**Executive Summary – Two Routine Newborn Screens During the COVID-19 Pandemic?**

**3/27/2020**

**Washington State Newborn Screening Program** (contact: John Thompson, Director, 206-418-5531)

**Background:** Washington Newborn Screening (NBS) Program recommends that all babies have two routine screens. This recommendation is putting families at risk and has the potential to tax the medical system during this critical time. This conflicts with the Governor’s “Stay Home, Stay Healthy” directive.

**Suggested policy change:** Newborn Screening Management suggests relaxing the recommendation that all babies have second screens for the duration of the COVID-19 pandemic.

**Benefits**

* Fewer families out in public getting a second screen
* Lower impact on hospitals, clinics, laboratories and midwives
* Fewer specimens needing to be processed by the state NBS lab (we are running split shifts in the NBS lab using two skeleton crews)

**Risks**

* Missing a baby - a small number of babies with NBS conditions have normal first screens, followed by an abnormal second screen; historical data show that the highest risk will be for congenital hypothyroidism and congenital adrenal hyperplasia (if zero second screens were performed, we would miss one or two cases each month – more data below on this impact)
* Primary care providers might be confused by the change in recommendations
* Primary care providers might not revert to collecting routine second screens after COVID-19 pandemic passes

NBS would continue to recommend second screens for babies in neonatal intensive care units (NICUs) and babies who have abnormal or unsuitable test results from the first screen.

**Support for temporary change:** The NBS clinical consultants for endocrinology (Dr. Patricia Fechner, Seattle Children’s Hospital) and biochemical genetics (Dr. Sihoun Hahn, Seattle Children’s Hospital) have reviewed the suggested change and are supportive of the action (email responses included below). Michelle Davis (SBOH, Executive Director), Gail Yu (AAG) and Judy Morton (agency risk manager) are supportive also.

**Next Steps:** This needs review and approval from Kathy Lofy (State Health Officer and Co-chair of the ad hoc NBS Advisory Committee). NBS staff will be reaching out to communications staff to help with the messaging. Because of the newest guidance from the Governor, we want to make this change as soon as possible. Thank you!

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**Washington State Newborn Screening Program** (contact: John Thompson, Director, 206-418-5531)

**Current policy:** Washington NBS Program recommends that all babies have two routine screens

**Impact to families:** Concerns about COVID-19 pandemic and direction from Governor Inslee have stressed the importance of social distancing. The DOH’s recommendations for two routine NBS specimens for each baby is inadvertently putting babies and their parents at increased risk for exposure to COVID-19.

Anecdotally, we have heard from colleagues in other states about difficulties in obtaining needed follow-up:

“We are beginning to experience delays in accomplishing needed screening or follow-up due to parent reluctance to take their babies in to get a repeat or confirmatory specimen because of the CoVid 19 virus, AND due to hospital policies turning parents away if they exhibit any signs, even if they have self-quarantined for 14 days.” – Julie Luedtke, NE NBS follow-up supervisor

**Impact to the health care system:** COVID-19 is taxing the medical system. Depending on the location, families bringing their baby to a laboratory for a second screen may be turned away. Other locations may be experiencing long wait times. If limited resources are available for patient care, we want those to be used for babies with first screens that were positive or unsuitable.

**Impact to NBS lab:** The WA NBS laboratory typically operates in two main teams: Alpha (works M-F, 7a-4p) and Team Bravo (works Tu-Sa, 7a-4p). The morning hours have the most interactions with one another: during specimen receiving/sorting and punching specimens into plates. Before and after this set of tasks, the analysts are typically in their own section of the laboratory beyond six feet of the next employee. Analysts and lead workers have frequent interactions about worklists and any special circumstances (instrument troubleshooting, special requests, etc.) that can be mitigated with technology solutions. We have already implemented (3/18/2020) social distancing practices for mail sorting and specimen punching processes. This will limit the close interaction of lab staff.

Despite these measures, the NBS laboratory runs the risk of shutting down services if one laboratory worker tests positive for COVID-19; if one lab worker is diagnosed, all close contacts will be quarantined for 14 days (see end of document for CDC’s definition of close contact). We have a MOA with TX NBS to help us in an emergency situation. They have a surge capacity of about 700 specimens per day. This would not cover our full need; we would need to send all newborn specimens and only follow-up specimens linked to a previous specimen with abnormal or unsuitable results. This would fulfill our need within their surge capacity. If TX NBS is also shut down or at limited capacity, we would explore other options. The worst case scenario is that we would not test for a period of time.

The NBS team implemented two laboratory teams during separate shifts. This way, if a laboratory worker is diagnosed with COVID-19, only that person’s team would be quarantined. The other team would cover all operations for the duration of the quarantine. This started 3/26/2020 and will continue for the duration of the Governor’s “Stay Home, Stay Healthy” directive.

**Policy for consideration:** DOH will temporarily remove its recommendation that all babies to have a routine second NBS specimen collected at 7-14 days of age (for the duration of the pandemic only).

**Benefits:** Improves social distancing for babies and their caregivers. This policy would reduce the number of patients being seen at laboratories, hospitals and clinics, as well as in-person interactions with midwives (for babies born out-of-hospital). Second screens would not be rejected; it would be fine for babies to have 2nd NBS collected during their 2 week well-child visit, since they will already be at the pediatrician’s office. DOH would continue to recommend second screens for babies with abnormal or unsuitable results on the first NBS and for babies in NICUs.

**Benefit:** Fewer specimens will be easier to process by the NBS lab in the event of quarantine (full or partial). Reduced staff would better be able to process the smaller sample volume. Fewer specimens would be easier to send to TX NBS if all lab staff are quarantined.

**Risk:** There is a small risk that this policy would cause a missed baby. We know that some babies with NBS conditions (primarily endocrine and metabolic disorders) have normal NBS results on the first screen and abnormal results on the routine second screen. This is a main reason for doing two routine screens. The risk of missing a baby is small. Based on historical data in WA, congenital hypothyroidism (CH) and congenital adrenal hyperplasia (CAH) are the two conditions most frequently with false negative first screening results that are later identified through a subsequent screen. CH is the most common condition on our NBS panel. We would expect to miss one or two babies each month if we didn’t obtain second screens. We would expect to miss one baby every six months with CAH. Other conditions are also possible, but have a much reduced frequency, so have lower risk (homocystinuria, PKU, MSUD, MCAD deficiency).

**Risk:** PCPs for babies who need a second screen (abnormal or unsuitable on first screen) might be confused by the new recommendations or be less inclined to coordinate getting the second screen because of the change in policy.

**Risk:** There is a risk that some providers won’t return to the standard of care (two routine screens) when the temporary measure is repealed. We need to be careful with the messaging for this policy, to be clear this is not a long-term change.

**NBS recommendation:** Implement temporary policy change relaxing the recommendation for two routine screens for all babies for the duration of the COVID-19 pandemic in Washington State. Probably tie this to the Governor’s state of emergency: we revert back to two routine screens when the Governor declares the emergency over.

WA will not change the NBS fee.

Input from our clinical consultants and policy partners:

**Dr. Romesh Gautom – Public Health Laboratories Director**

Supportive

**Dr. Fechner – endocrinology (Seattle Children’s Hospital)**

Dear John,

Thank you for sending. I support your decision for a temporary discontinuance on collecting routine second screens during the COVID-19 Pandemic State of Emergency.

Best,

Patricia

**Dr. Hahn – biochemical genetics (Seattle Children’s Hospital)**

Hi John,

Yes, I agree and support your decision to temporarily discontinue the second screen collection during the state emergency due to COVID-19 pandemic situation.

Best,

Sihoun

**Angi Miller – Deputy Assistant Secretary, DCHS**

Supportive, making sure stakeholders are aware and also supportive

**Michelle Davis – Executive Director (State Board of Health)**

[phone call – no email access available for her] Supportive and suggested that we reach out to AAG. Also asked me to write a paragraph about the policy change for the upcoming SBOH meeting (April 8)

**Gail Yu – Assistant Attorney General**

Dear Dr. Thompson,

The Department of Health Newborn Screening Program can legally amend its recommendation that babies receive a second screening as a policy change during the duration of the current declared public health emergency. It is supported by expert opinion and based on public health exigencies, including reasonable reluctance to risk contagion, as well as complying with the Governor’s proclamation to stay home in most circumstances.

The risk is quite small in relative numbers, but there may be legal risk from a few missed cases. This risk can be mitigated somewhat by reminding providers that a second screening could be done during the well-baby visit, during other pediatric visits, in NICUs, or where there are indications of suspicious symptoms that are not otherwise explained. I defer to your knowledge of the nature of these conditions.

This is a reasonable method to relieve some of the burden related to practices to lessen the spread of the virus.

Let me know if there is anything else I can do,

Gail

**Judie Morton – DOH Facilities, Risk and Adjudication, Deputy Chief**

Thank you for reaching out, and for the background information. Under the current circumstances, the recommendation supports the Governor’s directive, and I support.

Please let me know if you have any questions,

Judie

**Next Steps:**

* People who need to buy in: Kathy Lofy (state health officer)

If DOH supports this decision

* Heads up to consultants in subspecialties not affected, but may have interest: pulmonology, hematology, immunology
* Communication
  + Clear message – one-pager with FAQ on reverse?
    - Work with divisional PIO
    - No change to recommendation that babies in NICUs get 3 routine screens
  + Needs multi-pronged messaging
    - Listserv
    - Website
    - Mass mailing to clinics, hospitals, labs, midwives and birthing centers (all facilities that collected specimens in the past year) – maybe a postcard?