

Newborn Screening Continuity of Operations in a Pandemic

USE OF TELEHEALTH AND OTHER LESSONS LEARNED

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Newborn screening (NBS) is an essential public health program that relies on an entire system to ensure the methodical screening, diagnosis, monitoring, and treatment of babies affected by the screened conditions. As babies are born each day, and timely screening must occur in order to identify at-risk infants before symptoms become apparent, each part of the newborn screening system must maintain functionality even when confronted with unusual and unexpected circumstances. Newborn screening programs (NSPs) and all system partners (e.g., hospitals, birthing centers, clinicians, specialists, diagnostic laboratories, and treatment centers) must develop, exercise, and revise plans to ensure continuity of operations that are adaptable to the many situations that may interrupt typical daily functions. Interruptions may be as simple as a short-lived power outage or as extreme as a worldwide pandemic.

The COVID-19 pandemic unfolded over a relatively brief timeframe in the United States with the first domestic case reported in January 2020 in Washington State followed by rapid spread in metropolitan areas such as New York City. NSPs were forced to adapt quickly, contrary to their typical pace of change. During non-emergency circumstances, legislatively mandated NSPs operate like machines, with little variability in daily operations. Test volumes remain relatively static and necessary reagents, supplies, and materials are a constant. Because of this, programs do not often need to pivot, and certainly, not as quickly as was required by the pandemic. Though the COVID-19 pandemic has placed unfathomable pressure on the newborn screening system, lessons have been learned that must be incorporated into each state's continuity of operations plan. The utility of one particular resource – telehealth – has been highlighted by the pandemic experience and should be explored and further incorporated throughout the newborn screening system.

Electronic, Remote, and Accessible Solutions within the Laboratory

Programs are required to perform accurate and timely testing, reporting, and follow-up every day. Prior to the pandemic, NSPs, particularly the laboratory areas, required staff to be on-site to perform daily functions, and remote work was typically limited to after-hours, on-call duties, and primarily for non-testing activities like result notification and clinical follow-up. At the outset, information technology (IT) departments were hesitant to facilitate or provide telework capabilities for newborn screening staff due to data security concerns. However, as the number of COVID-19 cases soared, IT departments reconsidered providing virtual private network (VPN) access to servers within the laboratory as NSPs planned for the possibility that very limited staff would be available to perform necessary on-site functions. While data entry and follow-up duties may lend themselves more easily to remote work, the pandemic necessitated that remote data analysis be added to the 'telehealth' spectrum in some NSPs. Remote data analysis for laboratory staff allowed staff to work from home as if sitting in the laboratory at the instruments. Continuity of newborn screening system operations is particularly important for time-critical conditions. By checking results from home, the laboratory can alert follow-up staff more quickly, providing more time to notify the medical community and locate those babies requiring diagnostic evaluation.

Telehealth considerations in the NSP: The ability to perform remote data analysis lends programs several advantages:

- It decreases the density within the laboratory, and thus, in-person contact on-site;
- By requiring fewer staff on site, NSPs can absorb loss of staff due to disease quarantine requirements or reassignment to pandemic response;
- Most importantly, remote analysis helps ensure continuity of newborn screening system operations;
- Results can be analyzed during off hours, and in cases where specimen deliveries are delayed, staff can check for emergency referrals after-hours without having to come into the laboratory;
- Cross-training staff to perform on-site and remote functions also helps ensure that programs remain functional, affording staff some respite.

Electronic, Remote, and Accessible Solutions within Follow-up

Non-laboratory staff play a critical role in NSPs. These staff follow up on actionable results and perform administrative, financial, data management, epidemiological, and compliance/surveillance tasks. Prior to the COVID-19 pandemic, many NSPs offered these staff a certain measure of flexibility to work from home using telehealth solutions. This flexibility allows for results to be called out during non-business hours – a time-saving measure for time-critical disorders. In programs that allowed remote options, these telehealth solutions included the ability to connect via VPN to laboratory information management systems (LIMS), other program-specific databases, and secure email systems. Programs with telework capacity prior to pandemic stay-home mandates were able to adapt quickly by shifting most, if not all, of this work to home-based operations. The remaining programs were generally able to broker solutions with their IT departments to allow their staff remote access during the pandemic.

Telehealth considerations in the NSP: Remote access capability for NBS staff will pay dividends long after the pandemic resolves:

- Telework options allow faster response to critical laboratory results on weekends and holidays by follow-up staff because they do not need to travel to the office to access the LIMS and call out results.

Other telehealth solutions within follow-up teams played important roles in the success of continuing operations during the pandemic. Work telephone extensions to a mobile number or call center allowed follow-up and other office staff to forward their work phone lines to cell phones. This provided the opportunity to continue the telephone-heavy work of many of these positions, including calling out results and fielding calls from providers and the public. Electronic faxing capacity allowed follow-up staff to tailor messages to primary care providers regarding NBS results, make recommended follow-up actions, and continue to provide relevant

educational materials. NSP staff greatly benefited from being able to receive and process electronic faxes from providers and diagnostic laboratories. NSPs without this option were faced with two alternatives: bring staff in physically to print and send documents via fax and postal mail, or change protocols to eliminate this type of communication.

Online tools were also helpful in education/outreach efforts. In non-pandemic times, many NSPs would send staff members to site visits for birth facility-specific feedback and support. Many birth facilities were overwhelmed with the COVID-19 response and were in “all-hands-on-deck” mode. As a result, online resources, such as archived trainings, were a resource for educating new staff on NBS requirements during this time. Communicating with birth facility and other clinical staff via video conferencing provided an effective alternative to in-person meetings. These platforms were critical to keeping NBS teams and stakeholders in close communication during the pandemic, although they were separated physically. They also facilitated training of new NBS staff when in-person options were limited or not allowed.

A silver lining of the worldwide pandemic has been the careful evaluation of NSP activities, resulting in new efficiencies realized by trimming away unnecessary processes. Many programs have significantly reduced paper-based records for follow-up and other operational tasks, opting for electronic filing of related paperwork (which has the advantage of being traceable and auditable in LIMS). Furthermore, revision of policies to accept e-signatures have also sped up many bureaucratic processes, such as procurement requests, contracts management, and human resources paperwork.

Telehealth considerations in the NSP: Online tools will continue to be helpful to NSPs after the pandemic by:

- Making trainings available online (e.g., for NBS specimen collection, etc.) and circumventing the need to conduct trainings in person
- Facilitating regular communication between NBS teams and stakeholders despite physical distance
- Reduction or elimination of paper-based records in favor of electronic records which can be traced and audited
- Ability to accept e-signatures in place of wet signatures to facilitate procurement requests and contract management.

Electronic Reporting of Newborn Screening Results

Provision of newborn screening results to all relevant stakeholders remains of utmost importance during any incident, crisis, or lasting emergency. Assurance that all screening results (actionable or not) are available to clinicians and families is necessary to achieve the mission of newborn screening.

The ongoing COVID-19 pandemic highlighted the utility (and in some cases, necessity) of moving away from paper-based NBS results reporting (often accomplished via postal mail or fax) to electronic-based reporting options. Electronic availability of NBS results during the pandemic provided several benefits to NSP staff and to external NBS stakeholders alike (see Figure 1).

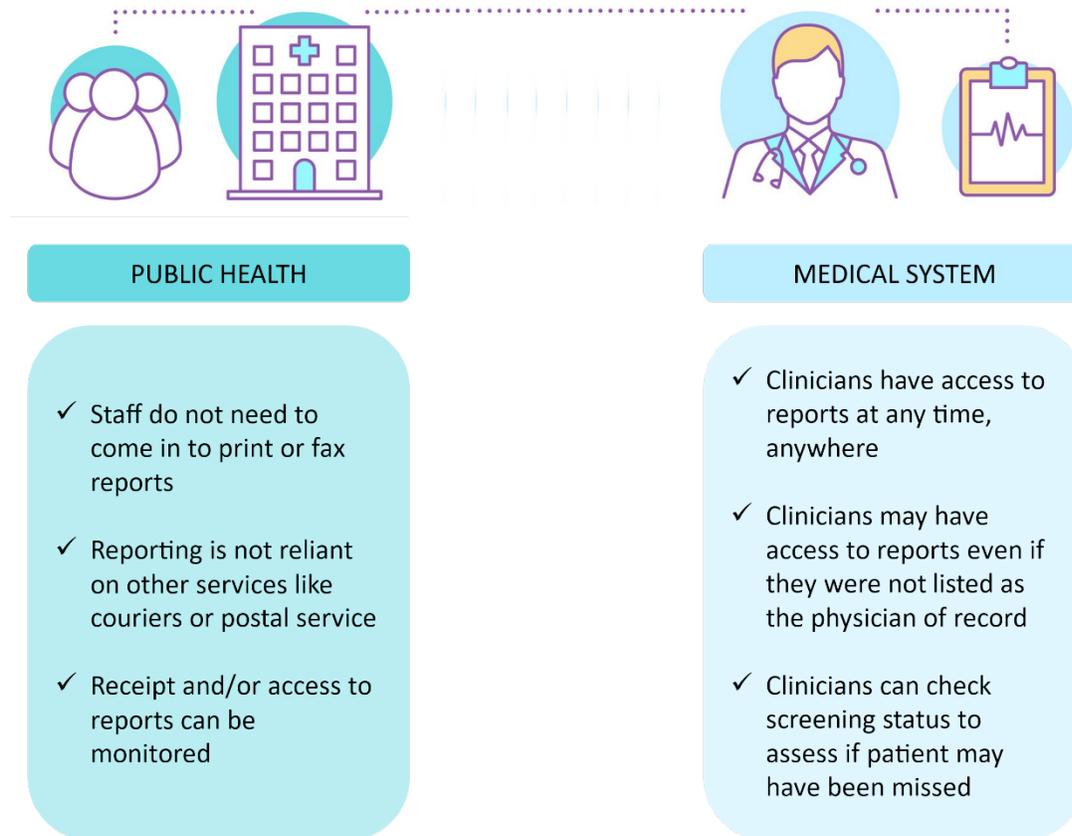


Figure 1. Benefits of Electronic Results Reporting Across the NBS System

While provision of NBS results is always an integral component of the NBS process, ensuring availability of results, delivery of reports, and recommendations to all relevant stakeholders across the NBS system during emergent situations, especially those that cover the entire nation and remain ongoing for months, is even more vital. Use of electronic reporting mechanisms can help lower risks for gaps in care when typical resources, staff, or back-up systems may not be available. Figure 2 outlines considerations for electronic reporting of NBS results across the NBS system.

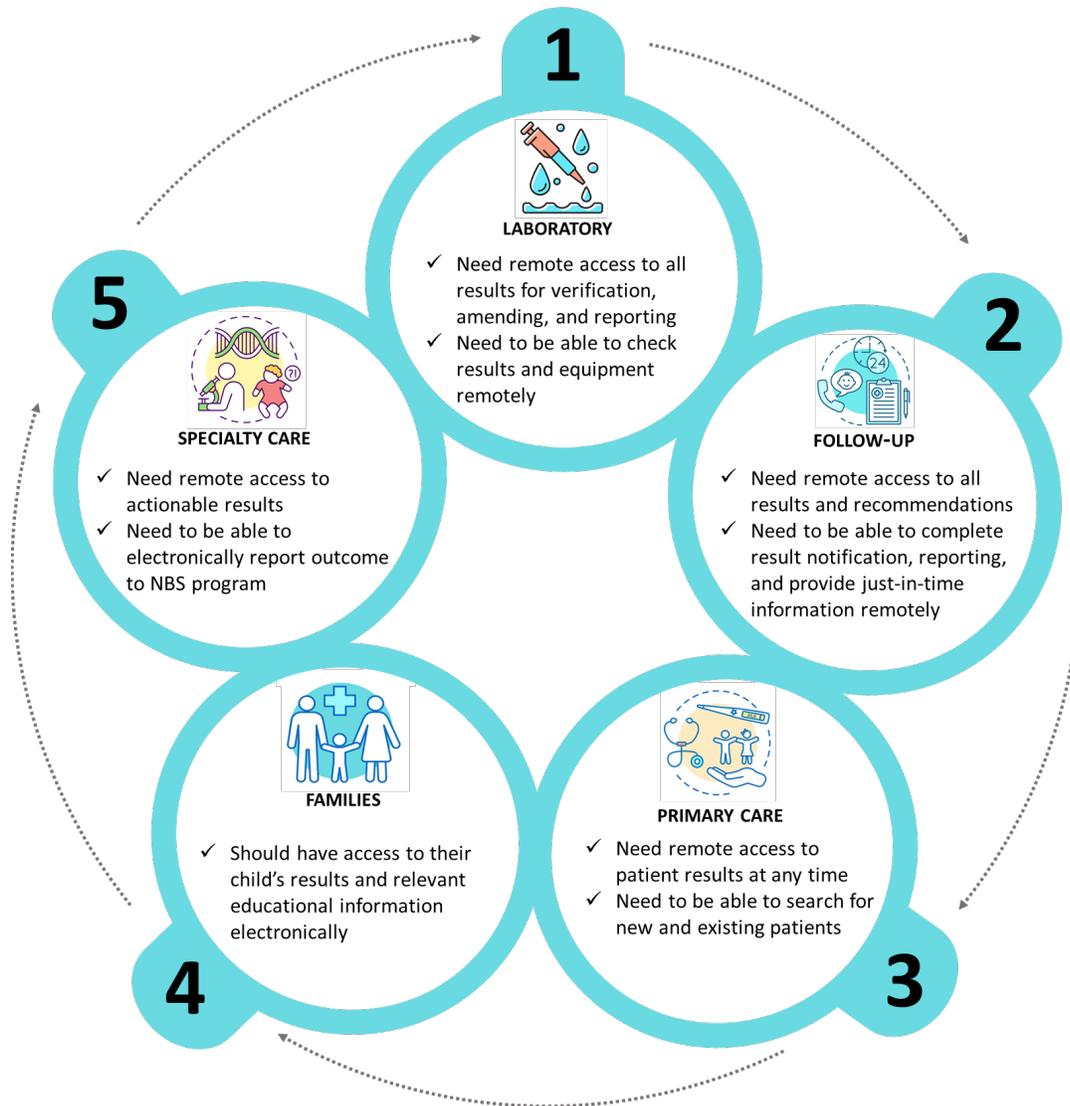


Figure 2: Ideal Capabilities for Electronic Results Reporting Across the NBS System

Telehealth Visits for Diagnosis and Ongoing Evaluation

During the COVID-19 pandemic, many barriers and restrictions on telehealth were lifted. One such barrier was reimbursement for services provided via telehealth. Low reimbursement rates had previously been seen as a barrier to investing in and providing telehealth services. Not only was reimbursement for telehealth services allowed during the pandemic, but the reimbursement rate was on par for in-person visits. State licensure requirements for clinicians and genetic services provided via telehealth were also relaxed, facilitating access to and delivery of care for families living in a different state from the provider's state of licensure. In newborn screening, once telehealth was made a priority to alleviate social distancing

requirements, it was utilized by clinicians, genetic counselors, and dietitians to address the span of NBS follow-up needs, including:

- meeting with parents to discuss newborn screening results and next steps for testing and/or treatment
- explaining dietary restrictions and monitoring
- completing routine follow-up appointments, and
- providing genetic counseling.

Telehealth provides the opportunity to do “just-in-time” clinical care, dietary management, and genetic counseling, often several days before the patient and family could otherwise be scheduled for an in-person appointment – and importantly, telegenetic appointments (i.e., clinical genetics services delivered using videoconferencing) have been shown to rank similarly to in-person genetic visits in terms of patient satisfaction.ⁱ Telehealth also affords individuals access to healthcare that they may otherwise choose to do without. During a pandemic, telehealth provides a potentially safer way to deliver healthcare services. While telehealth will never be able to take the place of physical exam or diagnostic testing, such as a sweat test for Cystic Fibrosis, it certainly opens up many viable options for better communication and follow-up care, particularly when parents are hesitant or unable to bring babies in to clinics or provider offices.

Ongoing Utilization of Telehealth for Monitoring of Diagnosed Patients (Long-Term Follow-Up)

All NBS disorders are life-long, often requiring careful coordination amongst numerous specialists and healthcare providers. Diagnosis and initial treatment are only the beginning of the family’s journey, followed by ongoing monitoring and interventions through the lifespan.

The rare disease community, which includes families with diseases detected through newborn screening, has unique medical needs that can often only be met by a small number of specialists nationwide. As a result, rare disease families often need to travel long distances to access needed care, monitoring, and interventions.

During the COVID-19 pandemic, 1 in 2 rare disease patients reported experiencing provider-initiated cancelled medical appointments, while 1 in 4 rare disease patients reported cancelling medical appointments themselves secondary to fears of contracting COVID-19.ⁱⁱ Additionally, as a result of unreliable public transportation options during the pandemic, rare disease patients experienced challenges accessing medical supplies, care, and treatment even when appointments are not cancelled. A silver lining of the pandemic for the rare disease community was expansion of telehealth services that allowed families to access care safely and effectively.

Looking Ahead

Though the pandemic necessitated an increase in telehealth capabilities and access for providers and families, the benefits of telehealth are not limited to emergent situations and should continue to be an option for NSPs, medical providers, and families now and in the future. Figure 3 highlights ongoing benefits of telehealth to newborn screening families.



BENEFITS OF TELEHEALTH FOR RARE DISEASE/NEWBORN SCREENING FAMILIES

- ✓ Allows safe access to ongoing care
- ✓ Allows for improved equity and access to rare disease specialists
- ✓ Allows for reduced non-medical expenses, like transportation, overnight stays, and time away from work
- ✓ Can provide increased access to early diagnosis and therapies, including enrollment in clinical trials

Figure 3. Benefits of Telehealth for Rare Disease and Newborn Screening Families

During the COVID-19 pandemic, NSPs found innovative ways to continue operating using telehealth and remote access systems as well as electronic reporting mechanisms. In future emergent situations, these systems could be extended to allow states to more easily and seamlessly assist each other during a regional or local emergency, with the appropriate access provided to the servers in the state requiring assistance.

Due to the demonstrated success of electronic reporting during the pandemic response, NSPs should continue to work towards making NBS results and reports available electronically as the benefits of doing so exist beyond crisis or emergent situations. Achieving electronic reporting of NBS results can generally be accomplished in one of two ways:

- 1) Health Level Seven (HL7)/Fast Healthcare Interoperability Resources (FHIR)/direct messaging, or

2) Web-based remote results portal.

Given the unique nature of NBS whereby the ordering physician is often not the physician who will follow-up on the screening results, the use of both mechanisms may be beneficial.

Guidance and HL7 standards for ordering a NBS panel and reporting NBS results already exist and can be found [here](#). Likewise, the Association of Public Health Laboratories (APHL) recently released a guidance document for implementation and administration of web-based results portals, which can be found [here](#).

These practices, in combination with lessons learned from the COVID-19 pandemic and state continuity of operations plans, will be crucial determinants of how effectively NSPs are able to respond in future emergencies, augmenting existing resources and practices elaborated in the national [Newborn Screening Contingency Plan Version II](#) (August 2017).

References

ⁱ Brown, E.G., Watts, I., Beales, E.R. et al. Videoconferencing to deliver genetics services: a systematic review of telegenetics in light of the COVID-19 pandemic. *Genet Med* (2021). <https://doi.org/10.1038/s41436-021-01149-2>

ⁱⁱ National Organization for Rare Disorders: COVID-19 Community Follow-up Survey Report. Available at: https://rarediseases.org/wp-content/uploads/2020/11/NRD-2061-RareInsights-CV19-Report-2_FNL.pdf