A POC blood glucose program turned upside down: How a 17-hospital system survived a rollout and new requirements

Anne Ford

July 2014—When Rosemary Frederick learned last year that her employer, North Shore-LIJ Health System of New York state, would be switching from the Roche Accu-Chek Inform I point-of-care glucose meter to the Inform II due to a maltose interference issue, she knew she and her colleagues were facing a heck of a lot of work.

“I want you to realize the enormousness of this project,” says Frederick, who is the point-of-care manager for the health system’s core laboratories. “It wasn’t one hospital and 1,500 people. We had to roll out over 1,000 meters, and we had to train over 13,000 people systemwide.”

No 17-hospital, 6,000-bed institution switches devices like that without a headache, but what Frederick and her colleagues got instead felt like a months-long migraine. Instead of the laborious but relatively straightforward conversion it had expected, North Shore-LIJ found itself facing down a massive, many-headed hydra of a project, one whose nature seemed to morph moment by moment.

“This was an ever-changing landscape,” says Jordan Laser, MD. “There was never a day when we thought we had a good understanding as to what was expected of us.” Dr. Laser is the health system’s director of near-patient testing, associate medical director of Core Laboratories, medical director of pathology and laboratory medicine at Long Island Jewish Medical Campus, and senior director of cytogenetics and molecular pathology.

Dr. Jordan Laser, from left, Hannah Poczter, Jaclyn Schindler, and Dr. Elaine Smith. Says Dr. Laser: “We had many balls in the air, more than we normally would with such a project. Time was not on our side.”

What brought about all this confusion? How did Frederick, Dr. Laser, and their team find their way through it? And what effect is it likely to have on patient care at North Shore–LIJ?

North Shore–LIJ had known for some time that it would eventually switch to the Inform II. But the situation began to

intensify this year on Jan. 7, when the FDA issued a draft guidance document ("Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use") announcing new, more restrictive requirements for point-of-care glucose meters. The document proposed specific language to describe clinical situations in which the meters' performance may not be acceptable, as in: "...FDA recommends statements such as the following: Critically ill patients should not be tested with a glucose meter because results may be inaccurate."

Dr. Laser didn't panic. "We recognized it was draft guidance," he says, "and we thought the document was not really applicable for hospitals and health systems. It sounded like a document that pertained to manufacturers getting FDA clearance on their product."

Instead, the panic struck after the arrival of a double whammy just a few days later, on Jan. 13. Whammy No. 1: The New York State Department of Health issued a letter saying that because the manufacturers of point-of-care glucose meters have not validated these products on critically ill patients, their use in that patient population is considered off-label and therefore high-complexity under CLIA. "This really shook us," Dr. Laser says. Among other things, it meant that only staff licensed by the NYS Department of Education would be allowed to perform this testing.

Whammy No. 2: That same day, Roche issued a letter of discontinuation for the Inform I meter, saying that as of March 31, it would no longer supply test strips for the device. In other words, not only did North Shore-LIJ have to figure out how to implement the Inform II in a way that complied with the state health department's announcement, but it had to do it fast. As Dr. Laser puts it: "Within two weeks, we went from blissfully using glucometers to 'Wow. What are we going to do?'"

What they did was get organized. Dr. Laser and Elaine L. Smith, EdD, RN, vice president of system nursing education, assembled a leadership group made up of personnel from the nursing, laboratory, IT, materials management, and procurement departments and representatives from Roche. (Dr. Laser says of the latter: "They were at the table problem-solving and supporting us throughout this process.")

"We realized this was an opportunity to standardize a process across the system," Dr. Smith says. "Keeping that as our mindset, we created working groups that looked at developing a policy to guide the performance of the test, the competency issues, and the laboratory-specific components." The leadership group communicated with all North Shore–LIJ sites that used glucose meters, making them aware of the new regulatory and supply-chain challenges.

The first question on everyone's mind: Did the health system have enough Inform I strips on hand to tide it over until it could complete the conversion to Inform II? "We were originally scheduled to convert by the end of August," Dr. Laser says. "But after the discontinuation letter from Roche, clearly that was not going to be an option. So we had to figure out how many Inform I strips we had, how many we would need, then reach out to all of the sites, and create a new schedule." With so many sites to convert, that schedule was a multifaceted, ever-moving target. "We had many balls in the air, more than we normally would with such a project. Time was not on our side."

Nor, at least at first, was the institutional grapevine. "You can imagine that in a system this size, we were hearing that some misinformation was out there at a local level," Dr. Smith says. "People were getting conflicting answers. So Jordan [Dr. Laser] and I decided we needed to establish ourselves as the people from whom the most up-to-date information was coming, so we could standardize the accuracy of the information being provided."

To that end, the two began sending out weekly updates on the project's progress. "We presented it as a united front," Dr. Laser says. "This weekly communication was always co-signed by me and Elaine Smith. It demonstrated that the laboratory and nursing were working together, and that it wasn't an issue of 'The lab is making us do this,' or 'Nursing is making us do this.' We were doing this together."

In February and March, two pieces of good news landed in their laps. First, the FDA and the NYSDOH said that for validation guidance for point-of-care glucose testing, laboratories could refer not to the FDA's January draft

document, but to the less stringent CLSI document “Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities,” or POCT12-A3.

Second, in a meeting hosted by the Greater New York Hospital Association, NYSDOH representatives announced it was up to each institution to define the term “critically ill” for itself. Dr. Laser calls the announcement “a huge win.”

“Our strategy was to define ‘critically ill’ geographically,” he says. “Clearly anything that had the word ‘critical’ in it was a pretty easy sell, so the ICU, the NICU, the PICU.” In those areas of any North Shore–LIJ site, use of the Inform II would be considered off-label.

But not in emergency departments. “We chose to consider that use on-label for two reasons,” Dr. Laser explains. “First, the majority of patients in an emergency department are not critically ill by any definition. Second, from a quality and operational standpoint, it would be difficult to have two parallel processes in a given unit. Imagine that if a patient is considered critically ill by some definition, the glucometer can be used only by a nurse, and if the patient in the bed next to them is not critically ill, nonlicensed personnel can perform it. To set up that process, bring it into operation, monitor it, track it, and enforce it, it would be extraordinarily challenging to provide a high-quality environment.”

On a side note, North Shore–LIJ administrative director of near-patient testing Jean Thompson found that the health system’s physicians firmly supported the use of glucose meters in critical-care units. “Our clinicians really felt that using these meters in these units was a standard of care, and that it would be very difficult to either use a different type of instrument or to have the laboratory perform testing for glucose as often as is required,” she says. “Sometimes with the glucose meters, they perform testing numerous times daily, especially prior to the patients’ meals.” For patients on insulin protocols, glucose testing may be performed hourly. “It would really cause a hardship for the laboratory,” Thompson says. “The clinicians strongly felt there really was no other option [than to use the handheld meters in these areas].”

As for overseeing the education and competency components of the Inform II rollout, that task fell to Frederick and to Jaclyn Schindler, the health system’s assistant director of corporate nursing education. The two had begun creating the necessary training materials in October 2013, long before the FDA and NYSDOH made their announcements.

“Everything was rolling out really nicely until the challenging regulation in January describing how the meters can be used,” Frederick says. “It wasn’t 100 percent ‘back to the drawing board,’ but we had to go back and look at our SOPs and competencies and quizzes and adapt them.” For one thing, she adds, “we had to specifically change the frequency of performing QC in all the different critical care areas.”
“It took over six months from beginning to end to really roll this out,” she continues. “Even as we went from one site to the next one, we continuously tried to improve the process.” Schindler says they took the opportunity to incorporate feedback from all users.

“When Rosemary and I encountered rationales for policy and practice as being required by the lab, or standard for nursing, we focused on what would provide practical and safe care to the patient whether cared for by lab personnel or nursing personnel. In this way, we developed a collaborative relationship, understanding that our respective practices need not contradict or supersede each other.”

Schindler, right, of nursing education, here with Dr. Smith, helped oversee the education and competency components of the Inform II rollout. “We wanted to have a brand-new user show they can do both a quality check and a patient test,” she says.

Part of their task entailed determining whether to require trainees to successfully perform a quality check on the device, an actual patient test, or both. “We felt as a team that we would be meeting requirements by just doing a quality check, and yes, that would make it easier to achieve compliance,” Schindler says. “But when you think about what’s the right thing to do, we really wanted to have a brand-new user show they can do both a quality check and a patient test, so that we’ve seen them use the machine in two modes and they’ve really gotten a handle on it.”

That said, it was decided to use only simulated fingersticks during training. “It was not always feasible to do training in a clinical area, so we came up with a mechanism with which we were all comfortable,” she says. “We have them take out the lancet, show us how they would use it, activate it into the air or into a piece of material, show us where on the finger they’re going to stick, wipe it with alcohol, let it dry. Just at the point where they’re going to take the blood, they use simulated blood.”

Barbara Callahan, too, was involved in the education and competency structure. She is senior administrative director for patient care services, nursing education, professional development, research, and nurse practitioners at Long Island Jewish Medical Center (LIJMC). “Initially, the vendors suggested point-of-care education on the clinical units, which we knew was not going to work because you don’t have the complete attention of the nursing staff.” The department of nursing education decided to use a two-tier education approach, with the first part consisting of completing an educational module and a quiz and a required score of 100 percent. Tier-one education has to be completed to participate in the second tier of education. “This tier encompassed attendance at a hands-on skills class facilitated by the Roche education team and coordinated by nursing education. We had a nurse educator participate in every class for education support and to validate the competency of every attendee,” Callahan says.

To educate more than 2,000 nursing employees at LIJMC, the classes had to be held several times a day over a two-and-a-half-week period as well as during the off shifts. While Callahan says the process worked well, she adds that in hindsight, it might have been better to use a single-tier approach, in which the module, the quiz, and the attainment of the skill set were all completed in one session, to avoid the educational challenges involved in making sure that all enrolled in a class had completed the module and received a perfect score on the quiz.

For many nights before her site rolled out the Inform II in early May, Cathy Drechsel, point-of-care supervisor for LIJMC, found herself lying awake, "having nightmares of what this was going to be like." But when implementation got underway, she discovered that the most troublesome things were those she hadn't dreamed of at all, such as how to recycle the five-foot mounds of discarded wires from the old meters ("People were taking pictures of them") and how to rotate the new meters on their bases so they all stayed charged until implementation.

And then there's the label issue. The Inform II features "such a tiny little bottle" of control solution, Drechsel says with exasperation. "It may seem silly, but you need to put on this tiny little bottle the open date and the expiration date so we meet regulatory requirements. Well, now we have to design a label that's small enough to fit, that's not going to cover the lot number or the manufacturer's expiration date, and that's not shiny, so when someone writes the open date, it's not going to smear. The thing I lost no sleep over, that's the hardest thing."

At the same time, she benefited from the experiences of colleagues at sites that went live before hers. At one site, for example, "they realized they had a port speed issue when they went to plug all their bases in," Drechsel says. "Nothing was downloading, and they realized that the port speed was set to a speed that didn't work for the Inform II bases. So while that site's point-of-care supervisor had a crazy time that day, she passed that information on to the rest of us, so I was able to get IT to re-set ours ahead of time." It's that kind of collaboration that leads her to conclude: "I can't emphasize enough how all this is such a team effort. It really, really is."

"I can't even begin to explain how everyone chipped in here," Dr. Laser agrees. That team spirit became especially crucial when a potentially catastrophic obstacle arose: At one point in the Inform II implementation, Roche announced a weeks-long manufacturing shortage. "They weren't in short supply. There was no supply," he says. "We had to delay our site conversions, and while this wouldn't normally have been so challenging, the shortage occurred after March 31, when we were no longer able to purchase additional Inform I strips. We were very nervous we were going to run out of Inform I strips while the Inform II couldn't be acquired."

In the core lab, Frederick found herself hanging on to Inform I strips as if they were silk stockings in post-war London. "I became the hub of hoarding strips," she says. "It was ridiculous. You have no idea where we had them hidden. As a site rolled out the Inform II, I said, 'Give me all your leftover Inform I strips,' and then we held on to everybody's supplies so we could get everybody rolled out."

In another effort to stave off the threat of a strip shortage, Inform II implementation at LIJMC was moved forward by one week. "It may not sound like much time, but that one week allowed us to save an additional 15,000 test strips to add to our stockpile and cover us until the Inform II meters were available," Dr. Laser says.

Meanwhile, he and the rest of the implementation team also had to design and carry out a systemwide validation plan for use of the Inform II in the critically ill. "Because everyone is in uncharted territory, our goal here was to make our validation plan bulletproof from a regulatory perspective," Dr. Laser says. That's why, despite the FDA and the NYSDOH statements that laboratories can use CLSI document POCT12-A3 for validation guidance, "we did take pieces from the [more stringent] FDA draft guidance."

For example, whereas POCT12-A3 requires only 100 patient samples for validation, the FDA draft guidance requires 350. "Because we are a large health system, we will actually reach the numbers that were suggested by the FDA," Dr. Laser says. "In fact, I think we're going to end up with data from nearly 600 patients."

They're collecting additional variables, too, he says. "For example, we're going to collect any hematocrit data from

the past 24 hours, because we know hematocrit is one of the interfering substances or limitations to the assay. In the POCT12-A3 document, there's really no mention of interfering substances. We're also collecting all medications that the patient is on at the time of the testing."

Another item of interest: "The POCT12-A3 document says, Perform a venous draw, and from that tube analyze the blood on both the glucometer and the lab analyzer. With this data you can then compare the results to see if they're concordant," he says. "Now that really isn't such a great experiment for critically ill patients, because the concern is that the glucose level in the fingerstick may not represent the glucose level in a major vessel. Although it's in neither the FDA nor the POCT12-A3 document, the New York State Health Department, appropriately so, has made it clear that they expect hospitals to compare the glucose fingerstick to a venous lab analyzer." Venous blood to venous blood is not acceptable, he says. "Obviously, our current validation plan increases the variation in the system that we're testing, and we'll see if it actually meets the acceptability criteria."

Donna Sidoti, point-of-care supervisor for North Shore–LIJ's Huntington Hospital, goes into more detail. "Our validation study design uses the CLSI POCT12-A3 standard, which says that 95 percent of results must be plus or minus 12.5 percent for glucose results greater than or equal to 100 mg/dL, and plus or minus 12 percent for glucose less than 100 mg/dL. Additionally, 98 percent of the results must be plus or minus 20 percent for glucose results greater than or equal to 75 mg/dL, and plus or minus 15 mg/dL for glucoses less than 75 mg/dL.

"These are the strictest criteria set forth so far for glucose meters that we have ever encountered," Sidoti continues. "Our data collection is ongoing, and we hope to finish it soon. We feel really confident that we will be able to show validity in what we have chosen to do, and also that we will be able to incite confidence in the user that we're providing a really well-evaluated and accurate method for use with their patients."

In May, North Shore–LIJ had the chance to obtain feedback on this validation plan when one of its hospitals had an unannounced NYSDOH inspection. "What we were told is that if we did not have the glucose meters validated for us in the critical-care units, we would receive a deficiency and have to submit a plan of corrective action," says Thompson, the administrative director of near-patient testing. "This facility was going to be cited, but then we had a collaborative and collegial conversation with the inspectors and representation from the senior leadership at NYSDOH and told them about our plan for our validation study, and our preliminary data, and they accepted it. They were very impressed at the comprehensiveness of our plan."

To Dr. Laser, the NYSDOH's positive reaction was an affirmation of everything that North Shore–LIJ had worked so hard to accomplish with its rollout of the Inform II. "We were trying to make decisions on a system level as best we could, given the information that was available in the changing landscape," he says. "We thought we were doing a good job, but we weren't sure until we were inspected. It turned out we were."

That's not to say, of course, that the team wouldn't do a few things differently, given the chance to go back and start over. "I do think there was a bit of a bump at the very beginning of the project," says Dr. Smith, VP of nursing education. "There had been discussions at the laboratory level regarding the maltose interference issue and the need to do a meter conversion relatively quickly, but the communication at that point wasn't shared with the nurse executive leadership group, and so plans were being put into place to operationalize this initiative without having all the stakeholders around the table. That was an early lesson. I think we probably lost a few months, but we learned quickly, we had a smooth rollout, and we've now developed these much stronger collaborative bonds."

Dr. Laser and Poczter, assistant VP of lab services. “By partnering with nursing,” Poczter says, “the perception of the laboratory has totally changed.”

Dr. Smith isn’t the only one who sees a stronger bond between nursing and the laboratory since the project began. “This is only the beginning of the wonderful relationship” between the two disciplines at North Shore–LIJ, says Hannah Poczter, MPH (DLM), assistant vice president of laboratory services. “Laboratories many times are not recognized for all the work they are doing in patient care. By partnering with nursing, the perception of the laboratory has totally changed.”

Meanwhile, POC supervisor Sidoti would like to see bidirectional connectivity added to the point-of-care glucose testing process. “We need bidirectional connectivity to really serve our patient population well,” she says. “Right now, it’s all manual data entry into an electronic medical record. The technology is there for a bidirectional interface. We have the RALS data-management system, and we have wireless glucose meters.” Connectivity is to be the next phase of the project. “Wireless connectivity is great,” she says, “but we need the bidirectional interface to fully appreciate the technology available. So I would like to see more efforts to get that piece of it in place.”

For her part, Frederick can’t think of anything she would change in the rollout process (except, maybe, finding a few more deep, dark hiding places for all those test strips). “I think we had a good grip on the project from the very beginning,” she says with satisfaction. “The issues that came up were unforeseen. As with all large interdisciplinary projects, you have to prepare for the worst and adjust thoughtfully to all unexpected challenges.”

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