



Toolkit for Expanding Newborn Screening Services: State NBS Programs Case Narratives

MARYLAND

Historically specimens from the Southern and Western parts of Maryland, as well as the Eastern Shore, did not arrive at the state public health laboratory until late evening or the next morning after the specimens were picked up from the County Health Departments. Frequently, facilities did not submit specimens until after the courier already had made the pickup for that day. This practice changed in 2016, after the release of the article, [Deadly Delays](#), with a mandate from the Secretary of Health to improve the timeliness of newborn screening services that required the state laboratory to implement longer weekday and Saturday hours for receipt of specimens. Furthermore, the Department of Health required the birthing facilities asking them to develop a plan to improve timeliness. A majority of the facilities responded positively and began sending specimens on Saturdays and in the evenings.

Now that facilities were holding up their end to improve timeliness by sending specimens in the evening, it only made sense that the NBS lab remain open to receive and accession the specimens on the day of receipt. The laboratory initially extended the weekly work shift on a rotating basis. The 18 staff were divided into six groups of three, each with one staff member assigned to cover each unit—hemoglobin, autodelifa/biochemical and MSMS. Every six weeks, one group works from 10:00 am to 6:30 pm (instead of 8:00 am to 4:30 pm) to allow specimens to be accessioned and marked as received on the day they arrived. Further, specimens are punched the same evening of arrival so that they could be processed the next morning. The lab develops a daily manifest of specimens using barcodes which is emailed to the submitters. This provides a cross-check of specimens sent by the submitter and received by the laboratory, holding both the lab and facilities accountable.

Laboratory management gave staff two months' notice for the extended shift but the advance notice did not resolve staff concerns about the schedule change. They requested that the newborn screening program hire more people for accessioning. The Deputy Secretary of Operations and the Union considered options for a year and half. Ultimately, the Deputy Secretary of Health resolved the impasse with the decision that staff could continue to work

their current shifts, and when a position opened, the new hire would be required to work the late shift. The laboratory now has three full time staff members who works until 6:30 pm and one on rotation every 13 weeks.

Given this impasse with staff and negotiations with the Union, some valuable lessons learned came to light including: 1) understand Union rules, including if there are any clauses related to shift change (i.e. in MD you can only change shift times if you provide 14 calendar day notice); 2) document all conversations and meetings with staff regarding scheduling changes, confirming their understanding of the changes and associated timelines; and 3) Find several peer “champions” to help your staff understand the big picture of why operating hours are changing as well as obtain their feedback on different approaches regarding how they might reach the goal.

The laboratory made additional arrangements for the extended weekday shifts with its Information Technology (IT) department, since regular laboratory hours end at 5:00 pm. Currently, the IT chief and network specialist are available via cell phone to address any concerns.

MICHIGAN

Courier: In 2008, the Michigan Department of Health and Human Services Bureau of Laboratories switched from the US Postal Service to a privately operated courier system – a driving courier for the Lower Peninsula and a UPS overnight courier for the Upper Peninsula – to remedy problems with delayed delivery of specimens resulting from cuts to the US Postal Service budget. With newborn screening and infectious disease specimens now delivered on Saturdays, the lab also became fully operational on that day to allow for processing of specimens.

The Laboratory Bureau’s selection of a contractor dedicated solely to development and maintenance of the courier system has proven to be a major factor in its success. The contractor coordinates routes and educates drivers about the importance of timely pickup and delivery of specimens. A training video explains that even an hour’s difference in delivery can be crucial in identifying potential abnormalities. The newborn screening follow-up team also works with birthing facilities to determine a location for specimen pickup when a shipping department is closed.

Staffing: Staff morale continues to be an issue. Staff voiced objections when the Saturday service was first announced, with the timing of hiring staff lending to various responsibilities for

staff with regarding to being required to work weekend hours. In response, the NBS lab formed workgroups of managers, scientists and technicians to provide a forum to share concerns and also engaged with union representatives. To reduce the burden on regular lab staff, the laboratory hired college students to work part-time on Saturdays but their varying personal schedules did not make this a sustainable solution.

After a voluntary sign-up program failed, the new laboratory director distributed Saturdays equally among staff based on seniority. Staff who work Saturday can choose an alternate day off in the next week. This approach has helped morale, but scheduling is difficult because managers must find staff with the right mix of skills to coverage every day of the week. The laboratory is beginning to cross-train all staff but in the meantime untrained staff cannot volunteer to work on Saturdays. It has been difficult for the Michigan lab to maintain cross-training as all personnel must complete a biannual competency test and an annual competency certification for each testing area.

Personnel cost is also a factor in scheduling Saturday shifts. Laboratory staff are paid overtime if they work a holiday or are called in on short notice to work a Saturday. According to the union contract, they are required to be given a two-week notice of any schedule change. So if there is an unexpected Saturday absence, the staff member substituted will receive overtime pay. To reinforce the need for Saturday operations, the program shares with staff the number of presumed positive cases identified on Saturdays.

MINNESOTA

Scheduling: When the Minnesota newborn screening program expanded to Saturday operations, they hired additional staff to work a Tuesday through Saturday schedule. Current employees remained on a regular Monday through Friday schedule. This created a division among staff, with the Monday-Friday team perceived by staff as having more seniority. If any problems occurred on a Saturday, the new staff often had to contact more senior staff for troubleshooting assistance. Mondays are usually high volume days but this scheduling caused the lab to be short-staffed due to the block scheduling.

After four years of the Tuesday-Saturday shift, the newborn screening program decided to have all staff work a Monday-Friday shift with a Saturday rotation once every two months and a rotation of 1-2 holidays per year. As an incentive, staff working Saturday receive a flex day (or time-balance) that must be used within the two-week pay period. On holidays, staff receive an additional eight hours of vacation time.

On-call rotations for follow up staff have always been part of the job description since the inception of expanded program hours. Four follow-up staff rotate the call schedule and one person is on-call one week each month. In addition to pay and/or comp time for being on-call for the week, the availability of remote technology (VPN) to access the Laboratory Information Management System (LIMS), Wi-Fi hotspot on agency cellphones, and to electronically fax results increased buy-in for follow-up staff, as it caused less disruption during evenings and weekends. Similarly, for lab staff, the ability to log into the instruments and update LIMS remotely made working Saturdays or holidays less of a burden because senior staff can remote access test results when lab staff are done with a shift.

Supervisors of both lab and follow-up are expected to work on weekends and holidays, which improves staff morale by showing that everyone, not only less experienced staff, are working weekends/holidays to save babies. Also, with flexible scheduling, staff are often willing to cover one another's evening/weekend/holiday shift.

Meeting union and/or civil service rules: When the Minnesota NBS program first decided to expand laboratory operating hours to Saturday, they contacted the union for clearance. If a staff member did not agree to an expanded or revised work schedule, they could not be forced to comply, since this was not listed in their job duties when they were hired. Now that weekend and holiday rotations are part of the lab and follow-up job descriptions, there are no union concerns.

To comply with union rules, laboratory staff are required to time balance the Saturday within the two-week pay period. To meet this requirement, the program reclassified lab staff from Environmental Analyst I (eligible for overtime) to Environmental Analyst II (not eligible), so that all staff would get straight time instead of time and a half. This reclassification made it easier to balance flex time.

For holidays, staff receive an additional eight hours of vacation time in addition to being paid for the holiday. Union negotiations for follow-up staff occurred on an agency level, since other laboratory sections, such as infectious disease, also need on-call staff. Unlike the newborn screening lab, the union agreement for the follow-up section specifies an Officer of the Day Code whereby any staff member required to be on-call receives a flat rate for the week plus a negotiated rate for any phone calls received or results called out.

MISSOURI

Courier: In Missouri, transit time means time from collection to when laboratory testing begins. Smaller birthing facilities were using the US Postal Service (USPS) to deliver 1-2 samples at a time, and some hospitals were unable to verify that the laboratory received the samples, resulting in official transit times of 5-9 days. To help alleviate this issue, the laboratory contacted the smaller birthing facilities who were utilizing USPS, and identified the closest county health department, which would serve as a drop-off point for samples. The courier would then visit every county health department, which were already included in the contracted courier deliveries, to collect the samples and return to the laboratory around midnight. After these smaller birthing facilities started self-transporting to the nearest county health department the delivery occurred within the same-day and testing could begin the next day.

Missouri has 13 holidays and many of these occur on Monday, causing frequent three day weekends. The combination of holiday closure and no Sunday courier meant that the lab would not get three days of samples until Tuesday or Wednesday. Starting in 2015, the NBS program received additional funding from the legislature that allowed for the addition of a Sunday courier and to add eight more birthing facilities to the pickup routes. By expanding the courier to operate one day before the lab meant that weekend babies were able to be tested on Monday instead of Tuesday.

Additionally, the laboratory developed a secure portal where submitters can track their samples and see the results in real-time. This portal has been a very helpful tool as submitters can verify each day that the lab received all the specimens from their facility. If the specimens are not marked as received in the portal, the submitter should contact the laboratory and both agencies will conduct an investigation.

The courier expansions in conjunction with expanded Monday through Saturday lab operating hours resulted in an improved transit time from 61% of specimens received within three days of collection to 90%.

Expanded Hours: In October 2015, the NBS laboratory received funding (\$290,000 per year) to implement Saturday and holiday testing and courier expansions, which was spearheaded by the legislature. To accommodate new hours on Saturdays and holidays (except for Thanksgiving, Christmas Day and New Year's Day), a skeleton crew of 7-8 scientists and two office support staff would be needed. Staff assignments for these days were 100% voluntary but one full-time employee at the manager level was required to supervise on Saturdays and holidays. The two

newest staff members are required to work Tuesday through Saturday until attrition allows them to move to a Monday through Friday schedule. They may volunteer to work holidays.

In addition to the new hires, five adjunct employees may volunteer to work Saturdays and holidays making straight time pay under a special classification called secondary assignment. This is not considered overtime, but instead pay is added to their regular paycheck. Staff from NBS, microbiology, chemistry and molecular staff are each trained on a single platform and asked to work at least one Saturday or holiday per month to maintain testing method proficiency.

Costs: The total cost to expand courier and operating hours came to \$286,000 per year, which equates to about \$3.00 added to the NBS fee. The breakdown includes:

- \$6,000/year for holiday courier
- \$36,000/year for Sunday courier
- \$44,000/year to add eight more birthing facilities to the courier route
- \$200,000 for Saturday and holiday testing

The Saturday and holiday staff are not paid overtime, but receive a special classification called a “secondary assignment.” Their hours are designated separately on their paycheck.

Laboratory Access Portal: Missouri’s laboratory access portal, a secure website for tracking of samples, allows users to view laboratory results in real time. Submitters at hospitals can verify that the laboratory has received their samples, and can print and save reports. If samples have not been received, submitters can contact the laboratory and conduct an investigation. The few times this has occurred, the samples have been located at the hospital.

Missouri’s NBS reporting system is paperless, with the exception of reports to physicians which are distributed in hard copy, and it has significantly reduced the number of calls requesting reports.

NEW JERSEY

Workflow: At the beginning of Saturday laboratory operations, the department wanted to improve newborn screening (NBS) timeliness using minimal resources. At first, only Tandem Mass Spectrometry (MS/MS) identified conditions were screened because it is a semi-automated platform and only requires three staff—an MS/MS supervisor, an MS/MS technician and a receiving supervisor. With this approach, the Saturday workflow consisted of reviewing Friday’s MS/MS results and running any retests. On Saturday morning, UPS delivered specimens

and all three staff members started accessioning the new batch of MS/MS specimens. All other assays were punched, but waited until Monday for testing. The supervisor checked the MS/MS results and notified follow-up staff of any out-of-range results.

During this process, the lab realized this was a large burden for Saturday staff, especially if there were many retests from Friday. In 2011, the New Jersey NBS laboratory was able to solve a lot of these workflow issues when they moved to a new building and switched technologies to PerkinElmer GSP. The switch in technology expanded the use of semi-automated methods, allowing the lab to perform first-tier analyses for all disorders on Saturdays except for hemoglobins and SCID. With the transition to GSP, the laboratory also added another Saturday technician to help with increased testing, so Monday staff only have to review Saturday results, perform any retests, and communicate out-of-range results. The GSP, including the ability to read results remotely, revolutionized efficiency in the lab—not only on weekdays, but weekends as well. New Jersey was able to cut two days from report out time because Friday results for time critical disorders were reported out on Saturday instead of Monday and specimens received on Saturday are called out on Monday instead of Tuesday.

Overtime: Lab supervisors are categorized as “no limit work week” under New Jersey’s civil service rules, so only lab technicians qualify for overtime on Saturdays. Therefore, only the two lab technicians working on Saturdays and holidays earn overtime, costing the lab less than \$30,000/year. Although this is a small amount in reference to the overall laboratory budget, department leadership wanted to cut overtime costs. This proposed cut would adversely impact Saturday lab operations, so the NBS lab started highlighting the number of babies that were identified with a condition on Saturdays to reinforce the need for Saturday laboratory operations.

OHIO

Results Reporting: In Ohio, the newborn screening (NBS) program has a central location for laboratory and follow-up processes. This provides an opportunity for some laboratory staff to be trained in follow-up protocols, so that they can call out preliminary and confirmatory results to physicians on Saturdays when the follow-up team does not work. Unlike the laboratory staff, where there is a Monday-Friday and Tuesday-Saturday shift, Ohio NBS decided not to have two separate shifts for follow-up. Physician offices are closed on weekends, therefore it is not necessary to have a full Saturday shift where follow-up staff could only complete a portion of their work. Since the majority of follow-up’s time is dedicated to interacting and closing cases with physicians, it was more efficient to cross-train lab staff to call-out results instead of paying for an additional follow-up Saturday shift. Since the Saturday lab staff does not work on

Mondays with follow-up, Ohio NBS implemented a communication system where all case information is securely emailed to the entire staff to ensure everyone is aware of next steps. This way, follow-up staff can conduct a secondary outreach to physicians on Monday.

IT and Vendor Support: Over the past couple of years, Ohio's laboratory IT vendor has become more limited in their after-hours support and future Saturday support will only be covered for an additional fee. At this stage, Ohio NBS is reviewing the need for weekend support in light of new vendor fees since the laboratory has duplicate instrumentation. If one instrument breaks down on Saturday testing can be completed on a different machine until Monday maintenance is performed. However, other states may want to consider writing in after-hour support into their vendor contract if they do not have the option to procure additional instruments. Although Ohio NBS IT is not on-site on Saturdays, they are very responsive and can offer support remotely.

TENNESSEE

Staffing: When the Health Commissioner mandated a six-day operating week, it took time for the laboratory to adjust to this change. One of the major impacts of expanding to weekend operations was staff attrition, which meant lost knowledge and experience in newborn screening. Tennessee has spent a lot of time retraining current staff or training new hires, taking time and resources. Although staff were eventually able to receive a compensatory day for working on Saturdays, it may have been more beneficial to offer some sort of monetary incentive to keep employees on staff throughout the transition. A weekend bonus or flat rate may have prevented experienced staff from leaving. As for new hires, working Saturdays was attractive as they were able to earn additional vacation time.

IT and Vendor Support: It is extremely important that NBS programs consider IT and vendor support on weekends. Tennessee does have agency IT staff on call if a server goes down on Saturday and any issues with the instrumentation currently have to wait until Monday for repair. The next vendor contract will clearly state that support should be available Monday through Saturday from 8:00 am-4:30 pm CT. This will ensure continuity of services, but the Tennessee NBS lab will need to determine if this increased cost for weekend vendor coverage is warranted.

TEXAS

Staffing: The Texas Newborn Screening Laboratory changed from five to six day operations in 2007. Five analytical staff were added to accommodate this change, resulting in a current total of 61 staff in the analytical portion of the laboratory. The laboratory is closed on most federal holidays, but open on all state holidays to receive, process and test specimens. The newborn

screening laboratory does not close for more than two consecutive days. Approximately 22 (of the 61) analytical staff work on Saturdays on a rotational basis. In addition, five staff work to accession the specimens and three employees do demographic information entry and print tests reports on Saturdays. Holidays are staffed to cover the expected workload.

Since the Texas laboratory began Saturday testing over a decade ago, scheduling for Saturdays has been a regular part of newborn screening program operations. Staff know that they are expected to regularly work a Saturday shift. Staff that work on a Saturday are scheduled a flex day the following week, such that staff work a 40 hour work week. Candidates for vacancies are asked on the application and during the initial interview process about their Saturday availability. Although staff are now accustomed to working on Saturdays and holidays, scheduling remains a challenge for managers to accommodate for time off requests, sick days, and flex days while ensuring the laboratory is sufficiently staffed.

The analytical area is composed of six teams. Each manager has a process for scheduling staff to meet each team's needs. The maximum daily workload is posted monthly and individual teams develop and distribute work schedules approximately a month in advance. For the major holidays of Thanksgiving and Christmas, schedules and workload are determined in August/September so that teams and staff can plan for any time-off requests.

Follow-up: Short term follow-up protocols are limited to time critical disorders on Saturdays and holidays thereby allowing for reduced staff. The 12 NBS nurses and 3 nurse leads rotate to cover the follow-up calls and are scheduled three at a time—one metabolic nurse, one non-metabolic nurse and one lead nurse backup. This Saturday/holiday schedule is frequently revisited depending on expected case load.

Vendor and IT Support: Every vendor contract requires that maintenance and support be available on Saturdays. For the internal IT help desk and laboratory application support, the NBS laboratory provides the on-call personnel with a cell phone so they can be contacted when there is an issue. Contracts with the courier services require regular deliveries on Saturdays.

Workload: Even though the laboratory runs all screening tests on Saturdays, it does not perform all activities, such as quality assurance (QA) monthly reviews, processing parental consent forms for specimen storage/destruction, review of missed or diagnosed cases, or evaluating cutoffs. As a two-screen state, the laboratory prioritizes the first screens and depending on quantity of specimens received there may be some second screens that will not be processed until the next business day. The laboratory processes about 2,500-2,600 samples on weekdays and generally processes a reduced workload of about 2,000 samples on Saturdays.

VIRGINIA

Staffing: In February 2018, the Virginia newborn screening (NBS) laboratory will implement full sample accessioning and testing processes on Saturdays in order to improve timeliness. Currently, Saturdays are spent reading results from Friday's testing, receiving specimens and setting up testing for galactose and GALT on Monday. While a mandate from the state government is not necessary to change to a six-day operating week, staff and senior management buy-in is essential.

Since staff were not hired with the expectation of weekend work, senior managers have provided multiple opportunities for input and ownership in the final decision. After considering the concerns raised by staff, the Division of Consolidated Laboratory Services (DCLS) decided not to use staff regularly scheduled for Monday-Friday as the primary coverage for Saturday work. Instead, the lab will utilize vacant positions to recruit for new bench scientists that will work an altered schedule to include Saturdays. In return, Saturday staff will have Sunday off and will receive an additional flex day for the following week. The NBS lab plans to hire a Senior Scientist to work Saturdays as well. Staff regularly scheduled to work Monday through Friday will serve as backups on Saturday if one of the primary Saturday team is not available; this will be on a rotational basis.

Fee increase: In the state of Virginia, there is no mandate to change to a six day operating week and the leadership of the public health agency is in charge of raising the NBS fee. Every couple of years, the laboratory reviews the strength of the current fee-for-service structure to meet budgetary needs and the memorandum of understanding (MOU) governing operation of NBS follow-up services. NBS fees go directly to the NBS lab, which pays the follow-up program quarterly per the terms of the MOU. More funding may have to be transferred to the follow-up program to hire staff needed to cover the added workload generated by Saturday services.

To determine the fee increase for expanded operating hours, the laboratory first reviews expenses and revenue based on the past one to three years, and projects when additional funding will be needed. It then determines when the increase should begin to maintain program operations. This increase of the NBS fee would support overtime cost for Saturday lab and follow-up staff, hiring additional laboratory staff and IT and vendor support for Saturdays.

Once the fee increase is determined, the Director of the Department of General Services, the agency within which the laboratory resides, reviews the request and refers it to the Secretary of the administration. Once the laboratory receives approval, it presents the fee increase to the

Commissioner of Health and to the Secretary of Health and Human Services. Because approval must be received at two secretarial levels, the process requires numerous presentations and reviews. Usually it takes nearly six months to receive final approval from all decision makers. Once the increase is approved, the laboratory meets with stakeholders to inform fee payers (i.e., Hospital Healthcare Association, Medicare, Medicaid, Department of Medical Assistant Services, etc.) of the increase and its start date. This fee increase model has been in place since 1992 when Virginia first implemented the NBS fee.

WASHINGTON

The Washington newborn screening (NBS) laboratory operated on Saturdays, but was limited to reading Friday's results and setting up repeat testing for urgent results. Starting in April 2016, Washington NBS moved to a more robust weekend workload and now screens for all disorders except hemoglobins and SCID. In 2014, the Washington state legislature passed a law requiring all specimens be delivered to the NBS lab within 72 hours of collection. With this new law, birthing facilities started using more reliable courier services that delivered specimens on Saturdays and thus providing a need for a faster turnaround time. Before, the Washington laboratory information system only recorded date of testing, but soon recognized the need to add in a data field for time of receipt. By differentiating between date of receipt and date of testing, the Washing NBS program was able to show that there was a huge time deficiency of specimens arriving on Friday and not being tested until Monday. With this evidence, the lab was able to hire two analysts to be able to expand weekend operations to nearly full testing on Saturday and respond to urgent results on Sunday.

Now on Saturdays, Washington NBS staffs one lead analyst and three lab technicians. Since this is a skeleton crew, an on-call system for an additional lead and analyst was implemented to provide backup in case of last minute absences. The staff on-call receives a \$25 flat rate and, if called in, they receive comp time off to be used at a future date. The additional Sunday shift (approximately 2 hours of work) is rotated among the other three Monday-Friday lead analysts for reviewing Saturday results and reporting any urgent findings to follow-up.