



NBS Advisory Committee Meeting MINUTES

Tuesday, April 19, 2022
1:00 p.m. – 3:00 p.m

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Attendees

Advisory Committee Members

Abdallah "Abe" Elias	Director of Medical Genetics and Clinical Geneticist, Shodair Children's Hospital
Amanda Osborne	Licensed, Certified Professional Midwife, Helena Birth Studio
Amber Bell	Newborn Screening Coordinator, Children's Special Health Services, DPHHS
Angela Dusko	NBS and Serology Section Supervisor, Montana Public Health Laboratory, DPHHS
Crystal Fortune	NBS Follow Up Coordinator, Montana Public Health Laboratory, DPHHS
Debbie Gibson	Lab Services Bureau Chief, Montana Public Health Laboratory, DPHHS
Kotie Dunmire	High School Business and Special Ed Teacher, Butte High School Parent of child with Cystic Fibrosis and PKU
Jennifer Banna	Center Coordinator, Family to Family Parent of child with rare metabolic disorder
Margaret Cook-Shimanek	Acting State Medical Officer, DPHHS
Sarah Sullivan	RN, Parent to two children with homocystinuria
Shelly Eagen	Nurse Practitioner - Pediatric Pulmonary, Billings Clinic
Marion Rudek	Nurse Practitioner, Blackfeet Community Hospital
Miranda Prevel	EPSDT Program Specialist, DPHHS
Mackenzie Petersen	Section Supervisor, Children's Special Health Services, DPHHS

Public

Steven Shapero	
Elisa Seeger	

Facilitators

Anna Schmitt	Co-founder, Yarrow
Kirsten Krane	Co-founder, Yarrow
Krystal Bosenbark	Public Health Specialist, Yarrow

Welcome & Introductions

(Mackenzie Petersen, Yarrow Facilitators, Voting & Non Voting Committee Members, Ground Rules)

- Mackenzie welcomed the group, and led introductions so each person could introduce themselves, providing their roles and a description of themselves.
- Yarrow reviewed Committee Q & A and public comment period at the end of the meeting
- Yarrow discussed ground rules for a successful meeting

Montana Newborn Screening Program Overview

- **MT Program Details**
 - Overview of voting and nonvoting members
 - Overview of congenital heart defects and critical congenital heart disease
 - Most babies are detected through ultrasound
 - History of CCHD screening
 - Sept 2011: CCHD screening added to RUSP for newborns
 - Oct 2011: Existing research done and recommendations published
 - July 2014: CCHD added to Montana NBS panel
 - Newborn Hearing Screening
 - Supplemented by HRSA grant
 - Two ways to screen: OAE and ABR
 - MT Rule
 - Healthcare providers attending the birth need to report hearing screening results; midwives not required to report
 - National Goals for Hearing Screening
 - All infants have access to hearing screening no later than 1 month
 - Hearing Screening Partners
 - Pediatric Audiologists
 - MT School for the Deaf and Blind
 - Hands and Voices
 - Genetics Program and Metabolic Clinics
 - Shodair's Medical Genetics Program provides Montana's only comprehensive care for children & adults with genetic conditions
 - Part of short and long term follow up of NBS
 - Addressing need for ongoing care
- **Lab and Lab processes**
 - 7 scientists in laboratory
 - NBS Lab is largest screening program in US, and it is also true for MT
 - Time from receipt of test to test results is 72 hours for up to 13,000 babies per year
 - Lab is integrated in public health laboratory, so many scientists are cross-trained
 - Newborn (bloodspot) Screening Background
 - NBS named one of top 10 great public health achievements by CDC
 - 1963 was first PKU testing
 - Primary Target Conditions should:
 - Condition must have a lab test to be detected, cannot be a high incidence of false negatives

- Condition needs to be detected sometime after birth but before symptoms appear
 - Conditions that benefit from early detection, intervention, and treatment
 - History of MT Newborn (Bloodspot) Screening
 - 1973: PKU and congenital hypothyroidism
 - 2008: MT mandated primary conditions on the RUSP
 - 2012: MT added SCID
 - 2022: First MT Advisory Panel
 - Bloodspot Screening in Montana
 - 33 screenings: 31 bloodspot, 2 hearing
 - Timelines are also available online
- **SMA Example**
 - Spinal Muscular Atrophy (SMA)
 - Genetic disorder characterized by muscle weakness and wasting in muscles used for movement
 - First nominated in 2008 - took about 10 years to be approved

Newborn Screening Advisory Committee Background

- **Committee Background**
 - RUSP: sets gold standard for including NBS disorders - standardized list of 60 disorders set by Secretary of the Department of Health and Human Services
 - Disorders based on the net benefit of screening
 - Recommended that all states screen for all conditions on the RUSP
 - Non-grandfathered health plans must cover screening and treatments for disorders on the RUSP
 - Each state screens for a unique list of disorders
 - TX & AZ: in the same region as MT for NBS
 - MN: good resources - attended their regional meeting for an example
 - WI: performs reference testing
- **Committee Roles & Responsibilities**
 - Gather info on recent developments in NBS testing, tech, and investigate staff & equipment requirements associated with new tests
 - Make recommendations to DPHHS regarding addition of metabolic and genetic disorder testing
 - Give priority to review of Krabbe disease
 - Meet at least twice per year
 - Terms of Voting Members
 - Initial appointment is staggered by 1, 2, or 3 years so no more than four members expire at any given time
 - Will determine what the staggered time limits will be at next meeting
 - Meetings, Quorums, and Voting
 - Meetings in accordance with Open Meeting Laws
 - Committee decisions must be made based upon a majority of members present
 - Committee Compensation and Administrative Support
 - Members are not entitled to compensation for services, but may be reimbursed for travel and meal expenses
 - A part of DPHHS
 - At the next meeting, committee members will be asked to vote on bylaws

Newborn Screening Advisory Committee Next Steps

- **Bylaws**
 - Will be sent out after meeting - Committee asked to review
 - May include survey to help narrow down ideas
- **Condition Criteria**
 - NBS New Condition Criteria Comparison - common themes
 - NBS New Condition Selection Criteria
 - Process that committee will go through in deciding on condition
 - Committee - is there anything missing? Please review
 - NBS Condition Selection Process
 - Breakdown of how the process will work in Montana
 - Summary of Nominated Conditions to the RUSP
 - Provides an idea of what to expect when a condition is nominated
 - For example, SMA took about a year: 2017 to 2018
 - Selection Criteria Review
 - Will be sent out after meeting with draft of nomination form
 - Members to review
 - Will vote on criteria during next meeting
- **Website**
 - Will include resources like nomination form, bylaws, and selection criteria
 - Will include meeting minutes, agenda, and other meeting materials
- **Meeting Schedule**
 - Must meet twice per year according to HB 423
 - Select end of summer month
 - End of year to discuss Krabbe
 - Doodle poll to follow for selection of meeting times
 - Next meeting, Committee will:
 - Review and vote on bylaws
 - Review and vote on condition selection criteria
 - Introduce Krabbe

Review & Wrap Up

- **Committee Q & A Period**
 - Abe - regarding nomination form - RUSP has a similar process; will there be standardized questions that will be sent out?
 - Yes, standardized questions
 - Will there be discussion about the nomination answers? Two Phases: receive a nomination, and review, then recommend?

- Every condition will be reviewed if there is complete info, and the determination will be made if it should be passed on for consideration
 - Subject matter experts would be invaluable to this discussion
- **Public Comment**
 - Elisa Seeger (founder of ALD alliance): If all RUSP conditions are mandated, what about the 3 (Pompeii, Krabbe, and ALD) remaining conditions not tested for?
 - All mandated RUSP conditions were those include prior to 2008
 - Those three are new, so not all states have adopted screening for them
 - When there is a low incidence state like MT, there is a greater chance of false positives, and want to avoid that
 - Every state has a different way to do this
 - Depends on local interest
 - NBS committee can inject some transparency
 - Steven Shapero: When will the NBS Nomination form be publicly available?
 - By next meeting or shortly after (fall 2022)
 - Depends on when selection criteria are determined
 - Steven Shapero: What does “introduce Krabbe mean”?
 - HB 243 mandates that the Committee must prioritize Krabbe
 - Steven Shapero: there is no fast track for other conditions?
 - No, because Krabbe was prioritized by HB 423 it will be discussed first
 - Hunter’s Hope, Krabbe Consortium are resources for Krabbe information
 - Elisa Seeger: What was the thought process behind condition criteria “benefits from treatment in newborn period”? - ADL manifests later in life (infant-onset & late-onset)
 - All criteria are proposed and based on RUSP and other states’ criteria
 - Will incorporate feedback into deciding which criteria to use

Thanks and Next Steps

- Follow up email will be sent soon
 - Meeting minutes
 - Recording
 - Presentation slides
 - Next meeting doodle poll
- Email if you have questions and comments or need anything

This meeting was concluded by Mackenzie Petersen at 2:44 pm on April 19th, 2022, via Zoom.