Waters™

OMNI-Lab NBS LIMS Facilitates Innovation in Newborn Screening

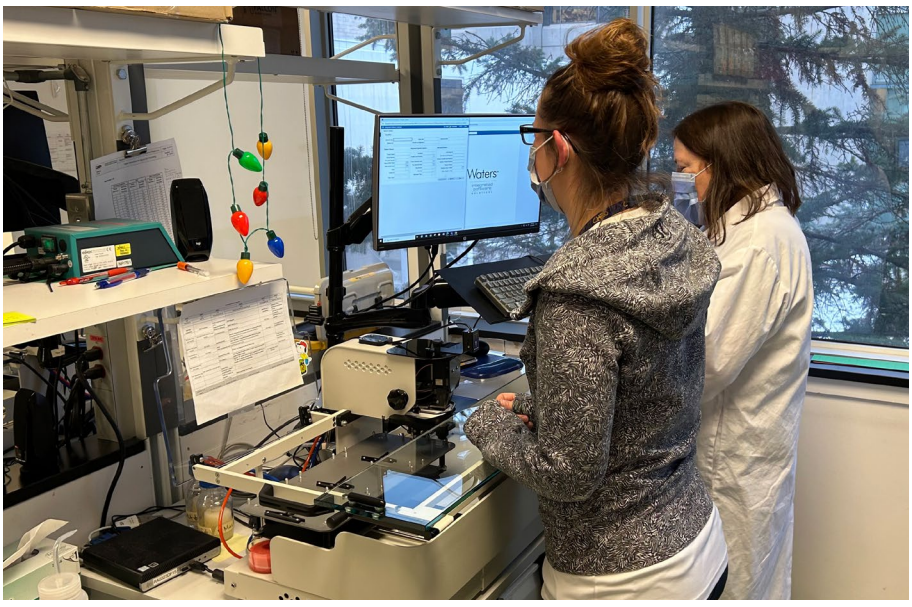
Newborn Screening Ontario (NSO) relies on the OMNI-Lab NBS Screening Information Management System to manage the complexity of samples and test data in an ever-evolving medical screening environment.

NEWBORN SCREENING AT NSO

Newborn Screening Ontario (NSO) screens newborns for several rare but treatable diseases. The goal is early detection so that treatment can be started early, and better health can be achieved. Located at the Children's Hospital of Eastern Ontario (CHEO), NSO is under the stewardship of the Government of Ontario.

In Canada as a whole, newborn screening is performed on a dried blood spot sample usually collected between 24–48 hours after birth by pricking the heel. NSO tests for metabolic and endocrine diseases, sickle cell disease (SCD), cystic fibrosis (CF), severe combined immune deficiency (SCID) and spinal muscular atrophy (SMA). Newborn screening also includes critical congenital heart disease (CCHD), which is performed via pulse oximetry at the bedside, as well as biliary atresia (BA) screening done at home by parents.

In addition to an academic mandate, NSO coordinates and manages programmatic elements of testing including pre-screening education, distribution of collection cards and parent communications; shipping and tracking of samples; case management for special screening circumstances such as transfused or premature babies, unsatisfactory samples, or missed screens; short-term follow-up of screen positive babies; and analysis/reporting of key performance indicators.



The NSO team works with Waters to optimize laboratory workflows.

WORKING WITH WATERS

Dr. Pranesh Chakraborty, NSO Laboratory and Medical Director, describes the advantages of working with Waters™ Instrumentation:

"Working with Waters allows us to have conversations about our goals and needs in a way that I feel is moving us forward more quickly now. We've used Waters MS instruments for a long time, and we appreciate Waters adding some of the structure to the OMNI-Lab NBS LIMS service and support that we were used to on the MS side."

Dr. Pranesh Chakraborty (pictured) and the wider NSO team collaborate with Waters support personnel to find cutting-edge solutions to challenges in newborn screening.

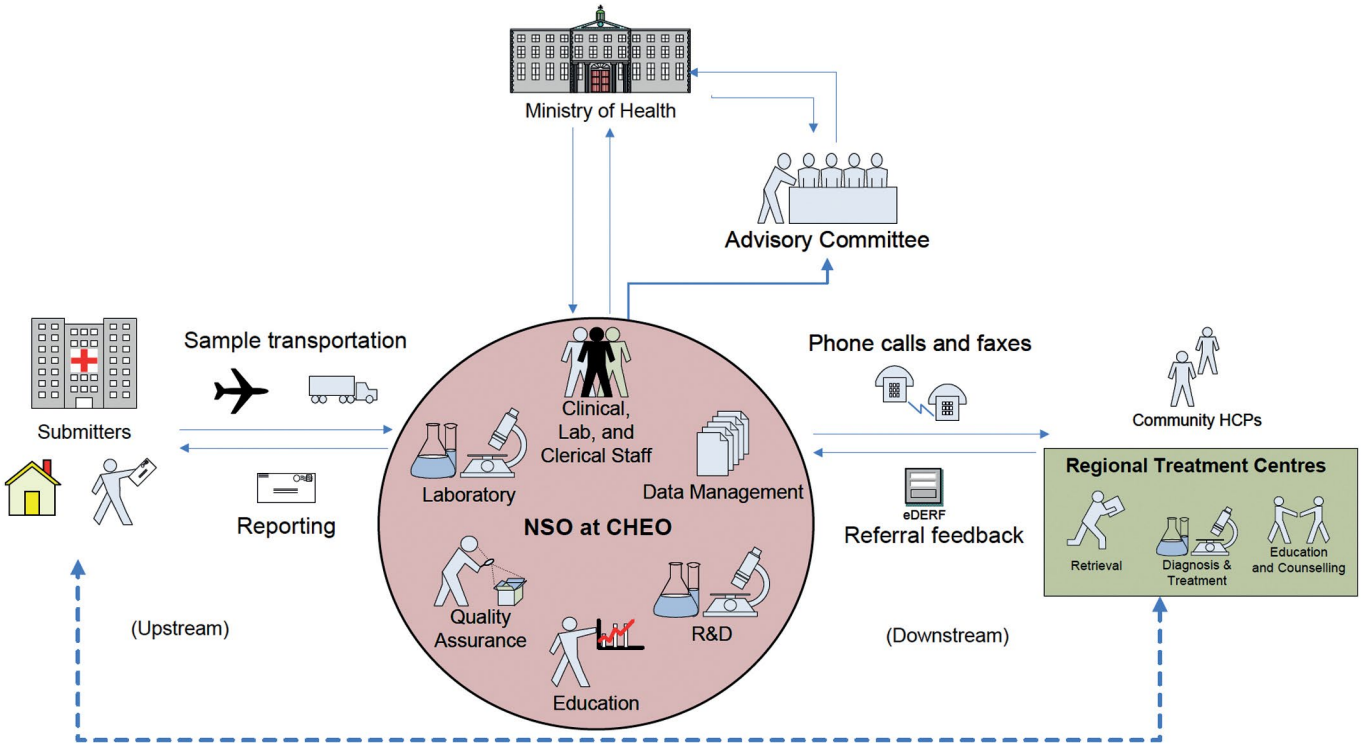


Figure 1. Communication flow between stakeholders involved in the province of Ontario's newborn screening program.

NSO's system based approach requires an information infrastructure to support these diverse, yet closely interrelated, activities (Figure 1). As NSO's executive director, Jennifer Milburn holds responsibility for the daily functions of the program, risk and resource management, program evaluation, and any special projects or quality improvement initiatives.

"Newborn screening is not just a laboratory program; it's a public health and clinical program. Over the last two decades, our panel has grown from primarily mass spectrometry (MS)-based analyses to a wide range of panels, particularly molecular testing as a second or third-tier test after out-of-range biochemical testing results. That's changed our service quite a bit, and means we need a flexible system that can adapt to the novel ways we develop algorithms, add new equipment, and make changes."

JENNIFER MILBURN
Executive Director of NSO

OMNI-LAB NBS LIMS

In late 2014, NSO undertook an end-to-end assessment of its information management needs, which resulted in a project to develop a flexible information systems ecosystem and related process changes. Ms. Milburn describes the need for new information management systems:

"As NSO matured and changed, alongside clinical and workflow needs, we needed more transparency and control over decision making within our systems. The autonomy to change algorithms or add testing fields and interfaces as we saw fit meant we needed a system with customizable features that allowed us to manage these elements and more."

After a review of available systems, the OMNI-Lab platform was selected as it offered the ability to accommodate improvements for program flexibility and the ability to innovate that NSO needed. The team felt OMNI-Lab NBS LIMS could provide the basis of a flexible information systems ecosystem that could adapt to process or analytical changes, current and future workflows, and communication needs.

"We have very knowledgeable and capable laboratory and scientific staff who understand the lab environment and can make changes in an informed manner. We're aware of our accountability, and we're able to take that risk to make the progress we see as necessary in maintaining patient safety and improving the quality of screening. We needed an information system that could support that."

JENNIFER MILBURN
Executive Director of NSO

Matthew Henderson, NSO biochemistry Lab Head, explains how OMNI-Lab NBS LIMS supports the NSO's ability to develop testing methods and interpret results:

"We screen approximately 145,000 babies per year. We've developed screening algorithms that we've encoded into OMNI-Lab NBS LIMS, to identify results that need more extensive review, so we're able to focus on those babies who need further attention. OMNI-Lab NBS LIMS allows us to have reflex testing to either repeat the testing or go on to a second tier of testing that gives an orthogonal measurement to add another dimension to the analysis. As a result, now we're able to focus more on the data we need to make decisions, whereas previously we had to weed through a lot of results to identify what's important. It's a better use of our efforts."

The NSO team works with Waters to optimize OMNI-Lab's potential for improving laboratory workflows.

OMNI-Lab NBS LIMS was designed to manage samples and test data with a scalable, browser-navigated approach, flexible rules wizard, and patient-centric features suited to each lab's individual needs. Users can ensure lab data is secure, traceable, and accessible with a single, high-performance database and comprehensive suite of data management features, including QA/QC, reporting, and role-based security access. That capability was particularly valuable as NSO made additions that varied in procedures and data collection.

INNOVATION AND CHANGE

Chloe O'Sullivan, NSO Manager, Data and Innovation, and her team work closely with the OMNI-Lab NBS LIMS support team to make changes to the system as the organization's needs evolve. She explains:

"We were adding new screening tests and a new way of ordering those tests to our existing screening, while also switching to a new LIMS. At that time, we often used the analogy that we were building a new plane while flying it. We do have to rely on Waters for some product changes and guidance on how to configure the system, but many of the changes we make to our LIMS can be managed directly by our team of project coordinators and technical architects. Any new project we tackle involves information and workflow management, so the ability to make those changes in-house, safely and seamlessly, really allows NSO to advance and achieve our program goals."

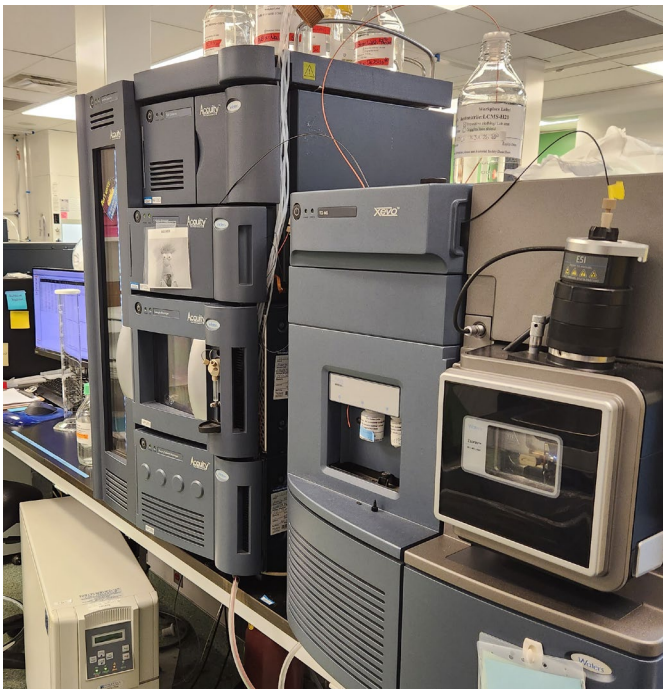
Ms. Milburn and the NSO team were particularly pleased with the collaborative attitude in making such changes. She explains:

"The capture of data for diseases such as CCHD and BA, the sharing of information with the infant hearing program, and the ability to view information in a patient centric way needed to be achievable within what we call our 'screening information management system' (SIMS), and not just have laboratory data fed into our LIMS."

ADDING MOLECULAR TESTING

The NSO team has recently been working to integrate molecular data with OMNI-Lab, which remains an on-going project. Melanie Lacaria, NSO molecular scientist, explains:

"OMNI-Lab is a LIMS, not a genetic data analysis package, so we need it to communicate with our Illumina system and integrate the processed data. It's been a lot of work to develop new connections with OMNI-Lab to improve our workflows. What's keeping us moving forward is we do see there's enormous potential for us. This type of integration really would make it so much easier for us to scale up to start new projects and be much more flexible with molecular testing."



The NSO team continues to work with Waters on making changes to the OMNI-Lab system to support enhanced screening technologies and workflows.

The NSO collaboration with Illumina marks a unique industry-first project and will allow NSO to link platforms and instruments irrespective of assay modality and vendor. Dr. Lacaria explains the collaboration in more detail:

"The basic concept is that samples sequenced by the Illumina system are analyzed and interpreted in the system software and, rather than having the Illumina system output a report on this data, we want to be reporting out of OMNI-Lab. Therefore, we're having to do analysis outside of the OMNI-Lab system, but then bring the data back to it to close everything out. This collaboration will help us build a bilateral data flow that avoids all this back-and-forth. I don't know of anyone else that's really doing that in this way right now, or at least got it integrated to this scale that we're planning. A collaboration of this kind will bring huge benefits to this industry."

NEXT STEPS

As NSO looks to the future, one of the organization's biggest priorities is developing a data warehouse for centralized reporting, analysis, and storage. Dr. Henderson explains:

"We're using our data all the time to make improvements in what we do. Labs don't just need to use their LIMS as a transactional database. They need to use it as their data repository because there's so much utility in the information that can help them improve the way they're doing things. That's something in the future that will be impactful."

While there is still much work to be done, Dr. Chakraborty is optimistic that the innovation of the NSO team and their collaboration with Waters support personnel can make these changes to better support newborn screening programs worldwide.

"We haven't been able to realize everything we wanted to achieve, but we're working towards that. There's more we can do with OMNI, and Waters is helping us move forward. We don't see any other alternatives in the marketplace that could do all the things that we want to do now. We want to reach the full potential of what we envisioned, and it feels like we're almost there."

DR. PRANESH CHAKRABORTY
Laboratory and Medical Directorat NSO

References

1. Pluscauskas M, Henderson M, Milburn J, Chakraborty P. Building a Newborn Screening Information Management System from Theory to Practice. Int J Neonatal Screen. 2019 Jan 23;5(1):9. doi: 10.3390/ijns5010009. PMID: 33072969; PMCID: PMC7510236.

OMNI-Lab NBS LIMS is solely intended for transfer, storage, conversion of formats, or display of medical device data and results.

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