# Updates from the Texas Health Department 2025



### **Disclosure**

I have no actual or potential conflict of interest in relation to any product or service mentioned in this program or presentation.

### **Agenda**

- 1.Describe the maternal and genetic risk factors associated with preeclampsia, cystic fibrosis, and conditions detected through newborn screening, including the timing and rationale for early detection.
- 2.Recognize the early signs and symptoms of preeclampsia and cystic fibrosis and identify the asymptomatic nature of conditions that are detected through newborn screening, emphasizing the importance of timely testing.
- 3.Examine current screening guidelines and protocol recommendations for newborn screening, including the two-screen protocol for 24–48 hours and 7–14 days of life.
- 4. Discuss evidence-based treatment and follow-up strategy options for preeclampsia (e.g., low-dose aspirin), cystic fibrosis (e.g., gene-targeted therapies, airway clearance, nutritional support), and early interventions for conditions identified through newborn screening (e.g., stem cell transplantation for Krabbe disease).
- 5. Analyze how early identification and management of preeclampsia, cystic fibrosis, and newborn screening conditions can improve maternal and neonatal outcomes, reduce morbidity and mortality, and support long-term health and development.





# March of Dimes: Low Dose ASA for Preeclampsia Prevention

Base on a Presentation by:

Alicia Lee, MHA, Director of Maternal & Child Health (MCH) Collective Impact

Lindsey Vasquez, MD, CPE, CPHQ, FACOG, Director of Maternal and Women's Health (Molina Healthcare of Texas) & OBGYN (Legacy Community Health) July 28, 2025







### Preeclampsia is defined as:

- 1. Elevated blood pressure after 20 weeks of pregnancy
- 2. Clinical signs that one's brain, liver, and kidneys are not functioning properly.

The onset of preeclampsia can happen from the 20th week of pregnancy through six weeks postpartum.



- Preeclampsia affects 1 out of 25 pregnancies in the US.
- According to the CDC, preeclampsia is one of the leading cause of maternal mortality.

https://blogs.cdc.gov/genomics/2022/10/25/preeclampsia/

Preeclampsia, Genomics and Public Health

October 25, 2022 by Erica L. Dawson, Population Health Surveillance Branch, Division of Population Health, National Center on Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention; Muin J. Khoury, Office of Genomics and Precision Public Health, Office of Science, Centers for Disease Control and Prevention



### Risks of preeclampsia to the mom:

- Maternal seizure,
- Stroke,
- Organ damage (particularly the kidney and liver),
- Increase in chronic hypertension,
- Lifelong increase of cardiovascular and renal disease, and
- In extreme cases, maternal death.



### Risks of preeclampsia to the infant:

- Insufficient blood flow through the placenta leading to:
- Low birth weight,
- Preterm birth, and in severe cases, Stillbirth.



## The science behind low dose aspirin

Low dose aspirin (LDA) is currently recommended for individuals at high-risk and moderate-risk for preeclampsia during pregnancy by:

- American College of Obstetricians and Gynecologists
- Society for Maternal Fetal Medicine
- U.S. Preventive Services Task Force
- World Health Organization



### The science behind low dose aspirin

Studies show that pregnant women at increased risk for preeclampsia who take daily prophylactic aspirin may mitigate risks such as:

15% reduction in risk of preeclampsia

20% reduction in risk of preterm birth

21% reduction in risk of perinatal mortality

18% reduction in risk of fetal growth restriction

### Despite benefits, low dose aspirin is greatly underutilized

- 1. USPSTF Recommendation Statement. Aspirin Use to Prevent Preeclampsia and Related Morbidity and Mortality (2021).
- 2. Krishnamurti T, et al. Use of a Smartphone App to Explore Potential Underuse of Prophylactic Aspirin for Preeclampsia. JAMA Netw Open. 2021.
- 3. Parrinella K, et al.Identification of criteria missed by clinicians among patients not prescribed aspirin prophylaxis for preeclampsia. SMFM. 2022.



### March of Dimes low dose aspirin campaign



### **Project purpose**

This campaign aims to mitigate the adverse effects of preeclampsia in at-risk pregnant individuals by implementing a multi-pronged initiative focused on increasing the awareness of using low dose aspirin to reduce the negative impacts of preeclampsia.

#### Goal

The primary objective of the project is to amplify awareness among health professionals and individuals of childbearing age on the risk factors of preeclampsia and the use of low dose aspirin to mitigate the adverse impacts of preeclampsia, and to diminish healthcare disparities by promoting equal access to information for all races and ethnicities.



# Benefits of low dose aspirin: reduce the risk and severity of preeclampsia Some of these benefits include:

- Reduced risk of preeclampsia
- Improved blood flow
- Potential reduction in preterm birth

- Lowered severity of preeclampsia
- Potential cardiovascular benefits
- Dose: 81 mg/d starting after the 1<sup>st</sup> 12 weeks of pregnancy



### Barriers to utilization of low dose aspirin:

These barriers requires a multifaceted approach. Some of these barriers include:

- Lack of awareness
- Healthcare provider awareness and prescribing practices
- Concerns about side effects
- Language and cultural barriers
- Complexity of regimen



The Campaign Focuses on:

Public Awareness

Professional Development

Quality Improvement



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# CYSTIC FIBROSIS AND THE CF FOUNDATION

**Donna Beth Willey-Courand,** MD, Director, UTHSCSA Pediatric Cystic Fibrosis Center **Olivia Dieni,** MPH, Healthcare Access Manager, CF Foundation **Adina Rubenstein,** State Policy Specialist, CF Foundation **July 28, 2025** 



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July 28, 2025



## What is Cystic Fibrosis?

Cystic fibrosis is a genetic disease that affects the **lungs**, **pancreas**, and **other organs**; **sinuses**, **gastrointestinal tract**, and **bones**. It is progressive

In the **lungs**, the mucus clogs the airways and traps germs, like bacteria. This leads to infections, inflammation, respiratory failure, and other complications. For this reason, avoiding germs is a top concern for people with CF.

Downloaded from the CF Foundation Website 9/4/25



## What is Cystic Fibrosis?

In the **pancreas**, mucus builds up and prevents the release of the digestive enzymes that help the body absorb food and key nutrients. This results in malnutrition and poor growth.

In the **liver**, the thick mucus can block the bile duct, causing liver disease.

In men, CF can affect their ability to have children.

Downloaded from the CF Foundation Website 9/4/25



# ABOUT THE CYSTIC FIBROSIS FOUNDATION

The mission of the Cystic Fibrosis Foundation is:

- To cure Cystic Fibrosis
- Fund research and drug development,
- Partner with the CF community, and
- Advance high-quality, specialized care



- **•**CF PATIENT REGISTRY:
  - -34,000 people with CF in the United States
- **•**CARE CENTER ACCREDITATION:
  - -280 Programs at 130 Centers
- •CF CLINICAL GUIDELINES:
  - -Supports development of consensus driven, evidence-based guidelines



- •THERAPEUTICS DEVELOPMENT NETWORK:
  - -Centralized clinical research organization
- •POLICY AND ADVOCACY:
  - -Supporting access to affordable and highquality care
- **•PATIENT SUPPORT:** 
  - -1:1 assistance in navigating insurance, financial, legal, and other life issues



Nearly 40,000 people in the United States

• Life shortening disease

• ~1,000 new cases/year

TEXAS
2409
cases

- Can impact people of all races and ethnicities
- Caused by a mutation in a gene controlling mucous
- Standardized care and therapies have significantly improved quality and length of life
- There is no cure



# 7 CF Care Centers containing18 care programs



- 2. Cook Children's Medical Center Fort Worth
- 3. Dell Children's Medical Center of Central Texas Austin
- 4. The Adult Cystic Fibrosis Center of Central Texas Austin
- 5. McLane Children's Hospital, Baylor, Scott & White Healthcare Temple
- 6. University of Texas Health Sciences Center San Antonio
- 7. University of Texas Southwestern/Children's Health Dallas
- \*Pediatric and Adult Programs



### **MEDICATIONS AND TREATMENTS**

Restore CFTR Function (dysfunctional gene)

potentiates the mutant CFTR protein

e.g., Kalydeco

**Mucus Clearance** 

CPT, Pulmozyme, Hypertonic Saline, Bronchitrol



#### **MEDICATIONS AND TREATMENTS**

### **Anti-Inflammatory**

Ibuprofen, Steroids

### **Anti Infective**

Azithromycin, Cayston® • Inhaled Tobramycin TOBI® Podhaler, AZLI

### **Nutritional-GI**

Pancreatic Enzyme Replacement Therapies, Fat-soluble multivitamins, RELiZORB



# MEDICATIONS AND TREATMENTS Needed for 5 y and older

- The CF Foundation (CFF) strongly recommends inhaled antibiotic therapy for the treatment of initial or new growth of P. aeruginosa from an airway culture (certainty of net benefit, high; estimate of net benefit, substantial; grade of recommendation, A)<sup>1</sup>
- In 2024, the median age for Pseudomonas aeruginosa infections is 5 years old based on the CFF Registry Report<sup>2</sup>
- The favored antibiotic regimen is inhaled tobramycin (300 mg twice daily) for 28 days<sup>1</sup>; however, Texas Medicaid currently approves coverage for this medication for people with CF age 6 years and older



#### **MEDICATIONS AND TREATMENTS**

Denial of tobramycin PA for Children (TMPPM)

### Standard Criteria for Inhaled Anti-infectives

Records documentation required:

- 1a) Diagnosis of CF;
- 1b) P. aeruginosa colonization
- 2a) 6 y and older for any tobramycin inhaled
- 2b) 7 y and older for any aztreonam inhaled



### **MEDICATIONS AND TREATMENTS**

**FAT-SOLUBLE VITAMINS** 

Supplementation of vitamins A, D, E, and K Vitamin deficiency can result in

- 1. Impaired vision,
- 2. Decreased bone density, and
- 3. Bleeding disorders.



# RESEARCH SUPPORTING USE OF INHALED ANTIBIOTICS IN CHILDREN

Inhaled tobramycin and aztreonam lysin for inhalation (AZLI) are often used by children with CF, despite FDA indication being for older populations.

#### **Current prescribing practices**

Cystic Fibrosis Foundation Patient Registry 2023 Annual Data Report Bethesda, Maryland ©2023 Cystic Fibrosis Foundation



# RESEARCH SUPPORTING USE OF INHALED ANTIBIOTICS IN CHILDREN

#### Data on safety and efficacy

Gibson RL, Emerson J, McNamara S, Burns JL, Rosenfeld M, Yunker A, Hamblett N, Accurso F, Dovey M, Hiatt P, Konstan MW, Moss R, Retsch-Bogart G, Wagener J, Waltz D, Wilmott R, Zeitlin PL, Ramsey B; Cystic Fibrosis Therapeutics Development Network Study Group. Significant microbiological effect of inhaled tobramycin in young children with cystic fibrosis. Am J Respir Crit Care Med. 2003 Mar 15;167(6):841-9. doi: 10.1164/rccm.200208-855OC. Epub 2002 Dec 12. PMID: 12480612.

Hennig S, McKay K, Vidmar S, O'Brien K, Stacey S, Cheney J, Wainwright CE. Safety of inhaled (Tobi®) and intravenous tobramycin in young children with cystic fibrosis. J Cyst Fibros. 2014 Jul;13(4):428-34. doi: 10.1016/j.jcf.2014.01.014. Epub 2014 Feb 22. PMID: 24565869.



# RESEARCH SUPPORTING USE OF INHALED ANTIBIOTICS IN CHILDREN

### Clinical practice guidelines

Lahiri T, Hempstead SE, Brady C, Cannon CL, Clark K, Condren ME, Guill MF, Guillerman RP, Leone CG, Maguiness K, Monchil L, Powers SW, Rosenfeld M, Schwarzenberg SJ, Tompkins CL, Zemanick ET, Davis SD. Clinical Practice Guidelines From the Cystic Fibrosis Foundation forPreschoolers With Cystic Fibrosis. Pediatrics. 2016 Apr;137(4):e20151784. doi:10.1542/peds.2015-1784. Epub 2016 Mar 23. PMID: 27009033.



# RESEARCH SUPPORTING USE OF FAT-SOLUBLE VITAMINS

Fat-soluble vitamins are widely used among both adults and children with CF.

### Pediatric nutritional clinical guidelines

Borowitz D, Baker RD, Stallings V. Consensus report on nutrition for pediatric patients with cystic fibrosis. J Pediatr Gastroenterol Nutr. 2002; 35(3): 246-259.



## **Cystic Fibrosis**

# RESEARCH SUPPORTING USE OF FAT-SOLUBLE VITAMINS

#### Adult care guidelines

Yankaskas JR, Marshall BC, Sufian B, Simon RH, Rodman D. Cystic fibrosis adult care: consensus conference report. Chest. 2004; 125(1): 1S- 39S.

#### Nutritional considerations in the era of modulators

Leonard A, Bailey J, Bruce A, Jia S, Stein A, Fulton J, Helmick M, Litvin M, Patel A, Powers KE, Reid E, Sankararaman S, Clemm C, Reno K, Hempstead SE, DiMango E. Nutritional considerations for a new era: A CF foundation position paper. J Cyst Fibros. 2023 Sep;22(5):788-795. doi: 10.1016/j.jcf.2023.05.010. Epub 2023 May 23. PMID: 37230807.



#### **Cystic Fibrosis**

# RESEARCH SUPPORTING USE OF FAT-SOLUBLE VITAMINS

#### **Vitamin D clinical guidelines**

Tangpricha V, Kelly A, Stephenson A, Maguiness K, Enders J, Robinson KA, Marshall BC, Borowitz D, for the Cystic Fibrosis Foundation Vitamin D Evidence-Based Review Committee. An Update on the Screening, Diagnosis, Management and Treatment of Vitamin D Deficiency in Individuals with Cystic Fibrosis: Evidence-Based Recommendations from the Cystic Fibrosis Foundation. J Clin Endocrinol Metab.2012;97(4):1082-1093.







# DSHS Community Health Improvement: Newborn Screening (NBS) Program Overview

Based on a presentation by:

Jessica Brown Obiora, MD, MPH, Medical Director, Newborn Screening Unit;

Leslie McKenzie, BSN, RN, Director of Newborn Screening, Maternal and Child Health

July 28, 2025



**NBS At A Glance** 

Texas requires two blood spot screens for each baby born in Texas.

These screens are completed at:

24-48 hours of life

7-14 days of life



#### **NBS At A Glance**

Newborn hearing screening and critical congenital heart disease (CCHD) screening are included in screening care.

Infants with abnormal or out-of-range results should receive prompt and appropriate confirmatory testing.

Once diagnosed, infants begin appropriate treatments and therapies.



# Current Disorders on Blood Spot Screens 31 core conditions and 24 secondary conditions:

- Congenital Hypothyroidism;
- Congenital Adrenal Hyperplasia (CAH);
- •Four Hemoglobinopathies, including Hemoglobin SS Disease (sickle cell anemia);
- Galactosemia (climate sensitive)
- Biotinidase Deficiency (climate sensitive)



# Current Disorders on Blood Spot Screens 31 core conditions and 24 secondary conditions:

- 14 Amino Acid Disorders, including Phenylketonuria (PKU)
- 13 Fatty Acid Oxidation Disorders, including Medium Chain and Very Long Chain Acyl CoA Dehydrogenase Deficiencies (MCADD and VLCADD)
- •15 Organic Acid Disorders, including Isovaleric Acidemia (IVA)



# Current Disorders on Blood Spot Screens 31 core conditions and 24 secondary conditions:

- Cystic Fibrosis(CF)
- Severe Combined Immunodeficiency (SCID) and Tcell-related lymphocyte deficiencies
- X-linked Adrenoleukodystrophy (X-ALD)
- Spinal Muscular Atrophy (SMA)



DSHS is in the process of adding the following Uniform Screening Panel (RUSP) conditions to the Texas panel:

Glycogen Storage Disease Type II (Pompe)

Added to RUSP in March 2015

Mucopolysaccharidosis Type I (MPS I)

Added to RUSP in February 2016

Mucopolysaccharidosis Type II (MPS II)

Added to RUSP in August 2022

Guanidinoacetate Methyltransferase Deficiency (GAMT Deficiency)

Added to RUSP in January 2023

Glucocerebrosidase deficiency - Infantile Krabbe Disease



Two Examples of RUSP Diseases Requiring Early Intervention

Krabbe Disease

Duchenne Muscular Dystrophy

**Krabbe Disease**: a lysosomal disorder causing impaired myelin function

Newborns are asymptomatic

The only available therapy is hematopoietic stem cell transplantation

Most effective if performed before 30 days of life



#### Krabbe Identified

- PCP notified
- 2. Clinical Care Coordination (CCC) Reviews case
- 3. Krabbe referral center

#### Three Centers in Texas

- 1. Christus Children's Hospital, San Antonio
- 2. Texas Children's Hospital, Houston
- 3. University of Texas Southwestern/Children's Health, Dallas



#### **Duchenne Muscular Dystrophy (DMD)**

A degenerative muscular disease affecting skeletal and cardiac muscle.

Early symptoms include regression of gross and fine motor skills

Genetic treatment is available

- Not for every child
- Very high cost



# Department State Health Services (DSHS) Public Health Laboratory

Largest NBS Laboratory in the United States.

2023 Specimen Volume:

•760,522 specimens received.

0.9% (6,827) of the total specimens received were unsatisfactory.

Lab operates **six days a week** (processing ~2,000-3,000 specimens each day).

Most testing is completed two to three business days after specimen is received.



#### Laboratory Result Reporting

Preliminary panic values for some disorders are immediately forwarded to the submitter by fax.

Final abnormal results immediately generate a case.

CCC staff begin follow-up protocols with health care professionals and parents.

All results are reported back to submitting provider via mail, fax, web portal and/or HL7 message.



Coordination of Car (CCC) at a Glance

Purpose: To provide immediate follow-up and care coordination for babies who have an abnormal newborn screen for one of 55 rare genetic conditions tested by dried blood spots.

CCC staff **notify medical providers** of results and **provide recommendations** for follow-up testing.

**2,600-3,000 cases are diagnosed** with a newborn screening condition **each year** and are placed under **long-term follow-up**.

CCC staff work six days a week, including Saturdays.



#### **CCC Teams**

- 1. Thyroid Team;
- 2. Hematologic disorders/CF/SCID Team
- 3. Metabolic Team;
- 4. Lysosomal Storage Disorders and CAH Team; and
- 5. Special Projects Team.

Teams collaborate with medical subspecialists caring for children under evaluation.



#### Short-Term Follow-Up

- 1. Opens a case for each abnormal result.
- 2. Begins the process of notifying providers and possibly parents 24 hours from result release.
- 3. Provides ACT/FACT Sheets for conditions.
- 4. Monitors cases until an infant is cleared or diagnosed.
- 5. Subspecialists return diagnostic forms to CCC.



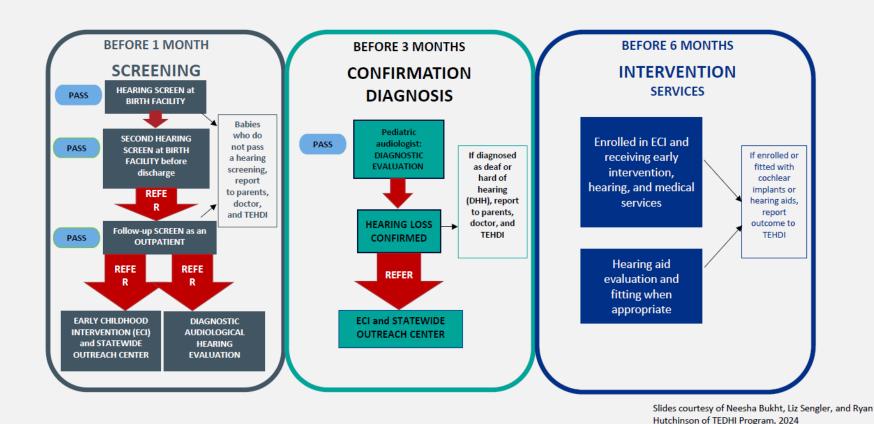
#### Long-Term Follow-Up

#### Goals for the process:

- Assess needs of patient and families;
- Connect families to care;
- Identify barriers and help find children lost-tofollow-up; and
- Develop a better understanding of disorder outcomes.



#### Following 1-3-6 Guidelines in Texas





Critical Congenital Heart Disease (CCHD) Testing

CCHD is a point-of-care test completed via pulse oximetry. Results are only reported to NBS when a baby is diagnosed.

Whoever makes the diagnosis (e.g., physician, PA, APRN, etc.) shall report a confirmed case to the department (NBS Dept.).



#### Critical Congenital Heart Disease (CCHD)

**Newborn Screening Algorithm** 

It is best practice to screen when an infant is on room air and has no supplemental oxygen requirement.

#### Measurement one

Pulse ox on right hand AND one foot around 24 hours of age (or earlier if being discharged)

#### **FAIL**

Pulse ox of 89% or less in either right Hand OR one Foot

ACTION: Do NOT repeat pulse ox AND proceed with immediate clinical assesment

#### RETEST

a. Pulse ox of 90% to 94% in either the right hand OR one foot

b. A difference of 4% or more between the right hand and foot

ACTION: Repeat pulse ox measurements in one hour

#### **PASS**

a. Pulse ox of 95% or more in right hand and and foot AND

b. A difference of 3% or less
 between the two

ACTION: Do NOT repeat pulse ox AND provide routine care

#### Measurement two

Pulse ox on right hand AND one foot one hour after measurement one

#### **FAIL**

a. Pulse ox of 94% or less in either the right hand OR one foot OR

 A difference of 4% or more between the two

ACTION: Do NOT repeat pulse ox AND proceed with immediate clinical assesment

#### **PASS**

a. Pulse ox of 95% or more in right hand and one foot

b. A difference of 3% or less
 between the two

ACTION: Do NOT repeat pulse ox AND provide routine care

#### TEXAS Health and Huma Services

Texas Department of State Health Services

#### **EDUCATE FAMILIES**

Remind parents that CCHD newborn screening may not find all types of problems in a baby's heart.

#### REFERENC

Matthew E. Oster, Nelangi M. Pinto, Arun K. Pramanik, Allison Markowsky, Bryanna N. Schwartz, Alex R. Kemper, Lisa A. Hom, Gerard R. Martin, and the SECTION ON CARDIOLOGY AND CARDIAC SURGERY, SECTION ON HOSPITAL MEDICINE, COMMITTEE ON FETUS AND NEWBORN; Newborn Screening for Critical Congenital Heart Disease: A New Algorithm and Other Updated Recommendations: Clinical Report. Pediatrics January 2025; 155 (1): e2024069667. 10.1542/peds.2024-069667



Newborn Screening Annual Report

# Annual Reports are published on the DSHS website:

dshs.texas.gov/laboratoryservices/programslaboratories/newbornscreening-laboratory/nbsannual-report.

**Educational and Training Services** 

# Resources for lab testing and methods can be found on the DSHS website:

dshs.texas.gov/laboratoryservices/programslaboratories/newbornscreeninglaboratory/newbornscreening-healthcareprovider



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# **Updates from the Texas Health Department 2025**

The TDH is exceptional in performing its legally designated responsibilities.

Thanks to Dr. Ryan D. Van Ramshorst, Chief Medical Director, and the presenters at the meeting for allowing me to reproduce and distribute this information.



# **Updates from the Texas Health Department 2025**







Q&A

