



Standard Operating Procedure

Testing infants for Congenital Cytomegalovirus (cCMV) following “No Clear Response” on Universal Newborn Hearing Screening

Disclaimer:

The National Clinical Programme for Paediatrics and Neonatology acknowledges that there may be changes required to the operationalisation of this SOP following implementation. If you have any feedback or wish to raise concerns in relation to the SOP please see page 16 of this document for information on whom to contact. The information provided within this document is in relation to **'Testing infants for Congenital Cytomegalovirus (cCMV) following "No Clear Response" on Universal Newborn Hearing Screening** and therefore should not be used for any other purposes. This is not part of a screening programme nor is it a substitute for professional care.

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1.0 Aim of Standard Operating Procedure (SOP)

The aim is to identify infants with hearing loss due to congenital Cytomegalovirus (cCMV) who may benefit from early antiviral treatment.

This SOP requires a multifaceted approach to ensure that the parents/legal guardians of all infants at the point of '**no clear response**' (NCR) recorded at screening completion of Universal Newborn Hearing Screen (UNHS), are counselled about the risk of cCMV and are offered to have a urine sample taken and sent to the National Virus Reference Laboratory (NVRL) to test for presence of CMV.

Any infant <3 weeks old with CMV detected in urine may have cCMV and should be offered thorough clinical assessment, baseline investigations and appropriate follow-up with the National Centre for Paediatric Infectious Diseases (NCPID), Rainbow Clinic, CHI at Temple Street and Crumlin.

The Standard Operating Procedure (SOP) seeks to provide direction, information and support for Maternity Hospitals/ Units, Neonatal Units, Paediatricians, the Newborn Hearing Screening Service, HSE audiologists, Directors of Public Health Nursing, laboratories and the NCPID, Rainbow Clinic, CHI at Temple Street and Crumlin.

2.0 Cytomegalovirus (CMV)

Based on international data up to 25% of confirmed Permanent Childhood Hearing Loss (PCHL) is caused by cCMV infection

- The number of symptomatic cCMV positive infants is relatively small, estimated at approximately 20 per year
- The cochlear damage due to cCMV that begins in utero continues after the infant's birth
- **Initiation of treatment for symptomatic cCMV is time critical for long term benefit.** Treatment should commence as soon as possible (preferably in the first 4 weeks after birth)
- Diagnosis of cCMV is established by detection of CMV DNA by PCR in body fluids (urine, blood or saliva) in the first 3 weeks of life
- Urine is the preferred specimen option. If blood or saliva are used, they should be in addition to and not instead of urine
- CMV urine testing is routinely used in the investigation of sensorineural hearing loss, infant sepsis, hepatitis, thrombocytopenia, hepatomegaly, splenomegaly and many more conditions.

3.0 Key Terms and Acronyms

CMV	Cytomegalovirus
cCMV	Congenital CMV
GP	General Practitioner
ID	Infectious Diseases
NCPID	The National Centre for Paediatric Infectious Diseases, Rainbow Clinic, CHI at Crumlin and Temple Street
NCR	No Clear Response
NEC	NEC Software Solution UK Limited (formerly Northgate Public Services) this company delivers the UNHSP on behalf of the HSE
NTGCHS	National Technical Group for Children Hearing Screening
NVRL	National Virus Reference Laboratory
OPD	Outpatient Department
PCHL	Permanent Childhood Hearing Loss
PHN	Public Health Midwife/nurse
SOP	Standard Operating Procedure
UNHSP	Universal Newborn Hearing Screening Programme

4.0 Overview of process

- a) The collection of a urine sample from infants who have **'no clear response'** recorded at UNHS screening completion
- b) Each unit will agree a safe and reliable care pathway for obtaining and processing urine for cCMV (**inpatient and outpatient pathways**)
- c) The NVRL will communicate the results of urine samples (received for cCMV testing) to the ID Consultant at the National Centre for Paediatric Infectious Diseases, Rainbow Clinic, CHI at Crumlin and Temple Street and the infant's paediatrician
- d) The ID Consultant will communicate the cCMV result, treatment and follow up plan to:
 - Infant's parents/legal guardians
 - Infant's paediatrician
 - Infant's GP

- National Clinical Lead for Audiology¹ to expedite diagnostic hearing assessment
- e) The ID Consultant will arrange follow-up for infants who test positive for cCMV
- f) The ID team will issue letter to families for whom **NO** cCMV was identified on sample analysis, informing them of the result and reminding of the importance for the family to still attend audiology review.

5.0 Criteria

This SOP applies to newborn infants at the point of NCR by UNHS at screening completion. Following counselling and consent² of parents/legal guardians, urine CMV testing should be initiated for these infants as soon as practical after birth.

Treatment for symptomatic cCMV should commence as soon as possible (preferably in the first 4 weeks after birth)

All 19 maternity units will need to establish pathways locally for infants with ‘no clear response’ on completion of Universal Newborn Hearing Screening. These pathways will need to be reviewed and adjusted by each site to incorporate referral to paediatrics/neonatology/designated liaison person for parental/legal guardian counselling, consent and urine collection for cCMV.

The pathways will require individualised local agreement as the approach will differ from maternity unit to unit. The following information should be considered and included when adapting the pathway to facilitate urine collection:

- i. The infant must be allocated a Health Record number on the hospital system and must be under the care of a Paediatric Consultant
- ii. A process should be clearly defined and agreed to identify the consultant who will receive the results of the urine sample (e.g. named consultant on call on the day the infant has NCR result documented. This consultant’s name will be entered on the laboratory form/electronic ordering system³)
- iii. There should be an agreed process in place when an infant has ‘no clear response’ at UNHS screening completion for the hearing screeners to refer

¹ Audiology will be notified of results by the ID Consultant via a specific email address (Audiology.CMVGroup@hse.ie). The Audiology lead will be informed before treatment and follow up is decided as soon as the ID team is made aware of the positive CMV result.

² Verbal **or** written consent should be documented as per local arrangements. Parents/ legal guardians must be provided with the Parent Information Leaflet

³ Units will vary in terms of paper or electronic ordering systems

urgently to paediatric/neonatal colleagues for them to counsel and consent parents/legal guardians for the collection of urine, completion of laboratory form and dispatch to laboratory/NVRL

It is important that hearing screeners have an urgent and reliable pathway identified back in to paediatric/neonatal/maternity services so parents/legal guardians can be conveniently and appropriately seen to counsel them and consent them for taking a urine sample and CMV testing. These steps are critical so as to avoid any delays in the diagnosis of cCMV and to determine the infant's suitability for antiviral treatment.

The majority of infants complete UNHS while still in hospital (on postnatal wards or neonatal units). However, infants who have NCR on first screen will usually complete their hearing screening in an outpatient setting. Therefore there is a clear need for units to agree an outpatient pathway of care to provide for this cohort of infants who have 'NCR' on UNHS screening completion (including for home births). The pathway should include:

- i. Role of the UNHS screener in the outpatient setting including communication pathway
- ii. Name of consultant paediatrician/neonatologist e.g. consultant on call (on the day infant referred by screeners to paediatrician/neonatologist)
- iii. Identify how (and by whom) the infant is to be assigned a patient record number (including homebirths) which is required for the laboratory form and other relevant documents
- iv. Identify who is responsible for providing information and consenting as appropriate, the parents/legal guardians in the outpatient setting e.g. registrar on call, midwife/nurse in OPD/ Neonatal Unit/Maternity Unit
- v. Identify who will have responsibility for collection and labelling of the urine sample and appropriate transfer of sample to laboratory/ NVRL with all relevant information included on the laboratory form (See 8.0 for details)
- vi. Identify an approach to ensure that all procedures completed in the outpatient setting are clearly documented in the infants Healthcare Record/file.

6.0 Health Professionals Roles

6.1 Responsibility of the Hearing Screener

- a. On completion of the UNHS, the screener informs the parent/legal guardian of a NCR result and asks the parent/ legal guardian for permission to share the result with the doctor or midwife/nurse (designated liaison person). **"Your baby has had 'NCR' to UNHS. Are you happy to consent to sharing the result of the hearing test with the doctor or midwife/nurse? The doctor or midwife/nurse will be able to give you some more information"**⁴
- b. With the parent/legal guardian's permission, the screener will refer the infant with NCR to the designated liaison person to discuss cCMV. It will be under the governance of that service/local contact to follow up the referral⁵.
- c. The screener will log all communications in the usual manner
- d. Where a parent/ legal guardian does not consent to the screener sharing the information with the designated liaison person the screener should advise the parent/ legal guardian as follows **'We strongly recommend you that you speak to the designated liaison person in the hospital. Here is an information leaflet in relation to the cCMV test which the hospital would like to discuss with you. If you wish to speak to someone on a different day please contact this number/ email'**⁶

6.2 Responsibility of Designated Liaison Person

- a. The doctor or midwife/nurse assigned as the designated liaison person (DLP) will be agreed at local level
- b. There must be a dedicated DLP phone number and email address available, through which all communications and/or correspondence relating to cCMV (NCR) will be received
- c. The DLP will receive a referral from the screener in relation to the infant with NCR
- d. The DLP will arrange to meet with the parent/ legal guardian on the same day (in so far as possible)
- e. The DLP will inform the parent/legal guardian that NCR may suggest that cCMV infection is a possibility and that best practice is to test the infant's urine for the presence of CMV in case an infection occurred during pregnancy

⁴ The outcome of this will be recorded on the UNHS IT system (S4H)

⁵ Each unit must design and agree the pathway for communication of results of hearing screening from screener to designated liaison person and the subsequent collection of a urine sample. A person of contact needs to be clearly identified for the screening team (mobile or pager number provided). The screener will liaise with staff as per the locally agreed communication process.

⁶ An agreed point of contact must be agreed locally which the screener can share with the parents/ legal guardian can contact to discuss their concerns

- e. The DLP will ensure that the parent/legal guardian is provided with a parent/legal guardian information leaflet relating to cCMV.
- f. If the parents/ guardians consent to providing a urine sample, the laboratory form (paper/ electronic) is to be completed by the DLP taking the sample. The form should contain information as detailed in **Section 8.0** of this SOP.
- g. Where a parent/legal guardian opts out of providing a urine sample, the parent/legal guardian must be informed by the designated liaison person of the risks associated with late diagnosis of cCMV. The information provided must be documented in the infant's records as per local arrangements⁷.
- h. The parent/ legal guardian should be offered an 'opt back in' option. This should be agreed at local level as to who the parent/ legal guardian should contact (ideally DLP) (phone number/ email address should be provided) if they choose to proceed at a later date with testing for cCMV. The parent/ legal guardian should be advised of the importance of early diagnosis if optimum benefits from treatment are to be attained. The DLP may wish to advise as follows: **'Early diagnosis and treatment for cCMV is important, we do recommend your baby has this urine test, if you would like to have this done in the future please contact us back on...** (provide phone number/ mail address to parent/ legal guardian)

6.3 Role of Midwife/ Nurse

The midwife/nurse or delegated staff member looking after the infant on the ward/unit will be informed by the screener that the parent/legal guardian has consented to sharing of NCR result of UNHS and they are referring the infant to the clinical team. The midwife/nurse will urgently arrange for the infant to be seen (preferably at the time of referral from the hearing screener) to discuss the recommendation of obtaining a urine sample from the infant following NCR at UNHS⁸. If the parents/ guardians consent, the laboratory form (paper/ electronic) is to be completed by the person taking the sample. The form should contain information as detailed in **Section 8.0** of this SOP. This information is required so the NVRL can prioritise the sample and will therefore be able to provide the ID Consultant at the NCPID Rainbow Clinic with the details of the infant and mother to ensure contact is made and follow up arranged without delay.

Details in relation to infants who have completed both stages of hearing screening and are confirmed as NCR **prior to hospital discharge**, should have the information

⁷ The screener must be informed of the pathway for escalation of issues arising, including where a parent/legal guardian refuses to consent to providing a urine sample, sharing of information etc.

⁸ Information provided must include the Parent Information Leaflet

documented as part of the standard discharge process by nursing and midwifery staff in the infants inpatient hospital records and in discharge documentation for the Public Health midwife/nurse (PHN). This should include (but not be restricted to) the following:

- ✓ The infant has had 'No Clear Response' on UNHS
- ✓ Follow-up audiology testing will be arranged
- ✓ Urine sample was (or not) obtained and sent to National Virus Reference Laboratory to test for cCMV
- ✓ Follow up for infant with positive CMV urine will be arranged by the NCPID Rainbow Clinic CHI at Crumlin and Temple Street.

It should be noted that most infants who have an initial 'NCR' will not have completed their hearing screening as an inpatient. However arrangements will be made by the screeners to complete the UNHS in the community.

6.4 Role of the National Virus Reference Laboratory (NVRL)

By consenting to providing a urine sample, the parents/legal guardians are also consenting to sharing of the result with the team at the NCPID, Rainbow Clinic CHI. NVRL will notify the ID Consultant at the NCPID, Rainbow Clinic, CHI at Crumlin and Temple Street of all urine cCMV results (positive and negative). Communication will be by phone (for positive results) with a follow-up email and laboratory report. NVRL will also send a copy of the result to the infant's paediatrician in hospital of birth.

6.5 Role of the Infectious Disease Consultant

All cCMV results will be communicated to the infant's parent/legal guardian by the NCPID, Rainbow Clinic with the result of the urine test. For **negative** cCMV tests, parents/ legal guardians will be informed by letter or direct communication from the ID Team.

Follow-up appointments with the NCPID, Rainbow Clinic will be arranged as required for those with a **positive** CMV test. The ID consultant may undertake further investigations to confirm the diagnosis of symptomatic cCMV infection and determine if antiviral treatment is indicated.

NCPID emails the centralised Audiology.CMVgroup@hse.ie account which is monitored by a number of staff. This email should include the minimal details so as to identify the infant. The Audiology CMV Group will then contact the respective local service with a request to expedite diagnostics. The outcome of the tests at the local

service will be emailed back to the ID team contact email which was originally provided⁹.

Information on the outcome of investigations will be communicated by the ID Consultant to the following:

- Infant's parents/legal guardians
- Infant's paediatrician at hospital of birth
- Infant's GP
- National Clinical Lead for Audiology¹⁰

6.6 Role of National Clinical Lead for Audiology

On receipt of the CMV results via email, the National Clinical Lead for Audiology will:

1. Update the S4H aetiology section re positive and negative CMV results
2. Expedite the diagnostic audiology appointment at the local service if the urine CMV is positive¹¹
3. Inform the NCPID of the outcome of the diagnostic audiology assessment, in CMV positive infants. Communication is by email. This communication is recorded on S4H.

6.7 Infant referred back to hospital from community after NCR¹²

Details in relation to babies who have completed both stages of hearing screening and are confirmed as NCR **in the community** will be referred in to the Designated liaison person (see **6.2** for role of DLP).

Documentation/ information provided should include (but not be restricted to) the following:

- Parents/legal guardians counselled re: cCMV, referral process, assessment, follow-up etc.
- Consent (verbal or written) obtained to test urine and sharing of results with NCPID
- Urine sample was (or not) obtained and sent to National Virus Reference Laboratory to test for cCMV
- Parent/ guardian information leaflet provided

⁹ ID will email the local Audiology service (rather than central email) to indicate if infant started on AV medications.

¹⁰ Results communicated to Audiology will be uploaded onto the S4H aetiology module. The National Clinical Lead for Audiology will be advised if anti-viral medications have been commenced in which case a follow up appointment (within 3 months) will be arranged for the infant All CMV exposed infants will require further audiology follow up including asymptomatic ones that we do not offer treatment.

¹¹ On receipt of the email from ID it will be redirected to the respective local service and a request placed to expedite diagnostics appointment due to the CMV status

¹² Each unit must design and agree the pathway for communication for infants referred from the community setting

- Information on NVRL sharing results with NCPID¹³ provided to parents/ legal guardians
- Follow up for an infant with a positive CMV urine, appointments arranged by the NCPID Rainbow Clinic CHI at Crumlin and Temple Street
- Where parents/legal guardians **do not** consent to entering the cCMV testing programme, the information provided regarding the risks associated with delayed diagnosis should be discussed and clearly documented
- The importance of ensuring that the infant continues attending their hearing test appointments as arranged
- Parents/guardians should also be advised that if they have any concerns about the development of their baby, to seek help in the usual way via their GP/PHN
- Where parents/ legal guardians initially refuse and wish to opt back into the process they should be provided with information and contact details of who to contact as per local pathway.

7.0 Scope of the SOP

The SOP applies to the following healthcare personnel:

- NEC Screening Team
- HSE Audiology
- Midwives and Neonatal staff
- Midwife/nurses/Public Health Midwife/nurses
- The infant's paediatrician
- The National Virus Reference Laboratory (NVRL)
- The National Centre for Paediatric Infectious Diseases (NCPID), Rainbow Clinic, CHI at Crumlin and Temple Street

8.0 Urine Collection

This SOP can only give guidance and general recommendations and does not provide the detail of the specific method each unit can employ to ensure a urine sample is taken in a timely manner due to the many variables involved. Consideration of the following key features of a local agreed care pathway should include:

- a. Checking if the infant has a result of 'NCR' on **second** UNHS, not just after initial screen after birth

¹³ Parents will receive results through NCPID

- b. Obtaining the urine sample is time critical. The collection of the urine sample should occur prior to infant's discharge, and / or on the same day as NCR (in so far as possible) if the infant has already been discharged from the hospital¹⁴
- c. Medical/nursing expertise should be available to provide appropriate information and clarification for parents/legal guardians as to the reason for collection of a urine sample¹⁵
- d. The method of taking the urine sample for cCMV can be done by cotton wool balls, urine pad, urine bag or clean catch. The sample needs to be as clean as possible to prevent overgrowth by bacteria. Local recommendations/methods may vary. The following approach to collection of urine may be considered:
Urine sample obtained by:
 - i. Cleaning the genital area with water. Pat dry with a clean towel/gauze
 - ii. Place a thick layer of cotton wool inside the infant's nappy, wait 10 minutes and check if it is wet.
 - iii. If it is wet, use the syringe provided to draw up the urine (approximately 0.5-1.0mls) from the cotton wool. Put the urine in a sample bottle/jar.
- e. The urine sample and accompanying request form must be dispatched to the NVRL as per hospital protocols/ policies
- f. The Laboratory request form¹⁶ should have the following information documented:
 - Name of the infant
 - DOB of the infant
 - Infant's Medical Record Number
 - Date sample taken
 - Indication for testing recorded as: '**CMV Hearing**'. The test code '**mcmh**' should also be included. For laboratories without electronic ordering, '**mcmh**' should be clearly hand-written or stamped on the request form accompanying the urine specimen to ensure samples can be identified at the NVRL.

**IMPORTANT:
THE TEST CODE 'MCMH' IS ONLY TO BE USED
FOR INFANTS WHO HAVE HAD NCR ON UNHS**

¹⁴ It will be the responsibility of the local unit to follow up with the parents/legal guardians to ensure that a urine is collected and sent for cCMV testing.

¹⁵ The availability of nursing/medical staff to provide information to parents/legal guardians must be agreed locally.

¹⁶ Hospitals with electronic health records and laboratory requesting systems should select the appropriate electronic request for CMV PCR.

- The name, address and **telephone numbers** of the infant's parents/legal guardians
- The infant's paediatrician¹⁷

8.1 Positive CMV Urine Result

- a. The NVRL will directly notify the NCPID, Rainbow Clinic, CHI at Crumlin and Temple Street of positive cCMV urine results by phone
 - b. A copy of all cCMV results (positive and negative) will be sent to the ID team at CHI at Crumlin and Temple Street (rainbow.cmv@olchc.ie) and to the referring clinician (in hospital of birth) by the **NVRL**
 - c. The Paediatric Infectious Diseases Consultants and their team will:
 - Contact the parent/legal guardian of the infant by phone and letter with a positive cCMV urine and arrange an urgent outpatient review
 - Arrange additional investigations (including an urgent diagnostic audiology test) to confirm symptomatic cCMV
 - Based on the clinical and laboratory findings and after discussion with the parents/legal guardian, make a decision on the advisability of commencing antiviral therapy
 - Inform the parents/legal guardian, infant's Paediatrician, National Clinical Lead for Audiology and GP of:
 - the diagnosis of cCMV
 - results of investigations
 - treatment plan
- **The infant will continue on the UNHS pathway for "no clear response"**
- d. The infant's paediatrician will review the infant as usual in relation to weight gain, head circumference and neurodevelopment.

8.2 Negative CMV Urine Result

- a. In the event of a **negative CMV urine result** but "no clear response" on the UNHS the infant will continue on the UNHS pathway
- b. The NCPID, Rainbow Clinic at Crumlin and Temple Street will communicate a negative urine cCMV result by letter to the parent/ legal guardian.

¹⁷ Include paediatricians phone number if available

9.0 Communication to parents/ legal guardians

- a. The parents/legal guardians must receive appropriate information regarding the reason for the request to provide urine for cCMV testing (Parent/legal guardian Information Leaflet)
- b. The parents/ legal guardians must be informed that urine cCMV test results will be communicated to the NCPID, Rainbow Clinic, the infant's paediatrician, and the GP
- c. The parents/ legal guardians must be informed that a positive urine test is suggestive of cCMV and that they will be contacted by the NCPID Rainbow clinic at CHI Crumlin and Temple Street to arrange timely follow-up for the infant
- d. The parents/legal guardians should be provided with contact details for the NCPID Rainbow Clinic to be used in the event that they do not receive a follow-up call/appointment (Parent/ legal guardian Information Leaflet)
- e. Parents/ legal guardians must be advised that treatment for cCMV should commence as soon as possible (preferably in the first 4 weeks after birth) highlighting the importance of attending the NCPID Rainbow Clinic as arranged.
- f. For a **negative urine test** for cCMV the parents/legal guardian must be informed that they should continue on the hearing screening pathway and attend follow up audiology appointments¹⁸.

10.0 Implementation and Revision of SOP

Implementation of various constituent parts is via:

- Director of Midwifery (hospital)
- Directors of Nursing (hospital)
- Designate Midwife Officers (Self-employed community Midwives)
- Hospital laboratories
- National Virus Reference Laboratory (NVRL)
- NEC Screening Team
- HSE Audiology
- Paediatricians
- National Centre for Paediatric Infectious Disease, Rainbow Clinic (ID Consultants)

¹⁸ This is in reference to an infant with an identified hearing issue that is not caused by cCMV. The parents/legal guardians will still need reassurance or possible intervention to deal with the possible hearing loss **not** caused by cCMV.

11.0 Governance

Governance for this quality improvement initiative rests with the **National Clinical Oversight Group for cCMV testing (NCR on UNHS)** ('No Clear Response' (NCR) on Universal Newborn Hearing Screening (UNHS)).¹⁹ This group will report to the National Women and Infants Health Programme (NWIHP) through the chair. The SOP implementation and quality assurance will be monitored on an on-going basis following initiation at all 19 Maternity units, and reviewed formally by the oversight group at regular intervals.

Governance for the UNHSP and referrals to paediatrics/neonatology remains unchanged and updates on referrals and implementation issues from the UNHSP in to the maternity hospitals will be raised and brought to the NTGCHS and interim national governance group for HSE Children's Screening Services.

On conclusion of the review all updates, modifications, development of KPIs', governance arrangements etc. in relation to the SOP will be communicated to all 19 maternity units. Feedback from all 19 units will be welcomed throughout the implementation phase. Sites can submit their feedback to the NCPPN via jacqueline.delacy@hse.ie

12.0 Registration and Start Date

This National initiative will be available for hospitals from **Monday 13th November 2023**.

Hospitals wishing to participate are required to register that participation with jacqueline.delacy@hse.ie. Implementation of this SOP should commence once local arrangements are in place as per the SOP. We ask that you inform jacqueline.delacy@hse.ie once your hospital has agreed a start date. We look forward to your participation, improving early diagnosis and care for babies with cCMV and to sharing the results and impact of the programme.

¹⁹ A national oversight group with representation from National Clinical Programme for Paediatrics and Neonatology (NCPPN), the National Women and Infants Health Programme (NWIHP) the Universal Newborn Hearing Screening Programme (UNHSP), NCPID Consultants, NVRL, the NTGCHS, NEC, regional clinical leads and key stakeholders.

13.0 Qualifying Statement

- a. This SOP has been prepared to promote best clinical practice and facilitate standardisation and consistency of practice
- b. Clinical material offered in this SOP does not replace or remove clinical judgement or the professional care and duty necessary for each infant
- c. Clinical care carried out in accordance with this SOP should be provided within the context of locally available resources and expertise
- d. This SOP does not address all elements of standard practice and assumes that individual clinicians are responsible for:
 - Discussing care with the parents/guardians, in an environment that is appropriate and one which enables respectful confidential discussion
 - Advising parents/guardians of their choices and ensure informed consent is obtained
 - Meeting all legislative requirements and maintaining standards of professional conduct

14.0 References

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15.0 Acknowledgements and Contributors

This SOP has been developed by the National Clinical Programme for Paediatrics and Neonatology (NCPNP) and The National Women and Infants Health Programme (NWIHP) in collaboration with representatives from the National Technical Group for Childhood Hearing Screening (NTGCHS), the National Virus Reference Laboratory, The National Centre for Paediatric Infectious Diseases, Rainbow Clinic, CHI at Crumlin and Temple Street, HSE audiology, maternity services, parent representatives and Public Health Nursing. The NCPNP and NWIHP would like to thank the contributors for their time and effort providing input and feedback on draft versions of this SOP throughout its development, and those who provided valuable input during the consultation process.

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Royal College of Physicians, Ireland (RCPI)	Neonatology Clinical Advisory Group
NALA	The National Adult Literacy Agency

16.0 Appendices

Appendix 1 Frequently Asked Questions

What is CMV?

Cytomegalovirus (CMV) is a very common virus. Most people are infected as children. Once infected, the virus stays dormant (asleep) in your body for life... a bit like the cold sore virus.

Most people don't know they have CMV because it rarely causes problems. But CMV can cause complications for people with weakened immune systems.

For example:

- People who have had chemotherapy.
- Transplant patients.
- Some people who are pregnant.

CMV can cause complications for some infants who got it in the womb.

What does my baby have?

Your baby's urine test suggests that your baby was infected with CMV in pregnancy. This is called congenital CMV.

What is congenital CMV?

This means that your baby became infected with CMV before they were born.

How did my baby get congenital CMV?

CMV can be passed on in pregnancy through the placenta.

This can happen because:

- you got CMV infection while you were pregnant, or
- your dormant CMV infection became active again in pregnancy

CMV can affect almost anyone. Most people won't know they have it. It is spread through body fluids like saliva, urine and breast milk.

Toddlers and preschool children are most likely to spread CMV. CMV infection in healthy children is usually not serious.

You are more at risk of catching CMV if you:

- work with children
- already have a young family

<https://www2.hse.ie/conditions/cytomegalovirus-pregnancy/overview/>

What are the complications of congenital CMV?

About 1 in 5 infants who become infected with CMV before they are born have complications. These complications can include hearing loss. The other 4 out of 5 infants will have no complications at all.

Is my baby deaf?

We don't know yet. The results of the first test only suggest it is a possibility. A more detailed hearing test is needed to answer this question. The second hearing test is one of the other tests we will arrange for your baby. Other tests include blood tests, an eye exam, and a brain ultrasound and MRI.

What other complications could my baby have?

Other complications can include delayed growth and development, visual impairment, liver inflammation and viral pneumonia.

We don't know yet if your baby has any of these complications. The other tests on your baby will help us to better understand your baby's risk of complications.

What happens now?

You will be given an appointment for the Rainbow Clinic. There the paediatric infectious diseases consultant will examine your baby. They will arrange more tests. These tests are done to find out if your baby has complications of congenital CMV infection. If your baby has complications, treatment is available. This treatment may improve or preserve hearing.

What treatment is available for my baby?

The consultant will talk this through with you. The treatment is a syrup. This should ideally be started within **4 weeks** of birth for the best benefit.

Why wasn't I tested for CMV in pregnancy?

There is no routine testing for CMV in pregnancy in Ireland. Practices around CMV testing in pregnancy vary from doctor to doctor and hospital to hospital.

I have other children. How do I protect them?

You do not need to change how you do things. Go ahead as normal.

I have a pregnant sister. Should I avoid seeing her?

No. You can see your sister but take precautions. CMV is transmitted through body fluids like urine and saliva.

Do:

Make sure everyone is washing their hands really well.

Don't:

- kiss
- share utensils like forks, spoons or cups
- allow her to change your baby's nappy

I have a family member on chemotherapy. Should I keep my baby away from them?

No. Same as above.

Who do I contact if I have more questions?

Your GP and general paediatrician will be able to answer many of your questions. The Rainbow Clinic will be able to provide more detailed information when results of the other tests are available.

Appendix 2 Parent/ Legal Guardian Information Leaflet

Important

If your baby's urine is tested, you will get the test result within two weeks. When you agree to provide a sample of your baby's urine, you are consenting to the testing of the sample. You also consent to sharing the result with the team at The National Centre for Paediatric Infectious Diseases, Rainbow Clinic, CHI at Crumlin and Temple Street. They will contact you with the results.

Important:

If you don't get the results in two weeks

You need to contact either the:

- ✳ The ward or unit of the hospital where you gave birth. Contact details are on the front of this leaflet.

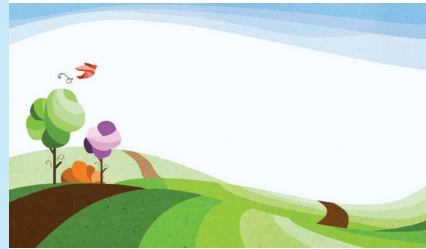
Or

- ✳ The National Centre for Paediatric Infectious Diseases, Rainbow Clinic, CHI at Crumlin on: 01-409 6338



Congenital Cytomegalovirus (cCMV)

Information for parents and legal guardians



Ward name:

Ward phone number:

Please talk to a staff member if you have any questions.



What is Congenital Cytomegalovirus (cCMV)? (Pronounced Sight-O-Mega-Low Virus. CMV for short.)

CMV is a common virus. In healthy children and adults, CMV usually causes no symptoms. However, unborn babies may develop health issues if they get CMV. 'Congenital CMV' (cCMV) means the baby is born with CMV infection.

How does CMV spread?

CMV is spread from one person to another through contact with body fluids. If you are pregnant and you get CMV, the infection can be passed to your baby. This is called a congenital CMV infection.

What are the symptoms?

Most babies with cCMV infection have no symptoms at birth. However, a few babies may develop complications. These can include hearing loss.

Hearing loss caused by congenital CMV can be mild or severe. It may get worse after birth.

If your baby has hearing loss, it may affect one or both ears.

What is the treatment?

The treatment is antiviral medicine. If it is decided that treatment will benefit your baby, ideally it should start before they are 4 weeks old. Getting early treatment for your baby gives them the best chance of long term benefits.

Please scan the QR Code for further information on CMV in pregnancy.



How is a cCMV infection diagnosed?

- 1 As your baby's newborn hearing screen outcome was 'No Clear Response' The newborn hearing screener has already referred your baby to Audiology for a hearing assessment. Your baby will also be offered a test for cCMV. This is a urine test.
- 2 With your permission, your baby's urine will be tested in the first 3 weeks after birth. We do this to check for cCMV. The urine sample is usually collected from a wet nappy. This is done using a cotton wool ball or another approach. You will be told about the approach.
- 3 Please make sure the nurse taking the urine sample has your correct phone number and address.

Negative urine test

A negative urine test means your baby does not have cCMV. You will be sent a letter if this is the result.

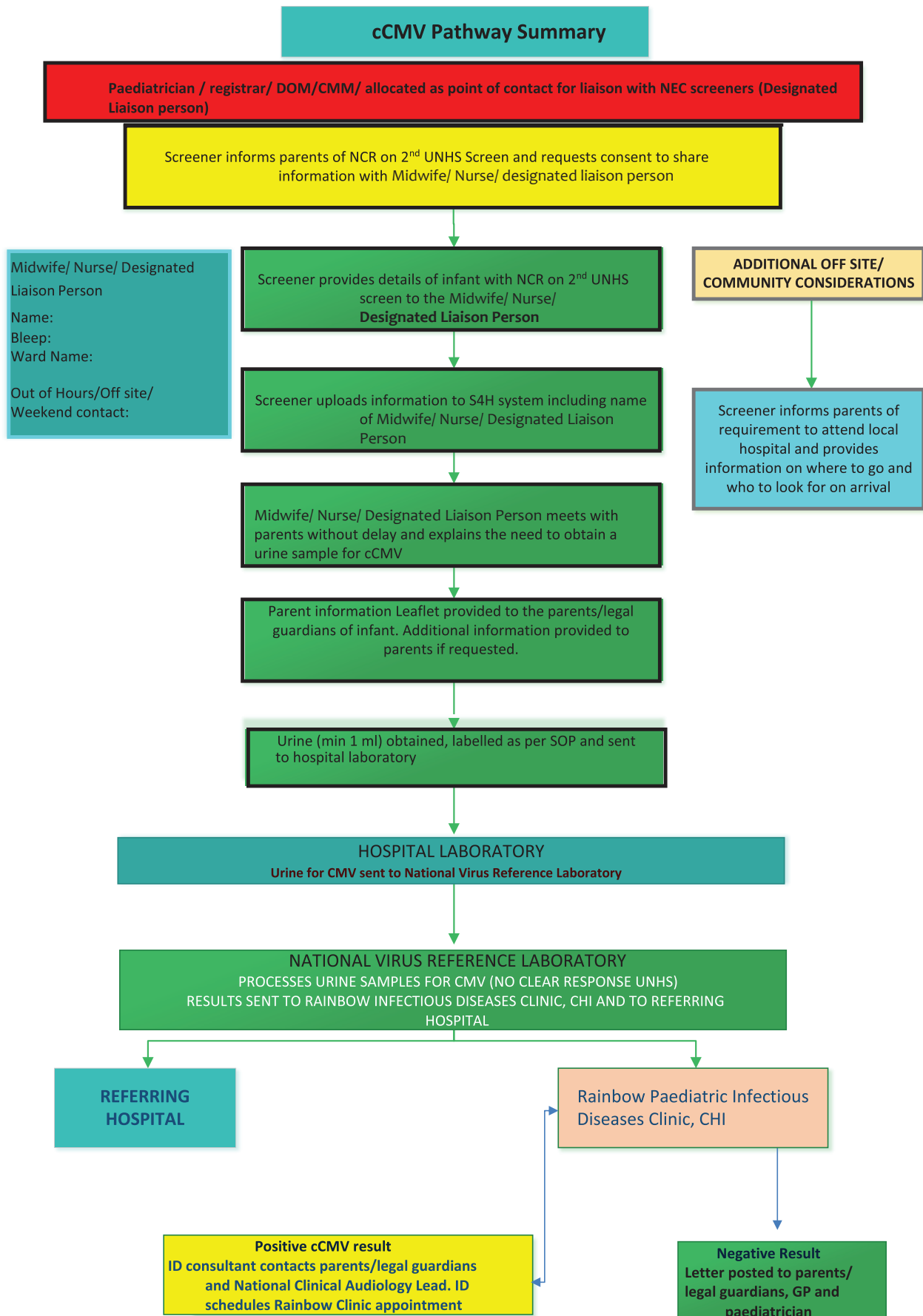
Remember: It is still important that you bring your baby to all follow-up appointments with the newborn hearing screening team.

Positive urine test

A positive urine test means your baby has a congenital CMV infection. The next steps would be:

- 1 The Rainbow Clinic Paediatric Infectious Diseases team at CHI Crumlin and Temple St. will contact you and arrange an outpatient appointment.
- 2 The team will examine your baby. They will decide if your baby would benefit from treatment.
- 3 We ask that you continue to bring your baby to all follow-up hearing tests as well as to routine visits to your GP. It is also important to bring your baby to public health nurse appointments. This includes getting your baby's vaccines.

Appendix 3 cCMV Pathway Algorithm



Appendix 4 SOP Checklist

Standard Operating Procedure (SOP) Implementation Checklist

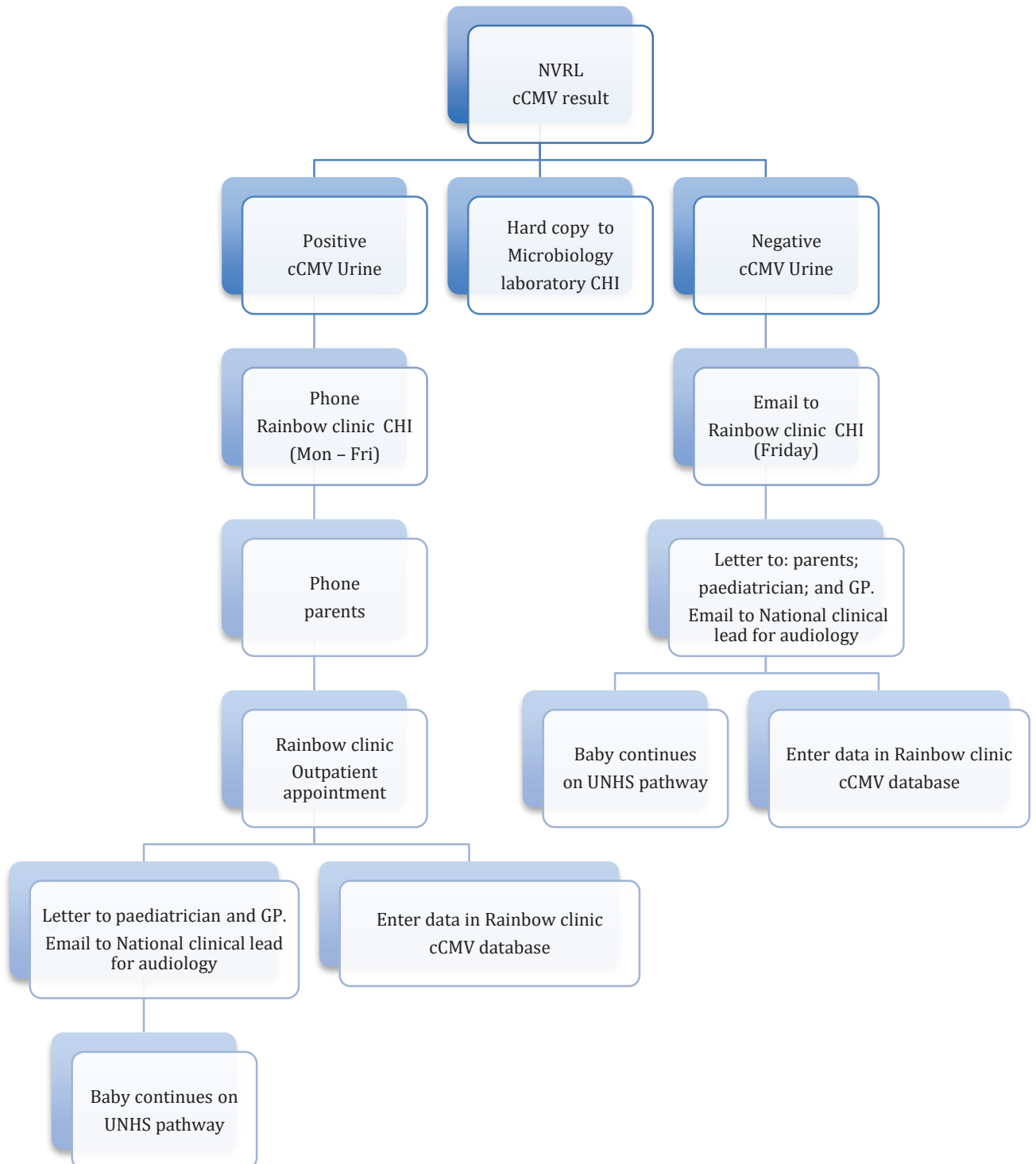
SOP Title:	
Testing infants for Congenital Cytomegalovirus (cCMV) following “No Clear Response (NCR)” on completion of Universal Newborn Hearing Screening (UNHS)	
Hospital:	
Hospital Unit/ Ward:	Date:
Clinical governance	NAME:
Lead for cCMV SOP Implementation	
Deputy Lead for cCMV SOP Implementation	
Midwife/ Nurse/ designated liaison person	
Deputy Midwife/ Nurse/ designated liaison person	
Hearing Screener	

Actions	Date
1. Hospital Executive endorses the SOP and it’s use, including communication to staff	
2. Appoint local Lead, designated liaison person and other key personnel as required	
3. Communication with local hearing screener: training, communication pathway, issue escalation, designated point of contact for screeners, start date etc. agreed prior to commencement of SOP roll out (c. 4 weeks prior to initiation)	
4. Table SOP at the local Patient Safety and Quality Committee meetings (or equivalent)	
5. Refer to the relevant SOP when recommending, initiating and/or reporting on quality activities to improve patient care	
6. Identify clinical champions to promote, reference and encourage other clinicians to use the SOP	
7. Include information about SOP in orientation/induction material	
8. Encourage staff to provide feedback on the SOP as per local arrangements or directly to: The National Clinical Programme for Paediatrics and Neonatology, HSE jacqueline.delacy@hse.ie	

This checklist is designed to support wards/units to implement the accompanying SOP appropriately and effectively. The approaches identified are suggestions only and may be customised as relevant to the SOP and local resources and practices.

Appendix 5 cCMV Results Algorithm

cCMV results Algorithm



Appendix 6 Pilot SOP Review

National Clinical Programme for Paediatrics and Neonatology
Neonatal Clinical Advisory Group, Faculty of Paediatrics, RCPI
National Clinical Advisor and Group Lead , HSE
National Centre for Paediatric Infectious Diseases, Rainbow Clinic, CHI at Crumlin and Temple Street
UCD National Virus Reference Laboratory
National Clinical Lead for Audiology
National Healthy Childhood Programme
National Women and Infants Health Programme
NEC Software Solution UK Limited (formerly Northgate Public Services) this company delivers the UNHSP on behalf of the HSE

