLY: My name is Shirley Eberly. Actually, if I might add, the logistic regression wouldn't converge. There were so few data points above 15.

MICHAEL RABINOWITZ: So on another topic, regarding the dust itself, I wish that somebody perhaps in the future could really characterize better the chemical form of the lead in the dust, what else is in the dust besides lead, the general chemical physical nature of the dust in this population. Not that it's all so uniform, even within Rochester, and I think this will help later on when people do compare studies and put other studies side by side to know whether or not you're looking at more or less industrial fallout or more or less old paint chips or whatever. They may be different from place to place, and I'm sure the technology exists, even within the State of New York. You may have to go as far as Syracuse, and most people like Andrew Hunt and others, to perhaps characterize better the dust.

BRUCE LANPHEAR: We are. In fact, we did propose a collaborative study with some people in Syracuse to look at that.

MICHAEL RABINOWITZ: Just two other points, if I could, one is race as an independent variable. And I guess that was one of your conclusions, secondary conclusions, perhaps.

BRUCE LANPHEAR: (Nods head up and down.)

MICHAEL RABINOWTIZ: And I just remain unconvinced of that for now and just await you trying to convince us it is race rather than race as a marker as perhaps some other sociodemographic features. I would look forward to some information you can shed on that.

BRUCE LANPHEAR: I would like to be skeptical of that finding as well and at the same time not simply ignore it. What we did was go back and try to get some information of whether there is a difference in calcium intake among the children who have a high versus low blood lead level, because there is some data to suggest black children ingest less calcium. There is a high prevalence of lactose deficiency. And while these

children may be too young to actually have that deficiency, if others in the household already have lactose deficiency, there may be less milk available, for example. Regardless, there is certainly some evidence that the dietary intake of calcium and dairy products is lower among black children in some parts of the United States anyway, and there is also some evidence to show if you have calcium and lead in the gut at the same time, there is competition for absorption, so I think whether that is a partial or even an explanation of the finding that black children seem to be at increased risk, I'm not certain, but we have attempted, given the confines of the study as it is in terms of product particularly, to begin to take that to the next step.

MICHAEL WEITZMAN: That's a real important question, and we have spent a lot of time within the group discussing it. It would help, I think, again, if I'm not -- it's not inappropriate to ask, how you see -- I think as much of the analyses as we're capable of, given the limitations of the data, and you see the findings, so the question is how does one frame that finding? It's

there in a potent way. We remain skeptical. We remain worried about the implications if you overstate it. I do think that it's quite possible it's confounded with other socioeconomic variables, even the geography within the City of Rochester. But what you see is what we found, so the question is how would you state it?

BRUCE LANPHEAR: Or what else would you do?

MICHAEL WEITZMAN: I don't know if there is much else to do with the data.

MICHAEL RABINOWITZ: I'm sure you tried such things as putting in the other variables you measured and see to what extent coefficient with race. If it's there in your data, you just have to report it, I suppose.

Lastly, I just want to talk about window wells. And I guess this is that groove the window goes into below the window sill, and I guess it takes a very energetic child to actually get the lead right out of the window sill, or perhaps not. Window well or perhaps not. I'm wondering if this isn't a marker that gets at dust lead levels unaffected by household cleaning, because although people may clean the floor, and clean other parts

of the house, probably less people would clean the window well than other parts of the house. I guess. I'm just speculating. I really don't know.

SHIRLEY EBERLY: That's true.

MICHAEL RABINOWITZ: I wonder.

BRUCE LANPHEAR: We were surprised as many as seven percent of people clean their window well every two weeks. We were surprised it was that high.

MICHAEL RABINOWITZ: Good. I just wonder if the window well itself isn't a good marker for other less well cleaned parts of the house. And that if they know you're coming to visit the house, well, they will clean the house, but that's an area perhaps that isn't cleaned and you're able to get perhaps beyond the effect of the observer coming, the technicians coming to the house by looking at the windows wells, so -- it could be a good predictor that way.

BRUCE LANPHEAR: I think in both cases, in one, to respond to the comment you made earlier, at least in the written comment, we measured approximately half, and this is really rough, of the children during times

when the windows might be open, and the other half during the times when the windows were probably closed. October, November. So there are going to be issues like that. Even if they are dirty in October, November, is it important, or how important is it, and it probably is quite different than if they are open and dirty in August.

And I guess we would expect people in November, regardless of how meticulous they are cleaning, probably not to open their window wells and clean them at that time of the season. I see there is one other point. I guess the other thing just to mention, at least in, I believe, the modeling, where we looked at different surfaces, that noncarpeted floors were the first to enter into the model.

SHIRLEY EBERLEY: Generally.

BRUCE LANPHEAR: In both cases, for whatever that is worth.

MICHAEL RABINOWITZ: Okay.

MICHAEL WEITZMAN: But as a pediatrician, there's a very practical implication, because not only is it very high lead levels in window wells, window wells

disrepair at quicker rates, I believe, than other portions of the window, and I don't know they are explicitly counseling the public about cleanliness activity directed toward window wells, so I think that we tripped upon something that may have practical import.

MICHAEL RABINOWITZ: Well, if there are no other general comments from this group, perhaps we should --

PAT McLAINE: Pat McLaine. I have a question about condition of the building. You have interior and exterior visual conditions noted here, and age of dwelling, and I wondered when you were doing the analysis of that data, I think you might find that some of this, especially the relationship between drapes, may be somewhat dependent, as Dr. Farfel suggested, the condition of the house and the age.

BRUCE LANPHEAR: One of the things that we do intend to do is to look at condition of housing as it relates each to lead loading, lead concentration of interior dust, but also to begin to look at biracial distribution, what it might be, some of the differences,

some of the differences in environmental exposures, and we -- Shirley has done some of that, but it was more to make sure nothing was grossly apparent, and we probably need to be a little bit more formal about that approach.

PAT McLAINE: Have you scored that information in terms of coming up with a variable based only either the interior or the exterior visual determinations?

BRUCE LANPHEAR: The condition was included in the modeling.

PAT McLAINE: Okay.

BRUCE LANPHEAR: But we haven't done anything more extensive, and we would like to do more than that. I am not sure which month in the next six we are going to do it, but we do think that's important.

MARK FARFEL: There are a couple of ways that the housing conditions are important. One is your overall description, but then also in the sample collection form, I noticed there is some type of rating of the particular surface with substrate that was actually sampled.

BRUCE LANPHEAR: Yes.

MARK FARFEL: I suggest you look at the comparison by that surface condition variable. I'm sure the condition within a house is variable within room to room. Goes with your sample site.

BRUCE LANPHEAR: Yes.

ROUTT REIGART: I have one just very small question. I didn't understand the comment from all the other reviewers. The blood sampling and analysis, there is something about triplicate. Is that triplicate analysis of the same sample, or three samples?

BRUCE LANPHEAR: It's the same sample. The sample was sent to Wadsworth Clinic, and I believe you received all that information of their QA/QC. The same blood sample was analyzed on the first day that they received it, the second day they received it, and the third day, and so that allows them to increase the precision of the estimate.

ROUTT REIGART: One of the comments the other reviewers raised some question in my mind, it looked like you were talking about three separate samples. I

just wanted to make sure about that.

MICHAEL RABINOWITZ: Three assays on the same blood sample.

BRUCE LANPHEAR: That's correct.

MICHAEL RABINOWITZ: Okay. Then maybe it's time now to hear from representatives of the EPA.

ROB ELIAS: Rob Elias, EPA. One of the questions I have about, mostly about the presentation, I'll bring it up now, you used the term low in reference to 40 micrograms per square foot. If you draw a comparison to the other sources of lead, that being food or water, low for food is about eight to 15 micrograms of lead per day. At 40 micrograms per square foot, we're looking at 400 micrograms of lead from dust per day. So that's the relative standard. I don't think it should be referred to as low.

I know that it's going to be difficult to achieve a low level of dust loading in homes, but a low level of dust loading in homes should be characterized as one or two micrograms per square foot, and you can see that very well from your data. That's the point at which

you get below five percent above ten micrograms per deciliter, so I think that language should be changed. And so that we're not forced into some preconceived notion about what is acceptable versus what's not acceptable.

The other point, I would like to reinforce what Mark was just talking about here, in some of the analyses that you've done, the multiple regression analysis, some things didn't quite make sense, at least as they were presented. One of these that stuck out for me was the apparent relationship between paint loading on the wall, measured XRF loading and blood lead, it's -- it doesn't necessarily follow that intact paint on the wall will cause elevated blood levels. But what will impact that is that subset of those high measurements that are in poor repair.

And so if you match that up, which I couldn't see where you had that, if you match that up in the regression analysis, then you may find a greater relationship to that form of loading. Those are two -- and by the way, I should have said this at the outset, that it is a rare opportunity that we have to register

these comments against such a well designed and a well carried out study. So if it seems like we dig in here and make a lot of criticisms, it's only because the opportunity is there --

(Laughter)

-- for really getting some information. If this were a badly conducted study, most of us wouldn't even bother to show up here. So everything that I say, and I'm sure my colleagues say, is let's see what more we can get out of it.

BRUCE LANPHEAR: Okay.

ROB ELIAS: I think what I would like to do is kind of let those comments ride at this point, and perhaps just back in later on with some other things as a topic.

BRUCE LANPHEAR: Except maybe simply could I respond to the comment about XRF. There is a perception of low, and there may be another way of describing low. It's not clear based on this one study what really is low, although we can define it in the limits of the study. I'm not sure whether it is or is not appropriate.

SHIRLEY EBERLY: We did include in the model -- I'm Shirley Eberly. We did include in the model the maximum interior paint value, the condition of the paint at that place, and the interaction between the two.

ROB ELIAS: And what did you find in the interaction value?

SHIRLEY EBERLY: Sometimes this group of three variables did enter models, but more frequently they simply did not enter the models.

ROB ELIAS: And what did you find in terms of dust lead loading? With that interaction you were comparing that to blood lead; is that right?

SHIRLEY EBERLY: Right.

ROB ELIAS: Did you look at dust lead loading as it related to condition?

BRUCE LANPHEAR: Not yet, but that is one of the things we want to do fairly soon.

ROB ELIAS: And this is the topic that I am going to bring up later, and that is, structural equation modeling.

BRUCE LANPHEAR: And we also have plans to

do that as well, Rob. Lots of plans.

BRION COOK: Brion Cook. I'm going to wear my regulator hat when I give some comments, and also ask some questions that EPA has to get answered in order for us to really use these data as much as it can be used.

Under Title X, Section 403, EPA has to promulgate standards, health-based standards, for exposure to lead-based paint, contaminated dust and contaminated soil. We have to actually set numerical standards that are health based, and they really have to be national in scope. We are in some way applying to the whole United States. This study was done to help answer some things that we don't know about dust. And it's great to look at kids whose primary exposure to lead has been through dust, and I think that that really affords us a good look at the dust exposure for kids to help us in the standards. So my questions, I guess, are in two areas.

First is really how useful are these data to set these national standards? Can this study by itself be used to set standards? Should it be used in conjunction with other data that Mark and Scott have, or other data

sets that are out there? It's gratifying to hear all the panelists say the study was well conducted and well designed and well executed, but I guess I haven't heard explicitly did the study meet the aims that Bruce put up in his first slide? Did we really establish a relationship on what is it, how useful is it, and also about sampling. What have we learned about sampling to help set the standards? How useful are the data to set these standards? If they are not useful, what else do we need to do? How useful is the national look at dust lead that Bruce referred to in helping us set standards under Title X.

So I think there are some questions there about the usefulness in setting national standards, and then also part of what we have to do is once we have those standards, we have to tell people how to collect the physical samples. And five different methods were looked at here. What have we learned from this study that will help us pick out a method or a group of methods or not pick out a method now on how people will take dust samples in order to comply with the Section 403 standards?

Those two areas are the questions that we really need to have answered in order for us to make the most use of these data.

MICHAEL RABINOWITZ: Any other comments from other government representatives?

STEVE WEITZ: Yes. I'm Steve Weitz. I'm with HUD, and as the agency that paid for this study using the taxpayers money, I'm naturally very pleased to hear generally favorable comments of the overall comments, and I want to thank you, Bruce, and the other Rochester people and the National Center for doing a good job. And then I would also kind of want to associate myself with the questions that Brion just put, because naturally the policy that EPA sets is the policy that HUD has to set in all of the housing that it's associated with, and it has major financial implications from the agency. Thanks.

STEVEN RUST: I guess I have a comment in response to Brion's questions. I think one of the main questions we were asked was the quality of the data. And I think that many of the comments you're hearing say that the data is of high quality, the study was well designed,

well conducted, and there is a data set here now that can be used to answer many questions.

I think also a lot of comments would point to they have had limited time to do analysis on this data and the limited analyses they have done have raised a lot of issues. They have answered some questions. They have raised some other questions, and that I think in order to get at some of your questions, more analysis of the data is going to need to be done, but I very much want to say I think the data is of high quality and will be amenable to these analyses and may very well answer those questions, but it may be impossible at this point to say whether or not it will ultimately answer those questions.

ROB ELIAS: I would like to expand on Brion's comments. I think what Steve was saying is a very good idea, but Brion has raised a question how can we extrapolate to a national standard. And the first thing to ask, we can't get from your report is how well does this population of children represent just the City of Rochester, and then how representative is the City of Rochester to similar municipal areas across the United

States? That's a step in the direction we want to go.

The first question you may have an answer to. Do you? You talked a little bit about. Can you talk some more about it?

BRUCE LANPHEAR: Yeah. If you just compare the demographics of children based on the 1990 census, we have tended to oversample by maybe 10, 15 percent children that live in low-income housing and children that are black. And the reason for that probably is not because of issues related to the criteria, but that because we used three urban hospitals that tend to provide care to the majority of families of lower income and/or minority. There's not a major difference, but there is some difference.

ROB ELIAS: You said now that you've found an impact on race, so I think that point is a good one, but did you find any impact of low-income housing relative to -- is that a factor that we should be concerned with?

BRUCE LANPHEAR: It is significantly associated, but not after adjusting for these other variables that we measured, so I guess the question is if

you had to go into a town and say can you identify houses that are more likely to be at risk, I think you could do that to some degree with either a lower income or rental property, but I don't know -- that obviously is not as precise as some of these other measures that we could use.

ROB ELIAS: That's one way of looking at it.

DAVID JACOBS: I think this study was specifically not designed to be representative of either Rochester or the United States. We designed the cohort so this exposure was due hopefully largely to dust in the house in which they lived. That's why we designed it so it's biased, and that has importance implications on how the agency decides to use it.

This was intended to be a high-risk low-income urban population, and therefore it's not going to be representative, so, for example, we talked about this chart at the end here, 10 percent being above a blood lead level at a certain dust lead level. That's going to be -- those data are only good for high-risk urban populations. And so therefore, to argue that we should allow 10 percent of the children to have blood leads above

ten micrograms per deciliter using this cohort would perhaps be overly conservative in terms of the general population.

In other words, if you were to extrapolate this to the general population, it would be much more protective. So I think it -- you know, it's a question, I suppose, as to whether the agency feels it needs a representative study instead of a high-risk urban population whose exposure was largely due to dust. We didn't decide to go that way in this study.

NICK FARR: I'm Nick Farr, but for what it's worth, we thought about two other populations, which we -- which this isn't. One would be population in what you might characterize, no offense, a dirty city, which at least we think Baltimore and some other places are. The ambient level of lead in the street and so on are probably greater.

And another is a suburb. Some places which is a super-clean city, high-income people, it just depends upon -- all these things take time and cost money. But we didn't do either -- this is not either of those things.

MARK FARFEL: Mark Farfel. I was just going to illustrate there may be differences across the study, populations, ongoing studies. The Repair and Maintenance Study in Baltimore has a group of children living in older lead-painted housing in the central areas. And we had a geometric mean also, studying geometric mean blood level in the children living in older houses. We have other categories in urban areas much lower than that you're seeing in this Rochester study.

ROB ELIAS: Now that you've brought that up -- Rob Elias. Now that you've brought that up, the question of dirty versus clean, there's a big -- you don't discuss dust loading. It's dust lead loading. We need to know that information. Obviously we need to know low lead information is how much dust is in the home. And by way of example, if we use the recommendation here that a wipe sampling taken and that being shown to, say, a pediatrician as a measure of risk, and some way predicting the blood lead, the pediatrician or anybody, the public health official, is going to look at that number of dust lead loading, dust lead loading of 40 micrograms per

square foot and say, well, I don't know whether you've got a dirty house or whether you've got a high lead-based paint, so you're going to have to go back and look at the situation in the home. We need to have tables of information here showing the dust loading in Rochester.

STEVEN RUST: By implication, Rob, it would also seem that you're implying that wipe sampling could not be the method used to compare to a standard.

ROB ELIAS: I think that's one factor that should be considered in determining which is the best method.

MICHAEL RABINOWITZ: So just to underline this a little bit, I know one of my comments was, and I'm sure you will do the statistics, just try to do blood lead levels from bulk dust in the house, it might convey a lot of information. How you use that to set standards, I leave to other people.

MARY EMOND: One finding -- my name is Mary Emond -- that might partially address this question was that concentration was less associated with blood leads, so it seems to imply when we have high lead loadings,

we're talking about dirtier homes.

ROB ELIAS: That's not surprising. There are circumstances where the concentration is important. If the dust load -- dust load is low, then concentration wouldn't be as important as dust level. It would be as easily identifiable as relating to blood levels, and that tells us a lot about what we would advise that family to do to resolve the situation. Whether they should keep the home cleaner or whether they need to get rid of some source of lead.

MICHAEL RABINOWITZ: Excuse me, Michael. You had your hand up.

MICHAEL WEITZMAN: Michael Weitzman. This discussion does raise another limitation of the study that I don't know that we've explicitly stated before. And that is that if you look at national data, it is true that children in urban settings are more likely to be poor than children elsewhere, but you're still talking about 40 to 45 percent of children in cities across the United States, and Rochester, I don't know that it's any cleaner or dirtier than Baltimore, to be quite honest with you. It

is an old city. It does have an inner city. We oversampled inner city kids. There are in Rochester, as in virtually every other city, more affluent, more privileged families who also live in older houses that may be in better repair, or irrespective of the repair, may or may not be cleaner.

So that setting a standard, one has to say whether or not we want to come up with some figure that protects all children, that puts some children at greater risk than others, or whether we're going to say for the group that's at highest risk, namely, the group that we believe is at highest risk, kids who live in poverty, in lead-infested homes that are in bad repair, that that's the group that we're going to try and set a limit at, even though that may be more intrusive and may overdo things for other kids.

Am I making sense in what I'm saying to you, Robert?

ROB ELIAS: Yeah.

MICHAEL WEITZMAN: I live in the City of Rochester. I live in a very old house, a very large house

that probably has tons of leaded paint in it, but my kids are more privileged, who live in a more affluent family than many of the kids in the study. I don't know that the dust lead blood lead or the household lead blood lead relationship would be the same for kids from a different social strata study than the kids in this study.

ROUTT REIGART: Reigart again. To just sort of expand on that discussion, you did not find the relationship between socioeconomic status? Did I understand that to be correct?

BRUCE LANPHEAR: We did find it in a univarate analysis, but after controlling for dust lead loading and some of these other covariates, it did not remain significant.

SHIRLEY EBERLEY: Except single parent households.

BRUCE LANPHEAR: Yes. Excuse me. Single parent households in the Wipe Model, using the covariates identified with all five method measures forced into a model was significant.

SHIRLEY EBERLY: It's also in our overall

Wipe Model for all the methods, the first model.

BRUCE LANPHEAR: For the one which included all the models, yes.

ROUTT REIGART: I sort of wonder if this would be a time for Rob Elias to introduce structural modeling. I'm just wondering whether that kind of modeling wouldn't help you. I mean, you have socioeconomic status related to condition of housing, cleanliness of housing, related to blood lead. Is this -- I'm asking.

ROB ELIAS: Yes. That's one piece of information that would come out of it, but the main reason goes a step beyond that. And, that is, that when we do structural equation modeling, when anybody does that for a number of different studies, and this is not a meta-analysis like Chuck was talking about, but if we look at the patterns that are established by pathways or association here in the relative strengths of those association, then we can get a better picture of what at least some group of studies would tell us toward a, say, boundaries for a national standard.

For example, if we were to see that there is no relationship between soil and house dust in one study, we would look for an explanation for that. And that explanation might be, as in Cincinnati, where the soil was quite separated from the house. Maybe down in a park or vacant lot or something like that, but more important, there are pathways that are sometimes not known to us, are not obvious, and that can emerge in the structural equation modeling, but I don't want to dwell on it because I think the general consensus is that analysis should be done. I don't think we need to take a lot of time here to discuss that.

MICHAEL RABINOWITZ: We'll make sure before the day's over that they have some sense of what sort of structural equation models you might have in mind. What pathways you might want to explore.

BRUCE LANPHEAR: We have talked about this. It is similar to what has already been done in Cincinnati. Is that the kind of model you're talking about or quite different?

ROB ELIAS: It depends on what you're

talking about from Cincinnati. It has evolved quite a bit.

MICHAEL RABINOWITZ: Are there any other comments from the panel or other government representatives? Maybe we should turn it over to public comments then at this time. And perhaps there are some comments from -- excuse my back. Sorry.

ALAN WHITTINGHAM: Alan Whittingham. You got down to Page 14, you said exterior dust and exterior paint variables were excluded from consideration due to the large number of missing values. Could you explain.

MICHAEL RABINOWITZ: Page what?

ALAN WHITTINGHAM: Page 14. I always thought that exterior paint and exterior dust was quite important. Really, just why was this?

MICHAEL RABINOWITZ: I'm sorry. Can you just --

ALAN WHITTINGHAM: Page 14. Four lines up from the bottom.

MICHAEL RABINOWITZ: Under Multivariate Analysis.

ALAN WHITTINGHAM: Exterior dust and exterior paint were excluded.

SHIRLEY EBERLY: I'm Shirley Eberly. Sometimes those exterior dust samples were not taken because it was raining or there was snow on the ground, so that severely limited the exterior sampling that was done.

BRUCE LANPHEAR: The type of surface the exterior house was made of may have also impacted on that. And apparently I think where we also lost some additional measurements was when we looked at the entryway which may have been where they did impart some of the exterior measurements they were included than say on a porch and so that was another reason for that.

ALAN WHITTINGHAM: I mean, I find it a very surprising omission. I thought it was a pretty important aspect of the study. And I see it as a major deficiency if you don't get the source of the lead, which I think we think would be important.

BRUCE LANPHEAR: We do want to go back and actually do a frequency table to understand why that happened, and so we are concerned about that without

having a better explanation and knowing some of the reasons without being able to quantify that.

STEVEN RUST: Bruce, is there enough data to do an analysis, including these variables, on a substantial subset of your data?

BRUCE LANPHEAR: Yes.

STEVEN RUST: Just to see whether or not further investigation is warranted?

BRUCE LANPHEAR: Yes.

ROB ELIAS: I had two comments on that. One, in addition to that subsetting, is it possible, first of all, to simply go back and make those measurements? That's one thing that's not likely to change. I realize you're all the way through with your environmental sampling. He's all ready to hand out the bucks here. That's probably one solution, because this can be a critical point. The other one is quite a bit more risky, and is it possible to develop some missing value procedure as a last resort?

BRUCE LANPHEAR: I don't want to speak to the second thing, although I'm sure it's possible, but

other people can say that better than I. I think the first thing I would like to do is understand and put together a frequency table of why those values are missing, and if it then appears that -- I don't believe they weren't done. Unless there was a valid reason for that. We didn't just have technicians who said, geez, I don't want to do the outside of the house, so once we have done that, then the first step that you mentioned may be appropriate.

ROB ELIAS: But if there is no lead-based paint there, it should be zero, not missing.

WARREN GALKE: That's right.

ROB ELIAS: But if it's only lead-based paint around, say, the trim of a brick veneer building, that can still be very important.

BRUCE LANPHEAR: That's right. And so once we understand why those values appear to be missing, then we would have that explanation, and actually a quantification of how many were not done because of that or because they appear to actually be missing, so that would be accounted for.

ALAN WHITTINGHAM: No --

MARY EMOND: We have one more.

SHIRLEY EBERLY: Yeah. One more comment here about exterior paint. For the samples that we do have, the correlation is extremely low. It's only .09 and with log of blood lead. So that's extremely low.

MICHAEL RABINOWITZ: Lead and exterior paint and blood lead.

SHIRLEY EBERLY: Um-hum. Um-hum.

ROB ELIAS: Once again, you really want to look at exterior paint and exterior dust. That's where the correlation should show up first.

MICHAEL RABINOWITZ: Yeah.

SCOTT CLARK: I have several comments. One, this is a very fine study, well done, under tremendous time pressures, and you did a fine job on that. I have some questions on Table 7, which shows the concentrations by the different dust lead collection methods, which is central to the whole process.

MICHAEL RABINOWITZ: Hold it, Scott.

SCOTT CLARK: I will. Table 7. And a

couple things, one, we've done -- well, one thing. Looking at the concentrations by the two vacuum methods, it appears to be quite higher with the BRM than the Dust Vacuum Method several fold, which means, except for the carpeted floors, that it's getting different dust. It's getting a different -- there's different components in there, whether it's picking up bigger particles. It could be picking up paint chips with a larger vacuum, which you expect, but it isn't measuring the same dust, so it's not surprising you get different conclusions from that.

The other -- we have done some side-by-side and same surface comparisons of the Dust Vacuum Method and the wipe, as I recall from my head, and we generally find on uncarpeted floors about a 30 percent. About 30 percent comes up with the vacuum. So the value you have here appears to be lower than I'd expect. I would expect more for the noncarpeted floors about four or five based upon our experience in several hundred samples.

Window sill we find about a 50 percent difference, where the vacuum would get about half what the wipe gets. So I'm not sure, you know, these are people

who, I'm sure, are well trained and so forth, but this was a new method to determine them, so there could be something in the method's use where you're picking up less dust than we do in a couple of areas.

One very intriguing thing about your results was on -- I forgot. I think it doesn't have a number on it, but where you had the predicted percent above ten at various dust levels, I think we found the answer here to lead poisoning, Steve, is actually sell houses to people. I think if you give them all houses, you own their home, you can have dust up in the hundreds. It's very flat. There a big difference between those who rent the home and own the home. And this factor I wonder if this showed up in your modeling at all, because this is a very key difference. This is remarkable, the difference in the particular levels for those who rent the home and those who own the home. That's very intriguing.

BRUCE LANPHEAR: (Nods head up and down.)

SCOTT CLARK: Also you mentioned I guess you had four environmental samplers; right?

BRUCE LANPHEAR: Three.

SCOTT CLARK: One person had four times the levels of some other people. There was one person who had much more variability. You did some in-lab comparison repeatability which was excellent and also some in the field. And the in-lab one, on Page 28, I want to comment on briefly. Because we have some relevant data on this.

Table 28 is the in-lab reliability results, where you had three technicians. I was intrigued where there were four whether the fourth person was left out. I don't know. I thought I saw four someplace.

NANCY WINTER: He was the supervisor in the field.

SCOTT CLARK: Maybe he was the one that didn't do so well.

BRUCE LANPHEAR: He wasn't included in the reliability.

SCOTT CLARK: Now, one of the things that actually surprised me was the recovery of the Dust Vacuum Method, and the higher Vacuum Method on linoleum was also the same in spite of having a much bigger pump. If I read this correctly, we even get slightly higher recovery with

a smaller vacuum pump than we do, which I don't -- it's hard for me to understand why that would happen. Because one is much more powerful, and the results elsewhere, so you got a hundred times more with the higher vacuum, although this is a different dust.

The other thing is on the carpeted floors, how did you embed the dust on the carpet? Is it just -- we did some embedding using ASTM methods on new carpets. It took us about ten minutes a square foot to get up to 60 percent. This was a surprisingly high number to get up presumably just on a one-type pass thing.

BRUCE LANPHEAR: But not using the method that you described also.

SCOTT CLARK: Right. You didn't embed it. I think the most difficult thing for me to understand is why the recoveries are the same for the two vacuums on this. Maybe Mark might have some suggestions, since he has used the BRM quite a bit.

MARK FARFEL: What struck me about the percent recovery is that it was as low as 64, 60 percent based on some of our in-laboratory samples vacuuming from

smooth tile vinyl surfaces, so that was one of the things that struck me. And I also -- I wanted to know what weight of material, what weight of --

BRUCE LANPHEAR: How much?

MARK FARFEL: -- material was placed on the surface. What was the dust loading?

BRUCE LANPHEAR: I believe it was .5 grams, but I really am pulling to get that out. This is the first number that comes to mind, Mark. I'll have to double check that. Total dust weight, correct. This was a particular urban particulate matter. And I don't know what the size particles of lead in that particular matter are, Scott. I wonder if that is partly what explains what we found in terms of the percent recovery with the DVM compared to the BRM, but I can't answer it.

SCOTT CLARK: I'm surprised it was higher on the carpet than on the bare floor. You would think it would be easier off of carpet, off of bare floor.

MICHAEL RABINOWITZ: Can I ask a question about that, since we seem to be on the topic of recovery of dust sample. I guess you used as a sample this SRM

standard reference material that I guess was prepared from St. Louis, where they burn a lot of coal. Historically I think that's where the sample came from. As I recall, the sample is kind of sooty. It has a certain adhesiveness to it, and it may be different in bulk characteristics than household dust, which may be a little more granular, sandy or hairy or whatever. Do you think that's the best material to use to test recoveries? Are there some recommendations people might have about better materials to use as a standard dust?

SCOTT CLARK: ASTM has a standard dust they lift off of carpet. It's a sand and talc, I believe, but it's in the ASTM standards. That's what we tried to use for our carpet.

MICHAEL RABINOWITZ: It's different than the one you used?

BRUCE LANPHEAR: We used 1649. I would have a couple comments. I'm not sure there is a good standard material to use. I don't know that we know how to mimic household dust in terms of in-lab reliability results, and I think one thing to be aware of is that this included

three people with one dust measurement for each of those -- three dust measurements for each of those surface types.

One dust collection using each dust collection method by surface type. Extremely limited. This was something we did as a very small part. So I don't think we should put too much weight on this. If we wanted to do an in-lab reliability analysis, I think we could do much better than what we've done here. This was a beginning and just a small attempt. But I am not sure that there is a good standard material to use.

I think the idea of collecting, this is what John Roberts from Seattle suggests, is we collect lots of household dust using vacuum cleaners, homogenize it, and apparently he has done that test and shown that the lead content is similar with repeated samplings of that. That would make much more sense than what we relied on. We did not have that available to us at the time.

MARK FARFEL: When we reevaluated the performance in-lab, we were faced with the same problem. We wanted to include materials that reflected the range of

particle sizes that we would anticipate being in house dust, and that range for us was less than one micron to two thousand. We used talc as a surrogate. We used SRM 204 as this middle range of dust. 38 to 150 microns, and then we used a composite that we got from Midwest Research Institute reflecting a range of 250 to three thousand, and we had ten replicates of each type of dust, and we also varied the loading. And the discrepancy with this result is that the BRM had recoveries all above 84.9 percent across that whole range of particle sizes, and we had never observed it as low as 54 percent.

SCOTT CLARK: On what surfaces?

MARK FARFEL: This is on a smooth tile surface in the lab.

MICHAEL RABINOWITZ: That's recovery of bulk mass material?

MARK FARFEL: That's right. So it ranged from -- the very smallest diameter dust that we used on the performance evaluation we had a geometric mean recovery of 87 percent. And on the mid-range material, depending on the dust loading, it was 85 to 89 percent of

the material recovered. And on the large diameter dust 250 to two thousand, it was 97 percent, so we tried to select materials that would reflect that range of particle sizes.

BRUCE LANPHEAR: One other comment I would make just to follow up is that the reliability, the in-field reliability, I feel more comfortable with. It has other kinds of limitations in terms of we really don't know how much dust was there to begin with, whereas we have a little better idea with the in-lab. There are certainly more samples included there. It is more what I would expect to see in the real world, and so although it has limitations, I didn't want to discount the in-field reliability, although I was saying let's look at the in-lab reliability with some caution.

STEVEN RUST: Just exactly how many data points go into this table? Are there three data points going into each one?

BRUCE LANPHEAR: I didn't say it clearly. Mary, can you give him just a quick overview?

MARY EMOND: It's three from that table.

STEVEN RUST: Thank you.

MICHAEL RABINOWITZ: Okay. Any other comments?

ELLEN TOHN: I have a comment. Ellen Tohn. First, I guess I'm a little intrigued by the window well numbers. I would like to pursue that a little from an implementation point of view. Everyone has said that this study raises a lot of questions. In the meantime, we all know Brion is trying to write something and come up with some numbers that will be used even in the interim. And the reality about what people are talking about is using some of the numbers that have been out in the field for some period of time, and window wells, that number is 800.

The data that you presented suggests -- indicated I think loadings with wipes, 68 percentage of the homes that you sampled had numbers that exceeded 800 in window wells, and this is a high-risk urban population. So my question is what would be the implication of coming up with an 800 number for window wells as a number that the agency might come out with in the interim for suggesting lead hazards, and is it really meaningful of

the risks that children are exposed to for lead?

BRUCE LANPHEAR: I'm not sure I can respond any more except to repeat the inferences I made earlier. And that is, we began to look at a similar kind of estimate using logistic regression with the window wells. But we didn't take it very far, and one of the problems was that it plateaued so quickly that I'm not sure I could say too much more about it than I've already inferred. I think we need to look at that a little more closely, because it appears that 800 may be too low based upon what we're seeing. And yet I say that, and I'm not going to be able to provide you with any specific level or a graph that says this might be where that level is. So I think you're right, but I don't know that I can say anything more about it.

MICHAEL WEITZMAN: I don't know that we can say whether it's too low or right or too high until somebody shows whether or not you can get it down below 800 by reasonable effort. I would imagine that that's the case. The fact that 68 percent of the families have substantially higher levels doesn't mean that you couldn't

obtain 800 or something less than 800.

I think what you need to do is convince yourself and have data that will show that there are practical ways to get below 800 on a regular basis. Disagree with me if you see it differently. That's how I would interpret that.

NICK FARR: That's not the only issue, though. I mean, the technical ability five minutes after you've cleaned the window well, get it down to something is interesting, but the likely reaccumulation rate the next day or six months later or a year later is also important. It's what you do when it reaccumulates. I mean, that's where I think it's going to be a problem.

Or, conversely, when assuming that people look at houses and decide whether that you do something, which we would like to have happen, then at what point do you say this is a house we need to spend a thousand dollars on or $10,000 on or something, so it's not just the technical ability of getting it down, but it's these other issues what is a house in which we need to do something or six or 12 months later, where the dust on the

window wells is reaccumulated, which is pretty likely to happen. At what point do you feel that you have to do something to that window well again? It may be a little expense or may be a large expense.

STEVEN RUST: Well, I guess what I was going to say, there's also a big difference between showing a relationship between house dust and blood lead and showing that if you somehow do abatement or remediation of some type to bring those levels down, that the blood lead levels will also drop accordingly. And I think we have to keep that in mind as we're discussing it, that the second simply has not been done at this level of blood lead.

BRUCE LANPHEAR: Correct.

MICHAEL RABINOWITZ: That's some of my concern about window well lead, I guess, is are you sure it's really a vector? Perhaps that your pathway analysis could help us understand that. Is it a vector on its way to the child, or is it just a marker, a place where certain types of suspended material accumulates? Things that aren't tracked in on the bottom of the feet but perhaps windblown. It's that type of dust.

And also the other thing that I'm a little concerned about, I just don't understand about window well dust as a standard is do you just clean out your window wells and you would pass the test? You could have a lot of lead in other parts of the house, so I guess the standards would be written with that in mind in some way.

SCOTT CLARK: We have to know what a window well is. We don't yet. Structural equation modeling would help that, tell us where it does add to the floor dust. Maybe it's just an artifact. We don't know.

STEVEN RUST: Structural equation modeling still is only going to be able to cull out the correlations between the data, and an important other variable that is a connector has been observed. Structural equation modeling isn't going to do everything.

MICHAEL WEITZMAN: So would I be correct in taking away from this that aside from doing a trial of window well cleaning, that one couldn't reach an answer that would be needed to address these particular issues?

SCOTT CLARK: Modeling would help. Structural equation modeling would help. I wouldn't

ignore that and go to the field.

DAVID JACOBS: It seems to me if the window wells did not matter, you would see no correlation. The fact is we did see a correlation of window wells independent of other sources, so therefore just on a rudimentary basis, we don't understand where it comes from and how it may be related to other things in the lead, the window wells do appear to matter. I think we can at least take that away.

BRUCE LANPHEAR: Whether you can do --

DAVID JACOBS: How much and so forth remains to be seen.

BRUCE LANPHEAR: Can I get a clarification of what you mean that window wells do matter? Do you mean that specifically the lead in the dust in the window sill gets to the child, or that window wells are a predictor of blood lead levels?

DAVID JACOBS: I mean that in one of those tables we saw a significant correlation between window well dust lead and blood lead levels.

STEVEN RUST: I think the important question

is is there any real connection between the lead in the window well and the child, and that one I think is wide open.

MARK FARFEL: Didn't you point out that may have a behavioral component to it? As the children get older and are able to access those areas and play in these areas may be changing --

STEVEN RUST: Or it may simply be a surrogate for lots of other things that are not being measured.

MICHAEL RABINOWITZ: That's like people who carry matches are more likely to get lung cancer.

PAT McLAINE: I think -- I mean, along the lines of this, do we see more of a relationship between dust lead levels in the children's bedrooms or their play areas as opposed to the house dust generally? I mean, again, I think the child is somehow missing in this equation and where the child actually is in the vector.

You know, young children and the windows are low can pull themselves up and put their little cars and people in the window well, so a window that is very low is

really accessible to a child, and I think there's a difference between windows that are four feet high versus a window that is a foot and a half or two feet off the ground. I think this is something real important, especially from the perspective of protecting an individual child in a home.

We're looking not only at standards, but what can we advise parents to do to protect their children from all the lead that we know is out there?

BRUCE LANPHEAR: If you look at some of the correlation of lead loading or lead levels and children's blood lead, certainly for the BRM, the child's bedroom is more highly correlated, just if you look at the correlation coefficient. For example, for the child's bedroom the correlation is .41 compared to the play area, which is .28. Now, I don't know if the play area versus the bedroom is a big difference there, but we have to consider a couple different things.

One, are we going into houses where people actually live and we know where their bedroom is, or are we going into houses where people may not be living, so it

is important if you're going to a house where there is already people living. It may be less important if you're doing this after somebody's left after renting a place for two years and you want to measure it before it gets rented again, and so we're interested in both.

We primarily emphasize more of a generic living space at this point. That's for the seventh month. We do want to do that. That is also very interesting too, looking at specific locations. How much it's involved in the policy setting, I'm not sure except it might be for what EPA calls Phase II Risk Assessment. That is when you know a child has an elevated blood lead. What kind of sampling do you do?

On the other hand, you could argue that a separate study should be done to look at those children who might be quite different than what we found, both in terms of which -- presumably, which dust collection method and what other measures do you need.

PAT McLAINE: As a follow up, have you separated out the lead dust levels by surface? In other words, floor, well and sill versus -- within the room to

see if any one of those are highly correlated, or just have the measurements of all three of those combined?

BRUCE LANPHEAR: Just the average of each surface type or the average across a room. We didn't look at the child's bedroom, four.

SHIRLEY EBERLY: We have the raw data to do that.

BRUCE LANPHEAR: Yeah. We have not yet done that, if I understood your question right.

PAT McLAINE: Right, right. I have one other question on the data. Did you ascertain whether these were single or multi-family, and -- because I didn't see anything in the forms that indicated that, and did you try to determine what kind of houses they were, if they were frame, if they were brick? I mean, there's, again, a big variation between the different types of housing across the country.

BRUCE LANPHEAR: That is all available in our data set.

ROUTT REIGART: Again, just to expand a little bit on some of what Pat is saying, I still get

struck by the wide age range. If you have a 12 or 14 month old that is just beginning to walk and spends most of their time on the floor, their pattern of exposure has to be different than a 30 month old who is climbing and he responds in a lot of different ways to his or her environment.

Do you have enough numbers to break down these any more by age group than you've done and look at window sills at 24 to 30 months versus window sills at 12 to 18 months? You may not have enough data, but it would be very interesting.

BRUCE LANPHEAR: I think we have done it, but I don't think it's answering the question. I don't think it's giving you the answer you're looking for. We didn't find a difference by the behaviors we've measured. We may not have measured certain behaviors that may differ.

ROUTT REIGART: Maybe I missed it. I didn't see analysis of relationship between window sill to age to blood lead. You looked at the behaviors by age group, but you didn't look at the predictors of blood lead of various

surfaces by age. It may be that floor is more important at age 12 to 18 months. Window sill at 24 to 30 months.

BRUCE LANPHEAR: Shirley just mentioned we did look at age as an interaction, but only as it related to the average dust measure across the whole house not by specific sites, and that also would be very interesting to look at.

ROUTT REIGART: You may not have enough data. I mean, clearly a 30 month old is different from a 12 month old in what they can reach.

STEVEN RUST: Once you reach a point where you have a fairly standard modeling protocol, you've gone through to do this whole thing, you might consider doing that by the three age groups. I realize maybe even at this point you don't quite have that streamlined to make it easy enough to do by all three age groups.

BRUCE LANPHEAR: (Nods head up and down.)

MICHAEL RABINOWITZ: Any other comments at this point?

MARCUS PEACOCK: Marcus Peacock. You mentioned before that you at some point halfway through

the study, I guess enhanced is the right word, enhanced the analysis you did, the dust samples in terms of the content of the lead, which I guess implied to me that, you can tell me whether this is correct, did you expect to get higher levels of lead in dust than you actually got?

BRUCE LANPHEAR: Yes.

MARCUS PEACOCK: Perhaps even more variability in the levels? I guess that raises a -- why do you think that the levels you got were so low? And do you think that has any implication for how representative this sample may be in terms of extrapolating it to other parts of the country?

BRUCE LANPHEAR: Yes. I'll try to answer that without falling into any traps. Yes, we did expect to find higher lead levels based upon previous studies. Most of those studies, however, typically looked at children who had higher blood lead levels. They were done during a time when there was more ambient air lead levels. Lead paint was being used. It had higher concentrations of lead, which might have had some role to play.

So based upon those earlier studies, most of

which found much higher levels than we did, we did expect to find higher dust lead loading. The only study that didn't actually was the study out of Boston, where it was a lower middle class population of families. And their levels looked relatively similar to ours, but with that exception most of them were higher. And we were looking at an inner city, we thought much higher risk population.

It may be that we're seeing some shifts over time in lead loading and that ours may be representative. That's why I pointed to the fact I think we need some additional sampling of some kind of representative units across the United States, or at least beyond Rochester, because it's very difficult for me to say whether our findings are, in fact, low compared to some other housing units in other cities, or whether there has just been a trend in randomly sample population, not of housing units but of children this is what we've found. So we did expect to find higher lead levels. Is it all that different than other houses in the United States right now? I'm not sure.

MARCUS PEACOCK: It could be temporal or

geography.

BRUCE LANPHEAR: Yes, or some of both.

MICHAEL RABINOWITZ: My current inclination, subject to change, is not to go through the document page by page and ask for comments page by page, but I could be dissuaded from that, but rather after we've really had a chance for everybody to make any other comments they want, perhaps it's worthwhile to revisit some of these issues on a topic-by-topic basis. Topics such as adequacy of the statistical approach, or how generalizable the results are. Or what might be done by some other group in the future. What more needs to be done here. And I welcome other ideas for those points to focus our discussion on. So maybe that would be the next order of business.

Since it's not lunch yet, maybe we could get started on that list of topics. And without any ranking by importance, let me just throw out the first one. And that might be how generalizable these results are, the results of this study, to the rest of the United States. And I guess we'll leave Kuala Lumpur out of it for now. I just threw it in really just because other countries -- as

I'm sure most of us know, lead pollution is a worldwide problem and other countries without our resources really do look to the United States to get some guidance. And standards setters really do look towards us, so it would be good to give them some information and take our information and apply it to their home situation or not. So if we could maybe talk about that first topic of generalizability of the results. That's one, and then I propose the topic after that to be what would be the sources of error, sources of noise or errors and sources of bias in your soil estimates. Maybe we could keep them as separate topics, so could I throw out that first, first of generalizability.

Does anyone want to make comments on how generalizable or not these are to other populations?

KAREN HOGAN: This is Karen Hogan from EPA. I would like to suggest the standards that might be developed from this study to other populations wouldn't necessarily be overconservative. We're only considering dust, and other populations would be more likely to have other sources, simultaneous sources than lead exposure.

Sources of lead exposure.

MICHAEL RABINOWITZ: You're saying people are exposed to lead from many other sources than --

KAREN HOGAN: The factors that might contribute to making the Rochester-based standard seem conservative because they are high-risk populations, inner city children, might be offset by availability of other sources, other locations.

MICHAEL RABINOWITZ: Okay.

BRION COOK: Does that mean these data are more generalizable than otherwise would be? Than what Dave said earlier about this being a high-risk group and that really -- if you're looking at high risk groups in urban areas, this might be representative of that population, but you're saying maybe it is not. It can be more generalized because of that?

KAREN HOGAN: In a qualitative sense. I don't know how to quantify it.

PAT McLAINE: One issue in my mind, and I think we can't fault this to the study, because it's due to the design of the study, is how do these results

characterize where children in America spend time? And I think if you look at the number of women that are working, the number of children that are cared for out of the home, this data represents those children perhaps at highest risk, because they are in their home maybe without adequate supervision, who knows what goes on. It is not representative of the children that are in care of various types, and I think, you know, it has been discussed for some time that perhaps children in day care are protected because the hours that they are awake, they are in environments that are generally cleaned more or monitored and maintained more, if they are licensed care, so I think this is a drawback, again, because of the study design.

You had to look at what the risk is at home and said this is the only population you can look at in terms of applying it broadly across the population. That's where I see that it doesn't get to it, although it certainly should be the basis for a standard in all types of care arrangements for children. I mean, that was the other issue, but we don't know the answers to these types of situations.

MICHAEL WEITZMAN: I would choose to paraphrase or modify that. The majority of kids are spending more time out of the home than kids in this particular study. The majority of the children in day care in the United States are not in licensed day care, so that most of them are in home, in other people's homes. We don't know about the exposure, so what you could say is that this particular sample spends more time in the environment that we have tested than most children in America spend in their homes, we would assume.

But I don't know -- I also would like to go back to the earlier comment about conservative, that other kids are more likely to have other sources of exposure. I don't know that we know that. I don't know how many communities have smelters or industrial sources of exposure.

I think one way in which Rochester's does differ from lots of other communities where other people live is that it's a fairly inclement environment where people spend a lot of time indoors, where winter comes early and leaves late, and so windows are closed. And

kids spend less time outdoors, I would imagine. Although other studies have shown that in the aggregate children spend about 70 percent of their time indoors in their own home, and that comes from the extensive literature on passive exposure to cigarette smoking. People have explicitly looked at that.

ROB ELIAS: Yeah. Rob Elias. I think that's an important focus on the issue. We're not looking at the sources. We're accepting the sources what are general household or neighborhood sources, but the differences that we're looking for in terms of extrapolating to a national standard or a national situation have to do with the rate of movement within the child's environment, and the total child's environment. As to whether it includes day care or parks, playgrounds and everything. Those are the issues that go outside of this study that Brion is going to have to consider and seek advice from other studies to get the result.

The real issue you have here, which we seem to have reached, is does this study adequately characterize that segment of subpopulation of Rochester.

And given that information, it gives us some confidence in that I think we can move carefully toward extrapolating to a national standard by comparing this study to other studies and by using other statistical and scientific techniques.

MICHAEL RABINOWITZ: Let me see if I can just understand. You're saying there is nothing really peculiar about Rochester, so it can be used to generalize to other places, and we characterize it enough so you could make the adjustments.

ROB ELIAS: Let me put it in different terms. Suppose on the basis of this study we were to say that an acceptable dust lead loading for a home is a hundred. That's a national level. If we base it only on this study then you can realistically say that this regulation is designed to protect the children of Rochester. Okay. I mean that's really what we're saying. That's all we can say. But in doing that, we feel that we will also protect a large population of the rest of the United States. We need then to look at what part of that population we would not protect by setting this

regulation. And that can be done through other deliberations, mostly scientific. Eventually we're going to have to come to a -- you know, typical type of decisions regarding how do we match up these studies, as Chuck will say -- ducked out when we needed him most -- meta-analysis can be a tool that may be possible here.

MICHAEL WEITZMAN: I need to say something provocative and go back to the match in the pocket. I'm not sure no matter how generalizable this is that one can draw causal inferences from cross-sectional data from a particular study or even from a large series of studies, but in particular, one study. I mean, sure, if it were robust and over and over again, you still could have confounding, so I --

MICHAEL RABINOWITZ: I'm sorry.

MICHAEL WEITZMAN: Pardon me?

MICHAEL RABINOWITZ: You want a longitudinal study?

MICHAEL WEITZMAN: I would like to ameliorate or eradicate lead poisoning. I don't know that we have the data to know the causal chain, nor the

practical issues that were raised earlier. I'm trying to think -- if you set it at a hundred, Rob, I'm trying to think of all the poor families in Rochester that I know. I'm trying to figure out how we in the pediatric and public health community would actually go about helping those families. I think there are a lot of unanswered questions.

STEVEN RUST: In terms of generalizability, too, I think we should perhaps look at what kinds of conclusions would be more generalizable to the general population than others, and I suspect that conclusions that have to do with the percentage of kids above a particular blood lead level will be less generalizable than, say, a slope factor between blood lead levels and dust lead, and you might want to think about that when we determine which aspects of this are more helpful in setting up this.

BRUCE LANPHEAR: Would that be where the log-additive model is more useful than what we have done so far? I mean would that help?

STEVEN RUST: Oh, I think that would help

firm up the basis for that slope factor, but I guess what I'm saying is, I think I'm coming back to Karen's comment earlier, in that if you establish a slope between dust lead and blood lead that may be applicable in another city where they have a significant other source of lead exposure, the blood lead levels of those two populations will be quite different. But yet that slope factor may very well extrapolate to that other city.

As well as Mark was saying earlier, in his study, he's got kids with higher dust and higher blood leads. So your populations are different in terms of blood leads, but it may perhaps turn out that slope factors are the same, so when you look at slope factors, I think you're in a realm that may perhaps be more generalizable and give Brion better data for setting the standards.

BRUCE LANPHEAR: Those would be unadjusted slope.

STEVEN RUST: I guess they can only be adjusted for what you can work into a sampling scheme for enforcing the standards.

BRUCE LANPHEAR: So only maybe environmental measurements or, for example, if you go into a house and there are no kids there, you can't measure behaviors.

STEVEN RUST: Right. Well, the standards they are looking for would preclude using that information anyway, so yes.

WARREN GALKE: Please speak up.

MARCUS PEACOCK: We're not looking for behavioral standards. We are looking for environmental standards.

BRION COOK: Health-based environmental standards.

MARCUS PEACOCK: Health-based environmental standards.

MICHAEL RABINOWITZ: There were some other hands up over there before.

MARY EMOND: I'm Mary Emond, and I just wanted to make one comment about generalizability to kids who spend time away from home. It's possible to define the problem so that you only want to look at the average kid who is at home, since it's a standard for the home.

I'm not sure if this is what is going to be done or not, but you may not want to look at the average over all kinds of kids but say what's the potential for the kid who's in the home most of the time, so what's the potential hazard for that child, especially if, as Bruce pointed out, you're going to be enforcing the standard for empty homes or empty apartments and you don't know what kind of child might occupy -- that's just another question actually to be answered.

NICK FARR: Twenty hours is a lot of hours. I mean, for example, the new Maryland statute defines as a house that has a child in it a house in which a child spends 20 hours a week, like grandma or something like that. Do you have any idea whether limiting -- the 20 was limiting, was really only five or three, or was it 19? Were these kids really at home most of the time? Because 20 hours, you can get a lot of lead.

BRUCE LANPHEAR: The average was 5.5 hours a week. And, again, I mean that may not be generalizable, but that's why we wanted these kids, is because they did spend so much time there.

Does that answer your question?

STEVEN RUST: I think in terms of extrapolation, too, you have to think, take this population of kids who spend a significant amount of time at home, now, perhaps you have a more general population in which they don't spend as much time at home, but of the time they spend away from the home, how much of that time did they spend in another environment which is really subject to the standard? And if that's the case, then it's really -- you're back in the same situation again, and it's okay to extrapolate to that population.

MICHAEL RABINOWITZ: Anything else on that topic then?

Let me just ask, is there anything -- maybe we touched on this before a little bit. Is there anything about Rochester's dust that's different than dust in other places?

STEVEN RUST: Their lead.

CHARLES ROHDE: I have somewhat of a concern about the advice that we're going to give Brion, because the issues of adjustment for or against in which estimate

Brion uses, I think is important, because if he gets an adjusted estimate, then all sorts of assumptions are being made about similar behaviors in children living in Rochester and in Atlanta and in El Paso, Texas and wherever. And if that really is -- certain variables are really site specific, then they need to be taken into account and you can't have a nationwide study.

On the other hand, if you want to say, well, we want a nationwide standard, then it seems to me that the slope estimates that Brion gives can't be adjusted for any of these other variables, because they are misleading and are very specific to the Rochester study, so I think that's an issue I think for EPA, but it's also a reporting issue for you, because I think you have to report all of these, all of these estimates, and probably even better, not only the estimates, but sensible confidence intervals around them.

ROB ELIAS: I think perhaps one example of what you're saying is a community education program that encourages personal hygiene training for parents and children. That will reduce lead exposure. We already

17 know that. We've seen it happen time and time again. But our standard is not going to be based on that kind of a universal educational program. I don't think so. And whereas we would certainly encourage every public health agency to do that. We have to base the standard on the assumption we're not doing it, so if there is some kind of training present in this study that has impacted this study, or any study we analyze, we would have to correct for that.

DAVID JACOBS: Are you saying that, therefore, the estimates of slope should not be adjusted?

CHARLES ROHDE: I'm saying you may want to adjust if they are going to be used for one purpose, and not adjust it if they are not going to be used for another purpose.

DAVID JACOBS: There is going to be a national standard. The Congress has already said. Therefore, does it imply, if these adjustments are site specific, that we should not provide them. If that's the position, I don't really understand why we took all the extra measurements that we did if we're not going to use

them to adjust the results so that we have some kind of basis for comparability.

CHARLES ROHDE: You may make the adjustments, but you have to realize then that you may be making an incorrect adjustment.

DAVID JACOBS: For another city.

CHARLES ROHDE: For other cities. It may well be you could set a standard for Anchorage, Alaska in which the children are not playing outside very much, and you make the same estimates for a city like Atlanta where kids may be playing outside, and in reality, the exposure patterns are entirely different. And the standard in the one case may be too low, and in the other case too high.

STEVEN RUST: Having collected the data, I think you're in a position -- you can define Rochester population in terms of these variables. And I think in terms of setting a national standard, at some point, a national population is going to have to be defined in terms of these variables, and I think you have the data to make the adjustment from one population to the other, and I think that's going to be important.

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BRION COOK: I think what Steve is saying is a good point, that probably you'll have to come up with a national population of some sort, and maybe that we have this data set plus other ones, that from each one we come up with a description of a population that those data represent, and then take a look at all of those different populations and see how well they can represent a national population, or some way take a look at how those groups of populations don't represent something that we think we have to represent or something. I guess we're not sure where -- what kind of populations we will come up with right now, because I'm not sure we know for sure all of those variables for all of the different data sets that are out there.

CHARLES ROHDE: I really don't envy your position, because it's very much like --

BRION COOK: Get that in writing.

(Laughter)

CHARLES ROHDE: It's very much like suggesting a drug for the entire U.S. population which may be gender specific in its action. What do you do then?

It helps males, but it's harmful to females. Do you still use it?

ROUTT REIGART: Just to expand on all that, it really has nothing to do with the studies. It seems to me what Dr. Weitzman was saying is until you have done either longitudinal study or intervention study, you don't know whether your standard is going to help the children or not. Whether lowering -- in fact, even though there is a relationship to the study, will lower their blood leads over time.

And two, I think Baltimore has some experience with whether you actually can lower it to whatever standard seems safe on a health base -- whether it's a possible and reasonable cost to lower it low enough to meet a health-based standard, but it seems to me those are your problems rather than the study's problems. Either of those can be answered with the database available.

BRION COOK: That's right.

BRUCE LANPHEAR: Yes. We would like to make them our problems, but EPA still has been mandated to come

up with a standard, probably before these longitudinal studies will be done, and so there really are two different issues. Yes, they must be done, and ideally they would have been done four years ago so that EPA and some of them would have only cleaned the window well and some of them not, or just cleaned the floor, so I guess it's -- even though I agree with that, at the same time I empathize with EPA and Brion. What can we do to help them? If anything.

STEVEN RUST: I've heard two approaches today in terms of one is looking at the entire U.S. population of children and somehow trying to deal with that and extrapolate to it. I've heard another suggestion if we define a specific population and say that we are protecting -- subpopulation -- and we are protecting that subpopulation, then by inference we are also protecting the rest of the population in some manner.

That second scenario is just a whole lot easier to deal with, and I suggested that's probably the first pathway to go down, having gone down that pathway, you can always revisit the first one and do perhaps a

better job, but I think to define a specific population that you want to protect, and then juxtapose that population versus Rochester, see if there are real problems, if there are any problems with the extrapolation between the two is probably an important step.

MICHAEL RABINOWITZ: Okay. Well, now that we've had a better idea how Rochester fits into the national picture, I guess the next topic to revisit briefly is how accurately the slope that you report represents the picture in Rochester in your population or the sources of noise and bias, but I guess that's going to have to wait until after lunch, so -- or we can do it -- well, we only have 30 seconds. We can do it after lunch. So why don't we adjourn for lunch. I thank you all very much. When do you want us back? Let's talk about that.

WARREN GALKE: 12:45.

MICHAEL RABINOWITZ: And where is lunch?

EVELYN BLOOMER: Lunch is to the left as you come out of the room here, for those who have been invited to lunch.

(A lunch recess was taken.)

MICHAEL RABINOWITZ: By the clock, it seems it's time to reconvene. Just looking ahead a little bit into this afternoon, while we're all assembled, I know later on we'll be talking about sources of bias and experimental error. Maybe later we'll have a chance to speak as a group about where to go from here. What sort of policy issues this study may present, but before launching into this, maybe we could take advantage of an offer made by Brion Cook to address us and explain to us a little more about the context of this.

BRION COOK: Okay. It was actually Rob's idea. When we stopped for lunch, Rob thought it might be a good idea to kind of give everybody here a perspective on where we are with the health-based standard. I thought about doing this this morning, but I didn't want to get that whole process confused with the reason why we're here today. And I still don't want to. But I think it might be good just to kind of give everybody a perspective on where we are and why this is important.

Title X requires EPA to develop health-based standards for exposure to paint, dust and soil. The

statute gave us an 18-month time frame to generate final regulations. That 18-month time frame ended this past April, and we don't -- do we not have a final regulation, we do not even have a draft of a regulation ready.

And the reason for that is the technical bases which will form the crux of the standards are really complex, as one reason why we're here. Over the last year and a half, what we have been doing is trying to look at a variety of ways to try to establish a technical basis to the rule and have come up to the conclusion that we still need to do a lot of work.

In fact, what happened this past spring, Lynn Goldman, who is the assistant administrator of EPA responsible for this, asked us to generate a small federal group of scientists, which Rob Elias and Kate Mahaffey co-chaired, to get together to recommend what we should do to establish a technical basis, and that group was about eight people. Rob and Karen were both on the group, and Tom Matte from CDC, Buck Grissom from ATSDR, and I think the rest were all EPA scientists.

What that group has come up with, we should

19 go down two broad paths. One, we should take a look at the agency's IEUBK model and undergo a validation of that model for its use to set standards, and the other path is to take a more detailed look at the available epidemiology data and do some more sophisticated analyses than just looking at slope factors and see how that data can be used to generate standards.

We estimate that is going to take nine to twelve months. We really haven't gotten that far started along the way other than to write up a strategy or a plan for how these two things will be done.

Another thing that has been assigned is in the meantime we will generate guidance for people to use until the standards are out in a final rule. And for the last three months, we have been working on that guidance. And now I think we're pretty close to having guidance out in the next couple weeks. And I'm not going to talk about the paint and soil numbers, but where we are on dust in the guidance is we're going to base whatever we say on the HUD clearance levels in some way.

If we start with the 200, 500 and 800

numbers, we're really right now looking at two different options, two broad options, for setting dust standards in guidance. We are going to lower the 200 number to 100 in both options. So we'll start out with really one, five and eight hundred.

One option is to leave those -- just to have those -- that set of numbers for the three surfaces, call them in a sense clearance and action levels, however you define an action level. It's not a health-based number, because we're saying we don't know enough right now to set a health-based number. What we are setting is guidance that is not health based, it is technology based, and maybe some other things that we know about dust.

So one option is 100, 500, 800 as both clearance and action levels, with the goal of just getting below those numbers on the surfaces. The other option is to use those three numbers as clearance levels and then have some other action level above that. Action again is not a health-based number, but is where a risk assessor would start his or her work, so that if you were above the action level, you would do something to reduce dust and

get down to below the clearance level, but allow some margin in there of not safety but maybe reaccumulation of dust on those surfaces.

And for lack of any other reason, we might just double those three numbers to get 200, 1,000 and 1,600 as the action level. But, again, none of this is really based on health-based principles. It's just numbers that are there. We know we can get down to below a hundred, so I think we're okay on floors with the hundred, and justify the doubling of those just based on allowing for some reaccumulation over time so you have some margin of something in there above the clearance level.

So one of the ways that this study will really help us is how well do those numbers work. So that's kind of the context of where we are right now. One of those two options I think will be decided on in the next few days.

And then the agency will now assess guidance to be used until the 403 ruling comes out, which is probably, (puts hand over face and mumbles).

(Laughter)

I guess that's kind of the perspective I wanted to leave you with. We know there is a lot of do in a health-based sense. We are going to work down that path. I think for the UBK validation as the epidemiology analysis, this study is critical to be available for both those procedures and both of those processes, so it's important that these data are available and accessible for us to use them to factor them into both of these approaches.

Do you have anything, Rob?

ROB ELIAS: That's fine.

BRION COOK: That's kind of a perspective of where we are.

MICHAEL RABINOWITZ: I'm just curious, after you made these pronouncements, is this then reviewed by the Science Advisory Board of EPA, or do they --

BRION COOK: No. This will be agency guidance until a rule making comes out, and the guidance itself will not be reviewed by the SAB, no, and maybe -- maybe not at all. That's just -- it hasn't been made.

Any questions or -- I don't want to get into that really, because I think that that takes away from our purpose here, but I think as much as the data we're talking about today fits into this, I think it's important to discuss.

DAVID JACOBS: I guess one comment would be is that in neither one of those scenarios have you both lowered the floor number and increased the window number, which is what we seem to have suggested here.

BRION COOK: That's right. Because I think to do both, we would have to argue that there is health-based information to allow us to do that. We're going down to 100 plus, we say it's achievable, and people can get to 100. And that's the only reason.

It may be some point in the future before the rule making comes out, we will be able to give a more health-based approach to those and change those around somewhere, and maybe then go up on the wells, but for now, the guidance as it is currently being developed is staying away from including anything about the health impacts on those numbers.

MICHAEL RABINOWITZ: Thanks for that.

BRION COOK: Thanks.

MICHAEL RABINOWITZ: Well, perhaps the next thing on our menu then is to discuss in more detail any points to be made on factors which may have affected the reported slopes. It may have deflected them away from their, let's call it true, in quotes, true yearly average value so far as there is one for Rochester. Is there sources of measurement noise, sources of bias, those sort of issues. Does anybody have any points to raise on that topic? Anything about the enrollment of the subjects that produce bias?

STEVEN RUST: I guess maybe a clarifying question, what information do we have on measurement error? And if you do have information, do you feel that that is a significant issue, that the slopes are probably biased by the error in measuring dust in lead?

MARY EMOND: We have -- it's Mary Emond. We have some side-by-side measurements, repeated measurements within particular surfaces in the house that are described in the report as in-field reliability data, and we plan to

use those to try and assess what kind of variability we have in the dust lead measurements, and perhaps use that to get an adjusted slope figure. We believe that the figures we have presented as they are probably biased downward by the measurement error in the dust lead measurements. And that's an analysis that we haven't embarked on yet, but it's in the planning stages.

STEVEN RUST: What about, is there -- can we take a ratio of any two numbers in the report to kind of get a feeling for what is the ratio of what you think is measurement error in a dust lead variable versus the spread of that across the study subjects? I don't know if there are numbers in the report right now where we can get a feeling for whether or not that is a --

MARY EMOND: Well, we do have the range of the dust lead measurements.

STEVEN RUST: I guess we would do that on a log basis probably.

MARY EMOND: Yes. We have geometric means of the dust lead variables which -- are they in the report?

SHIRLEY EBERLY: Yeah. Like Table 8 and Table 7.

MARY EMOND: So Table 8 and Table 7 show the variation in these composite measures across the houses.

STEVEN RUST: So if we take the range divided by two, that would -- oh, you can't do it, because it's extrapolated back up then. It's probably not an easy thing to do. I would be real interested in the answer to that question at some point. What is that ratio, and is it really worth pursuing in the sense of the bias that it may cause or is it small and therefore probably isn't causing much bias.

MARY EMOND: I believe it's practically significant, but I can't pull a figure out for you at the moment, but I might in ten minutes.

STEVEN RUST: Yeah, right. I didn't want to put you on the spot.

MICHAEL RABINOWITZ: Rob?

ROB ELIAS: I have a question here that I don't know the answer to, and I don't even know how to get to it, so this is just information, but what happens when

you do a linear regression when both variables have a significant amount of measurement error? And that appears to be the case here, and I would like to see that discussed.

STEVEN RUST: Well, I think what we're saying is that does appear to be the case here. The conjecture was that the measurement error in the X variable is practically significant, and has probably biased the slope factor downward so that the number reported is lower than the adjusted number would be after measurement error was taken into account, so --

ROB ELIAS: Okay.

STEVEN RUST: Am I paraphrasing that correctly?

MARY EMOND: Yes.

MICHAEL RABINOWITZ: Just so I understand when you say measurement error, I get the impression that in this particular study it's not mostly laboratory error for measuring how much lead is in the sample but rather talking about how well the sample represents the environment. What the sample, sample variabilities, what

variability would be within a home. If you revisit a home, that's the source of the noise, not the chemical laboratory analysis.

MARY EMOND: There's much more noise from things like variation in dust from within locations two feet apart in the house, the technician, how vigorous he happened to be one moment compared to the next moment, whether or not the person was careful when they cleaned and cleaned uniformly and things like that, so in terms of what the child's actual exposure is, there's a lot of variation of our number around that actual exposure.

STEVEN RUST: You mentioned side-by-sides, and I assume these side-by-sides were taken at the same time.

MARY EMOND: Yes.

STEVEN RUST: Did you also get temporal replicates? Did you revisit a house and get dust measurements at all?

MARY EMOND: No.

MICHAEL RABINOWITZ: I'm just wondering if this bears on standard setting. I hate to get involved

with that because I don't know too much about it. But I know it's been our practice so far to take samples of just, oh, one square foot, that sort of size sample, which is a good practical size to get enough lead to measure, but is that a realistic size for standards? What sort of variability is there if you micromapped a room to know what the optimal sample is? Maybe there is a strategy worked out for this kind of problem.

STEVEN RUST: Well, I guess to follow up on that a little bit, Title X asks for a definition of hazardous levels of lead in dust. Now, it's one thing to define that, and then it's another thing to define a sampling protocol and a decision process which for you to decide which side of that hazardous level you're on. And in terms of deciding what hazardous level of dust lead is, I think you have to take the measurement error into account and correct for that bias in those slope factors and send them up in the right direction.

When it comes to implementing it, though, then you've got the issue you can only afford to take so many samples and there is sampling error in those samples

and how you deal with that in terms of a practical enforcement of the standard. That's a whole other issue.

BRION COOK: Is the first part you're asking related to what Chuck was saying this morning about representativeness of unadjusted slope?

STEVEN RUST: No. It's really more representativeness of the sample for what's actually -- the dust that's in the house, so it's another representativeness issue.

MARY EMOND: I'm not quite sure, maybe you could explain a little further, how the measurement error would necessarily have to have an impact on the standard. It seems that you could get a predictive model if you used the same procedure over and over again that takes the bias into account, but as long as it's taken into account in the way the standard is set, that might be a possibility.

STEVEN RUST: I'm not sure what you're asking me, so --

MARY EMOND: Well, suppose our slopes are attenuated in terms of the real biological relationship so that the real biological relationship is more steep, but

we have a slope which is less steep, but we can still use that to predict blood leads.

STEVEN RUST: Yes, you could, but what I think it does is it mixes up two things. I think if the slopes are biased downward by a factor of two, I think it's important for us to know that, because how much sampling we do to enforce the standard ought to be a separate issue from what is the relationship between lead in the home and the child's blood lead, and I'm afraid in what we have got right now it's a little bit mixed up. If you don't correct for a measurement error, what you're almost implying, whatever protocol you would use here would be the same protocol you would use in the field and that probably won't be the case.

MARY EMOND: Well, that's an important issue, because, as we have demonstrated, there's a big difference in the outcome in terms of slope, depending on what sampling scheme you use, and so there certainly would have to be some standard protocol used.

STEVEN RUST: I guess I reacted to the 7.9 number in that it's just -- you've got a lot of data there

and so I suspect the numbers to come out of there would be somewhat precise, and so it was large, and I suspect it's somewhat precise, and so it jumped right out at me, and so --

MARY EMOND: What numbers?

STEVEN RUST: The 7.9 micrograms per deciliter per one thousand.

ROB ELIAS: Per 100.

STEVEN RUST: I'm sorry. Per 100. It just jumped right out at me as a huge number that I think we just have to be really careful to document that, and I think quickly, because this number has now been seen by a lot of people, and, I mean, you talk about the fact that you intended to do the log-additive model, modeling and whatnot, and I would be really interested to see if you get a comparable number out of that, and also, even if you get comparable numbers, what you may find is that one analysis says that it's a very precise number, and the other analysis says that it's a less precise number that when you do an analysis where the assumptions are valid, you now might say it's 7.9, but confidence interval

reaches down to two and up to 12, whereas I think your analysis indicated that it was a pretty precise number, so I am a little concerned about anybody running off with that number at this point until you do more analyses to either validate or make that number more precise.

BRUCE LANPHEAR: Just to make sure everybody's following, that's dealing back with the simple linear regression results again.

STEVEN RUST: Now, in your final conclusions, you drew the conclusion that blood lead levels rise sharply at low levels of dust. Now, I assumed it was coming from this number and the 4.5 number. You then pointed to the logistic regression or the empirical curves up there and said it was coming from there as well.

BRUCE LANPHEAR: That's really what I was basing it on, but it was more accurate to say that the proportion of children estimated to have a blood level over ten rises either sharply or steeply, and what appear to be small incremental changes of dust lead, and some of that was based on a perception of what is a low level, but it really was based more upon the logistic regression

model, not the simple linear regression.

STEVEN RUST: Will you be putting more details about that particular analysis in the report? The one you pointed to for the sharply rising? There weren't a lot of details in here about that, were there?

BRUCE LANPHEAR: In terms of how it was calculated or --

STEVEN RUST: I guess I wasn't sure. Maybe I'll just read over it.

BRUCE LANPHEAR: I think there's a couple pages on it. It may not be quite that much. There certainly, I'm sure, could be more, but I think there was reasonably detail.

STEVEN RUST: Where is it? I'll reread it so that I can -- we're talking about this curve; right?

BRUCE LANPHEAR: Page 15. It looks like just about a page.

STEVEN RUST: Now, the logistic regression part, I thought I understood. It's the empirical version of that that I --

BRUCE LANPHEAR: Okay. Wait. And the

comparison with what Mary had mentioned earlier about the empiric versus the nonempiric being very close.

STEVEN RUST: Right.

BRUCE LANPHEAR: I don't think that did make it in here. That's what you're asking for.

STEVEN RUST: Yeah. When someone says logistic regression, I think I know what that is. When you say the empirical method, I can guess as to what that is, but if you could describe that in a little bit of detail, I would appreciate that.

Let me ask a simple question.

MARY EMOND: There's only about two sentences on Page 16 describing this model independent procedure. We could provide technical opinions for you with the --

STEVEN RUST: Let me ask a simple-minded question. Did you basically just say okay, here is a dust level. Let me take all the people in the study who have dust levels below that and use a very simple binomial?

MARY EMOND: Exactly. That is exactly what was done.

DAVID JACOBS: If I could follow through that. Are you suggesting that we need to have additional analyses done to back up the slope estimate?

STEVEN RUST: Yes.

DAVID JACOBS: What exactly would those additional analyses be?

STEVEN RUST: The log-additive modeling. If you want to fit an additive model, I think you need to fit it in log space, and also verify the assumptions behind that analysis that they are valid. I suspect that if you did that for this additive regression model that was fitted in here, you would find, well, the data really looks more log normal than normal, and so you question any inference that you would make from regression analysis, because you would have validated it based on a check of normality for the residuals.

MARY EMOND: I think that we've probably excluded a number of the points that would be outliers in the residual analysis by truncating data. One thing we did not do is do the residual analysis, but that would certainly go a long way to, I think, perhaps giving us

more assurances in the confidence levels. If we do the residual analysis on that simple linear model, that excludes extreme points.

STEVEN RUST: Then I think if you want to stick with the simple additive model, then the other thing you have to look at is the influence of individual data points, and what you might find is that you're a little bit uncomfortable with the fact that there are just a few of the data points out on this end of the curve that are really driving things very much so. And then I think when you go into the log-additive frame, I think you'll find that that kind of washes away. That all the data points get more equal weighting and your normality assumption is closer to being met and therefore you might feel more comfortable with the slope that comes out of that, that analysis.

ROB ELIAS: Along the line of sources of error and so forth, on the tables beginning with 20, but going to 21 and 22, the calculation of the percent variation that is accounted for by the different covariates there, I have two questions that -- really

basically what I'm saying is you need more discussion on this perhaps.

Looking at Table 21, for example. Are these independent, these numbers here, independent? For example the BRM lead is independent of -- I assume that to be the case.

BRUCE LANPHEAR: That is correct.

ROB ELIAS: I think you need to explain it. But now there is a substantial amount of variation that's not identified; is that right?

BRUCE LANPHEAR: That's correct.

ROB ELIAS: And is it then possible that a substantial amount of that variation that's not identified could actually be, for example, BRM lead? I mean, that's not identified as that?

Are we talking about just strictly measurement error there, or what is that unidentified -- how would you characterize it?

MARY EMOND: That's an open question and an interesting question. Certainly some of it is due to measurement error, and some of it is due to sources which

we can't get our hands on. Just natural variation between several children that have the exact same exposure. There's that variation which you'll never be able to get rid of in any model.

ROB ELIAS: But it's still attributable to something. I mean technically it's there.

MARY EMOND: Genetics or something, yeah.

ROB ELIAS: Now, let's take, for example, black race. Now, you've identified in that particular table 6.5 percent to black race. And then let's suppose that there's 40 percent or 60 percent of the variation that's not identified. My question is what part of that 60 percent might also be attributable to black race?

Is there any at all? This is a question that keeps coming up whenever these data are put in tables right there, and we have never really gotten an answer, and because you're placing a high amount of significance to this ranking of these procedures, these methods, on this percent variation accounted for, the question then becomes is there some fraction of the unaccounted for variation that could be attributed to one or all of the

methods, and therefore make your statement invalid in terms of the ranking that you've shown here. And I don't know the answer to that question.

MARY EMOND: In terms of the ranking of the variables shown in Table 21? Is that the question?

ROB ELIAS: If you go back to Table 20, which shows that the BRM loading method has the highest percent of variation accounted for, 13.7, and therefore might be considered to be the method of choice, you've done this because 13.7 as compared to, well, let's say 7.5 for the BRM concentration method. That's all perfectly straightforward. I have no doubt about your statistical approach, but what I'm saying is that if you look at the variation that is not accounted for, and you say, well, maybe the 20 percent or 20 percent could be really BRM concentration, but it doesn't show up as that, and three percent could be BRM loading and it doesn't show up as that, now you've got 27 for concentration and 16 for loading and the whole thing flip-flops.

MARY EMOND: Well, I think concentration of lead is concentration of lead no matter how you measure

it. Certainly this ordering reflects the ability of a particular method to reflect some of the variability of a particular method. A method with a lot of variability is probably going to rank lower in this sort of analysis because of this attenuation factor that we're talking about, and that's a practical characteristic of that method. It's not as good a predictor because it has more variability.

ROB ELIAS: Does your method of statistical analysis say that 13.7 represents all of the variation that can be attributed to BRM loading? If not, then if there is some other variation there that because it cannot be identified, then I don't think this is a valid way to rank these methods. I don't think --

MARY EMOND: It doesn't represent all of the variation due to lead loading, that I'm fairly sure in saying, but whether the BRM could ever be the tool to measure that variation exactly is not clear to me.

ROB ELIAS: Yeah. I think if you look at what I'm trying to understand, then maybe you can see what needs to be explained in here. Just how valid this

ranking procedure is for making a decision for which method is best.

BRUCE LANPHEAR: I think the real question is how does one rank, and one could do it and statistically compare correlation coefficient, but those are unadjusted and they have limitations. How else could one do it -- and this is something we have struggled with quite a bit. How would you compare these dust collection methods other than how we have done it so far? And I would like to hear comments. If anybody's got comments about that, I would love to hear them.

CHARLES ROHDE: You get an absolutely pristinely clean surface and you put some lead on it, make sure it's equally distributed, and you put each -- use each for the methods and you do that about 50 times and you see which one comes closest to what you put down.

BRUCE LANPHEAR: That would give you some sense of recovery, but not necessarily how well that would relate to a child's blood lead.

CHARLES ROHDE: That's not the issue. Your first issue is what are you collecting -- which one

collects the lead. Right. And if you get closest to the true amount of lead there by one method, then if what's on the surface is what's really correlating the blood lead, you've got the best method for collecting, but that's not the issue here.

The issue here is how can we predict blood lead given the variables that we've measured and those that we haven't measured, and that 60 percent variability is represented by linear terms and nonlinear terms and covariates that we didn't measure and nonlinear terms and the covariates we did measure. There's just a lot of things going on in terms of a child's exposure to lead that we don't know about. And you haven't collected it and that's that 60 percent.

STEVEN RUST: So what are we asking them to do that they haven't done, I guess? Is there some analysis that they should do?

CHARLES ROHDE: I would like to know what the attenuation factor was, and I think they can get an estimate.

STEVEN RUST: I think they plan on.

CHARLES ROHDE: We can look at what that attenuation factor is, and if it's not very big, then --

STEVEN RUST: It may be -- along the lines of what you're saying, Rob, maybe some of this ordering could change. If the measurement error at concentration is a lot more than it is in loading, I don't know, that maybe could make the rank ordering change in some way. Could make the slopes a little stronger in one way than another. I don't know. It's possible.

ROB ELIAS: Basically I'm asking for more explanation of this table, because it appears to me that this is just a simple rank ordering of these methods. And it says BRM loading method is the best, because it's 3.6 percent better than the Wipe Method, which is second best, but when you look at it a lot longer, it appears to me -- maybe I'm looking at it too long. That might be my problem. But I see now it appears that there were five separate statistical analyses done here, because there were five -- you know, in other words, they were sort of done independently. When I looked at Table 21 and see that's where that 13.7 was derived against all of these

other covariates and then a separate analysis and on down the line.

Now I have to ask the question, the 13.7, how does that relate to the 10.1? There could have been a whole lot of variation for the BRM loading and not much variation for the Wipe Method, and so 13 percent of a whole lot is different from 10.1 percent of a little bit.

STEVEN RUST: The percent of the variation is the percent of the blood lead levels, though, which stays constant from model to model. And if I understood what I read correctly, these four covariates also stay the same from model to model, and so it's basically you take this page and you just replace the top line and refit the model and so --

BRUCE LANPHEAR: That's actually the area that I was a little concerned in our approach to comparing the different dust collection methods, because rather than let each dust collection method measure pick out its own covariates that were most significantly associated with that method, we created an even playing field, which has some impact on the R squared for the dust collection

method measure. I don't know that that would change the order, but it does to some extent, maybe rather small, change the R squared for that dust collection method measure.

STEVEN RUST: I don't know that I have a good reason for it, but I like your level playing field. That seems to me to be the way to look at it.

ROB ELIAS: Yeah. Now, Steve, I understand what you've said, and I kind of felt that was the case. And many I should stop talking here, because -- but the point is that if what you say, if the playing field is level, then why does the method that you used to sample seem to have an impact on these other parameters, even those very small?

Why is it that, for example, the fact that a child eats dirt and soil that the variation would be different if you used the BRM loading method than it is if you use the Wipe Method? I mean it's 3.4 versus 4.5. Is that just a numerical difference or what? Because all the other variations held constant.

Let's let that ride. That's what is not

explained here, and to be honest with you, somebody in a management position who does not have time to go into this is going to say that's what I need to know right there. It's going to be the BRM loading method because that scores the top of that column.

CHARLES ROHDE: You've raised a very good point. It's not clear to me if you perform the test that the quality of those two partial regression or correlation coefficients that they would be significantly different. You're talking about a very small, very small difference. My guess is they wouldn't be, but I know it's a nontrivial calculation, because they are both calculated from the same live variables, so they are correlated, so the variance and the difference are going to involve, but I think you could do it. The odds are it might not be --

MARY EMOND: We did a calculation similar to that just for the simple correlations, which is equivalent to a regression, including only one variable. And there was no significant difference between wipe loading and BRM loading, as you've predicted. There was a significant difference between BRM loading and BRM concentration. The

correlation between blood lead and BRM loading was significantly higher.

MICHAEL RABINOWITZ: Am I correct in understanding we do agree on the criteria of how to select which is the best method, which is not which has the highest slope, but which has the highest explained variance?

ROB ELIAS: I'm sorry. Did you say we agreed on that?

MICHAEL RABINOWITZ: I gather there is consensus on that. People agree if you --

NICK FARR: For research purposes.

MICHAEL RABINOWITZ: Right, for research purposes.

ROB ELIAS: I'm saying that's acceptable to me as long as I'm sure that it can be understood, but I'm not sure it can be understood with the level of explanation we've gotten.

MICHAEL RABINOWITZ: But we're not aiming for the highest slope. We're aiming for the highest explained variance, highest R squared.

CHARLES ROHDE: Provided there is a test that accompanies that that gives you some confidence that this really is significantly higher. And that test isn't here and probably ought to be here.

MICHAEL RABINOWITZ: What's the name of that test?

STEVEN RUST: He'll introduce it. It sounds like what they do on correlations. Full and reduce.

MICHAEL RABINOWITZ: I have my homework to do.

Well, can I ask it a little differently? I'm sorry.

STEVE WEITZ: Steve Weitz. Earlier this morning Harriotte Hurley asked the question about the confounding, possible confounding factor of recency of cleaning. And I wanted to ask, Dave suggested that perhaps if it was random, it didn't matter. I'm curious as to whether you could use the total dust variable creatively somehow to determine whether it was random or not. Total dust seemed to indicate something to do with cleaning. Does anyone have any suggestions on that?

STEVEN RUST: Isn't that confounded with cleaning habits?

DAVID JACOBS: It would be confounded with surface type. Some surfaces would retain more dust regardless of how well it is kept clean. It is possible perhaps, though, to correlate the measure of cleanliness, the observed cleanliness in the house with the total of dust level. You could do that correlation; right? And make some judgment about whether total dust loading is in fact a good measure of cleanliness, or whether it was related more to visual assessment of cleanliness. Didn't we assess cleanliness in here?

BRUCE LANPHEAR: Nancy, didn't we do that in the first phase?

DAVID JACOBS: Frequency of cleaning.

BRUCE LANPHEAR: Frequency of cleaning. I don't think we did observe by the interviews. In this second go round, we actually have two of the field team visually inspect and grade the quality of cleaning based upon their obversations. We'll be able to compare two different people's observations. I don't think we did

anything more than that question.

NICK FARR: Could you explain the second round? I don't know what you're talking about.

BRUCE LANPHEAR: Second round is rather than lose an opportunity with HUD's money, we asked families if they would be willing to participate in a six, seven month follow up, and to those families that said yes, we randomly assigned them either to receive a demonstration of how we would suggest they clean, some cleaning supplies, and a recommended schedule of cleaning, and we just got back -- we've just completed all the field work for 98 of the 99 children. One kid had chicken pox and we couldn't go back in yet. That's the second phase.

NICK FARR: And as part of the data you're collecting, you did something about cleanliness?

NANCY WINTER: Yeah. We went much more into depth with the frequency, the time, the thoroughness of the cleaning.

NICK FARR: Could you -- is there any basis for relating that back, I mean, to the same house, or is that such pure guesswork?

STEVE WEITZ: You're having an intervention.

NICK FARR: You tested the cleanliness before they started to do the new thing, so it was a -- it was a -- it was a data collection from the same houses before you told them how to clean. Is that true? But it also is some months later, so -- and they'd already been through something, so you don't know --

BRUCE LANPHEAR: And it's a different season.

NICK FARR: -- the previous conversations and work it had on their practices.

BRUCE LANPHEAR: I think it would be dangerous to try.

STEVEN RUST: Under the subject of other data, I might have hoped you would have collected but didn't, because of this attenuation of slopes relative to measurement variability, I think one of the things that become more and more important is also temporal variability not in soil levels, because I think they stay pretty constant; I think that's been demonstrated, but in the dust levels. And in other studies it may be wise to

consider revisiting at least a portion of the homes in the same time frame of the study to get a handle on that temporal variability as well and how it might attenuate the relationship.

BRUCE LANPHEAR: Yes.

MICHAEL RABINOWITZ: Just see if I understand that more fully. I guess a lot of us think that blood leads go up and down seasonally and just taking dust leads as an example, it goes up and down seasonally. You're saying it could be the slope between the two may vary or may not vary, and that the --

STEVEN RUST: I guess I'm not saying that the slope varies with time. It's really just another measurement error issue, that if you got it at that point in time, it means you didn't get it at all these other points in time when it was at a different level. Therefore, you're not only getting a snapshot of just the middle of the room in that particular spot, but it's Tuesday, you know, August 29, and not all the other days you could have sampled. And therefore it's an even -- when you look at temporal variability now, it's even a

smaller snapshot that you were going to sample, and that is the dust over time.

We don't have even an estimate of that change, and these issues that have been raised about cleaning, that certainly one of the big things that might affect how dust levels change over time, that you catch some of the top and some of the bottom of the cleaning cycle and you like to have some estimate of how big is that variation due to cleaning and other temporal issues.

MICHAEL RABINOWITZ: I guess I was thinking more of a longer term cycle rather than cleaning and not cleaning, but rather a seasonal cycle perhaps. It may be this slope that -- even though we think that the R squared is very important, just to look at that slope for a second also, that slope itself may or may not change with the seasons. And that as comparisons are made perhaps across studies in the future, you would want to know when that slope was measured.

BRUCE LANPHEAR: One other question that I think is a little bit -- it's certainly similar, and that has to deal with the half-life of blood leads or lead once

exposed, and I think it's been estimated to be about 29, 30 days, and I guess if that's true, or even if it's not 29 or 30 days, what does that imply with the time you would want to take an environmental sample and a blood lead ideally. We tried to do it at the same time, and that seemed to make some sense. Just practically, if one were to --

STEVEN RUST: The 29 or 30 days that you mentioned, that's just in the blood, and unfortunately, if the child is towards the upper end of your age range, bone lead probably plays a significant role, remobilization of lead from the bone, which will take that 30 days up to who knows what at this point in time, so -- but the issue you raise is an important one. The history, lead exposure history, and its effect on blood lead levels.

MICHAEL RABINOWITZ: You said 28 or 29 days, whatever it was. I think that is for adults.

BRUCE LANPHEAR: That is correct, yes.

MICHAEL RABINOWITZ: It may be quite different --

BRUCE LANPHEAR: I think only adults and

baboons have been studied, as far as I can tell.

MICHAEL RABINOWITZ: Beagles also.

BRUCE LANPHEAR: Beagles.

MICHAEL RABINOWITZ: Anything else on that very broad topic of measurement error or bias or slopes or R squared?

KAREN HOGAN: There was a comment in one of the interviewer's comments. I don't remember who it was. About some of the environmental measurements being made three months before the blood lead measurements.

BRUCE LANPHEAR: There were several comments. About 83 percent of children had a blood sample obtained the same day of the environmental visit. 17 children had it a median of eight days after the environmental visit. With three children having a blood lead obtained 30 days after the visit. One at 45. One at 75 and one at 95 days. These were for various reasons blood clotted. We had to go back, et cetera, but what we did was in the -- you must have the comments, the response to comments?

KAREN HOGAN: I can't find it right now.

BRUCE LANPHEAR: What we did is we provided a scatterplot of children's blood lead by dust lead and circled the three children who had blood samples obtained 45, 75 and 95 days after, and they all fell very close to the center of the scatter. So rather than simply exclude them because they were different in that regard, that was the way we approached it and left them in the analysis.

STEVEN RUST: You just mentioned in response to comments. I realize my response to comments is sitting in Columbus. I had no idea you had responded to the comments. I've been in Alaska, so if any of my comments seemed weird because you responded to them, I apologize.

BRUCE LANPHEAR: They were verbalized for other people as well.

STEVEN RUST: I'm sure it's sitting back in my office.

MICHAEL RABINOWITZ: I'm happy to talk about these again, just so that it's not lost in transmission.

BRION COOK: I think the dust collection method issue that Rob brought up about percent variation explained and also just the variability that the different

methods exhibited in some of the data, that's an important one for us, because with whatever standard we come up with, we will be recommending a data collection method or methods that go along with it, so as much as those things vary, that's important. So if reviewers or anybody else will be shedding light on that or comments or suggest additional analyses that might tease some of those differences out in a statistical or a scientific sense, we'll deal with that in a cost effective sense and these kinds of things later, but that's important.

MICHAEL RABINOWITZ: Just methodology.

ROB ELIAS: If I could broaden that just a little bit. Earlier, I suggested that you include total dust loading in part of your analysis. And if it turns out that total dust loading is a predictor of an important variable, then that eliminates the Wipe Method. You can't get total dust loading from the Wipe Method.

BRUCE LANPHEAR: What did you find in the three-city study of the data that you looked at, Rob?

ROB ELIAS: We don't have anything conclusive. That's why we're looking to this study and a

couple others. The other point is it's not preordained that we are going to go with a method that can predict blood lead that we're going to recommend that be used to determine the standard. All we need to know is what are the factors.

What I'm saying is that what we want to recommend to people is how do you assess your situation in your home and that may be a totally different method, but these are the methods that tell us which ones correlate the best with blood lead. I realize that's a little obtuse, but, you know, when it comes down to it, there may be a dozen other ways that this sample can be taken and analyzed.

STEVEN RUST: Is there something else that could be done with this data to help answer that question?

ROB ELIAS: Only to get the total dust loading in the picture so we have that information available to us to assess that.

MICHAEL RABINOWITZ: I guess I want to be a little argumentative for a second. If it turns out that total dust loading is important, and since wipe methods

are so much more convenient than vacuum cleaner type methods, isn't there some way by tare wet wipe or by the right sticky kind of wipe to recover a weighable sample in a systematic way?

ROB ELIAS: That is one of the things that have been kicked around in the New Jersey study. The New Jersey study has a different method for wipes that allows the loading, dust loading, but it would not be feasible in my mind to be done on a national scale.

DAVID JACOBS: I think it's worth pointing out that we did do a pilot study for this study where we looked at five sampling methods, just not sampling -- what did you call them?

STEVEN RUST: Sample method measures.

DAVID JACOBS: Not sample method measures, but five different procedures, if you will, one of them was a tare wet wipe method, but we also felt it was simply not sufficiently well developed to be of use. It's just too complicated to use, so it's not practical. It could be developed, but we think right now it's not likely to be recognized as a sampling method, so we rejected it.

STEVEN RUST: How would that method line up on that plusses and minuses chart relative to vacuum methods in terms of dirt? If it were developed to the point where it could be used, would it be closer to the current Wipe Method or closer to the current vacuum method?

SCOTT CLARK: Scott Clark. It will be very difficult to use in the field. It is not a good screening method.

ROB ELIAS: Let me ask a question then. The key question is if it could be developed. I mean, with that particular method you have complicated templates and complicated instructions. But if -- let's put the two methods side by side.

Suppose that you were to develop a kit for a homeowner. This kit involved a packet of filter paper or some sort of wipe material sealed in a bag that was sent -- you know, sent to the homeowner. And in one case, like the wet wipe here, it's wet and you wipe it and you put it back in the container. You mail it back to them and two weeks later you get the results.

Now, if by comparison, you had the same thing with a dry filter paper, and the instructions were to apply this solution to that, and then wipe the surface, seal it up and send it back, then there's relatively little on this sheet that has changed except the additional analysis that would be done in the laboratory for weighing the paper. And then the whole picture changes, is what I'm saying. So I wouldn't be too quick to say it would be low on this scale.

NICK FARR: You said two weeks, is absolute murder.

ROB ELIAS: Two weeks is the same time for analysis. I mean -- in both cases the time for analysis would be the same. There is no difference there. We're dealing with these issues across the board with soil and paint and everything, and it's important for us to get all of the information here. And it comes back to the same issue, that dust loading is going to be the determining factor, how important that is in determining the hazard to the child.

MICHAEL RABINOWITZ: Did you want to say

something?

Anything else on this general topic then?

STEVEN RUST: I did want to talk at some point about the different analyses and how maybe to bring them closer together. I don't know if that falls into this topic or not.

MICHAEL RABINOWITZ: Just on that topic.

STEVEN RUST: In terms of, for instance, the logistic regression that you do towards the end of the report, if, for instance, you did a probit analysis instead of logistic regression, I think it would match almost exactly the regression models that you've done, and so you might want to think about that kind of a match between the different types of analyses that you're doing.

MARY EMOND: I'm sorry. Could you be more clear about that?

STEVEN RUST: You could make the basic models be basic- -- exactly the same, in that you've got some type of linear relationship between blood lead and dust lead, and regression analysis is one way to fit that model.

If you did a probit analysis, you would essentially be making the same normal or log-normal analysis that you're making in regression, so it would just be a different way of fitting exactly the same model, and it would bring those two analyses together. It would make them coincide as just two different statistical methods for fitting exactly the same model as opposed to being two entirely different models for the data. That's one suggestion.

The other is if you do fit the log-additive model and you like it, and you decide to use it, when you think about correlation coefficients, rather than fitting a correlation coefficient between the logs of the variables, what you might want to do is do a log-additive regression of the two variables against each other and report the square root of R squared for that regression so that it would basically be the exact same kind of correlation coefficient as you are fitting regression models to the data.

So without getting into a lot of technical detail, there's an alternative to the correlation

coefficient that uses the log-additive model as opposed to an additive model or a log-linear model that you could use for consistency throughout the report.

MICHAEL RABINOWITZ: Now that that's cleared up.

(Laughter)

The coefficients would be different? You couldn't compare the coefficient from two methods, but the conclusions would be the same?

STEVEN RUST: That's right. But the correlations would be for an additive relationship between the two variables, and whenever you can get the relationship back to additive, then more people can understand the implications of the relationship. This is the way I think about it.

When you talk about log-linear relationship -- I mean, I have to scratch it out on the back of a pad. When you look at a log-linear model, and you say what's that mean in terms of the original space of the data? It always gets complicated to take it back.

MICHAEL RABINOWITZ: Anything else on this

topic then?

Well, it's still not time for a break, so perhaps we could turn to the next topic, which we have kind of alluded to already quite a bit, and that is where to from here as a topic. What might be the best next step? What might be the policy implications of this? Would anybody like to be first to address that topic?

STEVEN RUST: There was a question raised earlier, and I would like to raise it again. The question was can we really begin enforcing a standard prior to a longitudinal study that demonstrates that lowering dust lead levels in fact has the predicted impact on blood lead levels. And I guess I would like to raise that question again and have some discussion on that, if anybody's willing to state an opinion. My opinion, the answer is that we do need a longitudinal study before we enforce a standard on a widespread basis.

MICHAEL RABINOWITZ: And this is just because of an uneasiness that cross-sectional studies may not.

STEVEN RUST: Establish the causal.

MICHAEL RABINOWITZ: Show you the pathways that causes the relationships.

KAREN HOGAN: And there are ranks of variables -- or a more realistic picture in terms of variability.

MICHAEL RABINOWITZ: Could you just repeat that again louder for everybody else in the room?

KAREN HOGAN: I just wanted to add to what they said. A longitudinal study would also include a more realistic characterization in variables in terms of measurements.

DAVID JACOBS: I guess I'm actually not convinced that we do need a longitudinal study. Consider, if you will, an example for an occupational health standard. We would not require a decline in leukemias to basically argue for reduction in benzene exposure to workers, but what we would require, of course, is some evidence that there is known toxicity of benzene that argues for a reduction in exposure limits, and then perhaps we follow a group of workers through to demonstrate whether or not the new health standard is

effective.

But it seems to me that the language that Congress used in Title X was that the agency was simply to set a standard to defining a dangerous level of lead-in-dust, not whether such a level, if it was implemented and enforced, actually caused, you know, X reduction in blood lead levels. Obviously that's why Congress wanted to see such a standard set. But it seems to me we're caught sort of the horse before the cart type of problem here.

STEVEN RUST: Are you saying I said enforce?

DAVID JACOBS: I'm not opposed to doing a longitudinal study. I don't think we need to do it in order to impose the standard.

STEVEN RUST: Let me clarify what I said. I said enforce a standard, and I meant that I think you can set a standard. And what I'm saying is before you enforce it by expensive abatement to bring those levels down to meet the standard, and spend a lot of money doing that, I felt that a longitudinal study was necessary to show that that would in fact be an efficacious manner to bring blood

lead levels down. I think I'm in agreement with you. We can establish what appear to be hazardous levels of lead-in-dust, but then the method to go about remediating those hazardous levels would still remain unclear, I think.

NICK FARR: Two things to that. One, does reducing dust levels in fact reduce blood levels? And then the various things which you asked people to do, do they have the effect immediately and over time in reducing levels? All of which we'll know by the year 2008 or something if we're lucky.

DAVID JACOBS: It's not like that has not been done before. Charney obviously did some of this year and years ago.

STEVEN RUST: But at 30 micrograms per deciliter.

DAVID JACOBS: There is evidence that shows blood leads do go down if dust levels are controlled.

MARY EMOND: A longitudinal study might also shed some light on the reason for the differences between the blacks and those who say they weren't in the black

group, especially if you follow children from birth to two or three years of age, see at what point in time those differences appear might be of interest. Not for the standard in particular, but as a research question.

ROUTT REIGART: I have to agree with the position that going into a great deal of effort to reduce the lead levels in dust to a standard that's established on this basis may not be the wisest approach. If we have shown it is beneficial, I think you mentioned there is some data, the old stuff about getting dust in out of the house, but there is also some evidence where you try to remove dust at a lower level, you may transiently increase children's exposure. I also think there's perhaps as much probability that other interventions for these children may be as successful which might not remove the lead in dust but, for instance, improve their nutrition or change parental behaviors.

There are lots of other things that could be done that haven't been fully tested, and to set and enforce a standard would be very expensive to achieve prior to showing that doing that will actually help the

children, I think is not wise in this case, and I don't think benzene is a fair comparison, a fair analogy.

STEVE WEITZ: I would like to be on the record with a similar kind of comment. If you say, if I understood you correctly, that the purpose of -- is it Section X that you are --

DAVID JACOBS: Title X.

STEVE WEITZ: -- Title X is to establish a dangerous level. We have jumped to saying does dust removal help kids. I'm not convinced that cross-sectional data can even tell you what a dangerous level is. We have a correlation. We know that something that's associated with dust lead levels of a certain degree is associated with blood lead levels, but we don't know that it's the dust lead that's doing it, so I'm not convinced. I'm even a step before these guys that we've even demonstrated that it's the dust that's dangerous in this particular study.

ROB ELIAS: Are you showing that the children are eating the dust in their home? Does this study show what it says, there is a correlation between the lead in the dust in the home and blood lead? Are you

showing that the children are ingesting that dust?

STEVE WEITZ: No, I don't think so.

ROB ELIAS: Okay. And you really can't say that about any study, any cross-sectional study.

STEVE WEITZ: Not as I know.

ROB ELIAS: I don't know any study that shows it better than this one, so we're looking for that piece -- that's a pathway. That's a pathway statement. We've put all of our bucks on this particular aspect to show that there's a correlation between the dust in this home, the amount of lead in that dust, and the amount of lead in the child's blood, and we still can't say that the study shows that the child is eating the dust.

BRUCE LANPHEAR: It may not matter if they are eating it or if it gets in their ears. The question is if you remove it, do they not get it into their blood or are they not exposed to it as measured by the blood lead.

ROB ELIAS: That's not quite the direction I'm going in, but that's the next point. That once you establish this study shows that the children are ingesting

that dust or taking it in, whatever, but I mean that's my point. Is this house dust going into the body? Is it primarily responsible for the blood lead that's there? You know --

STEVEN RUST: I would be willing to go out on a limb, even though it is a cross-sectional study, and say based on the evidence in this study, I would probably conclude that children are ingesting lead from dust in that residential environment.

ROB ELIAS: Okay.

STEVEN RUST: From some dust somewhere in that residential environment. So that's a leap of faith. That's not a statistical conclusion. Whether or not it's from window wells or from the center of the room on the floor, you know, that's where I start to draw the line and say, you know, we simply haven't shown that it's the dust that we sampled. All we have are correlations and what we measured is correlated to what they are taking in and that's about as far as it goes.

ROB ELIAS: Title X is a hazard reduction act. It's not a health level act. It's a hazard

reduction act. If the dust in the home is a hazard, then it needs to be reduced.

STEVEN RUST: Irrespective of whether or not the method of reduction has any effect on blood lead levels?

ROB ELIAS: That's the point that we -- that's not what this study was designed to show. I'm not saying that the -- that that's -- now, I would also like to comment on this issue of dust abatement.

We have many, many projects ongoing and most of those almost to the letter where dust abatement has been done, dust abatement, simply remove the dust, in every case we have seen a reduction in blood level, an immediate reduction in blood lead that has persisted until the dust was restored. Lead in the dust was restored. It's an inexpensive technique. People can easily be made aware of methods for keeping their home dust free, if it is possible. Some homes are not easily cleaned. And we should not see that as an expensive way to reduce exposure to lead.

STEVEN RUST: What are the references there?

These are studies that have been conducted and documented?

ROB ELIAS: Yes. That's right.

STEVEN RUST: What studies?

ROB ELIAS: In the Boston study, Boston Three-City Study, there was a significant amount of dust -- of blood lead reduction there from dust intervention, and when dust and soil was done. There are reports from smelter studies in Australia in Idaho and British Columbia. There are ongoing studies that have not yet been published, and they all show the same thing.

STEVEN RUST: I think that's significant. If such data is there, it's very significant.

MICHAEL RABINOWITZ: Could I ask a question? Within the limitations of this study, measured many things, not everything. We've measured lots of things. Is there anything that predicted blood lead better than dust lead?

BRUCE LANPHEAR: No.

STEVEN RUST: Did soil come close?

BRUCE LANPHEAR: Not in the adjusted analysis.

MICHAEL RABINOWITZ: I hear silence.

STEVE WEITZ: There was ingestion of soil. It was not the soil leads.

BRUCE LANPHEAR: In one of the model, yes, so dust was by far the most important predictor.

STEVE WEITZ: Me?

MICHAEL RABINOWITZ: Yeah. I thought you wanted to say something.

STEVE WEITZ: No.

BRION COOK: Is that consistent with studies, that dust is the most important predictor of blood leads? Or is that a different thing?

ROB ELIAS: Yes, it is. There are cases where there have been large amounts of lead in drinking water and food. Those are pretty well in the past. If you took a select group of children only exposed to drinking water from glass faucets or something like that, then you might find a different story.

UNIDENTIFIED VOICE: For what it's worth, as we found in the older Boston study, the 249 kids, and that is, that house whose dust lead was a better predictor than

airborne lead or tap water lead or soil lead given the predictors at the time.

WARREN GALKE: I do want to remind people that there is one piece of data that Bruce's team has not yet gotten to in their analysis. They did do hand dust sampling as well, and that may give additional closure to the question that Rob was raising about proof of ingestion. It's not direct proof, but it may get one closer at least to the physical passage of lead through the body.

About the only thing I can think of that would get -- in a cross-sectional time analysis that would get closer, and I hate to suggest this, would be fecal analyses, where we actually looked for the passage of lead through the gastrointestinal tract, and I don't think at these levels we would detect it, although maybe we could give some hotshot laboratory scientist a way of giving him a couple million dollars and knock limit the detection down a factor of three.

MICHAEL RABINOWITZ: Perhaps it does call for the right tracer study, but we can't find that in this

data right now.

WARREN GALKE: But that's about as close as we can get when we have the hand data as well and look at that.

MICHAEL RABINOWITZ: That has problems, too. If it's on the hands, it's not in the --

PAT McLAINE: Just a question in terms of where we go from here. Did we have data that shows dust lead levels over time, say in houses over a year's period of time to show how dust lead levels vary with time, because if we set a standard that's based on dust in the summer, we're likely to have different findings in other seasons during the year, and I wanted to know is there a national data set that has that kind of information? This one only has, I guess, one collection of dust so far and possibly two with six months apart; right?

SHIRLEY EBERLY: Seven.

STEVEN RUST: The old Boston, but that's rather old.

ROB ELIAS: There is no national data, but there are several studies that have looked at that over

time. Usually separated by at least three-month intervals of measurement and so studies are ongoing.

BRION COOK: Will the HUD evaluation data have that over time?

SCOTT CLARK: Yes, for some cities we will have a three-year follow up, or five, but most only one.

ROB ELIAS: I think isn't the question more like a seasonal variation?

NICK FARR: Six and 12 months.

PAT McLAINE: I'm thinking every three months, because we have four seasons in many parts of the country.

SCOTT CLARK: We have some data from the soil project where we have, I believe, seven measurements of dust over a two-year period in the same houses. And there is tremendous variability. Tremendous. Several orders, you know, over time that appear to be connected to outside sources in our houses. We had rehab houses that were pretty much lead paint free or very little lead paint and we had large variations.

BRUCE LANPHEAR: Was there any particular

season that seemed to be highest?

SCOTT CLARK: No, but the demolition in the neighborhood on that block was a big factor.

ROB ELIAS: That's still -- your point's a good one, and I think the key information is more the variation in the dust. The dust.

PAT McLAINE: Right. For a standard, right.

ROB ELIAS: Because that's translatable to a national level. If we know from just the Rochester study and a few others what happens when that dust has a large amount of lead in it, what happens to the child's blood level, then we can take information on dust concentration in a variety of sources not even related to lead. There are a lot of indoor air projects, for example, that show, that beginning with pesticides and so forth, that show annual dust cycles and many like that.

BRUCE LANPHEAR: Michael, I never saw that you had in any of your analyses looked at seasonal variability in dust loading. Had you done that that you recall?

MICHAEL RABINOWITZ: I'm sure we looked at

it, and just plotting it out we can see it, and I'm thinking some -- they reanalyzed the data. I guess they had our data.

STEVEN RUST: They documented a seasonal component variation in the dust lead measurements in that study as well as the blood lead. And it is significant. I don't remember the levels, but it is something that you wouldn't worry about. If designing a study, if you read that report and designed a study, you wouldn't worry about it.

BRUCE LANPHEAR: I would like to get that afterwards.

STEVEN RUST: I think it's a draft EPA report at this point.

BRUCE LANPHEAR: Okay.

STEVEN RUST: We'll see about access to that.

MICHAEL RABINOWITZ: How this fits into standard setting, good luck. Seasonal adjusted standard.

WARREN GALKE: Add an extra margin of safety.

MICHAEL RABINOWITZ: Excuse me. Maybe anything else on this general topic of what to do next or what needs to be -- yes.

STEVE WEITZ: Steve Weitz. I guess one question I have, would it be worthwhile over the median term, three years or four years or something like that, in terms of this standard setting policy development process for the government to fund a couple more of these studies to take account of the fact this is just one study and we need to replicate them. And how valuable would that really be to us if we had the money.

And another question about further research would be how valuable would it be -- would it be worth the money to do a national prevalence, dust lead prevalence study in housing in the United States? You know, with DSU's 80 counties and all the segments within and all the -- I mean, it's horrible to think of, but how essential is it? I would just be curious if anybody has any reactions.

MICHAEL RABINOWITZ: I'll give you top of the head reaction without thinking too hard about it. I

don't think you have to do a lot more studies like this. This is a good study. You're not going to do a better one probably. But if you had a limited -- longitudinal studies are kind of expensive, so I think the money might well be spent on some kind of estimate of national prevalence that might be very useful along with predictors of house dust. Not only measure the house dust lead, but also measure a few other things about the household, paint, age of dwelling, that kind of thing. And that might be very useful if you're going to get serious about regulating household dust lead.

STEVEN RUST: I think you have to first answer the question does the blue nozzle simply collect less of what is collected by the method you might use in such a study or did you say it collects a preferential portion of that that gives you the wrong answer. If it simply was inefficient but collected the right stuff, then you can get some factor to apply to the national survey data. Then in some sense you've already got the answer to that question, I think. But if the blue nozzle was preferential for certain portions of the dust that has

less or more lead, then you might have to redo that. But I think it's an important question.

BRION COOK: Could a national estimate be constructed from things like the HUD evaluation?

WARREN GALKE: With regard to that, there's a new technique that -- it's not new in the wildlife literature, but it is in the epidemiologic literature, that might allow us to use the HUD evaluation data for that purpose. And that's capture recapture sampling. Some very interesting reports were presented at the Society for Epidemiologic Research meeting last week in Miami, and that technique may have application in a lot of environmental studies in support of environmental standards. And it may be something we might want to really take a real close look at and it might allow us to approach the desired target.

MICHAEL RABINOWITZ: How would that work, Warren? I'm trying to picture this. I know when you capture a swan and take it and release it, but how would it apply here?

WARREN GALKE: What you probably would end

up -- I'm not an expert on this technology, believe me. I didn't catch many fish in my life, but I could envision, I think, maybe conceiving of grantees, a collection of units being done by a single grantee in the context of the evaluation as being the first capture, and then doing some kind of identification of the next grantee as a second capture of the national housing stock, and then by -- as I understand, it's kind of like a Venn diagram assemblage. You come up with an overall estimate of what is in the sea of housing in the country, so it might be possible. Although I say I'm not an expert in it. Otherwise, our selection of locations leaves -- is definitely not geographically balanced to give a true national estimate.

MICHAEL RABINOWITZ: I don't know if you want a true national estimate. Maybe you want an estimate of where that poisoning occurs.

WARREN GALKE: Now that we're at blood leads of ten being levels of concern, nobody knows where lead poisoning is. Because people in new areas looking at it for the first time are finding some small but identifiable proportion above ten in places that haven't worried about

lead before.

MICHAEL RABINOWITZ: It's time for another break.

WARREN GALKE: Yep. Time.

MICHAEL RABINOWITZ: So see you all in 15 minutes. Thank you very much.

(A recess was taken.)

MICHAEL RABINOWITZ: Let's reconvene then. I guess we are at the point of the meeting to receive any other additional public comments, and then after that, we'll hear from Warren Galke about what needs to be done to get the most out of this meeting and what our charges are.

So to the first of those, are there any other further public comments? Additional comments from public? Welcome visitors? Government agencies?

BRION COOK: Yes.

MICHAEL RABINOWITZ: Yes.

BRION COOK: One thing that has been brought up is there need to be another study such as this. I want to get everybody's views on that. There was one or two

things about Rochester being dust lead levels lower than expected and does that mean anything as far as having another study like this done in an area where we might expect higher dust lead levels. I would like to get additional views.

STEVEN RUST: Let me ask an additional question. Will the Repair and Maintenance Study shed light on the need for an additional study?

MARK FARFEL: Yeah. In fact, it's been done. You can look at our additional data collection campaign, a hundred and five houses, a hundred and sixty some children as a replication. In some sense we can now go back and look at our slopes and do similar analyses and see where we are. We have the same data collection method, and the one common method was the BRM and similar covariates. So we could in short manner take a look at that.

BRION COOK: How does your study fit into this concept of longitudinal studies?

MARK FARFEL: Well, the Repair and Maintenance Study has two control groups. Modern urban

lead paint free houses, which are being resampled environmentally and biologically every six months for two years and may be extended.

We also have a second group of previously abated houses that were more fully and comprehensively abated under Maryland standards several years ago. They are being followed for an additional two years at six-month intervals blood lead and environmental also exterior. And the main intervention homes are groups of older lead painted and lead dust containing houses in the City of Baltimore which are getting three levels of intervention in a randomized trial.

And the follow-up schedule is more frequent in those houses, and we are getting an initial baseline and immediate postintervention campaign, and then at two months, six months, 12, 18 and 24 for the purposes of measuring that reaccumulation rate, so we will have repeated measures over time across different seasons across different groups of houses.

BRION COOK: Where are you now?

MARK FARFEL: We have multiple campaigns

going on at the same time. We are close to completing all of the interventions. We have many of the houses at post and two month campaigns and smaller numbers at six and 12 month campaigns, but we can take a look at another initial data campaign in similar ways to the Rochester study. That's possible in summary to do that.

BRION COOK: We would like to include that in the data sets that we use to go down this validation and epidemiology back to.

STEVEN RUST: Do you have any idea at what point you would be in a position to do preintervention to postintervention blood lead comparisons and feel that you have the data in a state that you'd be comfortable with that?

MARK FARFEL: Yeah. Our postintervention blood leads is at two months, and we will probably be finishing the two-month campaign at the end of the calendar year. I think we are probably even more interested in the blood leads at six months.

STEVEN RUST: Right.

BRION COOK: I would like to ask Bruce a

quick question. Your follow up, are you doing blood leads?

BRUCE LANPHEAR: Yes. Blood leads and dust lead measurements, but a little bit more abbreviated this time.

BRION COOK: They are still composite? I mean --

BRUCE LANPHEAR: We are doing individual wipe sampling of the same surfaces, and then we did composite of the BRM, composite sampling of the different surfaces using BRM.

ROUTT REIGART: Just a similar question, on this resampling, is there any opportunity to get blood lead on a couple of days on the same subjects?

BRUCE LANPHEAR: Well, we have already done it except for one child with chicken pox that we couldn't get into the house last week. Could we go back on 10 percent of the cases and get another blood sample?

ROUTT REIGART: There is some day-to-day biologic variation that could give you a little bit of a handle of what's going on within your patients and sort of

help you tease out whatever lab variation is from whatever biologic variation.

MICHAEL RABINOWITZ: We don't want to wear out your welcome, I guess. I'm just surprised to hear there is a day-to-day variation of the whole blood lead measure or the size of it. I don't know how big it is.

BRUCE LANPHEAR: What we might do, the only reason I hesitate is because the most difficult part of all this is just drawing blood on the children. I know it's a simple routine procedure, but that's what's most invasive and difficult for the parents. Kids too.

What we did do, and we may be able to look at, is that in -- I don't know -- maybe 20 cases, 30 cases in the first phase of both indexed children and siblings, if we had an inadequate ferritin level but we had an adequate iron, we went back and got a second blood lead and ferritin and sent them both off, so that would be maybe a better approach and we would look at that.

BRION COOK: That's it.

MICHAEL RABINOWITZ: Okay. Warren?

WARREN GALKE: Okay.

MICHAEL RABINOWITZ: Tell us what we need to know.

WARREN GALKE: I guess now is the time for the wrap up and to give to the peer review panel their charge over the next month or so, which they have all agreed to in some sense or the other. Basically, for the audience that may or may not remember the rest of the process, what is going to happen is the committee is going to draft a report summarizing their observations regarding the Rochester study. They will prepare a draft of that report and it will circulate among the committee members.

They will then provide comments on the draft report to Mike Rabinowitz and a final version of the report will be prepared. Then it will be submitted to the center. And the center will essentially keep it and make it available to those people who want to see it. We will send a copy to EPA. We will send a copy to HUD. We will send a copy to CDC and then other individuals who are interested.

STEVEN RUST: How about Rochester?

(Laughter)

WARREN GALKE: Of course Rochester. As the target guinea pig, they could have assumed that they would get it.

And so basically what this document will be, we'll be keeping it in quasi-perpetuity. I don't forswear that the organization will live beyond the decay of the paper, but we will keep it. We will keep a compilation of all your written comments from the panel, the Rochester responses to those comments, the transcript that we've been so diligently trying to speak with one voice, and we've done reasonably well that way. We may have been a little bit mild in our enunciation, but at least we haven't had a dozen people speaking at once most of the day.

And basically this will provide the documentation of how the study was done, the findings, and subsequently the data set will be made available through the center for other researchers to access to do their own analyses. That data set will be documented, and I can't tell you an availability date yet. Bruce and I have to continue to talk about that. But this is what has been in

the plan from the beginning, and so that is another thing for people to keep in mind.

Also, we encourage thoughts of collaboration on this set or any extension of the work that the university has done, and you can either contact Rochester directly or contact the center with regard to any ideas for collaboration sharing and things like that.

Now, specifically, what I would like to see in the report are the following: An overall assessment of the quality of the study, the comprehensiveness of the reported data, and a logical presentation of whether the data were logically presented and are complete as such. That's in -- kind of like an overall assessment of the work.

Then, in specifics, there are several topic areas that I would like to see the committee's joint assessment of the quality of work. These are overall study design, the adequacy of the subject enrollment procedures. The successfulness of the recruitment process as documented. The environmental sampling and the biological sampling. The adequacy of the laboratory

quality control activities and the results.

Then a section on the appropriateness of the stastical analysis plan and the implementation of the analyses. I would like comments on statements that are supportable and also not supportable based on the data that are presented in the report. And then an assessment of the overall conclusions that the University of Rochester draws in the report.

Okay. That's my agenda. Now, I'll ask first --

CHARLES ROHDE: You want that tomorrow or --

(Laughter)

WARREN GALKE: No. No, no, no, no, no.

DAVID JACOBS: Day after tomorrow is fine.

WARREN GALKE: I would like to ask Dave Jacobs from the center, who's the deputy director, to see if I've forgot anything on the list.

DAVID JACOBS: The only thing I would add is specific recommendations for what Rochester should put in the final report. This is a sort of -- it says draft final, but it's an interim report really. Rochester will

take -- he's smiling. (Referring to Bruce Lanphear)

Rochester will take the recommendations that you provide and together with us and the agencies we'll determine how to go about characterizing the final report. So your recommendations will carry a great deal of weight in terms of what the final product that we deliver to the agency actually consists of.

WARREN GALKE: We were actually rather clever. We did not cut off funding for the university before the final report was done. We gave them an extra kick after they did all the field work. So they still are obligated to do some additional work. Right, Bruce?

BRUCE LANPHEAR: That's right.

WARREN GALKE: I did this because when I worked for EPA, my contractors always ran out when they had all the data collected, and the analyses never got completed, so this is a diabolical approach.

ROUTT REIGART: Could I ask a small procedural question?

WARREN GALKE: Sure.

ROUTT REIGART: We got some additional

information verbally from them that supplements what's in the report. Should we assume that will be written into the final report?

WARREN GALKE: If you feel that any of the verbal material should be included, please indicate that in your report. And it will -- you know, within the general rules of scientific authorship, et cetera, that will strongly be considered.

BRUCE LANPHEAR: Can I say something?

WARREN GALKE: Sure.

BRUCE LANPHEAR: Also, particularly if there is anything that you feel you need to have in order to make a data assessment that you think we can put together in the next couple weeks, we will certainly be willing to try to provide that inasmuch as that will help you be comfortable with your final report, and hopefully that could be by tomorrow.

WARREN GALKE: Okay. I think that covers the center's interests. Brion, and Rob, if you would be willing to add any additional thoughts from EPA's perspective on what you would also like to see in this

report.

ROB ELIAS: No. I have nothing further.

BRION COOK: When you said assessment of conclusions, I took that to mean were the aims of the study achieved and were the conclusions supported by the data that were collected.

WARREN GALKE: A better way of stating it. I appreciate that.

BRION COOK: And also, since the study was then conducted to support the 403 standard development, based on everything that was said together, if there were things that reviewers see in the study that are not able to support or can't support those standards, if you would put those in. I wouldn't go into great detail, but just talk about the ability of the data to support the 403 standard.

WARREN GALKE: Okay.

BRION COOK: Thanks.

WARREN GALKE: Steve, since you are the funding agency and major consumer of our research effort, is there any perspective that you would like to add to

this report?

STEVE WEITZ: Just wondering what the schedule is.

WARREN GALKE: Basically, the final report from the committee is due at the end of July, I believe.

BRUCE LANPHEAR: The final draft or interim --

WARREN GALKE: No, it's their final report. They are supposed to have a draft report, and I must admit, I haven't looked at the contract in a couple of weeks, so I don't want to swear to it.

STEVEN RUST: My contract doesn't say anything.

CHARLES ROHDE: There isn't --

MICHAEL RABINOWITZ: On our contract?

WARREN GALKE: Yes. Your contract.

MICHAEL RABINOWITZ: No later that July 25 this year final from the review panel.

WARREN GALKE: What will happen is we will adjourn and the committee will have the room up until 5:00, or when any or all of them need to depart, to sit

amongst themselves and decide outline of the report, who might be willing to take which parts to prepare straw documents, and I'll make sure that everybody on the committee gets everybody else's addresses and phone numbers and fax numbers to expedite communication across the way. And I guess, Mark, since Scott already left, as a representative of the academic community, if you have anything beyond that.

MARK FARFEL: Yeah. One addition to the report may be if there's consensus on some of the next steps that were discussed.

WARREN GALKE: Okay.

MARK FARFEL: Future research next steps. I'm not sure there was consensus, but there were certainly questions about next steps.

WARREN GALKE: And then any additional comment from the public?

And any requests for information regarding the peer review process that we are in the midst of from the public, coordinate that through me, and I'll make sure that you get the materials that you are interested in.

And as I said, the center will retain a copy of the report as presented today and all the documentation as well as what the final report will be for a prolonged period.

Oh, by the way, one other critical thing for me to say is this does not preclude publication in the open scientific literature, and, in fact, this is just meant as a way of letting EPA have access to this data set in an expedited manner so they can include it in their rule making. We do intend to publish in the open literature.

Yes.

ALAN WHITTINGHAM: Will the raw data be available to us as the public?

WARREN GALKE: There will be a mechanism. I can't tell you yet exactly a target date on when the data can be requested, but it will be in the near term rather than the long term.

Anybody else have any other questions?

No?

Well, I want to thank everyone for taking their time to attend. I want to thank two people in

absentia. That's Ethel Bledsoe and Evelyn Bloomer from our office who jointly did 95 percent of the logistics work with the hotel and like. And I hope you all enjoyed the day. And thank you all.

(Discussion was concluded at 3:23 p.m.)

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CERTIFICATE OF NOTARY PUBLIC/REPORTER

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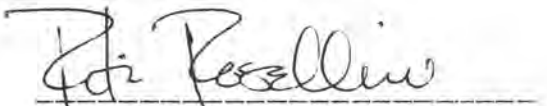
I hereby certify that the foregoing is a true and accurate record of the above-captioned proceedings.

In witness whereof, I have hereunto set my hand and affixed my notarial seal, this 3rd day of August, 1994.



Rita Rosellini, RPR-CM
Notary Public

My commission expires August 1, 1998.