Clin Lab 2.0: Add value, make patients better

Anne Paxton

January 2018—It was baseball's Yogi Berra who said, with the unique slant that was his hallmark, "In theory there is no difference between theory and practice. In practice, there is." More vividly, boxer Mike Tyson once summed up the same reality when asked to comment on an opponent's strategy in an upcoming match: "Everybody has a plan—until they get hit."

Laboratories may not have to fear such a sudden and traumatic hour of reckoning. But as new payment models change volume-based health care to value-based health care, these sports lessons are relevant to the laboratory industry's strategic planning. If adding value, in theory, is becoming essential to laboratories' survival, what does that mean they should do, in practical terms?

Dr. James Crawford (right) with (from left) Reeti Khare, PhD, assistant director of infectious disease diagnostics; Tarush Kothari, MD, MPH, physician informaticist; and Yehuda Jacobs, software architect. The question Dr. Crawford asks his laboratory colleagues is, "Can you demonstrate that patients are better for having received care from your lab as opposed to from other labs?"

To explore the next era for health care and what it means for labs, CEOs and directors from Geisinger Health, Henry Ford Health System, Northwell Health Laboratories, Kaiser Permanente North Laboratories, and TriCore Reference Laboratories began meeting in March 2016 as "Project Santa Fe." They see their concept of Clinical Laboratory 2.0, emphasizing demonstration of how the laboratory adds value to patient care, as a critical clinical and business model for re-engineering laboratories' role in the health care system.

"The value discussion has been underway for some years," says founding member James Crawford, MD, PhD, senior vice president of laboratory services at Northwell Health in the greater New York metropolitan area. "Project Santa Fe was founded to bring together like-minded laboratory systems to drive the momentum of these initiatives."

In 2017, Project Santa Fe shifted emphasis from visioning to practice by hosting a special session in May at the

Executive War College and an open workshop in November in Albuquerque, NM, aiming to provide leaders from a range of laboratories, diagnostics manufacturers, and lab service companies a grounding in case studies and examples of innovative strategies that are working.

The workshop was meant to go beyond theoretical approaches, says founding Project Santa Fe member Michael Crossey, MD, PhD, chief medical officer at TriCore in Albuquerque. “It was very tactical and tangible. It gave actual examples of lab-initiated activities that can directly enhance patient care, whether through patient safety or efficiency.” Several participants in the workshop asked him for phone consultations afterward because “they literally want to get beyond the ‘idea’ level and into ‘how did you actually do that?’”

In interviews with CAP TODAY, organizers and first-time participants in the November workshop give their take on the Project Santa Fe mission and how some of the approaches that laboratories are pursuing are adding value within their institutions. Restructuring of ordering and results reporting, improving the speed and accuracy of the diagnostic sequence, harnessing population data, and establishing more direct links between pathologists and patients are emerging as some of the most promising avenues.

Dr. Hanson

For Curt Hanson, MD, chief medical officer of Mayo Medical Laboratories in Rochester, Minn., and chairman of the American Clinical Laboratory Association, the workshop was his first opportunity to participate in Project Santa Fe. He found it an intriguing and stimulating chance to meet with thought leaders and interact with other executives facing the need to reorient their labs to a value-based perspective.

As a practicing hematopathologist at Mayo in addition to his leadership role, Dr. Hanson considers it no surprise that clinicians don’t always order tests in efficient ways to get to a final diagnosis because they are burdened with having to know so much information about laboratory tests. In the meantime, he notes, the role of payers has become much more that of a gatekeeper.

“Historically, payers paid for services, but in today’s world what they really do is allow access to patients through their payment policies. They determine who can see which doctor and increasingly they are part of the picture of how patients receive care, whether we like it or not.”

TriCore’s added-value program, directly providing patients’ positive pregnancy results to payer-based care coordinators in addition to ordering providers, to channel these women into prenatal care, is a reflection of this new reality. “Early prenatal care drastically affects outcomes and cost of obstetrical care,” Dr. Crossey says.

One way that Mayo Medical Laboratories is trying to adapt and be proactive in ensuring the right testing is being done is by partnering with a clinical decision support company to offer a tool to help clinicians with test ordering. Having access to information that looks at the impact of lab tests on overall outcomes is difficult, Dr. Hanson says. But he is glad to see the push to add value gain traction in the lab community and hopes that the clinical decision support is a great first step. Mayo is engaged in several other projects to try to understand how labs can better influence outcomes, he adds.

Hay

Andy Hay, chief operating officer of Sysmex America, attended the workshop with a sense that action is urgently needed and the belief that Project Santa Fe is in the vanguard in addressing it. “There are some very big gaps between where the laboratory industry is as a whole and where we need to be to survive in the post-PAMA era,” Hay says, referring to the 2014 Protecting Access to Medicare Act, which will cut an estimated $670 million per year from Medicare lab reimbursement beginning this year.

Hay strongly agrees that labs need to show value in the care pathway rather than just produce diagnostic results, and Sysmex wants to make sure the services it provides are geared to Clinical Laboratory 2.0. But he doesn’t think hospitals and vendors in general have gotten with the program yet.

“There were maybe 50 hospitals represented at the workshop, probably fewer. That means roughly 5,250 hospitals in the country don’t know the train is leaving the station.” The future of vendors hinges on them too getting up to speed, he adds. If they don’t, then “the wheels are going to come off their business model. It’s no longer going to be sufficient to sell instruments. You’ve got to put a wrapper around them that demonstrates their value to the patient experience.”

From the perspective that the diagnostic companies are an integral part of the laboratory industry, Hay stresses that industry must interact with clinical caregivers in a way that integrates the lab in care decisions. Sysmex, he notes by way of example, is using teams of nurse practitioners to educate providers on advanced clinical hematology parameters, but has found adoption to be slow. “The savings potential generated by these parameters outside the lab will be huge, either through reducing pharmaceutical costs or length of stay. In a 2.0 world, innovations from the lab would be widely adopted and very quickly.”

The surging quantities of population data also may serve as a catalyst to speed the adoption of innovations from the lab, he adds, although health systems’ information technology systems will need to have enough horsepower to crunch the data. Still, “a lot of simple solutions would move the needle somewhat,” and can be shared, Hay believes. “If you have a new test that can shorten length of stay of a hip replacement, for example, it will work as well on the East Coast as on the West.”

Robert Michel, publisher of the *Dark Report*, who also participated in the Project Santa Fe workshop, notes that added pressure is coming not only from the continued decline of fee-for-service payment policies but from the changing dynamics of laboratories’ relationships with payers. “Labs are experiencing greater difficulties remaining in-network for health insurers in their region and finding it more difficult to have their claims settled promptly and fully.” Together, he says, those dynamics are creating “sustained financial pressure on all labs.”

Most hospital and health system laboratories, tasked with managing shrinking budgets and falling revenue from outreach services, “aren’t really looking that far in the future, and that’s a major reason why relatively few lab professionals are actively organizing added-value lab services in their organizations,” he notes.

But the stakes of reprioritizing are high and laboratories are in a good position to positively affect that process, Michel believes. When fee-for-service was king, pathologists were often hesitant to talk with a doctor about better utilization of tests because such conversations might have led the provider to switch lab referrals to a competing laboratory, he points out. “Now, a doctor may be getting a budgeted amount per month and will be graded or rated based on factors such as patient outcomes and overall cost per episode of care,” and thus will be open to having a clinical pathologist help them improve how they use lab tests.

Michel

The value associated with laboratory testing can be improved in a number of ways, he says. “The first and easiest is for labs to work with their parent organizations and physicians to help improve utilization of lab tests. A growing number of physician practices receive payment in the form of a budgeted per-member-per-month amount, so reducing unnecessary tests does add value.” The low-hanging fruit in this context is helping doctors revise standing orders and eliminate duplicative testing.

A second way to add value is to collaborate with physicians to identify opportunities for better use of lab tests for a specific patient, improving diagnostic accuracy and guiding therapy more precisely, Michel says. The added value from these lab-physician collaborations comes from measured improvements in patient outcomes and reductions in cost per episode of care.

For example, the laboratory at Northwell Health collaborated with physicians to more precisely diagnose and treat hospitalized patients with acute kidney injury, resulting in a seven percent increase in diagnosing patients at stage one and two, versus at stage three where permanent kidney damage is more likely. Says Dr. Crawford: “The program developed because a hospital chief medical officer, also an ER physician, contacted pathology and said, ‘We think patients getting radiographic imaging studies are experiencing AKI at a higher rate than expected. Can you help us resolve this problem?’”

Other value-added projects can involve a more direct relationship with payers, such as the pregnancy test results reporting program at TriCore, Michel suggests. “I have always advocated that local labs would be well served to develop strong personal relationships with health insurer medical directors in their communities, as well as with the largest employers who design the benefit plans, because these are places where a lab professional can help a decision-maker understand the right test for the moment and the kind of downstream clinical actions that should be triggered by ordering the right test.”

“You still have to run a traditional ‘1.0’ laboratory and deliver customary lab services,” Michel cautions, “because it’s the data your lab produces that Laboratory 2.0 is going to use and combine with other clinical data sets to add value.” Where value will be derived is in labs’ processing the data from their lab results to create information, then distilling that to create actionable intelligence.

The stakes of embracing value-based paradigms are high, but they depend on the markets where health care systems are located, Dr. Crawford says. “The transition from fee-for-service to value-based health care varies, and if you are in a market well served by fee for service and you’re a preferred provider in that market, the imperatives are potentially less than in a market where there’s more high-risk-based payment. It’s only recently that an increased emphasis has been put on the programmatic leadership for value-based care that labs can provide.” But he believes labs now need to catch up. Even though his market in New York is transitioning more slowly than others, “I feel a high sense of urgency to be creating these value statements while we have time.”

To underscore the importance of value statements, the question he likes to put to laboratory colleagues is: “Can you demonstrate that patients are better for having received care from your lab as opposed to from other labs? If you can’t, you are a commodity. If you can, then you are demonstrating value added.” And there are many ways laboratories can demonstrate value because of all the wonderful data the lab produces. “Not only are we subject matter experts on what the data mean, we are also the first ones to see the data,” he points out.

However, pathology informatics is not the only route to adding value. “A lab can create data that’s latent and not

acted on; the point is to make that data actionable. For example, Northwell has been focusing on a care delivery issue—ensuring the right amount of blood gets put into blood culture bottles at the time of blood draw, to avoid potential false-negatives that delay diagnosis and treatment of bacteremia. You could call this a lab utilization management initiative, but in fact it is about the total patient experience. The Project Santa Fe paradigm we are after is favorably impacting the entire health care spend, not just the lab spend."

Showing the impact of such a care delivery improvement on the entire spend is the challenge. At a Project Santa Fe panel discussion at the 2017 annual meeting of the Association of Pathology Chairs, a distinguished audience member said during the Q and A, "Jim, people have been talking about this for years. What's different about you?" Dr. Crawford's answer: "Now we actually have to do something. We have to have demonstrable evidence that our programs and leadership are improving health care and doing so in a cost-effective fashion."

The ever-rising sophistication of IT is opening pathways to that demonstration. At Northwell, "Number one, we've created a data link to identify the managed care plans our patients are on, and so can do programmatic coordination in line with what payers need our health system to do on behalf of their patients. Number two, we are working with the providers and administrative leadership of both our shared- and full-risk portfolios to take the lessons from those efforts and map them onto the broader clinical space, which includes fee for service." Those steps allow Northwell to address gaps in care, utilization management to avoid wasting resources, and the need to optimize diagnostic pathways. "That's the broad strategy for our informatics effort."

Length of stay is a desirable metric but one of the toughest to map to, Dr. Crawford says. "The reason is there are so many contributing factors to length of stay. Assigning attribution [i.e. the link between LOS and the role played by the lab] to a lab-led program is not something we've been able to do yet." He is encouraged by recent reports of a Vanderbilt University project on LOS and intracranial hemorrhage that show the direct impact of disease management programs on LOS, however, and he believes it is an important step toward pinning down the lab-contributed variables affecting LOS. (See "How to spot the savings from a diagnostic team," CAP TODAY, October 2017.)

Operational metrics—such as whether a provider documented that a patient had acute kidney injury following evidence from the lab—are easier. "That's a strong proxy that we hope is correlated with better care, though it's not proof that better care was actually provided."

With its blood culture fill volume project, Northwell is using informatics to demonstrate clinical impact. "Ten thousand bottles a month means a lot of data that's coming out of our clinical microbiology lab. We now have evidence that, with a massive educational and training campaign, we've not only improved our blood culture fill volumes. We also have favorable clinical indicators that patients are getting fewer false-negatives, more rapid identification of what bacteria are in their blood [owing to the bottle having a full inoculum], and less contamination." In other words, "You work your way upstream to the clinical impact of the value-based programs you are building," Dr. Crawford explains.

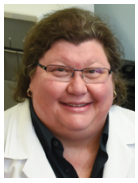
Other Project Santa Fe leaders are making headway with their own projects. TriCore's project relaying pregnancy test results, as well as changes in renal function and diabetic indicators, to insurers' care coordinators, for example, makes it possible for the laboratory to risk stratify this population and identify high-risk cases and gaps in prenatal care, ultimately allowing for targeted intervention and even decreasing frequency of neonatal ICU admissions at the time of birth, says Khosrow Shotorbani, MBA, MT(ASCP), former president and CEO of the reference laboratories. "This connection to outcome and a separate value proposition are minimum requirements of the Lab 2.0 approach to improve care and reduce the overall cost of delivery," he says.

At Geisinger, process improvement of anatomic pathology turnaround times is closing the gap between the diagnosis procedure and patient experience of learning their results. Kaiser Permanente is ensuring that latency of lab data is brought forward to the benefit of patient care through tracking data on whether providers are acting on it.

A clearer path to the trackability, or attribution, of the lab's programs, actions, or data is the realized financial

benefit. “That’s a very strong argument for value,” Dr. Crawford says. “If you do something for revenue or expense management or both, that is immediately evident to health system leadership. But you have to have done the advance work to ensure it’s a lab-led program you can attribute the favorable outcome to.” Laboratories shouldn’t be doing only what they can take credit for, he adds. “But with some things, you can say that this favorable outcome was because the lab did that thing.” A proactive stance on the part of laboratories, he says, increases the likelihood that if they’re doing something good, they might get attribution for it.

He places two questions at the fore: How can we maximize the value that comes from what we’re already doing? And how can we help drive enterprise-level programs that will, in concert with lab diagnostics, provide better health care outcomes? “For virtually every initiative in our health system, we ask those questions, and it’s very encouraging that in virtually every instance there is an opportunity for the lab to step forward and say: ‘We can help you on that. We can do something together.’”



Dr. Wolk

Generalizing one laboratory’s experience to apply to others is desirable, but it can be problematic. The process of adding value requires setting well-defined parameters that can be explained to other organizations that may want to undertake a similar project, says Donna Wolk, MHA, PhD, D(ABMM), system director for clinical and molecular microbiology at Geisinger in Danville, Pa. “The goal of Project Santa Fe is to allow the project, or the diagnostic intervention or quality improvement or the insight gained, to be generalizable to the broadest number of organizations. To allow that, there have to be some underpinnings of standardized analytical processes for certain projects.” She hopes that the collaboration encouraged by Project Santa Fe, through meetings and workshops, can bring group thinking to add value and context to understanding what makes a project successful and applicable to other settings.

At Geisinger, for example, a retrospective population health study of sepsis, analyzing preanalytical and postanalytical details about patients in a cohort, has the long-term aim of being able to prevent people from getting sick to the point of sepsis. “We’re doing predictive modeling of whether there are indicators that can tell us who is at risk to develop sepsis, and if there are, whether there are interventions we can make to prevent that from happening.” With this kind of pattern recognition, the population health study can help build predictive models with machine learning that may be applied in real life to improve care, she says.

Through Project Santa Fe, “a team of people from large health care organizations can answer these questions more quickly. We can learn from each other. We don’t have to recreate the wheel in our own organization. If somebody already has pilot data, let’s group together and come to some conclusions about whether we can provide insight and impact.”

The sepsis project is examining the impact of faster provision of lab results upon which providers can better tailor their antimicrobial therapy, Dr. Wolk says.

Among the interventions studied were, first, simply reporting Gram stain more quickly; second, identifying organisms faster through mass spectrometry; and third, identifying the organisms more quickly, directly from the blood culture bottle by PCR. “We don’t just put the results in the medical record. We’re phoning in all the positive results including the identifications for sepsis patients, so that the provider knows in near real time that they can make a change in the therapy.” Such quick results reporting is not new but has typically only been done after two

or three days, she says. “We’re talking in some cases less than 10 hours.”

Laboratory contributions like these are under-appreciated in the big scheme of things, Dr. Wolk says. “People focus on the sepsis bundles and getting fluids and broad-spectrum antibiotics to a patient, and all of that is important. But without a proper documentation of the lab processes, then changes made in care may or may not be the contributing factor to the actual improvement. What if your phlebotomist just became 50 percent faster in getting blood culture bottles to the lab for their placement into the incubator? You have to be able to control for those variables to know their impact.” Detecting such links helps meet Project Santa Fe’s mission of getting people to consider lab processes as key stepping stones toward meeting improved patient care goals, and working together in interdisciplinary teams to include individual department data in the assessment of a process, she says.

Succeeding at that mission will help improve laboratories’ standing within the hospital, she believes. “We want hospital labs to be able to survive these cuts and protect our infrastructure in such a way that we can continue to provide the expertise to hospitalized patients that we’ve been trained to provide.”

A possible future strategy might be to work with the pharmacy to provide the recommended dosing for certain organisms right in the lab report, Dr. Wolk notes, rather than having pharmacy look up an antibiotic stewardship guideline and match the organism with the drug.

More direct links between the patient and the pathologist may naturally follow, she points out. “I think the lab is moving toward diagnostic care teams in which pathologists and medical-board-certified PhDs will be doing rounds with providers on certain patients, just as pharmacists do, and that has already taken hold in certain places. The pathologist or PhD role in better educating patients about lab results through websites, phone calls, or patient portals will let us do the same thing for patients that we’re doing for providers right now.”

Providers, in fact, need more help as well, says Karen Kaul, MD, PhD, chair of the Department of Pathology and Laboratory Medicine, NorthShore University HealthSystem, Evanston, Ill. She attended the Project Santa Fe workshop for the first time in November and found this to be a focus. “Physicians don’t understand the vast number of lab tests available today and our field is expanding. We need to take a more active role in guiding their ordering patterns. And at the back end, we need a much more consultative role to help them understand results. We are sitting on an enormous amount of data and there’s a wealth of information we can leverage to provide value to physicians.”

Dr. Kaul

At NorthShore, the emphasis has been on building tools in the Epic electronic health record system to help physicians better utilize the lab by reducing unneeded testing. The prevalence of EHR software is making this possible, Dr. Kaul says, but none of the software comes with these tools built in. Fortunately, “Many of the physicians taking the new board exams in clinical informatics are pathologists, and there’s a great deal of enthusiasm about what we can do with data. It’s become a new type of science in the lab.” Her group has already had success with implementing EHR alerts to guide certain physician ordering practices, such as for blood products.

Another program of Dr. Kaul’s lab is to take control of complicated workup processes. With a hypercoagulable patient, for example, the lab might abandon the old-style repeated ordering of tests and waiting for results by ordering two or three tubes of blood at the outset and letting laboratory staff triage the testing to obtain a more

efficient diagnosis. “Why don’t we just direct workups in the most useful manner possible? We can add a lot of value because it’s our area of expertise, whereas a clinician may see only a couple of new patients with that disorder a year.”

While length of stay is a multifactorial index that is difficult to assess, NorthShore has already shown a demonstrable reduction in LOS from implementing automation in its clinical microbiology lab, and she sees other metrics becoming equally useful. “Cost per test is one our administration is very enthused about, but as we get a little further down the road, we may be looking at lab tests per DRG, perhaps, or time to diagnosis, or other indicators of the efficiency of the lab workup.”

Better communication with clinicians will help pathologists add value too. Her institution’s EHR has incorporated a “My Pathologist” button, built in-house, that allows clinicians to send a consult request or question and get an answer from pathology and laboratory medicine professionals within a couple of hours. “We’re finding that residents, hospitalists, PAs, and nurses find it useful, as well as physicians in the ambulatory setting who may be colleagues we’ve never met. This is a way for them to electronically get to know us and for us to answer their questions efficiently.”

There is more than one way to raise the profile of pathologists’ contribution to health care outcomes and cost-effectiveness, Dr. Crawford believes. While his lab does not have a button on its home page to reach the pathologist, “You can get access to a speaking voice at the laboratory within seconds with a phone call,” and he looks forward to a time when discussion between pathologists and patients is much more commonplace. The CAP worked with New York State pathology advocacy organizations to change regulations that made his state the only one barring pathologists from speaking with patients about their lab tests. Dr. Crawford was one of four pathologists whose 2016 testimony helped lead New York State to modify its regulations this past fall to allow pathologists to speak directly with patients.

Such developments underscore the notion that adding value starts with relationships well beyond the laboratory, Dr. Crawford says. “It’s all about teamwork: learning what your stakeholders’ needs are and looking for opportunities to meet those needs.”

TriCore’s Dr. Crossey says a lab doesn’t have to go from Laboratory 1.0 to be at 2.0. “You don’t have to buy into the whole 2.0 space. There are transitions, there are pilots, there are case studies that any lab can do within their system to prove their worth and prove the lab can do it. You can pick a few things within your institution or health system, working with other service line chiefs. Whether it’s a quality pain point, or service delivery pain point, or outcomes pain point—just start digging and see where the lab can help.”
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