Lab 2.0, Medicare 2030, AI—how they come together

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July 2024—*The term value-based care is spoken of often, but what part do laboratories play in it and how can they be paid for it? What is Medicare 2030, and what does it mean for laboratories? How can AI be used to practice the medicine of tomorrow?*

Myra Wilkerson, MD, in speaking in May at the Pathology Informatics Summit, answered these and other questions. She is chair of the Department of Laboratory Medicine and of the Diagnostic Medicine Institute at Geisinger Health in Danville, Pa. She is a founding member of the Project Santa Fe Foundation, for which she serves on its board and as treasurer. She opened her talk in May about Project Santa Fe's Clinical Lab 2.0 model—what it looks like now and the work they're doing. We bring to you here what she shared there.

The Project Santa Fe Foundation got its start in 2017. It's a coalition of lab leaders who explore alternative business models that expand the role of diagnostic services in the future health care ecosystem.

Clinical Lab 2.0 is an initiative that brings pathology and other stakeholders together to focus on value-based care because we know the trend nationally is to move away from fee-for-service payment models. Value-based care is the newer, euphemistic way of saying capitated care.

Dr.
Wilkerson

It's about looking at disease prevalence in your population, in particular at high-prevalence, chronic conditions, and leveraging the tremendous amount of longitudinal laboratory data we produce. Think of yourself in the laboratory as first responders. We're the first to know and to be able to identify something at a population level that can then be translated to an individual.

That means we need to develop new skills and tools in our specialty in terms of laboratory leadership because it's about risk stratification in a population and figuring out how to identify care gaps and care failures, then how to identify individual patients who are at high risk once you've done risk stratification, and then what role we can play to help them get into the right care pathways.

Once they're in those care pathways, how can the transition between different parts of the care system be made smoother? Because it can be rough going, particularly for patients who don't have much history in health care and are not health literate. It's not their fault; they just don't understand our jargon.

And then you have to be driving always toward improving outcomes within a population and translating what that means to an individual. That means getting involved in clinical care teams so you're helping promote intervention and prevention within your population. From a financial standpoint, you always have to identify risk and figure out how to mitigate it. Laboratory has a huge role to play in all of this because we're sitting on top of the best objective data present in health care.

All of that was in the first Clinical Lab 2.0 model we started with, and we're still working through that. But what we're doing now is moving into a newer model (see "Clinical Lab 2.0: Laboratories practicing the medicine of tomorrow") and figuring out how to write business cases for laboratory around it. The top row is Clinical Lab 1.0; it's what we do every day. It's proficiency testing, quality control, the total testing process, and making sure you have a safe environment for your workers. That doesn't go away. But the health care environment in that setting is what we have today: It's about sick care, usually acute episodic care, some disease screening, some wellness programs.

Clinical Lab 2.0 says laboratories can play in the game of value-based care. So what do we need to do to transition? Each column transitions: Clinical Lab 1.0 or current medical practice is about sick care, but in Lab 2.0 we need to be forward thinking and focused on outcomes. How do we do health optimization? Don't wait until they're sick and need acute care.

If you want to be transformative in the model, you need to build the evidence base, which laboratories can do, to help move organizations and patients into preventive care through, for example, diagnostic efficiency and clinical decision support. In column two the lab would move from disease screening into risk management, but if you want to up your game even more, then you would move into risk avoidance. So we're trying to work through the business cases for laboratory. How are we going to get paid to do this and to play in this field, and why is it important? What new skills will we need, as leaders in health care, as laboratory leaders, as pathologists, as residents, and as trainees, to play in value-based care?

It boils down to health economic research goals because, as Robert Michel of the *Dark Report* says, if you're not following the money, it doesn't matter what you're doing ultimately in a value-based care world because someone will take credit for what you do and eat your lunch.

Part of it is about building the evidence base for how we achieve positive outcomes as a result of the testing our labs do and the interventions that take place based on that testing. We have to know how to

communicate to payers, patients, patient advocacy groups, health care administrators, the C-suite. And we have to be able to solve their problems. If you're not solving their problems, they're not going to listen to you.

To do that, we at Project Santa Fe said, Let's start doing demonstration projects to help us build our database of evidence.

The multi-institutional projects we've been working on are related to acute and chronic kidney disease, anemia, critical values, sepsis, opioids, and steatotic liver disease, all of which can be adopted in other institutions. Eventually, once we create the evidence that our projects work, then it's about creating a playbook so that anyone with a laboratory can start to implement these solutions.

We don't want to keep this to ourselves. We want to help other laboratories know how to do this, including those with severely limited resources. A 25-bed critical-access hospital will have one IT person for the entire hospital and one pathologist who's probably part time. So we have to be able to automate these processes and make them as seamless and as easy to implement as possible.

That's where AI comes in. It's a way for us to be able to automate these processes, but also to look for what's important in our population by defining relationships and identifying new relationships in the data. At a population level, we need AI tools to enable this.

The pandemic delayed publication of some of our work, but we're in the process of publishing now, and our chronic kidney disease work was published recently as a preprint (Fung M, et al. *Research Square*. Preprint posted online April 4, 2024. doi:10.21203/rs-4032702/v1). We're not publishing in a pathology journal because if we do, we're speaking only to ourselves. It's easy for me to convince people in this room of what we're doing, but how do I convince payers and health care executives that it's important to learn about these models and to implement these practices in their institutions, or to pay for it? And regulators—what is their view of this?

Our study of chronic kidney disease was done at the University of Vermont, Northwell in New York, and Geisinger in partnership with the National Kidney Foundation. We took a year's worth of data and asked, how good are we? We think we're pretty lousy at identifying patients with chronic care disease, so let's prove it. And we *are* very lousy. An estimated 37 million adults in the U.S. are living with chronic kidney disease, 90 percent of whom don't know they have this very serious condition. It's confounded by diabetes and heart disease, which are the underlying causes for three of every four new cases.

By the end of the summer we hope our work on sepsis will be published. This one has been challenging. The patient probably shows up in their primary care setting two or three months before they have sepsis, before they present acutely in the ED. And there are abnormalities in their laboratory results. Can we identify what those abnormalities are and figure out how to do risk stratification that enables early intervention?

At Geisinger, we have a well-curated data set around this. We have more than 600 variables in that data set that covers 1.5 million lives. Our laboratory microbiologists worked hard to curate the data sets so we know it's clean data.

We tried to see if other institutions in our Project Santa Fe group could duplicate this. We found out that even though the majority of us are on Epic, we could map only about 200 common variables

together. This publication, too, will be out later this summer. There are ways, using simple, common laboratory tests, that you can figure out that a patient is moving into sepsis long before they know what's going on and before clinicians know what's going on.

Think of the morbidity and mortality associated with sepsis. If the patient reaches the point at which they're admitted to the hospital, morbidity is almost 50 percent. And the health system costs associated with their having to be in the ICU while people figure out what's going on are huge.

Why is value-based care so important for laboratories to address?

Here I'm going to move into Medicare 2030. If you haven't heard of Medicare 2030, start paying attention to this because however the government goes, since it is the largest single payer in the U.S., everybody else starts to follow—at least if it's a way for them to decrease the cost of care and examine reimbursement practices.

The CMS Innovation Center has developed five strategic objectives: drive accountable care, advance health equity, support innovation, address affordability, and partner to achieve system transformation. (The white paper on this is at https://www.cms.gov/priorities/innovation/about/strategic-direction.)

To drive accountable care, the goal is to have all Medicare Part A and Part B beneficiaries enrolled in an accountable care model by 2030. What does that mean for us? Over the past decade, to work toward this, Medicare piloted more than 50 different care models. Only six of them have fallen out to be worthwhile pursuing; only four meet their final criteria. They're largely based on primary care. Nowhere in those models do they talk about laboratory care and how we're going to be reimbursed for what we do. But I would argue that laboratory is primary care, as well as specialty care, and we're not here just to support—we are a clinical service.

To advance health equity, they are focusing on underserved populations and making sure people have access to care and that care is not based solely on employment status and zip code. More information on this is in the white paper.

What does this translate to for us? By 2030, an additional 30 million beneficiaries on Medicare will be moving into an accountable care organization. So our health care organizations and providers will be responsible for the total cost of care as well as providing high-quality care.

There's a lot of opportunity for labs to play in that space in terms of the metrics we produce, in terms of making sure we're providing the best testing possible and meeting unmet needs in populations. But it also means Medicare has figured out it is going to need to create new payment incentives to support this kind of delivery of integrated, equitable, person-centered care.

There's also a huge focus on Part D pharmacy benefits. Why? Because the national spending on prescription drugs in 2022 was $405 billion. They want to ratchet spending down but don't want to see patients go without their pharmaceuticals because they have a high out-of-pocket cost. That's a huge opportunity for us in pharmacogenomic testing, but there's no CPT code for it now.

At Geisinger, we're kicking off a project to look at that. There are good models in Europe, in particular the Netherlands. They do the right pharmacogenomic testing and get the right pharmacist involved in managing medications. They've shown up to a 30 percent decrease in total pharmacy costs in some populations.

The CMS is also partnering with the Health Care Payment Learning and Action Network and they are focusing on climate change and how it's affecting care. Last year emergency departments had the highest number of visits ever in the U.S. for heat-related illnesses in the summer.

The network is also trying to figure out how to make these accountable care models work when other payers are the ones providing the Medicare Advantage plans. That means there will be many new metrics to come—again, more opportunities for labs to contribute and support critical data.

Underpinning this is the Federal Health IT Strategic Plan, which has four goals: promote health and wellness, enhance the delivery and experience of care, build a secure and data-driven ecosystem to accelerate research and innovation, and connect health care with health data. The last goal presents huge opportunities for the laboratory, particularly if we can come up with the correct AI tools that help crunch through data quickly. (White paper is at https://healthit.gov/topic/2020-2025-federal-health-it-strategic-plan.)

I divide into five buckets my thoughts on where I think AI can help laboratories practice tomorrow's value-based medicine that is coming quickly.

One is care triage. How can we optimize the time to diagnosis, shorten the time to effective care, facilitate care coordination, and identify care gaps and care failures?

The second: improve quality metrics of value-based care. Again, think of yourselves as first responders in the lab, based on the data we're producing and the information we can provide to people. AI can help us discover and produce new metrics around improving the quality of value-based care to promote care equity, but we also need to help identify sources of bias in population data. There's inherent bias in the data we have because so much of health care is tied to insurance, which is tied to employment status. We're not truly covering our populations in the U.S.; we're covering those who have access through their payers. So we have inherent bias in our data. How do we overcome that bias? It's also tied to zip code and to care deserts. And we're seeing that play out in dangerous ways with maternity care in large parts of the country.

The third is discovery. We can work with our IVD vendors to discover what's going on in our labs—how to improve our laboratory processes and our assays. Do we need to do all the maintenance the FDA says we have to do because that's what the vendor got approved? Why not have an AI algorithm that identifies what needs maintenance in your processes before it ever happens? How can you improve your tests? What new markers should we be looking at? Are they relevant to the population? How do we tie those back to value?

The fourth is empowering patients. What can we do to help them become more health literate? When they get our surgical pathology report in their MyGeisinger patient portal, they have no clue what a lot of it means. So they start Googling. Maybe they call up ChatGPT and say translate this for me. Tell me what it means. Is ChatGPT the best tool for them? Or should we provide them with a tool that will be more accurate, or one that we've trained to help them interpret and to know what questions to ask at their next visit? There's opportunity for us to help with interpretive laboratory reporting and to facilitate health literacy. But also to connect them with research studies, clinical trials, patient advocacy groups, support groups, and so on.

AI-enabled pathology is the fifth bucket. Let's improve our narrative reporting by correlating diagnostic studies with clinical findings and socioeconomic data. Not just make it a static report that sits out there

by itself.

We have a lot of work to do.

Keep in mind that the business of what we do now, which is testing to produce information and make it available, is significantly different from the business of data analytics, which is producing clinical insights. It requires new business models, different value propositions, different stakeholders and customers we'll have to talk to. And we need to demand different payments for providing these services. In those accountable care models, we need to be recognized as a primary clinical service, not as an add-on.

Here's my to-do list:

- Evaluate the sources and quality of our data and figure out what's missing from our data. Identify sources of bias, whether it's social inequity, imperfect training data, or imperfect models. What about the reliability of those models? If I feed the same data into two different models, why do I get two different results? We need to be able to explain that in ways that we haven't in the past, so we can't just use traditional laboratory statistics that don't even begin to describe the data models we will have through AI. Standard deviation, coefficient of variation—that won't cut it anymore. We will have to get much more sophisticated.
- Talk to our new stakeholders and customers about their pain points, care gaps and care failures, transitions of care, and payment and incentive systems, and help solve their problems. They're interested in talking only to people who can help them.
- Protect the privacy and security of our patients.
- Set limitations on the new algorithms we develop, whether it's a simple testing algorithm or sophisticated machine learning algorithm or an AI algorithm, because we don't want to generate inaccurate or unverifiable results.
- Look at opportunities to be the intermediary between traditional diagnostics and self-learning algorithms, with a focus on clinical decision-making and bringing value to the patient. We have to be willing to integrate into care teams and be seen as an essential part of care teams and able to create value within those teams.
- Prove the value of what we're doing already. What's the value of a single test, of a battery of tests? When is it more valuable to not test? When is it valuable to have a testing algorithm? What value do we create downstream based on the test results and information we provide? What's the value of one testing platform versus another if they're using similar technologies and methodologies? Why would we choose one versus another? What's the value of one test method versus another? We don't always have good answers to basic Clinical Lab 1.0 questions.

We have to make ourselves as efficient and lean as possible because it's value-based care. Our resources aren't going to grow—they just cannot in a value-based care system. So it's about proving value, about inserting ourselves into clinical care teams and making sure we can bring value that's provable. Proven value to our patients, to our administrators, to our payers, to patient advocacy groups. There are many people who want to play in the sandbox with us if we can show value.