Original Study

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Update on an Expanded Targeted Early Cytomegalovirus Testing Program From a Large Health Care System

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Objective: Update our expanded targeted screening program for congenital cytomegalovirus (cCMV) detection among newborns born in a health care system in Utah.
Study design: A retrospective cohort study was identified prospectively.
Setting: Intermountain Health care (IHC) system in Utah.
Patients: Infants from IHC facilities, born between March 1, 2021, and August 31, 2024, were tested for CMV within 6 months of birth.
Intervention: Expanded targeted screening program for cCMV.
Main outcome measures: Prevalence of cCMV; clinical characteristics of cCMV-positive infants; effectiveness of expanded targeted screening program.
Results: Between March 1, 2021, and August 31, 2024, a total of 8598 tests were ordered for cCMV screening among 93,529 live births (9%) across 27 facilities within Intermountain Health care. Over 3.5 years, the expanded targeted screening program detected 32 confirmed cCMV cases among 93,528 live births, yielding an estimated prevalence of cCMV disease of 34 cases per 100,000. Hearing loss was detected in 9 of 32 children (28%), with varying degrees of severity, including unilateral (n = 4), bilateral asymmetric (n = 1), and bilateral symmetric loss (n = 4). Of these, 5 were fitted with hearing aids, and 3 underwent bilateral cochlear implantation at a median age of 11 months.
Conclusions: The expanded targeted early cCMV testing program has proven effective in enabling early intervention for children with cCMV. These results suggest feasibility and opportunities for improved early intervention and treatment.

Keywords: CMV, Congenital, Cytomegalovirus, Hearing loss, Infection, Newborn, Screening, Sensorineural, TORCH infection

Introduction

Congenital cytomegalovirus (cCMV) is the most widespread congenital viral infection and the leading nongenetic cause of sensorineural hearing loss (SNHL), accounting for an estimated 25% of childhood hearing loss by age 4 years.[1] In the United States, the prevalence of cCMV infection was estimated at 4.6 per 1000 live births during 2018–2022, with an overall incidence of 0.6%–0.7% in developed countries and up to 1%–5% in developing countries.[2,3] Nine in 10 children with cCMV do not present clinical signs at birth, though 7%–11% of those will develop hearing loss in comparison to 34%–41% of those who are symptomatic at birth.[4]

Despite its high prevalence and substantial disease burden, diagnosing cCMV remains challenging, primarily due to the narrow time window required for accurate diagnosis. To confirm cCMV, diagnosis relies on real-time PCR of urine or initial saliva testing followed by confirmatory urine testing within the first 3 weeks of life, as postnatal CMV infection is not linked to SNHL.[5] Beyond the 3-week mark, the diagnosis relies on PCR testing of dried blood spots (DBS) collected at birth.[6,7]

Early diagnosis is crucial, as demonstrated by clinical trials from the Collaborative Antiviral Study Group, which found that initiating a 6-month course of valganciclovir before 30 days of age led to better neurodevelopmental and hearing outcomes compared with a shorter 6-week regimen.[8] However, given the potential adverse effects of antiviral therapy (hematologic and reproductive toxicity), treatment decisions should be carefully weighed, emphasizing the importance of early detection to identify candidates most likely to benefit from those treatments.[9]

To enhance early cCMV detection, a Utah statewide CMV working group was formed, bringing together members of the Department of Health and Human Services (DHHS), pediatric otolaryngology, audiology, infectious disease, neurology, and neonatology.[10] This group expanded the 2013 hearing-targeted early cCMV testing law that required CMV testing for all children who fail their newborn hearing screen to include a wider range of CMV-related symptoms present at birth. This program was subsequently applied across the Intermountain Health Care

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(IHC) and University of Utah systems. As a result, cCMV detection rates increased by 750% from 4.2 cases per 100,000 live births to 35.7 cases per 100,000 live births.[10,11]

The aim of the study was to update and evaluate the expanded targeted testing program for cCMV detection among newborns in Utah. Subsequently, the study sought to assess the clinical outcomes and management strategies for infants diagnosed with cCMV.

Methods

An expanded targeted cCMV testing protocol has been implemented across Primary Children's Hospital and the IHC system in Utah since 2019. Data collection began in March 2021 to allow time for the expanded targeted cCMV testing program to mature and achieve consistent implementation across sites. The multidisciplinary team that created this protocol recommended CMV testing for newborns who meet any of the following criteria: failed hearing screening, idiopathic elevated liver enzymes or bilirubin, abnormal central nervous system (CNS) imaging findings suggestive of cCMV (eg, intracranial calcifications), unexplained thrombocytopenia, history of intrauterine growth restriction (IUGR), small for gestational age (SGA), macrocephaly, microcephaly, petechial rash, unexplained hepatomegaly or splenomegaly, or maternal history of CMV infection during pregnancy. A detailed overview of these indications and the subsequent diagnostic workup are provided by Suarez et al.,[10]

As outlined by Suarez et al.[10] the electronic medical record system (Powerchart-Cerner) was updated in collaboration with the Intermountain Information Technology team to track protocol outcomes. When a provider orders CMV testing for a child under 6 months of age, the system prompts the user to specify the indication for testing from a predefined list. The order cannot proceed until an indication is selected. Providers can select multiple indications or choose "unknown" or "other," in which case a free-text box appears for additional input. Indications such as abnormal ophthalmologic findings, sepsis workup, and prematurity were categorized as "other." These system modifications were intuitive and did not require any formal training.

Monthly tracking was conducted prospectively through an automated electronic medical records reporting system for all infants under 6 months of age who underwent CMV testing at an IHC facility. These reports included patient-level data such as reason for testing, sample type collected, date and time of sample collection, age at testing, gestational age, and mean birth weight, without the need for manual chart review. In addition, a coordinator was notified of any CMV-positive result in the state by the Utah DHHS. The CMV coordinator then contacted the infant's primary care provider, coordinated and tracked the appropriate workup, including CNS imaging and laboratory testing, and offered an evaluation in the multidisciplinary cCMV clinic. This study retrospectively analyzed all infants tested for cCMV between March 1, 2021, and August 31, 2024, to assess the detection rates of symptomatic and overall cCMV cases under the expanded targeted testing protocol.

An infant was diagnosed with cCMV if a urine CMV PCR was positive within the first 21 days of life, if both a saliva CMV PCR test and a confirmatory urine CMV PCR were positive within the same timeframe, or if a DBS CMV PCR result was positive at any age.[6,12] Infants with positive CMV results underwent a standardized evaluation that included a complete blood count with differential, comprehensive metabolic profile, ophthalmology examination, head ultrasound, and diagnostic hearing testing through auditory brainstem response testing, regardless of the results of the newborn hearing screening—conducted through otoacoustic emissions or automatic auditory brainstem response testing. Those infants with microcephaly or an abnormal head ultrasound underwent a brain MRI scan. Demographic information and clinical data, including audiologic, ophthalmologic, and imaging records were extracted from the IHC electronic medical records for all infants with confirmed cCMV.

Patients were classified as having symptomatic cCMV or cCMV disease if they exhibited one or more of the following associated conditions: thrombocytopenia (< 100 K/mm^3), petechiae, hepatomegaly, splenomegaly, IUGR/SGA, hepatitis (aspartate aminotransferase or alanine aminotransferase > 100 U/L or unexplained hyperbilirubinemia > 1.0 mg/dL), microcephaly, intracranial calcifications, or other CNS abnormalities consistent with cCMV, abnormal cerebrospinal fluid indices, or chorioretinitis.[12] Patients were classified as having cCMV infection if they displayed no clinical signs, symptoms or testing indicative of CMV disease. Infants with cCMV infection and SNHL but no other symptoms or testing abnormalities were categorized separately as having isolated SNHL.

Audiologic testing involved diagnostic auditory brainstem response (ABR), otoacoustic emissions, tympanometry, and if hearing loss was detected, bone conduction testing. For ABR assessments, hearing loss was defined as threshold responses > 25 dB eHL (estimated hearing level) for click or for any of the tone burst frequencies at 0.5, 1, 2, or 4 kHz.[13] For behavioral testing, hearing loss was defined as any threshold > 20 dB at 1, 2, or 4 kHz. We categorized SNHL severity based on the average of 4 frequencies: 0.5, 1, 2, 4 kHz. As defined by Torrecillas et al.,[14] severity was specified as mild for 30–45 dB eHL (ABR) or 21–45 dB (behavioral), then for all testing methods moderate for 46–70 dB, severe for 71–90 dB, and profound for > 90 dB. Bone conduction testing was conducted to rule out conductive hearing loss.

As described by Torrecillas et al.,[14] the hearing change was calculated using the threshold obtained in the first ABR as baseline. The average and range of change by ear were reported in decibels. A clinically significant change (worsening or improvement) in hearing was defined as a threshold change > 15 dB change in 1 frequency, or > 10 dB change in more than 1 frequency. Unilateral hearing loss referred to hearing loss in one ear with normal hearing in the contralateral ear. Single-sided deafness referred to severe or profound unilateral hearing loss. Bilateral asymmetric SNHL was defined as bilateral SNHL with a binaural difference in bone conduction thresholds of more than or equal to 20 dB at 2 contiguous frequencies or more than or equal to 10 dB at 3 contiguous frequencies (0.5–4.0 kHz).[15]

Descriptive statistics, presented as median and interquartile range (IQR), were used to summarize the outcomes. Data analysis was performed using Microsoft Excel. Institutional Review Board approval was obtained (IRB# 107443).

Results

Between March 1, 2021, and August 31, 2024, a total of 8598 tests were ordered for cCMV screening among 93,529 live births

(9.2%) across 27 facilities within Intermountain health care. The rate of testing has remained stable since the implementation of the expanded targeted testing program. The most common indication for testing was SGA (64.1%), followed by macrocephaly (14.2%), as shown in Table 1. The majority of tests performed were urine PCR (96.0%), followed by saliva PCR (2.6%) and neonatal DBS testing (1.3%). Among all 8598 tests, 63 (0.7%) came back positive. Two saliva tests were positive, and both were followed by a confirmatory positive urine test within the 21-day diagnostic window. The following indications for testing were associated with the highest positivity rates: petechial rash (21.1%), unexplained hepatomegaly or splenomegaly (20.0%), and elevated bilirubin and liver enzymes (7.2%).

Of the total 8598 tests conducted, 8322 (96.8%) were appropriately conducted within the recommended diagnostic window—defined as urine or saliva PCR within 21 days of life or DBS testing at any age. A total of 276 urine and saliva PCR tests (3.2%) were performed after 21 days of life and did not meet the criteria for timely cCMV diagnosis. Among all tests, 63 yielded positive results; however, 13 were duplicate tests ordered for confirmation in the same patients. This left 50 unique patients with positive CMV results. Of these, 18 were tested outside the 21-day diagnostic window and lacked confirmatory DBS testing, raising concern for possible postnatal acquisition. As congenital infection could not be confirmed in these cases, they were excluded from further analysis. This resulted in 32 patients with confirmed cCMV.

Table 1

Summary of indications for testing and types of testing utilized

Indication for Testing	cCMV (–) or Indeterminant	CMV (+)	Unknown	Total Number (%)
IUGR or SGA	5590	30	10	5630 (64.1)
Macrocephaly	1246	0	3	1249 (14.2)
Unknown/other	530	9	24	563 (6.4)
Abnormal hearing test	493	7	28	528 (6.0)
Microcephaly	470	4	1	475 (5.4)
Thrombocytopenia	108	3	0	111 (1.3)
Elevated bilirubin or liver enzymes	90	7	0	97 (1.1)
CNS abnormalities	41	1	1	43 (0.5)
Maternal CMV	37	2	0	39 (0.4)
Petechial rash	15	4	0	19 (0.2)
Unexplained hepatomegaly or splenomegaly	12	3	0	15 (0.2)
Intraabdominal calcifications	13	0	0	13 (0.1)
Anemia	1	0	0	1 (< 0.1)
Type of test performed				
Urine PCR	8154	57	46	8257 (96.0)
Saliva PCR	222	2	1	225 (2.6)
DBS	97	4	15	116 (1.3)
Immunologic testing	0	0	0	0
CSF	0	0	0	0
BAL	0	0	0	0
Blood PCR	0	0	0	0

This table summarizes the indications for congenital cytomegalovirus testing (cCMV), the total number of tests performed for each indication between March 1, 2021, and August 31, 2024, and the positivity rates, along with the types of tests utilized. Individuals may have had multiple tests performed and multiple indications for testing. "Indeterminant" refers to tests with inconclusive results, while "Unknown" represents cases where the result was not recorded or available. The "Other" category includes cases with abnormal eye exams, sepsis workups, and prematurity.BAL indicates bronchoalveolar lavage; cCMV, congenital cytomegalovirus; CSF, cerebrospinal fluid; DBS, dried blood spot; IUGR, intrauterine growth restriction; PCR, polymerase chain reaction; SGA, small for gestational age.

All 32 confirmed cases of cCMV in our cohort were classified as cCMV disease, as each newborn presented with at least one clinical sign at birth prompting CMV testing. No cases of asymptomatic cCMV infection or with isolated SNHL were identified. On the basis of these findings, the estimated prevalence of symptomatic cCMV disease cases as 34.2 per 100,000 live births (32 cases among 93,528 live births). Table 2 summarizes the demographic and clinical characteristics of the 32 cCMV-positive children detected since March 1, 2021. Of the cohort, 18 (56.3%) were female, and 22 (68.8%) were white, non-Hispanic. Insurance data revealed that 13 (40.1%) children were covered by public insurance, and 1 (4.8%) was uninsured. The median maternal age at the time of delivery was 26.5 years (IQR = 7.0). Newborns had an estimated gestational age of 37.9 weeks (IQR = 1.9), with a median birth weight of 2.4 kg (IQR = 0.6), and a median head circumference of 32.3 cm (IQR = 1.9).

Eighteen (56.3%) cCMV-positive infants passed their NBHS; 10 (31.2%) did not pass. NBHS status was unknown in 4 (12.5%) cases. All confirmed cCMV cases underwent diagnostic ABR testing within the first 3 months of life, except for 3 infants: 2 were lost to follow-up and one tragically passed away within 7 days of birth. The primary cause of death in this case was attributed to cCMV and rubella coinfection. Among the 32 children, 15 (46.9%) were started on valganciclovir or ganciclovir treatment shortly after diagnosis. The remaining 17 children did not receive antiviral therapy, likely due to the absence of severe symptoms or parental decisions.

A variety of clinical symptoms were observed at birth among the 18 cCMV-positive children (Fig. 1). The most reported symptom was IUGR or SGA, affecting 65.6% of the children. Thrombocytopenia, in addition to hyperbilirubinemia and/or elevated liver enzymes were present in 25.0% of children. Microcephaly was identified in 18.8% of children. Petechiae were reported in 15.6%.

Nine of the 32 children (28.1%) were diagnosed with sensorineural hearing loss. This included 4 cases of unilateral hearing loss (1 had SSD), 1 case of bilateral asymmetric, and 4 cases of bilateral symmetric hearing loss (Table 3). Six of the 9 failed their NBHS and 7 had hearing loss onset at birth detected through ABR, while the remaining 2 presented with hearing loss at a median of 20 months of age (Fig. 2). Of the 7 patients with congenital SNHL, none of them had progressive hearing loss; they either had improved hearing (n = 1) or stable hearing thresholds (n = 6). Five were fitted with hearing aids. Of these, 3 children had congenital hearing loss and were fitted with hearing aids within 6 months of birth with an median age at fitting of 4.8 months old. Three children underwent bilateral cochlear implantation at an median age of 11.4 months old. One child, who was eligible for bilateral cochlear implantation, declined the intervention due to parents' preference for American Sign Language (ASL) as the primary mode of communication.

Discussion

The expanded targeted early cCMV testing program detected a total of 32 cases of cCMV within the span of 3.5 years. If a

Table 2

Demographic and clinical characteristics of cCMV-positive children

	N (%) or Median (IQR)
Sex	
Male	14 (43.8)
Female	18 (56.3)
Race and ethnicity	
White, non-Hispanic	22 (68.8)
Unknown	5 (15.6)
White, Hispanic	3 (9.4)
Native Hawaiian	1 (3.1)
Insurance coverage	
Public	13 (40.1)
Private	17 (53.1)
Uninsured	1 (4.8)
NBHS status	
Passed NBHS	18 (56.3)
Did not pass NBHS	10 (31.2)
Unknown	4 (12.5)
Started on antivirals	15 (46.9)
Estimated gestational age (wks)	37.9 (1.9)
Maternal age (y)	26.5 (7.0)
Age at diagnostic ABR testing (d)	11.2 (16.9)
Birth weight (kg)	2.4 (0.6)
Head circumference at birth (cm)	32.3 (1.9)

(n = 32).ABR indicates auditory brainstem response; IQR, interquartile range; NBHS, newborn hearing screening.

Table 3

Characteristics of 9 children with sensorineural hearing loss (SNHL) and congenital cytomegalovirus (cCMV) Infection

	N (%)
Total children with hearing loss	9 (100)
Type of hearing loss	
Unilateral	4 (44)
Bilateral symmetric	4 (44)
Bilateral asymmetric	1 (11)
Age of onset	
Congenital	7 (78)
Delayed onset	2 (22)
Antiviral treatment	6 (67)
Hearing Intervention	
Hearing aids	5 (56)
Cochlear implantation	3 (33)
Hearing loss severity (by ear, n = 18)	
Normal hearing	4 (22)
Mild	5 (28)
Moderate	1 (6)
Profound	8 (44)

This table summarizes the characteristics of the 9 children diagnosed with SNHL among the 32 children with cCMV detected through our expanded targeted testing protocol in Utah between March 1, 2021, and August 31, 2024. Hearing loss was categorized by laterality, severity, and age of onset, with delayed onset hearing loss is defined as hearing loss detected at or after 1 year of age in children who had a normal auditory brainstem response around the time of birth.

hearing-targeted testing program was used, only 10 cases of cCMV disease would have been detected within this time period. Between March 1, 2021, and August 31, 2024, the estimated prevalence of symptomatic cCMV since the implementation of the expanded targeted screening program is 34.2 cases per 100,000 live births. Despite testing 9% of only newborns, this rate remains comparable to the prevalence of 34.9 symptomatic cCMV cases per 100,000 births reported during universal DBS CMV testing in Minnesota.[16] Both rates are significantly higher than the prevalence rates under no testing protocol,[11] and during the peri-implementation phase of the expanded targeted testing,[17] as illustrated in Figure 3.

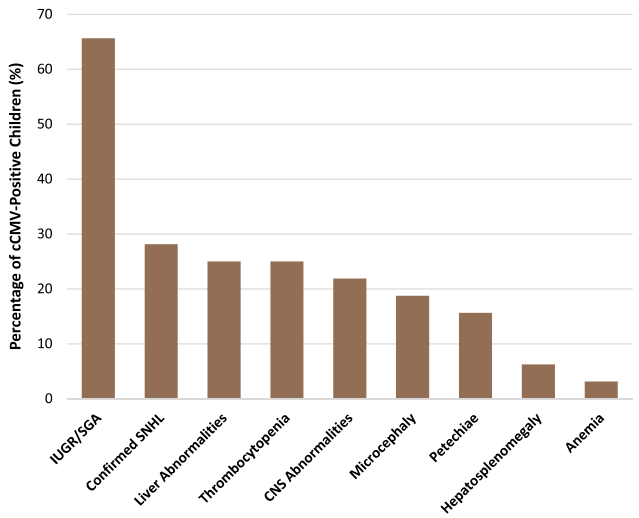

Figure 1. Distribution of symptoms at birth among cCMV-positive children. This bar chart displays the percentage of symptoms present at birth among the 32 children with congenital cytomegalovirus (cCMV), including intrauterine growth restriction (IUGR) or small for gestational age (SGA), liver abnormalities (hyperbilirubinemia and/or elevated liver enzymes), thrombocytopenia, microcephaly, petechiae, confirmed sensorineural hearing loss (SNHL), unexplained hepatomegaly and/or splenomegaly, central nervous system (CNS) abnormalities characteristic of cCMV detected through imaging, and anemia.

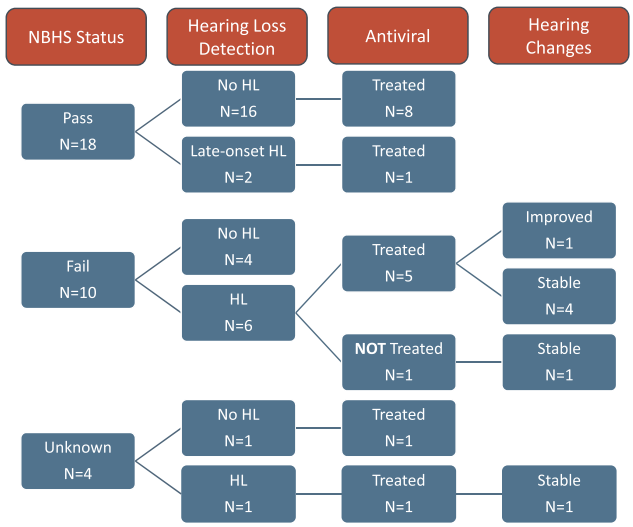

Figure 2. Flowchart describing the newborn hearing status, hearing outcomes, and antiviral administration of cCMV-positive children (n = 32). Children were first grouped by newborn hearing screening (NBHS) outcome. NBHS status could not be verified for 4 children; one of them was lost to follow-up and the other tragically succumbed to her illness. Among the 7 children with congenital hearing loss (HL) detected, 6 were treated with antivirals. None of them had hearing loss progression and one had improved hearing upon follow-up. Among the 2 patients who developed late-onset HL, one of them had been treated with antivirals after birth.

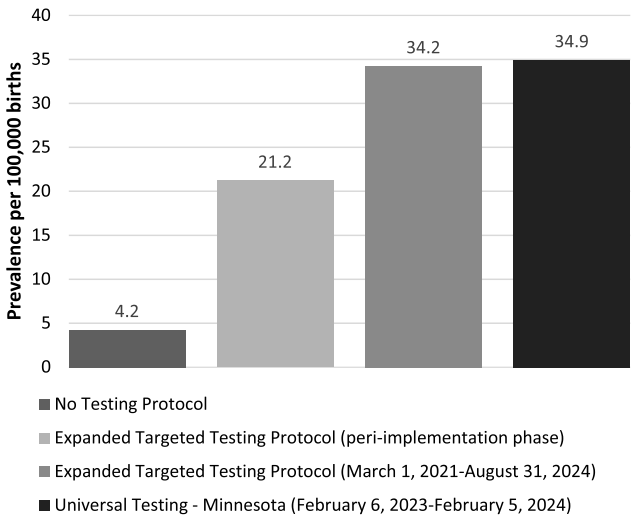

Figure 3. Comparison of prevalence rates of symptomatic cCMV cases per 100,000 births across different testing protocols. The figure compares prevalence rates observed with no testing protocol[11], expanded targeted early CMV testing during its peri-implementation phase[17], the more recent outcomes of expanded targeted testing in Utah (March 1, 2021–August 31, 2024), and universal CMV testing in Minnesota (February 6, 2023–February 5, 2024)[16].

This detection rate of cCMV has improved and remained consistently high following the implementation of the expanded targeted cCMV testing program across IHC facilities in Utah. Building on the findings of Suarez et al.,[10] who reported a significant increase in detection rates after the program's introduction, our update demonstrates that these gains have been sustained. While several cost-effectiveness analyses have compared universal and hearing targeted screening strategies, no definitive consensus has been reached between expanded targeted and universal DBS screening.[10,18] Accordingly, the selection of an appropriate testing strategy should be informed by the specific health care infrastructure, resource availability, and public health priorities of each state or country.

National trends indicate an increase in the total number of cCMV diagnoses over time, rising from 11 per 100,000 in 1998 to 25 cases in 2019, possibly driven by increases in awareness and early screening or testing for cCMV infection.[19] These findings highlight the impact of expanded testing efforts and evolving clinical awareness on cCMV detection nationwide. Both universal screening through DBS testing and expanded-targeted testing protocols have gained significant traction in recent years. The choice between expanded-targeted testing and universal screening carries distinct advantages and limitations.[20] Expanded targeted testing may miss those children with cCMV infection, because the protocol tests children with symptoms suspicious of cCMV. The extent to which this approach overlooks cases of late-onset SNHL remains uncertain. Universal DBS screening may fail to detect some infected infants due to its lower sensitivity compared with saliva or urine testing and requires more resources for tracking and workup due to the larger number of infants detected with cCMV infection.[20]

In our cohort, 28% of children with cCMV disease were diagnosed with hearing loss. Among the 9 affected children, the range of hearing loss presentations was diverse: 2 presented with late onset hearing loss and 4 had unilateral hearing loss. Of these 9 children, 5 were fitted with hearing aids and 3 underwent bilateral cochlear implantation. Among all 32 confirmed cCMV cases, 94% underwent diagnostic ABR testing within the first 3 months of life, with an average testing age of 11 days after birth, well within the 3-month diagnostic requirement outlined by the EHDI 1-3-6 guidelines.[21] These results are consistent with our experience with early CMV testing. We reported a marked improvement in time to diagnose hearing loss in ALL infants who failed their NBHS when early CMV testing was mandated in Utah.[22] Thus, early CMV testing benefits not just those diagnosed with cCMV but the larger cohort of infants who are diagnosed with sensorineural hearing loss.

Early diagnosis is crucial for the success of antiviral treatment in children with moderate and severe cCMV disease. Clinical trials from the Collaborative Antiviral Study Group found that initiating a 6-month course of valganciclovir before 30 days of age led to better neurodevelopmental and hearing outcomes compared with those treated for just 6 weeks.[8] A later randomized clinical trial comparing hearing outcomes in cCMV-infected children administered VGCV after 1 month of age failed to demonstrate efficacy when compared with untreated cCMV-infected children.[23] In our cohort, nearly half of the children with cCMV disease received a 6-month course of antivirals. Our program's early detection of cCMV provided us with an opportunity to identify children who were most likely to benefit from these interventions, focusing on those with severe cCMV disease, such as those with CNS involvement.

A major limitation of this study is the reliance on health care providers to thoroughly examine newborns, accurately identify any symptoms suggestive of cCMV, and ensure the appropriate testing is ordered. Any errors or omissions in these steps could result in missed diagnoses or delayed identification of cCMV cases. Our results, however, indicate that the prevalence of cCMV disease is comparable to that identified by universal cCMV DBS screening. Thus, these findings underscore the feasibility of this approach and suggest a similar detection rate for cCMV disease compared with universal screening. A significant strength of this study is the use of an electronic medical records system that prospectively required that the ordering provider document the reason for CMV testing and the ability to track all CMV-tested infants over time.

Conclusion

The expanded targeted cCMV testing protocol in all IHC facilities has identified 32 cases of cCMV within a 3.5-year period, with a prevalence rate of 34.2 cases per 100,000 live births. These long-term results suggest comparable detection rates to universal DBS screening and offer an alternative to this approach, which may be easier to implement in more resource-limited centers.

Conflict of Interest

The authors disclose no conflicts of interest.

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