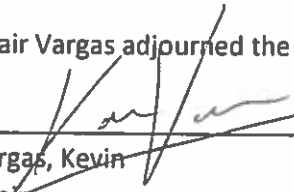


Aurora Immigrant & Refugee Commission
Tuesday, May 9, 2022 5:30pm
Virtual Meeting (Zoom)

Commissioners Present: Linda Skelley; Jackie Zvejniecks; Kevin Vargas; Salvador Cazun;
Lizzy Beachland; Mark Wideman
Commissioners Excused: Samuel Gebremichael
Commissioners Absent: None
Other present: Kathleen Adelgais; Rod Weber
Staff Present: Minsoo Song

- 1) Meeting was called to order at 5:40pm by Chair Kevin Vargas
- 2) OIIA Update:
 - 2020 Global Fest will be in-person event on Saturday, August 20, 2022.
 - Ms. Song asked AIRC members to share 2022 Global Fest news with their network.
- 3) Kathleen Adelgais with Children's Hospital and Deputy Chief Rod Weber with Aurora Fire Rescue made a special presentation on Pediatric Dose Optimization for Seizures in EMS (See attached ppt).
 - Dr. Adelgais shared that this
 - Commissioner Beachland asked if the group reached out to only children with existing condition with seizure
 - Commissioner Skelly asked what kind of interpretation service will be provided and Dr. Adelgais said that each paramedic officer will carry the device that provides interpretation and Deputy Chief Weber confirmed that AFR staff carry the device to provide interpretation.
 - Commissioner Skelly asked if they are connected with Community Health Clinic that works closely with local immigrant and refugee community. Dr. Adelgais said that they will reach out to local clinic. Commissioner Skelly will provide contact information from those community health clinics.
- 4) 2022 Global Fest
 - Chair Vargas encouraged AIRC members to share 2022 Global Fest information within their own network.
- 5) Meet & Greet Planning
 - Chair Vargas will be sending out email to finalize the meeting date
- 6) AIRC Goals
 - Chair Vargas suggested to revisit AIRC's goals for 2022 and asked AIRC members to identify the area where each member want to participate by next meeting
- 7) Member update
 - Commissioner Beachland is expecting a baby sometime in mid-June and hopes to attend 2022 Global Fest. Commissioner Beachland encouraged commission members to visit local business owned by immigrant and refugee family and send her information for social media promotion
 - Chair Vargas shared that VEC will be hosting Vaccination clinic providing \$100 stipend to Arapahoe County residents

8) Chair Vargas adjourned the meeting at 6:38pm



Vargas, Kevin
Chair

Pediatric Dose Optimization for Seizures in EMS

Kathleen Adelgais, MD
MPH
University of Colorado School of
Medicine
Children's Hospital Colorado
Emergency Department



Thank you

for taking time
out of your day to
discuss your ideas

OUR GOAL

Is to hear your thoughts
about research taking
place in your community
and research involving
emergencies



We are asking you for your thoughts
because you are a member of the
community where PediDOSE will take
place



Any child is at risk for seizure



The Purpose of the Presentation

- The PediDOSE study looks at how paramedics respond to seizures for children
- We will determine if age-based dosing calculations can improve seizure care
- You will learn more about the study and emergency research
- You are being asked for feedback on the study as an important stakeholder in the community of Aurora, CO



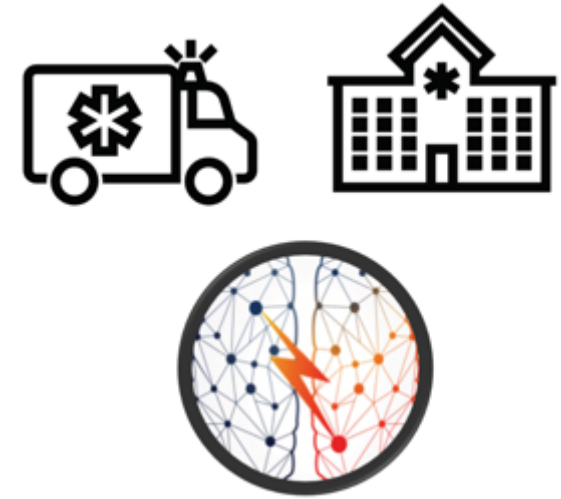
Ground Rules

- You are the expert, and we are here to learn from you
- There are no right or wrong answers



Seizures in Children

- The brain normally sends electrical signals to other parts of the body to control movements and life-sustaining functions such as breathing
- During a seizure, the brain sends abnormal electrical signals that can make a person
 - Become unresponsive
 - Cause their body to shake or stiffen up
 - Make their eyes move abnormally
 - Even result in difficulty breathing



Seizure Treatment in Ambulances

The PediDOSE study goal is to decrease the number of children arriving at hospitals having a seizure

- Most ambulances use midazolam
- Benzodiazepines can affect breathing
- The best method for selecting the right dose is unknown
- The study compares two methods
 1. The current method that uses calculations
 2. A standardized method based on age
- Medication will be given with a nasal spray or a shot (not an IV)

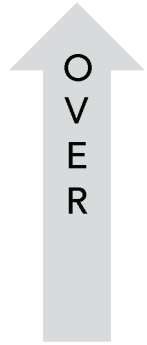


Multi-Site Need for Improvement

Opportunities to Optimize Pediatric Seizure Management



1/3



1/2



14 min



Shah MI. *Prehospital Emergency Care*. 2020

Dosing Problem



STEP 1

EMS arrives on scene



STEP 2

Determine patient's weight



STEP 3

Calculate the dose of medication to deliver to the patient

SLOW



Length-based tape to eliminate weight



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



Standardized Dosing

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



STEP 1

EMS arrives
on scene



STEP 2

Determine patient's
age

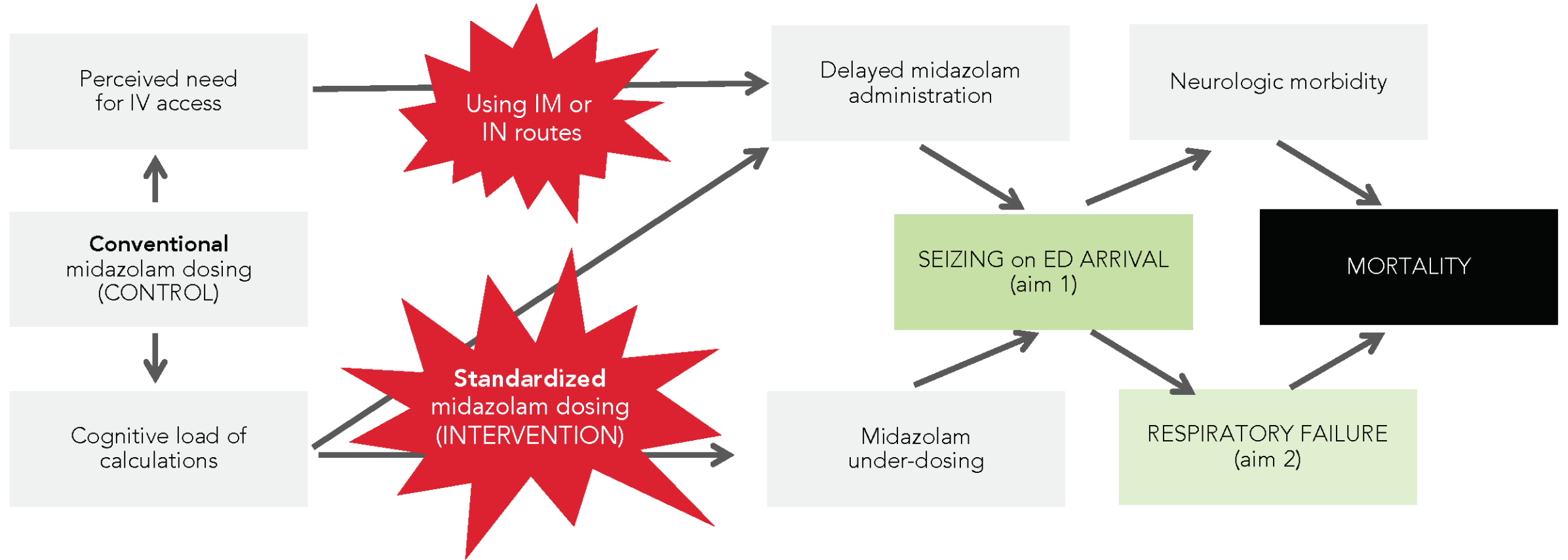


STEP 3

Administer the dose to give
in mL via the IN or IM route

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



Aim 1 (Effectiveness)

Aim

To compare 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 compare 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



Study Procedures

- AFR/Falck notifies CHCO* of “PediDOSE” patient
- On arrival if patient still appears alerted, fast EEG (Ceribell) will be applied
- ED routine care of patient
- EMS provider asked to link to a survey to provide self-report data



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



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



Data Safety Monitoring

DSMB role

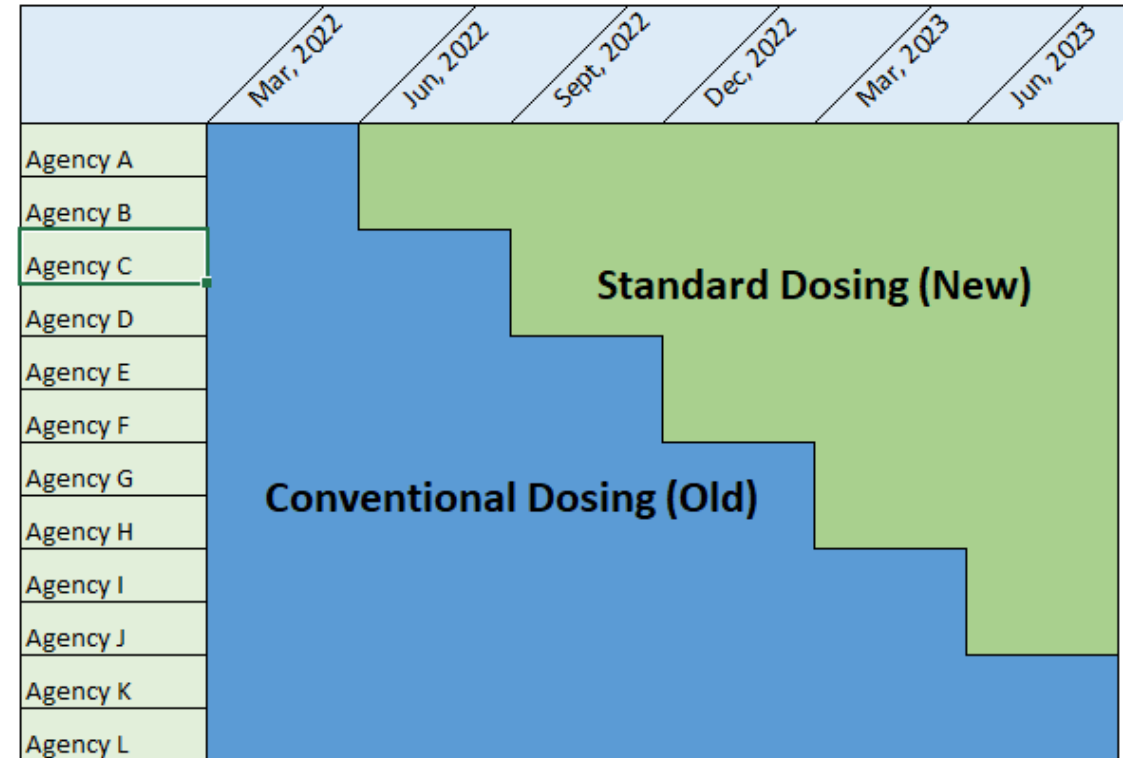
- Approve protocol
- Review interim data
- Advise investigators regarding safety, validity, and scientific merit of the study
- Monitor subject accrual, study protocol adherence, data quality, and adverse events

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



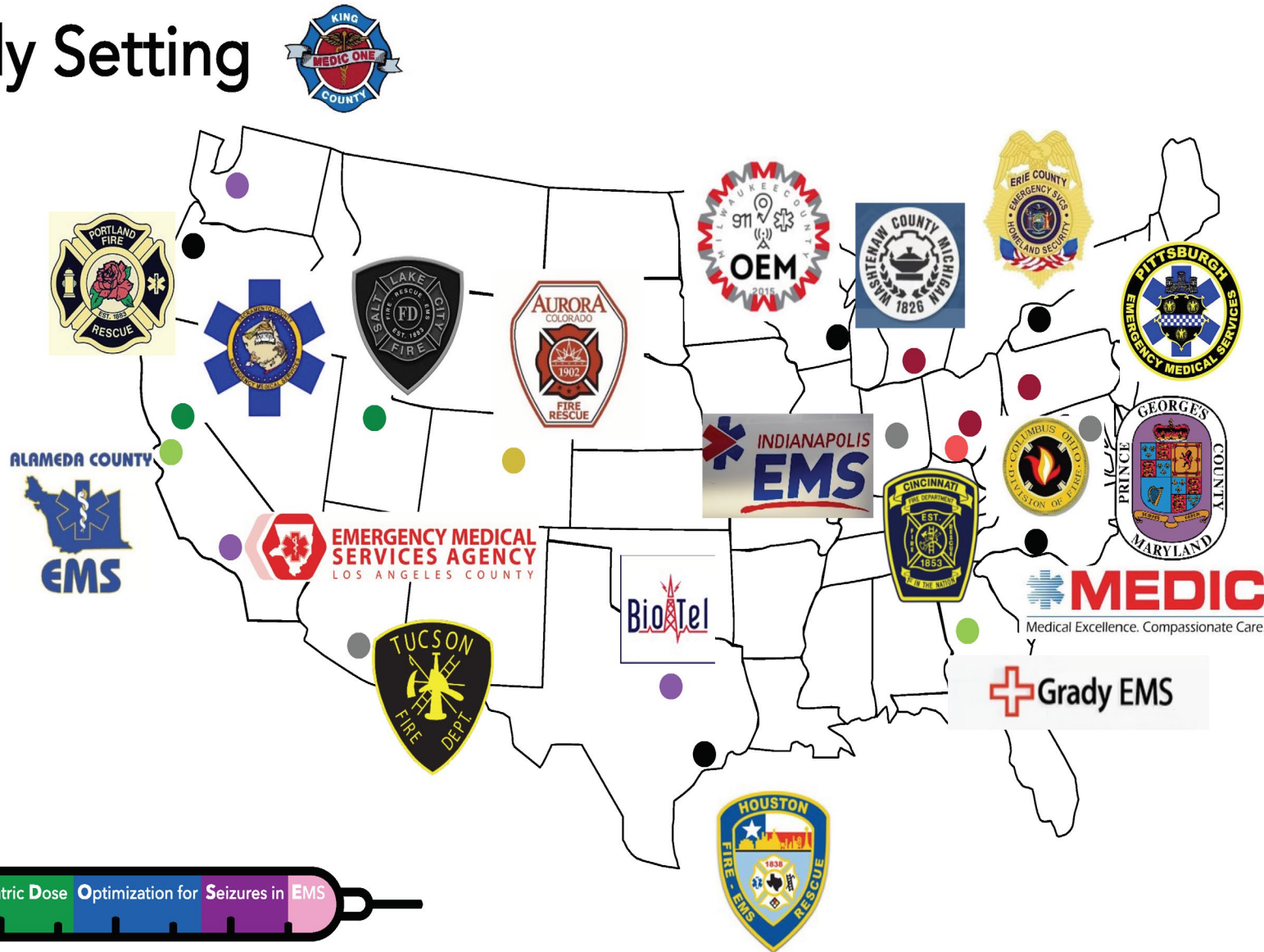
How PediDOSE will be conducted

- EMS protocol change randomly selected
- Paramedics will be trained in new protocol
- Information collected from medical records over 4 years
- Researchers will compare data for conventional vs standard methods



Who Will Participate?

Study Setting



- Age: 6 month-13 years
- Actively seizing during paramedic care
- Transported by a participating EMS agency

Pediatric Dose Optimization for Seizures in EMS

What is Informed Consent?

- Usually, research involves getting permission from a person or a family member
- The researcher confirms the person can understand the information before they participate
 - Like when we asked your permission to interview you.
- If the study involves people who are unconscious or children in a critical condition, there may not be time to ask for permission
- This is because the person is so sick that emergency healthcare professionals want to make sure this person receives treatment right away



Exception from Informed Consent (EFIC)

The U.S. Food and Drug Administration (FDA) has outlined governmental regulations for emergency research

- These regulations apply ONLY when:
 - Patients have a life-threatening situation **AND**
 - There is no proven treatment or available treatment is unsatisfactory **AND**
 - It is not possible to obtain informed consent from the patient or patient's family, and/or the doctor is not able to get informed consent because there is a very short amount of time possible for consent to occur.



What happens after enrollment?

- Parents will be notified of their child's enrollment as soon as possible
- Parents will be able to choose if they want their child to continue to participate in the study or not
- Children age 7-13 will also choose if they want to continue to participate
- Those who continue will have data collected until they are discharged



Community Consultation

- You are hearing this presentation today as part of the Community Consultation process that occurs before the study is presented to the board that can approve the study for implementation.



Contact Information:

If you have any questions, comments or concerns

- Local Principal Investigator:
 - Kathleen Adelgais, MD, MPH
 - Kathleen.Adelgais@childrenscolorado.org
 - (303) 724-2578
 - Research Participant Advocate:
 - Phone: (801) 581-3803
 - Email: participant.advocate@hsc.utah.edu

Contact the University of Utah Institutional Review Board (IRB) if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at irb@hsc.utah.edu



The PediDOSE Study

- <https://www.youtube.com/watch?v=Zqc5WJGtv6Y>



What questions do you have about the study?



Thank you!

Kathleen.Adelgais@childrenscolorado.org

