East Sussex Healthcare
NHS Trust

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FOI REF: 23/888

24th January 2024

FREEDOM OF INFORMATION ACT

I am responding to your request for information under the Freedom of Information Act. The answers to your specific questions are as follows:

1) Please provide copies of any Information containing or evidencing Practices used within your Trust whereby newborns who are referred to audiology following their newborn hearing screening test, or newborns/children who demonstrate abnormal hearing at a later stage, are tested for cCMV.
Such Practices could include, but are not limited to, early cCMV detection pathways whereby newborns are tested at point of referral to audiology from the newborn hearing screening programme. Please include details about the intended timescales for testing, carrying out tests and returning test results, if this information is recorded.

Please see attached the following documents:

ESHT Identification, Diagnosis and Management of Congenital Cytomegalovirus (cCMV) Infection in Newborns with Sensorineural Hearing Loss, April 2023.

ESHT Patient Information – Congenital Cytomegalovirus (CMV) testing in Audiology.

Please note that it is the FOI policy to only release the names of staff that are grade 8a or above. We have therefore redacted names of staff that are below this grade and also names of any individuals that do not work for our Trust.

We also refer to the 'Management of Newborns on the Postnatal and Special care Neonatal ward, Department of Neonatology, BSUH 2021'. Please contact University Hospitals Sussex NHS Foundation Trust for a copy of this document via the following email address:

UHSussex.foi@nhs.net

Cont…/

2) **If your Trust does employ Practices whereby newborns/children with abnormal hearing are tested for cCMV, please indicate at which stage samples are taken (you may select more than one):**

- ❑ **By the newborn hearing screener at the point of referral.**

- ✓ By the audiologist at the first appointment after babies have been referred from the newborn hearing screen.

- ✓ By the audiologist at detection of SNHL in a baby referred from the newborn hearing screen.

- ❑ **By the audiologist at the first appointment after babies have been referred from the newborn hearing screen.**

- ❑ **By the audiologist at detection of SNHL in a baby referred from the newborn hearing screen.**

- ❑ **By another healthcare professional (not an audiologist) following detection of SNHL in a baby referred from the newborn hearing screen.**

- ❑ **At detection of SNHL in older babies and children (i.e. after the newborn hearing screening and testing period).**

- ❑ **Unknown.**

- ✓ Other, please provide details. To clarify; A urine sample is collected by the audiologist at the first appointment after babies have been referred from the newborn hearing screen, if a SNHL is suspected or confirmed.

- ❑ **Other, please provide details:**

3) **If your Trust does employ Practices whereby newborns/children with abnormal hearing are tested for cCMV, please indicate what type of sample is taken (you may select more than one):**

- ❑ **Saliva swab.**

- ✓ Urine.

- ❑ **Blood test for the infant.**

- ❑ **Blood test for the mother.**

- ❑ Infant blood spot (Guthrie) card testing (if CMV DNA detected in urine)

Cont…/

4) Please provide copies of any Information containing or evidencing Practices used within your Trust whereby children are tested for cCMV as part of investigations of symptoms (in either the mother or child) that are unrelated to hearing. These could include:

Maternal symptoms of CMV (flu-like symptoms) Symptoms of congenital infection identified before or after birth, such as:

- **Antenatal abnormalities e.g. on ultrasound scan.**
- **Characteristic rashes caused by cCMV (petechiae or blueberry muffin rash).**
- **Intrauterine Growth Restriction.**
- **Microcephaly.**
- **Jaundice.**
- **Hepatosplenomegaly.**
- **Neonatal visual signs/symptoms.**
- **Neonatal seizures.**

The Trust follows University Hospitals Sussex NHS Foundation Trust policy to check IUGR babies. Please refer to question 1 for contact details.

The Trust does not have any policy in place for testing in babies with other symptoms. It is being done case by case and would include babies with the following symptoms:

- ✓ Characteristic rashes caused by cCMV (petechiae or blueberry muffin rash).
- ✓ Intrauterine Growth Restriction.
- ✓ Hepatosplenomegaly
- ✓ Persistent low platelet count

Symptoms of congenital infection in older children, such as:

- **Neurodevelopmental delays.**
- **Special educational needs and disabilities (e.g. autism, ADHD).**
- **Cerebral palsy.**
- **Seizures.**
- **Visual or sensory impairment.**

We do not routinely screen for congenital CMV in older children diagnosed with a neurodevelopmental condition and have no evidence of sensory deficit/ neurological deficit/ microcephaly. This is as per NICE guidelines that clearly state not to initiate investigations in older children with autism unless indicated.

Brain imaging is our first line of investigation into cerebral palsy. We may undertake congenital infection screening, if not undertaken, when brain imaging is suggestive of a congenital infection or there are other clinical features highlighted above.

Children with seizures by the epilepsy team/ acute paediatrics team.

Children with hearing impairment are seen in the relevant clinic and children with visual impairment are seen by ophthalmology.

Cont…/

5) Please provide copies of any Information containing or evidencing Practices used within your Trust following a diagnosis of cCMV in a child. This could include, but is not limited to:

- **Information about any Practices involving the prescribing of antiviral treatments.**

- **Details of the department(s) that the child would be referred to.**

Please see attached document:

ESHT Identification, Diagnosis and Management of Congenital Cytomegalovirus (cCMV) Infection in Newborns with Sensorineural Hearing Loss, April 2023.

On diagnosis of cCMV, babies are commenced on treatment (oral Valgancyclovir) after discussion and agreement with the Infectious Diseases (ID) Specialist team at Evelina Hospital. The baby will have a clinic follow up with Consultant Paediatrician locally, and will have regular blood tests to monitor FBS and LFT through the local Community Nursing team. The baby will also have an appointment with the ID team at Evelina Hospital.

The medication is supplied from our hospital pharmacy.

(Please see attached document for full details).

Questions 6-9 relate to the provision of data for a specific five-year period. If you do not hold data for this time period, please supply data for any period for which you have available data (preferably a recent five-year period) and specify the beginning and end dates. If the answer to any question is between 1 and 5 (and therefore the true figure cannot be shared in accordance with Section 40 of the Freedom of Information Act), please indicate this by giving the answer "<5". Please also indicate if the relevant hospitals or services within your Trust have changed during this period.

6) Between 1 January 2018 and 31 December 2022, how many children were diagnosed with cCMV within 28 days of birth, within your Trust?
This should include children born outside of your Trust who were diagnosed by services within your Trust.

<5

7) Of the children who were diagnosed with cCMV within 28 days of birth in this time period (Q6), how many:

a) Previously had a newborn hearing screening test?

<5

b) Had been referred to audiology following their newborn hearing screening test?

<5

Cont…/

c) Were given antiviral treatment for cCMV following diagnosis?

<5

8) Between 1 January 2018 and 31 December 2022, how many children were diagnosed with cCMV between 28 days and 18 years of age, within your Trust?

This should include children born outside of your Trust who were diagnosed by services within your Trust.

<5

9) Of the children who were diagnosed with cCMV between 28 days and 18 years of age in this time period (Q8), how many:

a) Previously had a newborn hearing screening test?

<5

b) Had been referred to audiology following their newborn hearing screening test?

<5

c) Were given antiviral treatment for cCMV following diagnosis?

<5

If I can be of any further assistance, please do not hesitate to contact me.

Should you be dissatisfied with the Trust's response to your request, you have the right to request an internal review. Please write to the Freedom of Information Department (esh-tr.foi@nhs.net), quoting the above reference, within 40 working days. The Trust is not obliged to accept an internal review after this date.

Should you still be dissatisfied with your FOI request, you have the right of complaint to the Information Commissioner at the following address:

The Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire SK9 5AF

Telephone: 0303 123 1113

Yours faithfully

Linda Thornhill (Mrs)
Corporate Governance Manager
esh-tr.foi@nhs.net

East Sussex Healthcare NHS Trust

Identification, Diagnosis and Management of Congenital Cytomegalovirus (cCMV) Infection in Newborns with Sensorineural Hearing Loss

Document ID Number	2495
Version:	V1
Ratified by:	Women's and Children's
Date ratified:	March 2023
Name of author and title:	Dr Nisha Gupta – Associate Specialist in Community Paediatrics, [redacted] – Senior Specialist Nurse Paediatric Audiology
Date originally written:	February 2022
Date current version was completed	February 2023
Name of responsible committee/individual:	Ian Woodward, Clinical Service Manager for Audiology, Obstetrics & Gynaecology, NHSP Team Leader, Dr Melanie Leibenberg, Chief of Division for Women's, Children's & Sexual Health Division, Leader Chair of the Guideline Implementation Group for Maternity Services
Division/Speciality:	Women's and Children's Division / Audiology / Paediatrics
Date issued:	18 April 2023
Review date:	March 2026
Target audience:	This document affects audiologists, Community Paediatricians with audiology interest, acute Paediatricians, and audiology nurses.
Compliance with CQC Fundamental Standard	Safe Care and Treatment, Need for Consent Good Governance, Person Centred Care
Compliance with any other external requirements (e.g. Information Governance)	Newborn hearing screening programme (NHSP) operational guidance, Public Health England, 2016 Newborn hearing screening programme (NHSP) operational guidance - GOV.UK (www.gov.uk) Guidelines for the early audiological assessment and management of babies referred from the Newborn Hearing Screening Programme Version 3.1 BSA recommended procedure: Auditory Brainstem Response (ABR) Testing in Babies, February 2019 BSA recommended procedure - Cochlear Microphonic Testing, January 2019
Associated Documents:	Audiology Department Clinical Guideline for the Surveillance of Children with Congenital Cytomegalovirus, August 2020 Audiology Department Clinical Guideline for the Assessment and Management of Children with Otitis Media with Effusion, August 2020 Audiology Department Management of Children with a Confirmed Permanent Childhood Hearing Impairment, Local Procedural Document, July 2021 ESHT Audiology Department Standard Operating Procedure - Patient Consent, January 2020

Version Control Table

Version number and issue number	Date	Author	Reason for Change	Description of Changes Made
V1.0	February 2022	[redacted], Dr Nisha Gupta,	New Document	New Document

Consultation Table

This document has been developed in consultation with the groups and/or individuals in this table:

Name of Individual or group	Title	Date
[redacted]	Advanced Paediatric Audiologist	December 2021
Dr Kandasamy	Consultant Paediatrician	7th September 2022
Dr Jonathan Cohen	Lead Consultant for Paediatric Infectious Diseases, ECH	Sent in August 2022
General Paediatric Consultants Meeting		7th September 2022
East Sussex CHSWG	Chair – Ian Woodward	December 2022
Ian Woodward	Service Manager Audiology	December 2022
Women and Children's Guideline Implementation group		March 2023
Women and Children's Governance and Accountability		March 2023

This information may be made available in alternative languages and formats, such as large print, upon request. Please contact the document author to discuss.

Table of Contents

1. Introduction

Congenital cytomegalovirus (cCMV) infection affects 1% of all newborns. It is the leading non-genetic cause of sensorineural hearing loss (SNHL) in children. Congenital CMV in a neonate occurs when a pregnant mother is exposed to CMV for the first time in early pregnancy or has reactivation or reinfection with CMV, leading to in utero transmission to the developing foetus.

90% of infants born with cCMV are **asymptomatic** at birth. Up to 15% of these children may go on to develop neurological sequelae.

10% of infants born with cCMV are **symptomatic** at birth. These symptoms include intrauterine growth retardation, microcephaly, petechiae, thrombocytopenia and abnormal brain imaging. Neurodevelopmental effects include severe neurological sequelae, blindness and/or sensorineural deafness. The characteristics of hearing loss in cCMV may be unilateral or bilateral. Severity of hearing loss can range from mild to severe or profound. Fluctuation or progression can occur.

2. Purpose

This guideline is intended to standardise the care pathway for babies with SNHL in order to ensure that congenital CMV is confirmed or excluded before 3 weeks of life whenever possible. A diagnosis of cCMV is clinically significant and the baby will require urgent medical assessment. When the diagnosis is made within 3 weeks of life, the baby will be assessed for suitability for medical treatment that may prevent progression of sensorineural deafness.

2.1 Rationale

Congenital CMV is one of the few childhood conditions where early identification allows timely treatment which may prevent progression of SNHL.

Urgent CMV testing is recommended at time of initial diagnostic ABR to expedite the diagnostic assessment for discussion of urgent medical treatment option.

Urine or saliva sampling from the child for CMV PCR is required before the age of 21 days as, thereafter, CMV infection may be acquired rather than truly congenital.

Oral Valgancyclovir treatment is recommended for symptomatic children with cCMV to attempt to prevent further loss of hearing. The Community Paediatrician with a lead role for children with SNHL will facilitate the urgent medical assessment of the baby, and make urgent referrals to relevant Paediatricians.

A specialist infectious diseases Paediatrician will oversee the child's medical care. An acute general Paediatrician will lead on the administration of Valgancyclovir treatment and monitoring of the patient.

2.2 Principles

To ensure local and national evidence-based guidelines are adhered to in the delivery of care to all service-users of ESHT.

2.3 Scope

This document provides guidance for Newborn hearing Screeners, Audiologists, Audiology Nurses and Paediatricians regarding the early identification of congenital Cytomegalovirus infection (cCMV) in newborn infants with confirmed sensorineural hearing loss.

This document is designed to provide guidance for audiologists involved in the electro-physiological assessment of babies following referral from the newborn hearing screening programme.

This document also provides guidance for Nurses working within the ESHT Audiology Service.

This document is designed to provide guidance for physicians treating babies with congenital CMV across the Trust. It must be used in conjunction with other ESHT guidelines.

3. Definitions

ABR	Auditory Brainstem Response
CMV	Cytomegalovirus
cCMV	Congenital Cytomegalovirus infection
CHSWG	Children's Services Working Group
CNS	Central nervous system
DBS	Dried Blood Spot (Guthrie Card)
ECCI	European Congenital CMV Initiative
ELCH	Eveline London Children's Hospital
FBC	Full blood count
G-CSF	Granulocyte-colony stimulating factor
ID	Infectious Diseases
IUGR	Intrauterine growth restriction
LFT	Liver function tests
NHSP	Newborn Hearing Screening Programme
PCR	Polymerase chain reaction
SNHL	Sensorineural hearing loss
U&E	Urea and electrolytes

4. Accountabilities and Responsibilities

4.1 Newborn Hearing Screening Local Manager

- To access, read, understand and follow this guidance
- To ensure the newborn hearing screening team read, understand and follow this guidance

4.2 Paediatric Audiologists and Paediatric Audiology Specialist Nurse

- To access, read, understand and follow this guidance
- To adhere to their own professional body's code of conduct (i.e. RCCP,HCPC, NMC)

4.3 Paediatricians

- To access, read, understand and follow this guidance
- To adhere to their own professional body's code of conduct (RCPCH, GMC)

4.4 Management

- To ensure the guideline is reviewed as required in line with the Trust and national guidelines
- To ensure the guideline is accessible to all relevant staff
- To monitor the audit process

5. Process

5.1 Diagnosis

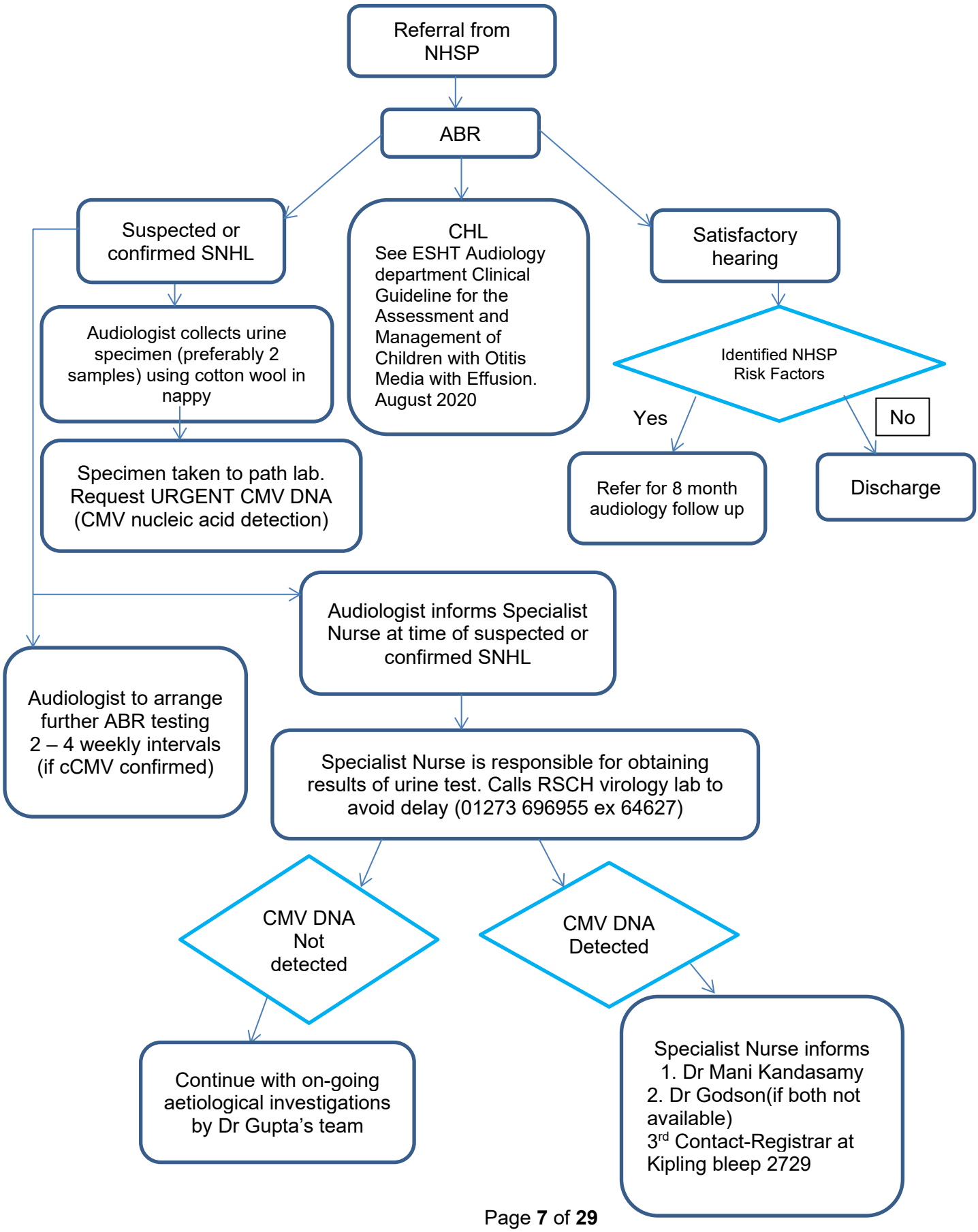
Diagnosis of cCMV is established by positive CMV PCR in bodily secretions in the first 3 weeks of life. Two independent samples are preferred to confirm cCMV and should include at least one urine or blood sample. If CMV DNA is detected after 3 weeks then there is uncertainty whether it was acquired postnatally and so this, on its own, is not confirmatory of cCMV.

Therefore, a urine sample should be obtained at the time of suspected or confirmed sensorineural hearing loss. This will require urgent processing by the laboratory to ensure that the results are available as soon as possible.

Whilst the aim is to complete screening and diagnostic audiological assessment by 21 days of life, urine samples should still be obtained for babies up to 12 months of age with suspected of confirmed SNHL. There are circumstances when completion of screening and diagnosis will not be possible before 21 days of life such as:

- Missed appointments for screening
- Delays in transferring or referring babies from out-of-area screening sites
- Unavoidable delays in providing screening clinic appointments within patient's local area
- Unavoidable delays in providing appointment for diagnostic ABR
- Babies requiring prolonged Special Care. PHE guidance states that newborn screening takes place as close to discharge from hospital as possible, therefore leading to a delay in completing hearing screening

5.2 Identification and diagnosis of congenital CMV in well babies with SNHL



5.3 Management of congenital CMV in well babies with SNHL

URINE CMV DNA by PCR positive

(<21 days diagnostic of Congenital CMV
>21 days not diagnostic of Cong CMV)

Audiology Nurses to Contact

1. Dr Mani Kandasamy on mobile: 07738301139 / email: manivannan.kandasamy@nhs.net (Mark URGENT)
2. 2nd Contact- Dr Godson Banibensu on mobile: 07974268941 godson.banibensu@nhs.net (mark urgent)
3. If either not contactable then bleep Registrar at SPAU, Kipling 2729.

Dr Kandasamy/Dr Banibensu(Godson)/Registrar

1) To arrange Urgent Daycare review

LATEST BY NEXT WORKING DAY (as per D/W ECH)

SPAU,DGH SSPAU ,Kipling

2) Inform Specialist Nurse [redacted]

(Nurse will accompany weekdays and try for weekends and provide leaflets for CMV action/Guthrie consent form)

Continued……

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5.4 Management of congenital CMV in well babies with SNHL (continued)

Daycare Management

Consultant

- Follow ECH **protocol** (history, examination,investigations)
- Urgent Request by Phone/email to **Radiology Consultant** for preponing MRI brain/IAM's(request sent by nurses at time of diagnosis of hearing loss for feed and wrap) due to possible/confirmed Cong CMV.
  a)Eastbourne -Dr Watson, Head of radiology department
  b)Conquest -Dr Dajiakidi,Head of Radiology Department
  e-mail: esht.radiologysecretarieseastbourne@nhs.net or esht.radiologyconquestsecretaries@nhs.net MRI. extn 5870
  If MRI cannot be preponed then make urgent request for USG Brain (Dr Watson,Dr Jenny Radiology Lead) explaining the new diagnosis of Cong CMV.
- Urgent Referral for Ophthalmic assessment: esht.ophthalmologypaediatric@nhs.net
- Counsel parents for Cong CMV and use of oral Valgancyclovir explaining adverse effects/plan for follow up.(provide Leaflet for Valgan)
- Inform [redacted],lead pharmacist or Pharmacist on call to stock medication Valgancyclovir for oral use if need be.

Audiology Nurse

- Arrange for written consent from mother for **Urgent Guthrie Card Retrieval (CMV DNA by PCR).**
- Need full name of mother and baby's surname at birth(if different).
- Provide support and leaflets- (CMV action).

Dr Kandasamy / Dr Banibensu/REGISTRAR

1) To **discuss the patient with tertiary team** on telephone after baby has been examined and investigations sent.

First point of contact:

Mon-Fri 9-5 ; Registrar Paeds Infectious diseases, ECH: Phone number : [redacted]

Out of hours- Consultant Paeds ID on call via switch board

2) Ensure you have a plan from Paeds Infectious disease department.
3) Chase results (blood investigations, brain imaging, vision assessment).
4) Discuss with paeds ID department again as per plan.

ALWAYS ENSURE PAEDS ID APPROVAL FOR US TO COMMENCE THE TREATMENT WITH THEIR OVERVIEW WITHIN AGREED TIMESCALES.

Follow the plan: -1) Start medication

2) Arrange regular follow up with Dr Mani Kandasamy.

3) Refer to Paeds ID team at ECH as per the plan provided.

Copy letter to Dr N Gupta, Associate Specialist Community Paediatrics; [redacted], specialist audiology nurse.

4) Audiology nurse to ensure Baby has been referred to Dr N Gupta for further investigations /developmental review.

6. Special Considerations

There are no known contraindications in relation to this clinical guideline. However, confirmatory tests for congenital CMV are included within table 1 below.
If the first urine test is taken when baby is less than 3 weeks of age, the Consultant will follow the protocol above(liaise with Paediatric Infectious Disease Department at ECH after having examined the baby and having done necessary investigations including imaging as per protocol. **Oral Valgan treatment may be offered for babies up to 12 weeks of age in certain circumstances.**

Table 1:

Test	Comments
CMV PCR urine in first 21 days	Can be obtained through a bag or cotton wool
CMV PCR saliva in first 21 days [14-16]	Take one hour after breastfeeding. No restriction in bottled fed babies. If not sending viral swab on the same day store in a fridge.
CMV PCR in whole blood in first 21 days	EDTA sample. This can be negative when other samples are positive.
CMV PCR on the Guthrie card (dried blood spot / DBS)	This can be used for a retrospective diagnosis but a negative result does not fully exclude cCMV as the sensitivity is variable: 34-80% [17, 18].See Appendix 1 for process to obtain this.

7. Evidence Base/References

Congenital Cytomegalovirus: Efficacy of Antiviral Treatment (CONCERT 2)Congenital Cytomegalovirus: Efficacy of Antiviral Treatment - Full Text View - ClinicalTrials.gov

Congenital Cytomegalovirus: A European Expert Consensus Statement on Diagnosis and Management Congenital Cytomegalovirus: A European Expert Consensus Statement on Diagnosis and Management - PubMed (nih.gov)

Valganciclovir Therapy in Infants and Children With Congenital CMV Infection and Hearing Loss - Full Text View - ClinicalTrials.gov ClinicalTrials.gov Identifier: NCT01649869

Fifteen-minute consultation: diagnosis and management of congenital CMV Correspondence to Dr Tejshri Shah, Department of Paediatric Infectious Diseases, St. Mary's Hospital, Imperial College NHS Healthcare Trust, London, UK; tejshrishah@gmail.com

Valganciclovir for symptomatic congenital cytomegalovirus disease
Randomized Controlled Trial N Engl J Med. 2015 Mar 5;372(10):933-43.
doi: 10.1056/NEJMoa1404599.

Trimble, K. Congenital cytomegalovirus causing deafness in children: an update.2018. ENT & Audiology News Congenital cytomegalovirus causing deafness in children: an update | ENT & Audiology News (entandaudiologynews.com)

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Dollard, S.C., S.D. Grosse, and D.S. Ross, New estimates of the prevalence of neurological and sensory sequelae and mortality associated with congenital cytomegalovirus infection. Rev Med Virol, 2007. **17**(5): p. 355-63.

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Peckham, C.S., *Cytomegalovirus infection: congenital and neonatal disease.* Scand J Infect Dis Suppl, 1991. **80**: p. 82-7.

Smithers-Sheedy, H., et al., Congenital cytomegalovirus is associated with severe forms of cerebral palsy and female sex in a retrospective population-based study. Dev Med Child Neurol, 2014. **56**(9): p. 846-52.

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Yinon, Y., D. Farine, and M.H. Yudin, *Screening, diagnosis, and management of cytomegalovirus infection in pregnancy.* Obstet Gynecol Surv, 2010. **65**(11): p. 736-43.

Tookey, P.A., A.E. Ades, and C.S. Peckham, *Cytomegalovirus prevalence in pregnant women: the influence of parity.* Arch Dis Child, 1992. **67**(7 Spec No): p. 779-83.

Pembrey, L., et al., Seroprevalence of cytomegalovirus, Epstein Barr virus and varicella zoster virus among pregnant women in Bradford: a cohort study. PLoS One, 2013. **8**(11): p. e81881.

Ebina, Y., et al., The IgG avidity value for the prediction of congenital cytomegalovirus infection in a prospective cohort study. J Perinat Med, 2014. **42**(6): p. 755-9.

Ross, S.A., et al., Detection of congenital cytomegalovirus infection by real-time polymerase chain reaction analysis of saliva or urine specimens. J Infect Dis, 2014. **210**(9): p. 1415-8.

Barkai, G., et al., Universal neonatal cytomegalovirus screening using saliva - report of clinical experience. J Clin Virol, 2014. **60**(4): p. 361-6.

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Atkinson, C., V.C. Emery, and P.D. Griffiths, Development of a novel single tube nested PCR for enhanced detection of cytomegalovirus DNA from dried blood spots. J Virol Methods, 2014. **196**: p. 40-4.

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Manara, R., et al., Brain magnetic resonance findings in symptomatic congenital cytomegalovirus infection. Pediatr Radiol, 2011. **41**(8): p. 962-70.

Nickerson, J.P., et al., Neuroimaging of pediatric intracranial infection--part 2: TORCH, viral, fungal, and parasitic infections. J Neuroimaging, 2012. **22**(2): p. e52-63.

Kimberlin, D.W., et al., Effect of ganciclovir therapy on hearing in symptomatic congenital cytomegalovirus disease involving the central nervous system: a randomized, controlled trial. J Pediatr, 2003. **143**(1): p. 16-25.

Oliver, S.E., et al., Neurodevelopmental outcomes following ganciclovir therapy in symptomatic congenital cytomegalovirus infections involving the central nervous system. J Clin Virol, 2009. **46 Suppl 4**: p. S22-6.

Kimberlin, D.W., et al., *Valganciclovir for Symptomatic Congenital Cytomegalovirus Disease.* New England Journal of Medicine, 2015. **372**(10): p. 933-943.

Kimberlin, D.W., et al., Pharmacokinetic and pharmacodynamic assessment of oral valganciclovir in the treatment of symptomatic congenital cytomegalovirus disease. J Infect Dis, 2008. **197**(6): p. 836-45.

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Choi, K.Y., et al., Emergence of antiviral resistance during oral valganciclovir treatment of an infant with congenital cytomegalovirus (CMV) infection. J Clin Virol, 2013. **57**(4): p. 356-60.

Kampmann, S.E., et al., Pyrosequencing allows the detection of emergent ganciclovir resistance mutations after HCMV infection. Med Microbiol Immunol, 2011. **200**(2): p. 109-13.

Coats, D.K., et al., Ophthalmologic findings in children with congenital cytomegalovirus infection. J AAPOS, 2000. **4**(2): p. 110-6.

Boppana, S., et al., Late onset and reactivation of chorioretinitis in children with congenital cytomegalovirus infection. The Pediatric Infectious Disease Journal, 1994. **13**(12): p. 1139-1142.

8. Competencies and Training Requirements

The newborn hearing screening will be undertaken by qualified NHSP screeners.

The Specialist Nurse and Paediatric Audiology Nurse are registered nurses with the necessary skills for undertaking the required duties.

The Community Paediatrician leading this pathway has received additional BAPA training for the assessment and management of babies and children with SNHL.

The General Paediatrician is qualified to undertake physical assessment and on-going management, treatment and monitoring of the baby. The Specialist ID Consultant at RACH or GOSH will oversee the treatment of the baby.

9. Monitoring Arrangement

Document Monitoring Table

Element to be Monitored	Lead	Tool for Monitoring	Frequency	Responsible Individual/Group/ Committee for review of results/report	Responsible individual/ group/ committee for acting on recommendations/action plan	Responsible individual/group/ committee for ensuring action plan/lessons learnt are Implemented
Policy effectiveness including: Compliance with screening, referral to audiologist, age at diagnosis of SNHL and urine test, and age results available	Lisa Ireland Dr Nisha Gupta	Audit	annually	Service Managers for Audiology and Community paediatrics	Women's and Children's Governance Group	Women's and Children's Governance Group

East Sussex Healthcare NHS Trust

Equality Impact Assessment Form

1. Cover Sheet

Please refer to the accompanying guidance document when completing this form.

Strategy, policy or service name	Identification, Diagnosis and Management of Congenital Cytomegalovirus (cCMV) Infection in Newborns with Sensorineural Hearing Loss
Date of completion	March 2023
Name of the person(s) completing this form	Lisa Ireland
Brief description of the aims of the Strategy/ Policy/ Service	This policy aims to standardise the care pathway for babies with SNHL in order to ensure that congenital CMV is confirmed or excluded before 3 weeks of life whenever possible, therefore ensuring timely access to medical treatment.
Which Department owns the strategy/ policy/ function	Audiology
Version number	1.0
Pre Equality analysis considerations	
Who will be affected by this work? **E.g. staff, patients, service users, partner organisations etc.**	All patients who are referred for audiological assessment following their newborn hearing screen. Paediatric Audiologists who are responsible for undertaking diagnostic ABR testing of babies. Paediatricians involved in the care of babies and children with SNHL
Review date	March 2026
If negative impacts have been identified that you need support mitigating please escalate to the appropriate leader in your directorate and contact the EDHR team for further discussion.	To whom has this been escalated? Name: Click here to enter text. Date: Click here to enter a date.
Have you sent the final copy to the EDHR Team?	

2. EIA Analysis

<table>
<tr><th></th><th>☺ 😐 ☹</th><th>Evidence:</th></tr>
<tr><td>Will the proposal impact the safety of patients', carers' visitors and/or staff?

Safe: Protected from abuse and avoidable harm.</td><td>No</td><td>This policy applies to all babies within ESHT boundaries</td></tr>
<tr><td>Equality Consideration
Highlight the protected characteristic impact or social economic impact (e.g. homelessness, poverty, income or education)</td><td></td><td>
<table>
<tr><th>Race</th><th>Gender</th><th>Sexual orientation</th><th>Age</th><th>Disability & carers</th></tr>
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<tr><th>Gender reassign ment</th><th>Marriage & Civil Partnership</th><th>Religion and faith</th><th>Maternity & Pregnancy</th><th>Social economic</th></tr>
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</td></tr>
<tr><td>Is the proposal of change effective?

Effective: Peoples care, treatment and support achieves good outcomes, That staff are enabled to work in an inclusive environment. That the changes are made on the best available evidence for all involved with due regards across all 9 protected Characteristics</td><td>Choose Positive</td><td>This policy promotes effective care for all babies within ESHT boundaries.</td></tr>
<tr><td>Equality Consideration
Highlight the protected characteristic impact or social economic impact (e.g. homelessness, poverty, income or education)</td><td></td><td>
<table>
<tr><th>Race</th><th>Gender</th><th>Sexual orientation</th><th>Age</th><th>Disability & carers</th></tr>
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<table>
<tr><td>What impact will this have on people receiving a positive experience of care?</td><td></td><td>This policy promotes a positive experience of care for all babies and their families within SHT boundaries.</td></tr>
<tr><td>Equality Consideration
Highlight the protected characteristic impact or social economic impact (e.g. homelessness, poverty, income or education)</td><td></td><td>
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<tr><td>Race</td><td>Gender</td><td>Sexual orientation</td><td>Age</td><td>Disability & carers</td></tr>
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</table>
</td></tr>
<tr><td>Does the proposal impact on the responsiveness to people's needs?</td><td>Choose:
Positive</td><td>This policy promotes responsiveness to the needs of babies and their families within ESHT boundaries</td></tr>
<tr><td>Equality Consideration
Highlight the protected characteristic impact or social economic impact (e.g. homelessness, poverty, income or education)</td><td></td><td>
<table>
<tr><td>Race</td><td>Gender</td><td>Sexual orientation</td><td>Age</td><td>Disability & carers</td></tr>
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<tr><td>What considerations have been put in place to consider the organisations approach on improving equality and diversity in the workforce and leadership?</td><td>Choose:
Positive</td><td>This policy will promote equality and diversity in the workplace, including tertiary centres.</td></tr>
<tr><td>Equality Consideration
Highlight the protected characteristic impact or social economic impact (e.g. homelessness, poverty, income or education)</td><td></td><td>
<table>
<tr><td>Race</td><td>Gender</td><td>Sexual orientation</td><td>Age</td><td>Disability & carers</td></tr>
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</table>
</td></tr>
<tr><td colspan="3">Access
Could the proposal impact positively or negatively on any of the following:</td></tr>
<tr><td>• Patient Choice</td><td>Choose</td><td>Positive</td></tr>
<tr><td>• Access</td><td>Choose</td><td>Positive</td></tr>
<tr><td>• Integration</td><td>Choose</td><td>Positive</td></tr>
</table>

Equality Consideration *Highlight the protected characteristic impact or social economic impact (e.g. homelessness, poverty, income or education)*		<table><tr><td>Race</td><td>Gender</td><td>Sexual orientation</td><td>Age</td><td>Disability & carers</td></tr><tr><td>☐</td><td>☐</td><td>☐</td><td>☐</td><td>☐</td></tr><tr><td>Gender reassign ment</td><td>Marriage & Civil Partnership</td><td>Religion and faith</td><td>Maternity & Pregnancy</td><td>Social economic</td></tr><tr><td>☐</td><td>☐</td><td>☐</td><td>☐</td><td>☐</td></tr></table>
Engagement and Involvement How have you made sure that the views of stakeholders, including people likely to face exclusion have been influential in the development of the strategy / policy / service:	Choose: positive	This policy is based on national guidance.
Equality Consideration Highlight the protected characteristic impact or social economic impact (e.g. homelessness, poverty, income or education)		<table><tr><td>Race</td><td>Gender</td><td>Sexual orientation</td><td>Age</td><td>Disability & carers</td></tr><tr><td>☐</td><td>☐</td><td>☐</td><td>☐</td><td>☐</td></tr><tr><td>Gender reassign ment</td><td>Marriage & Civil Partnership</td><td>Religion and faith</td><td>Maternity & Pregnancy</td><td>Social economic</td></tr><tr><td>☐</td><td>☐</td><td>☐</td><td>☐</td><td>☐</td></tr></table>
Duty of Equality Use the space below to provide more detail where you have identified how your proposal of change will impact.	Choose: positive	
Characteristic	**Rating** ☺ ☹ 😐	**Description**
Race	Positive	
Age	Neutral	This policy relates to babies and their families/carers
Disability and Carers	positive	
Religion or belief	Positive	
Sex	Positive	
Sexual orientation	Positive	
Gender re-assignment	positive	
Pregnancy and maternity	positive	
Marriage and civil partnership	Positive	

Human Rights

Please look at the table below to consider if your proposal of change may potentially conflict with the Human Right Act 1998

Articles		Y/N
A2	Right to life	**N**
A3	Prohibition of torture, inhuman or degrading treatment	**N**
A4	Prohibition of slavery and forced labour	**N**
A5	Right to liberty and security	**N**
A6 &7	Rights to a fair trial; and no punishment without law	**N**
A8	Right to respect for private and family life, home and correspondence	**N**
A9	Freedom of thought, conscience and religion	**N**
A10	Freedom of expression	**N**
A11	Freedom of assembly and association	**N**
A12	Right to marry and found a family	**N**
Protocols		
P1.A1	Protection of property	**N**
P1.A2	Right to education	**N**
P1.A3	Right to free elections	**N**

Appendix B

CMV testing of babies at ELCH Audiology Department

SCOPE

This pathway covers infants who are referred through the Audiology department NOT those where there has been a clinical concern in the mother when pregnant, nor those infants with other clinical concerns relating to possible congenital CMV (cCMV). Although some principles are similar, for other scenarios see the Trust's obstetric and neonatal infection guidelines. The audience is the PIID MDT and all documents are in S:\Paediatrics\PID\CMV\CMV audiology pathway 2021

INITIAL PATHWAY

Infants with *possible* Sensorineural Hearing Loss (SNHL) identified through the Newborn Hearing Screening Programme (NHSP) across the South East London network should be seen as soon as possible by Audiology at St. Thomas's.
Following NHSP there are two possible pathways: One group who have *possible* SNHL are referred directly for Auditory Brainstem Response (ABR), others are initially referred for Oto-acoustic emissions (OAE).
Only infants referred for ABR will be expedited and have a saliva swab taken at first contact with Audiology at St. Thomas's[1] and basic information regarding the CMV will be given to families at that time.[2]

[1] This is targeted for highest pick up and respects work load of Audiology department. Infants in this subgroup should ideally be seen <21 days. This is not a national target but is a commitment to improve our pathway.

[2] 171007 CMV informat ion leaflet.doc

Whenever a swab is sent to the GSTT laboratory the audiology team will communicate via PIID CMV emai[redacted] This email includes the PIID CNS teams and consultants involved with CMV. On receipt of this information, the PIID CNS will add the baby's details to the departmental cCMV database. This will be used to monitor the progress of referrals and assessments whilst the baby undergoes investigation.

At the time of writing, the current testing situation is that processing happens Monday, Wednesday and Friday with reports on Tuesday, Thursday and Monday respectively. Ideally the swabs should reach the laboratory before 2pm (especially Monday, Wednesday and Friday). The schedule of processing may change and this can be noticed / flagged through regular communication between virology and PIID team.
The results are not on EPR, unless the infant is already a GSTT patient, but can be found on RRS because Audiology is a community service (despite being based in the hospital) or call Ext. 83098. The virology doctors available on [redacted] will continue to communicate **positive swabs** as soon [2] 10/6/2021

as possible any, to the Paeds ID team PaedInfectiousDiseaseTeam@gstt.nhs.uk to ensure the on call team is aware of positive results.

SCENARIOS

Negative result

The PIID nurse specialist (or fellow as back-up) will obtain the result and communicate to audiology and family, and update the database accordingly.[3]

[3] Admin note: This work is captured as a PIID CNS "appointment" so outcomes on e-noting and a GP letter is needed. See SOP and negative result letter template, also on PID S Drive. PIID CNS SOP for CMV audiology pathway Feb 2021.docx Negative saliva swab template March 2021.docx

[4] Note: evidence of seroconversion during pregnancy could be helpful (negative CMV IgG at booking and later maternal blood positive) but we do not often do this as samples unavailable and we focus on baby results.

[5] cmvaction.org.uk/about-cmv-action is a helpful website for families and staff.

Positive result (CMV detected on saliva swab)

The important timelines:

Diagnosis

If the swab was taken in a baby <21 days of age it means cCMV is probable (this is even more likely in swab <14 days).

However, it is important to have a 2nd test to confirm this as there is a chance of false positive results especially if swabbed too soon after a breast feed. If the urine (and blood) is negative, this challenges whether the initial saliva swab was a true positive. Note CMV viraemia is not as reliable as urine and saliva samples in confirming cCMV.[4]

Treatment

The evidence of using antiviral treatment is from a study where treatment was commenced within 28 days of age with severe or CNS symptoms. Benefits for other babies are extrapolated from this study, as is the treatment of slightly older babies.

All infants with a positive CMV saliva swab, coming through the audiology route should be discussed with the PIID on call doctors.

ASSESSMENT AND PLAN BY PIID

It is essential to keep family and carers aware of plans, uncertainties and maintain informed consent throughout. The assessments are often over 2 visits as hard to arrange all investigations in one day. The PIID CNS team can arrange attendances to the hospital and support the family[5] but a PIID consultant should have at least one contact with the family.

Practical publications (as opposed to research publications) are on S:\Paediatrics\PID\CMV\CMV audiology pathway 2021\Associated documents\Papers to guide care [3] 10/6/2021

Purpose of assessment:
Is this congenital CMV? [A]
Is the baby symptomatic? [B]
If symptomatic, do they warrant being offered treatment with antivirals? [C]
What follow up do they need? [D]
All infants who have a positive saliva swab
[A] Urine and blood for CMV PCR. If urine not possible repeat saliva swab 30 mins after breastfeed.

If first swab taken > 21 days of age, obtain consent for a Guthrie card testing[3]**.**
[B] Clinical assessment of infant, overall and specific for cCMV
FBC, U&E, LFT (including conjugated bilirubin)
Arrange MRI Head and if SNHL is being considered ask for MRI of internal auditory meatus.[6] Consider discussing with Paediatric Neurology Registrar to place images on their MDT Tuesday 2pm.

6 Note it is easier to do a feed & wrap MRI when infant younger. If SNHL confirmed, aim communication of results to community paediatrician if known.

7 Checklist for jobs with positive saliva swab April 2021.docx

Refer to ophthalmology (on-call ophthalmologist via switchboard but often helpful to emai[redacted]
[A] and [B] can mainly be arranged by PIID CNS though doctor needs to request MRI. Clarity and communication between Consultant, Fellows and PIID CNS essential. Please see attached checklist that can be used for communication if convenient.[7]

If two tests (saliva, urine or blood) confirm evidence of CMV, **even when you cannot yet be sure whether it is congenital**, work up as if congenital CMV. This is justified because these infants have evidence of one known symptom of CMV (SNHL) and some evidence that cCMV might be the cause. Furthermore, the Guthrie is <100% sensitive. Therefore, a thorough investigation is warranted to look for any other clues of cCMV infection, to guide families and health providers.
[C] To help with clinical assessment and decision regarding treatment and follow up these two papers may help.
Congenital_Cytomeg alovirus__A_European_Expert.28.pdf CMV Education and Practice article.pdf

There is no evidence to offer antivirals after 28 days but many clinicians would still consider offering antivirals depending of severity of symptoms, age of infant and after a clear discussion with the family on possible benefits and short and long term risks. If the child is > 42 days the PIID consultant should discuss with colleagues in the PIID MDT and may consider discussion through cCMVNET (global network established in 2021 with regular case discussions). [4] 10/6/2021

[D] **All babies who are confirmed as cCMV need follow up** – see figure 4 in article attached.
SCROTCH archdischild-2020-318841.full.pdf

If they did not have antiviral treatment because the symptoms did not justify or parents declined, then the suggestion is to continue to follow up until the 2nd birthday. If the infant has a local paediatrician / or neonatologist who is caring for the infant then they can follow-up but this arrangement should be confirmed in writing. Community Paediatrics do not routinely follow up unless the infant has known or anticipated issues.

Audiology need to follow up and usually arrange themselves, but important to know this has been arranged. Audiology at St. Thomas's send letters to Lee Makin and she forwards these to consultant, PIID CNS and uploads to EPR.
Ophthalmology may sometimes need a prompt at 1 year.

RESEARCH & DATA COLLECTION
The details of all referrals are captured on an internal database, maintained by the PIID CNS team. This includes referral timelines as well as results and communication checks. The intention is to contribute to a pan-European database once it is established and trust procedures adhered to.

Appendix C

GOSH Department for Paediatric Infectious Diseases Standard Operating Procedure: The Diagnosis and Management of Congenital Cytomegalovirus (CMV) Infection (extract)

Clinical features

Document presence or absence of:

- Hepatosplenomegaly, jaundice, petechiae, and purpura (blueberry muffin rash).
- Prematurity, IUGR
- Microcephaly, hypotonioa, hemiparesis, seizures, retinitis, cataracts, unilateral or bilateral deafness.

• Investigations

Test	
Bloods	
FBC	Thrombocytopenia (< 100,000 /mm^3, nadir at 2 weeks)
U&E	Baseline renal function
LFTs	ALT >80U/L, conjugated hyperbilirubinaemia, parameters increase in first fortnight
CMV PCR for viral load	Needs EDTA sample
Radiology	
Cranial USS and Brain MRI	The spectrum of abnormalities is wide: Periventricular calcifications, ventricular enlargement, white matter changes, cysts, neuronal migration defects, and cerebellar hypoplasia support the diagnosis
Referrals	
Ophthalmologist review	chorioretinitis, optic atrophy, cataracts
Diagnostic auditory assessment	

- Table 4 Treatment options for infants found to have cCMV

cCMV, but no evidence of any end-organ disease	End-organ involvement +/- CNS disease
↓	↓
Asymptomatic infant	e.g SNHL, abnormal brain MRI, hepatitis
No treatment offered	Treatment offered
	Ganciclovir 6mg/kg IV BD if not fully enterally fed then switch to valganciclovir 16mg/kg/dose PO/NG BD[1] when fully enterally fed. Long course Treatment: complete 6 months of antiviral treatment
	Investigations whilst on treatment[4]

	FBC[2], LFT and U&E at least weekly on IV ganciclovir FBC, LFT and U&E at week 2 and 4 then monthly till completion of treatment course on oral valganciclovir[4] Viral load, alternate weekly for the first 2 months, then monthly whilst on antiviral therapy Consider therapeutic drug monitoring[3] if: -viral load increasing during treatment -toxicity is suspected - there is an increased risk of toxicity: prematurity <36 weeks, abnormal renal function
Follow up	Follow up
Keep under Paediatric ID review for first year of life. Monitor development and consider CMV VL, if levels were high at birth. Audiology assessment every 4-6 months until 6 years old	Paediatric ID clinic as soon as possible in first month, 2 weeks after starting therapy, at 1 month, then monthly until completes therapy, then at least annually. Audiology assessment every 4-6 months until 6 years old Neurodevelopmental assessment at one year in a child development service Ophthalmic assessment directed by ophthalmologist, but baseline annual review[5]

[1]Roche® make a 50mg/mL oral solution – do not crush the tablets

[2] Interrupt treatment if Absolute Neutrophil Count <0.5 x10^9/L

[3] Therapeutic drug monitoring is available, via virology, through Bristol Antimicrobial Reference Laboratory:

Trough 0.5 – 1.0 mg/L; Peak 1 hour post ganciclovir (7 – 9 mg/L); 2 hr post oral valganciclovir (5 – 9 mg/L). 1-2ml of serum required so need >2ml of blood in a serology tube.

[4] increase frequency and/or seek advice if there is a deterioration

[5] There is limited evidence on late ocular manifestations of cCMV. It is rare if no abnormality noted at the outset but late complications of cCMV are possible, notably visual impairment and strabismus [28][29]

Appendix D

Fifteen-minute consultation: diagnosis and management of congenital CMV:

Tejshri Shah,[1] Suzanne Luck,[2,3] Mike Sharland,[3] Seilesh Kadambari,[3] Paul Heath,[3] Hermione Lyall[1]

Fifteen-minute consultation: diagnosis and management of congenital CMV | ADC Education & Practice Edition (bmj.com)

Appendix E -

South East Thames Regional Newborn Screening Laboratory
4th Floor North Wing, St Thomas Hospital LONDON, SE1 7EH [redacted]

CONSENT FOR RELEASE OF NEWBORN SCREENING BLOOD SPOT CARD (v2)

Fields marked * must be completed. Incomplete or illegible information may delay or prevent the correct card being retrieved and processed.

The name of the child may be different to the information provided on the newborn blood spot card. The maternal surname is often used for the first few days of life.

***Child's Name**			
(Name at birth if different)			
***Date of Birth**		***Sex**	☐ Male ☐ Female
***NHS Number**			
***Mother's name**			

***Test required**	☐ CMV ☐ Other……	*Internal use only*	
		Episode Number	

I agree to the release of the newborn blood spot sample for the investigation detailed on this form and I confirm that I have 'parental responsibility' for this child:

***Signature of parent/guardian**			
***Printed Name**			
***Relationship to child**		***Date**	

***Requesting Consultant**	

***Consultant Address**	…….. …… …….. ……..
***Invoice Address** (if different to address above)	…….. …… …….. ……..

The report and invoice from the referral laboratory will be sent to the named clinician at the address provided above. The SE Thames NBS lab does not receive or hold copies of reports for additional tests.

Please note: there is a £60 charge to retrieve and forward the sample to the referral laboratory.

Congenital Cytomegalovirus (CMV) testing in Audiology

Introduction

Your baby did not have a clear response on their hearing screen and has been referred for a more detailed hearing test. The test may show that your baby's hearing is normal, but it might show that your baby has a hearing loss. In most cases hearing loss in babies is temporary, often as result of blockage in the outer or middle parts of the ear. A small number of babies will be found to have a permanent hearing loss that will affect one or both ears.

There are many causes of permanent hearing loss in babies and young children. Up to 20% of cases are caused by congenital CMV.

What is congenital CMV?

CMV is a common virus. In adults it can present as cold, flu or show no symptoms at all. CMV infection affects 1% of pregnancies in the UK. If an unborn baby is exposed to the virus it is called congenital CMV. It is diagnosed by testing body fluids (urine/saliva) before 3 weeks of age. About 90% of babies who have congenital CMV are well with no signs of the infection, however it can cause hearing problems in babies who are otherwise well.

Why is it important to test babies for congenital CMV?

CMV is the only treatable cause of hearing loss in newborn babies. To try and stop the hearing worsening and to see the full benefits of the treatment, it is important that infection is confirmed and treatment started within the first 4 weeks of life.

Will you test my baby for CMV and how will you do it?

Before your baby's hearing test we will place either a piece of cotton wool or a collection bag inside their nappy to collect a sample of their urine whilst their hearing is tested. If the hearing test shows that your baby has a permanent hearing loss, we will send the sample to a laboratory to test for the virus. If your baby's hearing is normal or has a temporary hearing loss the sample will be discarded.

What if my baby has congenital CMV?

A specialist children's doctor will contact you by telephone to arrange a medical review appointment. This will be arranged as soon as possible so that early treatment can commence if it is suitable.

Regular hearing tests will also be offered to your baby.

Sources of information

http://cmvaction.org.uk/
https://www.ndcs.org.uk/

Important information

This patient information is for guidance purposes only and is not provided to replace professional clinical advice from a qualified practitioner. If you wish to contact us please call Paediatric Audiology, Tel: 0300 131 5679 or Email: **esht.audiology@nhs.net**

Your comments

We are always interested to hear your views about our leaflets. If you have any comments, please contact the Patient Experience Team - Tel: 0300 131 4731 (direct dial) or by email: **esh-tr.patientexperience@nhs.net**

Hand hygiene

The trust is committed to maintaining a clean, safe environment. Hand hygiene is very important in controlling infection. Alcohol gel is widely available at the patient bedside for staff use and at the entrance of each clinical area for visitors to clean their hands before and after entering.

Other formats

If you require any of the Trust leaflets in alternative formats, such as large print or alternative languages, please contact the Equality and Human Rights Department.

Tel: 0300 131 4500 Email: esh-tr.AccessibleInformation@nhs.net

After reading this information are there any questions you would like to ask? Please list below and ask your nurse or doctor.

_____

_____

_____

_____

_____

Reference

The following clinicians have been consulted and agreed this patient information:
Dr Nisha Gupta – Associate Specialist in Community Paediatrics

The Clinical Specialty/Unit that have agreed this patient information leaflet:
Paediatric Audiology

Next review date: November 2025
Responsible clinician/author: [redacted] – Lead Paediatric Audiologist