No surprises—one lab's approach to costly genetic testing

Elizabeth Silverman

September 2014—Medical practice is no stranger to good things coming from bad, but lest anyone be in doubt, Children's Hospital and Medical Center in Omaha provides a striking example.

The bad, in this case, was an exorbitant bill for genetic testing delivered several years ago to the parents of a sick child. The family had no idea such an expensive test had been ordered or that their insurance company would not pay for it.

After receiving the bill, the family complained to the hospital, which, instead of just hoping something similar wouldn't happen again, set out to do something about it.

Deborah Perry, MD, director of the Department of Pathology at Children's, and the laboratory staff had been interested in studying how the hospital handled genetic testing even before the family's unwelcome surprise had become known.

"With the volume of genetic testing we saw going out of our lab, we knew we needed to improve the process both from the financial standpoint and from the standpoint of the patients and their families," Dr. Perry says. "As more and more genetic testing became available for syndromes, we thought we should find a way to make certain that physicians and practitioners were getting the right test."

They did, and the program they spent just over two years setting up could well serve as a model for others—and be in place elsewhere in three to six months, Dr. Perry estimates. "I think anyone can do this," agrees Donna Gombold, MT(ASCP), who, with a colleague, created and runs the program.

As knowledge grows about the clinical significance of individual gene variants and genomic structural elements, so too do the number of situations in which genetic testing becomes diagnostically appropriate. Leslie Biesecker, MD, chief the NIH National Human Genome Research Institute's Medical Genomics and Metabolic Genetics Branch, and Robert Green, MD, MPH, associate professor of medicine, Harvard Medical School, and a geneticist at Brigham and Women's Hospital, write in the June 19 *New England Journal of Medicine*: "We anticipate increases in the use of clinical genome and exome sequencing, the key attribute of which—its breadth—distinguishes it from other forms of laboratory testing" (370:2418–2425). While the decrease in the cost of gene sequencing has made its use feasible in a clinical laboratory setting, advances in sequencing technology and informatics have left physicians with an array of complex choices. Among them are whether to sequence the whole genome or exome or just one gene or a few; whether to sequence and analyze noncoding regions, and if so, which ones or how many; and which laboratory's technology and informatics software will yield the best diagnostic result for each patient. Turnaround times and prices can differ greatly. The variation in the genetic tests themselves and in their execution, costs, and reimbursement may present hospitals, patients, and physicians with something of a diagnostic Gordian knot.

Donna Gombold (from left), Dr. Deborah Perry, and Melissa Irving-Gass at Children's, where they set up a program to make sure the right genetic tests are ordered and no families are faced with unexpected costs. "We go back to the insurance companies three, four, five times to get the testing approved," Gombold says.

At Children's Hospital and Medical Center in Omaha, the Department of Pathology has streamlined at least some of the complexity. The family's complaint to the hospital served to bring the issues involved in genetic testing to the attention of an audience wider than the staff working in the laboratory. In fact, the complaint provided the impetus to assemble representatives from the finance, nursing, and medical staff to examine the hospital's procedures for genetic testing. The 145-bed Children's Hospital prides itself on being responsive to patients' needs, so it was clear something had to be done. But what and how? To answer those questions, the hospital hired Melissa Irving-Gass, RN, and medical technologist Gombold, whose job was to develop a program to make sure the type of miscommunication that had occurred with the family never happened again.

It was slow going in the beginning. "When we started there was a lot of resistance from the physicians because they felt we were going to be telling them they could not do genetic testing and denying all of the tests they wanted to do," Irving-Gass says.

"At first," Dr. Perry adds, "the medical staff was afraid we would be like police and say no to things, and then the testing would take too long because they would have to wait for us in the lab to approve it."

But the fear and the result were worlds apart, with Irving-Gass and Gombold easing the way by having become a contact point and an information clearinghouse for the medical staff, the families, the laboratories, and the insurance companies.

In essence, when a physician at Omaha Children's wants to order a genetic test, he or she calls Irving-Gass or Gombold who then discuss with the physician the specifics of the test the doctor wants to order. If the physician has no preference for a laboratory, the team will identify which laboratories offer the test and obtain comparative information on prices, turnaround times, analytical methods, and the details of what will be reported. All this information is provided to the ordering physician, who will make the final decision. The team's goal is to find the physician precisely the testing he or she wants performed in a CLIA-approved laboratory for the best price and with the quickest turnaround time.

Next, the team contacts the patient's insurance company to obtain prior authorization for the test. If the insurer does not approve the test, the team sets up a written appeal or a peer to peer—a chance for the patient's physician to talk with a physician working for the insurer. Irving-Gass and Gombold consider themselves advocates for patients and physicians and have become adept at running interference with third-party payers by understanding the rules and environment and establishing relationships with reimbursement decisionmakers.

Physicians and family members who are having problems with insurance companies can turn to the team for help. A denial by an insurance company is not the end of the process but the jumping off point for Irving-Gass and Gombold. "Physicians see that we advocate for them," Gombold says. "If we get a denial from an insurance company, we immediately contact the physician and ask if he or she would like to do a peer to peer. We ask, 'How can we help you get the information you need to get to us so we can get it to the insurance company?' In the past this would have just fallen to whomever had a chance to do it. We are very proactive and don't let a denial be the final say—we go back to the insurance companies three, four, five times to get the testing approved for our patients and our physicians."

Such work could involve finding articles in the literature that support the need for the test or finding a CPT code the insurer will accept. If a CPT code is not a covered benefit at a physician's preferred lab, the team will scour the field to find one where it is, and then provide the ordering physician with the information that's needed to evaluate it as an alternative. The goal is to get the physicians the tests they want, the insurers the CPT codes they cover, and the patients the testing they need.

Once the insurance company approves the test, the team contacts the physician or genetic counselor to inform them of the approval and then the patient or family to set up an appointment for a blood draw. The team meets with every patient or family before the blood draw and has them sign an Advanced Beneficiary Notice that lets the patient or the family know the approximate cost of the test minus their deductible. They ask the families to sign a consent form so it is clear what test is being done and why the physician ordered it. The families also receive notice that the team will contact the insurance companies on their behalf and are asked to give the team permission to access medical records they might need in the course of submitting the insurance authorization forms. Cognizant of the problem that triggered the creation of the program, the team wants there to be no surprises, financial or otherwise.

The team also coordinates with the laboratory to make sure the correct amount of blood is drawn, that it is in the appropriate tubes and sent to the right laboratory, and that it's done in the time frame the ordering physician has requested. Says Gombold: "We hand out paperwork to make sure the lab knows which patients can be drawn, which can't be drawn yet, who has been prior authorized, and who the lab needs or doesn't need to talk to. That way the lab can see from the paperwork what needs to be done."

Once the results are in, the team makes sure they are sent to the ordering physician and the patient's primary care physician. Irving-Gass and Gombold are not only the main contacts at the hospital for anything involving genetic testing but also are a personal resource the families can talk to for assistance.

Should test results get misplaced, their retrieval is only a phone call away because Irving-Gass and Gombold receive copies. Those copies serve another purpose: The team is able to intercept a duplicate test request, perhaps coming from physicians in different specialties.

“Donna and I are the main contacts for genetics in this hospital,” Irving-Gass says of the program’s comprehensiveness. “The physicians know who they need to call if they want to order something, and the parents get one of our cards so that we are their main contact.” They tell the parents how long it will be before a result is back so if they don’t hear from the physician in the specified time they can call Irving-Gass and Gombold to inquire.

“Has it been delayed, is it sitting on somebody’s desk, what’s going on? The lab knows that Donna and I are on call so they can page us anytime to say, ‘We just got an order on this baby, what do we do? Do we draw it, do we not draw it, how much blood do we need, where does it need to go?’ The lab knows we are the contact point if it has a question regarding a sample, say there’s not enough blood or the sample’s been compromised or they need a clinical history for something specific they need to test for.” On the back end, Gombold adds, “The physicians know Melissa and I are the people who have the results and information for them if they need it.”

The team can handle immediate requests too. If a result is needed quickly to make a clinical decision—on a newborn, for instance—the blood is drawn and sent out immediately and the team addresses the financial issues afterward.

“I think there’s been both patient and family satisfaction as well as provider satisfaction, and oftentimes we don’t get both,” Dr. Perry says. “The families are happy, they feel they’ve been informed on the front end and genetic counselors have talked to them, they know what the testing is, the financial people have spoken with them, and the family feels secure. Once the physicians decide what they want to look for, they know they don’t have to worry about the process.

“It’s one of those times when we get the patient or family, the physician, and the lab all on the same page. It’s great,” Dr. Perry says.

Stephen Kassel, MD, a pathologist at Children’s Hospital Central California in Madera, Calif., led a CAP inspection team this April through the laboratories at Children’s in Omaha and had praise for the approach. “The problem is that genetic testing is extremely expensive and runs into the multi-millions of dollars in written-off charges, and no one has figured out a good way to control that,” he says. “Plus everybody starts out by wanting to limit the number of tests that are performed. In Omaha what they decided to do was to attempt to maximize reimbursement rather than shut off the number of tests.”

The economics do look compelling. Omaha Children’s Hospital and Medical Center does more than $3 million in genetic testing annually with a monthly caseload of between 70 and 95 patients, and Irving-Gass estimates that their work on reversing denials and intercepting duplicate testing saves the hospital between $250,000 and $500,000 a year. This has been accomplished with 1.5 FTEs (Gombold is full time, Irving-Gass part time). The increasingly restrictive policies of insurance companies are likely to continue to drive such savings and to increase the value of the program. When the program started in 2012, the insurance companies were more willing to grant prior authorization than they are now, Irving-Gass says. She and Gombold have to fight harder now and do more legwork to get approval. Test volumes are up as well, making what they do even more pressing. A geneticist recently started a new clinic at Children’s and the hospital is getting calls from generalist pediatric physicians who want to use Children’s for all their genetic tests. The hospital is also picking up genetic tests from nonpediatric specialists in orthopedics, pulmonology, endocrinology, and neurology. Given the widening applicability of genetic testing across multiple specialties, this trend is likely to continue.

Dr. Kassel agrees that what’s being done in Omaha could be replicated or adapted at other hospitals. This is especially true, he points out, because most genetic testing is still pediatric and most pediatric hospitals are on the smaller side. Size is an issue to the extent that the program’s success rests on input, buy-in, and communication from a variety of groups. Initially, Dr. Perry says, they met with various group leaders, such as the director of the hospitalist service, the directors of the NICU and PICU, and the directors of the specialty clinics, to get their views. These consultations continued throughout the program’s development. Information about the program was also provided in staff newsletters and email. Most helpful, says Dr. Perry, was sitting down at section meetings, in small groups, to explain the program and to make sure everyone knew the contact people.

“We spent a lot of time going to the different areas,” Gombold says, “and asking: ‘In a perfect world how would you like this to be done, and what would you like to see? What is important to you?’ I think anyone starting their own program would have to do something like that.”

Yes, Dr. Perry says, this could be more challenging at large hospitals. One solution could be to start in one of a large hospital’s specialty clinics and work out the kinks there before expanding to other departments.

The team in Omaha had to design its own forms and procedures, and that accounts for some of the two-plus years it took to get the program going. With Omaha Children’s as a guide, other laboratories could get it done in far less time, Dr. Perry believes.

Word of mouth about the program is starting to grow. “As information goes out about the services we provide,” Gombold says, “we are becoming more and more of a resource.” Other hospitals have contacted them to ask how they do what they do and to ask for their help. “We are happy to provide information to everyone because what we do is not rocket science—we are just dedicated to making sure that tests are going to be paid for, that families aren’t left hanging, and that the doctors get exactly what they want.”

“It’s 100 percent worth setting up something like this,” Irving-Gass says, “and Donna and I are more than happy to share what we’ve developed because it works. Why re-invent the wheel?”

If genetic testing is to fulfill its promise, it will have to be not only legal, ethical, and accurate but also practical. The large number of variations of any one test, and the growing volumes, both pediatric and nonpediatric, make the Omaha program—with its focus on efficiency, economics, patient and physician satisfaction, and open communication—one to study.

“The program or some modification of it,” Dr. Perry says, “is a win for everybody.”
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Elizabeth Silverman, of New York City, is a writer who covers genomics.