



PROACTIVE **New York State**

ANDREW HANDEL, MD

ASSISTANT PROFESSOR OF PEDIATRICS

CO-PI, PROACTIVE NYS

DIVISION OF INFECTIOUS DISEASES

STONY BROOK CHILDREN'S HOSPITAL

Disclosures

Research support:

- PROACTIVE NYS: Funded by NICHD Task Order 75N94021D00018
- LINCATS Network Mentored Clinical Research Development Award

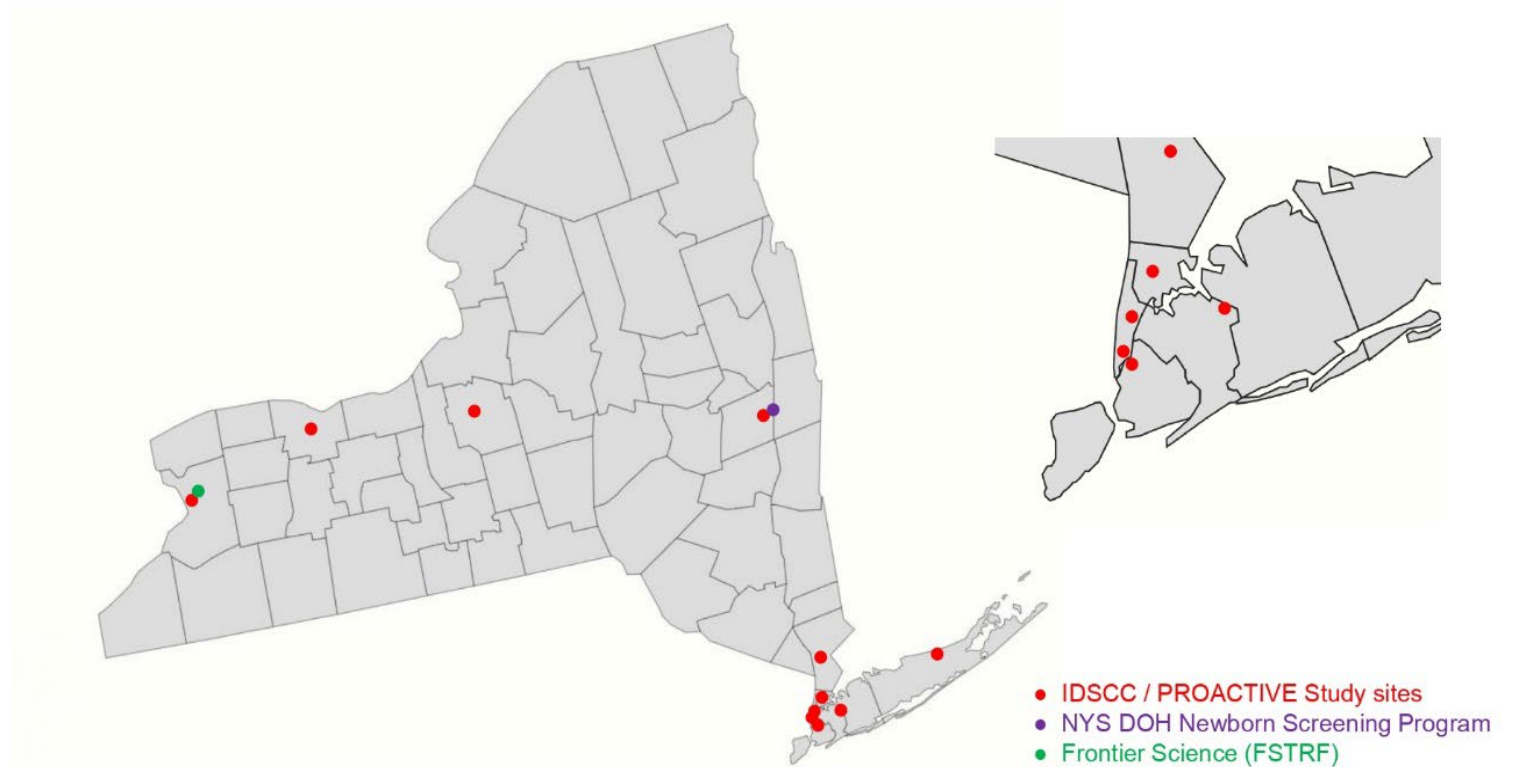
- Long-term follow-up study of cCMV screen-positive newborns
- Goal: Systematically follow all children through 2 years of life
- Enrollment estimate: 500-1,000 children (0.25 – 0.5% cCMV rate)
- Periodic assessments of:
 - Clinical findings
 - Antiviral treatment status
 - Neurodevelopmental outcomes
 - Audiological outcomes
 - Ophthalmological outcomes

Study Objectives

- To enroll at least 90% of all cCMV screen-positive infants across NYS
- To determine the rate of confirmed cCMV in a statewide cohort
- To describe the distribution of neonatal features among children with confirmed cCMV
- To describe trends in antiviral and non-pharmaceutical treatments, adverse effects, and impact on long-term outcomes
- To assess the long-term audiologic, neurologic, and developmental outcomes
- To describe the impact of a positive cCMV screen on the quality of life (QoL) of infants and families

PROACTIVE Study Sites

- Study referral & enrollment
- 11 study sites
- Study partners
 - NYS DOH NBS
 - Frontier Science



Participant enrollment categories

- **Category 1:** Confirmed cCMV identified by NBS
- **Category 2:** Confirmed cCMV **not** identified by NBS (False-negative cCMV screen)
- **Category 3:** False-positive cCMV screen
- **Category 4:** Premature infants with confirmed cCMV on late positive NBS

Study Entry Visit (Birth – 1 month old)

Newborn diagnostic evaluation

- Maternal CMV history
- Confirmatory CMV PCR results
- Physical exam findings
- Lab results
- Imaging
- Neonatal hearing screen results
- Ophthalmologic screening

Treatment decisions

- Treatment provided
- Toxicities

Long-Term Outcomes: Neurodevelopment

Neurodevelopmental Assessment Screening

- ASQ-3
- ASQ:SE-2
- MCHAT-R/F

Children with developmental delays identified

- Early Intervention referral
- Neuropsychology assessment
 - Bayley-III
 - Vineland Adaptive Behavior Scales

Long-Term Outcomes: Hearing and Vision

Audiological monitoring

- Every 3-6 months (or more frequent)
- Interventions provided

Ophthalmologic monitoring

- High-risk infants
- Every 6-12 months, per Ophtho recommendations

Quality of Life

QoL Assessment

- Cross-sectional QoL assessment at 1 year from study start date
- Second QoL assessment when each child reaches 2 years of life

Prospective Observational study of Asymptomatic cCMV Transmission to Infants for Virological Evaluation in New York State

Working **Together** to Improve Outcomes

While cytomegalovirus (CMV) is the most common congenital infection, the vast majority of newborns show minimal or no symptoms at birth and go undiagnosed.

One fifth of children known to have cCMV will develop long-term issues such as hearing loss and cognitive impairment, but there is little known about the treatment and long-term outcomes for those newborns without symptoms.

There is now an unprecedented opportunity to leverage New York State's new universal screening program to gain in-depth insight into the symptoms shown at birth and medical care provided for all newborns across a diverse state and work toward better outcomes for everyone.

[Learn More](#)

Period
Entry

Visit Date
3/3/2022 5/9/2023

Site Name
 (All)
 Albany
 Rochester
 Stony Brook
 Syracuse

Congenital CMV
 (All)
 Negative
 Positive

Symptomatic
 (All)
 No
 Unknown
 Yes

Prenatal abnormalities
 (All)
 Head
 Liver
 None
 Spleen

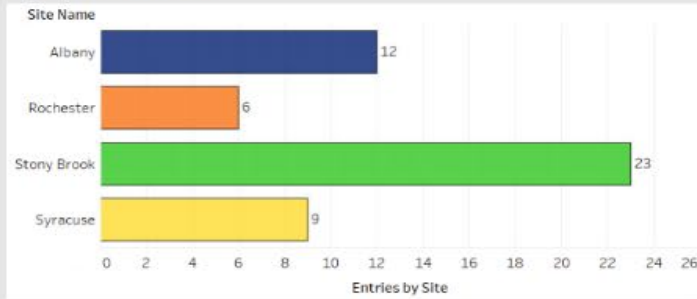
Gestational age at birth
29.30 41.90

Birth weight
4 000 9 940

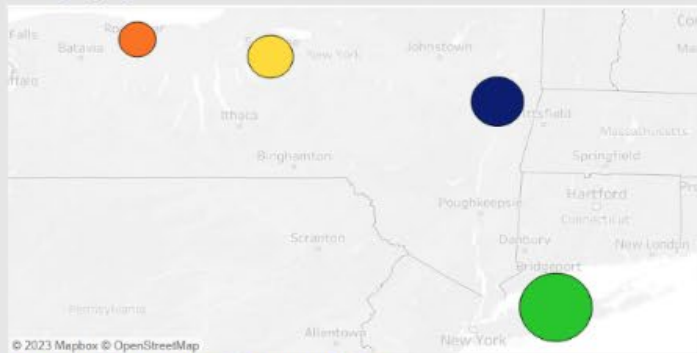
Prenatal Abnormalities
 Head
 Liver
 Spleen
 None

V 1.0.0.0

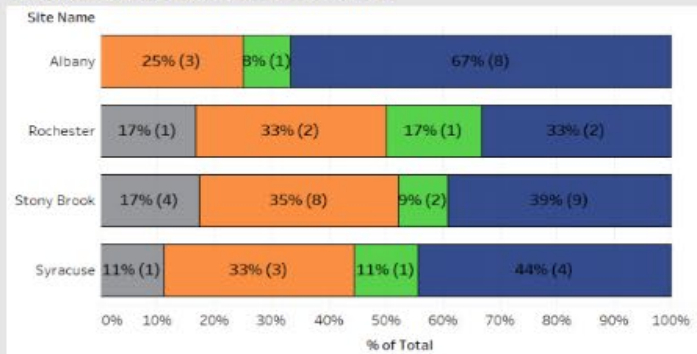
Enrollment by Site



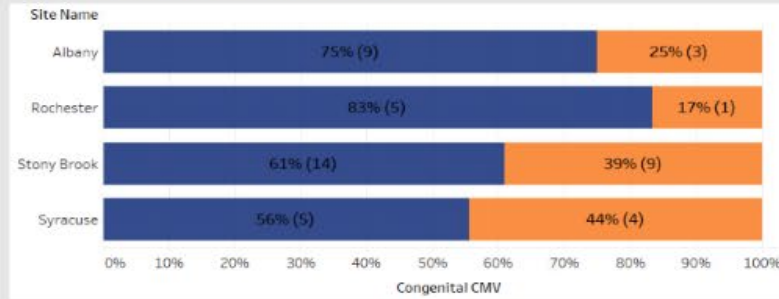
Geography



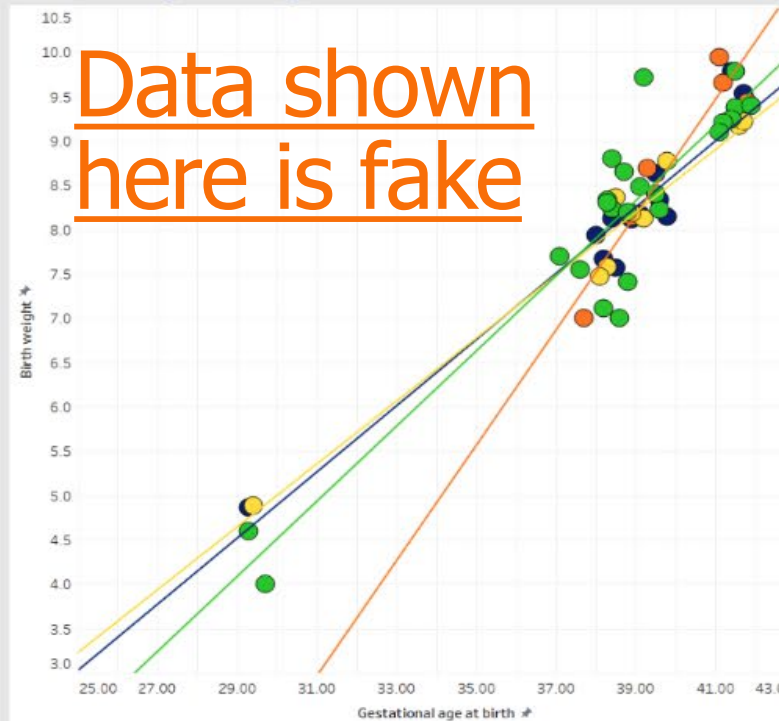
Prenatal Ultrasound Abnormalities



Congenital CMV Newborn Screens



Gestational Age and Weight



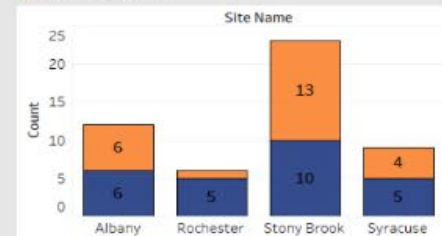
Symptomatic

Site Name	Symptomatic		
	Yes	No	Unknown
Albany	6	4	2
Rochester	4	1	1
Stony Brook	10	9	4
Syracuse	4	4	1

Hearing Impairment



Missed Cases



Quality of Life

Quality Of Life	Site Name			
	Albany	Rochester	Stony Br..	Syracuse
A. High	2	1	9	2
B. Medium prefer a..	3	1	5	4
C. Low - assistance ...	5	3	5	0
D - NA	2	1	4	3

Thank you!

PROACTIVE Co -PIs:

- Sharon Nachman, MD (Stony Brook)
- Michele Caggana, ScD, FACMG (NYS DOH)

NYS DOH Newborn Screening Program

Sarah Bradley, MS, CGC

Lequela Steen

Norma Tavakoli, PhD

PROACTIVE Study Site	Specialist
Albany Medical Center	Debra Tristram, MD Saul Hymes, MD Gillian Taormina, DO
New York Presbyterian - Brooklyn Methodist	Minnie John, MD
SUNY Upstate	Leonard Weiner, MD
New York Presbyterian - Weill Cornell	Christine Salvatore, MD
Stony Brook Children's	Andrew Handel, MD Sharon Nachman, MD
BCH/NY Medical College / Westchester Medical Center	Sheila Nolan, MD Patricia De La Mora, MD
NYU School of Medicine	Gail Shust, MD
Children's Hospital at Montefiore	Margaret Aldrich, MD
URMC/Strong Memorial	Geoffrey A. Weinberg, MD
Cohen Children's Medical Center / Northwell Health	Sunil Sood, MD
SUNY Buffalo	Mark Hicar, MD, PhD Karl Yu, MD, PhD

Questions?

Andrew.Handel@stonybrookmedicine.edu