



**Joint Advisory Committee for Newborn Bloodspot Screening
May 5, 2020
Virtual Meeting Minutes**

Members Present:	Thomas Brewster, Frank Chessa, Abigail D’Ambruoso, Meghan Dumas, Mary Ann Gordon, Maryann Harakall, Alex Marcotte, Nola Metcalfe, Jenn Moreno, Jerry Olshan, Jodi Philippon, Katherine Reilly, Holly Richards, Elizabeth Schweitzer, Wendy Smith, Daniel Sobel, Kassie Swallow, Anne Watson, Melissa Whitcomb.
Members by Phone:	
Guests:	N/A
Recorder:	Amy Fair

Welcome and Introductions	<p>Abby and Melissa welcomed everyone to the meeting.</p> <p>Holly introduced Amy Fair, medical secretary who started on April 13th.</p> <p>Amy went through the roster, introductions were made by each member.</p>	Abby, Melissa, Holly and Amy
Committee Business	<p>Review the minutes</p> <ul style="list-style-type: none"> • October 2019 minutes were reviewed and accepted. • Daniel Sobel - question regarding NBS rules, rules are still in process, does this mean all activities - birth defects, hearing, bloodspot, congenital heart disease, premie? Will this all be under the daily work of this committee? -Holly Richards explained that these are statutes with different rules being integrated into one rule. JAC will continue to oversee only bloodspot. 	Daniel Sobel Holly Richards Abby D’Ambruoso Anne Watson

	<ul style="list-style-type: none"> • Abby D’Ambruoso reviewed follow-up tasks: <ul style="list-style-type: none"> ○ Megan and Wendy had volunteered for a subcommittee on the new conditions with Anne Watson. Anne will give a report on this later in this meeting. 	
Updates and Highlights	<ul style="list-style-type: none"> • Wendy Smith and Anne Watson attended the annual NE Metabolics Consortium in November. • Clinics - Wendy Smith shared that Kassi is a new mother and is now back to the Portland Clinic. They hired a new dietician, Alex, to replace Caroline, who left in December. They are seeing patients remotely. Bangor clinic is working fine, they are remote as well. • Mary Ann Gordon- They made the difficult decision to cancel camp for this year. They couldn’t foresee a way to bring families together and to make everyone feel comfortable. When things re-open, they will try to do something. If not, they will carry on in 2021. Bangor is canceling as well. • Jerry Olshan – Wanted to discuss ways to avoid negative outcomes of congenital hypothyroidism, it was decided that at the end of the meeting we can revisit this specific case. • Wendy Smith – ACMG clinical guidelines for PKU are in the process of being updated and rewritten. Hopefully it will happen within the year. No major changes coming to the guidelines, just adding in evidence-based information on protocols that has become available. Changes since 2014 include new medication options as well as gene therapy in clinical trials. 	Wendy Smith Mary Ann Gordon Jerry Olshan
NBS Program Updates	<ul style="list-style-type: none"> • Holly Richards – Program has been primarily remote since the end of March. Everyone in the larger program is working from home, Amy is in the office and periodically others go in if needed. • Holly Richards - We are in the process of combining all the statutes into 1 rule for newborn screening which include the addition of 4 new bloodspot conditions. If the rules are not finalized by July 1st, we may look at an October 1st date instead for adding the new conditions. A fee increase is also involved in order to pay the lab for the new testing. • Holly Richards – Our Care Coordinator Pam sent out letters for those who participate in the assistance program as we ask people to reapply every year and fill out the new forms. We also went back to all our clients that may not have qualified for the program last year but because of any changes they may have encountered this year, they could now be eligible. We are encouraging people 	Holly Richards Daniel Sobel Jean Moreno Jodi Philippon Wendy Smith Anne Watson Melissa Whitcomb Mary Ann Gordon Frank Chessa Abby D’Ambruoso

to reapply and if they qualify, they will instantly be put onto the program. Over 200 letters have been sent out.

- Holly Richards – Quite a bit of work has been done to our website.
- Holly Richards – There is an existing law for preventative care of infants involving erythromycin, and we have added Vitamin K as a second mandatory preventative care of infants. The addition becomes effective June 16th. Brochures are being created for this that will go out to the hospitals to be used as education for parents on the importance of these two preventative care measures. A refusal form also had to be created - if parents choose to refuse one or both of these services this form has to be filled out and sent back to us. We are going to be tracking these refusals starting in June. The refusal form and education has gone out to all birth hospital nurse managers.
- Holly Richards – We have an electronic ordering system that midwives are using to order NBS filter papers. This hasn't been rolled out to hospitals yet because hospitals currently pay with a purchase order and this system requires a credit card payment.
- Holly Richards – There has been a lot of work done around safe sleep, materials are available if people are interested.
- Holly Richards – We are getting ready for our next 5-year work plan, based on some focus groups and priority settings the topics that rose to the top of interest were transitions from youth to adulthood healthcare and care coordination. We are currently working on some activities and strategies for those.
- Daniel Sobel – Questioned if there has been an increase in newborn screening refusals among midwife deliveries. He stated that the consensus was that they have not increased. We have data systems that help us to track midwife births, but we can only determine if an NBS has not been done if the parents file for a birth certificate. Refusals are followed up on.
- Holly Richards – Midwives became licensed in January of 2020. There is a work group being formed to determine if they can operate the same or differently and that doesn't have to be finalized until next January. Holly has had discussions with the policy department at MaineCare. MaineCare is willing to open a code or change their policy to cover home births. As licensed entities, midwives will have to follow guidelines that conform to the use of public funds for health care.
- Jean Moreno – Questions if there has been an increase in midwives requesting bloodspot screens? They see women who are unable to deliver at home who come into the hospital to deliver and refuse the newborn screen.

-Holly Richards – We have not seen an increase in refusals, and we are only able to track babies if they have a birth certificate. If we have a birth certificate and no newborn bloodspot screening result and no refusal form, Jodi follows up with the provider. If the providers don't have a refusal, letters go out to families along with the newborn screening brochure and a refusal form as certified mail.

-Anne Watson - No specific numbers but most of the refusals are home births. We need to keep thinking about how to encourage midwives to relay to patients the importance of newborn screenings, but we will always have people who do not want to participate.

- Jodi Philippon– Since COVID operations have gone into effect, the biggest changes has been the moratorium on sweat test referrals. We have only had one instance where new parents left the hospital early because they were concerned about COVID. We have had two issues where parents were initially reluctant to do a repeat screen because of COVID but after obtaining information they did have the repeat screening done.
- Jodi Philippon - When an abnormal screen occurs on a report that is titled “Preliminary” only the other results are actually still pending – the abnormal result is final. Jodi has been working with people to clarify this change, which occurred with the upgrade to the new laboratory reporting system.
- Jodi Philippon - Discussed the differences between results that the metabolic clinics consider urgent and what the UMASS Lab considers urgent, this is an area still being worked on. The labs wording is hard to work through sometimes. Wendy Smith allowed that the differences in the wording have to do with liability issues on the side of the lab.
- Anne Watson – Two new software systems:
 - Maine Newborn Screening Portal – This is our new CDC Maternal Child Health Program tracking system, that we are calling Nebulogic. In this system, birth certificate information, bloodspot screening results, hearing screening results, and birth defect data are imported and can be linked to create integrated files for individual children.
 - UMASS Medical School Laboratory Information Management System – In this system we access bloodspot specimen lab results and reporting, patient care follow-up algorithms and tracking for out-of-range results, documentation of confirmed conditions and quality performance measures. We continue to learn the capacity of both systems.
- Anne Watson COVID – We created a continuity of operations plan for COVID. Wendy Smith was very helpful in the process of figuring out how we would

deal with people wanting to leave the hospital early, not wanting to return for repeat screens and people coming into the state and giving birth and then returning to their home state where protocols might be different. This was successfully completed, and educational materials were sent out to all of the birth hospitals.

- Anne Watson – We currently screen for 51 conditions. Tentatively in the fall of 2020 we will be adding 4 new conditions: Pompe disease, X-linked adrenoleukodystrophy (X-ALD), mucopolysaccharidosis Type I (MPS-1) and spinal muscular atrophy. A subcommittee met earlier this year to discuss the new conditions: specialty clinics were identified, along with notification details, follow-up algorithms and special circumstances. A presentation was made to the perinatal nurse managers about the 4 new conditions. The addition of the 4 new conditions will not affect specimen collection, changes will only be on the analysis side. Anne is currently working on the standard operating procedures for how we will report out the results and working on putting together the packets of information that Jodi sends out when there is an abnormal result. We have started to prepare materials that will be used to announce the new conditions; new brochures, website, press release, facility guidance and professional societies. We will also assess the impact of adding the conditions after they are rolled out. The new conditions are dependent on gene sequencing testing so the timing of reporting out will be a little different.
- Holly Richards - We are in the rule making process. There will be a public hearing on finalizing the addition of these conditions to the Maine NBS panel. The filter paper costs are still under discussion, but because we are going to be increasing the number of tests that UMASS runs, the fees for the filter papers probably will have to go up. Current filter paper price is \$110.00 each.
- Anne Watson - shared preliminary 2018 vs 2019 data. Number of births has decreased slightly, number of initial specimens received has also decreased slightly, number of repeat specimens received has decreased, number of documented refusals has increased, number of no response refusals has decreased and the number of babies with out of range results has increased. We do require written documentation of refusals but sometimes even after letters are sent out, we do not receive a response.
- Anne Watson - shared a list of all out-of-range lab results for all the analytes that are tested by the lab 2018 vs 2019 but does not include results from gene mutation screening.

	<ul style="list-style-type: none"> • Anne Watson - shared another slide that shows confirmed cases by condition for the last two years, we have a lot of out of range results that when we do repeat testing or when additional follow up testing is conducted it turns out that the babies are ok. These data also do not show any results from gene mutation screenings. • Melissa Whitcomb – question regarding time period after the rules change that a certain amount of money is going to need to come in before you start testing for new conditions, or will it start at the same time? -Holly Richards - We need the rules to be finalized, once we have this, we can go through a budget initiative to request more allotment then we should be good to go. 	
Public Comments	<ul style="list-style-type: none"> • According to the attorney general if we allow the public to attend JAC meetings, they must attend in person. Anne Watson put on our website for people to contact her to receive Zoom information if they wanted to attend this meeting and she had no requests to attend. 	Holly Richards Anne Watson
JAC Membership	<ul style="list-style-type: none"> • Holly Richards - Colleen filled the Public Health Nursing role. Vacancies that we do have are a social worker, and 2 community representatives (ideally) parents of children with one of our condition on the newborn screening panel. Mary Ann Gordon asked Dr. Olshan and Meghan Dumas if they would be interested in reaching out to a parent. They both accepted and will work on this. • Anne Watson - suggested forming another subcommittee to look at how we have the membership organized to make sure we do have all the specialties represented, both providers as well as community members and parents. Also, looking at being a voting member vs. being an interested party. Mary Ann Gordon and Frank Chessa would like to help with this. Abby D'Ambruoso is going to reach out to one of the MMC social workers to see if she is interested in joining. 	Holly Richards Mary Ann Gordon Anne Watson Frank Chessa Abby D Ambruoso
New Conditions discussion	<ul style="list-style-type: none"> • Anne Watson covered earlier in minutes under NBS Program Updates. 	Anne Watson
Other	<ul style="list-style-type: none"> • Wendy Smith - question to Holly Richards – Can the legislators get the rule making done at any point? Holly Richards – It won't go through the legislators, it has already gone through the commissioners office, then it goes to the attorney general's office then there will be a public hearing where people can write for or against if they disagree with anything or they can come physically in person depending on how things are at that time. 	Wendy Smith Holly Richards Kelly Bowden Abby D'Ambruoso Meghan Dumas Anne Watson Jean Moreno

	<p>Holly Richards and Anne Watson are preparing to alert hospitals about a filter paper price increase. At this time Holly is unsure of what exactly the cost will be, but they are looking at doubling it. We haven't had a cost increase for NBS filter papers since 2008, the increase also doubled then from \$52.00 to \$110.00. The rule should be finalized by the end of the summer, so we are looking at a October 1, 2020 start date.</p> <ul style="list-style-type: none"> • Kelley Bowden – Will you be sending out a cost projection to hospitals? Holly Richards – We are going to check with policy folks to see if we are allowed to send out a cost increase projection. Kelly is willing to help with anything needed. • Abby has emailed Aaron Weiss, a social worker at Maine Children's Cancer Program about being part of the committee. • Meghan Dumas – Any thoughts on when sweat testing is going to restart? Anne Watson – Hoping this will resume by the end of the month. She will get back to Meghan regarding this. • Jean Moreno chat question - Do we have a record of how many unsatisfactory specimens we have at EMMC. -Anne Watson is going to get back to Jean about this. 	
<p>Next meeting dates</p>	<p>October 14, 2020 1:30-4:00 at Maine CDC, 286 Water Street, Augusta May 12, 2021 1:30-4:00 at Maine CDC, 286 Water Street, Augusta</p>	