>> All right. I hear that we are ready

to get started. So I'm Rebecca Leverson.

I'm a pediatric enfireworks disease Adam

Ward and I'm here with is it our CMV

coordinator for the Virginia department

of health so we between talk about

Virginia's hearing targeted congenital

CMV screening program.

Opportunities and put falls.

So we're going to go over an Oregon view

of congenital CMV, talk about the

development of the legislation and the

regulations related to it, the screening

protocols, what we did in regards to

training and education of stakeholders.

With a nuts and bolts of the screening

program are and to changes to make it

better and some legislation sons learned

. So with that we have no disclosures.

As an infectious disease doctor we are

very aware of CMV, so it is one of the

herpes viruses so you think about cold

sore, chickenpox, and shingles, maybe EPV.

you've heard of that that causes

infectious mononucleosis, CMV is in that

same umbrella and all of the herpes

viruses have this proclivity to stay in

the body so once you've been infected

you'll have evidence of that virus?

Your body but if your immune system is

good enough then you shouldn't have

disease again or rarely. It is transmitted

via secretions so mucus, saliva, you

know, not snot in toddlers and children

and also genital urinary so toddler and

is it other individuals Europe.

We care most about CMV really when it

causes a congenital infection and

really the other high rigsing areas if

you're talking about organ

transitional plantation, CMV can be

transmitted via breast milk but that

does not cause infection but it been

mess up interpretation of your

testing.

Just because a mother as CMV infection

during pregnancy does not mean the baby

will have infection. Actually only 30

to 35 percent of babies born to mothers

who have CMV infection during pregnancy

have Inuit utero transmission, so with

that you can't say mom had disease

therefore baby will have disease, you

can say baby needs to be screened at

birth because baby cough disease and

right now we don't have any the real

mitigation strategy once you have

infection during pregnancy. Because CMV

is a virus that stays withen the body

there is still about a one to

two percent risk of congenital

infections if mom has reactivation of

the virus during a subsequent pregnancy,

for example, and the numbers as best as

we know them and I serge grant the

epidemiological points, the best that we

know is somewhere between a half percent

or one percent of all live births in the

United States are thought to be

infected with CMV so have congenital CMV

infection and by adulthood most all

adults have seen CMV. So again, from

the data that we have which again is

imperil we understand that congenital

CMV infection presents like Bella, with

some symptoms at birth and that's only

about ten percent of babies who present

with symptoms and I would say it's very

few who present as obviously Bella saying

there's something that's going on here,

we need to investigate,

90 percent of databases have no some

symptoms and of the symptomatic babies

it's mild symptoms anded it's regards

as other things, the the placental nurse

or the platelets are low but that's not

a concern et cetera, what we do know is

one in five babies who have con

general call CMV will have some package

effect. Of the

babies who are designated as

symptomatic at birth, 2-30s will

go on to have lifelong impairments. A

third of which will have hearing loss.

There are some of those babies who

might have symptoms at birth and have noing

long term sequela but all of these put

tot are opportunities to identify. So

the long-term complications again

include developmental and motor delays,

mission vision loss, microcephaly so a

small head indicates a small brain which

indicates not being able to grow,

epilepsy can again about 35 to 50

percent will have hearing loss and

80 percent will have sensory neural hearing

loss. This is thoughts all present at

birth and it can develop over time and

that has implications for a hearing

targeted congenital CMV program at birth

. So we put together some handouts and

I think we'll handed them out to you

from the Virginia program in regards to

target to pediatricians or clinicianings

who take care of babies to think about

when to screen for congenital CMV but

we've also done it to be able to edge

power families to ask their clinician,

does my baby need to be screened, I need

to be aware of this, so who should be

screened? Any baby born to a mother who

has active CMV infections during her

pregnancy, regardless of what the baby

looks like. If the baby has small head

as Mirandized on head circumference needs

to be evaluated for a congenital C

many of Nevada infection. What about if

the baby is smaller than expect that

baby should be screened also F a baby

has aiming liver or big spleen, baby has

know low plate lets that's

also an caster. If the bean has

jaundice where it's due to the liver

having problems being able to process

the red blood cells, that is another

indication. And if that Barbie

failed that final newborn hearing test

or any newborn hearing test I think

it's also an opportunity to test this

baby for CMV and how do we evaluate?

The ultimate gold standard at this point

in time is a Europe C Nevada Ppr that is

done with a little simp lock bag put on

the diaper area, allow that Europe urine

to be collected and some of those have

pitfalls. We also look at do they

have a direct hypobill Rubin. Any of

these are risk factorses and for

sympathetic congenital CMV and those

babies should be further evaluated and

having a conversation with a family

about do you want treatment? Are you

interested in I don't think we have toll

mandate that families must

have treatment but they should be

offered. What we do know is that

treatment needs to start in the first 30

days of life to have benefit and the

benefit are modest to moderate at best

so that where a detailed about an hour

and a half conversation goes in with a

family doing a full evaluation to be

able to help answer questions and advise

. So with all of that I'm going to

turn things over to Paully and we'll

follow back up.

>> I'll start with a brief -- I'll start

with a brief timeline on how we

implement the hearing targeted CMV

screening program, so our

legislation was passed in February of

2019 St. and then we began startinged

CMV screening on September wannish 2020

so the first thing we did in March of

2019, we developed a stakeholder work

group. Some of the key stakeholders

that were involvedded in that work group

were audiologists and infectious disease

specialists, awe neo-naytologists

and hospital nursing staff, so with

what that work group did is they helped

us determine how and when the screening

would happen and they helped us develop

the testing parameters and what screen

methods were going to be use in the

hospital and what screening might

have haded would be used out patient

for any testing that was needed out

patient? And they had helped us develop

our educational materials, they helped

us write the lotion and the protocols

and on the top is a cope overour

protocols and on the bottom is prenatal

egg that we developed to inform pregnant

women as many of you said in the

previous session that many pregnant

women are not aware of CMV. And then

starting in January 2020, we started

enhancing our Eddy information system,

whey with call is the Virginia infant

screening infant tracking system knowing

and intelligent visits, so in the

middle here on the screen you can see

we've developed a pending list for

hospitals so that would be where every

baby that's born at that hospital would

be listed on this list for anything like

thats to be able to enter that CMV order

into our Eddy system.

And then on the left is the order

forming forming is the inference we

collect before the CMV sample is sent to

the lab. So we need to know the time of

collection, who collected the

screening and we do ask a

question and that's if a child was

breast-fed within an hour of the

CMR screen and we collect staff contact

information for any questions. So once

they input that information the form on

the right is the order form and they'll

print it and send wit a sample to our

lab.

And then hospitals can review results in

the Eddy information system, so once

that sample gets sent to our state

laboratory, they'll test it and they can

send results electronically back into

the Eddy information system so is that

homes and primary care providers can go

in and review the results. So the top

is a list of all the babies that were

screened at the hospital, they can

review the name, date of birth and the

printer icon is where then generate and

the print the report of the results and

then the bottom they can individually

review it in each child's start and they

can jean generate a .pdf version that

they can print or upload to their Emrs

so hospitals can review CMVs in their

decrease, and another key aspect was

training and outreach. The months prior

to to our implementation was the height

to have Covid-19 pandemic so

there was some he is tansy from

hospitals, so we had to shift our focus

because legislation was in 2019, we had

developed a big plan on how we were

going to I want our stakeholders to go

live with screening. We shifted our

focuser and developed virtual training

the sessions because we were not able

the travel or get into homes so we could

not educate them on-site and then we

developedded a three part training

serious so I would ended up being better

because it was virtual we could record

the sessions and provide them multiple

times, so all of the hospitals were able

to attend the sessions and they could if

there was new staff they could go back

and review the training and it

was always available. And then we also

used some of the materials and we

handed out them Texas and one is a

brochure for when the babies are

screened the

families get the information and we

medal out the protocols and information

to all of the hospitals prior to screening.

So now that we're like about two and a

half years into screening, we

know that there are some key personnel

that we really need in order to have a

successful screening program, so part of

our team we have two staff that are

dedicated for CMV screening. We have a

follow up coordinator and a follow up

specialist, and they kind of manage the

day-to-day screening

aspects and we have one central lab in

Virginia that does all of the initial

CMV screening testing and that's our

state lab, so they report the

results to us can that's been really

helpful. And then we have a parent or

family educator who has a child with CMV

and we can refer confirmed families --

falls with confirmed CMV diagnosis to

this parent educator for resources and

supports. So how do we do the test?

Virginia? So we have a we're validated

for cheek swabs so it's best to wait at

least an hour after breast-feeding to

collect the swab and it's inserting the

swab between the sleek and the gums and

that swab is placed in one milliliter

of viral trans port media and it's

transported to the lab. That sample

does need to be kept cold until it's

tested and it's only Arvada valid for

seven case so in Virginia we provide all

the collection materials to

the hospitals and we provide them with

the collection kilts so we can ensure

the very specific parameters are 18

takenned and we use in Virginia the

meridian test. That us with one -- or

maybe the only FDA approved test at the

time when our legislation passed in

2019. So that test basically targettings

the V Nevada genome using loop mediated

DNA application so if CMV DNA is

present in the sample the precipitate

will form in the tube so when there's

light shined through it basically

prevents the light

from passing through the tube. So like

I mentioned earlier that the

testing parameters are really

strict for this type of test to so we do

have some rejections that happen and

some of the common reasons are if the

sample -- if they put the ice pack or

used a different one than we provided

and it didn't keep the sample cold or if

they had less or more than one

milliliter of VTM. The the baby was odor

than 21 days the test is only approved

for children less than 21 days of age

and if two sample is more than seven days

those are reasons we would have to

reject the sample and

have that baby tested out patient once

the results are sent in we have an

automated follow-up which

includes mailing letters to the family,

we tension them through our alternated

system and the the ghoul goal is to see

what testing is needed out patient, so

some of the recommendations the baby is

positive on the saliva Pcr we would have

to collect a 3:00cr before 21 days. If

the baby mythed the CMV screen they can

have a saliva or urine P CR and then if

the baby is negative they would do out

patient hearing screening as

recommended. So since we started our

screening as we mentioned we're

targeted screen sog the blue line

represents the number of children that

failed the hearing screen and as you can

see we've over time since starting in

September the first the number is just

the month of September is it's a little

lower and the rest are quarters but you

can see we've closed the gap and we're

screening most of the babies

that fail. Our highest quarter was

98 percent and that was in in quarter go

and three of 2022.

And again the first is just September to

December 2020 and then the next two are

if the full year of 2021 and 2022. So

since implementation in September 20 to

December 2022, Virginia has screened

7,117 children for CMV and 1.5 percent

of those children screened positive with

the saliva P CR. And then for though

children that screened positive we

mentioned they confirmed with urine so

you noticed that 13 percent of those

children who were initially screened

positive for CMV were confirmed on urine

CMV.

And then of the children from September

2020 to December 2022, 111

children screened positive on saliva.

We noticed that ten of those were reported

to have a hearing loss and then of the

16 that were confirmed on urine C Nevada

Pcr seven

childrenner reported to have a cheering

loss and during that time frame we

noticed that out of the children who

screened negative on saliva Pcr 180

windshielded to

have a hearing loss. And since

implementation we haved inned more than

a 50 percent address in the age at

diagnosis for hearing loss so from 132

die-ins 2019 we're down to sight 603 days.

Civil share the successs of

our screening program. We did implement

in the the mid of a pandemic but over

all the hospitals were supportive of

implementing this new screening program,

the virtual trainings were beneficial

bus all the staff could watch those and

we have one central lab because they

help us troubleshoot the concern with

testing and we can ensure we get results

for all the babies.

>> Thank you. And some of the challenges

or opportunities that we saw again as

she went other are a lot of the sample

rejections so those decreased over

time as hospitals got more familiar with

the protocol in regards to making sure

that samples were delivered cold, the

amount of transport media was present,

else. Once of the issues with the high

false positive rate is the breast milk

exposure so we've tried to put out more

education in regards to making certain

the baby hasn't had breast mill health

care exposure for at least an hour,

before the testing, we're very happy

that families are wanting to

breast-feed, the double edged sword sha

potential false positive.

One of the other.

Thes has been of course this was

instituted in the midst of the Covid-19

pandemic and so most medical professionals

were focused on that and may not have

paid as much attention to

congenital C Nevada so we continue to

work on primary care education and out

stretch and overall increasing aware

ness, we know that screening is

not the solution, we know that we're

probably picking up less than

ten percent of babies based on hearing

targeted protocol. My hope is that with

education that we can also remind

clinicians that we need to think of all

the ore aspects is that fit symptomatic

congenital CMV and push toward testing

those babies based on those suddenly

or more profound symptoms.

However I fear that we have given the

message for hearing targeted but we haven't

achieved the male for all of the other

man fessations and

there's been provider to provider

education in addition to the 2019 key

stakeholder group, where we crafted the

regulations. They were

virtual sessions with the health

department, and every pediatric hospital

in the state gave grand rounds, a

year later in September because we

started in 2020 and in September we had

an American academy of pediatric state

sponsored lecture where we again engaged

pediatric clinicians and put together

since 2019 abentire network of pediatric

infectious disease physicians who are

willing to take a cold call about CMV

and walk through with any pediatric

provider what to do so we continue to

maintain that. This is at handout we

developed in 2021, really helping walk

clinicians through sort of what are the

next steps. You get a saliva positive

what do you doN, what follows that, what

kind of screening do you need to do from

a vision perspective from an early

intervention perspective. Do we

consider treatment and things like that

and what the timeliness is. So we have

those handouts up here and they're also

on our website. So to bring I would

home from the years we've been doing

this screening program one question

remains saliva versus urine, it's

certainly the gold standard and it gets

away from the screening aspect

and the breast milk contamination.

Always is going to be a key message

because it is required not only for

clinicians but also for families. We

have to get the message out there and I

put a universal symbol on here to

indicate is this our next step in

regards to universal screening that that

there are a lot of other things that

need to be worked out in regard to what

would you do with that test. So with

that we'll like to thank you and we're

happy to take questions.

>> Hi. I'm from Minnesota. And we just

started the universal so it's been

bloodsports in February and all the beans

that have tested positive they get

confirmed with urine and none of them

would have been tested under any

protocol or study we had before so it's

important the universal screening is the

key to catch those that would not

typically be tested.

>> I concur with you, I would like to.

You what's been Rotherred in if

literature is somewhere between 40 and

50 percent sensitivitiment where do

you think you fall?

>> I'm not sure.

>> So we have been looking that the at

the state laboratory level but again

based on protocols we're probably -- I

don't know the that it's going to be too

much better than saliva.

Certainly the follow up of the urine but

that becomes that -- you know how

do you do that in a baby who baseline is

dehydrated because they were just born

and you're sitting there waiting for

them tommy and the family is like I to

get out of here in 24 hours so --

>> Well most of the urine

confirmation tests are -- as soon as we

learn they test positive on the blood

spot we go to the PCP and get that.

>> We have one more minute. So why did

you choose choose too the two step

approach to the screening as opposed to

the urine out right?

>> So it was for feasibility. It is

much easier to be able the swab a cheek

and get a baby home because the hospitals

are looking at how quickly can we get

you home. We don't want to delay

discharge.

I would say this is a medical necessity

and so that we've got to get that

messaging out there. That's truly why.

>> I think we can take one more. And

don't forget there's evaluations on the

app.

>> The surveys indicate the entire

health care world nose about this much

about CMV, they know about it and they

know little bits and piece but they

do not know the

complete picture. How can we reach

physicians?

>>Ive proposedded to our vacked Eddy

group at the state level we do at

least annual pediatric practitioner

education looking at September's and we

have a robust website and we give talks

autolesion annually but it needs to be

nor the frequently. I would say

pediatricians are probably

more educated than the rest of all of

the medical -- physicians, obs, we need

a lot morework. ENTs so

that's part of why we put tolt this

network of doctors who in the state of

Virginia have knowledge and interest and

are the referral, referral recommended

sites to be able to go and get that baby

and that family educated in regards to

what would be the next step, by but I

agree it is an upward hill we climb.

thank you all very much.