



Newborn Screening Advisory Review Committee

Meeting Minutes

Virtual Meeting Conducted via TEAMS / Tuesday, May 9th, 2023,

9:30AM-12:50PM

I. **Call to order:** The New Jersey Open Public Meeting Law was enacted to ensure the rights of the public to have advance notice of and to attend the meetings of public bodies at which any business affecting their interests is discussed or acted upon. In accordance with the provisions of this act, NSARC has caused notice of this meeting to be published by having the date, time and place thereof posted in the *Courier Post*, May 5, 2023, and the *Star Ledger*, May 5, 2023. This notice is also posted on the State of New Jersey official website see link below: <https://www.nj.gov/health/fhs/nbs/> and filed with the Secretary of State. Members of the public are scheduled to address the committee at the beginning portion of the meeting.

II. **Roll Call**

Absent/ Excused/ Present	Members/Name	Role/Affiliation
P	Sharon Anderson, DNP, NNP-BC, APNG	Neonatal Nurse: Rutgers School of Nursing Rutgers RWJ Medical School
	(vacant)	Neonatal Nurse
P	Jennifer Barrett Sryfi, MHA	NJ Hospital Association (Resource Representative): Department of Health
P	Dalya Chefitz, MD	General Pediatrician: Rutgers, RWJ Medical School
A	Mary Coogan, Esq.	Advocates for Children of NJ
P	Debra Day-Salvatore, MD, PhD	Geneticist: Saint Peter’s University Hospital Chair of Metabolic and Complex Disorder Specialty Groups
P	Steven Diamond, MD	Pediatric Hematologist: Hackensack University Medical Center Chair of Hematology Subcommittee
A	Patrick Hill, PhD	Ethicist: Rutgers
	(vacant)	March of Dimes Representative
P	Thomas Lind, MD, FAAP	Medical Director: NJ Dept of Human Services (resource representative)



P	Michael McCormack, PhD, FACMG	Genetics Professor (ad hoc member): Cell Biology and Neuroscience, Rowan-SOM
A	Jeannette Mejias	Family Representative
P	Konstantinos Petritis, PhD	Centers for Disease Control and Prevention (CDC): Laboratory Chief, Biochemical Mass Spectrometry Laboratory, Newborn Screening and Molecular
P	Ernest Post, MD	Chair of NSARC: Chair of Endocrinology Subcommittee
A	Nicole Pratt	Family representative
P	Deborah Johnson-Rothe, MD	NJ Association of Health Plans
A	Genevieve Romond	Family Representative
P	Christiana R. Farkouh-Karoleski, MD	Neonatal Physician: American Academy of Pediatrics
P	Andrea Siering, MS, RD, CSP	Nutritionist: Saint Peter's University Hospital
P	Michael Katz, MD	Pediatric Neurologist: Hackensack Meridian
A	Alan Weller, MD, PhD	Pediatrician: Rutgers, RWJ Medical School
A	Thomas Westover, MD	Obstetrician-Gynecologist: NJ Chapter, American College of OB/Gyn
A	Gwen Orlowski, JD	Disability Rights NJ: Executive Director
P	Maryrose McInerney, PhD	Audiologist: Chair of EHDI Advisory Committee
A	Jennifer Heimall, MD	Chair of Immunology Advisory Committee: Allergist-Immunologist CHOP
A	Al Gillio, MD	Chair of Immunology Advisory Committee: Director, Children's Cancer Institute
P	Robert Zanni, MD	Pulmonologist, Monmouth Medical Center Chair: Pulmonology Specialty Group
Absent/ Excused/ Present	Guests/Name	Affiliation
P	Alena Siddiqui	ACNJ's Kids Count Coordinator
P	Mary Ciccone	Director of Policy
Absent/ Excused/ Present	DOH Employees	Position
P	Mary Carayannopoulos, PhD	Technical Specialist: NBS Lab
P	Miriam Schachter, PhD	Program Manager/Research Scientist 1: NBS Lab
P	Brielle Easton, MA	Pre- and Post- Analytic Supervisor: NBS Lab
P	Karyn Dynak	NBS Follow-up Program Coordinator: NBS Follow up
P	Hui Xing	Data/Research Scientist: NBS Follow Up
P	Kathy Aveni	Data/Research Scientist 1: Special Child Health Services
P	Michelle Seminara	Meeting Coordinator/NBS Public Health Representative 3: NBS Follow up
P	Rachel Hammond, CIPP/G/US, CIPM, HCISPP, Esq.	Chief Ethics & Data Privacy Officer: Chief Ethics & Data Privacy Officer



P	Suzanne Canuso	Program Manager: NBS Follow-Up
P	Caitlin Russo	Research Scientist 3: NBS Lab
P	Sarah Eroh	Quality Assurance Specialist: NBS Follow up
P	Victoria Floriani	Research Scientist 3: NBS Lab
	Public Attendees	Affiliation
A	Rebecca Hook	Genetic counseling student at Kean University

Dr. Post called the meeting to order at 9:05 am

Approval of November 15, 2022, Minutes: Approved

Introduction of Open Public Meetings Act	Actions/Resolved
<ul style="list-style-type: none"> Suzanne explained the Open Public Meeting Act (OPMA) in detail to the group and how the Newborn Screening Advisory Review Committee (NSARC) is subject to follow those guidelines. 	
<p>Introductions of Members and Guests: Attendees introduced themselves and their affiliations.</p>	
<p><u>Overview of the Special State Officer requirements:</u></p> <ul style="list-style-type: none"> Rachel addressed the group and shared a PowerPoint she created to better explain the Special State Officer requirements. Rachel is the Special State Officer representative for NSARC and offered her contact information to all committee members to use for future inquires. She is available via TEAMS and email; rachel.hammond@doh.nj.gov 	
<p><u>Revising the Bylaws:</u></p> <ul style="list-style-type: none"> Ernie shared his screen and presented the draft document of the bylaws. Rachel offered to investigate the proper way NSARC is to conduct voting since the committee is now following the guidelines of the Open Public Meeting Act 	

<p>requirements. Rachel will also create a confidentiality agreement for committee members to sign to assure their understanding the need for the committee meetings proceedings’ remaining confidential. The confidentiality agreement will be a one-time document that we should have on file for all members. It is important as members of the committee that they understand they are subject to the New Jersey conflict of interest law under the ethics code. The outside employment questionnaire, which is the recusal screening tool, gets completed at initial appointment and once every three years. Rachel will map out what needs to be completed and the time frame of that completion, then Michelle will send out what requirements are needed to all committee members (special state officers).</p>	
-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--

III. Public Comment on Agenda Items Only:

Motion: To open public comment on agenda items

Time will be allocated for public comment at this meeting. Members of the public wishing to address NSARC agenda items must state their name, municipality, and the group, if any, they represent. A member of the public shall not be permitted to speak until they are recognized by the Chair. Each comment shall be limited to three (3) minutes. No participant may speak more than once. No dialogue between a speaker and the Committee shall extend the three (3) minutes time limit provided herein. If the meeting is held virtually, participants must place their name and municipality only within the chat section of the virtual platform (Microsoft Teams Meeting). No written questions will be read from this section. Participants must have audio and video capability to present comments. Participants will be called upon to present in the order their names are received.



Although NSARC encourages public comment, the Chair of the NSARC may interrupt, warn and/or terminate a participant’s statement, if question or inquiry is abusive, obscene, or may be defamatory. The Chair of NSARC can request any person to leave the meeting when that person does not observe reasonable decorum. NSARC will use this public comment period as an opportunity to listen to resident concerns, but not to debate issues or to enter into a question-and-answer session. Issues that are raised by the public may require review and investigation and may or may not be responded to by NSARC during the meeting. All comments will be considered, and a response will be forthcoming, if and when appropriate.

Speakers	
<u>NO SPEAKERS WERE PRESENT DURING THE SPRING 2023 MEETING</u>	
Announcements	
<p><u>Lab Updates:</u></p> <ul style="list-style-type: none"> • Miriam spoke about the lab and overall progress in 2022. The Lab began screening for Spinal muscular atrophy (SMA) January 31, 2022. In July 2022 the lab improved the cystic fibrosis (CF) screening algorithm by switching the second-tier molecular assay. The Lab was screening for the most common variant, Delta 5F08. The Lab has improved testing for CF by using the Illumina kit which allows the lab to now screen for 139 variants. Screening for X-ALD began in December 2022. The newborn screening panel is officially screening for a total of 61 different disorders. • A pilot study has taken place to find better transportation between specimen pick up from the hospitals to the laboratory. The original transportation courier was UPS and now the lab is using 24/7 Enterprises. This new courier is being used to ensure specimen transfer does not get lost and gets delivered to the lab in a timely 	

<p>fashion. New Jersey is split into four routes and will have a driver for each route to pick up those samples. The routes are organized into north, northwest, central, and southern. The lab is fully live with the central route and plans to have all routes up and running by the end of the year, 2023.</p> <ul style="list-style-type: none"> The lab applied for a grant to have electronic messaging between lab and hospitals to be able to communicate more efficiently. This will enable hospitals to electronically submit the baby’s demographic information to the lab. This new electronic messaging system will eliminate handwritten errors and require that all fields be filled out entirely so no information can be missed. The lab will also be able to electronically communicate with the hospitals and electronically report the test results once they are ready. The lab applied for this grant through HRSA, and the funding requested would cover setting up electronic message between the newborn screening laboratory and the hospitals. The lab is still awaiting to hear if they will be awarded the grant. If the lab does not get the approval the lab will still continue to move forward with this project. 	
<p><u>Follow up Updates:</u></p> <ul style="list-style-type: none"> Suzanne shared that the Propel grant has 2 focus areas; focus area 1 is with the lab for electronic messaging, focus area 2 is to establish a long-term follow-up (LTFU) component for children identified through NBS. Jen Hopkins who works on grants for the newborn screening program is working on soliciting volunteers for lunch and learns to assist in educational opportunities. 	



IV.

	Actions/Resolved
<p>Subcommittee Reports</p>	
<p><u>Cystic Fibrosis</u>: Robert addressed the group and shared that at the CF meeting the group discussed the transition to the new CF algorithm utilizing the 139 panel and how seamless that process has been. Further discussion of potentially moving the IRT to a floating cut off still needs to be had and will be discussed again during the fall. The group also looked at the nine-month data on the new algorithm and there are some slight upticks in the numbers of diagnosis that the lab will continue to track.</p> <p><u>Endocrinology</u>: As per Ernie the group has an ongoing discussion and reached some conclusion about the endocrine management of XALD.</p> <p><u>Hematology</u>: Steven spoke about one issue within the data representing a large number of open cases that have remained unresolved. Steven also announced his plans for retirement for the end of this June and a replacement for chair for the Hematology Subcommittee meeting will need to be established.</p> <p><u>Metabolic and Genetic</u>: As per Debra there was an ongoing discussion on what disorders should be registered with special child health services. The second topic was a discussion on Guanidinoacetate methyltransferase (GAMT) deficiency, which is a creatine deficiency disorder, possibly being added to the RUSP. There was a discussion on Menkes disease as possibly being added to the RUSP, as well. At this time these disorders will not be brought to NSARC for a decision. The group also discussed non-adherent parents who have a child with a presumptive result and who is responsible and at what time DCP& P should get involved.</p> <p><u>CCHD</u>: No group has yet been established for this subcommittee.</p> <p><u>EHDI</u>: Nothing to report currently. Next meeting is in June.</p> <p><u>Immunology Meeting</u>: Neither chairperson was present at the meeting, therefore, no update was reported.</p>	



New Business	
<p><u>Overall Incidence and Program Data to Date Cases:</u></p> <p>Hui presented program to date data and discussed with the group.</p> <p>As per Ernie, “how many XALD have we picked up?” As per Mary, two presumptive and two borderlines have been picked up. As per Dr. Velinov the first presumptive had a variant of unknown significance to be reported but not necessarily with disease. There has been a total of four screen positives and two have been referred and the lab is still awaiting on the other two babies repeat specimens.</p>	
<p><u>Billing of NBS Kits:</u> As per Miriam, New Jersey NBS laboratory provides initial kits and repeat kits to all hospitals charging \$150.00 for the initial kits while the repeat kits are free of charge. The money from selling the kits covers the costs of running the newborn screening program. The initial kits are ordered by the hospitals, the hospitals then send the lab a check, and once the check is received the lab distributes the shipment of kits to the hospitals. If a repeat kit is used for an initial specimen collection, then the lab bills hospitals for that use. If the first sample is UNSAT the lab does not charge for the repeat. Sometimes a hospital will request an advance for kits because they might be low. Therefore, the lab sends 50% of the order to make sure the hospital is covered with kits as the lab waits for the check to come in the mail. Once the check is received, the lab sends the remainder of the kits to that hospital. The lab has run into problems with some birthing centers and midwife practices. Payments by these centers that have not been received, and sometimes they use repeat kits for initial specimen collection. It seems newborn screening is being offered to families as an add on and being billed to the parents because they are considered an outpatient facility. Or the parents are being told that if you would like newborn screening to be performed that parents would need to pay an extra \$150.00 dollars and some families are declining to do that. The lab has received checks directly</p>	



<p>from families. When families have their babies at a hospital, the newborn screening fee is part of the bundled, inpatient, billing.</p> <p>Ernie asked the insurance specialists present at the meeting whether there is, or can be, a mechanism whereby outpatient facilities, either a birthing facility or a pediatrician office can bill insurance for the \$150.00 cost of performing a newborn screen for a baby who was not born in a hospital? Thomas and Debra Johnson-Rothe will need to look into the proper coding and billing logic to make sure insurance companies would be able to pick up and pay for it. As per Ernie, there is a law stating babies need to be screened and Miriam is working with Department of Health licensing to discuss what they can do.</p>	
<p><u>Bilirubin NBS:</u> At 24 hours of life every hospital is doing at least one transcutaneous test. The hospital might be using a little monitor that is either on the forehead or the child’s chest to screen for bilirubin, or the hospital is still using the heel prick being done for NBS to get a bilirubin specimen from their lab. The hospitals were using Dr. Bhutani’s curves and we were following that very closely but just a few months ago the American Academy of Pediatrics (AAP) is recommending a new screening guideline which involves not using the curve. One benefit of this testing is to determine if the child has G6PD deficiency.</p> <p>Ernie asked, “Would it be beneficial for NBS to make an attempt to get data on what is going on with bilirubin screening or should we just stay out of it as we have essentially for CCHD?”</p> <p>As per Dalya she will get back to the group on if collecting data on bilirubin would be something with value or not.</p>	
<p><u>Enhancing Education Subcommittee Update:</u></p> <p>As per Ernie the subcommittee has met four times and has come up with a list of who the target audiences should be. There has also been discussion about improving the FAQ portion of the lab’s website. The group has been working on what information would be valuable to the public and how to</p>	



<p>make it a better search engine for the FAQ page overall. Currently, follow up and the lab have two separate websites that are hopefully going to be merged over the next couple of years.</p>	
<p><u>Vote to elect NSARC Chair:</u> A poll was given to all voting members via TEAMS to decide on and elect a NSARC Chairperson. <u>13 people have voted in favor of Ernie as continuing as Chair of the Newborn Screening Advisory review committee, for the next three-year term.</u></p>	
<p><u>Ernie announced that the Open portion of the session was completed. The guests were asked to disconnect from TEAMS and Michelle assured that they had done so.</u></p>	

I. Adjournment

Meeting Adjourned By: Dr. Post **Time:** 12:03 pm

Minutes submitted by Michelle Seminara