

Committee of Pediatric Emergency Medicine (CoPEM) Minutes April 14, 2022 9 a.m – 11 a.m. *Virtual Only*

Join Microsoft Teams Meeting

+1 248-509-0316 Conference ID: 680 069 647#

Attendance: Dr. Samantha Mishra, Nicole Babb, Dr. Edwards, Tom Frascone, Laura Rowen, Brandon Hausbeck, Lauren Korte, Justin Severs, Ashley Smith, Jessica Gould, Katie Puskar, Andrea Abbas, Steve Vernon, Dr. Noel, Bruce Trevithick, Rob Warnemuende, Chris Haney, Naomi Ishioka, Krisy Kuhl, Alissa Morrison, Terrie Godde, Vincent Cervantes, Heidi Hilliard, Amy Chapman, Ryan Dennett, Theresa Jenkins, Jessica Myers, Cheryl Moore, Wayne Snyder.

Call to Order: The meeting was called to order at 9:01 a.m. by Dr. Edwards.

Review of Minutes: Motion to accept the minutes and agenda (Gould, Korte). Approved.

1. Updates

- a. EMS for Children program updates
 - EMS for Children Survey (Dr. Mishra)
 - Dr. Mishra showed the map and went over patterns and participation (response map attached to the minutes). This will be an annual survey.
 The UP has been the most robust participant. Increased participation in areas where MCAs were supportive. Data should be available late summer.
 - Response rate map for the EMSC annual survey 2022
 - a. This is map is attached to these minutes.
 - EMSC Fellows and Scholars Program (Lisa Hill)
 - No update today.
 - PECC Workforce Development Collaborative: Phase 2 Improvement Project (PWDC)
 - Dr. Mishra provided an update. This is an improvement project that was applied for. Last year, there was a Midwest Symposium held and feedback from that was used to apply for this. Dr. Mishra discussed. The goal is to hold a two-day event for champions. If you wish to be a speaker at the next symposium, please let Dr. Mishra know.
 - https://emscimprovement.center/collaboratives/pwdc/
- b. FAN Updates
 - CarterKits[™] (Brandon Hausbeck, Justin Severs)
 - This month is Autism Acceptance Month.
 - Kits will be placed in 21 counties in Northern Michigan placed through a cooperative. All counties north of M55 will have a Carter Kit available at a variety of different locations.



- North Carolina's EMSC program has reached out to obtain kits.
- The training program is in the final stages. They have identified the first partner to do a trial run. A statewide roll out will happen after testing is complete.
- o They will be at the EMS Expo the first week of May with a table.
- c. Special Project Updates
 - Pediatric Dose Optimization for Seizures in Emergency Medical Services (PediDOSE) Study (Dr. Noel)
 - Dr. Noel introduced the study and gave a Power Point presentation to the group. That presentation is attached to these minutes. Dr. Mishra asked Dr. Noel to please keep CoPEM up to date on the project and offered support. Future expansion was discussed. If this happens, it will go as a statewide protocol through QATF.
 - Dr. Noel requested assistance with sharing the PediDOSE survey: https://redcap.utahdcc.org/redcap/surveys/index.php?s=HPHKPDJM39
 - Child Safety Network (CSN) Collaborative with MDHHS Infant Safe Sleep (Dr. Mishra)
 - They have been working on streamlining the process of providing this education. Online registration is functional and a toolkit for providers is being finalized. Updates will continue to be provided as this goes through development.
 - Introduce Alissa Morrison
 - Dr. Mishra introduced Alissa, who is the EMS Traffic Crash Data Quality Specialist. This is a grant funded position. Alissa went over what she is working on to improve the quality of this data set and how it may relate to pediatrics in the future.
- d. Education Updates
 - EMS pediatric education (Terrie Godde and Dr. Mishra)
 - Terrie reported a quarterly webinar will begin to be provided on Pediatrics. They will do one in each required category each year.
 - A virtual Pediatric Medication Administration credit will be offered monthly as well.
 - Engagement of EMS Regional Coordinators and EMS PECCs will begin to increase availability of pediatric education across the State.
 - Guardian CME (Geoff Lassers)
 - No update today.
 - Pediatric Champion Engagement
 - Pediatric Champion Office hours-NEW
 - a. Dr. Mishra and Chris Haney will be working on getting this going to support the PECs on a local and regional level and involve collaboration. Chris spoke about the plans. Updates will continue to be provided as this is developed and launched. Chris can be reached at chaney@thems.org or 248-459-7178.

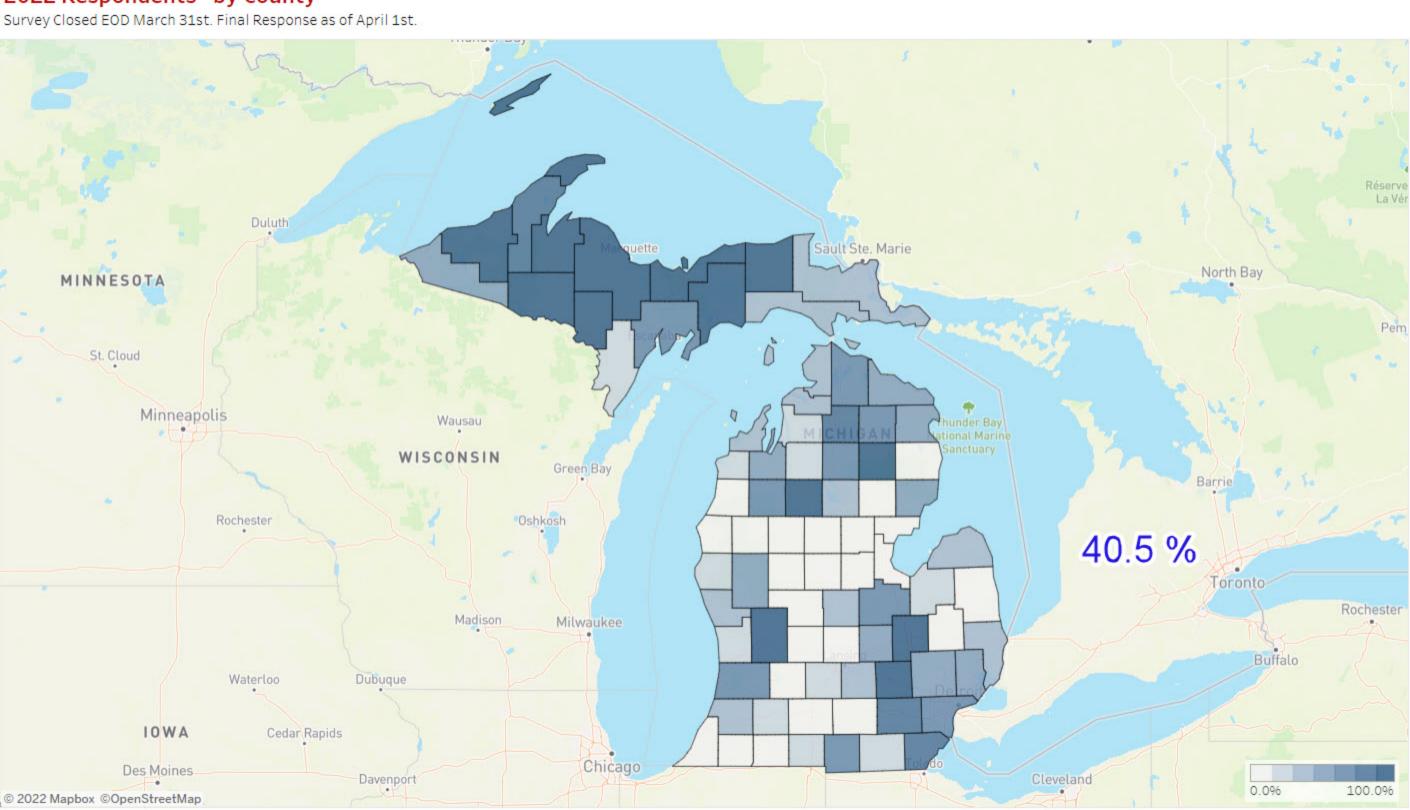


- ED office hours (Lauren Korte)
 - a. These are going well and have small groups that they are working on growing. Lauren discussed some of the topics.
- o Midwest PECC symposium (Dr. Mishra)
 - a. See PWDC update above.
- e. Collaboration and interdisciplinary updates
 - DEPR Division of Emergency Preparedness and Response (Lauren Korte, Amber Pitts)
 - ASPR COE ASPR Pediatric Centers of Excellence Collaborative
 - a. Lauren gave a brief update on this project.
 - o PCCC Pediatric Care Coordination Center
 - a. Lauren gave brief update on this project. This is still in concept form and work continues.
 - o New Regional Pediatric Pandemic Network
 - a. https://emscimprovement.center/news/new-regional-pediatric-pandemic-network/
 - Trauma Update (Theresa Jenkins, Cheryl Moore)
 - Theresa gave an update. The American College of Surgeons has released new guidance that will go in effect late next year. There are more requirements for pediatrics than in the past. They just had a Trauma Sprint to educate on translating this to Trauma and Theresa is developing a tool kit to assist.
 - Injury Prevention Update Laura Rowen
 - Pediatric vehicular heat stroke
 - a. Michigan has not had any of these deaths since 2014. Laura spoke about the success of the collaboration in getting information out about awareness. Work continues with NHTSA to move the kickoff of the campaign earlier than July. A governor's proclamation has been requested, as well.
 - Virtual Parent Conference Kristen Thompson, DHHS ThompsonK23@michigan.gov
 - a. Tuesday, June 14, 6:30-8:30 pm
 - b. Wednesday, June 15, 9:00 11:00 am
 - c. Wednesday, June 28, 9:00-11:00 am
 - MTC's 10th Annual Pediatric Trauma Conference June 8, Eagle Eye Banquet Center, 15500 Chandler Rd #3, Bath Twp, MI 48808
 - <u>Safe States 2022 Injury & Violence Prevention Conference "Destination Safer States"</u> Aug 31-Sept 2, Wyndham Grand Orlando Resort Bonnet Creek in Orlando, FL, SAVE-the-DATE
 <u>https://www.safestates.org/page/AnnualConference</u>
 - MTC 2022 Injury Prevention Symposium Oct 27, Park Place Hotel and Conference Center, 300 E State St, Traverse City



- a. MTC will most likely have a community event the day before; Oct. 26
- O 2nd Annual MSP Safety Day MSP Headquarters in Dimondale. This outdoor event will be free to the public and is planned for August 9, 2022, with a rain date of August 10. Each partner/volunteer organization will have space to set up a tent/table to display the informational items on staying safe, interact with the attendees, and hand out physical material regarding safety pertaining to your specific area of expertise. For more information, please contact Sgt. Martin Miller at millerm36@michigan.gov or 616-312-5137 as soon as possible. If there are other organizations that you think would benefit by attending this event and spreading the aspect of staying safe, please feel free to pass along this information and have that organization contact Sgt. Miller.
- Additional Items from Attendees-All
 - None.
- Adjourn: The meeting was adjourned at 10:10 (Trevithick, Haney).
- Next Meeting-Thursday, July 14, 2022, at 9 a.m.

2022 Respondents - by County



PediDOSE

Pediatric Dose Optimization for Seizures in EMS





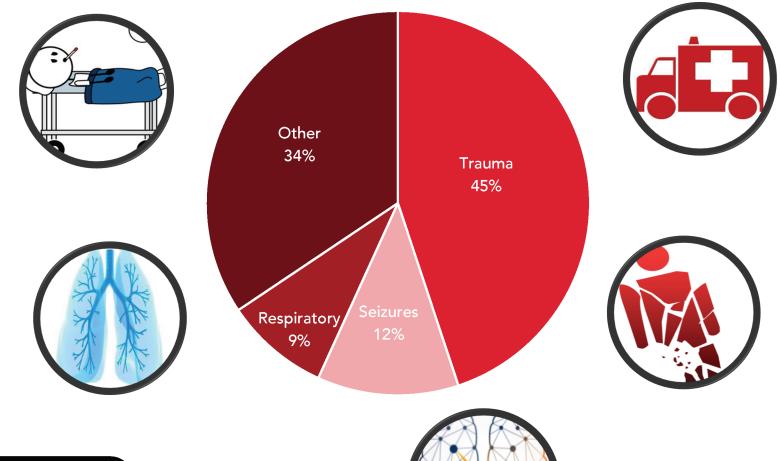






Pediatric Dose **Optimization for** Seizures in **EMS**

Pediatric EMS Transports







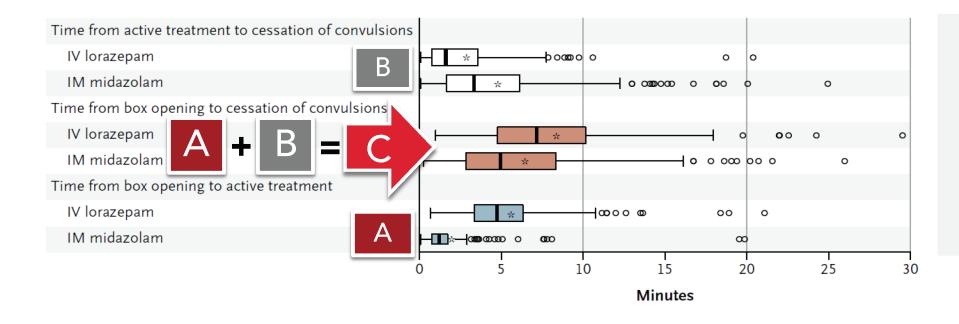
Richard J. *CJEM*. 2006; 8(1)

Evidence-Based Seizure Guidelines

| DO | DON'T | |
|---|--|--|
| Check blood glucose | Give rectal medication | |
| Give dextrose IV/IO (D10, 5ml/kg) or glucagon IM for hypoglycemia (<60 mg/dL) | Place an IV/IO initially | |
| Give IM/IN benzodiazepines as first line treatment (midazolam 0.2 mg/kg) | Require medical control for the 1st two doses of medication (apnea risk after two doses) | PREHOSPITAL EMERGENCY CARE OCIOLIANIA OF DE NATIONAL AND |
| IV/IO benzodiazepines (0.1 mg/kg) can be given for subsequent doses | | Secretary of the control of the cont |

Shah MI. Prehospital Emerg Care. 2014; 18(1)

RAMPART: IM More Effective Than IV



% Seizing on ED Arrival

IM midazolam: 26%

• IV lorazepam: 36%

 Absolute difference: 10% (95% Cl, 4.0-16.1, p<0.001)



Silbergleit R. *NEJM*. 2012; 366(7)

Multi-Site Need for Improvement

Paramedic Adherence After a Pediatric Seizure Protocol Change

50% → 70%

61% → 71%

61% ~ 56%



Preferred Routes



Received Midazolam



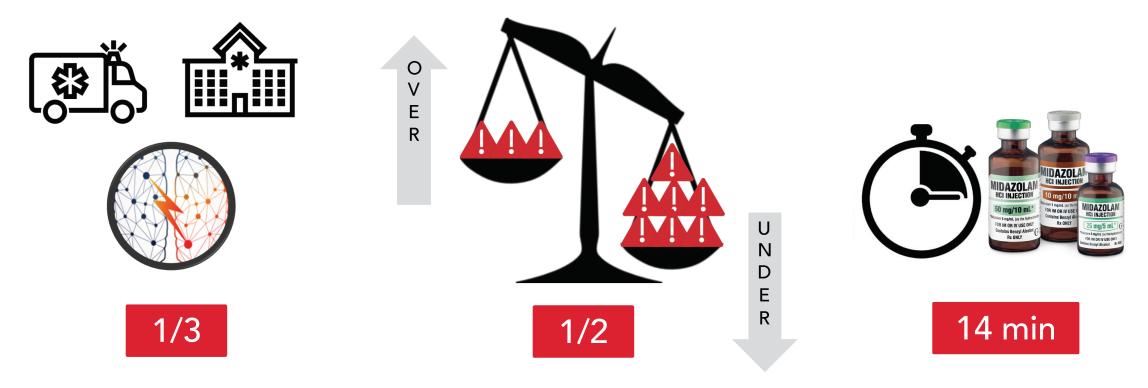
Correct Dose Given



Shah MI. Prehospital Emergency Care. 2020

Multi-Site Need for Improvement

Opportunities to Optimize Pediatric Seizure Management





Shah MI. Prehospital Emergency Care. 2020

Dosing Problem





Length-based tape to eliminate weight







STEP 1

EMS arrives on scene

STEP 2

Determine patient's weight

STEP 3

Calculate the dose of medication to deliver to the patient

STEP 1

What is the route?

X kg

STEP 2

What is the dose in mg for that route?

X mg

mg/kg

STEP 3

What is the quantity in mL to administer?

X ml

mg/ml conversion



System Changes are Required

Paramedic Identified Barriers and Enablers for Seizure Management



System Enablers



System Barriers



Paramedic Solutions



Carey JM. Prehospital Emergency Care. 2019

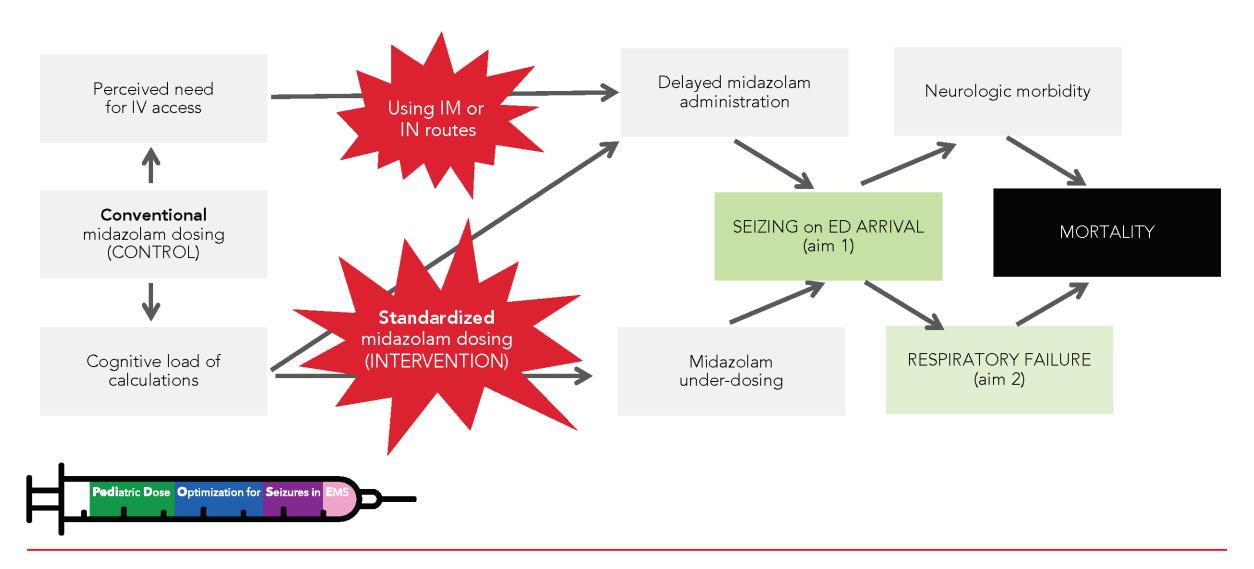
Standardized Dosing

Save time by using the chart below. Paramedics should not calculate the dosage.



| AGE | 0-5 mo | 6-16 mo | 17 mo-5 yrs | 6–11 yrs | 12–13 yrs |
|----------|---------|---------|-------------|----------|-----------|
| QUANTITY | Exclude | 0.25 mL | 0.5 mL | 1 mL | 2 mL |
| DOSE | Exclude | 1.25 mg | 2.5 mg 5 mg | | 10 mg |

PediDOSE Conceptual Model



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Aim 1 (Effectiveness)

Aim

To <u>compare</u> the impact of standardized EMS midazolam dosing relative to conventional dosing on pediatric **seizure cessation** upon ED arrival

Hypothesis

Standardized EMS midazolam dosing (of approximately 0.2 mg/kg IN/IM, based on age and/or length-based estimates for weight) is associated with lower frequency of active seizures upon ED arrival relative to conventional dosing with calculations from estimated weights



Aim 2 (Safety)

Aim

To <u>compare</u> the frequency of respiratory failure after implementation of standardized EMS midazolam dosing for pediatric seizures

Hypothesis

Standardized EMS midazolam dosing does not increase respiratory failure rates when compared to conventional dosing with current practice



Inclusion Criteria + Age De-Escalation

- 6 month 13 year old patients who are actively seizing while in the care of a paramedic (regardless of seizure type/duration)
 - Transported by a participating EMS agency to participating EDs

| Age | De-Escalation | When Added |
|--------------|---------------|------------|
| 2-13 years | No | All Years |
| 17-23 months | Yes | In Year 2 |
| 12-16 months | Yes | In Year 3 |
| 6-11 months | Yes | In Year 4 |



Exclusion Criteria

Excluded from the study

- Benzodiazepine allergy
- Pregnancy (known/presumed)
- Severe growth restriction (paramedic-determined)

Excluded from analysis

- Traumatic head injury in past 24 hours
- History of psychogenic, non-epileptic seizures
- Ventilator dependence
- Ingestion of a toxic substance in past 24 hours with potential to cause seizures
- Absence seizures during EMS/ED care



Protection of Human Subjects

Emergency exception from informed consent (EFIC)

- Community consultation may vary based on site, but will include interactive components to solicit feedback
- Hospital-based research coordinator will notify the patient's legally authorized representative about enrollment as soon as feasible after arrival to the hospital

Single IRB through the University of Utah

Food and Drug Administration (FDA)

- Investigational New Drug (IND) application for midazolam, since this is an EFIC study
- Investigational Device Exemption (IDE) for the rapid response electroencephalogram (RR-EEG)

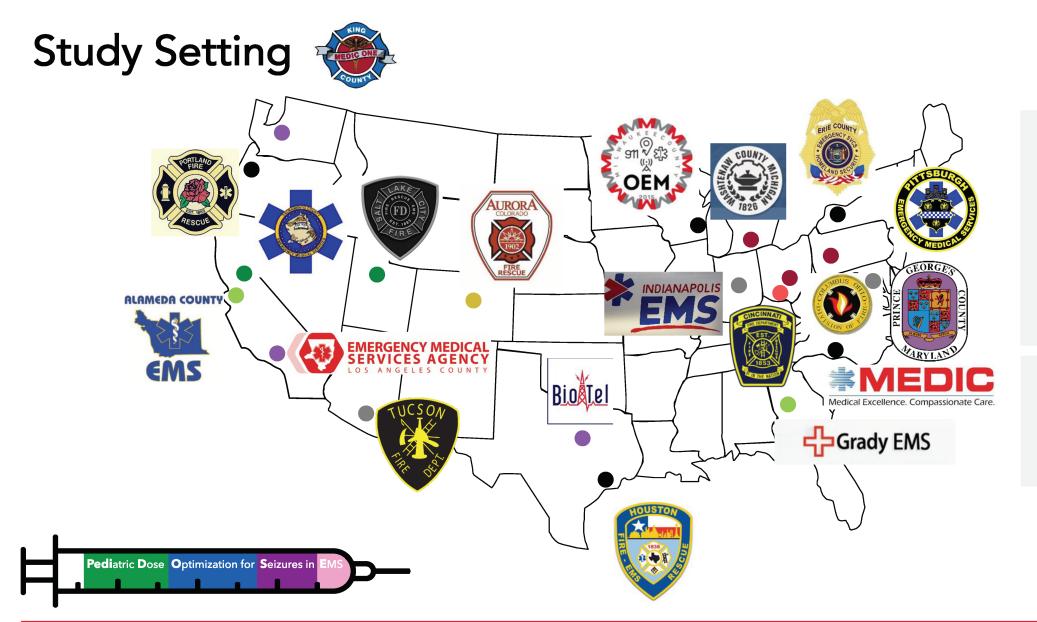
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Data Safety Monitoring

DSMB role

- Approve protocol
- Review interim data
- Advise investigators regarding safety, validity, and scientific merit of the study
- Monitor subject accrual, study protocol adherence, data quality, and adverse events

A data safety monitoring board (DSMB) of relevant subject matter experts will periodically meet



- = SPARC Node
- = GLEMSCRN Node
- = PEM-NEWS Node
- = WPEMR Node
- = CHaMP Node (or affiliate)
- = Other
- = PRIME Node
- = HOMERUN Node

Study Roles

Core Investigation Team

Principal Investigator Manish Shah, MD, MS

Clinical Trials Experts

James Chamberlain, MD (Pediatric emergency medicine, seizures) Henry Wang, MD (EMS)

Exception From Informed Consent Expert

Brooke Lerner, PhD

Pediatric Epileptologists

Lindsey Morgan, MD James Riviello, MD Rana Said, MD Joseph Sullivan, MD

Data Coordinating Center (DCC) Site Lead
John VanBuren, PhD

20 Enrolling Sites

Lead Site Investigator (Hospital >> EMS)
Additional Investigator (EMS >> Hospital)

Research Coordinator

Neurology Liaison*

Critical Care Liaison*

IT Contact for Ceribell*

Data Coordinating Center (DCC)

Project Manager

Kammy Jacobsen

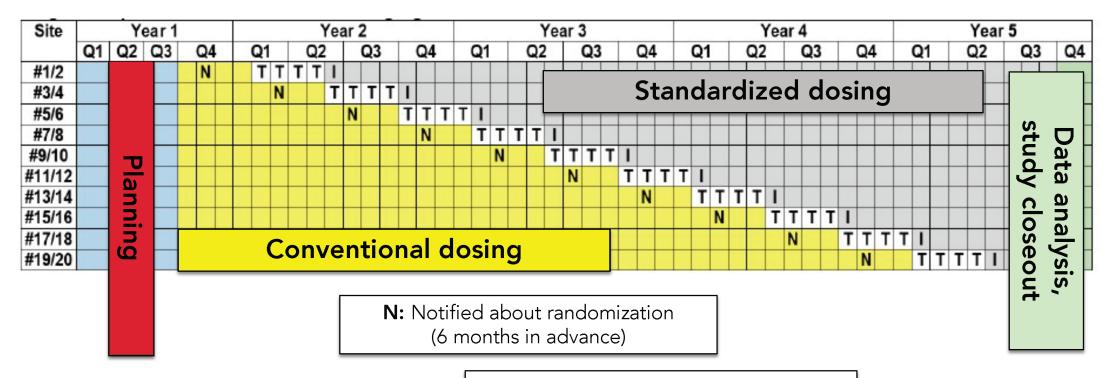
Data Manager

Casey Evans

Statistician

Emily Startup, MS

Stepped-wedge Design

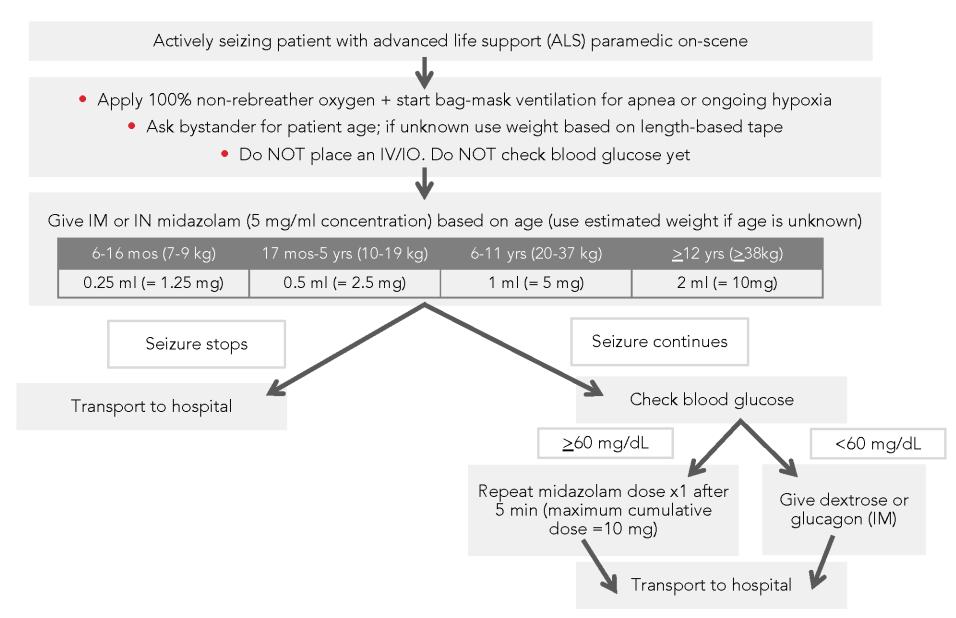


T: Training prior to standardized dosing (up to 4 months in advance)

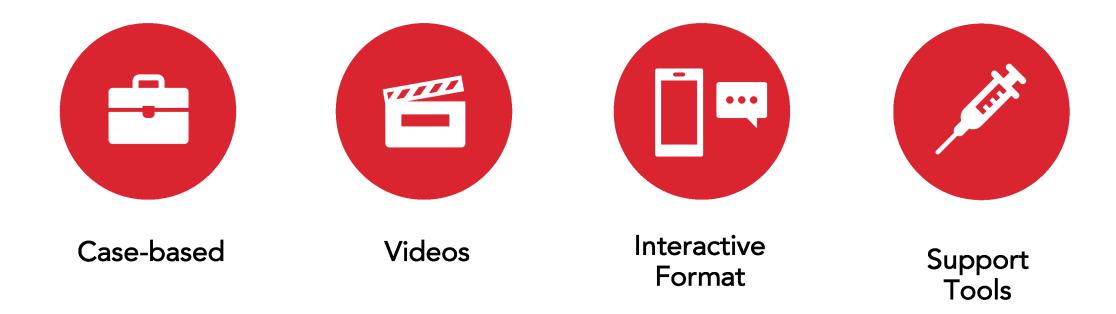


I: Implementation go-live for standardized dosing protocol for the EMS system

EMS Seizure Protocol



Training to Maximize Adherence





Study Outcomes

Primary

Seizing on ED arrival

Exploratory

- Time to seizure cessation in the ED
- Dose/route adherence

Secondary

- Respiratory failure
- Time to first midazolam administration

Safety

- Life-threatening hypotension
- Life-threatening cardiac arrhythmia
- Depressed level of consciousness

Paramedic Self-Report



Paramedic Reported Data

- Incident run number
- Name
- Date of birth
- Destination
- Route of 1st mzidazolam
- Amount of 1st midazolam
- Glasgow Coma Score
- Paramedic(s) names
- Arrhythmia present
- Respiratory failure
- Bystander benzodiazepines
- Seizing on ED arrival
- Method of weight estimation
- New vs. h/o prior seizures
- Single vs. recurrent seizures







Times

- Arrival to scene
- 1st midazolam given
- ED arrival

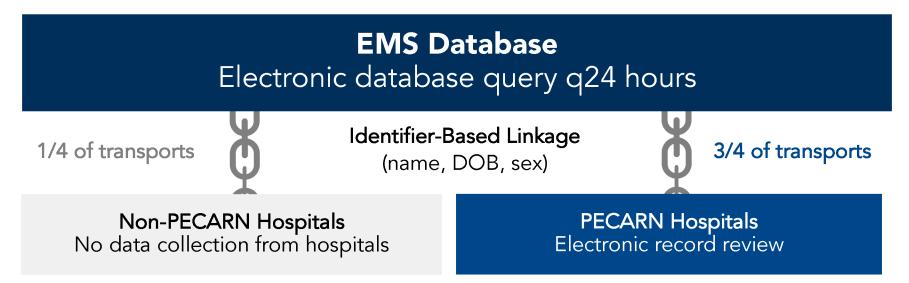
Data Sources

BLACK: also in EMS database

RED: must be captured by verbal paramedic report

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Data Collection



Hospital data to be collected within 2 weeks

- Patient demographics
- ED vital signs, GCS, glucose and weight
 - Seizure medications given
 - ED and hospital discharge times
 - Hospital admission and unit
- Seizures: on ED arrival and recurrence (RR-EEG)
- Respiratory failure: within 30 minutes of ED arrival

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Reach out to us

PediDOSE Principal Investigator

Stacey Noel, M.D.

% 734-936-7715

Research Coordinators

- Clarice Kruse
- Vincent Cervantes





REGISTER NOW!

Michigan Department of Health and Human Services
Virtual Baby Fair



Are you a new or expecting parent? Join us for a virtual baby fair to learn how to be better prepared for your best adventure yet! Learn about resources available to you, important information, and ask questions to experts.

Tuesday, June 14, 2022 from 6:30-8:30 p.m. Wednesday, June 15, 2022 from 9:00-11:00 a.m. Tuesday, June 28, 2022 from 9:00-11:00 a.m.

Registration:

https://mdhhsvirtualbabyfairsummer2022.eventbrite.com

Participating MDHHS Programs:

- Newborn Screening
- BioTrust for Health
- Infant Safe Sleep
- Childhood Lead Poisoning Prevention Program
- Women, Infants, & Children (WIC)
- Vital Records
- Unintentional Injury Prevention

- Immunizations
- Early Hearing Detection and Intervention
- Maternal Infant Health Program
- Michigan Home Visiting Initiative
- Birth Defects Education and Outreach
- Breastfeeding Support
- Children's Special Healthcare Services
- Eat Safe Fish







For more information please contact Kristen Thompson <u>ThompsonK23@michigan.gov</u> 517-284-4992

