Wisconsin Department of Health Services
Wisconsin Division of Public Health
Newborn Screening Program
Umbrella Committee Meeting
Friday, December 2, 2022
11:00am-2:00pm
Zoom: https://dhswi.zoomgov.com/j/1605368607?pwd=UmJ3akdRYkttOGxjNmtwOXhhWWxBQT09
Meeting ID: 160 536 8607
Or phone: +1 669 254 5252 or +1 646 828 7666 or +1 669 216 1590

Minutes

Meeting Members:

X	Dr. Nick Antos	X	Dr. Julie Kessel		Dr. Pilar Ossorio
X	Jonette Arms		Alison LaPean-Kirschner	X	Dr. James Schauer
	Dr. Mei Baker	X	Emily Kittell	X	Dr. Robert Steiner
	Anna Benton	X	Laura Leitch	X	Samantha St. Pierre
X	Dr. Jeff Britton	X	Mary Marcus	X	Dr. Julie Thiel
X	Dr. Norm Fost	X	Dr. Katie Marquart	X	Angie Thompson
X	Dr. John Hokanson	X	Dr. Anne Marsh		Paula Tran
X	Tami Horzewski	X	Dr. Roberto Mendez	X	Kelsey Wilde
X	Sarah Jensen	X	Dr. Michelle Miller		Dr. Jasmine Zapata
Meeting Guests					
X	Dr. Donald Basel	X	Rachel Reamer		

Agenda:

Friday, December 2, 2022 11:00 AM – 2:00 PM				
Time:	**Topic:**	**Lead:**	**Follow-up Items:**	**Notes:**
11:00 - 11:10	Welcome Review and Approval of Past Meeting Minutes	Dr. Steiner		Dr. Steiner welcomed everyone to the meeting and introduced Dr. Roberto (Tré) Mendez “” who is the new assistant director at the WSLH Newborn Screening Lab. Motion to approve May 13, 2022 minutes with two minor edits: 1st motion: Dr. Jeff Britton 2nd motion: Dr. Nick Antos Motion approved.

11:10 - 11:20	Department of Health Services (DHS) Updates	Dr. Steiner		Dr. Steiner shared the following DHS updates: There are several new DHS staff updates. Dr. Steiner introduced Julie Thiel, the new Children and Youth with Special Health Care Needs (CYSHCN) Unit Supervisor. Julie shared information on other new staff and positions: • Michelle Lund is the new CYSHCN Director. • Tamara Thompson is the new Out of Hospital Follow Up Coordinator, starting on December 5th. • Interviews are wrapping up for the new NBS Follow Up Coordinator position. Dr. Steiner shared news of the upcoming retirement of several health care providers working in the NBS program and thanked them for their service and contributions to NBS: • Kevin Josephson, Genetic Counselor at Gundersen. • Tami Miller, Dietitian at MCW.
11:20 – 11:30	WI State Lab of Hygiene (WSLH) Updates	Dr. Schauer		

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				• LuAnn Weik, Genetic Counselor at MCW. X-ALD has been approved by the Secretary of DHS to add to the NBS panel of conditions and is now moving through the rule-making process. There is a NBS funding shortfall. The costs for the NBS program continue to go up and there is not enough revenue to support the lab and the program. The program has been addressing this concern. There are two processes in place to address funding: • increase the blood card fee through the legislative process. This has been stalled for some time. • access funding through an internal DHS budgetary process. This is currently under review. DHS and the WSLH are working to find solutions to address funding challenges. Several committee

				members asked if they could get some further information to assist with advocacy. Dr. Steiner will follow up with them to provide this information. The Secretary approved several changes to the nomination process suggested by the SACNBS. The DHS website is in the process of being updated with these changes and the nomination form may need to be updated accordingly. An increase in the duration time for the retention of dried blood spots from one year to ten years passed through committees and s on hold. There are continued discussions with WSLH and DHS leadership. There are some concerns with what is happening nationally with lawsuits involving research use of dried blood spots as well as the need to look further into what the NBS Program is approved to do, per statute. Plans for designating a work group to review processes for approval of research using dried blood spots is

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				on hold pending guidance from the review of the issue related to dried blood spot retention. The program is also planning further discussions regarding the establishment of a Conflict of Interest (COI) review workgroup looking at the COI information submitted with nominations and participation in committee and subcommittee meetings. Dr. Schauer shared the following WSLH updates: The NBS Program funding shortfall is of major concern. Funding availability will need to be determined soon or the NBS Program will have to eliminate or downscale some services starting July 1, 2023. Blood spot retention and use outside of current practices is on hold. A legal counsel assessment is underway. The hope is to avoid a situation that would negatively impact the NBS Program. There are concerns with what is happening

				with other states with lawsuits involving research use of dried blood spots.
11:30 – 12:20	Subcommittee Updates Secretary's Advisory Committee on Newborn Screening (SACNBS) Update	All Chairs (**CCHD, CF**, Education, **Endocrine, Hearing**, Hemoglobinopathy, Immunodeficiency, and **Metabolic**) Dr. Fost		**CCHD: (Dr. John Hokanson)** Dr. Hokanson shared slides with the following CCHD information: • Looking at who is reporting and rate of failure, approximately 1/800 – 1/1,000 babies fail the screening. • Reporting has been easier now that centers can enter their data in WE-TRAC. • Getting data in WE-TRAC is going well but getting data out has been difficult. There is preliminary data on the first few years of the project. • The preliminary data assessment of screening shows the number of babies screened, the number with CCHD and the number suspected by pulse oximetry.

				There are about a handful of babies that are helped every year by the CCHD screening. One national study has shown that there is a 30% drop in the rate of deaths in correlation to state mandated CCHD screening. **CF/Molecular: (Dr. Antos)** Dr. Antos shared the following updates: • Dr. Baker shared the 2021 CF and Spinal Muscular Atrophy (SMA) screening summary. Rates were at what was expected. All SMA patients picked up were treated. • The current updated way of doing genetic testing for CF and CRMS is working and rates are at what is expected. • The Pediatric manuscript “Refinement of Newborn Screening for Cystic Fibrosis with Next Generation Sequencing”

				has been finalized. Dr. Antos will send to Tami once it is published to share with the committee. • There was discussion of an emergency plan if testing at the WI NBS Lab was interrupted. It was decided that there will be a short delay (1-2 weeks) in testing and if longer then MN would do the screen. The Minnesota panel is more restricted, so the subcommittee agreed to the importance of communicating the change in testing if it occurs. • There are two steps to the CF screening process and now with the advance in CF TR modulators there have been significant changes in outcomes for CF hospitalizations and use of special dietary treatment (SDT), both seeing decreases. Life expectancy

				for people with CF has increased into the 60s and hospitalizations have dropped. However, it was noted that babies of mothers with CF when on TR may have normal IRT. It is recommended if a mother has CF, infants should have genetic testing even if IRT is normal. There will only be about a handful each year in the next several years. • Several staff working in CF are planning to retire. Tami Miller (MCW), CF Dietitian, Kevin Josephson (Gundersen), Genetic Counselor, and Dr. Mike Rock (UW), Pulmonologist. Dr. Antos and the subcommittee thanked them for their years of service and contributions to CF and newborn screening.

				• Sweat tests ideally should be done within 2-4 weeks after NBS. The subcommittee will look at data at the next meeting to see if specific practices are contributing to delayed times for sweat testing. • There has been a separate workgroup formed to look at improving education for carriers. There are two guidelines' committees of the CF Foundation that Dr. Antos and Dr. Baker are involved in looking at CF management & treatment and CF NBS best practice. Mary Marcus shared involvement in a survey project of the CF Foundation looking at NBS practices around the country. She will share the paper when it is available. Mary also mentioned the dietitians are in the process of transitioning over CF patients that qualify for

				MA and receive SDT to MA coverage rather than the NBS program funding for SDT. The numbers are small and there are fewer CF patients requiring SDT largely due to the new modulators. She will have final data to share soon. **Endocrine: (Dr. Marquart)** Dr. Marquart shared the following updates: • Stafffing updates, DHS and WSLH updates were shared. • Dr. Baker shared 2021 data summary for rates of CH and CAH. There were 68 confirmed cases of CH and one confirmed case of CAH. Rates were in ranges as expected. • An update on 2nd tier CAH testing showed a decrease in false positive rates. • Discussion of a transition plan for the subcommittee chair role occurred. The

				subcommittee is looking at transitioning to a new chair every few years. **Hearing: (Dr. Kessel)** Dr. Kessel shared slides with the following hearing information: • Looked at screening trends over the years. In 2021 the numbers of babies that passed initial screen went from 98%-95%. Some of the down trend may be due to the covid pandemic and/or turn over in nursing staff. Babies enrolled in Birth to Three improved after suffering a bit during the pandemic due to virtual and zoom contact. This improved to 51% from 45%. • Quality improvement work has been done for babies at risk for late onset hearing loss. A project started in 2019 at Meriter Hospital targeted screening

				for congenital CMV. There was an increase in follow up for CMV. Not a lot were picked up but there was increased screening through salivary testing. There was an uptrend in those diagnosed with hearing loss in the testing group. • NICU babies are at a higher risk for hearing loss. A pilot screening program in the NICU was a success with only one baby out of 231 testing false positive. The pilot was missing a certain number of babies that may have been symptomatic with CMV. None of the babies less than 32 weeks had been screened by the recommended screen time of one month. There is work being done on quality improvement for testing babies earlier and trying to

				start a diagnostic hearing test in the NICU. **Metabolic: (Dr. Steiner)** Dr. Steiner shared the following updates: • Dr. Roberto “Tré” Mendez was introduced as the new Assistant NBS Lab Director. • Dr. Baker had shared that the WSLH submitted a proposal for a CDC grant that will help support XALD screening and testing. She also provided an update on the Recommended Universal Screening Panel (RUSP) at the national level. Four disorders were mentioned: 1. GAMT - recommended to be added but no response yet from the Secretary 2. Krabbe – an evidence-based

				review was commissioned 3. CMV – nominated to be considered 4. Duchene Muscular Dystrophy – nominated to be considered • Dr. Baker and Dr. Mendez shared the 2021 metabolic screening summary. • Discussion occurred regarding improving the screening algorithm for disorders with elevated C3 levels, homocystinuria and galactosemia reporting. • Dr. Baker shared an update on Pompe screening. There were very few false positives and mostly late onset cases picked up. • Dr. Jessica Scott-Schwoerer shared an update on the Genetics Exchange meeting. • The metabolic subcommittee considered

				the Mucopolysaccaridosis Type I (MPS 1) condition nomination and voted on the nine review criteria. The subcommittee recommended the addition of MPS1 to the panel and to forward their recommendation to the Umbrella Committee. **SACNBS: (Dr. Fost)** Dr. Fost shared the following updates: - The SACNBS prepared a letter to the Secretary urging attention to the funding shortfall. The letter should be going out within a week. - Of the six recommendations proposed to the Secretary, four were approved. The proposal regarding increasing the retention time for residual blood spots is on hold and under

				review. Dr. Fost is concerned about the final proposal for the development of guidelines for research. He is concerned about who is involved in decision-making /recommendations and not including those with expertise and experience in this area. He is asking that those involved encourage additional involvement in this review process. Jonette Arms to follow up with legal regarding opportunities for involvement in the legal review process.
12:20 – 12:45	Review Mucopolysaccaridosis Type I (MPS 1) Nomination	Dr. Basel/Dr. Mendez		Dr. Basel and Dr. Mendez shared background and testing information on MPS 1 and answered questions.
12:45 – 1:30	Review of Criteria & Recommendation: MPS 1 Nomination	Umbrella Committee	Review and Vote on Nine Criteria	Dr. Steiner led the voting committee members through a review of the nine criteria for

				consideration of the MPS 1 nomination. Voting members: 1. Dr. John Hokanson 2. Dr. Katie Marquart 3. Dr. Julie Kessel 4. Dr. Nick Antos 5. Dr. Jeff Britton 6. Dr. Michelle Miller 7. Angie Thompson 8. Mary Marcus 9. Emily Kittell 10. Samantha St. Pierre 11. Laura Leitch 12. Dr. James Schauer 13. Dr. Julie Thiel Criterion 1: mandated testing should be limited to conditions that cause serious health risks in childhood that are unlikely to be detected and prevented in the absence of newborn screening. 12 Yes 0 No 1 More information needed

				Criterion 2: For each condition, there should be information about the incidents, morbidity and mortality, and the natural history of the disorder. 12 Yes 0 No 1 More information needed Criterion 3: Conditions identified by new one screening should be linked with interventions that have been shown in well-designed studies to be safe and effective in preventing serious health consequences. 12 Yes 0 No 1 More information needed Criterion 4: the interventions should be reasonably available to affected new boards. 11 Yes 0 No 2 More information needed

				Criterion 5: Appropriate follow-up should be available for new ones that have a false, positive, newborn screen. 6 Yes 0 No 7 More information needed Criterion 6: The characteristics of mandated tests in the newer and population should be known, including specificity, sensitivity, and predictive value. 11 Yes 0 No 2 More information needed Criterion 7: If a new sample collection system is needed to add a disorder, reliability, and timeliness of sample collection must be demonstrated. N/A

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				Criterion 8: Before a test is added to the panel. The details of reporting follow and management must be completely delineated, including development of standard instructions, identification of consultants, and identification of appropriate referral centers throughout the State or region. 8 Yes 0 No 5 More information needed Criterion 9: Recommendations and decisions should include consideration of the costs of the screening test, confirmatory testing, accompanying treatment, counseling, and consequences of false positives. The mechanism of funding those costs should be identified. Expertise and economic factors should be available to those responsible for recommendations and decisions. 1 Yes

				0 No 12 More information needed The Umbrella Committee recommended the addition of MPS 1 by a vote of 12 – 1 to be forwarded to the SACNBS for review. The recommendation includes providing the additional follow up information to the SACNBS for criteria 5 & 9. Criteria 5 - appropriate follow-up should be available for newborns who have a false positive newborn screen. Criteria 9 - Recommendations and decisions should include consideration of the costs of the screening test, confirmatory testing, accompanying treatment, counseling, and the consequences of false positives. The mechanism of funding those costs should be identified. Expertise in economic factors should be available to those responsible for recommendations and decisions. Motion – Dr. Jeff Britton

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				2nd – Dr. John Hokanson Follow up information will be provided to the SACNBS prior to the March SACNBS meeting. Dr. Steiner will reach out to the nominators to gather the information.
1:30	Plan Next Meeting/Agenda Items	All		The next Umbrella Committee meeting will be on Friday, May 5, 2023, from 11-2.

Next meeting date: Friday, May 5, 2023

"Parking Lot" Items: