What You Need to Know: HB81 Cytomegalovirus Public Health Initiative

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House Bill 81, passed by the Utah legislature in 2013, was created to raise public awareness and provide education about congenital cytomegalovirus (CMV) infection and to reduce the disability associated with hearing loss due to congenital CMV infection. This bill contains three key elements: (1) it directs the Department of Health to create a public education program to inform pregnant women and women who may become pregnant about CMV and its transmission, fetal effects of CMV, methods of CMV diagnosis and prevention; (2) it requires the Department of Health to provide this information to licensed childcare programs, school nurses, health educators, and other organizations offering children's programs as a component of worship services; and **(3) it directs medical practitioners to test infants who fail two newborn hearing screening tests for CMV before three weeks of age and inform the parents of those infants about the possible complications that CMV can cause and the available treatment methods.**

This bill was enacted to educate the public about congenital CMV, its prevention and possible complications, particularly with respect to progressive sensorineural hearing loss (SNHL). CMV is the most common cause of nonhereditary SNHL and is thought to account for 20% of all childhood hearing loss in Utah. Most infants with congenital CMV infection are asymptomatic, but one-fifth of these infants (who may or may not have symptoms at the time of birth) may develop permanent disability such as hearing loss or developmental delay. **Approximately 50% of hearing loss from congenital CMV infection is progressive in nature**. Infants with known CMV-related hearing loss should undergo frequent audiologic follow up with an audiologist and a physician with expertise in the assessment and treatment of pediatric hearing loss due to congenital CMV. The timing and frequency of these visits should be individualized for each child.

In compliance with Utah's HB 81, in order to identify infants at risk for congenital CMV-associated hearing loss, infants who fail the second hearing screening should be tested for CMV by no later than 3 weeks of age. This can be performed with a PCR assay for CMV on urine or saliva. After 3 weeks of age, these tests cannot differentiate between congenital CMV and CMV acquired postnatally. Postnatal CMV rarely causes symptoms and is not associated with hearing loss. If the clinic or hospital is a client of ARUP, they can order the OraCollect OC-100 swabs from ARUP client supplies (item #49295). If they are not ARUP clients, they should contact their reference lab for kit supplies or contact the kit vendor directly (DNA Genotek). If kits for PCR on saliva are not available, a PCR for CMV can be sent on a urine sample.

Infants who have a positive CMV PCR assay should undergo a complete diagnostic audiologic evaluation as soon as possible. Frequent audiologic assessment is needed to promptly identify and treat progressive hearing loss. The frequency of this testing should be determined by the child's audiologist.

Children with symptomatic congenital CMV are at risk for ophthalmologic problems. These children need ophthalmologic evaluations early and often due to risk of retinitis. Those without symptoms, however, are at very low risk. Asymptomatic infants should have at least one thorough eye exam by a pediatric ophthalmologist after a diagnosis of congenital CMV has been made.

There is no drug licensed to treat congenital CMV infection. There are limited data on the use of antiviral medications in infants with symptomatic congenital CMV infection. Studies are ongoing to determine what types of therapy are of greatest benefit to CMV-infected infants. Infants with suspected congenital CMV infections should be evaluated by physicians who specialize in these infections. Currently, there are two treatment studies for congenital CMV in Utah. For information regarding clinical trials using valganciclovir and participation in these trials, contact:

- The Department of Pediatric Otolaryngology at Primary Children's Medical Center at (801) 662-1740 or
- The Division of Pediatric Infectious Disease at the University of Utah at (801)581-6791 (NIH sponsored clinical trial pending approval):
  A phase II, randomized, placebo-controlled, blinded investigation of six weeks of oral valganciclovir therapy versus placebo in infants with congenital cytomegalovirus infection and hearing loss

Objectives

1. To define the response of CMV viral load in urine as a measure of the efficacy of ganciclovir
2. To estimate the response of CMV viral load in blood as a measure of the efficacy of ganciclovir.
3. To estimate if a six week course of oral valganciclovir syrup can stabilize the hearing of children with congenital CMV infection who present with hearing loss.
4. To estimate the safety and tolerability of valganciclovir syrup in children of this age.
5. To estimate the pharmacokinetics of ganciclovir when valganciclovir is administered to children of this age.

Inclusion

1. Sensorineural hearing loss (unilateral or bilateral).
2. CMV detected within 30 days of birth (urine tested as neonate, or Guthrie card-positive).
3. CMV detected in urine by PCR or culture within 2 weeks prior to study entry.
4. Children between 1 month and 18 months of age.

State newborn hearing screening protocols have been amended to mandate notification of primary care providers after the first failed (inpatient) newborn hearing screening. Physicians who receive this notice should follow up with the family to ensure the timely completion of the second (outpatient) newborn hearing screening. The primary care provider will then be notified if an infant fails the second newborn hearing screening. As HB 81 directs care providers to perform CMV testing by 3 weeks of age, it is important that this notification be forwarded to the covering physician if the primary care physician is not available. To facilitate communication between facilities conducting hearing screening and primary care providers, it has been recommended that discharging hospitals/physicians provide families with a business card of the chosen primary care physician to bring to the follow up hearing screening appointment.

To read House Bill 81 in its entirety, click on http://le.utah.gov/~2013/bills/hbillenr/hb0081.pdf. For more information contact Utah Early Hearing Detection and Intervention at (801) 584-8215 or **Stephanie McVicar, Au.D., CCC-A,** at smcvicar@utah.gov. ✦