Diagnostic teams: five barriers but the time is now

November 2017— "We've been chewing at the edge of the pizza. We have just not gotten down to the part with the pepperoni."

That's how Michael Laposata, MD, PhD, sums up efforts to date to optimize the use of laboratory tests, shorten time to diagnosis, and increase diagnostic accuracy. The answer, in his view: diagnostic management teams of experts. In his first conference devoted to DMTs, in February in Galveston, Tex. (see CAP TODAY, April, June, July, October 2017), he laid out the obstacles and solutions. He is a professor in and chairman of the Department of Pathology, University of Texas Medical Branch-Galveston. Here is an edited and condensed transcript of what he said.

Many people have case conferences, but a true diagnostic management team is one in which four things happen. First, you have to meet frequently and regularly, and you have to provide a patient-specific report.

Second, the report must be delivered before or during the time when treatment decisions are made. This is why a once-a-month meeting doesn't work.



Dr. Laposata

Third, you have to put it in clinical context. We have women who have a stroke who have a factor V Leiden who are 26 years old and on oral contraceptives, and we have 95-year-old women who have a stroke and aren't on oral contraceptives but who also have a factor V Leiden. Don't you think the report should be a little different? Do we go to the Robbins book in anatomic pathology and get the paragraph on ductal breast carcinoma and just put that on every one of the breast reports? No. It's all personalized.

Fourth, you have to put it in the record. So for all the people who've shown me what they're doing and how they're interacting with clinicians, if you don't put it in the record, it's a problem. Somebody has to read it. Remember, health care teams are big. You have 10 people taking care of a patient, and the patient is probably going to come back, and they need your note.

Thousands of departments have clinical service lines outside of traditional anatomic pathology and radiology that meet two or three of these criteria. If yours is one of them, you're on the doorstep. If you have something like it, do the one or two additional things to make it a diagnostic management team.

If you do it where you come from, your neighbors have to do it, too. If you run a commercial laboratory and you have patient-specific information, you're better than the next commercial laboratory. If you're in a health care system and somebody in your system is doing it and somebody in another system isn't, you win, not to mention what the patient thinks and that your health care system will save money.

Who is on the diagnostic management team? A lot of people have asked if they can participate and contribute, but the government has, again, stepped in and put the wrong people in the room. It said that only MDs are allowed to do this. Guess what? I don't know a doggone thing about toxicology. We need a toxicologist. What degree do they have? Maybe it's a PhD. Great. You want them helping you. What if it's the doctorate in clinical laboratory science that is emerging, the BS medical technologist who can move up to the doctoral level? If they know it, they need to be in the room. How about all the medical technologist/clinical laboratory scientists who've been doing this for 30

years and know all about it? They have to be in the room too. And we need others from other departments.

What have we been doing up to now? We've been chewing at the edge of the pizza. We have just not gotten down to the part with the pepperoni. And so now we're stuck because everybody's saying appropriate test utilization is a big problem. For 20 years they've said it's a big problem. Time to fix it. The external environment has changed. If we push now, we're going to get farther. There was a time when we could push all we wanted and nothing was going to happen. We have to remove the obstacles, and I'll tell you what they are.

Obstacle No. 1: Do we have enough people to do this? No, the pathologist community doesn't have enough experts in laboratory medicine. The decision was made years ago to pay for anatomic pathology. But if I go to the emergency room and spend an hour down there, stop the bleeding through a chest tube that's coming out a unit an hour, and tell them what tests to use, I get \$25 for that. That is a problem. Everybody who's coming through a pathology training program is picking anatomic pathology. You can't even make a living if you do just clinical pathology, except if you're in an administrative position, in which case you earn a salary. I'm getting paid for something else, not for my clinical work.

And you have to have at least two DMT leaders because sometimes one leader has to be away and the other has to do rounds. Here's a proposed solution. If we're going to service everybody, we as individual medical centers can probably come up with two or three diagnostic management teams. You have two people who do coagulation, two can do anemia, two can do transfusion. But now we're in large health care systems with multiple hospitals and experts in all those hospitals. If we could link it all up, we can sign out cases for people in other locations. We have to be able to let the pathologist in Lubbock, Tex., connect into our DMT. This is a critical piece. We can't just serve people at one hospital and not at another.

So we have to figure out how we can get paid for an activity that is just as important as what is happening in anatomic pathology and radiology. It's an insignificant payment to regulate utilization. It does not work that only MD pathologists can get paid for this process. Non-MD experts are not paid, so they don't want to be a part of this. And it's been a big limitation at the American Association for Clinical Chemistry level. Somebody has to understand that the clinical impact is the same and that others need to be paid for it. In countries like Spain, where the government supports health care, people aren't regulated by these restrictions.

We have three levels of doctors—pathologists, PhDs, doctorates in clinical laboratory science—who can play a role in helping people pick the right tests and explaining what they mean. What about the PhD lab directors? The government says they don't deserve to be paid. UTMB and other programs across the country are now implementing a doctoral-level program that's like the doctorate in pharmacy. Medical technologist/clinical lab scientists can become doctors in clinical laboratory science. And right now we have a first class of seven that is terrific. It was so popular we admitted another class. The doctorate in clinical lab science people may be the major cohort that gets this done.

Obstacle No. 2: We get no credit for saving. People who run hospitals but don't practice medicine don't understand that you can have a discussion about a coagulation case, stop the use of a drug that costs \$10,000 per infusion, and in one case you save \$100,000. You may do 10 that day or 10 tomorrow.

You can have people saving \$800,000 for a health care system. But we're not generating revenue because that's coming in at \$25 a pop. In anatomic pathology, if you want somebody to sign out more GI biopsies, you hire them. If they make enough money, they can pay for themselves. The question is, as a medical center, would it be better to save \$800,000 or earn \$200,000? I know enough of math and business to know it's better to save the \$800,000. But the trouble is that people do not understand the savings, and we can't quantify it. I don't know when we put that report in how much we saved. What would have happened if we didn't get the diagnosis on that first day?

I can tell you that overutilization worsens when it's not managed by a DMT. Colleagues at another institution have told me they can order tests for less than \$1,000 without any comment from anyone. If the test is \$999 for a

genetic test, they can order all they want. When it gets to \$1,000, an alarm bell goes off and somebody calls them and says, "Do you really need that test?" But you can spend a fortune doing the wrong test, and the treating doctors are just going to go there unless somebody says, "Hold on. You probably don't need to do that one," or "Here, this test is better."

Part of the reason why the DMT is so important in this is that who knows what overutilization and underutilization really are? I read in a past issue of CAP TODAY a comment from a distinguished clotter that hypercoagulability tests are overused; they're not necessary. And I thought, who in America comes in and says, "Hey, I had a clot in my lung, and I don't give a doggone about why it occurred"? Everybody says, "Why did I get the clot in my lung?" I don't think you can treat Americans like that; they want to know why they got their clot. They want to know if they're going to pass it to their kids. To make a blanket statement, "You don't need the test," I don't think so. But if we talk about it in the diagnostic management team, we're talking about the specific person at that age with that family history and other comorbidities and deciding if it's useful or not. That's the gray zone. That's where we can really tell you if it's useful.

How much does overutilization cost? Think of all the labor in the lab, and if you don't do the particular test, you have to send it out. In large institutions, send-out tests add up to more than \$1 million. When I was in Boston [at Massachusetts General Hospital] our send-out budget from 1994 to 1999 rose \$1 million per year for five straight years. By the time I left, our send-out budget was our biggest lab by dollars spent. We had all these laboratory tests, but the amount we spent sending tests out was more than we spent maintaining even the large chemistry laboratory.

How much does underutilization cost? The necessary test for diagnosis isn't ordered; the patient has a delayed diagnosis. What are the outcomes? It could be that it worked out anyway, or it could have lengthened the stay. You should've had it figured out in three days; the stay is four days. How much does that cost? Up to \$2,000 a day plus all the medicine and everything else the patient got in that extra day.

What happens if you miss the diagnosis? Now you have a chronic disease. We thought it was anxiety. It wasn't. The patient had a heart attack and has a piece of myocardium that doesn't pump. Now you have congestive heart failure. For the rest of his or her life, the patient will be on a drug to help the heart pump and squeeze out more blood than it otherwise would.

The financial disincentives then are that anatomic pathology is paid well, and laboratory medicine is paid poorly, but both are needed for an accurate and financially appropriate diagnosis. And hospital leaders do not understand savings nearly as well as they understand revenue. Even though it's all their money, they would rather have you earn \$100,000 than save \$1 million. Big problem.

If I were the president of a hospital, I would say hire five more people in the clinical laboratory but only if they lead a diagnostic management team. You don't need five more people to manage a laboratory. You need five more people who are going to spend three or more hours daily going through the cases. That's where the savings occurs. Until you hire those people in those roles, you can't save the money while improving outcome. Will the insurance companies pay? Not yet.

Obstacle No. 3: We get sued in America. I learned in my visit to Holland this year that the physicians there are seen as human beings. You missed that? You thought it was asthma? You had a pulmonary embolism? Well, I guess you're human. Not here in America. For those of you who haven't stepped into a DMT yet, get ready. Somebody is going to say, "You screwed that one up, and we'd like you to tell everybody in a courtroom what it's about."

Back to the non-MD people who could be the DMT leaders—the PhD doctoral-level scientists in the laboratory medicine field. The last time I spoke with [the now late] Richard Horowitz, MD, a distinguished pathologist, he said, "You know what? People have to understand that nobody likes clinical chemistry. All your residents say, 'Oh, boy. Here comes the chemistry rotation.'"

In the editorial he wrote with Sarah Bean, MD, "Pathology's stepchild" [Arch Pathol Lab Med. 2017;141:186–187], there is this quote, "Clinical chemistry isn't very alluring!" Participating in a diagnostic management team during training and ultimately leading one would be an excellent experience, they say, even for the person who goes into community practice. The point here is that everybody who manages a chemistry lab needs to lead one or more DMTs. It's time to stop thinking that all I need to do is get the samples in and the numbers out.

Obstacle No. 4 is reluctance. Here are some of the reasons I've heard from those who are reluctant:

- "I'm a PhD, and don't feel comfortable making a final diagnosis. I didn't go to med school, so I'm not sure about my facts."
- "What? Wake up at 3:00 in the morning? I don't have to do that."
- "What if I go to court and they say, 'Do you know this and this?' and ask me the cranial nerves? I won't know that."
- "I can't do it because it limits my research program. You're not gonna pay me for it anyhow."
- "Who's gonna fill in when I'm out of town?"
- "I went into this field so I wouldn't have to talk to people."

Let me tell you something about all of us who do this: We didn't know a doggone thing when we started. Everybody says, "You knew a lot about coagulation the day you came in." No, I didn't. In my training as a resident, I presented 24 coagulation case conferences. That was it, and then suddenly here I was in a real job, and I was taking on the coag cases. Now I've done more than 50,000, and I think I've seen everything. Most of the learning was done by doing; it wasn't anything I did ahead of time.

Can you fill in the medical knowledge gaps? For our doctorate of clinical laboratory science program, we have a course for a bit about an EKG, and looking at an imaging study and other topics. Yes, there are little holes to fill, but they're little. For those who have a doctoral-level degree and are going to run a chemistry lab, you know enough about toxicology to help a patient. Do not underestimate your knowledge base and your impact on patients. You *can* do it. Take whatever you feel you know the best and organize a DMT for patients with those disorders.

Obstacle No. 5: The belief that pathology DMTs are not relevant to anatomic pathology practice. You look at a slide. That picture looks like alcoholic hepatitis. Okay, got it. Wait a minute—what if it's a tumor, and there are genetics to the tumor, and now we're learning that acute myelocytic leukemia has 53 relevant genes. So just looking at a bone marrow isn't enough. You have to say something about 53 genes. You have to know the genetics, right?

What about talking to the radiologist? You're the anatomic pathologist. Here's your prostate. Your biopsies are coming from over here, and they're normal. Wouldn't it be a good idea to have a conversation with the radiologist to say, "You didn't do the biopsy from the bump. Of course they're all normal because there was a sampling error."

What is diagnostics? Anatomic pathology, clinical pathology/laboratory medicine, and radiology. Radiology is our companion. We have to do this together. Some people have talked about the merger of all these departments to create a department of diagnostics. If you're an anatomic pathologist, what stops you from doing the next level of work that includes all diagnostic information in some way in your report?

There's going to be digital pathology for all those small biopsies. There will be a scan that is better than our eyes at picking up that small nest of tumor cells in the prostate biopsy. I can't imagine otherwise. What is our role then? It's putting together those genetics, that imaging study, the immunohistochemistry, and all the laboratory medicine for this patient. That's the value, and that means we will never be dispensable. We're not there just to

match pictures; we put facts together. So we have to use the latest technology. I'm sure we can do this.

The big job ahead of us is surmounting all these barriers. The biggest one is payment. I think we can get through the rest of them. And once the DMT becomes widespread, the guessing by health care providers goes away.

At Vanderbilt [where he was pathologist-in-chief] they decided they wanted to do it. We activated coagulation in 2010, and hematopathology, microbiology, transfusion medicine, endocrine-associated hypertension, and neuropathology followed. The neuropathology DMT was done without any encouragement. The neuropathologists started doing the genetics of glioma, and they brought radiology in, and they put all of it together.

Here at UTMB, we're on target to have the most DMTs soon, and we are not a large department. Right now we have coagulation, transfusion medicine, liver disease, and forensic medicine. We have pilot DMTs in microbiology and multiple sections within anatomic pathology. You too can do it at your own institution. Make sure you meet the four criteria, and please publish what you're doing so we have a large literature base.

The external environment is conducive to this now. The Institute of Medicine [now National Academy of Medicine] report on diagnostic error was the big door-opener. The Institute of Medicine said, "We need you to do this. The diagnostic process is too complicated, and people are getting sick because the diagnostic experts are not participating." And the doctors on the receiving end are willing. Before, the doctors didn't want to say "I don't know." Now they're throwing up their hands and saying "Please help me." Big difference.

The second Diagnostic Management Team Conference will take place Feb. 6-7, 2018 in Galveston, Tex.[hr]