

Lab Testing Matters

Building a Community to Support

Quality Laboratory Medicine

INFOCUS

When
each
second
counts

*The
forgotten
life line*

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patient
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saves
lives

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www.labtestingmatters.org

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June 2017



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COLA accredits nearly 8,000 medical laboratories through a program of education, consultation, and accreditation. The organization is an independent, non-profit accreditor whose education program and standards enable clinical laboratories and staff to meet U.S. CLIA and other regulatory requirements.

COLA

COLA is recognized by the Centers for Medicare and Medicaid Services as a deemed organization. COLA’s program is endorsed by the American Medical Association (AMA), the American Academy of Family Physicians (AAFP), the American College of Physicians (ACP), and is also recognized by The Joint Commission. For more information about COLA, please visit www.colas.org.

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In 2014, Congress enacted the Protecting Access to Medicare Act (PAMA), which required the Centers for Medicare and Medicaid Services (CMS) to implement a new payment methodology for determining the Clinical Laboratory Fee Schedule.

CMS was given the daunting task of developing a mechanism to determine how applicable laboratories will report their private payer market data to the federal government. The CMS intends to use this market data as a basis for determining what Medicare will pay for clinical laboratory services.

A deeper analysis shows that the data collection and evaluative pricing methodology, if implemented, would jeopardize the availability of patient access to clinical testing in community care settings where patients receive most of their medical care.

Specifically, if the current methodology is not revised, payment cuts would be substantial. These cuts would make it financially infeasible for independent community labs, physician office laboratories (POLs), and some rural hospitals to continue to provide laboratory testing.

About the Protecting Access to Medicare Act (PAMA)

We contacted physicians in rural and frontier communities to speak with them about their experiences.

We asked them to share with our researchers the role of near patient testing in their community and how elderly patients would be impacted if they were no longer able to provide lab testing within their practice.



An Urgent Message

Real stories
to challenge
the ongoing
discussion to
ensure access
to near patient
laboratory
testing.



8 The value of Near Patient Testing

As our national healthcare system evolves to address our aims as a society, it is essential to keep in perspective the interrelating and interacting services that support positive outcomes for patients.

The ultimate goal of clinical laboratory testing is to guide physicians in diagnosis and treatment. As such, laboratory information is essential to patient care. Near patient or point-of-care testing (POCT) not only serves this ultimate goal but it offers the advantage of early diagnosis and strengthens our effectiveness in chronic disease management.

From a systems perspective, we know that if patients don't have access to primary care, they will seek care in an emergency room for health concerns that could have been addressed in a lower cost clinical setting.

Likewise, if reimbursement policies are such that near patient testing is lost, we forfeit the benefits of early diagnosis and real-time continuous monitoring of treatment plans.

The objective of treating conditions up stream in less expensive settings should be our primary directive.

Innovation in laboratory science and technology make it possible for physicians to perform tests and obtain the information they need to serve patients in fast and effective ways.

In fact, laboratory testing is so integral to the way a physician treats patients that it can be likened to the importance of the Google search engine on your mobile phone, computer, or other device in accessing REAL-TIME information.

As an elected member of Congress, legislative aide, or regulator you see that a four-hour turn-a-round time -- let alone a four-day wait -- will dramatically affect your ability to have a positive impact. Why set aside progress and travel back to the time where you had less information seeking tools?

Today, near patient testing is modern, efficient, and effective in diagnosing and treating patients at the time of their office visit. A diagnosis based solely on clinical symptoms can lead to the wrong diagnosis (Jordan, Mitchell, Anderson, Farkas, & Batrla, 2015).

Furthermore, in our new delivery models, there is a growing appreciation that laboratory testing is not a commodity but instead an integral service giving rise to optimal patient health outcomes and improvement in the overall health status of our communities (Futrell, 2013).

Near patient laboratory services are vital to the care of elderly patients who often experience chronic diseases, such as hypertension, diabetes, heart disease, and cancer.





There is a growing body of empirical **evidence** related to the **multiple benefits** of **near patient laboratory testing**.

CONTINUE READING

We often discuss changes to our healthcare system in a largely technical-instrumental way. This can lead to over-reliance on abstract constructs such as the new market-based pricing model.

While these models may be rational in the 'laboratories of our mind', when implemented, they can have a devastating impact.

With the challenges facing the elderly it is imperative that we understand the impact of such policies on access, specifically in rural communities.

In addition, the argument that most routine lab tests are commodities is misleading and untrue.

Timeliness, service, quality, safety, and meeting the unique needs of a community are powerful differentiators. In our conversations with rural clinicians, we learned that these differentiators save lives.

Some of your own relatives may live in a rural or frontier community. Even if your parents live in a bustling city that in no way diminishes the value of your mother's physician being able to do testing during her office visit.

It is important to take note of the unique challenges of elderly patients in rural communities and this is why we highlight their stories in this sampling of vignettes.

Research data suggests that POCT may be a better approach for providers to direct rural patient treatment and health outcomes overall (Drain et al., 2014). It also allows for laboratory testing to have its place in patient-physician interactions at the time of the patient visit (Futrell, 2015).

There is a growing body of evidence related to the multiple benefits of near patient laboratory testing (i.e. in-office lab testing).

Patients can receive optimal healthcare and better outcomes when physicians combine their knowledge with laboratory information during diagnosis and treatment (Plebani, 1999).

Having lab results while the patient is still in the office supports the provider in forming a more complete clinical picture (Drain et al., 2014).

In addition, any uncertainty as to the quality of the laboratory result can be resolved by promptly running the same test with special attention to areas in the lab testing process and analysis that may have caused concern (Lippi, Mattiuzzi, & Favaloro, 2015).

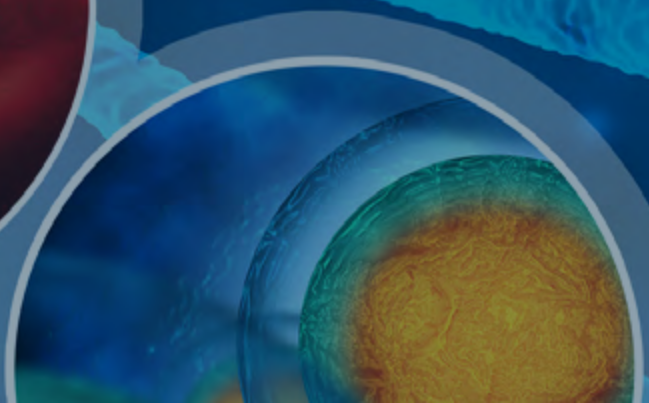
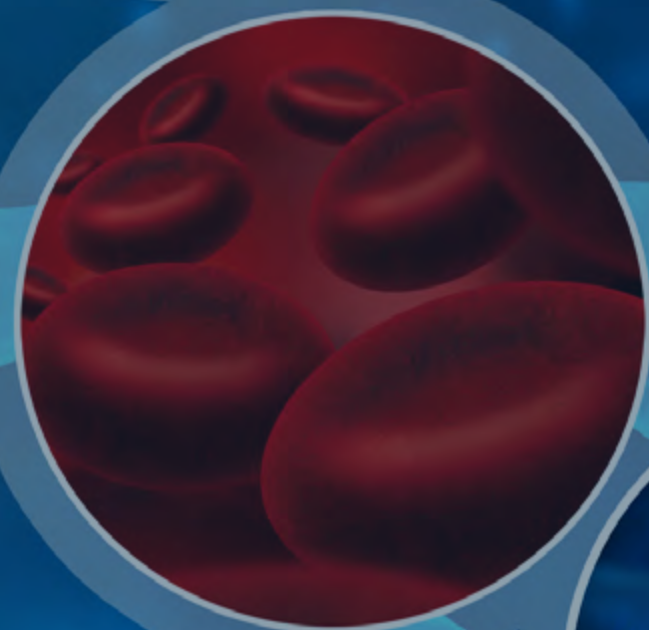
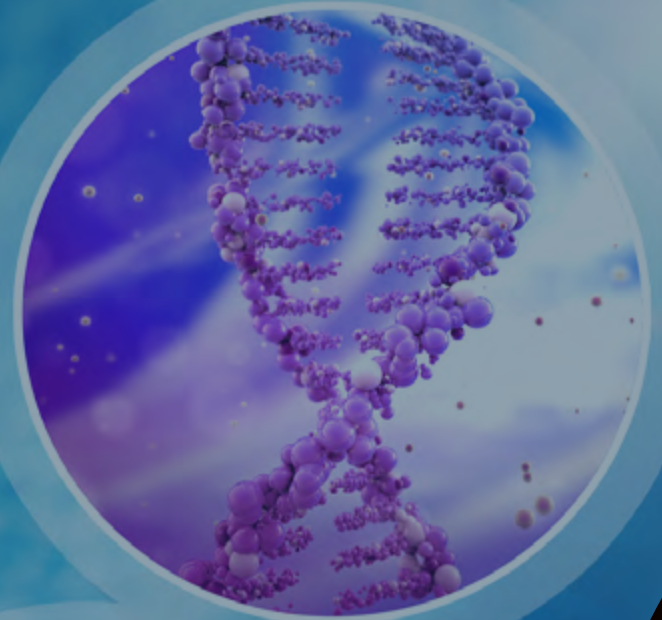
It enables direct feedback loops between the physician and laboratory personnel and an appreciation all around for the history and broader lifestyle of the patient. Near patient testing allows for practices to better identify and have a greater sense of responsibility for the test results they receive (Futrell, 2015).

Finally, a recent study found that when used within established guidelines, clinical laboratory testing can reduce direct and indirect healthcare costs while generating better outcomes (Rohr et al., 2016).

The following **Vignettes** illustrate and capture real facts and knowledge of physicians in our most rural counties.

These vignettes represent the preliminary data of a qualitative research study being conducted by COLA.

What do you think is needed to ensure access to lab testing in your community?



14 “It would have a **devastating effect** in our community.”

OKLAHOMA

Dr. OK is a family physician practicing in an entirely rural community. During the interview, Dr. OK shared about the scarcity of access to laboratory services in this community.

Dr. OK shared that the closest laboratory is “300 miles away.” If the 3 physician practice no longer provided laboratory services “it would be devastating to our community,” Dr. OK added.

Transportation challenges are especially hard on the elderly. While the community has a public transportation system, it requires a three-day notice for a patient to receive the services.

This three-day notice then creates delays in my patients’ ability to go in for laboratory testing.

To address the transportation issues, “labs have to be scheduled in advance.” This may not be in the patient’s best interest.

“We don’t have taxis. A lot of people don’t drive, some do,” stated Dr. OK. Dr. OK explained that the importance of their office laboratory is that it allows testing to be done immediately when the patient is at the clinic, which is beneficial for elderly patients in light of these transportation obstacles.

To further emphasize the importance of access to laboratory services for this rural clinic, Dr. OK described that the turn-around-time to receive test results referred out to another laboratory is about a week.

“When we perform testing in our practice, we don’t have to wait a week.”

Chemistry panel and Complete Blood Count (CBC) results are lab results “to get back as soon as possible.” Dr. OK shared a story of an elderly woman who didn’t want to come to the office but complained of feeling tired.

Luckily, she came in and when the bloodwork was done, it showed she had a hemoglobin level of 6. What is more telling is the fact that she didn’t have any symptoms. After receiving the results, “I was shocked,” stated Dr. OK. The lab screening “saved her life” Dr. OK noted.

From Dr. OK’s standpoint, “everything has gone up in costs” such as laboratory machines, personnel, reagents, and book-keeping management resources. However, each year payers, public and private, pay less.

“There is very little left on the table with Medicare,” Dr. OK stated. **“I just don’t know if Medicare cares.”**

In our community the nearest laboratory is **“300 miles away.”**

In the end it was direct access to our CCL that really saved her life.

I hope they never change that.

Dr. OK hopes to hold on to all of the in-house laboratory services afforded by the practice. “We have to have it. If we can at all, we have to keep it. We are even willing to eat [the costs] if we have to.”

From Dr. OK’s viewpoint, rural America is often excluded and overlooked in healthcare research studies. For this reason Dr. OK was willing to participate.

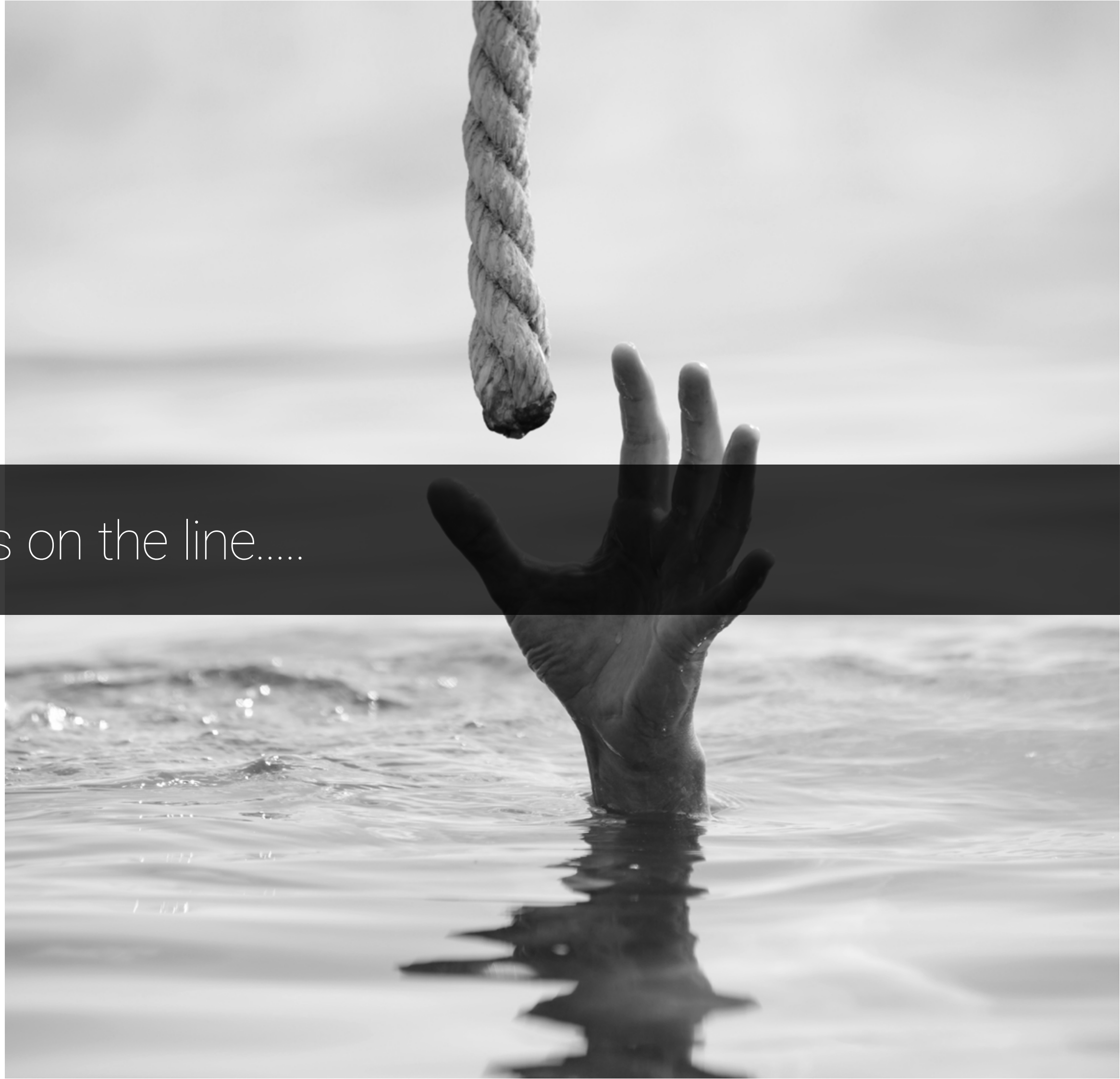
This study also gave Dr. OK the chance to give voice to the status of rural community healthcare and how patients are directly influenced by access to clinical laboratory services.

Dr. OK understands that a lot of other practices don’t offer in-office lab services because they can “refer out easily.”

However, for Dr. OK’s practice it is different. “It is well worth it for us to keep our in-house services for the well-being of our patients.”

Clinical Community Labs (CCL) Matter

When your life is on the line.....





“Patients are waiting in the emergency room because their diagnosis is delayed.”

According Dr. ID, near patient testing enables early diagnosis and treatment, which can help the patient avoid a medical emergency.

“I see patients in the emergency room because they have a diagnosis that is delayed.” **This leads to “increased cost of care** because you did not know sooner” also creating increased hospitalization and ER visits...” and then we “wonder why we didn’t take care of it during their office visit.”

For elderly patients, access to on-site laboratory testing is beneficial because they have mobility and transportation challenges. Physicians reduce these challenges by providing testing in the practice.

The availability of on-site laboratory testing is also a matter of patient safety because physicians are able to find a potential problem while a patient is in the office and can address it directly.

Furthermore, when making treatment decisions, **laboratory test results at the time of the patient visit serve as evidence for making treatment decisions and lab results might completely change the treatment.**

One thing that stood out as important is Dr. ID’s emphasis on the point that laboratory test results lessen the chances of misdiagnosis.

According to Dr. ID, combining laboratory information with a physician evaluation of symptoms and a physical exam strengthens the accuracy of the diagnosis and improves outcomes.

As an example, Dr. ID described a case of an elderly patient who came to the clinic without any signs of anemia. Access to immediate, on-site CBC testing helped Dr. ID better understand what was happening with the patient.

Dr. ID made it clear that this practice’s clinical laboratory services have been impacted by reimbursement policies.

This has led the practice to significantly utilize reference laboratory services. Dr. ID believes there are now other costs that should be considered. For example, reduced and limited access to near patient testing, leads to delays in patient care, increased hospitalization, and visits to the emergency room by the clinic’s patients.

Oh, my Gosh, someone is destroying our whole clinical lab infrastructure.

Dr. ID also shared that when sending tests out to reference labs “there is no payment for the time involved” in the testing process.

Dr. ID makes an important point. “I think Medicare took that position to save money but in the end, it may be more costly.”

We need to keep the big picture in mind.





**When each
second really
counts**



What!

They lost my specimen. I need to go through it all over again.

The experience of Dr. MI, who practices in a rural community, vividly illustrates near patient testing as integral to crafting a patient's treatment plan. If a cancer patient's kidney function is abnormal, Dr. MI explained the treatment may need to be adjusted. As revealed by Dr. MI dynamic, real-time laboratory information is crucial to treating cancer.

According to the oncologist, **a patient's condition "can change over days or hours.** To have testing on the day of treatment, before we start, is very important." Laboratory testing at the time of the cancer patient's treatment visit is necessary to determine prescription dosages and to assess side effects resulting from chemotherapy medications and any combination of other medications the patient may be taking.

Also, patients get better results when chemotherapy treatments are provided on a routine, systematic schedule. Interruptions in a patient's treatment schedule could occur if referring lab work to another site, resulting in negative consequences such as increased patient risk.

The oncologist noted that when patients come in for their chemotherapy treatment, lab work is first performed and **"I get the information I need right away."** Dr. MI shared it would be difficult to treat cancer patients without near patient laboratory information.

Dr. MI continued by mentioning an example of a patient that was "complaining of low-grade fever and weakness."

Lab work showed Dr. MI that the patient was suffering from neutropenia and low hemoglobin levels, which are quite common in patients undergoing chemotherapy. As a result of having laboratory testing information immediately available, Dr. MI planned "blood transfusion and growth factor treatments." This helped the patient significantly and prevented increased costs by avoiding a visit to the hospital.

Dr. MI's office often refers complex tests such as protein electrophoresis, thyroid function and lipid profile tests to another laboratory. Unfortunately, the experience has not always been positive when coordinating with reference labs.

In fact, Dr. MI shared that they have "had a lot of negative experiences" with specimen transport. "Specimens are sometimes lost, especially in commercial labs, or they arrive too late and have lost their viability." This requires the patient to return to the office so a new specimen can be collected.

Dr. MI explained that this is a major inconvenience, especially when a patient is scheduled for an upcoming chemotherapy treatment and must then urgently drive to a remote reference laboratory to repeat his or her blood test. On the other hand, when patients come to the physician office, this oncologist stated that:

"Tests can be done efficiently in 10 to 20 minutes, sparing the patient the inconvenience, cost, and other adverse impacts of driving 20 to 30 miles.



I will really be angry mom if they don't have the test results.

It's not the doctor dear...

Another challenge when testing is referred out is that the patient may not get their lab work done at all. **"This happens many times,"** reported Dr. MI. When asked about not going to get their needed labs done, Dr. MI added that "most of the time they say they forgot to get it done."

Considering all that was learned from this conversation with Dr. MI, referring out testing will delay treatment for patients of this rural practice. This will increase delays in information, interfere with treatment and put cancer patients in this rural community at greater risk.



.....and your time is running out.



The LAB is Essential to our Practice.

In this rural community the closest laboratories are 80 and 100 miles from the clinic. For Dr. WY, this means if the clinic “no longer provided lab work, elderly patients would have to travel a long distance.”

Elderly patients who are reluctant to give up their car keys put their safety at risk. “One of my elderly patients fell asleep while driving her car and drove off the road,” shared Dr. WY. Dr. WY made it clear that if the practice was not able to provide lab testing at their clinic, patients would need to travel to another lab and this would increase the risk of car accidents.

Dr. WY explained further that difficulties in traveling are compounded in this rural community during the winter months. “Our weather here has been unreal. We have had record snowfall.” Dr. WY shared that the record snowfall this winter season caused 10 to 15 different local road closures due to avalanches.

This creates highly unfavorable situations for any traveling patients, including elderly patients. During the winter months, travel for patients is “like taking a chance on life” added Dr. WY.

Adjacent to the clinic is an emergency room treating acute care patients. Dr. WY explained that patients come to the practice with chest pain symptoms daily.



“I want to protect our patients by ensuring access to my clinical lab.”

And by performing a variety of tests in the office laboratory, including a cardiac troponin test, it can be determined whether the patient is having a heart attack. Dr. WY added that, **“Troponins, CBCs, and comprehensive metabolic panels are the most commonly ordered tests. I don’t know how I would practice ER medicine without those.”**

Dr. WY shared that their ER patients can be transported by helicopter or ambulance to a neighboring community hospital, but at what cost? Dr. WY added if we can do the screening testing here it’s not necessary for elderly patients “to take ambulance and helicopter rides.”

Dr. WY explained that the clinic collects specimens for transport to reference laboratories; however, the interstate used for transport closes frequently and has caused significant delays. When specimens do get through to the reference laboratory, Dr. WY shared that the clinic “will get the results back the following morning or the day after.”

Dr. WY shared that the clinic’s experience with reference labs has “been pretty good” but Dr. WY mentioned that weather should not be underestimated. It is a barrier when referring tests out and that barrier is removed when the testing can be done in the clinic.



“As rural as you can get.”

“The result would have been too late. The patient would have died without it.”

In dialogue with Dr. KY, it was revealed that this community is “as rural as you can get.”

According to Dr. KY, **cell phone use “is nil” and land-line use is limited. “It can be very difficult to reach patients.”**

When asked about the relevancy of access to laboratory testing in their rural-community practice, Dr. KY described it is as “very important.” Dr. KY was asked to elaborate on the significance of lab testing access by way of an example of patients who benefited from having laboratory testing services in their rural clinic.

Dr. KY replied, “I could give **a hundred examples.**” In my area, we have a large population of diabetic patients. If I could not do A1C testing or a fasting blood sugar test, it would be detrimental to the patient.”

Despite being in a remote area, the clinic maintains needed patient care that is supported with convenient access to test results given by in-house clinical lab services.

However, if the practice had to reduce or lose the laboratory services available at the clinic, this would have a major impact on all of their patients, especially their elderly patients. “It would be severe,” described Dr. KY. In describing the impact, Dr. KY shared that the closest lab is approximately a 40-mile drive from the clinic.

Furthermore, if the clinic-based laboratory services were reduced or lost, patients would need to travel solely to receive laboratory services. Dr. KY notes that this would be **“very impractical.”** This increase in transportation would present not only logistical challenges for elderly patients but financial challenges as well.

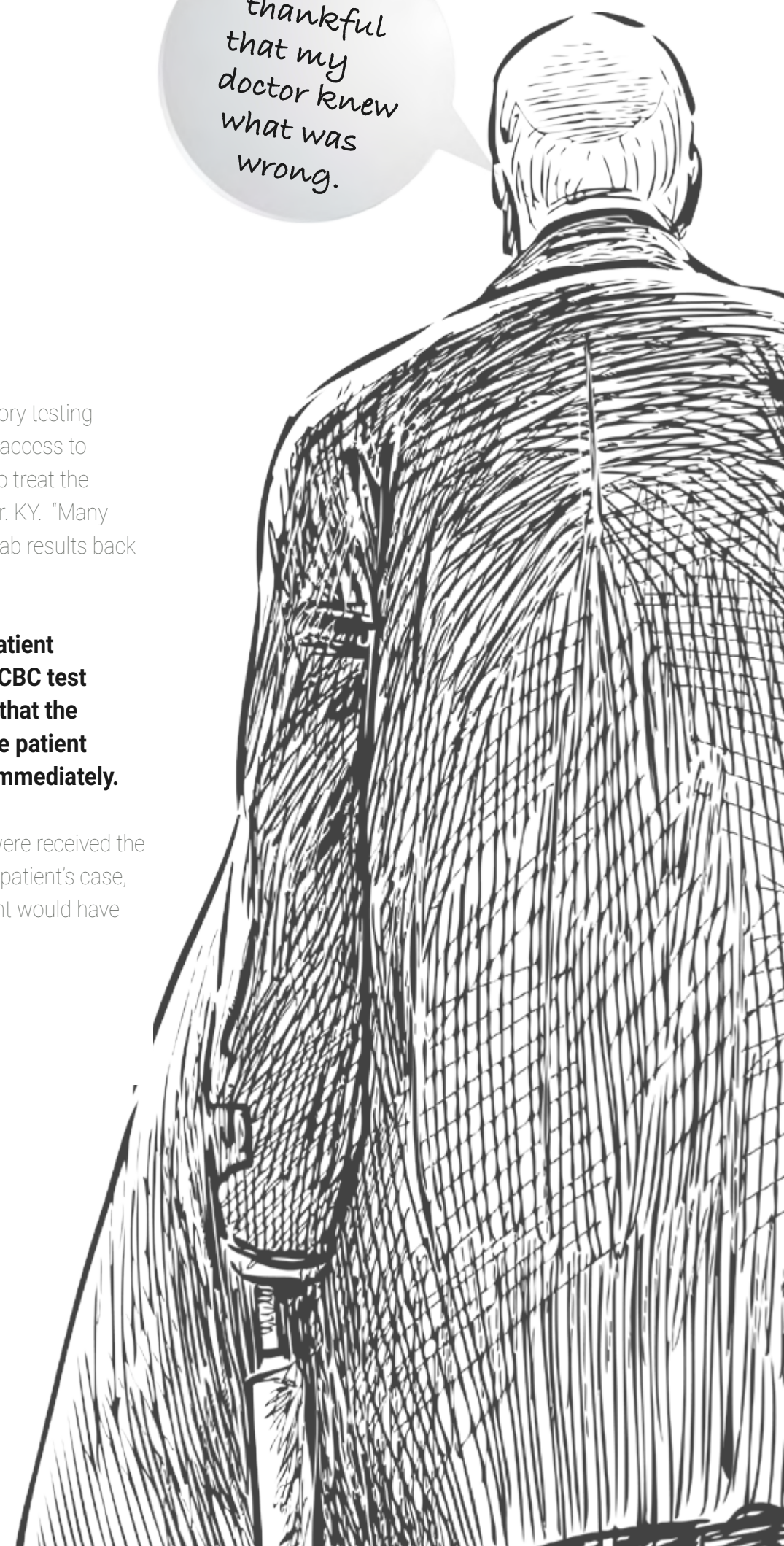
In Dr. KY’s expert opinion, if patients were to be referred to another lab to get their lab work done, the financial burden combined with transportation needs would be unbearable to many elderly patients and “most would not go.”

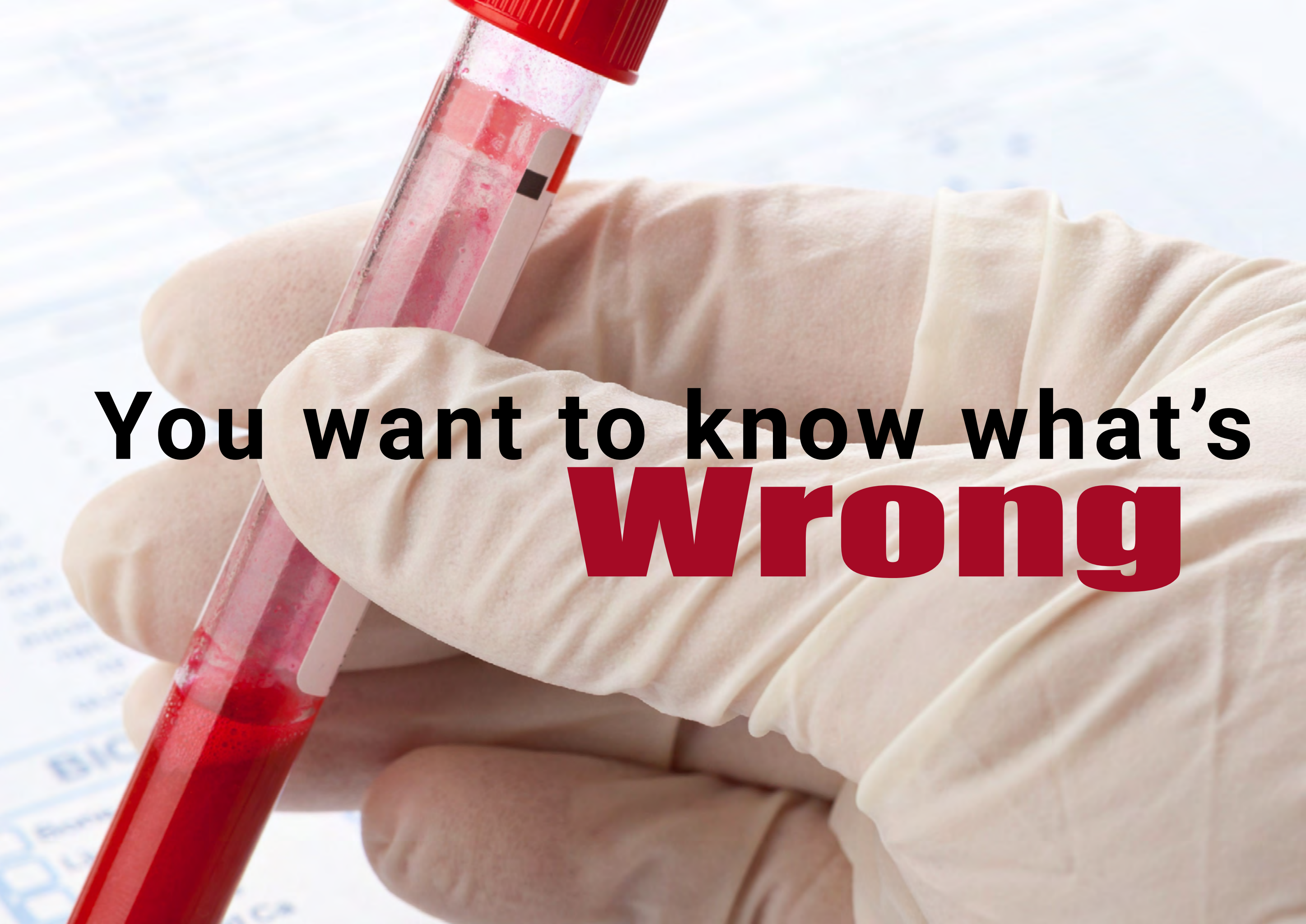
Access to needed clinical laboratory testing at the clinic also supports timely access to test results. “It simply allows us to treat the conditions promptly” explained Dr. KY. “Many times, it is not acceptable to get lab results back the next day,” he added.

In a recent case, an elderly patient complaining of fatigue got a CBC test done showing this physician that the “hemoglobin level was 6.” The patient needed a blood transfusion immediately.

Dr. KY shared that if the results were received the next day or 36 hours later, in this patient’s case, they would be too late, “the patient would have died without it.”

I am so thankful that my doctor knew what was wrong.





You want to know what's
Wrong

In dialogue with frontline physicians

In this explorative study, we seek to better understand the value of laboratory information at the time of the patient visit. Also, we are gathering data from physicians about how their office laboratory serves the unique needs of their community.

We began this pilot study by conducting confidential, in-depth interviews using a qualitative, narrative method. The five vignettes included in this publication represent a sampling of the preliminary data gathered during our interviews.

The participating physicians contacted were randomly chosen from counties that make up some of the most rural counties in the country based on the United States Department of Agriculture (2010).

The semi-structured format enables our researchers to capture specific data, while at the same time, allowing free space for an emerging generative dialogue to enrich a mutual understanding of the clinical importance of near patient testing. Study participants are not limited and are free to share specific cases, positive or negative, about the impact of laboratory services on patient care.

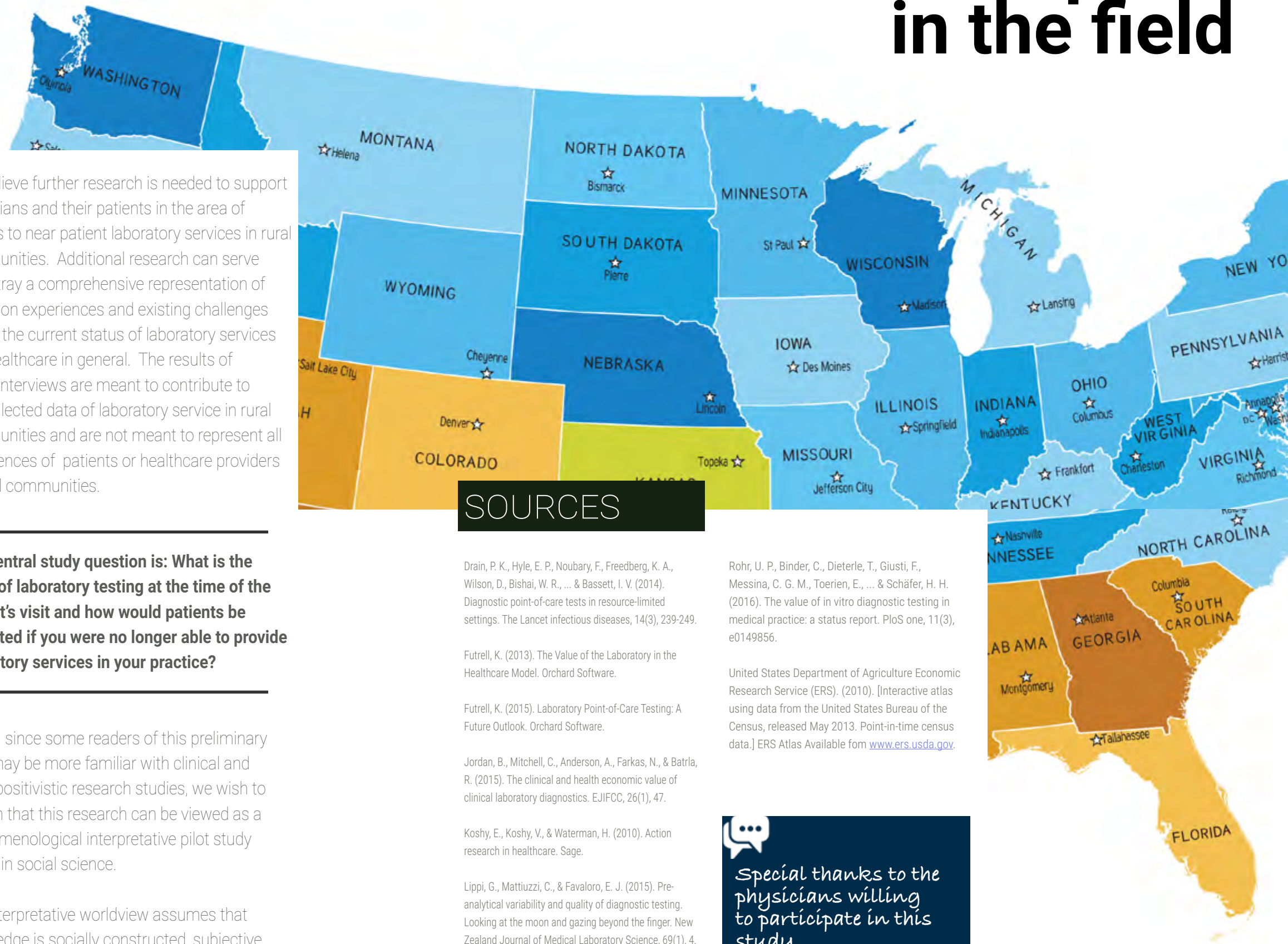
We believe further research is needed to support physicians and their patients in the area of access to near patient laboratory services in rural communities. Additional research can serve to portray a comprehensive representation of common experiences and existing challenges due to the current status of laboratory services and healthcare in general. The results of these interviews are meant to contribute to the collected data of laboratory service in rural communities and are not meant to represent all experiences of patients or healthcare providers in rural communities.

The central study question is: What is the value of laboratory testing at the time of the patient's visit and how would patients be impacted if you were no longer able to provide laboratory services in your practice?

Finally, since some readers of this preliminary data may be more familiar with clinical and other positivistic research studies, we wish to explain that this research can be viewed as a phenomenological interpretative pilot study based in social science.

The interpretative worldview assumes that knowledge is socially constructed, subjective, and influenced by our values and human interactions (Koshy, Koshy, & Waterman, 2011).

Data
from **experts**
in the field



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Special thanks to the
physicians willing
to participate in this
study.

For more information on this
explorative study, contact
research@cola.org

When?
right now

**Lab Testing Matters
for all of us**

#savepatient access