



Wisconsin Department of Health Services  
Wisconsin Division of Public Health  
Newborn Screening Program  
Umbrella Committee Meeting  
Friday, May 7, 2021  
10:00am-1:00pm

Zoom: <https://dhs.wi.zoom.us/j/85093123874>

Meeting ID: 850 9312 3874

Or phone: 1 312 626 6799 or +1 646 558 8656 or +1 301 715 8592

### Minutes

#### Meeting Members:

X	Dr. Nick Antos	X	Dr. Julie Kessel	X	Dr. Pilar Ossorio
X	Dr. Mei Baker	X	Alison LaPean-Kirschner	X	Dr. James Schauer
X	Dr. Jeff Britton	X	Mary Marcus	X	Dr. Paul Scott
X	Dr. Norman Fost	X	Dr. Katie Marquart	X	Nicole Sperl
X	Dr. Patrice Held	X	Dr. Michelle Miller	X	Dr. Robert Steiner
X	Dr. John Hokanson		Marilyn Noll	X	Kelsey Stevenson
X	Tami Horzewski	X	Dr. Anne Odusanya	X	Angie Thompson
				X	Ann Zenk

#### Meeting Guests

	Jennifer Ullsvik	X	Chuck Warzecha	X	Dr. Jasmine Zapata
X	Noel Fernandez	X	Sharon Gilbert		Beth Kalina
X	Elizabeth Seeliger				

#### Agenda:

Friday, May 7, 2021 10:00 AM – 1:00 PM				
Time:	Topic:	Lead:	Follow-up Items:	Notes:
10:00 AM-10:05 AM	Welcome Review and Approval of Past Meeting Minutes	Dr. Steiner		Tami Horzewski welcomed Dr. Steiner as the new Umbrella Committee chair and Newborn Screening Program Medical Consultant. Dr. Steiner started in his position in February 2021 and will be working part time (20%) with the Newborn Screening Program



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				<p>providing medical expertise. Dr. Steiner shared his background.</p> <p>Dr. Jasmine Zapata was also welcomed to the meeting. She was recently hired as the new Chief Medical Officer (CMO) and State Epidemiologist. Dr. Zapata shared her background.</p> <p>Review and Approval of Past Meeting Minutes.</p> <p>Motion to approve December 4, 2020 minutes:</p> <p>1st motion: Dr. Britton</p> <p>2nd motion: Dr. Scott</p> <p>Motion approved.</p>
10:05 AM -10:30 AM	Newborn Screening (NBS) Program Updates: Department of Health Services (DHS) Updates	Dr. Steiner		<p>Dr. Steiner shared the following DHS updates:</p> <ul style="list-style-type: none"><li>• Pompe Disease continues to move through the rule-making process. The Newborn Screening Program continues to work closely with the Office of Legal Counsel through this process.</li><li>• A proposed fee increase has started through the rule-making process as well.</li></ul>
10:30 – 10:50	WI State Lab of Hygiene (WSLH) Updates  2020 Condition Screening Summary	Dr. Baker  Dr. Baker		



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			<ul style="list-style-type: none"><li>A legislative bill was drafted for the addition of Krabbe Disease to the newborn screening panel of conditions and also includes an evaluation of additional Lysosomal Storage Diseases for mandatory screening. Krabbe Disease had recently gone through the nomination process a second time and there was a decision to table the decision to add the condition to the NBS panel pending more information especially on patient follow up care. As discussed at the previous umbrella committee meeting, a workgroup met to address possible patient care options. Testimony was provided for the legislative bill. A link to the testimony will be shared following the meeting. Link to testimony: <a href="#">sb0194 2021 03 17.pdf</a> (<a href="#">wisconsin.gov</a>)</li><li>Discussions continue at DHS in regard to the Krabbe bill. The Secretary's Office continues to be supportive of the current condition</li></ul>
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				<p>nomination and review process in Wisconsin.</p> <ul style="list-style-type: none"><li>• The newborn screening program continues to work with our dietitians and clinics on a Medicaid Policy Implementation Project to determine how to best implement the Medicaid policy for coverage of oral nutrition. Mary Marcus is the lead on this project and will be sharing an update later in the meeting.</li></ul> <p>Dr. Baker shared the following WI State Lab of Hygiene (WSLH) Updates: Dr. Baker informed the committee that WSLH is currently in a process to update NBS report structure and language. Here is a general project description. Project Rationales:</p> <ul style="list-style-type: none"><li>▪ NBS's limitations, such as false positive results and false negative results, may have not been sufficiently appreciated by health providers, parents, and the public, which results in unattainable expectations.</li></ul>
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				<ul style="list-style-type: none"><li>▪ Inconsistent terminology may inadvertently contribute to confusion between “screening” and “diagnosis”. Media attention and lawsuits</li><li>▪ Current NBS report structure/format is unable to meet needs for increased analyte complexity and number of screened conditions, and for electronic exchange system.</li></ul> <p>Project Goals:</p> <ul style="list-style-type: none"><li>▪ Emphasize risk assessment in NBS<ul style="list-style-type: none"><li>✓ Screen positive interpretation</li><li>✓ Screening negative notes</li></ul></li><li>▪ Harmonize terminology<ul style="list-style-type: none"><li>✓ CLSI recommendations</li><li>✓ CDC PT program languages</li><li>✓ CAP check list</li></ul></li><li>▪ Coordinate and co-locate interpretations and recommendations for actions</li></ul>
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				<p>Process and Tentative Timelines:</p> <ul style="list-style-type: none"><li>▪ Systematical report review and identifying needed changes (by end of June, 2021)</li><li>▪ Report structure and language construction (July, 2021 – February, 2022)<ul style="list-style-type: none"><li>✓ Subcommittees' inputs</li><li>✓ Submitters' feedback</li><li>✓ CAP compliance</li></ul></li><li>▪ Report structure and language updates build in LIMS (March – April, 2022)</li><li>▪ Evaluation and training, and education/information material update (May – June, 2022)</li><li>▪ Implementation (July, 2022)</li></ul> <p>The committee members commented that it was an important project, and suggested the following:</p> <ol style="list-style-type: none"><li>1. To seek the primary care providers' input and feedback</li><li>2. To consider that parents might review the NBS report through My Chart, so the report language needs to be reader friendly for the general population.</li></ol>
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				<b>2020 Condition Screening Summary</b> Dr. Baker provided a summary report on 2020 newborn screening. There were 59,896 infants screened in 2020. The outcomes are summarized in the table below.																		
				<table><tr><th>Condition</th><th>Number of Confirmed Cases in 2020</th></tr><tr><td>Aminoacidopathies and Urea Cycle Disorders</td><td>1</td></tr><tr><td>Biotinidase Deficiency</td><td>0</td></tr><tr><td>Congenital Adrenal Hyperplasia</td><td>7</td></tr><tr><td>Congenital Hypothyroidism</td><td>59</td></tr><tr><td>Cystic Fibrosis</td><td>10</td></tr><tr><td>Fatty Acid Oxidation Defects</td><td>7</td></tr><tr><td>Galactosemia</td><td>0</td></tr><tr><td>Organic Acidemias</td><td>8</td></tr></table>	Condition	Number of Confirmed Cases in 2020	Aminoacidopathies and Urea Cycle Disorders	1	Biotinidase Deficiency	0	Congenital Adrenal Hyperplasia	7	Congenital Hypothyroidism	59	Cystic Fibrosis	10	Fatty Acid Oxidation Defects	7	Galactosemia	0	Organic Acidemias	8
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				Phenylketonuria (PKU)	6
				Severe Combined Immunodeficiency (SCID)	2
				Sickling Disorders (SS, SC, S-Beta thal, Beta thal)	23
				Spinal Muscular Atrophy (SMA)	6
10:50 - 11:30	Follow Up – Retention NBS Blood Spots	Dr. Baker/Dr. Kessel	<p>Dr. Kessel and Dr. Baker shared a presentation on the retention of NBS dried blood spots.</p> <p>Dr. Steiner had shared with committee materials general information on retention of NBS dried blood spots, potential uses including quality assurance/quality control (retroactive retesting if potential missed cases identified), program development (development of new screening tests), clinical testing (e.g. CMV), and research.</p> <p>Some committee discussion items included:</p> <ul style="list-style-type: none"><li>• Researchers may request using residual NBS dried blood spots. Longer retention time for residual NBS dried blood spots could lead to more such requests.</li></ul>		





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				<ul style="list-style-type: none"><li>• There were requests to clarify the process when researchers request use of residual NBS dried blood spots.</li><li>• There was a suggestion to consider separating research issues from the clinical care purpose, but the consensus seemed to be to attempt to come to agreement on all issues related to retention at the same time. There was discussion on establishing a process for evaluation of research requests with the implication that the NBS Program carry out the evaluation (e.g. DHS and WSLH).</li><li>• Some of the issues to be discussed related to NBS dried blood spot research include existing State or federal laws. IRB rules</li><li>• Consent</li><li>• The committee discussed training materials for health care providers to address language/information shared regarding NBS in general, and retention of residual NBS dried blood spots specifically?</li></ul>
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			<ul style="list-style-type: none"><li>• Important to protect the “trust” of the public when considering changes to the process e.g. increased retention of residual NBS dried blood spots. Change in process (retention yrs) important to consider the language provided and consider a gradual process in making the change. Establish a communication strategy.</li><li>• Chuck Warzecha to check with the office of legal counsel regarding who has the authority to approve the use of residual blood spots for other uses</li><li>• Review and if needed develop additional policy WSLH/DHS policy in place to address permitted uses of residual NBS dried blood spots</li><li>• Create a workgroup to discuss the issues around retention (including research) and bring back to the committee a proposal for a vote at the next committee meeting. The workgroup to discuss research, clinical care use of residual NBS dried blood spots, quality assurance, assay development, retention time, etc.—</li></ul>
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				<p>all the relevant issues. The workgroup will bring a proposal back to the umbrella committee.</p> <p>Motion to form a workgroup to further discuss the retention of blood spots and report back to the umbrella committee at the December meeting. 1st motion: Dr. Britton 2nd motion: Dr. Kessel Motion approved. There was a request to send out information from the workgroup discussion in advance of the Umbrella Committee meeting to allow members time for review.</p>
11:45 – 12:10	Update on Medicaid Policy Implementation Project Mary Marcus			<p>Mary Marcus shared an update and presentation on the Medicaid Policy Implementation project for coverage of oral nutrition. The dietitians are looking at Wisconsin patients on medical assistance to see if they can obtain coverage through their Medicaid benefit for their newborn screening medical foods rather than using newborn screening program funding. There have been many challenges finding providers and vendors for these rare and expensive products. Mary shared that there has been</p>



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				minimal success in receiving coverage with several denials. She shared reasons for denials in addition to what is working well, time spent on this work, next steps and the development of future guidelines. Data will be compiled and shared in a report to be shared with the Newborn Screening Program and DHS.
12:10 - 12:20	Update Review of Nomination Process	Dr. Fost/Dr. Steiner		Dr. Fost shared a brief update on the plan for the upcoming Nomination process review workgroup meeting. The meeting is scheduled for Tuesday, May 11th. Depending on time, some discussion items will include: 1) Must the nominator or co-sponsor on the nomination be a physician? 2) Must the nominator and/or co-sponsor be based in Wisconsin? 3) How should research be addressed?
12:20 – 1:00	Secretary's Advisory Committee on Newborn Screening (SACNBS) Update  Subcommittee Updates	Dr. Fost  All Chairs (CCHD, CF, Education, Endocrine, Hearing, Hemoglobinopathy, Immunodeficiency, and Metabolic)		The following updates were shared: <b>SACNBS</b> (Dr. Fost) Krabbe legislative bill was the only update but was discussed during the DHS update. No other committee updates.  <b>Critical Congenital Heart Disease (CCHD) Subcommittee</b> (Dr. Hokanson)



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				<p>The CCHD Subcommittee met in March. Dr. Hokanson shared that there is a greater than 98% reporting rate for CCHD screening. There has been good reporting.</p> <p>The proposed change in algorithm for CCHD screening will not go forward at this time. The AAP cannot endorse the change as it hasn't been tested. In the survey conducted, 88% of participants were satisfied with the current algorithm.</p> <p>Kelsey Stevenson briefly shared CCHD screening data.</p> <p><b>CF Subcommittee</b> (Dr. Antos) No update. The subcommittee meeting was postponed until fall. Dr. Antos reported that Dr. Baker had shared some CRMS numbers.</p> <p><b>Education Subcommittee</b> (Alison LaPean-Kirschner) No update. The Subcommittee will meet again in late summer or fall. The Education Subcommittee will continue to look into the language provided in various NBS resources to parents/families.</p>
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			<p><b>Endocrine Subcommittee</b> (Dr. Marquart)</p> <p>The endocrine subcommittee met in April. Dr. Marquart shared the following updates: Dr. Held and Dr. Preet Matharu presented “modifying 17OHP screening cutoffs for improved detection of 21 hydroxylase deficiency”.</p> <p>This project resulted in a proposal for modified 17OHP cutoffs based upon both birth weight and timing of collection. A motion was made to accept and implement the new cutoff over the next six months. The committee will review and re-evaluate these cutoff changes in a year.</p> <p>Dr. Baker shared the following items with the subcommittee:</p> <ol style="list-style-type: none"><li>1) The 2020 summary report on CH and CAH screening.</li><li>2) Data on X-ALD NBS assay development and validation. The Metabolic Subcommittee has an approved motion to nominate X-ALD to be added to the Wisconsin NBS panel.</li><li>3) WSLH is currently in the process of updating the NBS report structure and language. Dr. Baker will be seeking input from the subcommittee for the items that</li></ol>
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			<p>may affect clinical follow up and are relevant to screening.</p> <p><b>Hearing Subcommittee</b> (Dr. Kessel) Dr. Kessel shared that the hearing subcommittee workgroups met in December. The subcommittee is currently working on a reorganization.</p> <p><b>Hemoglobinopathy Subcommittee</b> (Dr. Scott) No update. The Hemoglobinopathy Subcommittee meets annually in the fall and will meet again in October 2021.</p> <p><b>Immunodeficiency Subcommittee</b> (Dr. Baker) The Immunodeficiency Subcommittee met on April 19th. Dr. Baker shared the following items: 1) Dr. Baker informed the subcommittee that WSLH is currently in the process of updating the NBS report structure and language. Dr. Baker will seek input from this committee for the items that may affect clinical follow up and are relevant to SCID screening.</p>
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			<p>2) Dr. Baker reported an APHL led a SCID screening in premature infants project. This project will evaluate characteristics and outcomes of SCID screening in premature infants among multiple state newborn screening programs, and identify best practice in handling and providing recommendations for low TREC newborn screening results in different gestational age or birthweight groups.</p> <p>3) Dr. Baker provided the 2020 summary report on SCID screening.</p> <p><b>Metabolic Subcommittee</b> (Dr. Steiner)</p> <p>The metabolic subcommittee met in February. Dr. Steiner shared the following metabolic subcommittee update:</p> <p>1) Pompe and Krabbe Disease updates were shared. Pompe is currently moving through the rule-making process for addition to the WI NBS panel. The proposed legislative bill for Krabbe Disease was mentioned.</p> <p>2) Dr. Baker shared an update on the Recommended Uniform Screening Panel (RUSP). The current RUSP list has 35</p>
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				<p>conditions, and the Wisconsin NBS panel includes 32 of these conditions.</p> <p>3) Dr. Baker provided an update on X-ALD NBS Assay Development. The Metabolic Subcommittee has approved a motion to nominate X-ALD to be added to the Wisconsin NBS panel. Drs. Jennifer Kwon and Mei Baker are working on this nomination.</p> <p>4) Dr. Scott-Schwoerer shared considerations and outcomes for screening for vitamin B12. The subcommittee reviewed whether Newborn Screening for B-12 should be considered in Wisconsin or should be addressed as an incidental finding.</p> <p>5) Dr. Scott-Schwoerer, Emily Singh, and Dr. Held shared testing and outcomes for screening for PA/MMA.</p> <p>6) Mary Marcus provided an update on the implementation of the Medicaid policy for oral nutrition.</p> <p>Policy implementation will be addressed as a part of the blood collection card fee increase process.</p> <p>The NBS fee increase is processed through administrative rule making and the 18-24 month process has been initiated.</p>
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1:00 PM	Plan Next Meeting/Agenda Items	All	<ul style="list-style-type: none"><li>• Follow up on review of the nomination process</li><li>• Follow up on specimen retention</li><li>• Update on final report of the Medicaid implementation project</li><li>• SACNBS and Subcommittee updates</li></ul>
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Next meeting date: Friday, December 3, 2021

**“Parking Lot” Items:**