Developing a Guide for cCMV Surveillance in US Health Departments

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DEPARTMENT OF HEALTH

NJHealth New Jersey Department of Health

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Disclaimer

The views and opinions expressed in this session are those of the speakers and do not necessarily reflect the views or positions of any entities they represent.

Agenda

- **Introduction/Background/Context** (15 mins)
  - cCMV surveillance in the U.S
    - History/context around cCMV surveillance
    - CSTE cCMV position statement
    - US cCMV surveillance landscape
  - Introduction to SET-NET

- **State presentations: Screening, Surveillance, & Lessons Learned** (70 - 80 mins)
  - NJ (20 mins)
  - UT (20 mins)
  - MN (20 mins)
  - Q&A (10 mins)

- **Discussion** (30 - 40 mins)
  - Goal/ask of the session
  - Discussion questions/prompts
  - Recap

cCMV Surveillance in the US: Background and Context

Why conduct state-based surveillance?

- Provide population-based data on **cCMV disease burden and trends**

- Identify **risk groups for cCMV disease** who might be targeted for future interventions

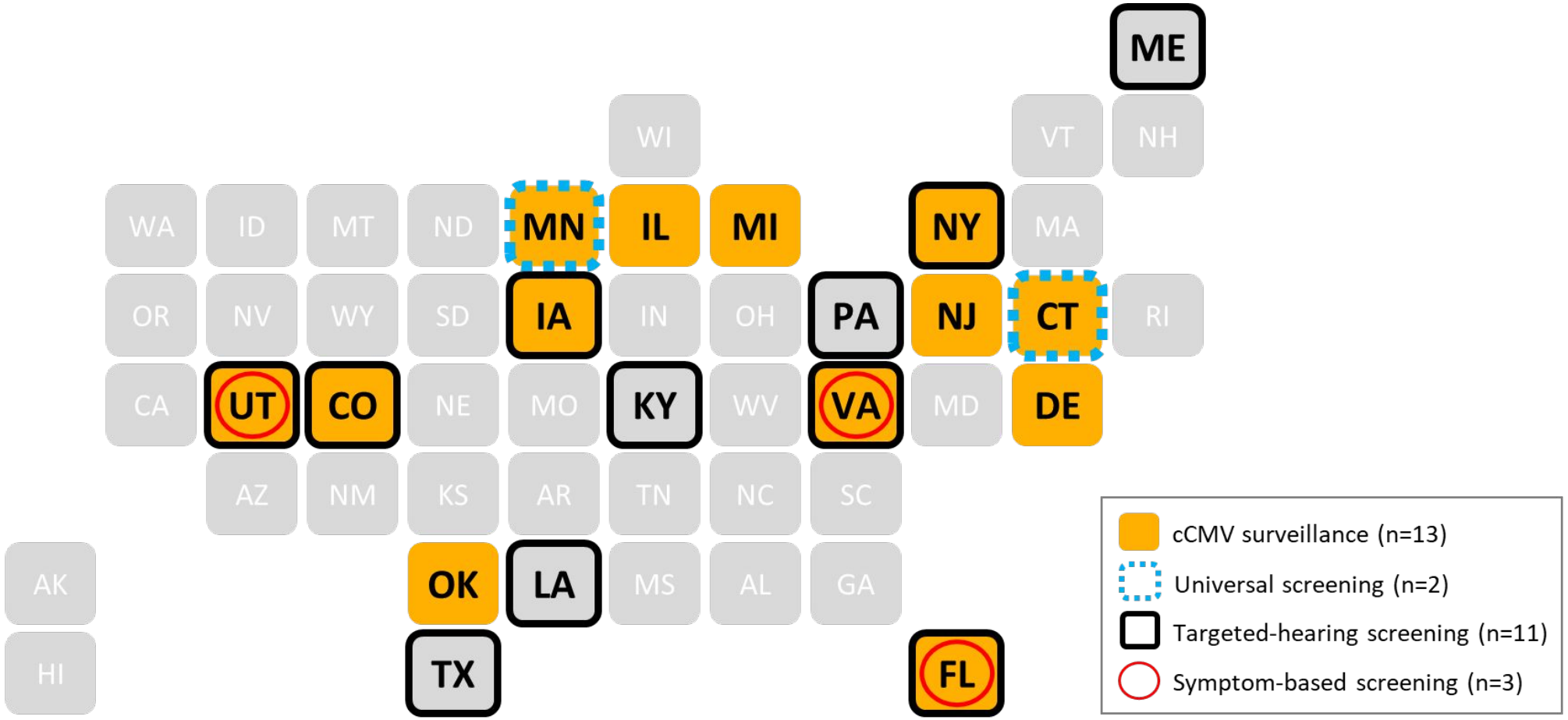
- Provide baseline data **for evaluations of impact of future intervention programs** (e.g., vaccine, behavioral interventions, newborn screening, treatment)

Background on cCMV surveillance

cCMV surveillance in the United States is complicated by several factors:

- Universal prenatal screening for cCMV is not recommended
- Most newborns with cCMV infection have no clinical signs at birth
  - Not identified without universal screening
  - Late onset sequelae can present (e.g., sensorineural hearing loss, developmental delays)
- Neonatal clinical signs of cCMV are nonspecific and potentially attributed to other conditions
- Postnatally acquired CMV infection is common among infants (incidence of at least 3% by 4-6 weeks of life)
- Not all newborns with a laboratory diagnosis of cCMV have an associated diagnostic code
- Diagnostic codes have been used for case ascertainment; however, they have not been validated

US landscape on cCMV screening and surveillance

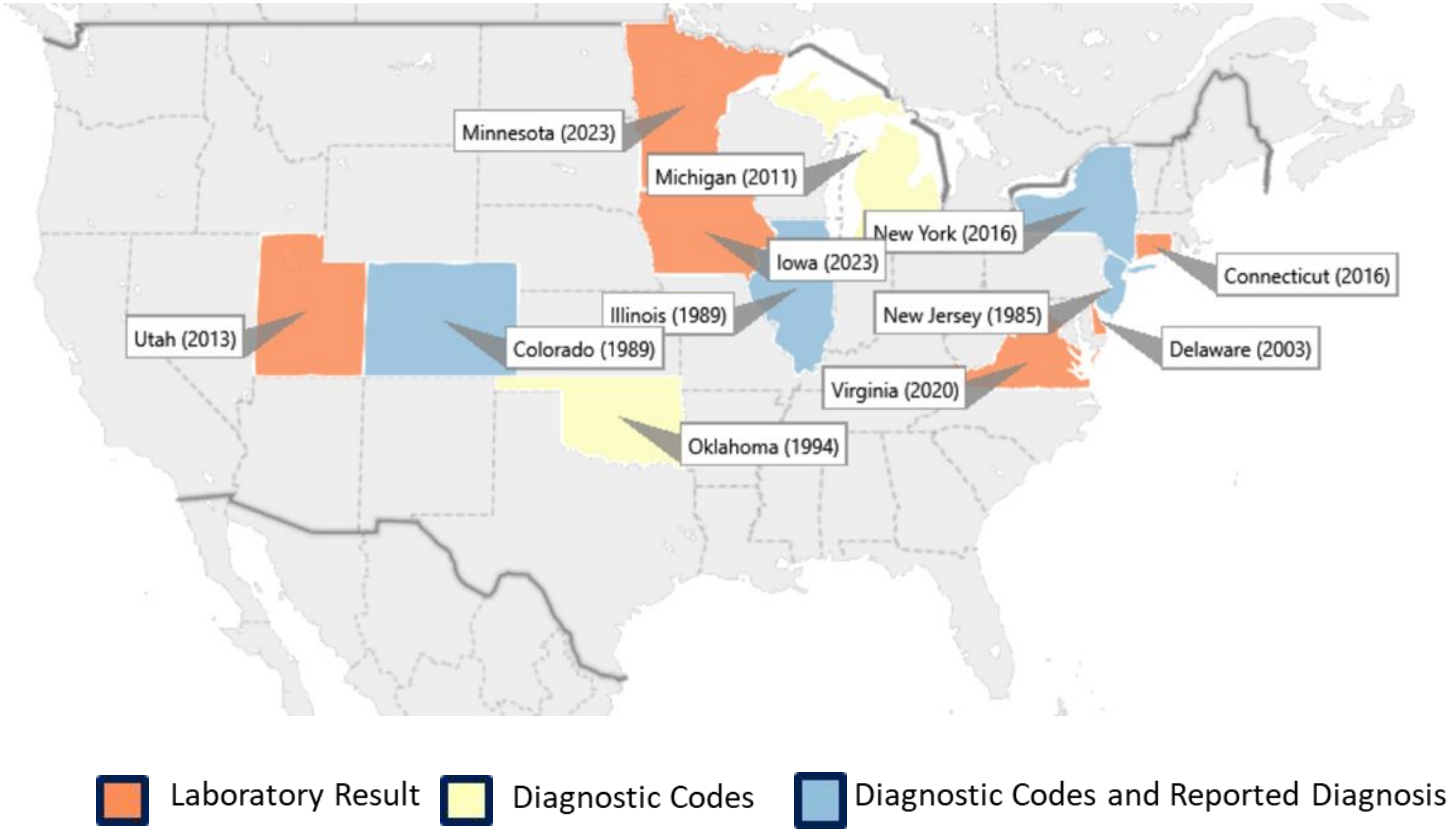


Last updated February 2025

13 States* have initiated efforts to conduct cCMV surveillance

- cCMV is **not a nationally notifiable** condition

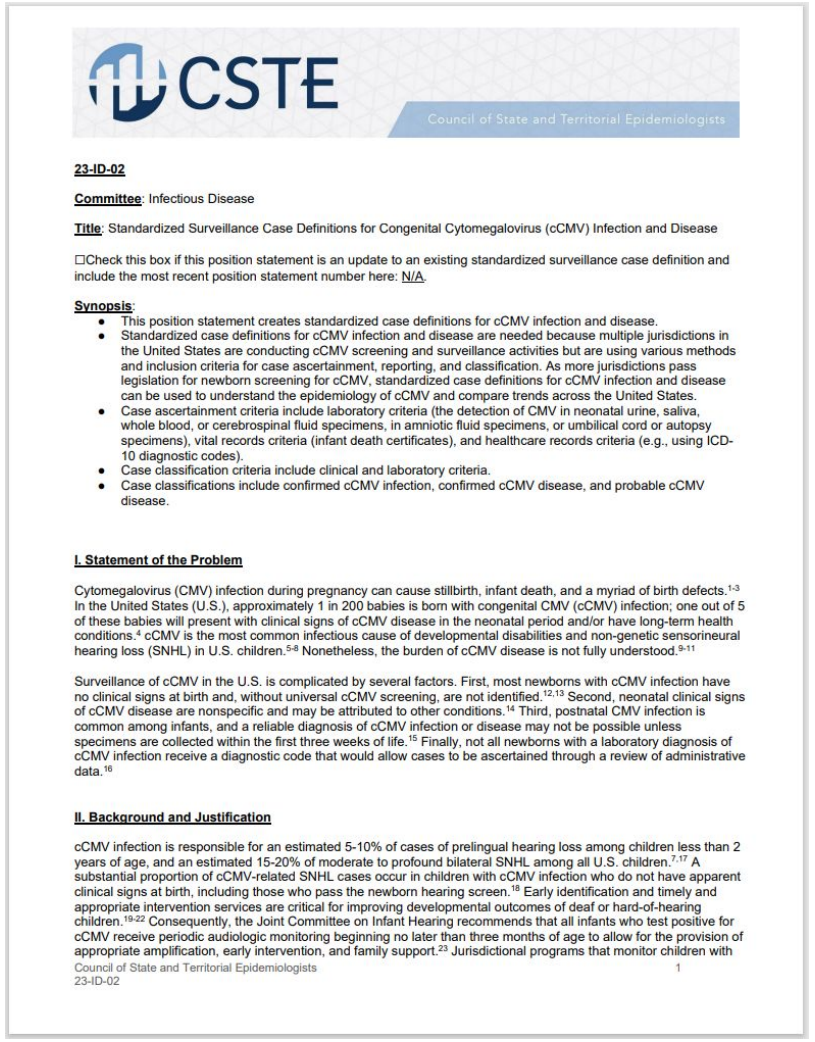
- Case ascertainment methods vary across states
  - Laboratory reports: 6 states
  - Diagnostic code reports: 2 states
  - Diagnostic code and clinical reports: 4 states



*Since 2022, legislation for cCMV screening has been enacted in Florida, Kentucky, Louisiana, Pennsylvania, Texas, and Maine with cCMV surveillance practices unknown

cCMV CSTE Position Statement!

- 2023 CSTE Position Statement on cCMV responded to the need for a standardized definition for cCMV infection and disease:
  - “Multiple jurisdictions… are conducting cCMV screening activities but **are using various methods and inclusion criteria** for case ascertainment, reporting, and classification. As more jurisdictions pass legislation for newborn screening for cCMV, **standard case definitions**… can be used to understand the epidemiology of cCMV and compare trends across the United States.



CSTE

Council of State and Territorial Epidemiologists

23-ID-02

Committee: Infectious Disease

Title: Standardized Surveillance Case Definitions for Congenital Cytomegalovirus (cCMV) Infection and Disease

☐Check this box if this position statement is an update to an existing standardized surveillance case definition and include the most recent position statement number here: N/A.

Synopsis:

- This position statement creates standardized case definitions for cCMV infection and disease.
- Standardized case definitions for cCMV infection and disease are needed because multiple jurisdictions in the United States are conducting cCMV screening and surveillance activities but are using various methods and inclusion criteria for case ascertainment, reporting, and classification. As more jurisdictions pass legislation for newborn screening for cCMV, standardized case definitions for cCMV infection and disease can be used to understand the epidemiology of cCMV and compare trends across the United States.
- Case ascertainment criteria include laboratory criteria (the detection of CMV in neonatal urine, saliva, whole blood, or cerebrospinal fluid specimens, in amniotic fluid specimens, or umbilical cord or autopsy specimens), vital records criteria (infant death certificates), and healthcare records criteria (e.g., using ICD-10 diagnostic codes).
- Case classification criteria include clinical and laboratory criteria.
- Case classifications include confirmed cCMV infection, confirmed cCMV disease, and probable cCMV disease.

I. Statement of the Problem

Cytomegalovirus (CMV) infection during pregnancy can cause stillbirth, infant death, and a myriad of birth defects.[1-3] In the United States (U.S.), approximately 1 in 200 babies is born with congenital CMV (cCMV) infection; one out of 5 of these babies will present with clinical signs of cCMV disease in the neonatal period and/or have long-term health conditions.[4] cCMV is the most common infectious cause of developmental disabilities and non-genetic sensorineural hearing loss (SNHL) in U.S. children.[5-8] Nonetheless, the burden of cCMV disease is not fully understood.[9-11]

Surveillance of cCMV in the U.S. is complicated by several factors. First, most newborns with cCMV infection have no clinical signs at birth and, without universal cCMV screening, are not identified.[12,13] Second, neonatal clinical signs of cCMV disease are nonspecific and may be attributed to other conditions.[14] Third, postnatal CMV infection is common among infants, and a reliable diagnosis of cCMV infection or disease may not be possible unless specimens are collected within the first three weeks of life.[15] Finally, not all newborns with a laboratory diagnosis of cCMV infection receive a diagnostic code that would allow cases to be ascertained through a review of administrative data.[16]

II. Background and Justification

cCMV infection is responsible for an estimated 5-10% of cases of prelingual hearing loss among children less than 2 years of age, and an estimated 15-20% of moderate to profound bilateral SNHL among all U.S. children.[7,17] A substantial proportion of cCMV-related SNHL cases occur in children with cCMV infection who do not have apparent clinical signs at birth, including those who pass the newborn hearing screen.[18] Early identification and timely and appropriate intervention services are critical for improving developmental outcomes of deaf or hard-of-hearing children.[19-22] Consequently, the Joint Committee on Infant Hearing recommends that all infants who test positive for cCMV receive periodic audiologic monitoring beginning no later than three months of age to allow for the provision of appropriate amplification, early intervention, and family support.[23] Jurisdictional programs that monitor children with

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23-ID-02

Browning McVicar, S, Sidesinger, M, Debolt, C, Dufort E, Kaye T, Kumar, J, Longcore D, McInerney M, Rosendahl S. “Draft: Proposed 23-ID-02.” June 26, 2023, https://docs.google.com/document/d/1T1y3fa5eg6mKdQQAmqzMAfCUNip-oXmI/edit

cCMV CSTE Position Statement

Position Statement approved by the Council of State and Territorial Epidemiologists (CSTE) in June 2023:

- Regarded as standard for cCMV surveillance as of January 2024
- Position statement establishes:
  - Case ascertainment and case classification criteria

Case classifications:

- **Confirmed cCMV infection:**
  - Meets confirmatory laboratory evidence
- **Confirmed cCMV disease:**
  - Meets clinical criteria *and* confirmed laboratory evidence
- **Probable cCMV disease:**
  - Meets clinical criteria *and* presumptive laboratory evidence

cCMV CSTE Position Statement **Laboratory Criteria**

A2. Laboratory Criteria*

Confirmatory Laboratory Evidence[†]*:*

- Absence of a negative test (CMV DNA by NAAT or culture) on a urine specimen collected within 21 days of life, **AND**
- Detection of CMV DNA by NAAT from urine, whole blood (including dried blood spot [DBS]), or cerebrospinal fluid (CSF) collected from an infant within 21 days of life, **OR**
- Detection of CMV DNA by NAAT from amniotic fluid specimen, **OR**
- Isolation of CMV in viral culture from urine, whole blood, or CSF collected from an infant within 21 days of life, **OR**
- Isolation of CMV in viral culture from amniotic fluid specimen, **OR**
- Demonstration of CMV antigen in an autopsy specimen by IHC, **OR**
- Detection of CMV antigen by antigenemia test in whole blood collected from an infant within 21 days of life.

Presumptive Laboratory Evidence:

- Absence of a negative test (CMV DNA by NAAT or culture) on a urine specimen collected within 21 days of life, **AND**
- Detection of CMV DNA by NAAT from saliva collected from an infant within 42 days of life[§], **OR**
- Isolation of CMV in viral culture from saliva collected from an infant within 42 days of life[§], **OR**
- Detection of CMV DNA by NAAT from urine, whole blood, or CSF collected from an infant within 22–42 days of life[¶], **OR**
- Isolation of CMV in viral culture from urine, whole blood, or CSF collected from an infant within 22–42 days of life[¶].

** Note: The categorical labels used here to stratify laboratory evidence are intended to support the standardization of case classifications for public health surveillance. The categorical labels should not be used to interpret the utility or validity of any laboratory test methodology.*

[†] *Only valid in the absence of a subsequent negative test on a urine specimen that was completed for confirmatory purposes.*

[§] *If CMV is detected in saliva, repeat testing should be performed using urine.*

[¶] *Only valid in the absence of a prior negative test on a urine specimen collected within 21 days of life.*

cCMV CSTE Position Statement

Clinical criteria

- Hepatomegaly, splenomegaly, petechiae, or purpura identified in **neonatal period**

A child ≤ 6 yrs with at least one of the following permanent conditions:

- Microcephaly
- Brain imaging abnormalities consistent with cCMV (e.g., intracranial calcifications, leukomalacia, polymicrogyria, lissencephaly, pachygyria, schizencephaly, or ventriculomegaly)
- *Sensorineural hearing loss*
- Seizures
- Cerebral palsy
- Chorioretinitis
- Vision impairment resulting from conditions consistent with cCMV (e.g., retinitis, retinal scarring, optic neuritis, optic atrophy, or cortical visual impairment)

Browning McVicar, S, Sidesinger, M, Debolt, C, Dufort E, Kaye T, Kumar, J, Longcore D, McInerney M, Rosendahl S. "Draft: Proposed 23-ID-02." June 26, 2023, https://docs.google.com/document/d/1T1y3fa5eg6mKdQQAmqzMAfCUNip-oXmI/edit

cCMV CSTE Position Statement

Table VII.A. Classification Table: Criteria for defining a case of cCMV infection or disease.

Criterion	Case Classification				
	cCMV Infection	cCMV Disease			
	Confirmed	Confirmed		Probable	
Clinical Evidence					
Hepatomegaly		O		O	
Splenomegaly		O		O	
Petechial rash or purpura ("blueberry muffin rash")		O		O	
Microcephaly††			O		O
Brain imaging abnormalities*			O		O
Sensorineural hearing loss			O		O
Seizures			O		O
Cerebral palsy			O		O
Chorioretinitis			O		O
Vision impairment¶			O		O
Absence of a more likely alternative etiology		N	N	N	N
Infant in neonatal period		N		N	
Child aged 6 years or younger			N		N
Laboratory Evidence					
Absence of a negative test (CMV DNA by NAAT or culture) on a urine specimen collected within 21 days of life	N	N	N	N	N
Detection of CMV DNA by NAAT from urine, whole blood (including DBS), or CSF collected within 21 days of life	O	O	O		
Detection of CMV DNA by NAAT from amniotic fluid specimen	O	O	O		
Isolation of CMV in viral culture from urine, whole blood, or CSF collected within 21 days of life	O	O	O		
Isolation of CMV in viral culture from amniotic fluid specimen	O	O	O		
Demonstration of CMV antigen in an autopsy specimen by IHC	O	O	O		
Detection of CMV antigen by antigenemia test in whole blood collected within 21 days of life	O	O	O		
Detection of CMV DNA by NAAT from saliva collected within 42 days of life§				O	O
Isolation of CMV in viral culture from saliva collected within 42 days of life§				O	O
Detection of CMV DNA by NAAT from urine, whole blood or CSF collected at 22–42 days of life				O	O
Isolation of CMV in viral culture from urine, whole blood, or CSF collected within 22–42 days of life				O	O
Epidemiologic Linkage Evidence					
N/A					

N = All "N" criteria in the same column are NECESSARY to classify a case.

O = At least one of these "O" (ONE OR MORE) criteria in each category (categories=clinical evidence, laboratory evidence, and epidemiologic evidence) in the same column—in conjunction with all "N" criteria in the same column—is required to classify a case.

Browning McVicar, S, Sidesinger, M, Debolt, C, Dufort E, Kaye T, Kumar, J, Longcore D, McInerney M, Rosendahl S. "Draft: Proposed 23-ID-02." June 26, 2023, https://docs.google.com/document/d/1T1y3fa5eg6mKdQQAmqzMAfCUNip-oXmI/edit

Surveillance for Emerging Threats to Mothers and Babies Network (SET-NET)

What is Surveillance for Emerging Threats to Mothers and Babies Network (SET-NET)?

WHO

Health departments work with CDC to identify the impact of emerging health threats on pregnant women and their infants

WHAT

Information collected on pregnant women and their infants (birth through first 3 years)

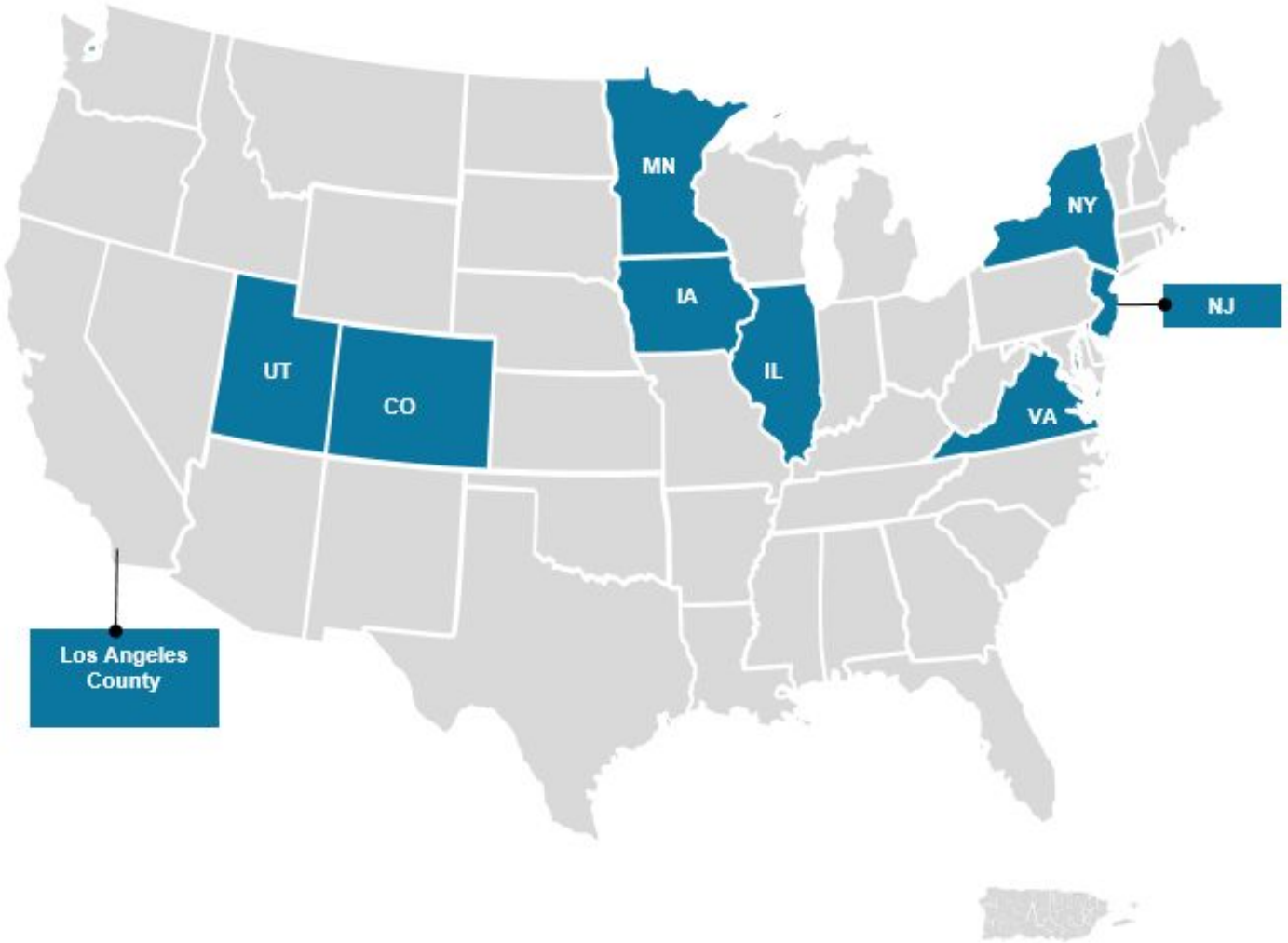
HOW

Linkage to data sources and medical record abstraction

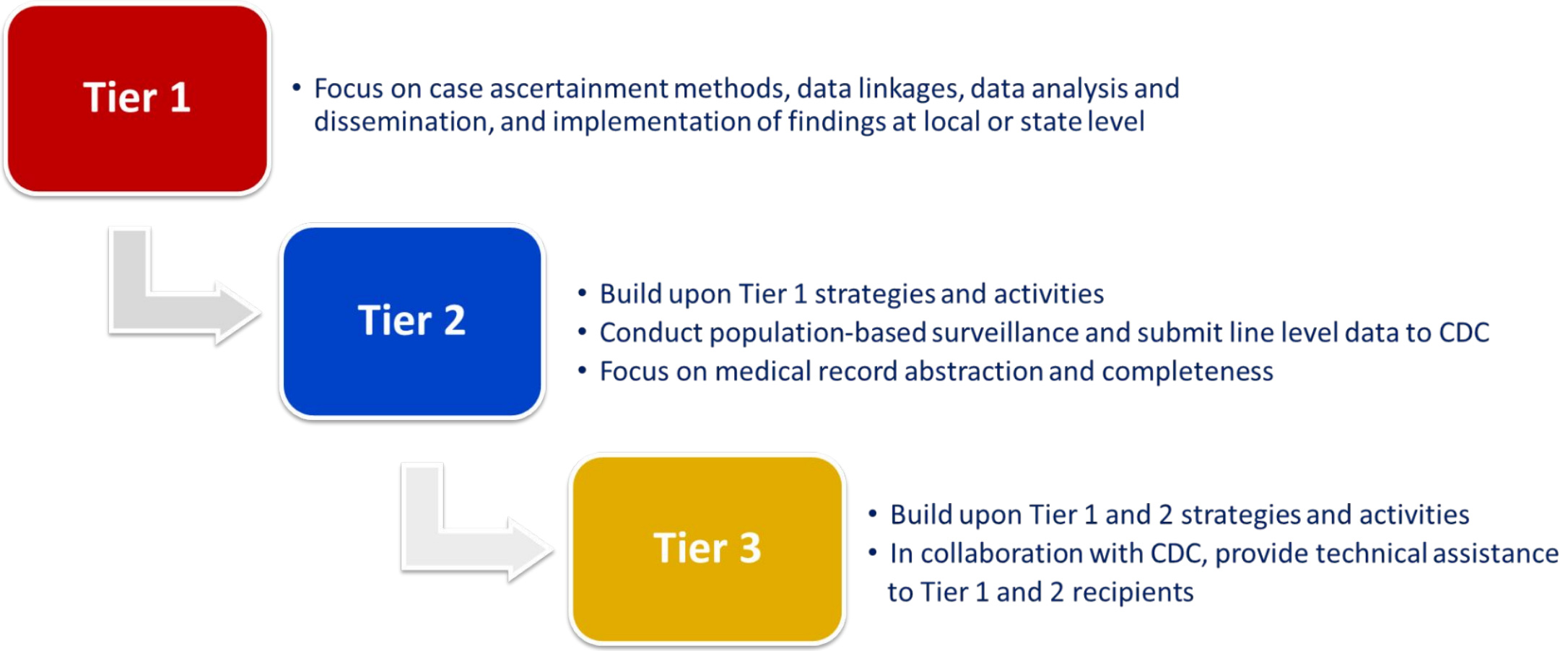
WHY

To inform clinical and public health guidance

SET-NET Jurisdictions Funded for CMV



Tiered Approach



SET-NET Inclusion Criteria

- Meet the CSTE cCMV case definition
  - Confirmed infection
  - Confirmed disease
  - Probable disease
- Reside in a participating SET-NET jurisdiction AND
- Have a birthdate no earlier than January 1, 2013, and no later than December 31, 2026

SET-NET Data Sources

Vital records

Electronic laboratory reporting

Early Hearing Detection and Intervention (EHDI)

Birth defects registries

Birth medical records

Well child visit medical records (2, 6, 12, 18, 24, and 36 months)

Lexie:

SET-NET Key Questions for cCMV

Surveillance Methods

- Current landscape and changes in surveillance methods during project period
- Implementation challenges and best practices for cCMV case definition

Pregnancy

- Description of CMV diagnoses in pregnancy and types/timing of testing

Birth outcomes

- Full range of adverse birth outcomes among exposed infants
- Frequency of clinical characteristics among those with confirmed infection

Infant/child outcomes

- Patterns of loss to follow up
- Patterns of and disparities in recommended follow up and treatment

Audience feedback

What are your jurisdictions currently doing/planning on doing in cCMV surveillance?

The cCMV Surveillance Experience: New Jersey, Utah, and Minnesota

cCMV surveillance in New Jersey

Jessica Redeker, BSN, RN, CRRN, CPN
Betia Zeng, MPH

NJHealth
New Jersey Department of Health

cCMV Legislation for Universal Screening

Public Law 2021, c.413 was passed on January 18, 2022

C.26:2-111.9

- "All infants born in this State shall be tested for congenital cytomegalovirus infection (cCMV), unless an infant's parent or legal guardian opts out of testing…"

C.26:2-111.10

- "The Commissioner of Health shall establish a public awareness campaign to educate pregnant persons about cytomegalovirus (CMV) and cCMV and the value of early detection of, interventions for, and possible treatments for, CMV and cCMV."

NJHealth New Jersey Department of Health

Status of cCMV Screening Implementation

Legislation for universal cCMV screening is conditional, meaning that screening is to begin within **six months** of meeting the following conditions:

- Development of a reliable test and quality assurance testing methodology
- Availability of quality assurance materials
- Inclusion of newborn screening for cCMV in the Recommended Uniform Screening Panel
- Recommendation by the Newborn Screening Advisory Review Committee that the test be included in the State Newborn Screening Program
- Commissioner of Health's approval to include the test in the State's Newborn Screening Program
- Acquisition of equipment necessary to implement the expanded screening tests by the State's Newborn Screening Laboratory

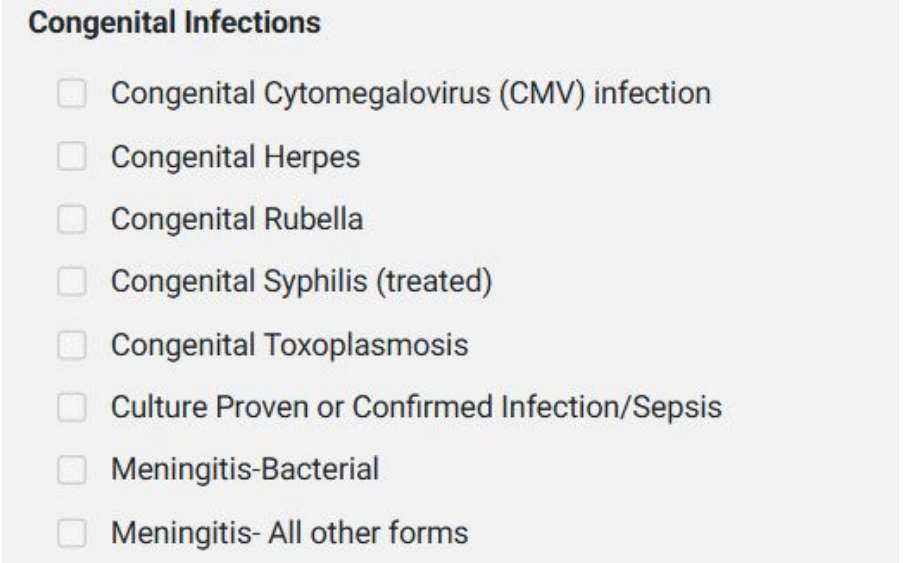
cCMV Targeted Screening

- Encouraged through NJDOH Best Practices Document (Feb 2025)
  - Testing methodology
  - Timing of testing
  - Clinical indications for testing
  - Procedural considerations
- 23 of 50 birthing facilities conduct targeted screening, 6 are in the process of adding a CMV screening policy
- cCMV is a registrable condition under the NJ Birth Defects Registry

NJHealth New Jersey Department of Health

cCMV Surveillance in New Jersey

- Started through SET-NET in 2023, under Division of Family Health Services, Special Child Health Services
- Data sources for suspected cases:
  1. Birth Defects Registry (BDR)
  2. Birth certificates (VERI) - CMV checkbox
  3. Uniform Billing data for birth admissions
  4. EHDI - TORCH Testing risk code
- 2018-2025 Births: Investigated 235 cases, 76 met CSTE criteria for cCMV



VERI Congenital Infection Section

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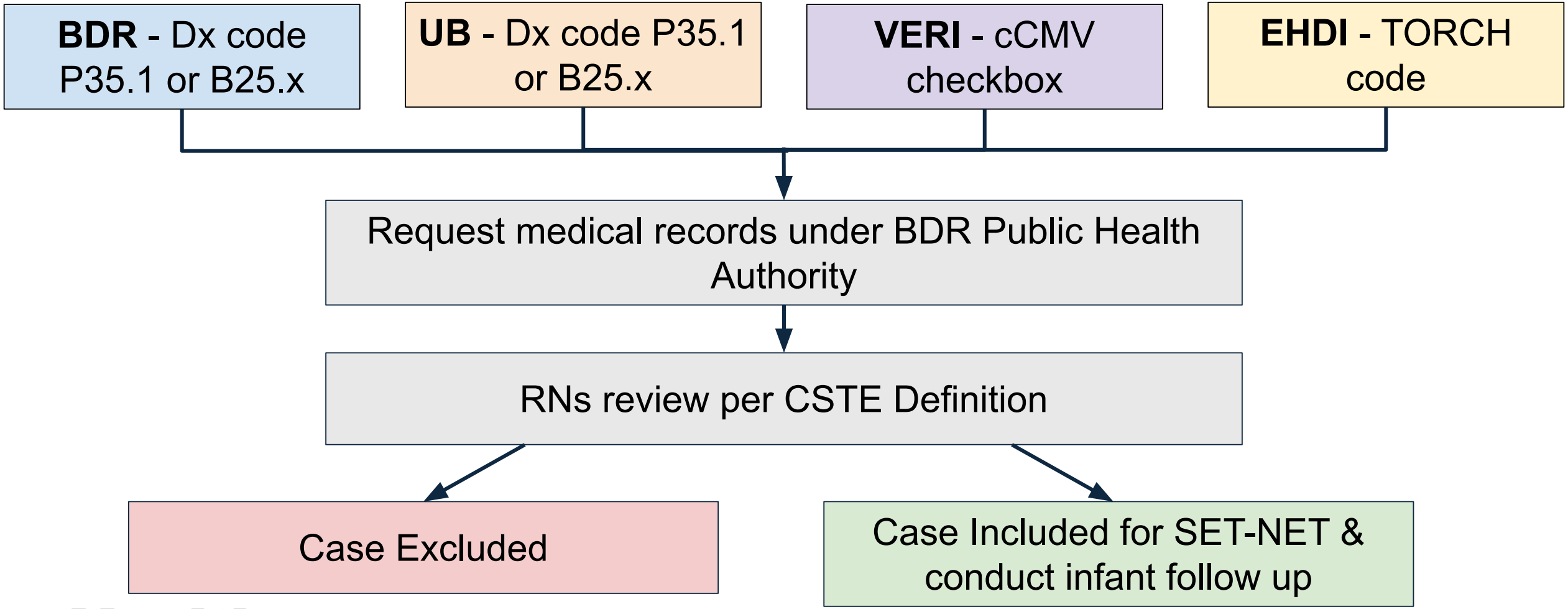
cCMV Case Ascertainment Methods



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cCMV Surveillance: Infant Follow Up

Short-Term

- Up to age 3 through well-child visits
- Follows SET-NET data collection format
- “Next steps” letter to PCP if case was identified by 6 months of age

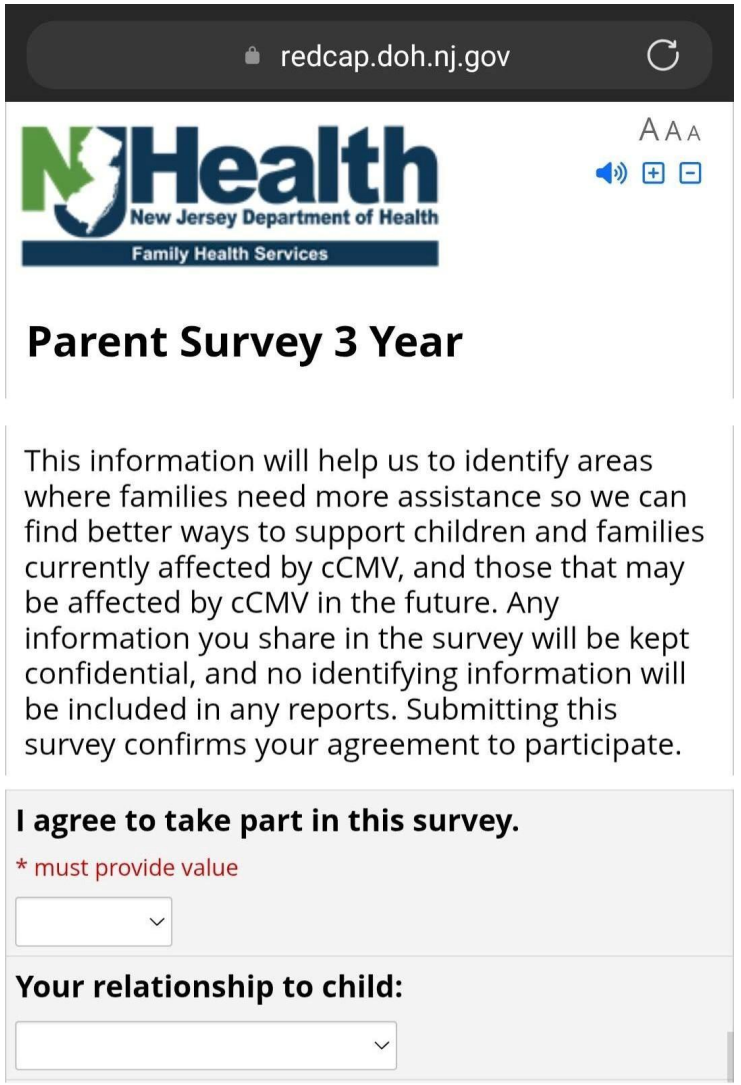
Long-Term

- Up to age 6 through yearly parent surveys

NJHealth New Jersey Department of Health

Long-Term Follow-Up Parent Survey

- Participation in the Parent Survey is voluntary.
- Participation is solicited through personalized telephone outreach by program staff.
- Families interested in participating can complete the survey over the phone with a live person or online (using a computer or smartphone)
- Surveys aim to learn about the parent/family experience and perspective



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Challenges

- Many missed cases
  - Case ascertainment is slow and reliant on BDR registration by hospital staff
- Complexity of cCMV cases and challenges with appropriate categorization according to CSTE criteria
- Low response rate for parent survey
- Challenges for NBS lab to add CMV to bloodspot panel

Lessons Learned

What do we wish we knew when starting surveillance?

- How to optimize our data collection/case ascertainment process
- How to categorize cases according to CSTE criteria (especially probable cases)
- Plan to communicate with infectious disease doctors, neonatologists, pediatricians

New Jersey Q&A

cCMV surveillance in Utah

Stephanie Browning McVicar, AuD, MS, CCC-A

Utah Department of Health & Human Services

cCMV testing in Utah

2013: Utah CMV law 26-10-10 (recoded 7/1/2022: **26B-7-105**)
"Cytomegalovirus (CMV) Public Education and **Testing**"

If a newborn infant fails the newborn hearing screening test(s)...

Medical Practitioner shall: ***Test the newborn infant for CMV before 21 days of age***… unless the parent objects;...

cCMV testing in Utah

2013: Utah CMV rule
R398-4-3.Clarification of when a newborn fails a hearing screen.

- The newborn **must fail both hearing screens**, the initial hearing screen routinely done at birth **and** the subsequent follow up screen, **OR**
- **if/when the initial failed hearing screen is obtained after 14 days of age** the medical practitioner is required to test for CMV, **OR**
- The newborn must be referred for CMV testing if they have failed an inpatient screening and have not completed or been able to complete the outpatient screening before 14 days of age.

cCMV testing in Utah

2013: Utah CMV rule

R398-4-4.Special population of newborns.

- In special populations of newborns where newborn hearing screening(s) cannot be accomplished prior to 21 days of age, **testing for CMV is left to the discretion of the medical practitioner(s) caring for the newborn**.
- Special populations of newborns may include, but are not limited to, premature or medically fragile newborns or newborns receiving ongoing medical care.

cCMV surveillance in Utah

2013: Utah CMV rule

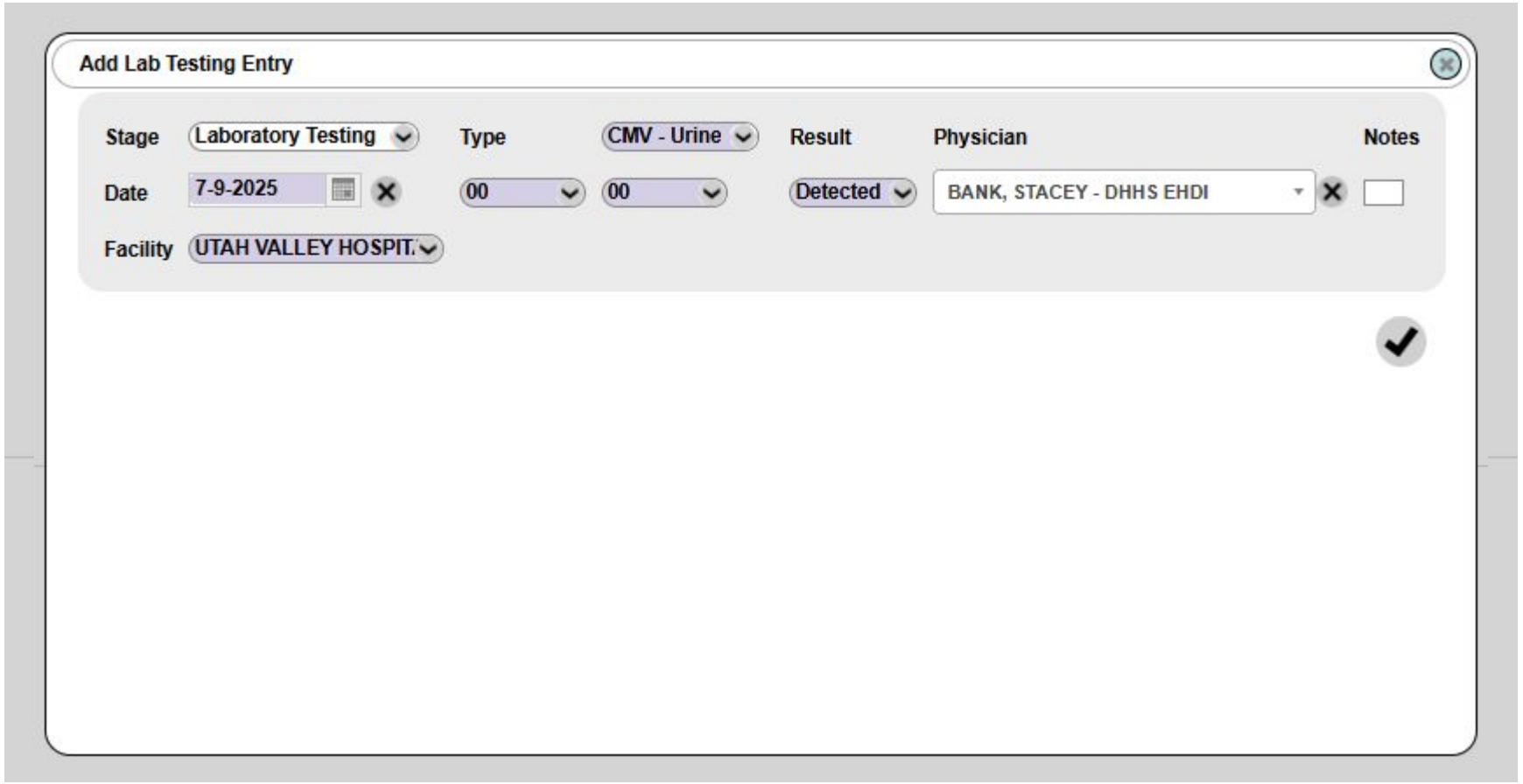
R398-4-5.Reporting requirements.

- Medical practitioners are **required to submit results of the CMV testing to the Department** for each newborn under their care who is referred for CMV testing **within ten days** of receiving results.

- **Laboratories** testing for the presence of congenital CMV must submit results of the CMV testing to the Department **within ten days** of receiving results.

cCMV surveillance in Utah

Late 2013: CMV results module in EHDI (Early Hearing Detection and Intervention) database



cCMV surveillance in Utah

2015: **R396-702. Communicable Disease Rule.**

(7) Laboratory results reportable by electronic reporters are as follows:

(a) In addition to laboratory results set forth in Subsections R386-702-3(2) through R386-702-3(6), entities reporting electronically shall include the following laboratory results or laboratory results that provide presumptive evidence of the following communicable diseases:

(i) influenza virus;

(ii) norovirus infection;

(iii) Pseudomonas aeruginosa, resistant to a carbapenem, or with demonstrated carbapenemase production;

(iv) Staphylococcus aureus from a normally sterile site with methicillin testing performed, reported as either methicillin-susceptible Staphylococcus aureus (MSSA) or methicillin-resistant Staphylococcus aureus (MRSA); and

(v) Streptococcal disease, invasive due to all species.

(b) Entities reporting electronically shall include any laboratory results including positive, negative, equivocal, indeterminate, associated with the following tests or conditions:

(i) CD4+ T-Lymphocyte tests, regardless of known HIV status;

(ii) chlamydia;

(iii) Clostridium difficile;

(iv) novel coronavirus COVID-19 (SARS-CoV-2), including IgM and IgG serology;

(v) cytomegalovirus (CMV), congenital (infants less than or equal to 12 months of age);

(vi) gonorrhea;

(vii) hepatitis A;

(viii) hepatitis B, including viral loads;

(ix) hepatitis C, including viral loads;

(x) HIV, including viral loads and confirmatory tests;

cCMV surveillance in Utah

Rule R398-4 updates:

R398-4-3. (4) The Department may make **referrals to help coordinate care and provide resources** for the affected child and their family.

R398-4-6. CMV Registry.

Pursuant to Section 26B-7-105, the Department shall maintain a database of infants tested as well as a **Positive Congenital CMV Registry** that contains results, demographics, symptomology, specialist services, long-term outcomes, and other items as deemed necessary.

R398-4-7. Confidentiality of Reported Information.

(1) The confidentiality of personal information obtained under this rule shall be maintained pursuant to Title 26B,Chapter 8, Part 4 Health Statistics. The reports are confidential and are not open to public inspection.

(2) Pursuant to Section 26B-1-229, **persons who report information covered by this rule may not be held liable for reporting the information to the Department**.

cCMV surveillance in Utah

R398-2. Newborn Hearing Screening: Early Hearing Detection and Intervention (EHDI) Program.

R398-2-6. (4) The Department shall have access to infants' medical, diagnostic, amplification, implantation, and early intervention records to obtain information necessary to ensure the provision of timely and appropriate follow-up diagnostic and intervention services, **including CMV testing results and follow-up, congenital CMV sequelae, treatments, and anything else deemed necessary to determine long-term outcomes.**

cCMV surveillance in Utah

R398-5. Birth Defects and Critical Congenital Heart Disease Reporting.

R398-5-2. Definitions.

As used in this rule:

(1) "Birth defect" means any medical disorder of organ structure, function, or biochemistry that is of possible genetic or prenatal origin. This includes any congenital anomaly, indication of hypoxia or genetic metabolic disorder listed in the ICD-10, International Classification of Diseases, 10th Revision, established by the World Health Organization, with any of the following diagnostic codes: A92.5, E03, E25, from E70 to E90, from D55 to D58, H90.0 to H90.8, H90.A, H91.0 to H91.9, J96.00 to J96.91, P09, P35.1, P35.4, P96.1 to P96.2 and from Q00 to Q99.

Congenital CMV infection code added in 2019

cCMV surveillance in Utah

DSA with Vital Records:

Were there any maternal infections antepartum during pregnancy or at delivery? (check all applicable)

◯ Cytomegalovirus ◯ Chlamydia ◯ Group B Strep + ◯ Herpes+ (HSV) (active lesions)

◯ Hepatitis A ◯ Hepatitis B ◯ Hepatitis B not found

◯ Gonorrhea ◯ Hepatitis C ◯ Syphilis ◯ HIV/AIDS

◯ None ◯ Unknown

Parent 1 tested for hepatitis B by a healthcare provider during this pregnancy? ◯ Yes ◯ No ◯ Unknown

Obstetric procedures

Were there any obstetric procedures?

◯ None ◯ Cervical ripening ◯ External cephalic version ◯ Successful version ◯ Failed version

◯ Unknown version

DHHS-OVRS-105 January 2024 Page 3 of 3 Maternal Care Worksheet

Mother's medical and delivery information worksheet

Utah Department of Health & Human Services

Mother's current legal name (first, middle, last): Date of last period (LMP) mm/dd/yyyy ___/___/_____	Utah licensed physician and/or CMN:
Prenatal care history ◯ No prenatal care Was the prenatal care record used to gather prenatal care history? ◯ Yes ◯ No Date of first prenatal care visit: mm/dd/yyyy ___/___/_____ Date of last prenatal care visit: mm/dd/yyyy ___/___/_____ Total number of prenatal care visits for this pregnancy: _____ ◯ No previous live births (if none, enter "0")	**Method of delivery** A. Was delivery with forceps attempted but unsuccessful? ◯ Yes ◯ No B. Fetal presentation at delivery ◯ Cephalic ◯ Breech ◯ Other C. Final route and method of delivery (check one) ◯ Vaginal/spontaneous ◯ Vaginal/vacuum ◯ Vaginal/forceps ◯ Cesarean: If cesarean, was a trial of labor attempted? ◯ Yes ◯ No D. Hysterotomy/hysterectomy ◯ Yes ◯ No
Pregnancy history Live births now living ____ (do not include this child) Live births now dead ____ (do not include this child) Date of **last** live birth mm/dd/yyyy ___/___/_____ **Number of other terminations** ◯ None (Spontaneous or induced losses or ectopic pregnancies) 00-15 weeks _____ 16-19 weeks _____ 20 weeks or more _____ Total # of terminations _____ **Date of last termination** ___/___/_____	**Maternal morbidity** (complications associated with labor and delivery) Check all that apply: ◯ 01 Maternal transfusion ◯ 02 Third or fourth degree perineal laceration ◯ 03 Ruptured uterus ◯ 04 Unplanned hysterectomy ◯ 05 Admission to intensive care unit ◯ 06 Unplanned operating room procedure following delivery ◯ None of the above
Mother transferred for maternal medical or fetal indications for delivery? ◯ Yes ◯ No If yes, name of facility and state: _____ **Mother transferred to hospital from an attempted home birth?** ◯ Yes ◯ No ◯ Postpartum (within 24 hrs of delivery) ◯ Unknown	Weight of fetus: _____grams **AND** _____lbs. _____oz. ◯ Single (1) ◯ Twin (2) ◯ etc. _____(specify) If not single, birth order: _____ Obstetric estimate of gestation at delivery:_____(completed weeks)
Medical risk factors (check all that apply) Diabetes ◯ Pre pregnancy (diagnosis prior to this pregnancy) Gestational diabetes during this pregnancy (per parental worksheet) ◯ Yes ◯ No ◯ No response/no worksheet Gestational diabetes confirmed in mother's chart ◯ Yes ◯ No ◯ No prenatal care record available Where was GDM information found _____ GDM found other _____ Hypertension ◯ Pre pregnancy (CHTN) (chronic) ◯ Gestational (PIH, preeclampsia, eclampsia) ◯ Previous preterm birth (36 weeks or less) ◯ Other previous poor pregnancy outcome (includes perinatal deaths, small-for-gestational-age/intrauterine growth restricted birth) ◯ Vaginal bleeding during this pregnancy before the onset of labor ◯ Pregnancy resulted from infertility treatment (if yes, check all that apply) ◯ Fertility enhancing drugs, artificial insemination, or intrauterine insemination ◯ Assisted reproductive technology (in vitro fertilization (IVF), gamete intrafallopian transfer (GIFT)) ◯ Mother had a previous cesarean delivery. If yes, how many?____ ◯ None of the above	**Stillborn medical screens 1 & 2 - Fetal anomalies** (check all that apply) ◯ 01 Anencephaly ◯ 02 Meningocele/spina bifida ◯ 03 Hydrocephalus ◯ 04 Microcephalus ◯ 05 Other central nervous system anomalies (specify)_____ ◯ 06 Cyanotic congenital heart disease (specify) _____ ◯ 07 Tracheo-esophageal fistula/esophageal atresia ◯ 08 Omphalocele ◯ 09 Gastroschisis ◯ 10 Other gastrointestinal (specify) _____ ◯ 11 Urinary system anomalies (specify) _____ ◯ 12 Cleft lip with cleft palate ◯ 13 Cleft palate alone ◯ 14 Limb reduction defects (excludes amputation and dwarfing syndromes) ◯ 15 Other limb anomalies (specify) _____ ◯ 16 Diaphragmatic hernia ◯ 17 Other musculoskeletal anomalies (specify) _____ ◯ 18 Down syndrome ◯ Karyotype confirmed ◯ Karyotype pending ◯ 19 Chromosomal anomalies ◯ Karyotype confirmed (specify) _____ ◯ Karyotype pending ◯ 20 Hypospadias ◯ 21 Other anomalies not listed above (specify) _____ ◯ 22 Unknown ◯ None
Infections present and/or treated during this pregnancy (check all that apply) ◯ 01 Gonorrhea ◯ 02 Syphilis ◯ 03 Herpes simplex virus (HSV) ◯ 04 Chlamydia ◯ 05 Listeria ◯ 06 Group B streptococcus (GBS+) ◯ 07 Cytomegalovirus ◯ 08 Parvo virus ◯ 09 Toxoplasmosis ◯ 00 None of the above ◯ Other (specify) _____	

DHHS OVRS Fetal death mother medical worksheet for NCHS January 2024

cCMV testing in Utah - expansion

2013-2016: Hearing-targeted

2016-2019: High-risk targeted (symptom) testing recommended in Intermountain Healthcare NICUs

Fall 2019: High-risk targeted testing standard practice in all Intermountain facilities

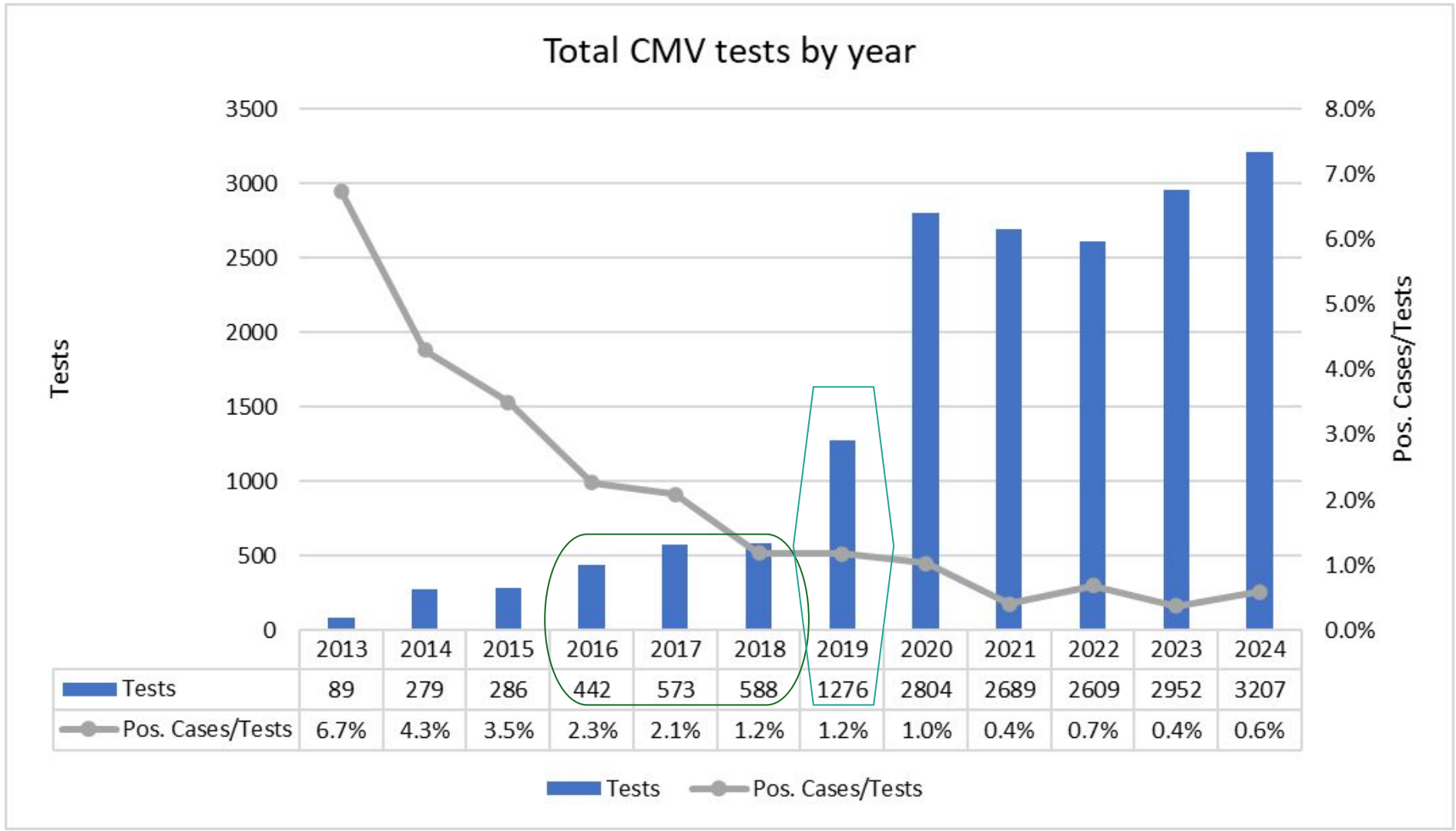
If any of the following present:

1) Mother positive for CMV infection during pregnancy
2) Abnormal head size (OFC <10th %ile OR >90th %ile at birth)
3) Intrauterine growth restriction (weight <10th %ile for gestational age)
4) Unexplained hydrops
5) Intracranial OR intraabdominal calcifications on first imaging exam
6) Unexplained hepatomegaly OR splenomegaly (>1 cm below the right or left costal margin)
7) AST or ALT >100 U/L OR unexplained direct bilirubin >1.0 mg/dL
8) Petechial rash or blueberry muffin rash at any time
9) Leukomalacia, polymicrogyria, lissencephaly, pachygyria, schizencephaly
10) Unexplained persistent thrombocytopenia (platelets < 100k/mm^3)
11) Failed hearing screen

Send urine CMV PCR

(obtain by 21 days of life when possible)

cCMV testing in Utah



cCMV surveillance in Utah

2013 - Me
2015 - CMV data coordinator - PT (SLP/AUD)

2019 - CMV data coordinator / EHDI epidemiologist - FT

2022 - CMV epidemiologist (SET-NET) - FT

Jacinda Merrill, MPH, CHES

Max Sidesinger, MPH (2021)

cCMV surveillance in Utah

CMV data coordinator / EHDI epidemiologist - FT

- Conducts CMV surveillance through electronic lab reporting - weekly reports
- Ensures adherence to universal newborn hearing screening targeted CMV testing through assistance and education to providers, caregivers, and laboratories
- Improves data quality and completeness for CMV laboratory, clinical, and demographic information using medical record abstraction and establishment of new data linkages
- Analyzes CMV and early hearing data and provide results and takeaways to relevant stakeholders

cCMV surveillance in Utah

CMV epidemiologist (SET-NET) - FT

- Abstracts data from electronic medical records of children who have tested positive for CMV within the first year of life (and all confirmed/probable/suspect cases)
- Determines if a positive case meets cCMV case classification criteria based on CMV test results and abstraction efforts
- Maintains Utah's cCMV registry and performs analysis on confirmed and probable cCMV cases
- Sends letters to primary care providers, OBs, and parents of newly diagnosed cases to notify of diagnosis, provide information and resources for cCMV
- Participates in outreach opportunities, such as creating and disseminating materials (i.e. rack cards, handouts, social media posts) to spread awareness of cCMV

cCMV resources in Utah

Utah Department of Health & Human Services

Dear **(Parent name)**,

Congratulations on the birth of your new baby! As part of Utah's goal to improve the health outcomes of Utah babies, we screen babies for congenital Cytomegalovirus (CMV) if they meet certain criteria. Because your baby _____, he/she had testing done on **(date)** on **(urine/saliva)** looking for congenital CMV.

Your baby's testing came back **POSITIVE**, meaning there is evidence for a congenital CMV infection. We will also notify your primary care provider **(name of provider, phone #)** of these results. CMV is the most common viral infection that infants are born with in the US. About **1 in 150 babies are born with congenital CMV** each year (30,000 - 40,000 babies). Ninety percent of babies with a congenital CMV infection will not show any signs or symptoms at birth; however, they are at risk for delayed hearing loss and other health problems.

Because congenital CMV related hearing loss and other health problems may be delayed, it is important to follow up with all recommended testing and services. The additional evaluations for your baby include:

- Diagnostic audiological evaluation ASAP, if not done already, with frequent monitoring of hearing;
- Referral to an infectious disease physician;
- Referral to an ENT;
- Referral to a pediatric ophthalmologist;
- Referral to early intervention services.

We know that this diagnosis and additional evaluations are overwhelming to say the least. To help with this follow-up process, one very helpful resource is the **multi-disciplinary cCMV clinic at Primary Children's Hospital**, facilitated by Albert Park, MD. This clinic includes an expert team of specialists that provide consultation, the evaluations listed above, treatment as needed, follow-up, and support to cCMV babies, families, and their providers. The **cCMV clinic phone number is 801-662-1705**.

We can also refer babies with congenital CMV and/or hearing loss to Utah's **Baby Watch early intervention program**, familyhealth.utah.gov/oec/baby-watch-early-intervention. This program provides early identification and developmental monitoring services for

1

Utah Department of Health & Human Services

infants and toddlers (ages birth to 3 years of age) that have or are at risk for disability or developmental delay.

Since we feel it is important for parents to be empowered by information, we wanted to include our website, familyhealth.utah.gov/cmv, where you can find more information about CMV. Additionally, one of the best ways to gain useful information is through parents sharing with other parents. We have included information on the National CMV Foundation www.nationalcmv.org/. This organization was developed by parents and for parents. Lastly, if you would like to be connected to other Utah parents who have a baby with congenital CMV or if you have any unanswered questions, please feel free to contact us at 801-273-6600 or cmv@utah.gov.

We want you to feel supported while you navigate your baby's congenital CMV infection and care. Please let us know how we can help.

Best regards,

Stephanie B. McVicar, AuD, CCC-A
EHDI and CMV program manager
Division of Family Health

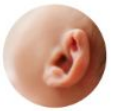
Jacinda Merrill, MPH, CHES
CMV epidemiologist
Division of Family Health

Early Hearing Detection and Intervention (EHDI)
Street Address: 195 N 1950 W • Salt Lake City, UT 84116
Telephone: (801) 273-6600 • Fax: (801) 536-0492
Websites: familyhealth.utah.gov/ehdi
familyhealth.utah.gov/cmv

2

Your baby has cCMV, now what?

A baby with congenital cytomegalovirus (cCMV) requires additional evaluations and testing. Even without symptoms, the following are recommended:



Referral to a pediatric audiologist

Even if your child passed their newborn hearing screen, they should receive a diagnostic audiological evaluation **as soon as possible**. This needs to be conducted by an audiologist who has expertise in testing infants. They should have regular and frequent monitoring throughout their childhood. If a change in hearing is suspected, hearing testing needs to be conducted immediately. Following these guidelines is important because cCMV can cause a late onset

cCMV clinic at Primary Children's

We know that this diagnosis and additional evaluations may be overwhelming. **The cCMV clinic at Primary Children's Hospital** offers a follow-up process that includes an expert team of specialists to provide consultation, required evaluations, treatment as needed, follow-up, and coordination services for babies and families affected by cCMV. **The cCMV clinic phone number is 801-662-1705.**

Early intervention services

These services evaluate and help your child in various areas of development. Utah's Baby Watch Early Intervention Program (BWEIP) provides early identification and developmental monitoring from birth to 3 years for children that have, or are at risk for, disability or developmental delays. Because cCMV can cause development delays, your child qualifies for early intervention services. Anyone can refer a child to BWEIP at: familyhealth.utah.gov/oec/baby-watch-early-intervention.

Additional parent resources

familyhealth.utah.gov/CMV

National CMV Foundation: nationalcmv.org

If you would like to be connected to other Utah parents who have a baby with congenital CMV or if you have any unanswered questions, please feel free to contact us at 801-273-6600 or cmv@utah.gov.

EARLY HEARING DETECTION AND INTERVENTION (EHDI)
Mailing Address: PO Box 144620 • Salt Lake City UT 84114-4620
Telephone: (801) 273-6600 • Fax: (801) 536-0492

Utah Department of Health & Human Services
Family Health

cCMV resources in UT

Congenital cytomegalovirus

Congenital cytomegalovirus (cCMV) is the most common viral infection that infants are born with in the U.S. and can result in brain damage, hearing and/or vision loss, developmental delays, and on rare occasion, death.

According to Utah's CMV legislation, if a newborn fails their initial and follow-up hearing screen, or just their initial hearing screen after 14 days of age, they need to be tested for cCMV.

In addition to testing based on hearing screening results, most Utah hospitals also test for cCMV if the infant has certain risk factors, such as petechiae, microcephaly or low birthweight. For more information, contact cmv@utah.gov or 801-273-6600.

Utah Department of Health & Human Services
Family Health

What to do with a positive case

Infected infants should receive follow-up care as soon as possible. Infected infants could have immediate, delayed, or progressive concerns and may benefit from anti-viral treatment.

Follow-up includes:

- Diagnostic audiological evaluation;
- Referral to an infectious disease specialist;
- Referral to an otolaryngologist (ENT);
- Referral to a pediatric ophthalmologist;
- Referral to a neurologist;
- Referral to early intervention (familyhealth.utah.gov/oec/baby-watch-early-intervention/)

cCMV clinic

The cCMV clinic at Primary Children's Hospital offers an integrated follow-up process. This clinic provides consultation, evaluation, treatment as needed, specialist coordination for babies and families affected by cCMV, and support to their providers. **When you receive notice of a positive case, please reach out to the cCMV clinic at 801-662-1705.**

Resources

- Utah CMV public health initiative: **cmv@utah.gov**, 801-273-6600, familyhealth.utah.gov/cmv

Challenges

- Originally, not getting all lab results (dependent on provider/lab faxing to us) - overcome through ELR, access to EMRs
- Pushback - overcome through education and partnership
- Started everything from scratch - did best and pivoted as we went along :)

Successes

- Mandate brought top of mind awareness and evolution of testing over time (increased)
- Mentoring others, helping to increase testing in US
- SET-NET for cCMV

Lessons learned

- Just dive in and do your best
- Communication, education, partnerships
- Be consistent with your surveillance (definitions and follow-up)

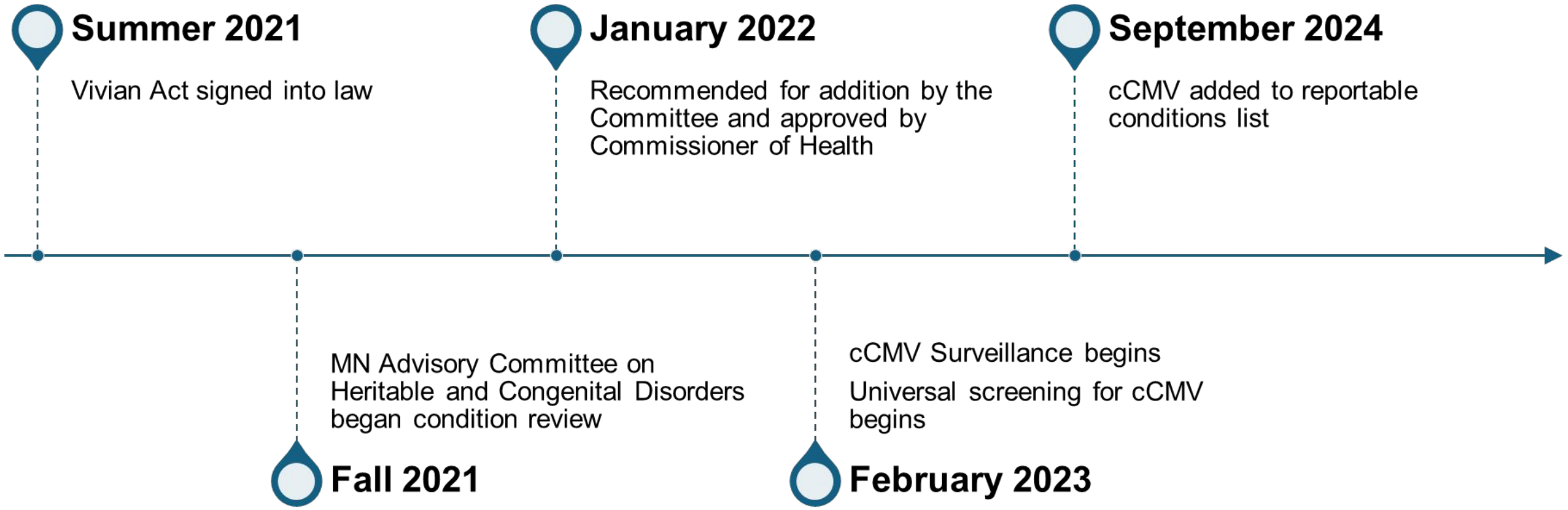
Utah Q&A

cCMV surveillance in Minnesota

Lexie Barber, MPH

DEPARTMENT OF HEALTH

cCMV Surveillance in Minnesota



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Case Ascertainment

- Universal screening – majority of cases
- Reportable condition
  - Health care providers, labs, etc required to report (electronic reporting form and ELR)

Data Sources

- Newborn Screening (NBS)
- MDH EHDI
- MDH Birth Defects
- Vital records data - birth and death records
- Chart abstractions

DEPARTMENT OF HEALTH

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Congenital Cytomegalovirus Reporting Form

Congenital cytomegalovirus (cCMV) must be reported to MDH within one working day.

Case Definition: Cytomegalovirus (CMV) detected by nucleic acid amplification test (NAAT) or culture, or by antigen testing, on any specimen source, excluding dried blood, from an infant less than or equal to 90 days of age.

Patient information

Patient first name:
* must provide value

Patient last name:
* must provide value

Date of birth:
* must provide value
Today M-D-Y

Sex:
* must provide value

Address **City**
State **Zip**

Parent/guardian phone number
* must provide value

Mother's name:
* must provide value

Mother's date of birth:
M-D-Y

Birth hospital:
* must provide value

Reason for testing:
(Select all that apply)

- [ ] Referred on hearing screen or diagnosed with hearing loss
- [ ] Mother tested positive for CMV during pregnancy
- [ ] Symptomatic
- [ ] NICU
- [ ] Positive on NBS blood spot
- [ ] Other:

Specimen collection date:
* must provide value
Today M-D-Y

Age (days) at time of specimen collection
This is an automatically calculated field

Ordering facility:
* must provide value

Specimen type:
* must provide value

- ( ) Dried blood spot
- ( ) Urine
- ( ) Saliva
- ( ) CSF
- ( ) Blood (whole blood, serum, or plasma)
- ( ) Other -

reset

Results:
* must provide value

- ( ) CMV Detected (Positive)
- ( ) CMV Not Detected (Negative)
- ( ) Indeterminate

reset

Performing laboratory
* must provide value

Primary care clinic:
* must provide value

cCMV in the Minnesota Department of Health

Public Health Lab Division

Newborn Screening Program

Confirmation of blood spot positives

Short term follow up

Child and Family Health Division

Children and Youth with Special Health Needs

Longitudinal surveillance

Non NBS cases

SETNET Case reporting

Minnesota Process

NBS cases -

- Genetic counselors provide just in time education to provider
- Recommends collection of urine CMV PCR by 21 days of age

Recommend -

- Lab testing - AST/ALT, complete blood count
- Audiology exam with monitoring
- Ophthalmology
- Brain imaging
- Developmental assessment and referral to Early intervention

Section 4: Audiology Guidelines For Infants With Congenital Cytomegalovirus

Minnesota Process (cont.)

NBS short term follow up program

- Gathers initial information on symptoms and evaluations
- Sends cases to surveillance team to continue data collection

MDH NBS longitudinal follow-up/surveillance team

- Determines CSTE case classification
- Connect family to local public health nurse
- Send booklet to family on cCMV
- Continues longitudinal data collection
- May connect with surveillance only cases (no DBS) as well

DEPARTMENT OF HEALTH

Data abstractions and longitudinal follow-up

- Physical exam
- Measurements
- Symptoms
- Brain imaging
- Audiology exams and findings
  - Hearing loss
  - Vestibular concerns
- Ophthalmology exams and findings
- Treatment information
- Referrals
- NICU stay
- Comorbidities
  - Seizures
  - Developmental disorders
  - Cerebral palsy
  - Liver disease
  - Cancers
- Well Child Visits
- Other specialty care

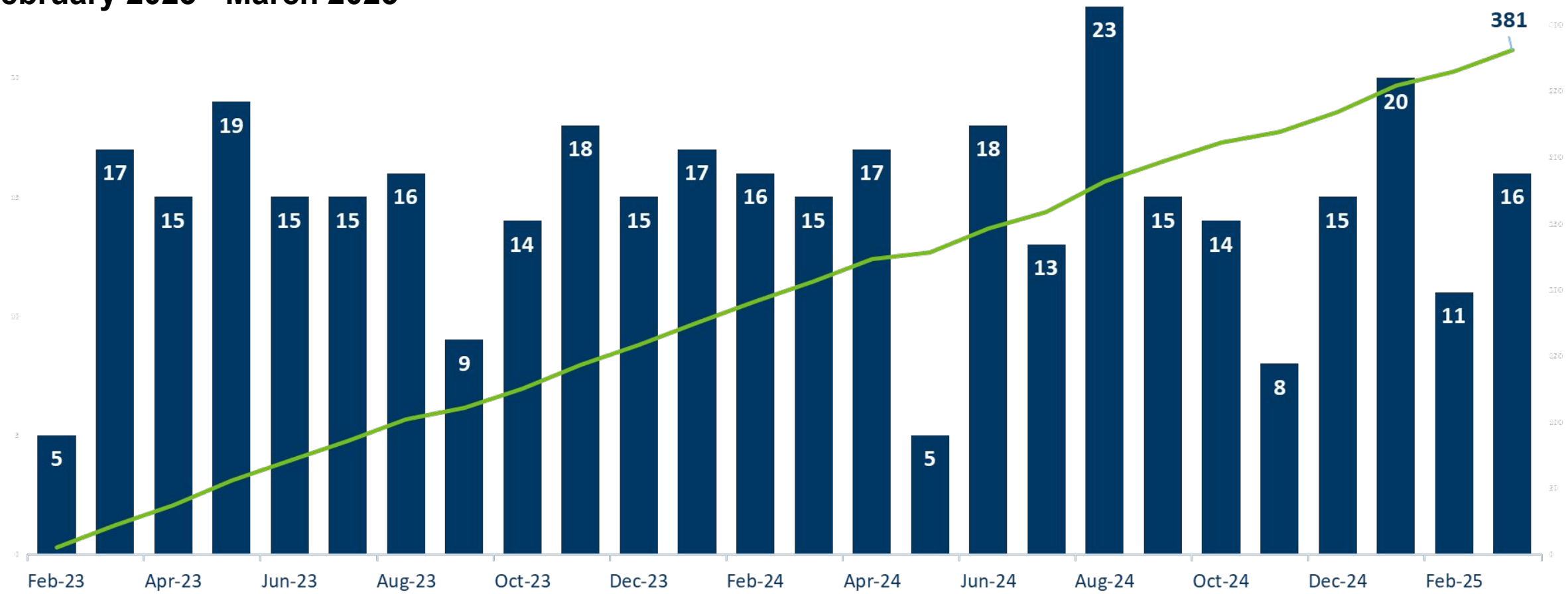
Data abstractions and longitudinal follow-up (cont.)

Data timepoints

- Prenatal care
- Birth hospitalization
- 2 months
- 6 months
- 12 months
- 24 months
- Annually

cCMV surveillance in Minnesota

February 2023 - March 2025



DEPARTMENT OF HEALTH

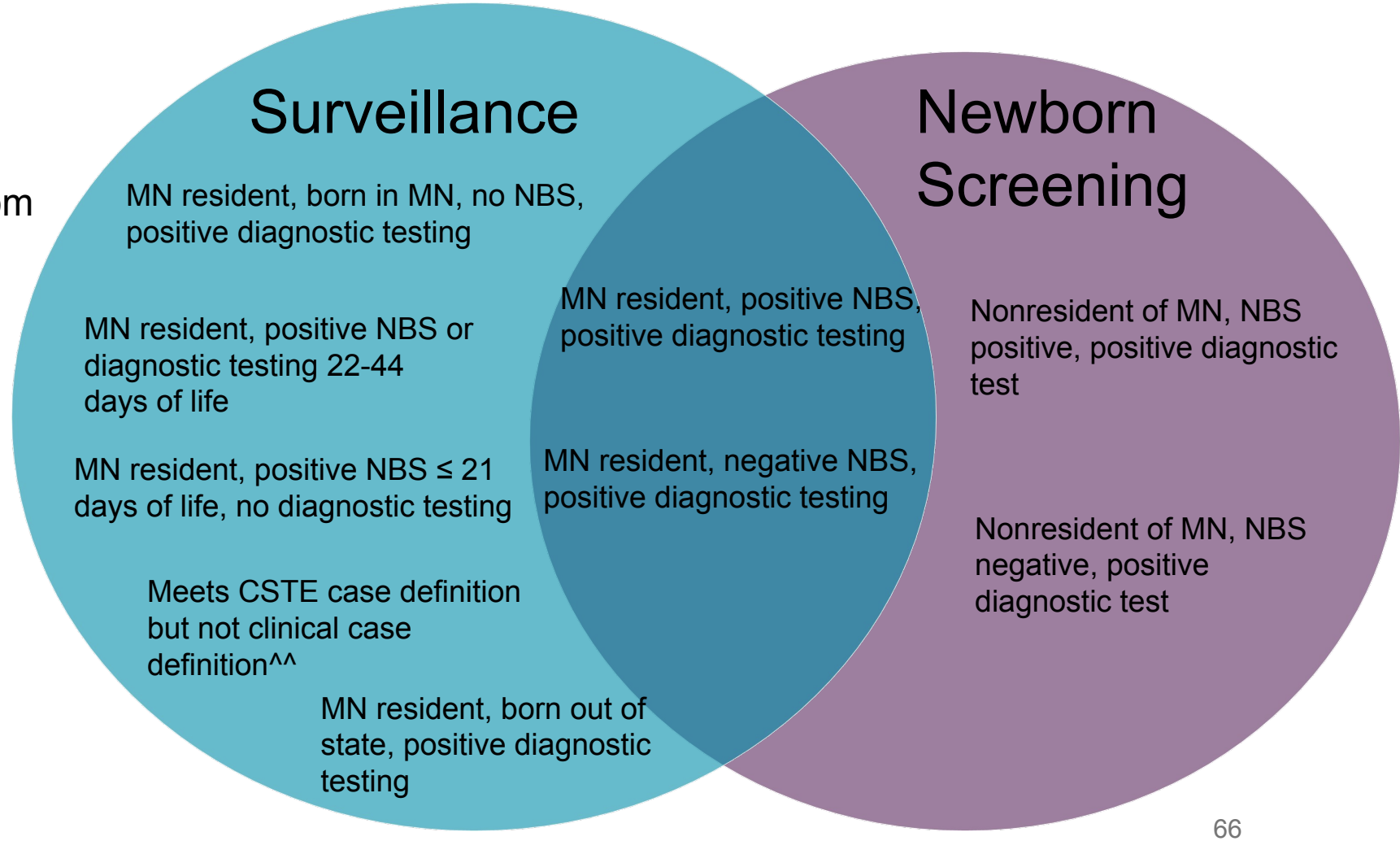
Surveillance vs newborn screening

Challenges

- Counting cCMV cases in different ways and for different reasons
- Duplicating efforts
- Re-requesting charts/information from health care facilities

Multiple databases

- NBS short term database
- NBS longitudinal database
- Surveillance



^^NBS takes provider diagnosis into consideration, whereas surveillance follows a strict case definition

DEPARTMENT OF HEALTH

Challenges

- Acquired cases are picked up on 30 day DBS regularly (NBS testing protocol)
- Not receiving all ELRs
- Asymptomatic vs symptomatic - difficult to categorize
- Brain imaging results are very complicated
- Developmental status is hard to gather from charts
- Chart abstractions are time consuming
- Access to charts varies by health system

Successes

- Finding cases
- Getting kids in for hearing evals where cCMV would not have been suspected
  - Passed initial hearing screen, no obvious signs or symptoms at birth
- Treatment for children we wouldn't have otherwise caught
- Decrease in time to diagnosis
- cCMV now a reportable condition in Minnesota
- Many labs onboarded with ELR
  - Caught a few out of state cases
- cCMV Consortium
  - Ophthalmology workgroup
  - Neurology workgroup

Minnesota Q&A

	Data Sources	Screening Type	Legislation
New Jersey	• Birth Defects Registry (BDR) • Birth certificates (VERI) - CMV checkbox • Uniform Billing data for birth admissions • Early Hearing Detection and Intervention (EHDI) program - TORCH Testing risk code	• Screening not mandated • Some hospitals do hearing targeted and/or high-risk targeted screening	• cCMV is not a reportable condition • Legislation for universal screening signed in 2022 • Required conditions have not been met; therefore, universal screening has not been implemented yet
Utah	• Electronic Lab Reporting (ELR) • Electronic Medical Records (EMR) • EHDI program • Birth Defects Registry (BDR) • Vital Records	• Hearing targeted • High risk targeted	• Utah CMV Law 26-10-10: 2013 - Newborns who fail hearing screening tested within 21 days of birth. • 2015: R396-702. Communicable Disease Rule. *All* CMV *testing* under 12 months reported. • R398-5. Birth Defects and Critical Congenital Heart Disease Reporting. - cCMV added in 2019
Minnesota	• Newborn Screening (NBS) • MDH EHDI program • MDH Birth Defects • Vital records data (birth and death records) • Chart abstractions	• Universal	• cCMV added to reportable conditions list in MN in September of 2024 • Vivian Act signed into law in 2021 - education component and require MN Advisory Committee to review cCMV for possible inclusion on MN NBS panel

[1] Minnesota begins newborn screenings for a common cause of birth defects | MPR News

Any other questions?

Discussion

Questions/prompts for group discussion

- If we have a guidebook, would it be helpful? What content should be included?
  - Where is the surveillance “home” or who has ownership?
  - CMV data sources - where you can find information?

Questions/prompts for group discussion

- Things to discuss:

  - Capacity, personnel needed (surveillance, state resources, e.g. ped specialists like ophtho, neuro, ID, etc.)
  - Plan for positive cases? Positive without clinical signs? Is someone responsible for f/u?
  - What are barriers to surveillance? what haven't we discussed?
  -

Thank You

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NJHealth New Jersey Department of Health

Utah Department of Health & Human Services