Neonatal Hyperammonemia Clinical Pathway

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Center for Clinical Excellence

Inclusion Criteria

- Neonates with an unexplained, non-hemolyzed NH_3 level >64uM (*upper limit of normal at NCH lab*)

Exclusion criteria

- Premature infants <34 weeks GA
- Onset in first day of life
- Liver failure

¶ Sampling Considerations

- NH_3 should be collected as a free flowing sample (not capillary), transferred to the lab on ice and run STAT.
- Thresholds in this pathway presume non-hemolyzed samples.
- Whether a hemolyzed NH3 level is sufficiently elevated to warrant attention even while it is being repeated is outside of the scope of this pathway.

*** Moderate or Severe Encephalopathy:**

- Attributable to hyperammonemia
- By Sarnat exam (including seizures)

ᵛ Rapidly Rising NH_3:

- Rising by more than 300uM in a few hours despite adequate therapy (per clinical discretion)

Abbreviations

- NH_3: Ammonia
- GIR: Glucose Infusion Rate

Elevated NH_3 level?¶

No → Off Pathway

Yes

Immediate Stabilization & Transport Recommendations

- Care of neonates with hyperammonemia best provided at a metabolic referral center
- Airway: Consider cuffed Endotracheal Tube (if requiring intubation)
- Breathing: Control respiratory alkalosis (if intubated)
- Circulation: patients with severe hyperammonemia are at risk for circulatory collapse. Steroids are relatively contraindicated.
- Make neonate NPO. Start IV fluids with GIR: 10 mg/kg/min (for transport or if unstable)
- Consult Genetics early in the transfer process

NH_3 >400uM OR rapidly rising^{v} OR moderate/severe* encephalopathy?

Yes →

- Primary service stat consult to Nephrology and Genetics.
- Huddle with Genetics and Nephrology for collaborative decision-making regarding CRRT and medical management

No ↓

NH_3 150-400uM?

No → Repeat NH_3 in 2 hours

Yes → STAT repeat NH_3 and follow LOW RISK Pathway

Consult Genetics

Preferred Location of Care: NICU

Repeat NH_3 in 2 hours → Is the repeat NH_3 <64uM?

Yes → Off Pathway

No → Is the NH_3 64-150uM?

Yes → Individualized care by the primary team in collaboration with Genetics

No → Is the NH_3 > 400uM?

Yes → STAT repeat NH_3 and follow HIGH RISK Pathway

Urgent Nephrology Consult for Continuous Renal Replacement Therapy (CRRT)

Preferred Location of Care: PICU

DO NOT delay management while awaiting repeat NH_3

No → STAT repeat NH_3 and follow LOW RISK Pathway

Consult Genetics

Preferred Location of Care: NICU

Low Risk Hyperammonemia Care Management

Patient with Low Risk Hyperammonemia

Abbreviations:

- PIV: Peripheral IntraVenous line
- NPO: Nothing by mouth
- IL: Intralipids
- ABG: Arterial Blood Gas
- CBC: Complete Blood Count
- CMP: Comprehensive Metabolic Panel
- UA: Urine Analysis
- PAA: Plasma Amino Acids
- ACP: Acylcarnitine Profile
- UOA: Urine Organic Acids
- CK: Creatine Kinase
- LTM: Long-Term Monitoring

Access & Supportive Care

DO NOT DELAY therapies for central access

- **Access:**
  - Arterial access: preferable to monitor NH_3 levels
  - Venous access: either PIV or central access as determined by the NICU team

Supportive Care/ Monitoring

- Neuro checks q1h
- Consult Neurology
- Avoid steroids
- Normothermia with active temperature control if needed
- Continue workup for nonmetabolic causes for hyperammonemia

Labs

Initial Labs:

High Priority

- ABG/Lactate/iCal
- CBC
- CMP/Mg/Phos
- β Hydroxybutyrate
- UA/urine ketones
- PAA, ACP, UOA - Genetics team to notify lab

Lower Priority

- CK, total Homocysteine
- DNA/RNA co-extraction

Subsequent Labs:

- NH_3 & Glucose q2-4h
- Electrolytes q24h
- Discuss need for further diagnostics with Genetics daily

Nutritional Therapy

Initial Nutritional Therapy:

- NPO
- Goal GIR ~8-10mg/kg/min (No TPN)
- Composition and rate of IV fluids per primary service to meet GIR goal
- Treat hyperglycemia with insulin
- DO NOT lower GIR

Subsequent Nutrition:

- Discuss NPO status daily
- Discuss TPN/IL daily
- ICU team is responsible setting enteral volume & total fluid goals
- Genetics will provide appropriate macronutrient goal and formula recipes

Goal to re-introduce protein within 24-48 hours

Medical Therapy

If NH_3 is rising despite optimal nutritional therapy, medical therapy and/or escalation to **High Risk Pathway** may be considered per Genetics recommendations ⇈

Medical Therapy Considerations

- Ammonul
- Arginine
- L-Carnitine
- Biotin
- Hydroxocobalamin
- Carbaglu

⇈ **Special Considerations**
NH_3 scavengers have significant side effects and are reserved for patients approaching high risk despite maximal nutritional support. Depending on the underlying reason for low risk NH_3, NH_3 scavengers may not lower NH3 and may cause further decompensation.

Risk Stratification Algorithm

High Risk Hyperammonemia

High Risk Hyperammonemia Care Management

Patient with High Risk Hyperammonemia

CRRT
- CRRT should be pursued in parallel to, and not delayed for, medical & nutritional therapies
- Mechanical clearance is life saving and improves neurological outcomes
- Early consultation with Nephrology and Interventional Radiology to facilitate rapid initiation of CRRT

Access & Supportive Care

DO NOT DELAY therapies for central access

- **Access:**
  - Dialysis catheter
  - 3 central venous lumens for fluids, metabolic meds, ICU/resuscitation meds
  - Arterial access
  - Use PIVs if needed while obtaining central access

Supportive Care

- Strongly consider intubation with cuffed ETT to control CO_2
- Consult Neurology/LTM
- Avoid steroids
- Normothermia with active temperature control
- Place Foley bladder catheter for careful quantification of urine output

Risk Stratification Algorithm

Low Risk Hyperammonemia

Labs

Initial Labs

High Priority
- Type & Cross
- ABG/Lactate/iCal
- NH_3
- CBC
- CMP/Mg/Phos
- β Hydroxybutyrate
- UA/urine ketones
- PAA, ACP, UOA-Genetics team to notify lab

Lower Priority
- CK, total Homocysteine
- DNA/RNA co-extraction

Goal is to obtain at least high priority labs prior to meds

Subsequent Labs:

- NH_3 q1h until step down CRRT
- Glucose q1-2h
- Gas & Electrolytes q4-6h (NH_3 scavengers can induce significant electrolyte and acid-base disturbance)

Nutritional Therapy

Initial Nutritional Therapy:
- NPO
- Goal GIR 10mg/kg/min (No TPN)
- Composition and rate of IV fluids per primary service to meet GIR goal
- Treat hyperglycemia with insulin
- DO NOT lower GIR

Subsequent Nutrition:
- Discuss NPO status daily
- Discuss TPN/IL daily
- ICU team is responsible setting enteral volume & total fluid goals
- Genetics will provide appropriate macronutrient goal and formula recipes

Goal to re-introduce protein within 24-48 hours

Medical Therapy

Initial Medication Orders:

Goal is to give the loading Ammonul dose within 90 minutes of order placement
- Ammonul/Arginine loading and maintenance
- L-Carnitine loading and maintenance
- Discuss with Genetics:
  - Biotin
  - Hydroxocobalamin
  - Carbaglu

Subsequent Medication Considerations:
- Discuss above medications daily
- Nephrology-Genetics to discuss continuation of Ammonul/Arginine while on CRRT
- Discuss renewal of Ammonul/ Arginine at least 6 hours prior to needing next bag

CRRT For Severe Hyperammonemia

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Inclusion Criteria

- NH_3 >400uM
- NH_3 <400uM but anticipated to rise based on trend
- Moderate or Severe Encephalopathy

Exclusion criteria

- Inability to obtain vascular access (generally, weight <2.5 kg)

NH_3 >400uM OR rapidly rising[v] OR moderate/severe* encephalopathy

- Urgent Nephrology Consult for CRRT
- NICU/ED Team huddle to prioritize transfer, consults and hand off
- Do NOT delay initiation of transfer to PICU while waiting for the repeat NH_3 level

Primary team to arrange **urgent transfer** to H2B PICU.
Goal is to transfer within 1 hour

Primary Team to consult IR for **urgent placement of dialysis catheter** [β]
Goal is catheter placement within 2 hours

1) For patients outside NCH main (including NCH Neonatal Network) utilize PCTC for urgent transfer straight to PICU
2) For patients at NCH main, Vocera "**Call PICU Admitting Fellow**" to initiate transfer to the PICU. PICU fellow will alert the Charge RN and resident team.
   - Upon confirmation of transfer to the PICU, Primary patient RN to give report to PICU RN (call **722-9022** and ask for the bedside nurse who will be taking the patient).
   - Primary Team to give verbal report to PICU provider team prior to transfer of patient

PICU team to coordinate urgent
High Dose CRRT
Goal is to initiate CRRT within 4 hours [§]

Moderate or Severe Encephalopathy:

- Attributable to hyperammonemia
- By Sarnat exam
- Including Seizures

[v] Rapidly Rising NH_3:

- Rising by more than 300uM in a few hours despite adequate therapy (per clinical discretion)

Special Considerations

- Infants should NOT be transferred to the NICU for central venous access (NICU team can place umbilical lines in PICU, if needed)
- If the patient is unstable for transfer to PICU and needs ECMO, prioritize stabilization on ECMO prior to transfer to PICU for CRRT

[β] Catheter Considerations

- Use 7F, 7 cm dual lumen catheter (Internal jugular [IJ] preferred, or femoral).
- Catheters are located in the NICU Pyxis, Dialysis Unit Pyxis (T6)

[§] Response to Medical Therapy while awaiting CRRT

Goal is to initiate CRRT within 4 hours. However, in response to medical & nutritional therapy, if the NH_3 is <400uM or falling rapidly, Genetic and Nephrology may jointly decide to defer CRRT.

Risk Stratification Algorithm

Diagnosis & Definition

1. **Treatment of severe hyperammonemia (> 400uM or moderate/severe encephalopathy due to hyperammonemia) is a medical emergency**. Patients with hyperammonemia are at high risk for irreversible severe neurologic impairment. This risk increases with the duration and level of hyperammonemia, so prompt reduction in NH_3 is critical.

2. Treatment of severe hyperammonemia will be a collaborative effort between Genetics, Nephrology, Critical Care, and Interventional Radiology (catheter placement).

3. Treatment includes medical management in all patients, and high-dose CRRT in a select group of patients. Decisions regarding CRRT will take into account the underlying diagnosis, patient stability, trend in NH_3 levels, and response to nutritional and nitrogen-scavenger therapy.

4. **In patients with severe hyperammonemia with potential need for CRRT will be transferred urgently to H2B PICU for care coordination**.

5. Patients identified to have severe hyperammonemia (NH_3 > 400uM) at an outside institution will be admitted directly to H2B PICU.

6. The NICU team will provide consultative care for neonates during H2B PICU admission. As soon as stable off CRRT, neonates will be transferred to the NICU for continued care.

Risk Stratification Algorithm | Low Risk Hyperammonemia | High Risk Hyperammonemia

Hyperammonemia Huddle

1. Primary team places STAT Nephrology consult and notifies Nephrology attending of Hyperammonemia huddle
2. Primary team places STAT Genetics consult and notifies Genetics attending of Hyperammonemia huddle
3. Primary team coordinates multidisciplinary care huddle that includes the Primary team, Nephrology and Genetics teams (attending physicians to be involved with respective team members)
4. Depending on situation, this can be achieved through In-person or virtual group meeting, or 3-way phone/vocera communication
5. Primary team should proceed with process for PICU transfer during interim (see pathway specifics).

Risk Stratification Algorithm

Medications

Sodium Benzoate-Sodium Phenylacetate 10% & Arginine 10% (Ammonul & Arginine)

- Utilize Ammonul Infusion Load + Maintenance Orderset in EPIC for dosing
- Loading dose given over 90-120 minutes
- Maintenance dose given over 24 hours
- Infusion via central line is preferred. May be given peripherally if emergently needed.
- Repeated boluses of Ammonul & Arginine are to be avoided
- Patients should be monitored for electrolyte and acid-base disturbance while on Ammonul & Arginine
- Administration of analogous oral drugs, such as sodium phenylbutyrate, should be stopped prior to Ammonul infusion (patients may arrive receiving such medicines on transport)
- Continuation of Ammonul & Arginine during CRRT is a joint decision between Genetics and Nephrology
- Medical necessity of maintenance doses of Ammonul & Arginine should be discussed with Genetics daily

Levocarnitine

- Loading: 50 mg/kg IV or enteral
- Maintenance: 100mg/kg/day IV or enteral, continuous or divided q6-8h

Biotin

- 10mg flat dose, enteral
- Discuss with genetics prior to ordering
- Genetics may recommend a one time dose or daily dosing based on the clinical scenario

Hydroxocobalamin

- 1mg flat dose, IM
- Discuss with genetics prior to ordering
- Genetics may recommend a one-time dose or daily dosing based on the clinical scenario

Carglumic acid (Carbaglu)

- 100-250mg/kg/day enteral, divided q6h
- Round each dose to the nearest 50mg
- Discuss with genetics prior to ordering

Risk Stratification Algorithm | Low Risk Hyperammonemia | High Risk Hyperammonemia

High Dose CRRT

1. PrisMax machine with HF20 (<12 kg)

2. Blood flow of 30-50 ml/min

3. Dialysate and replacement fluid at total clearance of 8000 ml/hr/1.73m2
   a. Dialysate rate at 7000 ml/hr/1.73m2
   b. Replacement fluid rate at 1000 mL/hr/1.73m2

4. Citrate anticoagulation per CRRT protocol
   a. Reduce citrate rate by 50% due to immaturity of neonatal liver function.
   b. Administer standard calcium rate.

5. Duration of high dose CRRT will be determined according to serum NH_3 levels and clinical status

6. Lab monitoring:
   a. Serum NH_3 - hourly
   b. Serum osmolality, renal function panel and magnesium – every 6 hours

7. When serum NH_3 falls < 200uM x 2 consecutive measurements, plan will be to provide **step-down CRRT** to prevent NH_3 rebound.
   - In select cases, Genetics and Nephrology may consider stopping CRRT and providing only medical management. This should only be considered in patients felt to have low risk of NH_3 rebound.

8. If CRRT is required for a patient on ECMO, the PrisMax machine will be placed in line with ECMO circuit with clearance rates as outlined in previous sections
   - CRRT must still take place in PICU (NICU does not have CRRT nursing staffing)

Risk Stratification Algorithm

CRRT Algorithm

Step-Down CRRT

1. When NH_3 is <200uM x 2 measurements, nephrology will modify CRRT orders to reduce clearance to 2000 ml/1.73m2/hr (50% dialysate, 50% replacement fluid)

2. Lab monitoring:
   a. Serum NH_3 - every 4 hours
   b. Serum osmolality, renal function panel and magnesium – every 8 hours

3. Step-down CRRT should be continued until NH_3 is <100uM x 1 measurement and Genetics team feels patient is likely to be stable on medical management only.

4. At completion of CRRT, lines should be clamped if the circuit was primed with blood (i.e., do NOT return the blood in the system to the patient to avoid acutely increasing the child's blood volume and providing a protein load from blood cells).

5. Continue monitoring NH_3 levels in PICU q 4 hours for 24 hours after CRRT discontinuation to assess for rebound.

Risk Stratification Algorithm

CRRT Algorithm

References

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3. Raina R, Bedoyan JK, Lichter-Konecki U, et al. Consensus guidelines for management of hyperammonaemia in paediatric patients receiving continuous kidney replacement therapy. *Nature Reviews Nephrology*. 2020;16(8):471-482. doi:10.1038/s41581-020-0267-8

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Risk Stratification Algorithm

Quality Measures

Goal:

- Initiate CRRT within **4 hours** of identification of severe hyperammonemia (NH_3 >400uM OR rapidly rising NH_3 OR moderate/severe encephalopathy).

Outcome Measure:

- Time to initiate CRRT

Process Measures:

- Time for transfer to the PICU (Goal is to transfer within 1 hour of identification of severe hyperammonemia)
- Time for dialysis catheter placement (Goal is catheter placement within 2 hours of identification of severe hyperammonemia)
- Time from order to administration for Ammonul (Goal is to give the loading Ammonul dose within 90 minutes of order placement)

Risk Stratification Algorithm

Team & Process

Pathway Development Team

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Clinical Pathway Development

This clinical pathway was developed using the process described in the NCH Clinical Pathway Development Manual Version 6, 2022. Clinical Pathways at Nationwide Children's Hospital (NCH) are standards which provide general guidance to clinicians. Patient choice, clinician judgment, and other relevant factors in diagnosing and treating patients remain central to the selection of diagnostic tests and therapy. The ordering provider assumes all risks associates with care decisions. NCH assumes no responsibility for any adverse consequences, errors, or omissions that may arise from the use or reliance on these guidelines. NCH's clinical pathways are reviewed periodically for consistency with new evidence; however, new developments may not be represented, and NCH makes no guarantees, representations, or warranties with respect to the information provided in this clinical pathway.

For more information about our pathways and program please contact:
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Risk Stratification Algorithm

Appendix

+NEUROLOGIC EXAM (Modified Sarnat) CERTIFICATION FORM

- **Seizures?** **Y N**

See definitions for Neurologic Examination on page 2

CATEGORY N=6	SIGNS OF HIE IN EACH CATEGORY		
	NORMAL/MILD HIE	MODERATE HIE	SEVERE HIE
1. LEVEL OF CONSCIOUSNESS	1	2 = Lethargic	3 = Stupor/coma
2. SPONTANEOUS ACTIVITY	1	2 = Decreased activity	3 = No activity
3. POSTURE	1	2 = Distal flexion, complete extension	3 = Decerebrate
4. TONE	1	2a = Hypotonia (focal or general) 2b = Hypertonia	3a = Flaccid 3b = Rigid
5. PRIMITIVE REFLEXES			
Suck	1	2 = Weak or has bite	3 = Absent
Moro	1	2 = Incomplete	3 = Absent
6. AUTONOMIC SYSTEM			
Pupils	1	2 = Constricted	3 = Deviation/dilated/non-reactive to light
Heart rate	1	2 = Bradycardia	3 = Variable HR
Respiration	1	2 = Periodic breathing	3 = Apnea or requires ventilator 3a=on vent with spontaneous breaths 3b=on vent without spontaneous breaths

- CATEGORY — SIGNS OF HIE IN CATEGORY

1. Level of Consciousness ____
2. Spontaneous Activity ____
3. Posture ____
4. Tone ____ ____ (Note a or b)
5. Primitive Reflexes (Suck or Moro, code highest level) ____
6. Autonomic System (Pupils, Heart Rate or Respirations, code highest level) ____
   If vent, code 3a or 3b

- **Is the infant sedated/paralyzed?** **Y N**

Total # Categories should be NO MORE THAN 6 (Count Only the Highest Level in each sign)

The level of encephalopathy will be assigned based on which level of signs (moderate or severe) predominates among the 6 categories. If moderate and severe signs are equally distributed, the designation is then based on the highest level in Category #1: The level of consciousness.

- **Signs of moderate or severe HIE in at least 3 of the 6 categories above?** **Y N** (circle one)

  If yes,* what is the Level of HIE?** **MODERATE** ***or **SEVERE** (circle one)

Name of examiner_____**Exam date & time:** ____/____/____ **at** __ __:__ __

DEFINITIONS FOR NEUROLOGIC EXAMINATION

• Did the infant have documented seizures? Record 'Y" if seizures have been diagnosed or if the infant's chart or verbal summary included the diagnosis of seizures. Seizures can be subtle such as ocular deviation, sucking and lip smacking movements, swimming or "rowing" or "bicycling" movements of limbs. They can be tonic/clonic, localized, multifocal or generalized.

• Does the infant have signs of moderate or severe encephalopathy in > 3 categories (3 of the 6 categories) on the neurologic examination?

1. Level of consciousness: Code "1" if infant arouses to wakefulness, responds appropriately and promptly to external stimuli, or appears hyperalert or inconsolable/irritable, Code "2" if lethargic delayed but complete response to external stimuli (start with mild stimuli first then proceed to more noxious stimuli. Code "3" if stupor/coma (infant is not arousable and is non-responsive to external stimuli. may have a delayed but incomplete response to stimuli).

2. Spontaneous activity: Code "1" if infant is active. Code "2" if activity is decreased. Code "3" if no activity.
Spontaneous Activity Notes: if infant is, sedated clinical judgment has to be used to decide whether the examination is reliable. Paralysis will preclude a meaningful exam.

3. Posture: Code "1" if infant is moving around and does not maintain only one posture, should have flexion or lower extremity at hip and/or knees Code "2" if strong distal flexion, complete extension, or "frog-legged" position. Code "3" if decerebrate with or without stimulation.

Posture Notes: If posture is abnormal, but does not fit 2 or 3, code as 2.

4. Tone: Code "1" if tone is normal (resistance to passive motion). Code "2a" if hypotonic or floppy, either focal or generalized. Code "2b" if hypertonic or increased tone or tension of extremities or trunk upon passive movement. Code "3a" if infant lies like a rag doll with no tone at all (flaccid). Code "3b" if the infant is rigid with extreme stiffness or inflexibility of extremities or trunk upon passive movement.

Tone Notes: Evaluate extremities, trunk and neck tone and make clinical judgment of tone based on tone in these areas. If responses differ in multiple areas, base code on the lower extremity.

5. Primitive reflexes: (remember: count only one sign in this category—the highest level of HIE)

□ Suck: Code "1" if infant vigorously sucks your finger inserted in mouth or around the tube if intubated. Code "2" if suck is weak or infant has bite. Code "3" is suck is absent.

□ Moro: Code "1" if Moro is normal – extension of limbs opening of hands, extension with abduction of UE (flexion of the UE has been removed) Code "2" if incomplete. Code "3" if absent.

Moro Notes: If neonate has fracture of clavicle or brachial plexus injury, evaluate other extremity. Moro has to be done by gently raising and lowering the head when infant is intubated

6. Autonomic system: (remember: count only one sign in this category—the highest level of HIE)

□ Pupils: Code "1" if normal in size and reactive to light. Code "2" if constricted and reacting to light. Code "3" if skew deviation of eyes, pupils are dilated or non-reactive to light.

Pupil Notes: If pupils asymmetric, assign 3. Pupils are difficult to assess in the newborn infant with edema of eyelids---you will need to gently separate the eyelids while a second person shines light.

□ Heart rate: Code "1" if normal heart rate > 100/minute consistently or tachycardia. Code "2" if bradycardia (< 100/minute) with only occasional increases to > 120/minute. Code "3" if heart rate is not constant and varies widely between <100 and > 120

Heart Rate Notes: Heart rate should be evaluated based on documented rate over the previous min/hrs. Do not code heart rate if cooling has been initiated.

□ Respiration: Code "1" if breathing spontaneously. Code "2" if periodic breathing associated with desaturation events (< 80%). Code "3" if apnea or requiring ventilator support.

Risk Stratification Algorithm