The Secretary's Advisory Committee on

Infant Mortality,

US Department of Health and Human Services

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Olender Reporting, Inc.
1100 Connecticut Avenue, Suite 810, Washington, DC 20036
Toll Free: 866-420-4020

COMMITTEE MEMBERS

Jeanne A. Conry, M.D., Ph.D.
President
Environmental Health Leadership Foundation
Granite Bay, CA

Steven E. Calvin, M.D.
Obstetrician-Gynecologist
Minneapolis, MD

Edward P. Ehlinger, M.D., M.S.P.H.
Acting Chairperson of SACIM
Minneapolis, MN

Paul E. Jarris, M.D., M.B.A.
Senior Principal Health Policy Adviser
Health Transformation Center
The MITRE Corporation
McLean, VA

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Tara Sander Lee, Ph.D.
Senior Fellow and Director of Life Sciences
Charlotte Lozier Institute
Arlington, VA

Colleen A. Malloy, M.D.
Assistant Professor of Pediatrics (Neonatology)
Ann & Robert H. Lurie Children's Hospital
Chicago, IL

Janelle F. Palacios, Ph.D., C.N.M., R.N.
Nurse Midwife
Kaiser Permanente
Oakland, CA

Magda G. Peck, Sc.D.
Founder/Principal, MP3 Health Group
Founder and Senior Advisor, CityMatch
Adjunct Professor of Pediatrics and Public Health
University of Nebraska Medical Center
Richmond, CA

COMMITTEE MEMBERS - continued

Belinda D. Pettiford, M.P.H., B.S., B.A.
Women's Health Branch, Head
North Carolina Division of Public Health
Women's and Children's Health Section
Raleigh, NC

Paul H. Wise, M.D., M.P.H.
Richard E. Behrman Professor of Child Health
Policy and Society
Stanford University
Center for Health Policy
Stanford, CA

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Office of the Secretary

Washington, DC

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USPHS (ret.)

Director

Centers for Disease Control and Prevention

Atlanta, GA

Office of Planning, Research and Evaluation

Wendy DeCourcey, Ph.D.

Social Science Research Analyst

Washington, DC

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Director of the Office of Safe and Healthy Students
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Division of Policy and Data
U.S. Department of Health and Human Services
Washington, DC

Office of Women's Health
Dorothy Fink, M.D.
Deputy Assistant Secretary, Women's Health
Director, Office of Women's Health
U.S. Department of Health and Human Services
Washington, DC

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Chief Quality Officer for Medicaid and CHIP
Director, Division of Quality and Health Outcomes

Kristen Zycherman
Coordinator for the CMS
Maternal and Infant Health Initiatives
Center for Medicaid and CHIP Services
Baltimore, MD

Agency for Healthcare Research and Quality

Iris R. Mabry-Hernandez, M.D., M.P.H.
Medical Officer
Senior Advisor for Obesity Initiatives
Center for Primary Care, Prevention, and Clinical Partnerships
Rockville, MD

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Division of Vital Statistics
Centers for Disease Control and Prevention
Hyattsville, MD

National Center of Birth Defects and Developmental Disabilities
Cheryl S. Broussard, Ph.D.
Associate Director for Science
Division of Congenital and Developmental Disorders
Centers for Disease Control and Prevention
Atlanta, GA

U.S. Department of Labor
Elizabeth Schumacher, J.D.
Health Law Specialist
Employee Benefit Security Administration
Washington, DC

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National Institutes of Health

Alison Cernich, Ph.D., ABPP-Cn

Deputy Director

Eunice Kennedy Shriver National Institute of Child Health and Human Development

Bethesda, MD

Indian Health Services

Suzanne England, D.N.P., A.P.R.N.

Women's Health Consultant, Great Plains Area

Office of Clinical and Preventative Services

Aberdeen, SD

U.S. Department of Agriculture

Dexter Willis

Special Assistant

Food and Nutrition Service

Alexandria, VA

EX-OFFICIO MEMBERS – continued

Not Present at the Meeting
Dianne Rucinski, Ph.D., for CAPT Felicia Collins, Deputy Assistant Secretary for Minority Health and Director, Office of Minority Health, U.S. Department of Health and Human Services

Not Present at the Meeting
Diana Bianchi, M.D., Director, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health

Committee Staff

EXECUTIVE SECRETARY

Michael D. Warren, M.D., M.P.H, F.A.A.P.
Maternal and Child Health Bureau
Health Resources and Services Administration
Rockville, MD

ACTING DESIGNATED FEDERAL OFFICIAL

David S. de la Cruz, Ph.D., M.P.H
Acting Division Director
Maternal and Child Health Bureau
Health Resources and Services Administration
Rockville, MD

MANAGEMENT AND PROGRAM ANALYST

Michelle Loh
Division of Healthy Start and Perinatal Services
Maternal and Child Health Bureau
Health Resources and Services Administration
Rockville, MD

C O N T E N T S

P R O C E E D I N G S

DR. DAVID DE LA CRUZ: So, good morning, and welcome to the Secretary's Advisory Committee on Infant Mortality. My name is David de la Cruz, and I'm the committee's Designated Federal Official. So, in that role, I'll call this meeting to order.

Thank you all for your patience and flexibility with the late changes to the webinar platform. We did have a few dry runs with Adobe last week and based on some challenges and obstacles over the weekend, we made the switch to what we hope will be a more user-friendly Zoom platform, obviously still working out some -- some last-minute concerns and obstacles, but we'll get there.

So, I do want to acknowledge and thank my MCHB colleagues, who spent some time this weekend making the switch, especially Juliann, Vanessa, and Michelle, but also to our logistics contractor, LRG, for going really above and beyond on the weekend to make that happen, that's Vincent

and Dante.

So, considering how busy and full our agenda is and that we're running a little bit late already, I'll stop there. I do look forward to a very successful next couple of days, and I'll turn the meeting over now to our committee's acting chair, Dr. Ed Ehlinger.

DR. DR. EDWARD EHLINGER: Thank you, David. I'm glad you're with us. I know David is set to be detailed for COVID response somewhere in the United States. So, it's nice that he's going to -- he's still with us today.

So, good morning everyone and welcome to this SACIM meeting that is being done virtually. I'm Ed Ehlinger. I'm the acting chair, and I know that all of you have many other things to do. Here in Minnesota, we've got six inches of fresh snow, and if it wasn't for this meeting, I'd be out skiing on it. So, I know all of you are giving up some really important things to be with this meeting and I really appreciate it.

And this is a good time to be meeting. I

mean, so much has happened since our last meeting, you know, the COVID pandemic continues, and our hospital systems have been overwhelmed. We had an election. We had an insurrection. We had a trend -- a change in administration. Just so many things have -- have gone on. And that's -- so, that's -- so, I mean, that's the good news and the bad news that so many things have gone on that -- that we have to respond to some things that we have never had to respond to before. But the good news is that it gives us some opportunities to -- to make some differences in -- in this world.

So, I'm glad you're here, and I have changed all my clocks in my house to be Eastern time. So, I hope we can stay on schedule and I don't get behind an hour, and I really appreciate the people on the West Coast who are, you know, still getting their -- their morning cup of coffee.

But before I go to introductions, I, you know, I think some of you know that I always like to put things in the context of something that's

happened in the world and history on this day. And you may not know that on January 25th in 1890, Nellie Bly beat Phileas Fogg's time around the world by eight days. She went around, you know, Jules Vern and Phileas Fogg went around the world in eighty days. She made it in seventy-two days, and that's what she's most known for, and she finished that on this day in 1890.

But you may not know probably the most important -- we can't say the most important -- one of the most important things that she did was that she was a reporter -- and advocate reporter -- and she faked insanity to be incarcerated in Blackwell's Island in New York for a story that she was doing about how people were treated or how women were treated when they were incarcerated. And so, using the name of Nellie Brown, she pretended that she was from Cuba and she ranted that she was searching for some missing trunks and so, she got admitted as being insane to Blackwell's Island and she -- and it was basically a poor house, a Smallpox hospital, a prison for

the insane -- and an insane asylum, and she was there for ten days. And from that, she did some reporting that actually changed criminal justice in our society -- that work that she did. She said, "I would like the expert physicians who are condemning me for my action, which has proven their ability to take a perfectly sane and healthy woman, shut her up, and make her sit from 6 a.m. until 8 p.m. on straight-backed benches, do not allow her to talk or move during these hours, give her no reading, and let her know nothing of the world or its doings, give her bad food and harsh treatment, and see how long it will take to make her insane. Two months would make her a mental and physical wreck."

And this is relevant to us in terms of the things that she's not most well-known for that but has a big impact. And particularly today, when we're going to be -- when we know in our -- in our country we have more people incarcerated than any other country in the world, and we're going to be talking about stuff that's going on at

the border later this afternoon. So, I think it is relevant to our thinking about how we can actually make a difference. This may not be the most -- SACIM may not be the thing that you're most well-known for, but we really can make a difference. And Nellie Bly says, "I've always had the feeling that nothing is impossible if one applies a certain amount of energy in the right direction. If you want to do it, you can do it." I think that's going to be the charge for us today. If we want to do it, we can do it, and we have an opportunity to make a difference.

So, with that, I'm going to go around and do some introductions, and most often, the moderator says here's a question you should answer. There's so much going on that it would be sort of presumptuous of me. So, let's just -- let us know who you are and if there's one thing that you want to share sort of briefly, that's what's going on relative to our work here, let's do it.

So, let's start out. I'll go down my list, Jeanne Conry.

DR. JEANNE CONRY: Good day. Jeanne Conry with the American College of Obstetricians and Gynecologists. I'm past president of ACOG and incoming president for the International Federation of Gynecology and Obstetrics. So, I'd like to bring a US view to the world and sometimes the world view to SACIM. And I'm most excited that we're going to be talking about the environment tomorrow. So, I look forward to tomorrow. Thank you.

DR. DR. EDWARD EHLINGER: I'm looking forward to that also. Steve -- Steve Calvin.

DR. DAVID DE LA CRUZ: Dr. Ehlinger, this is David. Can I jump in real quick? So, we did -- we did arrange to get captioning, closed captioning.

DR. DR. EDWARD EHLINGER: Excellent.

DR. DAVID DE LA CRUZ: So, for those folks who need it, there's a little button on the bottom that says closed caption, please click that. I apologize for interrupting, but I wanted to grab that and make sure you all knew that.

DR. DR. EDWARD EHLINGER: Right. Thank you for that work. Steve.

DR. STEVEN CALVIN: Sure. So, Steve Calvin. I'm in Minneapolis as well as Ed. I'm a maternal fetal medicine specialist. I work with midwives and I'm really interested in improving maternity care, especially for the most vulnerable populations, and I am very excited about the opportunities that are arising or around now.

DR. EDWARD EHLINGER: Paul Jarris.

DR. PAUL JARRIS: Thank you. I'm Paul Jarris. I am the chief medical advisor at MITRE Corporation. We're a nonprofit that operates the Department of Health and Human Services federally funded research and development center and over the past year, we have built a system that we're now working with CDC on to facilitate the epidemiologist monitoring actively monitoring people in isolation and quarantine. We right now have about -- we cover -- the jurisdictions involved, there's over 700 of them and they cover about 40 million Americans and we monitor about 2

million people.

But the real -- two things to say are the real interest here is having a tool that can be stood up on day one of the next outbreak. So, it is agnostic to the disease that we want it there and ready to go so we don't have widespread community problem.

So, one thing I'll say relevant to some of this work though is we do capture -- in the database, there is the ability to capture racial, ethnic, and sexual orientation, gender identity information. And I have to say I'm -- I was quite surprised to see how infrequently that is being captured. It's just being left blank and passed, and I think this may be a reflection on people's comfort in asking about these issues. So, we may have some work to do.

DR. EDWARD EHLINGER: Great. Thanks, Paul.

Tara -- Tara Sander Lee.

DR. TARA SANDER LEE: Hi. Thank you. Great to be here this morning. I am the senior

fellow and director of Life Sciences at the Charlotte Lozier Institute just located outside of Washington, DC. But because of COVID, I am in my home town and state -- the state of Wisconsin.

So, my -- I have experience as a Ph.D. in the sciences but also working in various medical complexes studying pediatric disease and am interested in policies and practices that will protect the health and lives of women and children. I am particularly interested today to talk about COVID-19 and the vaccine -- very exciting news how we have vaccines that are now available for use. So, I'm very interested in those conversations that we'll have and how to use vaccines and get them into the hands of every woman and help protect their health. So, thank you.

DR. EDWARD EHLINGER: Great, welcome.

Colleen -- Colleen Malloy, and if you could turn on your video, that would be great.

DR. COLLEEN MALLOY: Yeah, can you -- can you hear me?

DR. EDWARD EHLINGER: I can hear you. Yes, I can.

DR. COLLEEN MALLOY: Yeah. I'm just -- I'm not -- I'm almost to my video. So, I'll do this by audio and then I'll switch to video. I had to take my mother somewhere this morning.

So, my name is Colleen Malloy. I'm a neonatologist. I work for Northwestern University in Chicago and Lurie Children's Hospital. I also am nearing the end of my pursuit of a master's in health informatics degree, which has been really illuminating in terms of what we can offer from maternal medicine standpoint and my interest is related to just kind of keep bringing it back to improving the health of infants and babies, which is in the title of our mission of the Advisory Committee for Infant Mortality and keeping kind of the scope of this committee focusing keeping like infants and babies in the forefront of our minds, I think is really helpful because there's obviously so many great wonderful things we all want to accomplish with our lives, but this

particular committee is really -- the purpose of it is to focus on infant mortality.

So, I'm happy to be here, and thank you so much.

DR. EDWARD EHLINGER: Great, and we look forward to seeing your face on video eventually.

DR. TARA SANDER LEE: Yes.

DR. EDWARD EHLINGER: Janelle Palacios is not joining us today. She has some family obligations. So, she won't be joining us.

Magda.

DR. MAGDA PECK: Good morning. This is Magda Peck. I'm calling in from Richmond, California. I am an independent maternal and child health and public health consultant with MP3 Health Group, also academically affiliated with the University of Nebraska Medical Center in the Departments of Pediatrics and Public Health and the founder and senior advisor to CityMatch, the national organization focused on health equity and women, children, families in America's cities.

I also want to just add that more

recently, since the last SACIM meeting, I've been participating as a liaison informally to the Satcher Health Leadership Institute at Morehouse's Health Equity Task Force, which is designing a health equity data tracker. So, Paul Jarris, you and I can have some offline conversation. But as the lead for SACIM's Data and Research to Action Workgroup, the DRAW Group, the idea of strengthening the capacity and access and robustness of data particularly to look at racial disparities and health equity is a primary focus.

And I am coming today also refreshed around the possibility of better data to address racial equity in the wake of the new presidential executive order.

I want to just add one more thing in that the other part of my portfolio is about a different kind of data -- the data of story and the power of story-telling and Hearing Her stories. So, I want to thank Ed and CDC and Wanda Barfield around Hear Her and the Voices of humans who can tell us about the lived experience is a

qualitative data that we must listen to to inform our work.

Glad to be back for SACIM and thanks for the opportunity to serve the nation.

DR. EDWARD EHLINGER: All right. Thanks, Magda, and thanks for your work with the Satcher Institute and representing SACIM on that. That's really important.

Belinda Pettiford.

MS. BELINDA PETTIFORD: Good morning, everyone. I'm Belinda Pettiford. I'm in North Carolina. I'm head of Women's Health here, which is part of our state-qualified agency. I'm also a board member for AMCHP and the National Healthy Start Association. So, I also feel good about supporting the work of those two entities.

And Ed, I would love some snow here in North Carolina. I'm not sure we're going to get any. So, if you would care to send yours, we would -- Belinda would like to have some. I don't know about the rest of my state.

Our number one priority right now, of

course, is vaccine surge in our state. So, it's an all hands-on deck process. So, I'm really excited to have on the agenda the work around COVID-19 and specifically the vaccine, how it's impacting pregnant women and their children, but also individuals of reproductive age, which would include men and women and any possible side effects that we may anticipate there because those are the types of questions we're getting here in our own state.

So, I look forward to working with everyone. I'm always excited to be part of the Health Equity Workgroup. I look forward to meeting with them later today. So, good morning, everyone.

DR. EDWARD EHLINGER: Welcome, Belinda.

Paul Wise is not going to be with us this morning. He will be joining us this afternoon. He has -- he's been working on the border, which he'll be telling you about, and they've got some release of data -- some public release of data that's going on this morning. So, he's at a press

conference doing whatever he's doing related to the data. So, he will join us this afternoon.

I'm not sure all of which Ex-Officio members are on. So, I'm going to take this risk and say if you're an Ex-Officio member, just jump in and introduce yourself.

DR. MICHAEL WARREN: Good morning or good -- I guess its good morning still for everybody. Michael Warren, I'm the Associate Administrator for the Maternal and Child Health Bureau at HRSA.

DR. ALISON CERNICH: Good morning. Alison Cernich, I'm the Deputy Director for the Eunice Kennedy Shriver National Institute of Child Health and Human Development at the National Institutes of Health.

DR. CHERYL BROUSSARD: Good morning. I'm Cheryl Broussard. I'm an epidemiologist at CDC and the Associate Director for Science in the Division of Birth Defects and Infant Disorders.

MS. JOYA CHOWDHURY: Good morning. This is Joya Chowdhury. I'm representing HHS Minority -- Office of Minority Health.

DR. DANIELLE ELY: Hi, I'm Danielle Ely. I manage the Linked Infant Mortality File at the National Center for Health Statistics.

DR. EDWARD EHLINGER: Anybody else from Ex-Officio? And I know -- and Michael Wise, as part of the staff was there, and -- and Michelle Loh is on. Michelle, do you want to say hi or Vanessa Lee, one of their staff helpers, and introduce yourself?

MS. MICHELLE LOH: Hi, this is Michelle. Hello, everyone. Nice to see you all, and it's great. Thank you.

DR. EDWARD EHLINGER: Yeah and thank you for all of the information and then keeping us on track. I appreciate that.

MS. MICHELLE LOH: You're welcome.

MR. JULIANN DESTAFANO: Hi, this is Juliann. Welcome everybody and thanks for being here. I look forward to a great meeting.

MS. VANESSA LEE: And good morning, this is Vanessa Lee, also with HRSA and MCHB. Happy to be here and offer any support. I oversee the

Infant Mortality COIIN as well as help with SACIM and some other infant health activities in the division.

DR. EDWARD EHLINGER: All right. Anybody else from MCHB? All right. And I know there are a bunch of other folks who are on this call, and I think that they will be -- they may be speaking later on and they will introduce themselves or will get introduced at that point when we get to that point in time. So, thank you all for -- for being here.

I'm looking -- you know, I really packed a lot of things into this meeting. So, we've got a lot of things to cover and -- and just to set the stage, I mentioned that a lot of things have changed. We have a new administration and they're dealing with a lot of issues that we really want to know about, and we want to know the approach that they're taking. But I think we may be at a situation where our federal partners here are also waiting to get some clarity about where -- what direction they're going to go. So, we may have

some questions that they won't be able to answer. That doesn't mean we shouldn't ask the questions, but don't be surprised because we don't have an HHS secretary, you know, confirmed yet. We don't have clarity on a whole lot of things that are coming out of this new administration.

So, this meeting really is to set the stage to gather a lot of information so as things start to clarify, what are our opportunities to move an agenda forward so that when we have our next meeting, probably in May, we will have much more clarity about the direction that we're going to go.

So, with that as a background, let's call for approval of the minutes. I know we have the -- the 508-page briefing book -- I hope everybody got it and read every page of that -- yeah, right. And as you'll note, the minutes are, you know, almost word-for-word transcription. What we're trying to do is with the help of MCHB to actually try to get the minutes to not be so word-for-word but actually reflect the content in a little bit

more succinct and useable format. We're hoping to work on that and I know David and Lee have been worked on that. David, any -- any update on how we might be able to do that in the future? Is that something that we can look forward to?

DR. DAVID DE LA CRUZ: It is something that we continue to work on. We are committed to making sure that there is a difference between meeting minute summary minutes and the transcription, and we want to make sure that they are -- they tell the story of the good work that you've done during the meeting, but if there's a need for more detail or more specifics, they can always go back to the transcription or to other documents. So, we have some new folks at our logistics contract and they are being very helpful in understanding of how we want to best adjust these as we move forward.

DR. EDWARD EHLINGER: Great. Given that, does anybody want to make a motion to approve the minutes that we have from our September meeting?

DR. STEVEN CALVIN: I move to approve the minutes from the September meeting. Steve here.

DR. EDWARD EHLINGER: Is there a second?

DR. MAGDA PECK: Second from me, Magda.

DR. EDWARD EHLINGER: All right. Any discussion?

DR. MAGDA PECK: Just to say thank you for the detail. This is -- you know, as someone who co-leads one of the working groups, it is very helpful to be able to have this as background. So, sometimes the timeliness of it is also something that can -- you can be more informative. But thank you to the staff support.

DR. EDWARD EHLINGER: All right. Any other comments? If not, all in favor signify by saying aye or raising your hand.

[CHORUS OF AYES.]

DR. EDWARD EHLINGER: All right. Anybody opposed? All right. The minutes are approved.

Well, let me -- and before we get into our presentations, let me just go over sort of the

objectives for this meeting. I gave you a little bit of background in terms of, you know, we may not be able to get all of the information that we want just because of the transition that's going on and where we are in terms of a new administration. But I put together some objectives for this meeting that I think are really important.

Back when we first started, we really were focusing -- we said -- over several meetings, we said we wanted to focus on equity, that we wanted to be centered to all of the work that we do or our North Start, however you want to put it. You know, we're going to center around equity. And in our discussions about that, we really identified that systemic structural racism is at the core of much of the inequities that are there. So, the question was, should we have a session on, you know, on racism. And I thought no, let's not have a session on racism, but let's build it into our conversations in every one of the areas that we have.

When we talk about the Maternal Health Initiative, when we talk about COVID, when we talk about health on the border, when we talk about environmental conditions, let's keep in mind the racial implications, the structural -- the policies that have been put together that have really disadvantaged some populations over another. So, that's going to kind of run, I hope, through the entire discussion that we have today and tomorrow.

Also, in terms of that, we're always wanting to have essential partners. If we're not building capacity to change things, building capacity of our federal partners, building capacities of our communities, we're not doing our work as well as we should. So, we're always looking for partners. Who do we bring at the table? Whose voices should we hear? So, that's also going to be part of our thinking as we walk through these things.

Certainly, we're going to be looking at the challenges and opportunities of COVID, and we

have an opportunity to, I hope, after we get some information, if there are new things that we want to advise at this point in time, I hope that we're going to do that, and I look to our -- I know Steve has been working on some stuff, and so, that we might be able to actually come up with some recommendations in addition to what we had back in June.

So, that's, you know, really looking at updating on COVID since that is front and center of almost everybody's conversation, certainly you're in Minnesota, but I suspect everyplace else, you know, the headlines in the paper are always about COVID, how many deaths, how many hospitalizations, are we overwhelmed, who is getting the vaccine. And particularly for us, how are the vaccines coming out in terms of pregnant women and women of reproductive age and how are the -- is the disease affecting infants and mothers in our society. So, that's our second objective, just really kind of get an update and more depth in terms of our work around COVID.

The third objective is to establish a framework and strategies to execute our charges. We do have a new administration. So, that gives us some opportunities to really recalibrate what we do with an administration. I want SACIM to be more visible. I want to have SACIM to be looked to as a resource that this administration and the federal agencies can partner with. That is one of the reasons why I wanted to have us look at that initiative on maternal health because that was put together without input from SACIM, and I want to make sure that we know what's going on, that we can help facilitate any kind of initiatives like that, and also learn from initiatives like that so that we can actually move forward.

And also, in that objective, I initially had said we were going to be working on bylaws as sort of the practical stuff. Those are still getting vetted. They have to be -- they have to be run through the HRSA lawyers, and they haven't been able to do all of that. So, even though I brought up bylaws over the last several meetings,

we're still not to the point where we're going to be doing that.

So, those are the things that I hope we accomplish. You know, we've got our particular -- in addition to COVID and the initiative on maternal health, health at the border and environmental contaminants or environmental conditions and how they impact. These are huge issues -- current issues that we need to be looking at. And so, I want to get some background information. We've not spent a lot of time on these issues in the past, but I want to really focus on them now to see how they fit into our agenda. Are there things that we need to do right now, or how do we use the information we gain today to set the stage for further action down the road?

So, with that, let us move into our regular agenda unless there are some questions or comments about the objectives for the meeting. Magda.

DR. MAGDA PECK: Yes, Ed. I noticed in

the third area, there is look at the praxes from the workgroup, and I know that the charter goes through 2021 and some recognition that the membership is robust but could be expanded, and I'm just wondering as we come to tomorrow afternoon and what we can do. Will there be time to refresh our sense of timing about the charter and the reports from the -- and report that we said would come from each of our workgroups and then the membership of SACIM itself?

DR. EDWARD EHLINGER: Yes. That will be -- when I sort of referenced that obliquely in terms of our practice, our objectives, or organizational structure. So, some of us, we're going to review the terms of our appointments. For example, my term, and I think many others, ends in May of 2022. We -- our charter needs to be refreshed in the end -- or at the end of the summer, and I would like to have Michael and David work with us because I want to actually embolden our charter so that we really become much more proactive, much more visible, and that we actually

get some resources. It's different than our charter, but I also want to work with MCHB to try to free up some resources so that we have more dedicated staff for the work of SACIM, because I think that's -- a lot of times, you know, all of us are volunteering on this committee, I mean, even though we -- I guess we get paid as federal employees, whatever the amount is, but basically, this is a volunteer effort and having staff that would be dedicated to SACIM would be good. So, I'm hoping to bring that up in our discussion at the end of the day tomorrow.

Any other comments? Questions? All right. So, next, we're going to look at a video from the Hear Her Campaign of CDC, and this comes from the fact that over the last couple of meetings, I have asked to have Voices from the Community, you know, particularly we've had women come forward and share their stories, and it's been difficult to find individuals who are willing to come forward, feel comfortable coming forward, and who can afford you come forward. You know, we

had some women on the border who would have loved to have come and talk, but they didn't feel safe sharing their stories. But I've had feedback from members of this committee and from actually the people who have testified and shared their stories, but this is an important thing to do. They really appreciated it, and it's nice to hear that. And as Magda talked about her storytelling, just hearing these 5-minute stories from women throughout the country is really important.

We do have a couple of stories that will lead into our environmental health section tomorrow, but we don't have individuals who come forward. So, we're going to use the Hear Her Campaign to set the stage for our discussions. But I challenge you or encourage you to look around your communities, the people you work with, to see if there are women or men who can come in and tell a story briefly.

I'm also working with MCHB to make sure that we do this in a respectful way, that we actually compensate them in some way, shape, or

form for the work that they do so that many of these people are, you know, not well resourced and are also doing -- would be doing something on a voluntary basis. So, like the last time, we were able to get compensation for one of our storytellers last time, and so, I want to make sure that we set up a process for doing that.

So, be aware of the people that you work with, the communities that you work with, and as we start planning for our next meeting, trying to get some of these voices to come and be part of our meeting.

So, with that, let's do the Hear Her Campaign as one way of getting voices of the community.

[Video playing]

DR. EDWARD EHLINGER: I find these stories to be quite powerful and I know in the past when we've had women come, their stories have been powerful. Any thoughts that you might have as committee members on the importance of doing this? How important do you think it is and how do

we go about getting the voices of women at our meeting in a respectful and responsible way?

MS. BELINDA PETTIFORD: Hi, Ed. This is Belinda, and you know, you've heard me say it more than once before, I think this is some of the most critical part of our work because I think it centers us at the beginning of each of our meetings, but it also keeps us focused on the individuals that we're designed to support. I mean, this is why we're here doing this work. This is why there's a Secretary's Advisory Committee on Infant Mortality. It's so that we can make sure we're listening to the voices of the community and working to address their needs through the systems that we have access to. So, I think this is a critical part. I think we need to always have this at our meetings. We try to do that in many of our North Carolina venues, you know, with our Maternal Health Task Force that we stood up as part of our Maternal Health Innovations work. We make sure we have at least -- we have six perinatal care regions, so we have

at least six individuals with lived experience. One is a co-chair of our group because we think always having that in the forefront is the most critical piece, and we also think their time is as valuable as anyone else sitting around the table. So, we make sure we have resources to support their time, if they're traveling, to support their travel, if they need support with childcare, to support whatever their needs are to make sure that they can be an active participant. So, I think all of us should value this work and know how important it is to always listen to the voices of our community.

DR. EDWARD EHLINGER: Thank you, Belinda.

DR. PAUL JARRIS: Really nice models. This is Paul. I wonder, Ed, you know, whether SACIM could have a similar model where we brought people from the communities on and really supported them to be full committee members and speak up. I think we'd have a lot to learn. There is some -- in the health care sector, they

did do some what they used to call patient engagement, and there is some literature on how to do that and how to engage people in those meetings. So, it might be something to look at. Again, it would keep us honest.

DR. EDWARD EHLINGER: Right. And I do know that we made some recommendations to MCHB about potential things to look for new members because we, you know, only have about half of our members -- our allotted members -- have been appointed. Having some community voices as actually part of our SACIM would be something that I think really should be considered.

DR. STEVEN CALVIN: And I would add too, you know, Jeanne and Janelle and I having been in clinical situations, these stories really are heartbreaking. We, you know, maybe earlier in our career we might have ignored something, but these kinds of stories are just really instructive to say when somebody tells you that she is not feeling well, we can't ignore it. And I agree with Paul that we need to include these other

voices that can give us insight and the experience that mothers are having because it affects them and it affects their babies for sure.

DR. EDWARD EHLINGER: And I know some of you in clinical practice, community practice, actually have connections with some of these women. So, I would like to have you consider how we might be able to connect SACIM with those voices in the future. Magda.

DR. MAGDA PECK: let me also add the encouragement that SACIM make this a model for how to incorporate storytelling and the power of stories in the practice of maternal and child health and beyond. Specifically, that would mean that we have explicit ethics statements about the respect of voice and not be exploitative, that we offer the opportunity for capacity building so that she or he or they can find their voice and feel at ease in being able to share it. So, there is a capacity building piece that we can encourage and invite. This is what we're doing in Fetal and Infant Mortality Review and soon-to-be Child Death

Review, funded by MCHB, is explore how to bring up her voices and their voices and I know that's also been a huge part of Healthy Start and elsewhere.

And then the question of ownership -- whose story is it -- so that we can be very clear upfront that its primary storytelling and not secondary storytelling. So, the idea of a practice as opposed to episodic voices being heard is something that I would encourage us to do and I'd be glad to work closely with you on making that happen.

Final point, I think we tend to hear heartbreak stories -- stories of loss, stories of fear, stories of adverse outcomes. I encourage us to also lift up stories of strength, lift up stories when things did work, and have voices let us know when it is working for them in a way that leads to the best possible outcomes. And the balance of the portfolio of stories will be very important as we go forward so as to not just only hear disaster.

DR. EDWARD EHLINGER: Good point. I

appreciate that, and I look forward to working with you on maybe trying to develop those ethical guidelines for how we would use these stories.

All right. Anything else? Jeanne.

DR. JEANNE CONRY: I think what we're trying to do is put our raised hands to get attention with the little --

DR. EDWARD EHLINGER: Oh, good idea.

DR. JEANNE CONRY: Yeah. I agree with what everybody else has said and what I'd like to point out that I believe when you look at SACIM and the reason we've had obstetricians added to this after the first decade is that if we do not have a healthy mother, if we do not have a mother who survives, we've failed everything. We will have not delivered a healthy infant or possibly a mother and infant don't survive. So, these stories are just as important as what happens in the neonatal intensive care unit or some other location or the first month or time period of the baby's life. So, making sure that we're hearing moms say why they need good attention, why they

needed help, and bringing the breadth of those stories, I think, is absolutely critical to our mission. We want a healthy mom and healthy baby.

DR. EDWARD EHLINGER: Thank you. Colleen.

DR. COLLEEN MALLOY: Yeah, I thought's a really great campaign. I watched it when it first came out. The stories are great. Magda just added to hear the voice of the fathers, which I think is fantastic too. I would also think, I mean, I personally could think of a number of families that would be thrilled to present something about their experience with infants who have experienced different forms of morbidity -- not necessarily mortality. But along with what Magda said, I think it is great to hear the success stories also -- infants and families who have been kind of at the brink of situations and have survived that and have had great outcomes.

I think it's also important for the benefit of everybody -- the families, the providers -- if sometimes just a little bit of

reassurance that we're doing a lot of really good things. But I think, you know, these stories are fantastic. There is also, I mean, the depth of stories that you see in a neonatal intensive care unit is phenomenal. You see all walks of life. You see people at their most extreme moments of joy, sadness, the gamut. That's really why I actually really enjoy what I do because we treat everybody and it's a really special part to play in a family's life. So, just I agree completely with Magda to add that kind of the whole family situation.

Although, I think this campaign was focusing on Hearing Her because often times I do feel like the obstetrical side, we hear that a lot from mothers. I was, you know, kind of replaying where they say well, I was telling my OB this, I was telling my OB this, and they were kind of never heard or in situations where mothers have babies with prenatal diagnoses and they are saying I want to deliver this baby, I want to keep and maintain the pregnancy, and over and over again,

the obstetrician was saying you should terminate, you should terminate, you should terminate, and they really weren't hearing the mother who was saying I want to maintain this pregnancy and take care of this baby even knowing it might have problems. So, I think that that would be a great component to the Hear Her Campaign is to hear the families who have this NICU experience as well.

DR. EDWARD EHLINGER: Great. Yeah, thank you. Well, as you know, our committee is diverse geographically, professionally, the kinds of organizations we work with. That means you have connections with a whole variety of different voices. So, it would be good. That's why I will be calling on you as we clarify this a little bit more to get input from each of you on how we might be able to connect with the voices in the communities that you work with, the communities you live with, the communities that you interact with. So, it's a responsibility for all of us to bring those voices forward. So, thank you.

All right. With that, let's now move

into sort of the other kind of content and other voices. Michael Warren, our MCHB director, so, Michael give us -- come and update us about what's going on with MCHB. I'm sure that nothing much is happening and you're just waiting for something to do.

DR. MICHAEL WARREN: Always, always. Good morning. It is so good to be with you always. Happy new year. I appreciate the opportunity to give you some updates from MCHB.

The slides were showing, now they've disappeared. Okay, they're coming back. There we go. If we could advance -- I'm going to walk you through really quickly because I think the most important thing that I hope to be able to do is get your input on this last bullet, and it builds on our last conversation at the last meeting around infant mortality in Helping People 2030.

But I did want to give you a quick update on MCHB appropriations and then spend a little of time talking about the connection between Title V and infant and maternal health. One of the things

that Ed raised was that Title V had not been raised as a resource and there may not be some awareness, and so, it really is a tremendous resource and I wanted to share that with you. So, we'll be doing that and then again sort of recapping our presentation from last time around infant mortality and how we eliminate the racial disparity in infant mortality by 2030 and what's your input.

So, on the next slide, you'll see as we look at -- one more, yep, thank you -- look at our '21 appropriations. We have eleven different legislative authorities in MCHB, so eleven different sets of instructions in the law that tell us what to do. Many of those will look familiar to you. They're each represented as a different budget line and just some things to point out. We did get an additional $25 million in the MCH Block Grant line, an additional $2.5 million in Healthy Start, $1 million in Autism, $1 million in Heritable Disorders, and $2 million in Sickle Cell Treatment Demonstration Programs.

Importantly, we didn't lose any funding anywhere. So, all the other lines were flat. And so, even though we don't call them out, that's also important to note, and we are grateful for that.

So, within that $25 million that's noted for the Block Grant on the next slide, the Block Grant legislation includes both the Block Grant to states, and so, $5 million of that 25 goes to the Block Grant to states. But the Block Grant line also funds something called Special Projects of Regional and National Significance or SPRANS, a number of years ago AIM, the Alliance for Innovation of Maternal Health before it was really a thing and the bureau thought we really need to invest in this, this is an opportunity. Because of the good work that has been done, we were able to get a $4 million increase for AIM this year. Also included in that SPRANS bucket, if you will, an additional $2 million increase for Sickle Cell Disease Programming that's on top of the $2 million for the Sickle Cell Treatment Demonstration Programs. There was a new

allocation of $10 million for Regional Pediatric Pandemic Network, a new $3 million for a Nationwide Maternal Mental Health Hotline, and a new $1 million for an Adverse Childhood Experiences study.

So, the budget just recently passed. So, we will be working on those new funds as well as the places where we got increases to implement those moving forward. But I wanted you to have a head's up and an awareness about that and to be able to share that good news.

We can go to the next slide. Also, in the appropriations, sometimes there's other language that directs us how to administer our programs. We were excited to see there were provisions included for MIECHV, the Maternal, Infant, and Early Childhood Home Visiting program that allows us to use MIECHV grant funds to provide emergency supplies that families may need. So, in the course of the pandemic, it's become very apparent how critical home visiting is and that relationship to meet families where they are,

but also to be able to provide families with basic supplies that they need to take care of themselves and stay well during the pandemic. So, now legally, we can use those grant funds to do that.

We can also support virtual visits and there were some provisions in the law that really specified that a virtual visit counts the same as in-person visit and there was allowance for funds to be used to help families acquire appropriate technology to be able to participate in virtual services. So, it's one thing to have a home visitor who has a tablet or a tool; it's another to make sure families have the resources to be able to connect in that way as well. Next slide, please.

So, I'm going to move through quickly the Block Grant to States. Some of you know a lot about the block grant, some of you less, but I wanted to make sure everybody has this foundational knowledge as we think about levers that we all have to move this work forward.

So, if you'll click a couple of times, I

think the slide has some animation on it. Just the foundation of the block grant. So, the block grant is different from a categorical grant in that it really is designed to gives states maximum flexibility, and there are relatively few strings. So, states have to spend at least 30 percent of the funds they get on children and youth with special health care needs, at least 30 percent on primary preventative care services for children, and they can't spend more than 10 percent on administration. Beyond that, that's it. Those are the strings that they have from the federal government. That gives them great flexibility to build their block grant around what the needs and priorities of their states are. So, every five years, they do a comprehensive needs assessment. They've just don't those this past year. Hopefully, in your states, you were pulled in as subject matter experts in those. They engage a broad group of stakeholders and identify through that process what are their state priorities, what are their capacities, what are the emerging issues

they need to deal with. The needs of kids and families are different in Oklahoma than they are in Oregon. They're different in New York than they are in Texas. And so, the block grant structure in this periodic needs assessment allows states to see what their own needs are and how to design a program that's responsive to that.

So, once they do that assessment, they build an action plan. And then on an annual basis, they describe what are the activities they've done at the state level related to those priorities? They report on a series of performance measures, and we'll talk about those in a bit. And then, from an accountability standpoint when they do that, they meet with a federal project officer once a year, and that team also includes external subject matter experts at MCH who come together to provide a review. One of the things that's been particularly exciting this past year, we switched to virtual reviews rather than in-person reviews because of COVID. What that allowed us to do is actually increase the

number of family reviewers and so, to the point earlier about getting consumer voice and hearing the voice outside of those who are normally at the table, those family reviewers are incredibly helpful. And I will tell you as a former State Title V Director, when you're sitting across the table from your reviewer, it's a big deal, and when you add a family member to that mix, it really holds you accountable because you can say you're engaging families, but that family member is able to really ask those tough questions and assure that you are. So, again, this mix of flexibility and accountability makes this block grant very different.

On the next slide, you'll see the performance structure. And so, ultimately what we're trying to do is move a series of national outcome measures. I picked infant mortality because that's what this committee is focused on. But if we'll click again, what you see is that, you know, those measures are lagging measures, right? We count that once the outcome occurs --

it's often a year and a half or two years before we've got data at the national or state level, and we want to know more quickly, are we moving in the right direction.

So, for each of those national outcome measures, there are a series of national performance measures that are more leading indicators, recognizing that if we make movement on these performance measures, we are likely to move the needle on the outcome's measures. So, in the case of infant mortality, we look at performance measures around safe sleep position and smoking during pregnancy and breastfeeding, for example, and those are -- those are national performance measures, but we have state-level data on that, so state partners can look at that.

But if you go one level further down, if we click again, states can actually -- they implement these -- or select these national performance measures that align with their priorities. But they actually implement the state action plan. So, what do they do to drive those

performance measures? So, for example, if they're trying to improve breastfeeding initiation rates, maybe they work with hospitals in their states on implementing breastfeeding promotion and support policies. If they're trying to address safe sleep, maybe they implement programs to train parents and caregivers on safe sleep. But these activities really, really help move this work forward at the state level and drive these national performance measures. Next slide, please. One more, thank you.

So, just to give you a sense, I mentioned the states pick their priorities. In the area of maternal health, sixteen states in this most recent cycle noted that a priority is reducing maternal morbidity and/or mortality. Six states specifically called out reducing disparities in maternal morbidity and mortality. In the space of infant health, twenty-three states noted that reducing infant mortality is a priority for them, twelve listed improving perinatal and birth outcomes as a priority, and then eight listed

disparities in birth and infant outcomes as priorities.

So, just to give you a flavor, lots of states have recognized a need and are working in this space, which really allows us to amplify this effort nationally. And when I say states, I should point out we're talking about states and jurisdictions. So, this is the fifty states, DC, as well as the territories. Next slide, please.

I mentioned the national performance measures earlier. So, again, we're trying to improve really, really big measures like infant mortality, maternal mortality, maternal morbidity. But those performance measures really drive the work and allow states to measure what they're doing. And so, this just gives you a flavor of performance measures that are related to infant and maternal health. So, forty-seven states picked the well-woman visit as their -- one of their performance measures. Forty-two picked breastfeeding, another thirty-six-safe sleep, and you can see as you go down the list, the different

performance measures that states have selected. So again, their action plan is aligned around these performance measures. They're measuring these performance measures on an annual basis that ultimately, as we make progress there, should result in changes in those national outcome measures as well. Next slide.

Just to give you a sense, I want to walk through -- so, with each click, we're going to see some state examples pull up that really drills down to what folks are doing at the state level. Again, state-level work that influences those national performance measures.

So, in Massachusetts, they're drilling down to look at the percentage of cases reviewed by maternal morbidity or maternal mortality review committees within two years of maternal death, recognizing that if we don't have timely data, it's not very useful to us. We need those timely reviews to be able to move forward.

In New Mexico, they're looking at the proportion of eligible families receiving a plan

of safe care for substance-exposed newborns. So, these give you a flavor of maternal and infant health outcomes.

In the US Virgin Islands, they're looking at the percentage of women who enroll in prenatal care in the first trimester.

Wisconsin is looking at the percentage of women receiving what they call a quality postpartum visit.

American Samoa, they're looking at percentage of newborns receiving a newborn metabolic screening.

Ohio is looking at the percentage of women 19 to 44 with an unmet mental health need or unmet counseling need in the past year.

And I think there may be one more -- yep. So, in Utah, they're looking at the percentage of mothers that report a doctor, nurse, or other healthcare worker ask if they were feeling down or depressed at any point during their prenatal and postpartum care experience.

So, again, these state performance

measures are things that really reflect what the states are doing actively in their action plan. Those will, in turn, drive those national performance measures that we talked about, which will in turn drive those national outcome measures. So, this builds this accountability framework for the block grant. Next slide, please.

People also talk about the block in terms of the services that we're able to provide in states. And so, I wanted to give you an example of some of the kinds of things that block grants fund in states.

Now, the old adage, you know, if you've seen one block grant, you've seen one block grant. It looks different in every state because it does meet the needs of those states. But this is just a representation of some examples of things that we can fund.

So, in the space of direct services, states can use their block grant to fund clinical services in local health departments -- everything

from prenatal care to well visits to oral health. They may fund tobacco-cessation programs. When I was in Tennessee, we jointly funded a 24/7 breastfeeding hotline with both WIC and block grant funds. So, direct services that are provided directly to folks in that state.

There's also a category of enabling services helping people to actually get to a point where they can use those direct services. So, health education, home visiting, case management, but also things like transport. So, if you're in a state that has a regionalized perinatal system, but maternal and neonatal transports can be funded through the block.

And then this last broad category, really the base of the pyramid, if we think about being able to move from an impact standpoint, it's really in this category. It's the public health services and systems building work. So, being able to implement the entirety of a newborn screening system, engaging hospitals on safe sleep policies that will change their practice, systems

that support risk-appropriate care, partnerships with Medicaid on policy changes or perinatal quality collaboratives. All of these kinds of things fall into that systems building bucket that's supported by the block grant.

So, hopefully that gives you a flavor of the breadth of things that are being done. I wanted to give you some specific examples. When people say what does the block grant do, sometimes it can be difficult to come up with your elevator speech on that. But the team came up with these verbs: lead, partner, convene, providing MCH data expertise, leverage, and fund as examples. And so, I just want to close this section by giving you some examples of what folks are doing in states in these areas in the space of maternal and infant health.

So, on the next slide, we'll use the example of leading. So, in Arizona, their governor identified maternal mortality as a breakthrough project for the state and actually tasked the Title V Program and the MCH Block Grant

Program with being the ones who developed and executed the plan. They are trusted and recognized leaders and are asked to move that work forward.

On the next slide, we'll talk about partnering. Maine coordinated with WIC. So, we know many families access services through WIC and so, they worked with WIC to conduct a survey to learn about behavior change as a result of doing safe sleep messages in a media campaign. It's so important to be able to hear that voice of consumers and think about how it drives our work moving forward. Next slide.

Convening. This is a really important role. A lot of states really use that what I call the bully pulpit of Title V to bring folks together. So, in New York state, they supported staffing and financial support for a series of listening sessions, where they engaged Black women in conversations about how to improve their experiences and outcomes with giving birth in New York state. That feedback ultimately found its

way into the Governor's Task Force Report where they were looking at reducing disparities in maternal mortality so that convening role supported that ultimate work.

We do a lot of work in states providing MCH data expertise. So, this example comes from Alabama where they convened their Children's Cabinet to look at infant mortality and they had a subcommittee that was developing the action plan. The State Title V Program actually funded program managers and MCH epidemiology staff to develop and implement strategies and data support for that plan to make sure that we had the right people with the right expertise at the table.

The next really key part of what states do is leverage their Title V resources. So, this example comes from Wisconsin, where they leveraged Title V-supported staff time and data products to be able to demonstrate the need for establishing a new organizational unit focused on maternal and infant mortality prevention. So, using that Title V expertise and products as the stepping stone to

move forward with this work.

And then finally, Title V provides funding. So, a couple of examples here in Minnesota, the Title V Program funded a county public health department to be able to implement a Birth Equity Community Council. In the state of Ohio, they had been using Title V and state funds to be doing pregnancy-associated mortality review early on so when the opportunity for new federal funds came specifically for that and for maternal mortality prevention efforts, they were well positioned to be able to move that forward.

So, I know that's a whirlwind. These slides will be available to you. But I wanted to make sure you had an idea of the breadth of things that states are doing and really how far they are leveraging their block grant dollars to support maternal and infant health. I'm happy to talk to you all about that more at any time.

If you're interested in learning more about the block grant, you can visit what we call our TVIS system, the Title V Information System

that's on the web. The link is there for you. You can see not only this national rollout, but you can look at state-specific profiles, what's going on in a given state, what are their priorities, how much did they spend on each population area? You can actually drill down and see their action plan and what are their five-year priorities and needs for the next needs assessment cycle. It's a real treasure trove of data and a great way to find out opportunities to work with folks in your particular states.

So, I want to switch gears and wrap up by talking about Infant Mortality and Healthy People 2030, and I'm going to move through these first slides quickly because we spent some time talking about them last time.

But, if you remember, we talked about this question of what would it take to achieve equity in infant mortality rates by 2030. On the next slide, we'll see the Healthy People 2030 target is 5.0 infant deaths per 1,000 live births, which is all well and good. But when you look at

the next slide, as you will see, we're already there for parts of our population. If we can advance one more slide.

So, for non-Hispanic white babies, Hispanic babies, and non-Hispanic Asian and Pacific Islander babies, we're already past that Healthy People 2030 goal. And there's no reason to believe that those populations won't continue to improve. In fact, we hope that they do. But the reality is if we don't do something different to accelerate equity, we're going to get to 2030 and have persistent inequities.

And so, our team looked at projections to say where do we think the populations that have already hit that target, where do we think they're going to be by 2030. We estimate that's going to be at a rate of about 4 deaths per 1,000 live births. And so, then we started to say what would it take to get everybody to 4, because as you'll remember, my colleague, Dr. Wanda Barfield, saying on the last call, we're not there until we're all there, and that really is our goal, to think about

how we bring everyone to the same rate. Continue to improve, but actually achieve equity for the first time ever.

So, if we go to the next slide, we want to ask the question where do we go from here. Ultimately, of course, we want to prevent every infant death possible. But the reality is there is a large and persistent gap between black and white infant mortality. And so, we need to accelerate those efforts to achieve equity now. It doesn't mean we don't continue to try to drive past 4. But we need to make sure we get to equity and we've got a great opportunity as we look toward this next decade with Healthy People 2030 goals.

So, with those questions in mind, these are the data we shared with you before. To get to 4.0, if we look at the additional deaths that we need to prevent, it's about 4,200 a year. So, 4,200 additional babies that we want to celebrate their first birthday every year. In context, we have over 10,000 babies born each day in the

United States. We're talking about saving an additional 12 babies a day. This is imminently doable for us as a country. Next slide, please.

So, we drill down to look at the state-level data. Again, you saw this data before. What you'll see is in three states -- so, Texas, Florida, and Georgia -- those three states alone account for 24 percent of all the deaths that we would need to prevent to be able to close that gap. What you'll also see is that in some of the states that are shaded lighter, the lift is relatively small, preventing anywhere from 1 to 4 additional deaths per month will get us there. But there is definitely geographic variability, and so we'd want to think about how we focus our efforts.

On the next slide, we really get down to drill down to the lower level. This is county-level data, and I want you to notice on the table, the very bottom row, three counties in the entire country account for 10 percent of all the deaths, 9 percent of all the deaths that we need to

prevent to be able to close that gap. But I think also importantly, if you look at those top three rows, 61 percent of all the deaths we need to prevent are in counties where we need to prevent one additional death a month.

So, the thought behind this, when you look at that number nationally and you say gosh, 4,200 deaths, that is a lot; it is a lot. But when you break that down to the local level, I want us to be able to look at county mayors or county managers, state legislators, state governors in the eye and say what do you mean we can't save one more baby every month in this county? Why can't we do that? What would it take to do that? So, that was our goal in breaking this down.

Clearly, if you're in one of those three counties where your lift is heavier, that's going to be a different conversation. But these are going to be locally designed solutions to be able to address this if we're going to hit that goal of saving those additional 4,200 babies.

So, the last slide that I have -- this was all stuff you had seen before -- but I want to spend some time with you all thinking what can we do to help achieve equity, and in the charter for this committee, one of your roles as a committee is to advise us on how we coordinate various federal, state, and local and private programs and efforts including implementation of Healthy Start, but also other federal initiatives. And so, we wanted to have some time to hear from you about directions we may consider with existing programs, new approaches that you may have ideas for us, communication strategies, key partners, anything you'd like to share, and this is not your only opportunity. Certainly, I'm available to you at any point and our staff is to hear from you. But I wanted to have this committee have an opportunity to be able to spend some time thinking about that in light of this goal of getting to equity by 2030 and thinking about how we save those 4,200 additional babies per year.

So, I will stop and open up the floor for

your thoughts.

DR. EDWARD EHLINGER: Thank you, Michael. And let me just, you know, while people are formulating their questions and their comments, I just wanted to go back to your presentation on this infant mortality piece and your Title V piece. You know, Title V has been around forever and we haven't really made very much progress in infant mortality disparities over the last forty to fifty years. And so, when you have states who are doing sort of their own thing, how do you evaluate are they doing -- how are they advancing equity, are they really focusing on equity, because at the local level, policies can, you know, seem appropriate for the general population, but they're not equity focused.

Similarly, how much innovation is allowed within Title V to address these -- really these huge racial disparities because obviously just doing more of the same of what we've done for the last forty years is not going to get us where we want. So, how do you -- how do you assure equity

focus and what kind of innovation is possible?

DR. MICHAEL WARREN: Both really. I'll start with the first one. So, the innovation is actively encouraged. States really have a lot of flexibility to do what they need to do and want to do to address their priorities as long as they fall in those -- within those broad funding buckets, so the 30 percent on primary and preventative care, the 30 percent on kids with special health care needs, and no more than 10 percent on administration. So, the action plans will look very different, and states really get to design those. They tell us about those. We provide technical assistance as needed, but the plan is really state driven. So, there's a lot of space for innovation.

I think one of the places where there's an opportunity is thinking about how we spread innovation that works, and so, how do we use our technical assistance investments to be able to identify those and share those?

With regards to equity, I think there are

a few things we can do. Every few years, we have the opportunity to rewrite the guidance for the block grant. And so, we ask states to report on things that are of interest to us or that we want them to really focus on. So, we can think about how we work that into the block grant guidance, how they are specifically addressing equity and eliminating disparities. We also have an opportunity, when we talk about those national performance measures and outcome measures, to get states to drill down. So, it's not enough just to look at that overall number. But you really need to look across populations.

And so, we published something called the Federally Available Data so we can go to the TBIS website. You can actually download a dataset that allows you to drill down, for example, by race and ethnicity across a number of these indicators.

We're also looking at ways where we don't currently have the ability to stratify in that way but we build the capacity to do that because that's so important. It's going to be key. If

we're going to get to equity, we have to have the data. We have to have the data in front of us stratified in such a way that allows us to know where we are. So, I think that's another place where we can continue to push.

DR. EDWARD EHLINGER: Other questions or comments? I notice that Colleen has her hand raised. I don't know if that's still from the past.

DR. COLLEEN MALLOY: That's a new question.

DR. EDWARD EHLINGER: Okay.

DR. COLLEEN MALLOY: For Michael, I was just looking at your map on the slide previous to this, and my question is really whenever I -- I don't know if you can put it back up there, but if you can't, you can't. So, when you're looking at geographically throughout the country and the entire rates of disparity in terms of infant mortality, does that correlate with the population percentages that are drawn on racial lines in those areas, meaning that there will be more

disparity in places where there are more -- so, like say North Dakota might not have a lot of black babies that die. Maybe they're not having that many black babies. So, that kind of -- would that graph correlate with population density in terms of the way people live, because I think it's -- I'm just trying to understand like is there something unique about certain states or is there a reflection of the population where if you have more people of a certain racial group, they would have more deaths in that group?

DR. MICHAEL WARREN: So, if we can go back one slide, please, to the state map, I think Dr. Malloy, what you're asking about -- so, the -- when we talk about rates and then we talk about raw numbers, it's important to distinguish between the two because you could have high rates and high rates of disparities in states where populations are low and just a few occurrences of any event, positive or negative, could move those rates in a big way. Is it possible to go back one slide for our logistics coordinator?

So, what you see though on those slides -- and if not, we'll make sure you've got them -- the blue dots actually represent raw numbers. So, those are actual numbers of deaths and the larger the size of the blue dot -- thank you -- the larger the size of the blue dot, the larger the actual raw number of deaths. So, this is not adjusting for population. This is looking at raw number.

DR. COLLEEN MALLOY: So, I guess what I'm saying like is would it, I guess, seem that, say Chicago, has a big blue dot -- there's a big African American there. So, would they -- would they have more black babies die than a state that doesn't have as many black people? Is that like what -- I'm trying to wrap my head around how does population -- like, would it make -- is it better data to make these dots kind of with the denominator of the racial proportion of that state? Would that help at all or is it --

DR. MICHAEL WARREN: So, this is where there are data folks who are far smarter than this

general pediatrician on this call. And so, I'll ask them if I start to go off in the wrong direction to save me. I've always thought you have to look at both. You can't look at rates in isolation, and you can't look at numbers in isolation. You really need --

DR. COLLEEN MALLOY: Yeah. No, I'd like to see both.

DR. MICHAEL WARREN: Yeah. So, I think that's -- and we can work to get you that at the state level. I think the caveat always with rate data, again if you're talking about a small number of occurrences -- so, if you're in a state that has small population and baseline, whether we're talking about births, deaths, you know, any vital event, a change in just a few numbers is going to really shift those rates. And so, that's important to know for the standpoint of like getting the rates to move in the direction you want. But if you're looking at disparities and closing that gap, again, lots of counties in the country need to save one additional baby per month

to be able to help us close this gap, but that's not going to get us there as a nation for those areas where the numbers are the highest. We really have to do a more focused concerted effort there. So, I think you've got to look at both.

DR. EDWARD EHLINGER: All right. Let's go to Lee -- you have your hand raised. Do you -- is yours a clarifying comment?

MR. LEE WILSON: Yes, it is. Thank you for your question and just to build off of what Dr. Warren has been saying, we have run these analyses in a variety of different ways. So, we have looked at the percentages, which would be reflective of -- so it would be proportionate. We have also looked at the -- so, that would be the prevalence, and we have looked at the incidents as well, which is where Dr. Warren was going with the large blue dots. So, the proportion of African American deaths may not differ significantly from a large population area to a small population area, but it may be, from an impact standpoint, much more significant to influence that large

population area because while the proportion of deaths might be the same, the number of deaths would be so much larger because the population is larger.

And for many of you, I'm just, you know, reiterating the general approaches that we're taking to looking at the data, trying to determine how best we prioritize the work that we're doing and the questions that we're asking of groups like you.

So, if we're going to address numbers like the Healthy People target and we want to, aside from just achieve the percentage goal, we want to bring equity those measures, how do we do that in a way that we could change the areas where there are few people but that's not going to change the overall rate in the country as much as if we're able to change areas where there are a large number of people. Not to say that we prefer one area over another or we're favoring them, but if we're going to make the change, how do we use our dollars most effectively?

DR. EDWARD EHLINGER: Thank you, Lee.

MR. LEE WILSON: So, we're looking at from proportionately -- we're looking at it from proportion and we're looking at it from population, and we can make other slides available to you.

DR. EDWARD EHLINGER: Thank you, Lee. Let's go to Magda, then Paul, then Belinda.

DR. MAGDA PECK: Thank you so much for bringing this back, Michael. I want to commit that the Data and Research to Action Workgroup of SACIM can be a good place working together with the other two working groups to get more refinement in our feedback to you. So, I want you to know that we don't ample time here, but we have a structure to be able to look at what you are proposing here. So, that's one point. Two more quick ones.

I put in the chat the unit of analysis is the unit of change. And so, getting to the county level given that Title V is a federal state partnership is wonderful. I certainly bring

thirty-five years of investing in CityMatch and other local partners and I think that this understanding how that state local coordination can be better, particularly with local public health agencies who can get beyond the county level to the city level to the neighborhood level, particularly as it relates to the social and environmental determinants of health and systems that manifest as racism. So, I just think local, local, local is how we're going to do it, and I would like to connect with you further and encourage investment in local capacity to augment what states can do.

Third and last point is thank you for acknowledging that you get guidance to say what's in your block grant. If I understood you correctly, there were six states that put in indicators relative to racial disparity and for infant mortality, and eight for maternal mortality. I just -- how can we possibly count on Title V data systems if it is not mandated to look at racial inequity in every state in its own

manifestation. So, I just think pursuant to the new executive order, which is -- which we'll be talking about later, addressing advancing racial equity, I would just encourage that Title V is well positioned to mandate a state -- across all states and territories a much more rigorous collection and use of data around racial disparity.

So, those are my three points, and I thank you for going further and encouraging you to be even bolder.

DR. MICHAEL WARREN: Thank you, Magda. And just to clarify, so, those states were states -- the eight and the six -- were ones that had elevated that as a priority. It does not mean at all that others aren't working on that. States often say okay, we're going to pick, you know, five to ten priorities but their breadth of the work is much larger. So, I do want to be -- I hear you and don't disagree that we've got the opportunity to move further, and I don't want to underrepresent that more states are working on

disparities.

DR. MAGDA PECK: And to see that every state action plan is explicitly addressing racial equity would be something that would be quite remarkable and essential to get us to 2030 with equity for all.

DR. EDWARD EHLINGER: Just as -- just as a sideline, that was one of the issues before -- before Title V got block granted. There were those federal requirements that -- that really led to a lot of change. Paul Jarris.

DR. PAUL JARRIS: Thank you. I just wanted to say I really commend MCHB and HRSA on how you manage the block grant. It really is the model for creating a balance between flexibility to local needs and accountability, and I know that it's what we've continually pointed to when we were talking to other agencies about things like the prevention block grant and things like that. So, thanks for championing, thanks for doing such a good job. I mean, I do share some of my modest concerns about, you know, how do we push a little

bit. But there's little -- little funds available to the states that allow them to meet local needs.

I also want to say I really appreciate your 2030 goal of closing or eliminating the racial disparities gap. I think it's a really important significant of leadership that you set this both in overall goal as well as a racial disparities goal.

One of the questions I have is as you get into more rural populations or populations where there's lower numbers, because of the rarity of infant mortality in those cases, what surrogate measures do we have? Like, for example, in maternal mortality, you know, if it's several maternal morbidity, it's common enough that you can systemically approach it. Are there corollaries in infant mortality or where it's less common that you can approach those surrogates that would prevent the mortality ultimately?

DR. MICHAEL WARREN: I think that's a great question. You know, two that come to mind for us to think about -- and again, there are lots

more people far smarter than me on this call -- I would think about things like preterm birth and low birth weight, which just proportionately are going to happen more than the number of deaths. We also know there are disparities in those as well. And so, that may be the kind of thing we could look at that would be representative enough that it's going to happen frequently enough you could see it at the -- the county or local level but also connected from sort of an evidence chain, if you will, to being able to move that larger outcome measure of decreasing death.

DR. EDWARD EHLINGER: All right. Belinda, you had your hand up. Did you take it down?

MS. BELINDA PETTIFORD: I did. My -- my comments were pretty much on point with what Magda was saying that I, you know, there is some concern about the smaller number of states that are really focused on equity, and I know, you know, we've had this conversation, I know, more recently in the AMCHP board meetings and specifically around the

Health Equity Workgroup of SACIM as well as AMCHP and I wonder how much of this -- or do we have a way of determining how much of this is that states are waiting for guidance on things that they can do. You know, is it a knowledge base or how much of this is political will? And I'm -- because I think it's a different conversation with states if they say we're wanting to focus on equity, but we're not quite sure what to do in our communities and our state versus they don't see it is an issue because they're not even looking at their data that way. And I think we need to spend some time really focusing on it.

I know one of the things that we talked about in the AMCHP Health Equity Workgroup -- and I don't know if Cheryl Clark or others are on from AMCHP -- was really around developing a compendium of what states are doing to address their equity issues around maternal morbidity and mortality as well as infant and birth outcomes, because we still hear from states on a regular basis. We hear from individuals on a regular basis saying

well, tell us what you're doing in your state and is it working. And I think we may be doing a lot of things, but I wonder do we know which of those things are actually working.

And so, I would love to know, you know, how much of this is that political will. People really don't want to focus on it, you know, it's the issues they have to deal with. I know in my own state, even though we have flexibility on the block grant, we can't submit our block grant without our general assembly signing off on it. So, there are times when we want to do things, you know, one way, but the general assembly puts another focus on it and while we may want to utilize funds to address equity, they may move those funds and say no, you need to use those to address another issue. So, it is a combination of all of those efforts.

DR. EDWARD EHLINGER: All right, and Magda, one more comment. Magda, you're on mute.

DR. MAGDA PECK: Sorry, I'm going to type it instead, and I did not put my hand back down.

So, I'll just -- it's -- it'll be coming in the chat for you, and I want to use our time well.

DR. EDWARD EHLINGER: All right, very good. Thank you all for your questions and comments. Michael, thank you for the presentation. You teed it up very well. This is a lot of work. These are some of the issues that were raised here are particularly relevant for later on this afternoon in your workgroups, you know. What are the things that you can come out with from the workgroups -- the Quality and Access, the Data, the Equity workgroups -- that can actually help inform the work that MCHB is doing around infant mortality in this area? So, I appreciate that.

All right. Oh, and welcome to Paul Wise. I'm glad to see you're on board. Introduce yourself, Paul Wise.

DR. PAUL WISE: Thank you. I apologize for being late. I'm Paul Wise, Professor of Pediatrics, Health Policy, International Studies at Stanford, and a member of SACIM. Thank you.

DR. EDWARD EHLINGER: Very good, welcome.

All right. Let's now move into the HHS Maternal Health Activities. This is something that, you know, we've got a bunch of presenters here. I know that in December, there was a kickoff for this initiative and it raised questions in my mind because I really wasn't aware of it until really close to when it actually happened, and I don't think many of the SACIM members were engaged in it in great detail. So, I wanted to just know what it was and how it came about and what it learned and where it's going and how SACIM can learn from what's going on with this initiative and how can SACIM be engaged with it. So, I will -- you will have, you know, Dorothy is going to be -- Dorothy Fink is going to be the first presenter and all of their -- the bios from all of the folks are in your -- your board packets. So, I won't go through those. So, I'll turn it over to Dorothy.

MS. DOROTHY FINK: Okay, great. Good

afternoon, everyone. Can you hear me?

DR. EDWARD EHLINGER: Yes.

MS. DOROTHY FINK: Okay, great. So, let me share my slides.

DR. EDWARD EHLINGER: You had it there for a second. Oh, there you go.

MS. DOROTHY FINK: Great. All right. Good afternoon, everyone, and we're excited to join all of you today and discuss more about what all of our offices are doing to address maternal morbidity and mortality. We have a significant amount of coordination that occurs across the federal government and we really appreciate all of your efforts in addressing infant mortality and you well know, infant mortality goes hand-in-hand with maternal health, maternal morbidity, and mortality.

So, let me go into presentation mode here. Okay. So, in terms of the Office on Women's Health, we provide national leadership and coordination to improve the health of women and girls through policy, education, and innovative

programs. To address maternal health disparities during pregnancy and postpartum, we are leading a number of initiatives aimed at improving the health of women over the life course.

We have all talked in great detail about the disparities in maternal health, but I would like to reemphasize them here in terms of thinking really about how there are disparities across race and ethnicity as well as across a number of other aspects that we'll get into as we go forward with this presentation.

Pregnancy-related mortality is two to three times higher for non-Hispanic Black and American Indian, and Alaska Native women compared to white, Hispanic, and Asian/Pacific Islander women.

Severe maternal morbidity is 1.5 times higher for a non-Hispanic Black and American Indian and Alaska Native women compared to white, Hispanic, and Asian/Pacific Islander women. And this is data from the CDC from 2007 to 2016.

Additionally, we'll be getting into some

of the work in our office that focuses on both maternal morbidity and mortality as well as hypertension and breastfeeding. But in terms of taking a step back and thinking about the disparities that really inspires our work, we also know from the NHANES data that black women ages 20-44 years have a prevalence of hypertension more than twice that of other racial and ethnic groups.

Additionally, pre-pregnancy hypertension has approximately doubled in the past decade and the rural urban gap has persisted. And this was a really interesting article that was just published at the end of last year that was based on data from the CDC Natality database from 2007 to 2018.

And then the last important point that I want to make is that fewer non-Hispanic Black infants are ever breastfed compared to Asian infants, non-Hispanic white infants, and Hispanic infants, and this is based on the National Immunization Survey data from 2017.

And so, when we look at all this data, we say that okay, well what are we doing to address

all aspects of this, and I can tell you that we also really monitor the messages that our office sends out in terms of connecting with women on our different social medial platforms, and earlier this past year in October, we had this new observance that our office leads. It's called National Women's Blood Pressure Awareness Week, and during that week, we had a number of different feeds, et cetera. And if you can believe it, one of the most popular ones was actually connecting breastfeeding to hypertension. It's just something that I think we don't often too. Often times we think of breastfeeding and hypertension as totally separate things. But we appreciate the impact that breastfeeding has on a lot of these chronic conditions that are now really impacting women during the years that they are getting pregnant and having events of both maternal morbidity and mortality.

And in talking with all of you today, you know, yes, we have a very significant focus on maternal health, but we really do appreciate the

impact on infant health. And so, we think about even preeclampsia as being one of those examples. How can we really get in there and think about how to impact hypertension control during pregnancy and even before that so that we don't have those long-term impacts.

And then on the next slide, you'll see more information about some of the work that we are doing in these spaces and in the upcoming weeks, we'll be really excited to announce the phase 1 winners of our Hypertension Innovator Award Competition, and in this project, it's a national competition to identify effective preexisting programs that care for people with hypertension where the programs could be or are already applied to women with hypertension who are pregnant and/or postpartum. And the goal of this competition was to really focus on racial, ethnic, and urban/rural disparities and to demonstrate sustainability and the ability to replicate and/or expand a program that provides effective monitoring and follow-up of hypertension for women

who are pregnant or postpartum.

Something that we found -- and I think this is not news to all of you -- is that so much of hypertension awareness work, of impletion work, policies, so much focus on women at later decades of life, and we really moved the pendulum to say no, we have to really be thinking about these conditions and addressing them through different policies and programs during pregnancy.

So, we're really excited to announce the twenty winners of this competition who will go on to phase 2 and phase 3, and our hope is that we'll have a network of incredible programs that really and truly address disparities in high blood pressure across our country.

The next slide goes into our Breastfeeding Innovation Challenge. And so, in this competition, we're really looking to identify effective programs that increase breastfeeding initiation and continuation rates and decrease disparities among breastfeeding mothers in the US. And this also builds upon a lot of the data that

we talked about in earlier slides looking at disparities in breastfeeding rates.

And in this challenge as well, we're specifically focused on having programs demonstrate that they have improved disparities and really decreased disparities. We are really excited to share that in working with challenge.gov, which is the site in the federal government where these challenges are posted, across the entire federal government, these were the most popular challenges when they were active in the past weeks. The deadlines have now closed for them, but that doesn't mean we're not still looking to engage with everyone who applied and to groups like yours to share the groups that make it to phase 1 and then there will be two more phases in the upcoming two years really looking at awarding plans for sustainability and replication and then in the phase 3, the final phase, awarding programs that have successfully replicated or expanded.

We appreciate that there are so many

incredible projects that go on across the US, but we don't always know about all of them, and a lot of them are hidden in communities and amazing in that community, but we appreciate that getting some networks together and I think another aspect of this that I think you all would be interested in is, you know, the breastfeeding community is a very well-established community. OWH, my office, has done incredible work with breastfeeding outreach over the past years. We definitely realize that we want the same to be for hypertension in the upcoming years, and we're going to be really excited to share more about what comes with these things as well as all of you as the awards are made.

I'll briefly go into a few other projects including our Postpartum Depression Survey and Campaign. We are pleased to say that our survey for this campaign has been approved and we're going to be really working as we implement the survey in this campaign to lower the barriers women face in talking to their health care

provider about symptoms of postpartum depression.

Another project that our office is leading is the Move Your Way Campaign with the Office of Disease Prevention and Health Promotion. You all are definitely familiar, I'm sure, with Move Your Way. That was implemented for everyone across the country, but we specifically wanted to focus on exercise and physical activity guidelines during pregnancy and have a great link that you can go to and share with your contacts regarding how we can share information that is evidence based about physical activity during pregnancy and postpartum and really think about impacting the outcomes such as gestational diabetes and hypertension. So, that was just released as well.

And finally, in the last part of my presentation, I'm going to talk a little bit more about our initiative to improve maternal morbidity and mortality data and drive clinical quality improvements and high-impact hospitals. I think even in my earlier slides today, you know, when we look at the data that we present, we say well, my

goodness, this data is from 2016 or 2017 even and it's hard to imagine it's already 2021, and I think some of the biggest challenges we have is how do we obtain up-to-date maternal morbidity and mortality data that will inform program planning and policy development for HHS.

So, we're really looking to fill the existing gap in information from government data sources and evaluate nationally representative changes in maternal morbidity and mortality over time and the impact of interventions on maternal health outcomes.

So, as part of this project, the data analysis in reporting, we're really going to be looking at different data and relationships that look at the data describing the impacts of both maternal and infant mortality that is nationally representative from standardized inpatient data and hospital discharge data platforms. And we will be excited to share with you and are happy to do it with upcoming meetings or in any platform looking at a national baseline of maternal/infant

outcomes from 2008 to present, the relationships between maternal and infant mortality, as well as cost analyses for maternal/infant mortality and morbidity, by impact by payer, hospital designation, and geographic region, as well as developing heat maps of SMM and mortality in the US to include racial, ethnic, geographic, and other associated disparities.

We appreciate that a lot of our data is either maternal or infant, and we, you know, I appreciate in the discussion you all just had, you know, thinking about these all track together, but we don't always have them connected in a way where we're analyzing them and figuring out the real impacts. So, we're super excited to share that with all of you.

Additionally, in the implementation and analysis of evidence-based interventions, we will be recruiting at least 200 diverse birthing hospitals with very clearly defined areas of focus with overarching real focus on disparities and analyzing the direct impact of evidence-based

interventions on maternal/infant outcomes. And we're really going to be measuring the association between maternal health and infant outcomes as well.

This is just a quick summary of some of the outcomes areas of focus that we will be including in our analysis where we are committed to including disparity information with all of this and we will really be capturing an incredible number of measures to understand both the clinical and non-clinical factors that impact overall maternal/infant outcomes.

So, to conclude, you know, as we think about our coordination across the federal government, we're excited to have our federal colleagues present during this presentation today and we really want to commit to you all and let you all know of all the coordination that goes on on a day-to-day basis among the different agencies. It's incredible all of the people who are committed to maternal and infant health.

And as we have more updates from the

programs that we shared with you, and as we look to think about policies, we're really looking forward to sharing anything and everything to really move the needle and leverage all of the data and information that we have. So, thank you.

DR. EDWARD EHLINGER: Thank you, Dorothy. Because of the number of presenters, I'm going to ask you to hold the questions until we get all of the presentations done. But just a reminder that our charter does include maternal mortality in addition to infant mortality. So, it is part of our agenda. So, let's now move forward to Caryn Marks.

MS. CARYN MARKS: Good afternoon, everybody. I'm going to go ahead and share my screen. I might need Dorothy to stop screen sharing so that I can switch over. Thank you. Great. Can everybody see that now?

MS. BELINDA PETTIFORD: Yes.

MS. CARYN MARKS: Okay, great. Thank you and thank you again for inviting me to join everyone on the panel today.

I'm Caryn Marks, and I'm a Policy Advisor in the Office of Intergovernmental and External Affairs. We are definitely a newer office to the HHS Maternal Health space, but we are excited to be here today. And just for a quick background, the Office of Intergovernmental and External Affairs is the Secretary's primary liaison to state and local elected officials, and our external affairs office really leads the departments stakeholder engagement effort. So, we work with private sector partners in a bidirectional way to share information from the department and to take the polls on stakeholder reactions to departmental policy.

So, as part of the stakeholder work over the past couple years, we've undertaken some work on the maternal health space. And as we conducted that work and conducted listening sessions, there were a few common themes that we heard across all the settings that became the genesis of this new public-private partnership that we recently announced that is focused specifically on

addressing racial disparities and maternal health outcomes.

So, as Dorothy just mentioned and you all are very well aware, from the CDC data, we know that mortality rates for pregnancy black women are three times higher and morbidity rates are two times higher than for white women. And additionally, in reviewing the research, when we look at hospital quality and the relationships to disparities in care, particularly along racial lines, some of the research shows that black women receive different and lower quality care associated with the hospital of delivery.

We also know that in terms of the time of adverse maternal health outcomes, that one-third of pregnancy-related deaths occur on the day of or within six days of delivery.

So, combining the data and research as well as the insights that we gained from the stakeholder events, we developed a project to make a very concrete and focused effort to address the black/white racial disparity gap in the hospital

setting. And in designing this project, we recognized that hospitals are really only one piece of the puzzle and one part of the solution. However, we chose the hospital setting at the outset of the project due to the existing infrastructure in hospitals and the prior relationships that we have. But we also acknowledge that focusing on the hospital setting can potentially have a ripple effect in the community and other spaces.

As we continue building out the project, there is potential to expand beyond this hospital setting. But for now, we're starting with this.

So, what are we trying to do with this initiative? As mentioned, our goal is to reduce the disparity gap in morbidity and therefore mortality in the hospital setting between black and white women. Through this initiative, we're hoping to create a meaningful shift in the culture of hospital-based maternity care resulting in greater safety and equity for all mothers within and beyond the hospital setting.

We want to address -- one important aspect is that we want to address disparities both among and within hospitals. Ideally, we'll be able to identify and implement interventions in hospitals that are both majority/minority focused hospitals that have poor maternal health outcomes but also some hospitals that may not be majority/minority hospitals but have large disparity gaps within the hospital between black and white women. And we aim to really achieve this vision through effective cross-sector partnerships and multidisciplinary collaboration that not only generates but also sustains improvement.

So, what is it? We are trying to design a quality improvement initiative recognizing that we are very much at the early stages of the project. So, what that intervention is still yet to be determined. It will be hospital-based at the get go and specifically address -- specifically designed to address and reduce disparities and morbidity between black and white

women.

We're going to start with a pilot in twenty-five hospitals and aim to expand to at least a hundred hospitals over a five-year period.

In terms of the intervention, it will be collaboratively developed and tailored for a specific hospital setting. However, nothing is formalized or finalized in terms of what that intervention will be until we conduct stakeholder engagement on our approach and methodology.

So, I wanted to raise a couple of the guiding principles that we have designed and incorporate in this project. We feel very strongly that the outcomes, the planning, the process, and the evaluation of it is equitable, collaborative, sustainable, scalable, easy to implement, and is able to be evaluated. And ultimately, our vision is to demonstrate via data improved maternal health outcomes among black women who are the highest risk for maternal morbidity and mortality in the US.

So, IEA is a newer office. This is where

come into play of why is IEA leading this initiative. This is a public-private partnership. As we structured it, we really wanted to focus on organizations that have a shared goal and vision but also wanted to do the public-private partnership as a way to really identify what gaps are there that the federal government can't quite fill yet where private sector may have strengths that we don't have. So, we want to use the private sector and leverage that to complement the work that is being done by the department already. We really wanted to use private sector partnership, their ability to convene, to innovate, to go faster, and to scale and go further.

So, our partner for this is the March of Dimes. They will be the lead organization. They are serving as the core and the backbone for the public-private partnership. They are taking on an external stakeholder engagement, management, and coordination, and options for identifying data to use as we develop the methodology.

As a department within HHS, we are bringing their expertise on evidence-based practices, hopefully some baseline analytics for hospital identification, and really coordinating across all the HHS offices for expertise and advise as we design the project.

HHS and March of Dimes are working very closely in the strategy and development. We have been working on this. We started this about six months ago with the idea, announced it in early December, and then just a week ago started the announcement of our pilot, which I'll talk about in a moment. We are still in the nascent stages for identifying the methodology for hospital selection and working together to create communications for hospital recruitment, developing what the intervention and strategy is, and measuring outcomes as well.

One thing I want to flag for this is the importance of illuminating black women's voices throughout the planning and implementation of this project. March of Dimes is committed to and

applies the common adage, "Nothing about us without us," and that applies to this project as well. So, we're looking to experts in black maternal health from all levels of involvement to guide us as we plan this. We have contracted with the National -- the March of Dimes has contracted with National Birth Equity Collaborative to lead the stakeholder engagement portion of the project. And then, we're also obviously coordinating internally across HHS and actively working together with the other offices including Office of Women's Health, HRSA, CMS, CDC, and others.

So, overall, our timeline, it's a five-year project. We have completed the plan -- the initial planning phase and are now in the real rubber-hits-the-road planning phase where we're designing the methodology for hospital selection, finalizing our partners, stakeholder groups, getting staffed up, and identifying potential QI interventions and data sources for the hospital selection.

As I mentioned, we just -- about a week

and a half ago, January 12th -- announced United Healthcare. They are the first funder of the project. They are going to -- they worked with March of Dimes on that side of things. So, there will be a pilot for the project. It will be different from the methodology for the project at scale when we expand, which will have a robust hospital methodology for selection.

For this one, we will have a regional focus with six states and twenty-five hospitals, and we are working now to identify what the quality improvement will be, but we'll be working with experts on that.

For the focus of the pilot, we'll be focused on a primary -- reduction in primary cesarean section rates at the outset, recognizing that hospitals will be in different places and we may need to pivot, depending on the hospital that we joint with in these six states.

And then, over the two years, HHS and March of Dimes is continuing to work together with the expert consultants to create a methodology for

hospital identification for scaling to the larger one hundred set of hospitals.

And lastly, we are still working with other entities and organizations that want to participate and contribute. There's plenty to go around. As I mentioned, we want to make this a very collaborative effort. So, keeping that in mind, it's very important for us to have stakeholder perspectives and engagement throughout, working with a number of organizations that are potentially interested in funding as well as amplifying the initiative, most importantly, sticking to the shared vision among all of our partners and commitment to making the US a safer place to give birth regardless of race, ethnicity, or geography.

That is it for me. Thank you.

DR. EDWARD EHLINGER: Thank you very much, and we're going to hold questions until we're done with the presentations. So, hang around because there will be lots of questions, I'm sure. Charlan Kroelinger.

DR. CHARLAN KROELINGER: Hi, everybody. I would love for LRG to pull up my slides and advance them for me. Thank you. And while they are doing that, I'll introduce myself. I'm Charlan Kroelinger. I am the Acting Director for the Division of Reproductive Health at the Center for Disease Control and Prevention. I am honored to be here today and present on behalf of Dr. Wanda Barfield, who is our director, who has been called to deploy to the COVID-19 response because of her expertise and dedication to the efforts of CDC.

So, I'm happy to be here, and I'll give you a summary of what we've been doing in the Division of Reproductive Health. Next slide, please.

I'm happy to give you some updates on a couple of activities that I know you're very familiar with, and we'll move forward. Next slide, please.

I'd like to thank the committee members and committee leadership and partners for playing

the Hear Her Campaign story this morning and the vignette later today. As you know, DRH launched the Hear Her Campaign in August 2020 with support from the CDC Foundation and Merck for Mothers. Our goal is to raise awareness of urgent maternal warning signs that occur during or after pregnancy.

This campaign was successfully launched in the middle of the COVID-19 pandemic with a suite of resources including the CDC website, five testimonial videos -- a couple of which you may see during this meeting -- a Facebook page, social media messages, two downloadable action guides, and much, much more. All materials are also available in Spanish. Next slide, please.

Here are just a few metrics giving insight into the campaign's performance in 2020. Since launching in August, there have been over 240,000 views of the Hear Her web pages, largely driven by targeted audience media buys. We have also seen strong reach and engagement with our priority audiences on Facebook and Twitter. Since

launch, we have also seen significant interest from news media. There have been 319 mentions including coverage from Good Morning America, Fox News, Parents Magazines, STAT News and more.

Feedback from our stakeholders and priority audiences have been extremely positive. So, we are thrilled and would say that we have made significant progress in reaching our intended audiences with these campaign messages. Next slide, please.

Now that the campaign has launched and hit its stride, the campaign team is looking at how to expand our reach. We already have many exciting opportunities on the horizon for the Hear Her Campaign in 2021. As we all know, family, friends, and health care providers are critical in this effort. It's important that we approach the issue from all sides. It's about empowering women to speak up when they have concerns, but also about making sure their friends and families and providers are really listening and taking those concerns seriously. As such, we are working on

developing more messages and materials to reach support networks and providers.

It is also a priority for us to develop materials for American Indian and Alaska Native women who experience disparities in maternal health and mortality. This month, we shared a dear Tribal leader letter informing Tribal leaders around the nation of our intent to develop materials with and for Tribal communities. We are excited to move forward on this effort with the Office of Minority Health, Indian Health Service, and CDC's Office of Tribal Affairs and Strategic Alliances and other Tribal partners. Next slide, please.

I'm also thrilled to share that Allyson Felix, US Olympic track and field athlete and black mother, who experienced a pregnancy-related complication, is serving as a campaign spokesperson. Her testimonial video and PSA will be released in early 2021. If you're interested for more information about this campaign, please feel free to contact our team by E-mailing

hearher@cdc.gov. Next slide, please.

The Hear Her Campaign is part of CDC's larger integrated and strategic approach to addressing maternal morbidity and mortality. Another key effort is our work to strengthen maternal mortality data through the Maternal Mortality Review. Next slide.

Dr. Barfield and I have shared updates on Maternal Mortality Review Committees or MMRCs in past meetings. So, I won't go into too much detail here. But briefly, MMRCs are a part of a multidisciplinary process where a committee at the state or city level identifies and reviews maternal deaths that occur within one year of pregnancy. CDC works with MMRCs to conduct and strengthen review processes that identify actions to prevent future deaths.

CDC also supports state and local MMRCs by providing a common data language through the Maternal Mortality Review Information Application or MMRIA. MMRIA facilities documentation of a wide range of data on the life and death of a

woman to ensure a review committee can develop strong prevention recommendations.

Over time, we have added components to MMRIA based on feedback from state users that has facilitated enhanced data collection on things like maternal substance use. Next slide.

We are excited to share that in fiscal year 2021, appropriations included an increase for Erase MM. The Consolidated Appropriation Act included $63 million for Safe Motherhood at CDC with an increase of $5 million for Maternal Mortality Review Committee.

The language for this increase highlighted efforts to improve data in heart conditions. The agreement provides an increase to expand these efforts and expect CDC to build stronger data systems, improve data collection at state level, and create consistency in data collection. Further, the agreement encourages CDC to support data collection efforts to further understand maternal heart disease and improve outcomes for pregnancy women with heart

conditions.

MMRCs are one component in an interconnected system. That system also includes things like HRSA's Title V Program, of which we've discussed today, Maternal Innovation Project, and AIM Safety Bundles, and CDC-supported Perinatal Quality Collaborative and Efforts and Risk-Appropriate Care. Together, these have the potential to form a network at the states to connect data, informed recommendation, to prevention initiatives to improve outcomes and save the lives of mothers.

Today, I'd like to highlight our work to build the systems that capture key data on social determinants of health. Next slide, please.

As Dr. Barfield shared in September, one area that states want to better understand are community-level indicators in the social determinants of health. To work toward meeting this need, we have partnered with Emory University to build a pilot of Community Vital Signs Dashboard for MMRC that considers a wide range of

factors that might play a role in maternal health and maternal mortality.

As shown on the slides, Community Vital Signs data points to answer the question, "How do social determinants of health measure in the community the pregnant or postpartum person lived in compare to that of all pregnant or postpartum persons in the same states or in the US as a whole?" These indicators of system-level factors can reflect disparate structures based on historical and contemporary social factors that systematically disadvantage certain groups. By understanding and documenting contextual factors such as those in the examples shown here, MMRCs can develop targeted recommendations that specifically address health disparity. Next slide, please.

Another component we've added based on state request are tools to identify, document, and address bias. We partnered with CDC Foundation and Dr. Elizabeth Howell at Mount Sinai School of Medicine to co-facilitate a workgroup of MMRCs

members and subject matter experts to understand and capture bias as a potential factor in a review of the maternal deaths. The work culminated in the addition of discrimination, interpersonal racism, and structural racism as data fields available in MMRIA with new [indiscernible] to define these three contributing factors as shown here.

We are expanding across this tool so by the end of the year, all MMRCs will be able to collect these data. Next slide, please.

Going forward, excitingly, HHS Office of Minority Health and CDC are working together to award of a suite of initiatives that will provide tools and resources to more fully inform MMRC efforts to address the social determinants of health.

We plan to conduct an assessment with select state-arranged MM programs to identify opportunities for collaboration between state MMRCs, Perinatal Quality Collaborative, and state and local community organizers to move data to

action, to prevent maternal mortality, and reduce disparities. This will lead to a roadmap for state MMRCs to effectively collaborate with community organizers on initiatives to prevent maternal mortality and design an approach to compile, store, and update the data sources used to create the Community Vital Signs Indicators for use on web portal dashboards to support the identification of social determinants of health. Next slide, please.

Thank you for your time and attention, and I look forward to questions at the end of the panel session.

DR. EDWARD EHLINGER: Thank you, Charlan. And now, let's turn to Alison Cernich.

DR. ALISON CERNICH: Thank you again for the opportunity to present, and I would really appreciate it if LRG could pull up my slides, which I think I submitted. Thank you.

So, I want to thank you again for the opportunity to present. Next slide. And I'll be presenting on the NIH's efforts in maternal

morbidity and mortality. I'll be covering the IMPROVE Initiative, which is Implementing Maternal Health and Pregnancy Outcomes Vision for Everyone, information related to the Task Force on Research Specific to Pregnant Women and Lactating Women, PRGLAC, and the Severe Maternal Morbidity and Mortality Electronic Health Record Data Infrastructure effort that we are going to be funded for through the Patient-Centered Outcomes Research Trust Fund Initiative from HHS. Next slide, please.

Back when we could be in person with each other, December 11, 2019, and that seems like a million years ago, the NIH had the opportunity to meet with the Black Maternal Health Caucus and in that meeting, we really did learn about their specific interests with respect to equity and have really tried to continue our work to make sure that our research continues to be inclusive and focused on equity and community engagement, as we were urged by these congressional members, and you'll see this involved Dr. Collins, RIC

Director at NICHD, Dr. Diana Bianchi, the Director of the National Institute for Minority Health and Health Disparities, Dr. Eliseo Perez-Stable, and also Dr. Gary Gibbons from the National Heart, Lung, and Blood Institute. Next slide, please.

And generally, we have a fairly robust portfolio of maternal health research at the NIH and you will notice that NICHD is the leading funder of this research, which is why we are leading this presentation today. But there are a number of institutes across the NIH that are very heavily involved in this work. Next slide, please.

And together, we've been led by the Office of the Director of the Office of Research on Women's Health and the National Institute for Child Health and Human Development in the IMPROVE Initiative, which encompasses both what NIH does best -- which is foundational biology -- as well as social behavioral research to really try to understand the root causes of maternal morbidity and mortality and also to integrate community

partner voices to assess the needs and implement interventions.

And over the past two years, we've held three workshops -- one specifically focused on community voices so that we could really plan a research agenda that captures the community's needs. Next slide, please.

To start our work, we started with an administrative supplement program for NIH grants to add or expand research focused on maternal mortality, and in 2020, we awarded $7.2 million through this notice of special interest that funded thirty-six supplements to ongoing research focused on cardiovascular disease, infection and immunity, mental health and substance use, severe maternal morbidity and maternal mortality, and other conditions related to maternal morbidity and severe maternal morbidity.

These included areas such as heart disease, hypertension, hemorrhage or bleeding, and infection. The contributing conditions that we were looking at obviously included diabetes,

obesity, mental health disorders, substance use disorder, and structural factors that contributed to delays or disruptions in maternal care, and we ensured that there was strong representation of under-represented groups in these supplements with many concentrated on specific efforts in African American communities and also in maternity care deserts such as rural communities. Next slide, please.

In IMPROVE, we are really now looking at additional efforts across the NIH that are being led by various institutes from an administrative perspective. So, one of the lead institutes on one of them, the National Institute for Minority Health and Health Disparities, as well as other institutes are supporting work to address racial disparities and maternal mortality and morbidity including mechanisms like underlying racial and ethnic disparities, testing the efficacy of multi-level interventions, or research strategies to optimally and sustainably deliver proven effective prevention and treatment interventions to reduce

disparities. This initiative has yielded six awards.

The notice of special interest that was led by the National Institute on General Medical Sciences in cooperation with the Office of Research on Women's Health really focused on the idea states, and these are states that do not have a high level of NIH funding, and this was a very broad initiative. And so, the applications to the participating institutes resulted in a success rate of about 51 percent in total funding for the nineteen selected applications was about 4.8 million in total cost, really looking at maternal and infant morbidity and mortality and the underlying causes of the same.

There are some upcoming initiatives that you should be aware of, one that has a notice of intent to publish already out on the street looking at Early Intervention to Promote Cardiovascular Health of Mothers and Children. This the ENRICH Initiative that's being led by the National Heart, Lung, and Blood Institute, and

this is a very large-scale initiative that I hope that all of you take a look at. Really, this is to look at family and community-based effectiveness implementation interventions to promote ideal cardiovascular health in mothers and children 0-5 years of age, interventions that address maternal cardiovascular health risks such as preeclampsia, obesity, or gestational diabetes, and which link home visiting with primary care to improve cardiometabolic health of mothers and children.

There is also another NIH solicitation that we are planning for fiscal year '21 that will likely focus specifically on COVID-19, and then there are going to be some challenge opportunities really looking at technologies to better detect conditions related to maternal morbidity and mortality, secondary use of existing data already hosted by NIH, and ideas to address disparities in maternal care. Next slide, please.

And I just want to highlight some of the research that we may think about but that NIH is

sponsoring that, you know, I think does talk to some of the differential causes of severe maternal morbidity and mortality.

So, for example, there was a recent publication by an NICHD-funded researcher that examined maternal mortality in Louisiana, and they looked at really all-cause mortality and then particular death due to obstetric causes. These were significantly elevated among women residing in maternity care deserts compared to women in areas with greater access. And so, when we refer to maternity care deserts, I think many of you are aware these are locations where people have to travel relatively far to access obstetric or gynecologic care, and there was a large racial inequity and risk that persisted above and beyond differences in geographic access to maternity care.

The same researcher also recently published on the association of homicide in pregnancy in Louisiana and we've also then supplemented this group to study gun violence and

its impact on pregnant women.

So, we're trying to look past just the biologic causes and look at some of the social aspects that are contributing to deaths of women or severe maternal morbidity. Next slide, please.

So, I'd like to move then to the Task Force on Research Specific to Pregnant Women and Lactating Women. Next slide, please.

So, about 6.3 million women per year in the US become pregnant. Greater than 90 percent of them take medications and 70 percent are prescribed medications, and about half a million women have difficulty producing milk for lactation.

There are some real concerns related to liability in terms of testing medications in women who are pregnant, obviously because of the teratogens that are potential there in some medications, but this also is a concern because, as you know, many women are taking medications off label where we do not have those impacts well documented.

There is obviously the complexity of pregnancy with changes in the fetus and placenta over time, the timing of the exposure to the medication, the physiologic changes in pregnancy that change the metabolism of drugs, the impact of external factors such as obesity and the environment, and then also these co-existing chronic or acute conditions that a woman may need to balance.

Similarly, in lactation, we have even less evidence of medication with this in terms of the benefits of breastfeeding versus medications that women may take, and there are very limited assays for assessment of medications in breast milk. Next slide, please.

So, the task force that we were asked to stand up in 2016 as a result of the 21st Century Cures Act resulted in report recommendations in 2018 in terms of not only culture change that has limited our ability to give knowledge of therapeutic product safety effectiveness in dosing but is something that was echoed in an item in NPR

today, and I think we are seeing very clearly related to COVID-19, we need to protect pregnant women through research instead of from research. We are now in a position, for example, with COVID-19 where we have not tested vaccine in pregnant women, but because of the emergency use authorization, we are offering that vaccine to pregnant women and leaving it to them and their providers to make a decision about this vaccine on a new platform that has not even had full preclinical testing in animal studies. We wanted to remove pregnant women as a vulnerable population through the US Common Rule, and we have done that and expanded the work force of clinicians and research with this expertise. So, all of the recommendations are available online. If we can go to the next slide.

We were then asked by Congress -- on the next slide we'll talk about the implementation plan -- we were asked to follow up that initial recommendation with how would that be implemented, and this was submitted in September of 2020 and

again, the full report is available online.

And what we really looked at is leveraging or expanding our existing federal programs or networks, which we have many at the NIH that could be of use, but also in the FDA and CDC and others, developing new research, tools, and strategies that could help us to better evaluate some of these medications in pregnancy or lactation, look at alternative trial designs, figure out how to prioritize which drugs we would study, try to address some of these ethical or liability concerns or give incentives to pursue research in this area, foster education and awareness among health care providers and pregnant and lactating women about the need for this research, and then also explore partnerships.

And really, everyone has a role in this implementation plan, not only our federal agencies but also our nonprofits, industry, and our advocacy groups to help us move this forward. Next slide, please.

And I'll just mention one other project,

but it's in its nascent stages, but we signed the interagency agreement to receive the funding to move this forward. Next slide, please.

So, this is a data infrastructure that we are proposing through the Patient-Centered Outcomes Research Task Force. What we've seen over time is a need to better link women to the data on their pregnancies, both across the pregnancies that women experience as well as to their infants. We saw this with Zika, we've seen this with other infectious diseases, and it's happening again with COVID-19. If we can't link, we have very big difficulties making a determination through electronic health records what the impact of these diseases are.

We also have difficulty linking a woman across her pregnancy. So, seeing the subsequent health impacts becomes very difficult. We are looking at developing a data structure using the HL-7® FHIR Implementation Guide process that would allow us to look at standards and develop them for EHR implementation to be able to pull data related

to pregnancy in a standard way and to use their person-matching techniques to provide matching of a woman across her pregnancy and with an infant.

We'll then pilot these standards to assess their feasibility in two NIH data systems -- one in the All of Us program, which is our Precision Medicine Initiative and the Gabriella Miller Kids First Pediatric Research Program.

We'll also consider a pilot with CDC to look at health departments in either one to two states and/or the District of Columbia to link electronic health record data with maternal mortality vital records data. And then, we'll produce a report that includes the implementation guide and related materials so that researchers can use electronic health records data, and this will be about a $2 million project that will advance over the next two years and will involve stakeholder contributions to help with those standards. Next slide.

And with that, I'm done, and I will pass to the next presenter. Thank you.

DR. EDWARD EHLINGER: All right. Michael, you are on. Thank you, Dr. Cernich. I appreciate that.

DR. MICHAEL WARREN: Thank you. And LRG has my slides as well, and I will move quickly. And so, if we can advance.

Just as a point of reference, our work is all rooted in the Life Course approach. You've heard me talk about our accelerate upstream together paradigm before, and certainly if we think about improving maternal health, we need to think about women's health across the life course. So, you see some statistics here that I think only speak truth to the notion of combining chronic disease and MCH efforts that were raised in the chat earlier. We really can't think about those as separate if we're going to really think about improving women's health across the life course. We have to integrate those efforts. Next slide.

This is just our framework. I've shared this with you all before. So, just in the interest of time, I'm going to not spend long on

this other than to say we've been dealing with a lot of these issues whether we're talking about infant mortality or maternal mortality for decades. We have to accelerate the pace of change, particularly with relationship to eliminating disparities. To do that, we've got to think upstream. We can't just think about clinical care. We have to think about the broader determinants of health including social and structural determinants of health, and we have to do this together. I think this panel really speaks to that. No single federal agency does this alone. It really works when we're all working together in partnership with states and communities. Next slide, please.

So, just a few of our core investments. These are ones that you know well. I spent a good bit of time already talking about the Title V MCH Block Grant. You know about MIECHV, the Maternal Infant and Early Childhood Home Visiting Programs. This is evidence-based, voluntary home visiting that's done through local implementing agencies

across the country. And then, we have our Healthy Start Initiative focused on eliminating disparities in perinatal health. So, these are one hundred and one community-based sites across the country. Particularly, they are in areas with high rates of infant mortality. So, those are core investments.

We then have a number of other investments, as you'll see on the next slide that we have added over time with additional appropriations. So, the State Maternal Health Innovation Grants work, as you heard Dr. Ehlinger say, in coloration with PQCs, with AIM, with MMRCs to look at how we improve that state-level surveillance work in innovation and service delivery. There are nine states that currently have those grants.

We also have AIM and AIM-CCI. So, AIM, folks know a lot about it. It's those safety bundles that are typically deployed in clinical settings, birthing facilities. But we know -- and our colleagues at CDC have shared data in the last

year -- that many pregnancy-related deaths occur outside of that immediate labor and delivery, immediate postpartum setting. So, about two-thirds of all deaths happen in the period around that. So, about one-third of deaths are during pregnancy, about one-third from a week following pregnancy, all the way to a year out.

So, the AIM Community Care Initiative really gets at this notion of how do you take that concept of bundles and take that out to the community outside of those birthing facilities outside of that immediate labor and delivery postpartum period.

And then, adding to this portfolio, we will be adding our new Maternal Mental Health Hotline. This was just appropriated with the budget that passed in late December. This will provide for a national level Maternal Mental Health Hotline that will be staffed by qualified counselors 24 hours a day. And so, we will be working on implementing that in the year to come. Next slide, please.

We also have $5 million that supports the Screening and Treatment for Maternal Depression and Related Behavioral Disorders. So, this is in seven states and uses telehealth to provide training and real-time psychiatric consultation and care coordination. This is modeled after the work that was initially done in Massachusetts around child psychiatry access. We've got a parallel component of this focused on pediatric mental health care access, but this is really an extension of that work into the maternal mental health space.

You've heard my colleague, Dr. Fink, earlier mention the Challenge Competitions. MCHB has launched a number of these challenges. We are just wrapping up two that are focusing on maternal health. For those of you who don't know about the challenges, it's very different from the typical federal grant competition. It's almost like the television show Shark Tank where you have people pitch ideas to you. Very low bar to entry, typically a three-to-five-page application, so not

the typical sixty-to-eighty-page federal grant application and folks win prizes -- cash prizes to be able to test and scale their innovation.

So, we've recently held Challenge Competitions around remote pregnancy monitoring as well as optimizing the care of women with substance use disorder.

And then, we also support the Women's Preventive Services or WPSI. This is the women's health corollary to Bright Futures. So, whereas Bright Futures is that roadmap to preventive care for children and adolescents, WPSI is that path for well-woman care. It is up for competition this year, and so we will be announcing that award later this year.

So, those are some additional targeted investments that we have in this maternal health space. Next slide, please.

Just to give you an idea, we really are focusing our efforts on being able to measure the impact of these investments and so, just a few examples of that. In MIECHV, they've really

focused in some of their programs on screening for depression and so have shown an increase over the last couple of years looking at women who were screened for depression within three months of enrollment or three months of their delivery.

Similarly, with Healthy Start, we've got a renewed focus on data collection and expectations there and with some exciting results seen around the entry into prenatal care in the first trimester, which actually exceeded the program targets.

And then, the Maternal Health Innovation grantees, which are new, have been engaging in a lot of activity that again is very state specific, but doing things like mobile obstetric simulations for clinical providers, setting up mobile clinics, and supporting telemedicine, all to increase access to care. And those grants are in about their first year and a half. They'll be wrapping up year two later this summer. Next slide, please.

Also, just to share some examples of

impact from AIM, so, currently AIM is in thirty-eight states representing about fifteen hundred hospitals as of this past fall. You see three state examples here. Whether this is looking at increasing the percentage of women who have opioid use disorder, how many of them got medication-assisted treatment at discharge. Tennessee showed some remarkable increases there. Louisiana focused their efforts on hypertension and reducing severe maternal morbidity among birthing women with hypertension. And then, Florida focused their efforts on reducing low-risk cesarean births.

The team has put together a number of these what we're calling AIM Impact Statements to show the -- the accomplishments of a variety of the states that have been participating in AIM up until now. Next slide, please.

MCHB is not the only bureau within HRSA. There are a number of other bureaus and offices and a number of them are also thinking about maternal health. So, we partner with the Federal

Office of Rural Health Policy on the implementation of their RMOMS Project, the Rural Maternity and Obstetrics Management Strategies Program, and this initiative really is about networking approaches to care. So, coordinating maternal and obstetric care, particularly in rural regions, and they're focused on how we can increase the delivery and access of preconception pregnancy, labor and delivery, and postpartum services, and importantly, how do we do that in a way that's sustainable financially in the long run. They're in three sites across the country right now. Next slide, please.

We also have within HRSA the Bureau of Primary Health Care, which manages the health-centered program. Many, many women across the country receive care in community health centers or federally qualified health centers including women's health services like contraceptive management, Pap test, and prenatal care.

And then, we've got HRSA's Health Workforce Programs, so initiatives like the

National Health Service Corps and other workforce development programs that are really focused on putting providers in areas with the greatest need, and those programs, of course, train women's health and maternal providers including midwives, as we think about how we strengthen the workforce to meet the needs of women across the country. Next slide.

And that's it. That may be the fasted I've ever talked as a southerner.

DR. EDWARD EHLINGER: Thank you, Dr. Warren. All right. I'm going to open it up for some questions for a little bit. We can make up some time after lunch. So, don't be discouraged. We'll take about ten minutes now.

We've got Jeanne Conry, Tara Lee, and Paul Jarris. Let's take them in that order.

DR. JEANNE CONRY: Thank you so much. Great presentations. I always love to hear the summaries and just the diverse amount of work that's taking place. So, my sincerest thanks to everybody doing this.

For Caryn Marks, I had a question, and it may have been that I wasn't understanding. First, is there a priority to doing some of the work or the research that's going to take place in the counties where we saw the highest number of infant deaths that Dr. Warren had discussed? That was the first question.

And then, the second has to do with, I believe, part of the research that's going to take place is nulliparous term singleton vertex deliveries, and we do see the cesarean section rate amongst them. Have you seen the California Honor Roll and the focus so that we've got 140 hospitals with reduced cesarean section rates? Are you using something like that with what CMQCC has done? Thank you.

MS. CARYN MARKS: Let me -- sure. Let me address the first question in terms of reducing the NTSV rate. We are doing our due diligence now and have been in many conversations with Dr. Maine out of California to advise us on the best options for reducing c-sections. So, yes, we are taking

that into account.

Your question on maternal mortality and mapping it in the states with infant mortality. So, for the pilot phase, we are focused on the southern states, which generally have higher rates of maternal mortality and morbidity. As we develop the methodology for hospital selection in the fall when we scale the project, I think we will be looking to those states and will have a focus to the extent possible on those with the higher rates of maternal mortality and looking at infant mortality as well.

DR. JEANNE CONRY: Thank you so much.

DR. EDWARD EHLINGER: Tara.

DR. TARA SANDER LEE: Okay, thank you. This question is for Alison Cernich. Thank you so much for your presentation. I was really interested in your comment that you made about the vaccines and your statement that, you know, you want to protect women through vaccine research, not from vaccine research, and I think that is really important. I guess, if you can maybe

clarify that a little bit more since pregnant women are routinely excluded from clinical trial out of extreme caution. Are you thinking that for your initiative, you want to move forward to have more research done like on animal studies or could you just elaborate on that a little bit more, especially just right now since, you know, everybody is so concerned and they want to make sure that pregnant women are, of course, safe if they do take the vaccine. Just kind of what your thought on the COVID vaccine, what your concern -- what your thoughts were about that.

DR. ALISON CERNICH: Sure, and I'll also invite our CDC colleagues, because I think what we're trying to do is almost as a post-marketing surveillance sort of methodology and I'll let them talk about the v-safe Program. I mean, I think we are offering it and the FDA is offering it because there does not have a -- there's no theoretical threat to this particular vaccine or vaccine platform with the mRNA platform. And similarly, when the Johnson & Johnson vaccine comes forward,

there's no theoretical concern with respect to the platform that they are using. But neither of them are licensed products in pregnancy.

I think one of the approaches is to accelerate some of the preclinical studies -- so, have them come earlier in the process. They are just completing them really now or working on them now, so, those phase 2 studies where we look at this in animals. If there would be ways for us to accelerate those with industry, I think that would be useful.

I think the other piece is related to consent, ethics, and liability protection. So, in the context of a public health emergency, what can we do as a research community in partnership with industry as the federal government and the regulatory agencies -- how do we approach some of these questions? And so, part of it is accelerating the pre-clinical trials, but I think one of the other concerns is when can we feasibly start a safety study in pregnancy if we had accelerated those trial, knowing full well that

we're going to, you know, essentially what we are doing right now is we are providing the vaccine under emergency use authorization with the ethical understanding that the benefits will outweigh the risk, right? But we're not doing that in the context of research, and I think that is the concern that we raised during PRGLAC and that we continue to raise. I know that the pregnancy studies are being talked about with industry now and I think, you know, we're going to try and help any way we can. But they have to feel that the safety is such that they are not going to have a liability issue.

And I'll pass over to CDC to talk about -- I think the v-safe Program is another way that we'll get data related to vaccine in pregnancy. So, do you all want to talk about that?

DR. WANDA BARFIELD: Yes, I think that is an opportunity. Dana Meaney-Delman should be joining us also from the task force as well.

Yeah, so hi, I'm just joining in. so, I assume that we're starting that 1:45 session.

DR. EDWARD EHLINGER: No, we're about a half hour.

DR. ALISON CERNICH: We're still on the other session, Wanda, but I brought up v-safe because I think it answers the question about looking at vaccine in the context of pregnancy. So, I thought you just might want to -- I didn't want to represent you guys' program.

DR. WANDA BARFIELD: Yeah. So, it does -- so, many of you are familiar with v-safe, which is an opportunity to look at complications for vaccine for all populations, but there are questions that specifically ask if you are pregnant. And so, with that, there's an opportunity to then follow-up pregnant women and get more information ideally about their condition post-vaccination as well as other information about the mother and baby. We're also trying to, you know, continue to follow that group as well.

DR. EDWARD EHLINGER: All right. I want to let the panelists who are coming on this session that was supposed to start at 1:45 to let

them know we're going to start it at 2:15, and I apologize for that delay. But that also tells the rest of you that our lunch is going to end at 2:15. So, however long we want to talk here, we can do that, but that will -- it will take out part of lunch. And we will be able to catch up a little bit later on, but we will be starting that last -- that panel on COVID at 2:15.

All right. Paul Jarris had a question.

DR. PAUL JARRIS: Thanks, Ed, and hi, Wanda. I have a question for Caryn. Caryn, you know, our health care system is largely oriented around the provider's specialty or the site of service as opposed to the mother/child dyad going through the system, and one of the limitations in looking at maternal/infant morbidity and mortality has been that it's been organized by hospitals who look within the four walls, and they often don't include prenatal or postnatal care. And then even within a hospital, there's obstetrics and pediatrics. So, as you approach this with a public-private partnership, are you doing anything

to make sure that we're following the mother and child through the system rather than splitting it in so many different ways and lacking coordination and integration?

MS. CARYN MARKS: That's a great question, and these are all great things to bring up now as we're in the design stages of the project. I think that's something we'll take back and also, I think there's an opportunity with the data that Dorothy is collecting on the maternal -- the mom and infant data to potentially leverage that data to be able to do that as we design this project as well. So, thank you. And yes, it is a consideration for us.

DR. EDWARD EHLINGER: Yeah. And also consider all the social issues -- social determinants of health that impact the care that they get in the hospital.

MS. CARYN MARKS: Absolutely.

DR. EDWARD EHLINGER: Magda.

DR. MAGDA PECK: First of all, I want to just acknowledge the remarkable whole of

government approach that I'm hearing about in addressing maternal mortality and morbidity. You know, for the years that I have been involved mostly on the infant mortality side, it has been a while since there's been such a -- an attempt towards alignment and leveraging each other's assets.

So, my first general question is, how is this different -- for all of who have been involved in this -- how is this whole of government, full court press on maternal mortality prevention different from what we're already doing around fetal and infant mortality, and what is the -- the connectivity and the leverage to be able to change systems on the maternal health side or the maternal mortality side that will then have a secondary effect on infant mortality and vice versa? It's a larger level systems question. But I'm just remarkable and confused because I don't see a whole of government approach similarly to preventing fetal and infant deaths. So, that's one commentary that you may want to put on

specific to that and to get to the shortness of this.

Charlan, thank you. Lovely to hear from you. Wanda, thank you for being here as well. When you talk about Community Vital Signs just as a very specific part of Maternal Mortality Review and it brings in specifically metrics around discrimination, interpersonal racism, and structural racism, how is this new enterprise also being applied to the field of infant mortality infrastructure in the nation, which is addressing the same piece? It is a reflecting of what Paul talked about from a health systems perspective. I don't see the dyad piece in this from a data perspective, and I'm wondering how -- what is the portability and the leverage and the connection for a maternal, fetal, and infant review enterprise that brings data that talks to each other, and that to me feels like a missed opportunity or perhaps I just missed it in your hyper focus on Maternal Health Initiative. So, we can talk about that later. But I'm excited and a

bit confused. Anybody want to pick that up, Charlan in particular speaking to the social determinant health measures in the community as part of the work that you're doing in the Vital Signs work as just one example?

DR. CHARLAN KROELINGER: Thanks, Magda. Those are great points, and I would say you're right. We need to be focusing on the maternal and infant dyad. In our example today about the work that we're doing to prevent maternal death, I would say that's -- the social determinant of health piece is critical to understanding the context around maternal death and I agree, we have great colleagues at HRSA who run the Fetal and Infant Mortality Review Process and Child Death Review. We should be cross-walking some of these strategies, and I think that's something we can discuss moving forward.

The Community Vital Signs is sort of the piloting of this concept of the community context because it does matter, and it is important to recognize these other contributing factors. I

think our recognition from the feedback from these Maternal Mortality Review Committee is that implicit bias impacts maternal mortality and severe morbidity. Racism and discrimination affects those deaths. It's really important to recognize and we're working to build that into our system to standardize that across different jurisdictions, and we're hoping to test that out. This is certainly something that we can reach across federal agencies to test in a broader way once we have the evidence in support of the jurisdictions and the testing process.

Wanda, would you like to add to that?

DR. WANDA BARFIELD: So, I think that's really an important point, Charlan. Part of it is that we, I mean, we definitely have this interest in looking at the maternal/infant dyad -- and sorry that I'm sort of coming in in the middle of this -- but part of it is just getting to the point of even understanding, particularly the maternal areas as it relates to social determinants of health and racism because, as you

know, for far too long, we focused on babies, okay? And again, a while ago when I was training, we were all talking about genetics, right? And the field as far as infant health, I think, we are understanding the factors that contribute, but we really do need to better understand the factors that affect women so that we can then also talk about the dyad and the infant.

So, we're really excited that we're able to really come together as a large group of federal entities to actually address this, but we do have to be honest that it's been a while for us to even sort of get to this point.

And from the CDC side on the data side, I mean, we're learning a lot also from organizations and universities about the approaches that are more appropriate. So, we talk a lot about all these datasets that we have, but we have to understand that there are some components that have limits, right? That it's not just about the medical conditions and the information in the hospital record, but also about process issues.

So, if I have an effective intervention or I need to provide an appropriate support, how is it happening, how quickly is it happening, when is it happening, is it happening at all, and really getting a better understanding of those contextual factors in health and care that really make a difference and save lives.

DR. EDWARD EHLINGER: And I'm going to go to Colleen for the last question.

DR. CHARLAN KROELINGER: I'll follow up later. Thank you.

DR. COLLEEN MALLOY: I just had a quick question. So, when you mention taking pregnant women off of the vulnerable population group for vaccine research, I just -- I don't know that much about it. I mean, I guess by doing that, you are able to have better research and studies for pregnant women and vaccines. Is there any negative to taking pregnant women out of the vulnerable people description in the common rule that you referred to?

DR. ALISON CERNICH: Sure. Colleen,

thank you for that question. So, you know, vulnerable populations generally include those that cannot consent for themselves because of concerns related to power structures; so, for example, individual in prison and/or individuals who can't provide consent because of cognitive limitations; so, for example, individuals with intellectual disability, older adults who have guardianship or have cognitive limitations.

So, what the common rule change allowed us to do, the vulnerable population is more about the consent process for research rather than the scientific understanding of what the potential risks and benefits are. It's essentially putting a woman in control of the decisions being made related to her participation in research. Does that make sense to you? So, that's the reason that we were moving towards that, and that has been a long time in coming. And it really is similar to what we're talking about now in terms of the decision-making around the vaccine. So, we are telling women, you can make this decision,

right, with your health provider, but it doesn't involve the consent process, which is where it gets a little bit tricky.

So, I think you're consenting to the vaccine, but similarly, you could consent for research, and I think there's still the consensus that pregnant women are in some way vulnerable and need protection from, and that's sort of the bottom line.

DR. COLLEEN MALLOY: Okay, thank you.

DR. EDWARD EHLINGER: All right. Well, thank you all for the great presentations and great discussion. A lot more that could be discussed, but I get a sense that people might be getting a little hypoglycemic or their butts are getting a little sore. So, we do need to take a break, and sorry, we're going to have six minutes of break or sixteen minutes of break for our lunch. So, I know you're supposed to take at least twenty minutes to eat, but you know, take smaller bites and we'll see everybody back at 2:15 for our panel on COVID, which also will be very

intense. Thanks

[A lunch break was taken from 1:59 p.m. until 2:15 p.m.]

DR. EDWARD EHLINGER: All right. It is 2:15 by the various clocks that I have that are set to Eastern Standard Time, and so, we're back and ready to get started. Always putting these together always highlights the fact of what Robert Burns said. Robert Burns -- it's his birthday today -- he's the Scottish poet -- he said, " The best laid schemes o' Mice an' Men, Gang aft agley, "And, you know, no matter how you put an agenda together, it often goes awry. But then he ends up with, "An' lea'e us nought but grief an' pain, for promis'd joy!" So, my guess is we're going not learn a lot from all of these sessions. So, even though it's painful to fall behind, we are going to catch up and we are going to get some joy from all of the data that we're having and the impact that we can have.

So, this is a session that we're going to be looking at COVID. In listening to the national

experts, they all seem to say the more I learn about COVID-19, the more than I understand that I know very, very little about this disease. And so, every time -- every day we're learning more and learning more about what we need to learn. And so, we certainly know that COVID is affecting pregnant women and infants and, you know, women of reproductive age. So, this is a session -- and we talked about it a lot at our June meeting and again in September and we made some recommendations to the Secretary -- this is a chance to come back and revisit given the new information that we have to see if there is anything that we can step into with some additional recommendations at this point in time.

We're going to have a panel again of people to give us an update on various federal activities related to COVID-19 in terms of data and immunizations and all of those kinds of things, and I have a little change of agenda. So, we're going to start with Dr. Wanda Barfield, then go to Alison Cernich, and then Michelle Osterman

in that order. So, that's how we're going to start because of some needs that they have that they have to get to. So, why don't we start. Dr. Barfield, welcome. I appreciate you taking time to be with us.

DR. WANDA BARFIELD: Great. Thank you so much. I really appreciate the time to talk and I'm going to have the person who is advancing the slides advance the slides today. Thank you so much.

So, I just -- I'm Wanda Barfield, and I direct the Division of Reproductive Health, but I'm currently deployed in the COVID-19 response, and I just want to join you to discuss some of these important and pressing issues. Can you go to the next slide, please?

First, I just want to acknowledge the CDC-wide effort and particularly of the Pregnancy and Infant Linked Outcomes Team or PILOT in this response. They consist of maternal and child health expertise throughout the agency and work in partnership with many of you. CDC is supporting

multiple efforts to understand the impact of COVID-19 on pregnant women and infants and this includes developing new systems such as SET-NET, leveraging surveillance systems such as PRAMS, NDSS, and [indiscernible] and working with clinical partners such as the Icahn School of Medicine at Mount Sinai, the University of Washington, and the Epidemiology of SARS-CoV-2 in Pregnancy and Infant Electronic Cohort Study in order to really better understand the characteristics and impacts of COVID-19 on pregnant women.

And this includes providing support and resources to state, tribal, local, and territorial public health agencies to add to COVID-19 questionnaire supplement to existing maternal and infant surveillance systems such as PRAMS and the questionnaire supplement collects data on the effects of COVID-19 on pregnant and postpartum women and infants. And CDC is also supporting studies with clinical partners. So, next slide, please.

Initially, we had very little data, but we're getting more and more information and are better able to understand the impact of COVID-19 on pregnant women, and we know that pregnant women are at increased risk for severe illness from COVID-19. There are physiologic changes in pregnancy that can increase the risk for severe illness including, but not limited to, increased heart rate and oxygen consumption, increased lung capacity, and the shift away from cell-mediated immunity. And it's also known that severe disease has been associated with other viral respiratory infections during pregnancy.

We also know that pregnant women with COVID-19 might have an increased risk of adverse pregnancy outcomes such as preterm birth. And we also know that Hispanic and non-Hispanic Black women appear to be disproportionately affected by COVID-19 infection during pregnancy. So, we really need to make sure that all women have access to care that they need in order to prevent their potential risk for COVID illness. Next

slide.

CDC has released two studies in September 2020 with important information on the characteristics that birth outcomes of hospitalized women with COVID-19 and about half of hospitalized pregnant women with COVID-19 didn't have symptoms. Among hospitalized pregnant women with COVID-19, more severe outcomes were observed among those who had symptoms at hospital admission compared to those who did not. And several effects on babies were observed including the baby being born prematurely in about 8 to 23 percent of pregnancies. However, pregnancy loss occurred in about 2 percent of pregnancies, and this was experienced by both symptomatic and even asymptomatic women.

There isn't enough data to say for sure that pregnancy loss, including miscarriage or stillbirth, has been more frequent among pregnant women with COVID-19 compared to those without. But we're continuing to watch this closely.

Severe COVID-19 disease is just one of

the outcomes that we're interested in. We also want to know the impact on pregnancy complications and adverse outcomes. In general, COVID-19 has been associated with a prothrombotic state, and there have been some observational studies describing a pre-eclampsia-like syndrome in pregnant women with severe COVID-19. Next slide.

In November, a revised analysis found that pregnant women were 3 times more likely to admitted to the ICU, 2.9 times more likely to have received invasive ventilation, 2.4 times more likely to have received ECMO, and 70 percent were more likely to have died. Pregnant women were more frequently Hispanic or Latina and it's important we focus on mitigation efforts for pregnant women.

Testing pregnant women is based solely on symptoms and testing pregnant women on symptoms alone can miss COVID-19 infections during pregnancy. So, identifying infections early among hospitalized pregnant women can help ensure that appropriate prevention measures are implemented.

Surveillance among pregnant women with COVID-19, including those who don't have symptoms, is key to understanding the short- and long-term consequences of COVID-19 from mothers and newborns and to guide preventive measures. It's also important that we emphasize preventive measures for pregnant women, their close contacts including wearing a mask, washing hands often, staying six feet apart, and avoiding large gatherings. These measures can help prevent COVID-19 spread that may lead to associated pregnancy complications. These prevention measures are especially important in women who are obese before getting pregnant and for women with gestational diabetes. Next slide.

We also know very little about severity of disease among neonates and infants. The current evidence suggests that SARS-CoV-2 infection among neonates are uncommon and that most neonates with SARS-CoV-2 reportedly in the literature are noted as asymptomatic or may have mild symptoms. Limited data suggests infants may be at higher risk of severe disease compared with

older children, and CDC is committed to documenting and understanding the impacts of COVID-19 on women and infants and will continue to share findings including a paper in JAMA next month looking at preterm births during the stay-at-home orders. Next slide.

Thankfully, we now have authorized recommendation vaccines to prevent COVID-19 in the US, and I'm going to defer on this and go to the next slide because you're going to hear a lot more from my colleague, Dana Meaney-Delman, who is going to share more on the recommendations and the v-safe from the ACIP COVID-19 Work Group.

But it's really important for us to now really also talk about health equity in the context of this is exciting news. Next slide.

So, we know that there is clear evidence that among some racial and ethnic minority groups, that they are disproportionately affected by COVID-19 and longstanding systemic and social inequities, which many of you are more than aware of, have put many people in these groups, and

they're at increased risk of getting sick and dying from COVID-19. And the inequities and social determinants of health such as economic stability and health care access and quality disproportionately impacts disadvantaged groups and influences a wide range of health and quality and life course outcomes.

Many of these inequities and social determinants of health that put racial and ethnic minority groups at increased risk of getting COVID-19 and dying include discrimination and systemic racism and unfortunately, discrimination exists in systems meant to protect the well-being or health. Examples of such systems include health care, housing, education, criminal justice and finance. Discrimination, which includes systemic racism can lead to chronic and toxic stress and shape social and economic factors that put people from racial and ethnic minority groups at increased risk. And then health care access and utilization, we know that some racial and ethnic minority groups are more likely to be

underinsured and that health access can be limited for these groups by many other factors such as lack of transportation, child care, or the inability to take time off from work.

We also know that occupation is a factor here and that people from some racial and ethnic groups are disproportionately represented in essential work settings such as health care facilities, farms, factories, grocery stores, public transportation, and some people who work in these settings have more chances of exposure to the virus that causes COVID-19 due to several factors such as close contact with the public, other workers, and being able to work from home and not having sick paid leave days. Next slide. So, go on to the next slide.

CDC reports a number of laboratory-confirmed pregnant women from all fifty states, DC, and territories on a weekly basis. As of January 15th, we have over 55,000 laboratory-confirmed pregnant women and 66 deaths, and this website provides cases by selected demographics

such as race, ethnicity, and indicators of severe illness to include hospitalization, ICU, and mechanical ventilation. And I'd like to note that there is a new webpage with infant outcome data to complement the data on COVID-19 during pregnancy. We're also initiating monthly reports of birth and infant outcomes from states, territories, and participating COVID-19 surveillance through SET-NET and as of January 15, seventeen states reported data on 6,895 completed pregnancies. The webpage provides additional data on trimester of infection, delivery type, preterm birth, and SARS-CoV-2 lab results for infants born to pregnant women with COVID-19. And we'll hear more about the work of CDC Center for Health Statistics that is working together to add additional data to better characterize women with COVID-19 during pregnancy and their newborns, and those data are being updated bimonthly.

So, now I'd like to turn things over to Alison Cernich so that she can talk about the work at NIH. Thank you.

DR. EDWARD EHLINGER: Thank you, Wanda. Dr. Barfield, I appreciate that.

DR. ALISON CERNICH: Thank you. So, can we pull up my slides, please? Great, thank you so much. This was current as of when it was submitted, January 12th, and I'm thankful to Wanda for covering the most recent statistics. If we can go to the next slide, please.

So, just as a summary, I'm going to cover our project in Maternal-Fetal Medicine. I'm going to give you an update on our global network. We're going to talk a little bit about breast milk. We'll talk also about Multisystem Inflammatory Syndrome in children and then some other work related to our Intramural Scientific Program at NICHD. Next slide, please.

Dr. Barfield gave a fantastic overview of the situation in pregnancy, and I'll also add for children that at this point -- this was current as of the 12th, and as we know, everything changes -- and so, now we're at 1.8 million children as of January 15 -- that's the last update that we have

-- with the majority still in the ages of 5-17. Deaths are up to 237 total, and really, there's a rate of increase in the pediatric COVID-19 cases from the time where the presumptive positive cases started to actually be tested. There was a sort of artificial jump in positivity rates. But now that positivity rates are being monitored through testing, we're looking at significant trends of increases of cases over time and this narrows the community spread. Next slide, please.

Related to NICHD's efforts, as many of you know, NIH was initially through the CARES Act given large supplements to accelerate research in the area of COVID-19. And so, there were a number of efforts launched through various institutes and centers who were given specific funding and through the Office of the Director.

NICHD was not provided funds such as this. So, what we tried to do was leverage what we had internally to pivot some of our studies to make sure that we were covering issues specific to our populations of interest.

So, one of the first things we did was pivoted money internally to fund our Maternal-Fetal Medicine Units Network to examine maternal and neonatal outcomes for pregnant women with and without SARS-CoV-2 infections. So, we are looking at medical records of about 24,000 women who had given birth at a clinical center and the map over to the side shows the sites, and to determine whether pregnant or immediately postpartum women experience higher maternal morbidity and mortality, and we also have pre-pandemic data. So, we're able to compare both symptomatic women, asymptomatic women, non-CoV-2 positive women, and then also pre-pandemic status, evaluate women whether women with the infection -- both in- and outpatient-- have higher maternal morbidity and mortality rates than pregnant women without infection, and then look at the outcomes for pregnant and immediately postpartum women and their infants. And so, we're looking at maternal morbidity and mortality composites defined as at least one of the following during pregnancy and

through 6 weeks: mortality, morbidity related to hypertensive disorders of pregnancy, morbidity related to postpartum hemorrhage, or morbidity related to infection, and I will tell you that that will be presented this week at the Society for Maternal-Fetal Medicine, some of the initial findings. So, please look for that this week. Next slide.

We also were able to pivot some dollars to look at the global impact of COVID-19 infection on pregnancy outcomes in our global network. These are studies that are active in eight low- and middle-income countries including the Democratic Republic of Congo, Kenya, Zambia, Guatemala, Bangladesh, India -- two places, Negour and goodness, I can't remember the other and I can't see it very well -- Pakistan -- I think it's Belagavi -- and then Pakistan.

So, this is a coordinated network that is really looking at the prevalence of COVID-19 infection. And so, they are getting antibody testing at delivery. We're looking at the impact

of COVID-19 exposure on maternal, fetal, and neonatal outcomes in the global network and also looking at the knowledge, attitudes, and practices of pregnant women related to COVID-19 during their pregnancies in these global settings. Next slide, please.

We've also been funding work related to the presence of SARS-CoV-2 in breast milk. So, we've had investigator-initiated work in an existing collaborative network that's supported by NICHD, NIAID, and mental health. As of this moment -- this was in August, but we have one other study that we've looked at -- it does not seem that active virus is transmitted to an uninfected infant via breast milk and in many cases with proper hygiene and practices, it is safe to breastfeed even if infected. There seem to be antibodies directed against SARS-CoV-2 in human milk. So, our director has mentioned, you know, this might be a really novel way to look at antibody development or antibody treatment because of the presence of these antibodies in breast milk

for therapeutic use. Next slide, please.

We also, as many of you may know, we have looked at the development of a very severe condition very similar to a post-infectious condition such as Kawasaki's disease in children called Multisystem Inflammatory Syndrome in Children, and we've been involved in the Trans-NIH effort to study this condition with our colleagues in the Heart, Lung, and Blood Institute and the Immunology and Infectious Disease -- Immunology, Asthma, and Infectious Disease Institute to really look at these children to determine what places them at risk for this post-infectious condition.

So, the three studies are looking at various outcomes. The NIAID study is really looking, not surprisingly, at the immunologic mechanism, immune signatures, and predictive biomarkers associated with disease phenotypes in both hospitalized and non-hospitalized children who do not have MIS-C.

We also have our study at NICHD that is really looking at the pharmacokinetics and

pharmacodynamics and safety profile of the treatments provided to these children and looking at the drug safety profiles or adverse events.

And then the NHLBI study is looking at the long-term cardiac and pulmonary impacts of the condition.

We are developing common data elements and coordinating protocols across the sites and the data are going to be publicly available across three of our data-sharing platforms when they are at a point where they can be shared. Next slide.

The other thing that that we are looking at obviously is, you know, with Zika, we learned that the placenta was an entry point for the virus and so, our intramural program includes a large perinatology research branch. This is located in Detroit at Wayne State University.

And they looked at the foundational biology to determine why it is that it seems vertical transmission is not happening in SARS-CoV-2 as it did with Zika. And when they looked at single-cell RNA sequencing of mainly women who are

infected with COVID-19 in their third trimester, which is the bulk of infections in pregnancy according to CDC data at this point, really at this point, what happens is the placenta cannot manufacture this receptor. And so, the SARS-CoV-2 can't gain entry. It also lacks the mRNA to make the enzyme that the virus uses to enter a cell. The fact that this receptor and enzyme are present in only miniscule amounts in the placenta may explain why there's been less vertical transmission of the virus from the mother to the baby. Next slide, please.

We also have a number of other intramural activities we were able to pivot in some of our labs internally to start looking at various foundational biology as well as device development projects looking at the human lungs, looking at similar particles that can be used to test vaccine candidates, looking at the innate immune response, and determining how the virus actually replicates and propagates at the very basic level, looking at various therapeutic targets that we could explore,

developing a multimodal biosensor for monitoring of symptoms and presentation that would not require human interaction, and also then looking at the molecular biology of the SARS-CoV-2 virus itself. Next slide, please.

We hosted a couple of workshops related to COVID-19. One that I think would be of major interest to this group was held in September and this was looking at COVID-19 in pregnancy, looking at clinical research and therapeutics updates, looking at the approach to obstetric therapeutics development in COVID-19, and there was a large-scale overview of pregnancy registries for COVID-19.

We also partnered with HRSA and AHRQ to talk about Child Health Services Research in Light of COVID-19 where we listened to the community to help us determine where we could potentially focus our efforts moving forward. Next slide, please.

I'm going to talk a little bit about things that are happening at the Trans-NIH level. One of which you may have heard about is the RADx

Initiative. The RADx Initiative is a large-scale program looking at diagnostics, which started with things that you heard about in the press very early, the Shark Tank, where we looked at diagnostic methods to get quickly information about SARS-CoV-2 and expand our diagnostic efforts across communities.

The next part of that effort was called RADx-rad or RADx Radical, and these were radical approaches to quickly understand and diagnose SARS-CoV-2 or provide surveillance, so, for example, in wastewater testing, and give that as an early indication to a community about spread. We were fortunate -- NICHD was fortunate to receive an allocation of money through RADx-rad to look at predicting viral-associate inflammatory disease severity in children who had laboratory diagnostics through the use of artificial intelligence and these were really looking at trying to help predict the longitudinal risk of disease severity after exposing to and/or infection by SARS-CoV-2, and we wanted to help to

manage the health outcomes.

So, we recently made these awards in phase 1. These are milestone-based awards, so we will not transition all of these to phase 2. So, we have these starting out, and if they meet their milestones, we will determine which of these will continue into phase 2. Next slide, please.

We also were able to get some supplements through the RADx Underserved Populations Program. This is a program that is really looking at the use of diagnostic testing in underserved populations, and that can include both individuals who are more at risk for experiencing health disparities, but also other populations that we deem vulnerable to the virus because of their living situation such as individuals in nursing homes or in prisons or children and adolescents who are not getting diagnostic testing at the same rate as adults and other people who may be vulnerable, for example, individual with disabilities or individuals with mental health or substance use conditions.

We were able to supplement one of our Intellectual Disability Research Centers, and this is a grant looking at health and well-being of children with intellectual and developmental disability and getting them back into in-person learning in a special school district in St. Louis. They are using a saliva-based test, and they are also trying to get usability and feasibility of these tests and the perspectives of COVID-19 from the parents and children and staff regarding the impact of the pandemic.

We also have another supplement that came through this program, the Safety, Testing/Transmission, and Outcomes in Pregnancy with COVID-19. This is also at the Washington University at St. Louis, and this is looking at antibody testing to determine how asymptomatic COVID-19 infection in pregnancy may increase the risk of adverse pregnancy outcomes. Next slide, please.

I also want to highlight that our group has been working on, as part of a Trans-NIH

effort, standardization of data elements on psychosocial, biomedical, and biospecimens in pregnancy. We are developing a core set of elements, so they are priority elements from an initial set of 400 and recommended measures to be used in pregnancy studies in COVID-19, but these will also serve as a platform moving forward potentially to develop CDEs for pregnancy to help harmonize studies in pregnancy where we want to try to make sure that we are capturing the same data across studies for the purpose of say meta analyses. Next slide, please.

Some of the data elements obviously include baseline maternal characteristics, maternal outcomes, neonatal characteristics, neonatal outcomes, specific things related to COVID-19 testing, but also psychosocial data elements in terms of social determinants of health, medical care, stressful life events, maternal mental health, and also health-related behaviors. Next slide, please.

We're also trying to do -- with other

ICs, we've promoted some supplement projects for pregnant women and children. This was co-led with the National Institute on Drug Abuse. We had three NICHD projects that received supplements, one looking at MRI of placenta accreta, and this was about viral attachment, entry, and transport within the placenta. Another one looking at infections in youth and also the potential to examine vulnerability and resilience in the context of studies that are looking at child maltreatment, which we know is elevated but being underreported in children as a result of the pandemic. And then, we were also able to supplement a grant looking at maternal inflammation during pregnancy and neurodevelopmental disorders, and we're getting co-funding from the Environmental Health Sciences Institute, who you'll hear from tomorrow, and this is looking at the impact of the COVID-19 pandemic on child neurodevelopment. Next slide, please.

And that is it from me. So, with that, I will turn it over to the next speaker, and thank

you for adjusting.

DR. EDWARD EHLINGER: Great. Dana Meaney-Delman, you're up.

MS. DANA MEANEY-DELMAN: Wonderful. Is your team going to put the first slide up?

DR. EDWARD EHLINGER: They can, I hope.

MS. DANA MEANEY-DELMAN: Great. If not, I can share my screen. But that's what I was operating under. Okay, great. Thank you.

So, thank you for the opportunity to speak with you all today. I'm here representing the Vaccine Task Force of the CDC COVID-19 Response as well as the Advisory Committee on Immunizations Practices Workgroup that's focused on maternal immunizations. It's my pleasure to be here.

As you heard from Dr. Barfield just a few minutes ago, the CDC response has had multiple initiatives to ensure the needs of all women including pregnant, postpartum, and lactating women, as well as infants are integrated into our efforts to combat the COVID-19 epidemic. And this

work brings together collaborators from across CDC, from the National Center for Immunization and Respiratory Diseases, the Division of Reproductive Health, as well as my branch, the Infant Outcomes: Research and Prevention Branch within the National Center for Birth Defects and Infant Disorders. And I am pleased to be here. I currently serve as the Chief of this branch. However, I have spent the last nine months in the broader COVID-19 CDC Response as initially the principle Deputy Incident Manager working with Ann [?] and Jay Butler and then for the past four and a half months working as the Vaccine Lead. So, I was involved in the initial vaccine rollout.

Dr. Barfield has shared much of the efforts of the pilot team, which is staffed collectively by members of her division and our branch division and really, this group of individuals is a seasoned group that has worked on H1N1, Ebola, Zika, and all came together very quickly early on in the response to ensure that we could address the needs of pregnant women,

lactating women, and children.

And all these critical efforts have been crucial in determining vaccine recommendations for CDC. So, next slide, please.

As you saw from Dr. Barfield, you know, COVID-19 has had a preferential impact on women who are pregnant and we saw early on in our initial observational data from our surveillance systems that there were higher rates of ICU admission and mechanical ventilation. And when these data were first analyzed and published in June 2020, I think our main question was whether there were true physiologic differences or whether there were differences in treatment. We know there's a pretty low threshold in the clinical community to provide higher levels of care for pregnant women because of the needs -- the entire physiologic needs to sustain a pregnancy -- changes in heart rate, respiratory function, as well immune function.

But as we continue to look at our observational surveillance data, it became clear

that that observed differences in care did not appear to be the main drivers of the differences we were seeing between pregnant women and non-pregnant women, with, of course, the caveat that this is observational data, surveillance data, but when we were able to accrue additional information, it was clear that there was a higher risk of the need for ECMO, extracorporeal membrane oxygenation, as well as a higher risk of death during pregnancy. Thankfully, the overall risk is still low, but it does appear that there is a disproportionate burden based on observational data for some of these populations.

So, we're excited that NIH and others are continuing to look at this in research trials. Our surveillance is, of course, hypothesis generating, but we're really looking forward to the results that NIH and others will have to determine whether our initial observational data was accurate.

Same thing about preliminary data suggesting preterm birth may be a risk,

particularly for women with more severe clinical manifestations of COVID. Next slide, please.

The data that we showed earlier and that Dr. Barfield mentioned that we received from our case surveillance data as well as from our SET-NET, our Surveillance of Emerging Threats to Moms and Babies Initiative, you know, these data were critically important as CDC, the American College of Obstetricians and Gynecologists, and the EICP in general developed recommendations for vaccination of pregnant women because we really need to think with any of these illnesses about the risks and benefits of vaccination, and there's a clear benefit to vaccinating mothers and we certainly see that for reducing the risk of the severe outcomes we've talked about, but also, perhaps, and this is, you know, still too early to tell, but perhaps even for the infant based on the preterm birth findings.

But the second part of the equation, of course, is what about the safety of these new vaccines -- these new mRNA vaccines and pregnant

women weren't included in the clinical trials of the mRNA vaccinations for Pfizer and Moderna. Pregnancy testing was specifically included as part of the protocol to screen out pregnant women.

So, this resulted in, you know, really limited data when the ACIP and CDC were formulating their recommendations for the first tranche of vaccinations. It was really limited data on the safety of COVID-19 only from those women who were inadvertently vaccinated when they didn't know they were pregnant, and this is you know, a small number compared to the large trials.

And yet, you know, as we approached the need to make these recommendations, we need to balance both the risks and the benefits. We did have some animal developmental and reproductive toxicity data that was reassuring, and we knew that studies were ongoing but really had very limited information to make recommendations.

What we, of course, did know is that mRNA vaccines are not live vaccines. They are degraded quickly by normal cellular processes and don't

enter the nucleus of the cell. And so, when recommendations were being made, these were really the tenants by which we came up with our recommendations.

And also, as discussed, I think it was Alison was discussing this earlier, you know, the discussion about pregnant women and vaccination really took into account this notion of shifting away from a vulnerable label. You know, this was a robust part of the discussion with ACOG and the American Academy of Pediatrics and CDC and the Society for Maternal-Fetal Medicine and women's health providers across the US government. And really, the main takeaway that I think influenced the recommendations was as we were defining the phased approach and planning to vaccinate health care workers first, it was strongly felt that being pregnant should not penalize -- be a reason to penalize health care workers. And so, based on all the collective information, you know, the higher risk of severe outcomes, you know, the unlikely risk the vaccines play based on being,

you know, mRNA vaccines and quickly degraded, and the totality of information, ACIP relied heavily on the advise of ACOG and AAP and ultimately recommended that if a woman was pregnant and she was part of a group already recommended for the vaccination that, you know, she could choose to receive a vaccination and that a discussion with her health care provider may help her make an informed decision, but was not required, and that was a really important point to make sure that there were no barriers for women who wanted to receive the vaccine. Next slide, please.

But because there is such limited information about the safety of these vaccines and these decisions may be difficult for pregnant women, CDC and ACIP provided some considerations to inform discussions and the decisions pregnant women may make even on their own without talking to their health care provider. And these include things like the level of COVID-19 community transmission. In other words, what's the risk of acquisition locally for personal risk of

contracting COVID-19, so, as a health care worker or as an essential worker, this risk, the risks of COVID-19 to her, and the potential risk to the fetus.

You've seen and you've heard from Alison that the risk of transmission during pregnancy is low. But, of course, we, you know, do know that, you know, these children could become infected with COVID-19 postnatally. The high efficacy of both of these vaccines -- Pfizer and Moderna -- both have very high efficacy, the known side effects, and the lack of data about the vaccine during pregnancy so that, you know, these conversations -- whether they were occurring at the vaccine clinic, at the health care provider's office, or, you know, even within pharmacies now -- these are the critical things for folks to think through as they're making a decision about getting vaccinated while pregnant.

The other thing that we made sure to emphasize, we know that both the Pfizer and the Moderna vaccine have a pretty high rate of fever

and side effects, particularly after the second dose, and we wanted to be sure that any fever was promptly treated with acetaminophen but that it was not recommended to use any of the antipyretics as preventive medications.

And then, it's not listed here on the slide, but subsequent to the ACIP recommendations and through our initial vaccination program, we discovered that anaphylaxis does occur, and so we also included guidance on anaphylaxis treatment during pregnancy to emphasize that prompt treatment is necessary. We know anaphylaxis is or can be life threatening, and we didn't want to there to be any delays in the treatment of anaphylaxis just because a woman was pregnant. So, that was specifically emphasized in our ACIP guidance as well.

And then, of course, we were explicit to state that routine testing for pregnancy prior to receipt of COVID vaccine was not recommended, which was a departure obviously from the clinical trials. Next slide, please.

So, what about breastfeeding and lactating women? There are no data and there's a little bit now emerging, but in general, when we're making the recommendations, there really were no data on the safety of the vaccines in lactating women and the effects of mRNA vaccines on the breastfed infant or milk production.

Subsequently, I am pleased to hear that NIH is aware and we are aware as well of some trials that are going on and some breast milk banks that are actually being created. But really, when we talk to the experts both in the American of Obstetricians and Gynecologists as well as the breastfeeding group within the American Academy of Pediatrics, again, we didn't really have any real reason to believe that these mRNA vaccines were a risk.

And so, if lactating women were part of a group recommended to receive the vaccine, again, the recommendations where she may choose to be vaccinated. Next slide, please.

And then finally, I just wanted to

mention our v-safe application, so recognizing the very limited data -- extremely limited data about the vaccine, CDC started the v-safe program which is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after receiving COVID-19 vaccine.

And as part of this, we have created the Pregnancy Registry, that allows for follow-up with patients who receive the vaccine during pregnancy or within thirty days of becoming pregnant, and this includes direct follow-up with these women who are, at this point, all health care providers with a call each trimester, after delivery, and when the infant is three months old, and it's been wildly successful, more than we ever expected, and we are now in the process of beginning to make those phone calls with the idea being that you would hope to better understand COVID-19 vaccine effects and have denominator data, of course, recognizing that this is all observational and we still need the clinical trials to fully assess the effects.

And with that, I think I'm within my allocated time -- I hope so. I'm happy to take any questions.

DR. EDWARD EHLINGER: Great. Thank you, Dana. Really interesting information.

When we planned this session, we were going to start with the basic data from the National Center for Health Statistics, but because of the needs for people to get other places, we changed the format a little bit and I overlooked Michelle. So, Michelle Osterman, my apologies for putting your fourth as opposed to putting you first. So, now you're up, so take advantage of us.

MS. MICHELLE OSTERMAN: Thank you. If you could put my slides up, thank you.

So, today I will be covering a recent data release titled Maternal and Infant Characteristics Among Mothers with Presumed or Confirmed COVID-19 During Pregnancy. I'm Michelle Osterman, and I co-manage the National Birth File at the National Center for Health Statistics, and

I'd like to acknowledge my colleagues, Claudia Valenzuela, and Joyce Martin for their collaboration on this project and presentation. Next slide, please.

To give you some background on this project, in March, NCHS's Division of Vital Statistics, Reproductive Statistics Branch began efforts to encourage states to collect maternal COVID-19 status via the vital statics system. We worked through the National Birth Data Quality Workgroup to encourage collection and to develop standards and processes for reporting maternal COVID-19 status.

Through this, we learned that some jurisdictions have the flexibility to modify their electronic birth certificate reporting system to add maternal COVID-19 while others were able to link COVID-19 status information from their infectious disease surveillance systems to the birth certificate or to collect data through the use of supplemental forms.

Our main goal of this effort is to assess

the impact the COVID-19 on pregnancy, childbirth, and newborns on an ongoing basis. Next slide, please.

Participating jurisdictions began reporting at different time periods with some states starting as early as March and all participating jurisdictions reporting by mid-June. The total reporting period for this release is April through October and data for June 19 through October 31 include all reporting jurisdictions.

Along with differing start dates, states also differed in how they collected COVID-19 status and some states report both presumed and confirmed COVID-19, while others report confirmed cases only. Next slide, please.

Here's a map of all of the fifteen reporting jurisdictions that participated in this effort and on the left side, you can see a list of those jurisdictions. Because we had a limited number of participating states, please keep in mind that the results I'll be showing in a little bit are not representative of the entire US. Next

slide, please.

Before I get into the results, I want to show you where you can find this information. Here is a link to our website where you can find the results as well as -- and here is just a snapshot of what the website looks like. We plan on releasing updated results every two months. So, please be sure to refer back to this site. And this is our second release, which was published not quite two weeks ago on January 12th. Next slide, please.

On our site, you can find the main table that shows select characteristics of women with COVID-19 at any time during pregnancy and their newborns. The characteristics presented are maternal race and Hispanic origin, maternal age and educational attainment, Medicaid as a source of payment, ICU admission, preterm birth, low birth weight, NICU admission, and infant living at the time the birth certificate is recorded.

These data are based on cases of COVID-19 reported to NCHS and linked to the standard birth

record, allowing an analysis of birth-related data by maternal COVID-19 status. Next slide, please.

Also, on our site, you can find in our technical notes, more information about the participating jurisdictions.

As I mentioned earlier, jurisdictions differed in the date they began collecting this information and also in their method of data collection. And here is an example of that. Alabama began collecting in March and Alaska began collecting in mid-April. Alabama was able to match COVID-19 positive tests from their electronic disease surveillance system to their birth records, while Alaska opted to add an item to their birth certificate to indicate confirmed or presumed COVID-19 status. Next slide.

So, quickly before I start on the results, I'll point out that we haven't done any statistical testing on these results and they may change as we get new data. Next slide.

The maternal COVID-19 reporting area -- those fourteen states and DC -- comprised 26.9

percent of all US births during the April to October reporting period. There were 9,195 births to moms with presumed or confirmed COVID-19, and we were able to link 99.6 of all of the COVID cases that were reported to us with the full birth record. There were 461,038 births to moms without COVID during this time. Next slide, thank you.

This figure shows the race and Hispanic distribution of COVID and non-COVID births. You can see that the proportion of Hispanic births was more than twice as high among births to women with COVID-19 compared to births without COVID-19; 50.4 percent versus 23.8 percent.

Non-Hispanic white women accounted for 25.3 percent compared with 52.1 percent of births to women without COVID-19. Births to non-Hispanic Black women made up 13.1 percent of non-COVID births compared with 17.8 percent of COVID births. In non-Hispanic other, which includes non-Hispanic Asian, Native Hawaiian, or Pacific Islander, and American Indian or Alaska Native births, which together account for 6.5 percent of COVID births

compared with 11.0 percent of non-COVID births. Next slide, please.

This figure shows the maternal age distribution for moms with presumed or confirmed COVID-19 and those without COVID. Women with COVID giving birth were more likely to be younger with 52.9 percent compared with 46.5 percent being in their 20s and 6.7 compared with 4.4 percent being under 20. Next slide.

This figure shows the distribution of maternal educational attainment by COVID-19 status. Moms with COVID were more likely to have less than a high school education, 25.1 percent compared with 11.5 percent, and more likely to have a high school diploma or GED, 33.1 compared with 27.0 percent. Combined nearly 60 percent of moms with COVID had a high school education or less compared with less than 40 percent of moms without COVID. Next slide.

Births to women with COVID-19 were more likely to be covered by Medicaid than births to those without COVID; 61.0 percent versus 41.3

percent. Nearly 70 percent of non-Hispanic Black and more than 70 percent of Hispanic births with COVID were covered by Medicaid. Next slide.

ICU admission among women with COVID was 1.2 percent compared with 0.2 percent in women without COVID. This was the pattern by race and Hispanic origin as well. Next slide.

This figure shows that overall and for the race Hispanic origin groups, total preterm, late preterm, and early preterm were all higher among women with COVID during pregnancy than among those without COVID. Overall, the preterm rate for women with COVID is 13.49 percent compared with 9.85 percent among births without COVID. Next slide.

And finally, NICU admission was more likely for infants born to women with COVID than to women without COVID overall and for each race and Hispanic origin group. Overall, 11.8 percent of infants born to women with COVID were admitted to the NICU compared with 8.7 percent of infants born to women without COVID. Next slide.

There are some limitations on the data, all of which were mentioned in the methods. The data set is not national data and is not representative of the entire US and also California is over-represented. Some of the reporting areas did not report COVID-19 status for the entire reporting period. For example, California did not report until June 10th, and Oklahoma started reporting on June 19th. Though, to account for this, births were excluded from the analysis if they occurred prior to when a jurisdiction began reporting COVID status.

And finally, there are different reporting methods. Some jurisdictions use surveillance systems that are matched to birth certificates, whereas others report it directly on the birth certificate, and further, some reporting areas include only confirmed cases rather than presumed or confirmed COVID-19. Next slide, please.

The next steps for this project are to update the web table bimonthly, to add states as

they start reporting COVID status to us, and to possibly add more items to the table. We are also planning to perform more details analysis on these data to further explore some of the differences that are shown on the website.

Thank you for your attention. I'll pass to the next speaker.

DR. EDWARD EHLINGER: Thank you, Michelle. Interesting, interesting, interesting. Let's now go to Leyla Sahin from Division of Pediatric and Maternal Health. Leyla, are you there?

MS. LEYLA SAHIN: Yes, hi. Yeah, I'm here. Hi, everyone. Yeah, this is my first time participating in this meeting. So, thanks so much for the opportunity to talk about FDA is doing related to pregnant women and lactating women related to COVID-19.

DR. EDWARD EHLINGER: We're very interested. I know that for sure.

MS. LEYLA SAHIN: Okay, great. Can I have my slides up, please? Yeah, thanks. Next

slide, please. Okay, next slide. And next slide, please. Okay, great.

So, unfortunately, there is not a lot of drug and vaccine development in pregnant women as everybody knows, and the reality is that FDA does not have the regulatory authority to require sponsors and investigators to include pregnant women in clinical trials. And so, this, of course, is very problematic and that being said, FDA is committed to, you know, doing what it can in terms of advancing research in pregnant and lactating women. FDA, of course, oversees regulated pharmaceutical industry and, of course, data is needed to inform drug labeling and vaccine labeling to inform prescribing, and we recognize that it's really not acceptable to say no data or insufficient data on the risks in pregnancy in labeling.

FDA continues to do what it can within its authorities to advanced data collection in pregnant and lactating people, and FDA was involved in the collaborative workshop with NICHD

on COVID-19 in pregnancy in September that was also mentioned earlier. And then, FDA has also published guidance that address these populations.

Additionally, FDA is a participant on the Task Force on Research Specific to Pregnant and Lactating Women, which is also referred to as PRGLAC, and PRGLAC was required under the 21st Century Cures Act of 2016, and the objectives are to identify and address gaps in knowledge and research regarding safe and effective therapies for pregnant women and lactating women. This task force is led by NICHD, and so, it also includes several members across federal agencies, includes industry representatives, professional organizations, patient representatives, and so, this task force met over, you know, a period of four years and prepared a report and recommendations that were submitted to the Secretary of HHS. The first report was completed and submitted in September of 2018, and that was followed by an implementation report that was submitted in October of 2020. Next slide, please.

In terms of COVID-19 overall, FDA's Coronavirus Treatment Acceleration Program provides rapid response to pharmaceutical company developers and scientists who are working on new treatments, single patient expanded access requests are reviewed around-the-clock, and FDA is working closely with applicants and other regulatory agencies to expedite the assessment of products to treat COVID-19. As of the end of December, there were over 590 active drug development programs in the planning stage, over 400 trials that were reviewed and allowed to proceed, 8 treatments that were authorized for emergency use, and 1 approved treatment. Next slide, please.

FDA has provided rapid and wide-ranging response in advancing development of vaccines, therapies, diagnostic tests, medical devices, and monitoring of the human and animal food supply. FDA has taken swift actions against fraudulent products and is participating in Operation Warp Speed, an HHS Agency partnership to accelerate

development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics. Next slide, please.

FDA has published 70 guidance for industry since March 2020 related to COVID-19 with some of the relevant ones that are listed here. Next slide, please.

The guidance on developing drugs and biologic products for treatment or prevention of COVID-19 published in May of 2020 encourages the enrollment of pregnant and lactating individuals in phase 3 trials, if appropriate, and children should not be excluded from participation either. Next slide, please.

The guidance on vaccine development published in June of 2020 recommends the early conduct of developmental and reproductive toxicology studies to allow pregnant women to enroll in clinical trials. And this was discussed earlier by one of the presenters as well.

The guidance also discusses the importance of planning for pediatric assessment of

safety and effectiveness. Next slide, please.

In terms of evidence generation, FDA is funding a study using the Sentinel System. This includes various cohorts including pregnancy and pediatrics to address regulatory questions. This study is part of an international collaboration related to pregnancy that is being conducted in collaboration with other regulatory agencies as part of the International Coalition of Medicines Regulatory Authorities. Next slide, please.

And so, this is the -- my last slide. I wanted to share that FDA is holding a public workshop next week on February 2nd and 3rd in the afternoon specifically on the scientific and ethical considerations for the inclusion of pregnant women in clinical trials where we will be bringing stakeholders together so other federal agencies are involved as well, industry participants, researchers, IRBs, all with the intent of discussing how to change the culture around inclusion of pregnant women to not default to automatic exclusion of pregnant women and to

shift that paradigm to one of thoughtful inclusion of pregnant women.

So, there is -- you may have had a chance to see the draft agenda. There isn't a session that's dedicated to COVID-19, but I'm sure that that will come up as part of the panel discussions, since of course that's what everybody's talking about. This pandemic was a huge missed opportunity to include pregnant women in clinical trials, so I'm sure that that will be part of the discussion.

And that's the end of my presentation and thank you.

DR. EDWARD EHLINGER: Great. Leyla, thank you very, very much. Dr. Warren, you get to bat cleanup on both of these panels on maternal health and COVID. So, take it away.

DR. MICHAEL WARREN: Great. Thank you. We'll lean on LRG to put our slides up again. Thank you. So, I wanted to share a bit about the activities across HRSA that have been going on in response to the pandemic, and I will start with

MCHB activities. Next slide, please.

Early on, we were able to award $15 million. This was funding that came through the CARES Act, specifically tagged for telehealth-related activities. And so, we funded awards in four categories: Maternal Health Care, State Public Health Systems, Family Engagement, and Pediatric Care. So, we really tried to cover the spread of our MCH-related activities, specifically those that had been impacted by the pandemic, and mind you, this was early April, so we were all still learning at that point, but based on what we were hearing probably from the field. And I should say the State Public Health Systems award that's noted there is primarily around newborn screening, home visiting, and engagement of State Title V programs. So, those have been in effect -- those were awarded at the end of last April really again with the goal of increasing access to telehealth in the various settings that are germane to those topic areas. So, that was an early focus of ours. Next slide, please.

Another major focus of ours has been supporting our grantees. So, as an agency, the Maternal and Child Health Bureau is primarily a grant-making agency; 96 percent of our budget goes out the door in the form of grants. And so, a lot of work to support our partners in states and in communities in a variety of areas. So, for example, in Service and Program Delivery, many of the ways people were doing business had to change early on. So, if you're a Healthy Start program or you're a MIECHV home-visiting agency, those in-person home visits or in-person lactation support classes or group prenatal care, all of those things changed, and so we worked really quickly to be able to support those grantees in transitioning to virtual services, and the grantees were incredibly creative. Early on, we had some Healthy Start grantees, for example, who really led the way in thinking about increasing access to virtual lactation support and how you do that in communities.

Many of our programs also shifted to

virtual trainings and meetings, really shifting the paradigm for the way they do their routine work, and I'll say, you know, we all have been thinking through the challenges of this pandemic, but there are some bright spots as well. I think early on, someone was talking about what are the lessons we've learned around accessibility, and I think this notion around trainings and meetings is one of those where we can actually have the opportunity in some cases to reach more people where travel or funding may have previously been a barrier. We may have some opportunities in engaging our public health workforce, particularly MCH workforce.

The other thing that we've supported in this is temporary reassignment of personnel. So, we know that for many of our grant-funded positions across the country, there is a need in an emergency situation to repurpose those positions and reassign them. So, for many of our grants, states can request that personnel be reassigned temporarily. They can still be funded

by that grant but actually be working on something else, and there's a process states go through to request that.

Of note, the only one really that we can't do that with is MIECHV. The MIECHV -- the home-visiting authorizing legislation doesn't allow us to do that. So, with all of our other programs, we've been able to temporarily reassign personnel. States can reassign MIECHV personnel, but they have to find alternate sources of funding. And again, that's a legislative limitation; that is not an MCHB- or HRSA-imposed limitation.

We've really worked to try to be as flexible as we can for grantees, recognizing that the most important thing they can do is support MCH populations in this pandemic. So, we relaxed lots of reporting requirements. I think maybe for the first time ever, we extended the Block Grant reporting deadline, and this was a big year. It was the State Needs Assessment year. But we pushed those back and moved all those reviews to

virtual, which really helped states to be able to focus their energy on responding to the pandemic.

I mentioned earlier about use of funds, that we now have the ability for MIECHV grantees to be able to support family supplies. So, formula, baby food, diapers, which we know are incredibly important for families during this time when many folks are out of work and don't have access to resources otherwise.

And then lastly in this category, thinking about Title V is that backbone for state Public Health MCH activities. Folks across Title V programs have been involved in a variety of ways: Epi and data support, doing messaging campaigns, working on public awareness, coordinating with state and local emergency preparedness staff. I think particularly after Zika, we saw MCH programs being more included in state emergency response activities and folks recognize now the value of having MCH staff at that table, recognizing that the needs of pregnant women and children are different than the rest of

the population and that we need to really think about that in advance.

Title V has also been helpful in helping to forge partnerships with health care providers and community partners. That is part and parcel of what they do every day. So, as states have needed to think about new ways or different ways to respond to the pandemic, Title V has been able to model that and make those connections in the community. Next slide, please.

We've also tried to be innovative and responsive in this space. You know, part of the challenge of federal work in normal times is that it is difficult to move quickly sometimes and difficult to be nimble, and yet, I think you've heard from colleagues across all of HHS that really has been the approach. There has been so much work done rapidly and we've tried to follow suit in this space as well.

One of the things we worked on over the summer was the social media campaign. Many of you know that early on in the pandemic, after the

declaration of the public health emergency, there was a precipitous drop in routine immunizations and well-child visits across the country, and -- and for good reasons if you think about concerns that providers and parents had. But even as we learned more and we're able to open back up and have those available, lots of families weren't seeking those, and we knew the risks both of vaccine-preventable illnesses but also for things that are normally picked up in well-child visits. So, you heard one of my colleagues earlier today talking about child maltreatment. There is great concern about children who are in communities and families where there is increased stress and yet they're not in school. They're not going in for well visits. They're not in those places where normally you'd have other folks engaging families and asking about stressors and linking them to supports. So, we wanted to focus on getting kids back in for those visits and we did the Well-Child Wednesday's Campaign. That was a fairly time-limited campaign over the summer on social media,

but it prompted a new challenge for us, and when I say challenge, a good challenge, one of our prize challenge competitions.

So, I mentioned those earlier. We've launched a new challenge related to COVID. It's called our P4 Challenge Promoting Pediatric Primary Prevention, and the goal of this is to increase immunizations and well-child visits within the context of the pediatric primary care medical home. So, it is really easy when there is a lot going on to forget that various systems that are in place that are the fabric of well-child care. And so, we really wanted to think about how do we bolster support for the medical home and encourage innovation there.

So, this challenge has been open since mid-December. We've got a million-dollar prize purse that's available. This challenge will be different from other ones we've run in that it's going to be a performance-based challenge. So, in phase 1, we've asked applicants to submit their best ideas -- again, this is easy, three to five

pages, not a complex application -- submit their best ideas for how they might partner with folks in the community to increase well visits and immunizations. From that pool, we will select fifty winners. They will get $10,000 each for a good idea and to go onto the next phase of implementation. Those fifty will take their idea that they submitted, they'll implement it in cooperation with their community partners. They'll do that for six months, they'll measure their performance, they'll tell us about their innovative strategies, and from those fifty, we will select twenty winners to receive $25,000 each. We've had a great show of interest in this. We had the introductory webinar a couple of weeks ago and had well over five hundred folks on, which is about five times as many as we normally have on these challenges. So, I think there's a lot of interest.

And we've also framed this differently as an opportunity to really think about how we build and promote those community partnerships. While

we're focused on the here and now and this response to the pandemic, my secret hope is that this is going to strengthen partnerships between primary care practices and local public health, family-serving organizations, community-based organizations who may be able to work together on other topics once this is done.

We've also just released a new funding opportunity called Emerging Issues in Maternal and Child Health. So, frequently, states and our grantees are limited to funding opportunities that draw on established programs or established needs. There's not really a pool of money that exists for folks to think about building capacity for things that haven't happened yet and building their capacity to address emerging issues. So, this was launched a few weeks ago. We'll provide some -- some grants for partners to look at the needs and priorities in their states and where there are some gaps in their current capacity and how they might enhance that capacity to be able to respond to emerging issues. So, excited that we've been

able to move forward in this space. Next slide.

As I mentioned before, we're not the only bureau in HRSA. There's a lot of activity going on, particularly when you think about COVID. Our health centers have been very involved on the front lines providing care to some of the populations most at risk. Our Health Center Program puts data on their website weekly. So, this data is not actually a little bit dated, but it's from when we put these slides through clearance. And you can see this is as of January the 8th, the response is typically pretty robust at over two-thirds of health centers across the country are responding weekly. To date -- and again, this is early January -- health centers have provided about 8 million COVID-19 tests and administered more than 55,000 COVID vaccines. The impact of COVID has not been only on the patients of these health centers, as you all know, but also on staff. So, since April of last year, 13 percent of health center staff across the country have tested positive for COVID-19.

The pandemic has changed the way they think about doing their business. So, the vast majority of health centers are doing walk-up or drive-up testing; 82 percent of them have that capacity and 30 percent of them at this point in time were doing virtual visits. That has shifted, as you can imagine over the course of the pandemic and still, even at this time, 95 percent of health centers are providing a portion of their services via telehealth modality. And the links are at the bottom of the slides if you'd like to go -- again, you can see the most recent data updated on a weekly basis. Next slide, please.

Our Federal Office of Rural Health Policy has also been involved in this response. So, they made new funding available for rural health clinics, rural hospitals, some focused on general care but some focused-on things like COVID-19 testing. They also made funding available for tribal communities in rural areas and they've really focused on making resources available for telehealth. So, they launched the

teleheath.hhs.gov site, which a clearinghouse of information and resources both for clinicians and for patients, and they have existing telehealth resource centers that have been a hub of technical assistance for providers across the country. Next slide, please.

This effort has really been a heavy lift for HRSA. So, just for context, the annual budget of HRSA in a typical year is about $11 billion but early last year in calendar year '20, HRSA was tasked with administering the Provider Relief Fund. Over the course of last year and early this year, that has been $180 billion in funding. So, that's about 18 times our normal budget and a really tremendous team has come together. We actually had a number of staff from the Maternal and Child Health Bureau including our Deputy Laura Kavanagh who were detailed to that effort to stand up that program and quickly get money out the door.

There have been two primary focus areas for that work. One has been on direct provider

payments and the other on claims reimbursement. The provider payments went out in multiple tranches. One was a general distribution that was really focused on getting money out quickly with broad eligibility determinations and very standard payments and then subsequently there were targeted distributions looking at different groupings of providers. So, providers who were in areas where there was a high disease burden, residential facilities, rural and safety net providers, and then pediatric providers and children's hospitals. So, those different tranches of money went out following the general distribution.

On the claim's reimbursement side, the goal was really to make sure that we were removing as many barriers as we could to accessing testing, treatment, and vaccine administration for people who are uninsured or underinsured. And so, that work has been going on as well through this group that's working on the Provider Relief Fund. Next slide -- that maybe it for ours.

Yep, that's a wrap of HRSA activities.

Thank you.

DR. EDWARD EHLINGER: Great. Thank you, Dr. Warren, and thank you all the presenters. Talk about warp speed from when we started this whole conversation just looking at the new data that are there to how we're looking at the data. It's warp speed all the way.

I'm going to open it up for a few minutes of questions. I know you'll have some chance when you get into your workgroups to go into a little bit more detail about this. But raise your hand if you have some questions for any of the presenters. You know, and while we're waiting, there we go. Paul Jarris.

DR. PAUL JARRIS: Yeah, thank you for a series of great presentations. I wanted to ask Leyla for FDA's point of view. There were systems stood up during H1N1 vaccines somewhat similar -- emergency use authorization. Is the PRISM system or the vaccine data link system up and monitoring for post-COVID-19 adverse effects and if so, any focus on pregnant women?

MS. LEYLA SAHIN: So, thanks for the question. I think that you're asking specifically about what FDA is doing to collect safety data in the vaccines that have been authorized under emergency use authorization. Is that what you're asking? Yeah? Okay. Great.

Yeah. So, Moderna has already set up their own pregnancy registry and it is -- the information is in the labeling for the -- for their EUA vaccine. So, there is contact information where pregnant women who have been vaccinated can call. And then, a -- so, I don't -- I don't think the other manufacturer -- I don't think Bio-NTech-Pfizer has set up their own, you know, similar type of proprietary pregnancy registry, but they may be participating in, you know, CDC ongoing studies, and I don't know if anybody from CDC is available to, you know, to provide any kind of comment on that question.

DR. PAUL JARRIS: Could I clarify because rather than the manufacturers proprietary system, this is a system you call -- once again, we have a

passive system from theirs. But after H1N1, the PRISM system, P-R-I-S-M, PRISM, was set up with large provider organizations like my managed care organization so that they would mind their own electronic health records to see if there were any increased incidence of any kind of an event as a signal and then look to see if they could verify that signal as an adverse event. But I know we picked up early on some Guillain Barre, but it was felt actually to be background by the time it was researched. So, I was talking about more active surveillance rather than the passive surveillance like theirs or what sounds like Moderna has.

MS. LEYLA SAHIN: Yeah, I don't know what the current status is. I am sure that -- yeah, unfortunately, I don't have the answer to that at this point. There is probably some ongoing discussion related to that issue. But I don't have the answer right now for that.

DR. EDWARD EHLINGER: If you could find that and get it back to the committee, that would really be great.

MS. LEYLA SAHIN: Okay. Yes, I will. Yeah.

DR. EDWARD EHLINGER: Good. All right, Tara Sander Lee.

DR. TARA SANDER LEE: Great, thank you. This is just a question that's going to be for Dr. Dana Meaney-Delman. Thank you for your -- for the information that you provided on the vaccine task force. It's kind of a two-part question just -- you discussed how you're going to have like the v-safe -- the smartphone-based tool so that people can provide, you know, personalized health check-ins after receiving the COVID vaccine. I guess my one question is how is this going to be expanded because now we have two vaccines that have been approved for emergency use, but it looks like we have more in the pipeline like Astra Zeneca and Johnson & Johnson, Novavax. So, I think as these candidates become approved and it's just going to get more complicated, and there's going to be more information out there, how do you -- I'm just curious like how you plan to provide education to

these pregnant women so that they know what their options are and how -- and what are, you know, and how to compare, I guess, all of their options and I guess access is going to be a big issue -- what they have -- which vaccine they have access to. But I know your -- your push is to kind of -- or your recommendation is to put choice in the hands of these pregnant women. So, how are you kind of going to expand this, I guess, as more options become available so that pregnant women know best what to do? I'm just curious of your thoughts. Thank you.

DR. EDWARD EHLINGER: Dana, are you there? No? I guess not. Jeanne.

DR. JEANNE CONRY: Thank you. Just a comment. Thank you to everybody for such incredible presentations and detailed information that helps and for partnering with our member societies. I would like to just point out it's been very interesting balancing between the US and global whereas ACOG came out, you know, with strong support and obviously collaborating with

you and rural college took the same dataset and took a different interpretation and basically told every woman she has to abstain from pregnancy for three months after the vaccine and nothing to address the health care workers who were the first ones getting vaccinated here. So, it helps to have our member societies working so closely.

I do have a question for you. Given the access or the possible to big data systems and something like Kaiser Permanente where we've got a hundred thousand deliveries in California -- California with its epicenter for COVID infections -- is there any plan to work with [inaudible] probably 20 to 25,000 of the deliveries annually are in California. It would seem like that's a great database to be able to delve into, and especially with an electronic record linking the infants to the moms. Have you guys been able to contact them or see if you can work with them for their data or is that just a wishful thinking?

DR. ALISON CERNICH: Jeanne, I'm not sure who you're directing the question to. I will tell

you from NICC's perspective. Can you hear me?

DR. EDWARD EHLINGER: Yes.

DR. ALISON CERNICH: Okay, perfect. I switched platforms, sorry. So, I think we have talked to Kaiser. We have talked about supplementing some efforts with them, and to be honest with you, I'd have to check in where we are. We've also had some investigator-initiated proposals from Kaiser as well as from [inaudible]. We have gotten applications also from the priority registry and we've gotten some applications from larger [inaudible.] So, you know, I think where we can try to work to fund their research efforts in this community, we are happy to do that.

We are also trying to think through how we can partner with people who already have those established connections. One of the ways that we've done that as well -- and I didn't put it in my presentation -- but I think very easily accessible. If you put in N3C COVID into your Google machine, N3C is a large-scale big data effort that has been put forward by the National

Center for Advancing Translational Sciences, NCATS. They have put together through their Clinical and Translational Sciences Centers, they have put out of CTSC, they have put together this very large repository of electronic health records, and you can query for pregnancy, you can query for conditions. They have a number of COVID records in there and so, it's not exclusive. It is coming from EHR. So, there are big data opportunities and if you know scientists that want to take advantage of that, they have to have a data use agreement and an intent to use those data in order to access it with some approvals. But I think we are really trying to build that big data repository and then make it available to the research community. So, multiple efforts to do that moving as quickly as we can.

DR. JEANNE CONRY: [Inaudible.] One of the lead scientists for our WPSI from Morgan Health Sciences has just moved to Kaiser Permanente's Research Center in Pasadena with the medical school down there. So, a good person to

maybe see if there's any way to link some of the data or get hold of the data.

DR. ALISON CERNICH: Sure. I'm happy to -- happy to connect with you.

DR. JEANNE CONRY: Thank you.

DR. EDWARD EHLINGER: Thank you to all of the presenters. This was just a lot of really good information.

Before we move on to your next section on Immigrant Health, I just want -- I have to share just one observation that I have. As we look at Project Warp Speed, you know, we've developed vaccines just tremendously fast, but a lot of investment in that. However, we didn't invest anything into the basic infrastructure of getting vaccines out to the population. So, we invested in the really high-tech biomedical stuff at the expense of basic core public health activities. And as I hear our conversations today, we're also investing a lot in the data collection and the biomedical stuff and what Michael Warren identified with some of the core stuff, $1

million, $4 million, I mean, it is paltry compared to the amount of money that's really going into the biomedical stuff.

You know, we know that medical care is really important and all the biomedical stuff is really, really important and the basic public health infrastructure -- the social issues are there that have to also get invested.

So, when we look at the gaps in what we're doing in terms of research, we really need to broaden our scope throughout the whole enterprise of health -- the whole enterprise of public health -- the whole enterprise of what keeps people healthy and really sort of balance off our investments so that we have a broad-based approach to improving health and reducing disparities. So, now I'm off my soapbox. But that was just my observation from all of this discussion.

And I'm going to take the chair's prerogative to not do the Voices of the Hear Me Campaign. I think you've heard -- you've seen

some of those, and I just want -- because I want to take the time to really listen to what's going on in the -- on the border, and so, spend a little bit more time with that.

So, we have got two presenters that are really going to be talking about Immigrant Infant and Maternal Health Issues, and one is Paul Wise, who is a member of our committee, and Annie Leone, who is a midwife in Weslaco, Texas, and so, we're going to get sort of the overview policy activities and also on the ground insights from these two people. So, Paul, I'm going to turn it over to you. So, welcome. I'm glad you could be with us.

DR. PAUL WISE: Thanks so much. I really appreciate it, Ed. It's a pleasure to speak with everybody on the committee about this issue.

My engagement on this issue really is two-fold. One is I was appointed to the US Federal Court overseeing the treatment of migrant children in US Immigration Detention about a year and a half ago, and my role has been to provide

the court independent assessments and monitoring of the care -- both the custodial care and medical care for children in US Immigration Detention and to work with the agencies responsible for the care as well as with advocates and lawyers representing the children to address issues and make improvements in the custodial medical care being provided.

In addition, I've been working in Highland, Guatemala since I was a sophomore in college, which is a long time ago, and I'm there four or five times a year still and have some sense of why people are leaving Central America and trying to attempt to seek asylum and come into the United States.

Could I have the first slide, please? Next one. Thanks.

I'm just going to provide a broad overview of this issue -- an issue that has attracted considerable public attention and concern over the last couple of years. My intent here is not to go into great detail but to provide

a description of the structure and systems of care that exist for migrant children in US detention in an effort to ground our discussion and Q&A that's coming up regarding the challenges and opportunities for this committee and for HHS more broadly.

Basically, the structure for care for children, particularly unaccompanied children, crossing the border and apprehended by immigration authorities looks like this. The apprehension is primarily Border Patrol, Customs and Border Protection, and they are responsible for the initial processing of children, both unaccompanied children and children in family units, and then unaccompanied children are generally transferred to the Office of Refugee Resettlement, ORR, which is part of Health and Human Services. That's in charge of sheltering and continuing the processing of unaccompanied children, ultimately for reengagement with sponsors or family subsequently.

Families leave Border Patrol, Customs Border and Protection, and if they are going to

continue to be detained, they will be turned over in general to Immigration Control and Enforcement, ICE. And they have three family residential centers -- two large ones in Texas, one in Pennsylvania -- for continued detention and for processing through the legal procedures associated with asylum and other requests for release into the United States. There are also special cases including pregnant women in their third trimester, particularly their ninth month, often will be released relatively quickly. Also, at times, children with significant special health care needs will be released into the United States pending continued legal processes. Go to the next slide.

So, what are the issues? Basically, there are two general components that need to be aligned and too often are in tension. One arm we're calling the Immigration Policies -- the consequences of coming across the border without legal papers. The asylum procedures, the procedures for being released into the United

States, and the lawyers and advocates are primarily focused on these immigration policies -- the consequences of being apprehended at the border.

The second component we're calling the Care Component -- what the Custodial Policies are for taking care of children and families once they're in US Immigration Detention. How are the families processed, humanitarian provision, food, warmth, medical care, child-friendly environments? But the problems emerge when the care and the consequences are not appropriately aligned. Problems emerge when people trying to create consequences, particularly deterrents, to attempts to cross the border through using inadequate care as an instrument of policy or consequences. And we'll see when that has emerged at different times. But these two components are general immigration policies that can either reduce incentives or enhance incentives for people trying to cross the border, but also the custodial care for families and children once in detention is a

different issue. Go to the next slide.

We can see just how dynamic these immigration policies have been, which in turn have placed an evolving series of requirements on custodial policies.

The first that got a lot of attention was called Zero Tolerance Policy, which was family separation on the border, and that was implemented in a non-publicized program in the El Paso sector in the fall of 2017, was announced as a general policy on the border in April/May 2018, and basically the Zero Tolerance Policy was that any adult coming across the border without appropriate papers would be taken into custody and separated from any children that they had entered the country with. So, mothers and fathers were separated from their kids because of this Zero Tolerance Policy, and it didn't matter what age the child was, and we know that a lot of very young children were separated and probably about 7,000 children came under the Zero Tolerance Policy during this period and separately, and

there are approximately 700 children that remain un-reunited for a variety of reasons including the fact that some adult family members do not want to be identified as the parent because of fear that that would instigate proceedings against them.

The second major consequence changes was what was called the Migrant Protection Protocols or MPP or Remain in Mexico. And that was initiated in the spring of 2019 and basically that required a Border Patrol and Customs and Border Protection to return families to Mexico to await an asylum hearing sometime in the future in the United States. Unaccompanied children were not supposed to be subject to MPP. So, generally, they continued to be transferred to ORR within Health and Human Services.

The last, which is the Title-42 CDC Protocols or the COVID-Expulsion Protocols were instituted in March of 2020 in response to the COVID pandemic. And basically, that required Border Patrol to turn back -- to basically immediately return all families, minors to their

home country or into Mexico, depending on where their home country has been. The way that the Title-42 procedures have been addressed by the courts over the last few months has altered how children are being handled under the Title-42, but this remains a major disincentive to crossing into the United States because almost always, they will be immediately returned under the Title-42 Expulsion Protocols. Go to the next slide.

And this is just a graph of unaccompanied alien children, unaccompanied kids or UACs over different periods of time. The blue in the middle is 2018, and you can see the Zero Tolerance Program along the full Southwest border occurred. But the biggest increase took place in 2019 where 80,000 UACs came into detention during that fiscal year and the peak, as you can see, was in the spring of 2019. That was just before I was appointed to the court because of the deep concerns for the custodial and medical care that was being provided at that time.

In 2020, you can see there was a

significant drop. However, over the past few months, we've seen significant increases in UAC and family units crossing the border in addition to major increases in single adults being apprehended on the Southwest border as well.

We're talking about close to 10,000 children a month coming into these detention systems. Go to the next slide.

So, the challenges for Health and Human Services, I think can be outlined as you see in this slide. One is COVID protocols have required dramatic reductions in the capacity of the detention systems to handle numbers of kids because of isolation requirements within these facilities. And so, current system capacity has to be viewed as dropping by at least half in some facilities up to two-thirds so that our ability to handle large numbers of children and families within current systems has been reduced because of the COVID protocols in these facilities.

The second is to recognize that any change in consequences -- in other words, the

incentives of disincentives or perceptions of incentives for crossing the border -- could place new burdens on detention systems, Border Patrol, ORR, and ICE in ways that we haven't seen since 2019. Once ORR becomes saturated and cannot take any more children from Border Patrol, Border Patrol may have 1,000 children a day that are coming across the border seeking apprehension from Border Patrol, and they have nowhere to send the kids, and that's when you begin to see major humanitarian concerns being generated. We really need to understand the implications of changes in immigration policy under the Biden administration and make sure that these systems are well equipped to handle whatever is required to implement these policies.

The other issue that I think is relevant here is enhanced cooperation/coordination between the different agencies. This has been a difficult issue that requires attention but this coordination is particularly important not only during the detention process but once children and

families are released into the United States to provide support and infrastructure for children who require ongoing medical care and services once they are released into the United States. We have children with special health care needs coming through these symptoms being released pending their asylum or other legal procedures being released into the United States without adequate coordination of care. Now, there are networks that have been established by pediatric specialty care providers but they are in desperate need of significant financial support and integration into other HHS, HRSA, and I would suggest MCHB programs that have long led the establishment of appropriate high-quality care for children with special health care needs.

And last is consider new integrated approaches to the custodial and medical care for migrant children and families in US detention. Basically, the detention systems that exist were built primarily for adult Mexican men seeking work, and these systems, particularly Customs

Border Protection, try to tweak their capabilities and facilities and training and staffing and service provision to be able to take care of tens of thousands of children, some as young as infants, that come into the care of these facilities. And there is an opportunity now to take a step back and seek more comprehensive coordinated approaches to the care of children coming through the immigrant detention systems.

But the bottom line, particularly in linking consequences and care, is that you can be pro-immigrant, you can be anti-immigrant, you can be Republican, Democrat, Progressive, Conservative, it doesn't matter. Once they come into the custody of the American people, we need to take care of them, and we need to make sure that these agencies that are responsible for the care for these children and families have the adequate resources and leadership to ensure that the custodial and medical care is appropriate, is of the highest quality, and attends to their basic needs in ways that would make all Americans proud.

So, let me stop there and turn it over to Annie.

MS. ANNIE LEONE: Hi, everyone. Thanks, Paul. Can you hear me? Is the audio good?

DR. EDWARD EHLINGER: Yes.

MS. ANNIE LEONE: Okay, good. I just wanted to make sure, okay. I think LRG is going to pull it up. Great.

So, hi, everyone. I'm happy and honored to be here talking with you today. My name is Annie Leone. I'm a nurse midwife. I live in Weslaco, Texas, about ten miles from the border of Mexico in the Rio Grande Valley, and I work at a freestanding birth center called Holy Family Services in addition to the Humanitarian Respite Center Border Shelter. So, I'll be speaking a little about my experiences working at the shelter with migrant moms and babies. You can advance the slides. There we go, thanks.

So, first I'm going to give some background context of Humanitarian Respite Center Border Shelter and the clinic program there, which

we've titled "Babies at our Borders." Then, I'll talk about the experiences of the women and families I see, why they're seeking asylum, some of their specific stories, and some common health issues that I've noticed. Finally, I'll offer some suggestions for policy and a handful of examples of successful programs that I believe could guide in better serving this community. Next slide, please.

So, the Humanitarian Respite Center, which is run by the Catholic Charities of the Rio Grande Valley, has been around since 2014. We serve migrant families seeking asylum. This means the folks who come to us are adults who are pregnant or have a child with them -- often not intact families. They come to us from CPB or ICE custody and we give them food, clothing, care, and assistance arranging travel to their destination. The respite center is the largest shelter in the Rio Grande Valley and in busy times, like in 2018, there might have been up to 1,000 people per day coming through the doors. Most are from the

Northern Triangle -- Honduras, El Salvador, and Guatemala -- but not exclusively from those countries.

We saw a major decrease in numbers since the Remain in Mexico policy started being enforced in 2019, but we're definitely expecting that to change again this year.

A little over a year ago, we were able to get funding for a basic clinic inside the shelter, where I've been providing midwifery care to moms and babies. In addition to doing a full history and clinical evaluation of each migrant, we sign them up for the Migrant Clinician's Network, which is an organization that helps connect them to health care in their destination. Next slide.

These are some of the most common reasons I hear for why folks are seeking asylum. It's often something traumatic, but not always. There are some folks who are just relieved and excited to be heading to live with their family member or loved one. Often, it's a combination of something intense and something happy like fleeing after a

family was murdered or to escape an abusive or threatening situation, but also heading to reunite with their parent or sibling they haven't seen in many years.

Recently, we've had many people come because they lost everything in the hurricanes in Honduras. And when I say kidnapping here on this slide, I want to point out that it's a common experience folks have during their journey in Mexico, not necessarily in their home country. Next slide, please.

So, now I'd like to share a few stories of some of the women and families I've cared for at the shelter. For their privacy, I've changed all of their names, and although the photos in my presentation are all of people I've cared for at the shelter, the photos don't necessarily match up with the women whose stories I'm telling.

So, this is the story of Fabiana from Guatemala who arrived to us in May. Fabiana had lost her two prior husbands. One had been murdered. The other drowned while they were

crossing the Rio Grande together years before. Fabiana has two older teenage sons who have been living in L.A. for a number of years with a tia. She ended up meeting her current partner and they got pregnant. They decided to cross the river together when she was 36 weeks and then they were separated immediately by CPB. She didn't hear of his status for a couple weeks and she was naturally very distraught thinking he could be sick with COVID in a detention center, especially after having lost her two prior partners.

Fabiana ended up having a cesarean alone in the hospital in June, and she stayed with us for a few weeks postpartum at the shelter. She finally was able to leave for L.A., where she has been living in a shelter there close to her sister and her sons. She still hasn't been reunited with the father of her son. Next slide, please.

This is Yesica from Nicaragua, her story. She came to us in October. Yesica and her partner were fleeing political persecution. They were separated after crossing the border, and she

couldn't reach him for a while, so she wasn't sure if he was deported or in detention. She had experienced some harassment during her journey while in Mexico. She ended up deciding to cross the river in the last month of her pregnancy because she was afraid of having an unattended birth in Mexico. She was sent to the hospital by CPB and diagnosed with preeclampsia after crossing. She had a preterm birth alone in the hospital. Yesica has since shown some signs of PTSD and anxiety since her experience of the journey and being separated from her partner.

She stayed with us for a while at the respite center, never had a sponsor, and so, she moved to a long-term shelter in the Rio Grande Valley. I still visit her sometimes. She's smitten with her son but still doesn't know when his father will get to meet him. Next slide, please.

Seydi from Honduras arrived in October. About three years ago, her ex-husband brought her oldest daughter, who was 12 at the time, to the

United States with him. She later found out her daughter was being sexually abused and potentially trafficked. The dad was put in jail, and her daughter went into the foster care system. Seydi's only goal since then has naturally been to reunite with her daughter. So, she made the journey with her two young sons to cross the border. They were sent back to Mexico and were stuck at the tent camp in Montemorelos for more than a year. While she was at the camp, she was raped in front of her sons and became pregnant. She has almost no prenatal care. Finally, she decided to try crossing the river and was allowed entry at 34 weeks pregnant.

We connected her with CPS and she was able to take a bus to see and hug her daughter briefly for the first time in years. Then, she and her sons had to move onto the other state where her sponsor lives. Seydi will have a long process to get custody again of her daughter. Next slide, please.

Laura from Honduras came to us in the end

of 2020. She had been working at a tienda and was regularly extorted and harassed at her work. Then one day, she was gang raped. She became pregnant. Laura wanted to terminate the pregnancy, but she was unable to access an abortion. Later during her pregnancy, she found that her 5-year-old daughter had been repeatedly sexually abused by her stepfather, who had been babysitting the kids whenever she worked. She fled with her two young children. While they were in Mexico traveling, they were kidnapped and held hostage for a number of months before they managed to escape with the help of someone and finally made it across the border.

Laura had no prenatal care. She was treated for an STI. I recently heard that she gave birth, and she reports she is doing okay. She sent me photos of her and the children. Next slide, please.

In terms of the health status of the migrant mamas I see, I wanted to point out some common scenarios that I notice frequently. Not

surprisingly, many of them arrive to the border having had little to no care with no medical records usually. The stress and conditions of their long journeys lead to a lot of infections and to a higher risk of preterm labor. I would say probably around half of them were sent to a local hospital by CPB to rule out preterm labor after they crossed. I have also seen plenty of women who had a preterm birth in a day or two after crossing, and they often arrive to the shelter without their baby who has had a longer hospital stay.

I've had to send several women to local hospitals for postpartum hypertension, which is probably partially due to all the stress of their experience. Most of these women have obviously higher risks for mental health concerns like postpartum depression, given the trauma they have endured. There is a high level of concern for exposure to COVID in this population during their journeys, during their time in the CPB facilities, and during their time in refugee camps or

shelters.

We've also noticed that there is a certain level of trepidation sometimes with the migrants and/or their sponsors to seek services and care due to how they perceive this might impact their immigration status. Next slide.

So, as you can see, there are some pretty challenging scenarios to address with this community. I would like to offer some suggestions for policy changes that I believe could be helpful for helping these families thrive.

First, I've listed some immediate actions that should be taken at the border. We need to end the separation of fathers of babies from pregnancy mothers. From what I have seen, any pregnant woman who comes with her partner or father of baby is separated from him, and he is sent back immediately unless they have an already living child with them. Most of these women have no idea when they will see him again or when he will meet their child.

We also need to be granting entry to all

pregnant mothers regardless of what stage of the pregnancy they're in. I've heard countless times from women who had tried crossing one or more times prior but were sent back until they were near term.

It's also extremely upsetting that in recent times, it seems these families are forced to cross the river instead of being allowed entry at a bridge on foot. We need to open up the bridges again as entry points instead of creating the scenario where people have no other choice but to dangerously cross the river to be allowed into our country. For anyone, and especially for someone who is pregnant, and/or with young children, this presents enormous health and safety risks and is completely preventable.

Another concerning thing that I see is folks having had their medical records or medications confiscated by CPB. That's an obviously unsafe and unnecessary practice that needs to end.

And through my work at the shelter, it's

become apparent that we absolutely need to have clinicians on site to be the first point of entry into our health care system for these families. Having social workers and potentially therapists as well would be essential. These folks are sometimes in crisis mode and could use a therapist. All of them should have the chance to be evaluated by a social worker right after entering to make sure that they get immediately connected to counseling and other important community services in their destination. Next slide.

So, looking at the bigger picture beyond the actual border, it's essential to focus on expanding access to care for vulnerable communities like these families that I see at the border. As mentioned, getting them plugged into the health care system from the moment they enter the shelters is huge. To do this, I believe we should invest in networking systems like the organization we work with at the shelter clinic called Migrant Clinician's Network. They help

arrange health care services for the families in their destination cities, which I'll highlight more in a minute.

A barrier that we've also noticed to getting folks into care is that many federally qualified health centers done want to accept new pregnant patients past a certain point of gestation because there seems to be a penalty for that. We need to remove this penalty so that FQHCs will not have a reason to turn away folks who have no other sensible place to seek care.

Unfortunately, as we're all aware, so many people in our country like these families still can't get appropriate health insurance, and this translates into poor outcomes. Working in the state of Texas, I've seen very clearly how the incomplete coverage of Medicaid and CHIP services here can impact choices my patients make about when to seek medical attention, even when they may be recommended to seek urgent evaluation.

CHIP here in Texas basically only covered prenatal care and the labor and birth. This

leaves out so many potential scenarios when a person might need care that they are then hesitant to seek because it will cost them an arm and a leg.

A really good example of how we're failing folks with inadequate coverage is the scenario of getting contraception postpartum. I've had many moms here in Texas whose Medicaid runs out before they even make it in for their 6-week postpartum visit. I believe we are failing and neglectful in the realm of postpartum care in our country. Routine postpartum care at most places currently means you get only one visit around 6 weeks, which this visit is often missed and is nowhere near enough to be catching and addressing all the challenges that can come up in the vulnerable postpartum period. This is reflected in our very poor maternal mortality rate.

At the birth center, where I also work, we do two home visits in the first two weeks after birth in addition to the 6-week visit, and yet

this often still seems not enough. Next slide.

So, now I'd like to touch on some program models that we can look to as great models for how we can better serve folks like the migrant families I work with.

The Migrant Clinician's Network or MCN is the organization we work with at the shelter that I've mentioned. They were founded in 1985 and they have been an incredibly effective support system for migrant families since then.

After I evaluate someone clinically at the shelter, we consent them to participate in the MCN program, and then they get assigned a case manager, like Naeli [phonetic] who is pictured there in the top photo. This case manager stays in contact with them and is tasked with coordinating their care, meaning they search for the right clinic in their destination, such as the nearest FQHC, they set up the visits, they send the medical records, and they follow them until the care is complete or until they opt out of the program. It's been amazing to see the impact of

MCN instead of worrying if it will be weeks or months until someone finally finds a clinic and gets in for an appointment. I can rely on MCN to be managing their case and make sure they get into care ASAP after arriving -- within a few days sometimes. This is especially essential with any cases that I label as urgent.

Special Care Access Network is another program that has made a big impact. The SCAN program coordinates care for migrant children with complex care needs. Dr. Marcia Griffin, who is in that second photo, along with Paul and other advocates, help to set up this network, which consists of fifteen communities with academic medical centers that provide low-cost or pro bono care to children in need.

For example, there was a young girl who had been tortured and had a resulting arm deformity. SCAN was able to get her a very needed surgery for minimal or no cost near her destination city.

Washington state, as I'm sure you all

know, is an example of a state that extended Medicaid and CHIP coverage and added a family planning extension to make sure folks aren't falling through the cracks. This has not surprisingly translated into better outcomes [inaudible.] In Washington, a postpartum mother doesn't need to worry that she won't make it in for a covered postpartum visit [inaudible] contraceptive method of choice or lose her insurance [inaudible.]

The Centering Group Model of Care is something that has a growing body of evidence-based benefits like reducing the rates of preterm birth and is therefore gaining more recognition. I was able to do centering group prenatal care at my job in [indiscernible] and have seen the enormous impact it makes on outcomes and experience, especially in communities with lower resources and health literacy.

It's beautiful to watch the way a group unfolds over the course of a pregnancy and to see how it encourages people to be so much more

engaged, educated, supported, and taking charge in their own experience.

The centering model was originally created for prenatal care, but it's now being applied in other areas of health care as well.

I think making centering the standard way that we do care for pregnancy and postpartum and enhancing the reimbursement for group care is a step in the right direction. Potentially creating centering groups specific to refuges or asylees in areas with large populations could be a gamechanger.

Nurse Family Partnership is an innovative and yet simple care model that does a great job of focusing on the whole picture of a family's health, not just the medical aspects, but the social and public health perspectives as well.

This home visiting program, which aims to serve low-resource families, is relationship based, and it strives to fill the gap in addressing all the needs that our typical routine medical visits can't meet. NFP is unique because

it allows the nurse to identify and address the particular challenges that each family faces to build trust with them and provide thorough education, and to connect them to all the resources in the community that will make an impact on their health trajectory. Next slide.

And finally, how can we better prepare our health care workforce to be advocates and care providers to folks like these migrant families? It seems imperative to me that we need to start by revamping our medical and nursing school curriculums to include mandatory thoughtful and rigorous education about medical and institutional racism and implicit bias. I believe this education is absent in a meaningful way from most programs and it will be critical to achieving the goal of creating health equity.

We know the impact that racism has on health outcomes, especially in the realm of maternal and infant health. Addressing this needs to be at the forefront of our conversations, starting in school. We should also strive to make

alternative health care entities like peer support networks and advocacy programs more integrated into our health care system. Examples of this would be doulas and breastfeeding peer support endeavors. There's a growing body of evidence that demonstrates the immense value of doulas on birth outcomes and experiences, especially for folks like migrant women who might not have an adequate support system. However, doulas are often still shunned and undervalued in the health care setting.

I'll add that even the profession of midwifery is in many places not as integrated and respected as it should be in our health care system, and I truly believe the midwifery model of care is critical to moving us forward in the field of maternal and infant health.

Breastfeeding peer networks have also been shown to improve rates of exclusive breastfeeding and are something we should expand widely. Where I work in the Rio Grande Valley, I've seen firsthand the impact of community health

workers or promotoras like Maria, who works with us at the birth center. She helps with endeavors in the community like our classes and our mobile unit outreach. Making these vital entities a more respected and mainstream part of our health care workforce would do us a lot of good. Last slide.

And I hope I've given you some food for thought today. Thank you for inviting me to have a conversation with you.

DR. EDWARD EHLINGER: I think you've done more than just give us food for thought. Thank you for the work that you do. Paul, thank you for your involvement in this issue. Thank you for bringing it forward from both sort of an administrative oversight systems perspective and the on-the-ground perspective of the stories that are really facing the women and their families and the providers in those communities. And here I am in Minnesota on another border, but, you know, what's happening down in Texas and Arizona and California is a problem for the people up here just as much as it is for the people down there.

We need to have a national approach to this is from my perspective.

So, let's open it up for some comments and questions that people might have, and I see that Steve has his hand raised.

DR. STEVEN CALVIN: Thank you. Thank you, Annie and Paul, for your work. It brings me back thirty years ago to my five years on the Arizona border as a National Health Service Corp physician. So, it rings true, and I also have to say that of all of the nurse midwives, the many, many that I've worked with, the best ones have come through Holy Family. They have experience there.

MS. ANNIE LEONE: I appreciate that. I will tell everyone at Holy Family.

DR. STEVEN CALVIN: Well, and the other point too is, I mean, this is such a complicated problem. It's overwhelming. What you're dealing with is heartbreaking and overwhelming, and I think it really points to the need for comprehensive immigration reform and, you know,

things that are kind of beyond what you're doing. But what you're doing is crucial. So, thank you.

MS. ANNIE LEONE: Thanks.

DR. EDWARD EHLINGER: Other questions or comments? Yeah, I was just, you know, Jeanne.

DR. JEANNE CONRY: I just want to thank them. I think Magda is the one who said that a story is worth all of our words, and those stories there were so moving and it's what I'll remember from the presentation. And just to say that this is very much like the refugee crises that are going on around the world. So, we're no different than all of the other border exacerbations. So, putting this into an ethical perspective on ethically how we should treat everybody is the basis of it, and I think you framed the problem and have given us a very good understanding of the problems we face. So, thank you.

DR. EDWARD EHLINGER: Thank you. I should point out the fact, Jeanne, that you put it in terms of the sustainable development goals. I think that's also a really important thing. Paul

Wise, you had a comment?

DR. PAUL WISE: I was just going to mention that the most dangerous place in the world -- the highest rates of violent death in the world -- Syria. Number two is Honduras. Number three is Salvador. The most dangerous city in the world is Caracas. Guatemala is also high up on the list. Then, you get to Somalia. Then you get to Libya. In other words, the places that most of these families and children are fleeing are among the most dangerous places in the world, and sometimes we forget that because they are not formally listed as being in conflict. But yet, the risk of death, being a victim of violent crime and sexual predation is among the highest in the world.

DR. EDWARD EHLINGER: Magda.

DR. MAGDA PECK: Several of us on SACIM have a history at the border. For me, it's over forty years ago with the National Health Service Corp in Brownsville at the Brownsville Community Health Center as one of the first physician's

assistants to serve mothers and children. And so, thank you for sustaining purposeful and passionate work.

My question -- two if I could. One is given this extraordinary moment of changing administration and we have seen that there have been changes in migratory patterns and movement of people that are in anticipation or accompany such times of change, can either of you speak to what you see ahead for the next six to twelve months as communications are incredibly savvy and word gets passed, what are we -- not just in this point of time -- but what can we anticipate in the next three, six, twelve months without action? What actions do you hope will happen, and what are the most urgent ways that we can push policy at this moment given transition of administration?

DR. PAUL WISE: Annie, do you want me to take that first?

DR. MAGDA PECK: Paul, I want to start with you first, if I course, and then Annie down on the ground, and then I'll come back to another

question later about what data do we need to continuously monitor what's really going on of what will happen next.

DR. PAUL WISE: The perception is that many of the highly restrictive Trump administration immigration policies are going to be revised or rescinded. The COVID Expulsion Protocols, the MPP, is under scrutiny, and many advocates want MPP to be lifted because of the humanitarian concerns for families basically in informal encampments on the Mexican side of the border that are very unsafe with inadequate humanitarian provision or security.

The issue is greater anticipation for rescinding of the Title-42 Expulsion MPP, changes to the asylum protocols. There will be incentives for more people to try to cross. There is a huge backlog of people who want to cross into the United States that the concern is now will be trying now. One person mentioned to me -- who has great experience on the border -- is that the biggest problem for these detention systems is

hope. That the greater the hope for entering the United States and being able to live in the United States, the more pressure you will see on these systems of care. And we need to ensure that changes in consequences, these changes in the immigration policies, are met by comprehensive planning, resources for the systems so that they are able to treat all people coming across, but particularly kids and their families appropriately, ethically, humanely, with the highest quality of custodial and medical care.

The concern is that if we're not careful, we could go back to the spring of 2019, where you have this -- particularly now with COVID -- the systems get saturated quickly and you still have thousands coming across every day, and that is a recipe for disaster, and even the best intentions and systems begin to unravel because of overcrowding, and we need to make sure that the consequence changes are reflected in our ability to care appropriately for the people who come into these systems.

I don't know, Annie, do you want to add anything?

MS. ANNIE LEONE: I agree with all of that for sure. I would say this is -- this time is like a unique opportunity because we have had this lull where the numbers have gone down so much that we now have an opportunity before, you know, we get this huge surge in numbers again to potentially get a little better about implementing some practices and bolstering resources.

And so, one thing I would certainly say is preparing all of the facilities -- the shelters and the immigration facilities -- to better handle COVID, which I think would probably mean more masks and ability and money for sanitation and isolation practices. Certainly, the slide that I had about the border policy actions, I feel like in my head, those are the immediate things that need to happen. There's no reason why any father of a baby should be separated from, you know, his pregnant wife because they don't already have a living child with them. There's no reason why the

immigration officials should be taking people's medications and, you know, medical records. Just all of those feel like they are very -- we can make those things happen kind of right away -- or we should. Yeah.

DR. PAUL WISE: I should also point out there is something called the Flores Settlement Agreement or Flores, which is basically the identified standards for caring for children in immigration custody. It's a legal agreement signed under the Clinton administration but that continues to provide sort of the infrastructure, the scaffolding for conditions -- custodial and medical conditions -- within the immigration system. The court supervising the Flores Agreement is the court that I was appointed to and why this court has jurisdiction over these kinds of issues and concerns.

DR. MAGDA PECK: So, Paul, as a quick followup, given that this is SACIM and that our particular focus is on the prevention of maternal and infant mortality and this is a particularly

at-risk population, could we look to you to help us on how to elevate this sentinel group of immigrants as a way to prioritize policy recommendations? I'm just, you know, there will be a larger surge, but I'm just wondering if you could follow up as a member of SACIM and be a bridge and help us to be able to shine a spotlight on this being the sentinel population that we should pay extraordinary attention to right now?

DR. PAUL WISE: There are steps that SACIM could and I feel should take to address opportunities within HHS, perhaps within MCHB, HRSA, but also more broadly to provide expert guidance to other agencies that have not had a long history of responsibility for the medical care for children with special health care needs or for the appropriate emotional behavioral care of children experiencing intensely traumatic events.

DR. EDWARD EHLINGER: Thank you for that challenge to us, Paul, and I look forward to your leadership on SACIM to help us do that so that we

can move forward. Thank you, Paul and Annie, for your presentation. This was just -- I can't say wonderful -- I mean, it was chilling, it was sad, it was heartbreaking, but it was certainly informative, and I think challenging to all of us to deal with this complex, very important issue.

DR. PAUL WISE: Thanks for the opportunity.

MS. ANNIE LEONE: Yeah, thank you all.

DR. EDWARD EHLINGER: And so, now we're going to move into our breakout -- our work group sessions and there's a lot of work to be done in these sessions. You know, just from the issues that we've talked about today, there's lots of work. So, I'm just sort of, you know, the initiative to improve maternal health. I mean, you brought up some issues that already are there that how can we enhance it, so you've made some good recommendations that people were listening to from those federal partners. So, how do we move some of those forward? How do we guide the Infant Mortality Initiative that MCHB is working on?

Again, same kind -- you brought up some good issues. So, some of those, I hope, will lead to some recommendations. We got an update on COVID and it's changing so rapidly, and we had our letter to the Secretary back in June. Things have changed dramatically since then, but some things haven't changed. Are there some recommendations that we should bring forward immediately, and are there some things that we should ask for long-term that need to be addressed related to COVID? Certainly, the issues that were just raised just now about immigration and border health. What is SACIM's role in that? What can we do to help change the policies in the programs beyond, you know, like yes, we recommend -- make recommendations to HHS Secretary, but our reach is much broader than that. What is the federal government and other partners to do?

And we haven't even gotten to the environmental health issues that we're going to be talking about tomorrow. And so, you know, I couldn't fit it all into this day, so keep a space

open because they're also going to be raising some huge issues for us to consider and we may have to just, you know, make a place in your planning and your workgroups from the data piece, from the health equity piece, from the community quality and access piece.

And then finally, we really started to focus on racism, and then you heard it over and over and over again about structural racism being a core foundation for many of the disparities that we have. And last night, I sent you a letter to the President -- a draft from input that I got from multiple members of this committee and others saying SACIM has a role to play in addressing this issue to the President, because this is core to what we're doing. So, put that on your agenda also, and we'll get back to that tomorrow afternoon as we talk about sending a letter from SACIM to the President related to addressing racism.

And I'd love to have as much conversation in the workgroups as possible on all of those

issues, and I know you may have to prioritize some of those because you may not be able to get to all of those. But I do know that we will be coming back to that letter to the President. I do know that there might be some urgent issues related to COVID that we have that might, you know, want to bounce up to the top of your agenda. But you're going to have a lot of stuff to do in an hour and fifteen minutes or whatever we have.

So, given that, David, how do we get into the breakout sessions?

DR. DAVID DE LA CRUZ: Right there. We just posted the link. So, everybody just clicks on that link, and that will take you to one of the three -- it will list out the three different workgroups. You click on the workgroup that you want to join, and it will take you right into a breakout room. And that's for the members and also for any member of the public, and it's also in the chat box. So, it's a hotlink in the chat box.

DR. EDWARD EHLINGER: Okay, yeah. And

then you will close out the day from your workgroup just like we did on the last meeting that we had, and we will reconvene tomorrow at 11:00 Eastern Standard Time.

DR. DAVID DE LA CRUZ: Right. And please do use the link that's in the updated agenda that you got. We will continue to use the same process. We'll use this Zoom account and HRSA will continue to support the closed captioning. So, it should be no change for tomorrow, but the agenda does have the link for tomorrow.

DR. EDWARD EHLINGER: All right. So, where is the agenda -- the one that you -- in the briefing book?

DR. DAVID DE LA CRUZ: No, the one that -- Vincent, do you want to explain tomorrow's --

MR. VINCENT LEVIN: Yep. So, if you go to the -- we actually sent out an updated agenda it should have been last night in an E-mail that contains the most recent links to the meeting, and we can also send those tomorrow morning, so you'll also receive separate links tomorrow morning.

DR. EDWARD EHLINGER: It would be good it if you could -- I think it would be good if you could resend by E-mail --

MR. VINCENT LEVIN: Of course, definitely.

DR. EDWARD EHLINGER: -- a link to everybody.

MR. VINCENT LEVIN: Absolutely.

MS. BELINDA PETTIFORD: That would be great.

UNIDENTIFIED FEMALE SPEAKER: Yeah because I never received it from this morning, but I did go in the other way and just was able to get moved over.

MR. VINCENT LEVIN: Gotcha, yep. We'll make sure to send everything out twice.

DR. EDWARD EHLINGER: All right. What a day.

DR. MAGDA PECK: Come join us in the Data and Research to Action. I'll be leaving now, and I'll see some of you there when we're able to reconvene. Thank you for a very full rich day.

DR. EDWARD EHLINGER: All right. Take care everybody, and I'll see you all tomorrow.

MS. BELINDA PETTIFORD: This is Belinda. Come join us in Health Equity.

[Whereupon the session was adjourned at 4:40 p.m.]

R E P O R T E R C E R T I F I C A T E

I, GARY EUELL, Court Reporter and the officer before whom the foregoing portion of the proceedings was taken, hereby certify that the foregoing transcript is a true and accurate record of the proceedings; that the said proceedings were taken electronically by me and transcribed.

I further certify that I am not kin to any of the parties to this proceeding; nor am I directly or indirectly invested in the outcome of this proceedings, and I am not in the employ of any of the parties involved in it.

IN WITNESS WHEREOF, I have hereunto set my hand, this 9th day of February 2021.

_____/s/_____

Gary Euell

Notary Public