Challenges and Opportunities for the Medical Laboratory in the Era of Direct Patient Access to Test Results

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ABSTRACT

Providing patients access to their health records promises to improve patient safety. However, there are concerns that clinical laboratory test results are not optimized for patient interaction through web portals. We asked medical laboratory professionals (MLPs) about the current state of direct patient access (DPA) to electronic health records to assess their knowledge and attitudes on how this may affect laboratory practice. Data were collected through interviews with MLPs working in clinical laboratories in the United States ($n = 15$), which were analyzed following a grounded theory qualitative approach. We found that MLPs' perspectives on DPA were informed by the area of the laboratory where they worked and by perceptions about patients' understanding of test results. Knowledge and attitudes differed based on test type, laboratory process, and laboratory setting. While respondents agreed that web portals could support patient self-advocacy, they cautioned that test information could be misconstrued by patients who see values without the guidance of a clinician. The level of MLPs' interactions with patients varied, but they all agreed that communicating results to patients was outside their scope of practice. Additional efforts must be directed at empowering the laboratory workforce to share pertinent medical information adequately and effectively to patients.

ABBREVIATIONS: CLTR - clinical laboratory test result, DPA - direct patient access, EHR - electronic health record, MLP - medical laboratory professional.

INDEX TERMS: patient safety, electronic health record, medical laboratory personnel, patient access to records.

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INTRODUCTION

Recent policy changes and investment in health information infrastructure have facilitated consumer adoption of secure web portals in which patients can access the electronic health record (EHR).[1] In the Health Information Technology for Economic and Clinical Health Act, enacted as part of the American Recovery and Reinvestment Act of 2009, the US government called for meaningful use of the EHR and mandated that healthcare providers give patients access to information that can empower them to be more informed about their health.[2-5] Similarly, the 2010 Clinical Laboratory Improvement Amendments of 1988 Issuance of Revised Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services asserted that patients are "responsible for using test results" and that they may receive test results directly from clinical laboratories.[2-4,6] Direct patient access (DPA) to clinical laboratory test results (CLTRs) is considered a measure that can improve patient safety and help increase understanding regarding test results by patients.[3] Despite limited involvement in direct patient care, in alignment with the 2002 Institute of Medicine competency recommendations for healthcare practitioners, medical laboratory professionals (MLPs) are responsible for promoting patient-centered laboratory care by disseminating information through the EHR.[2,7]

There is considerable literature documenting the attitudes and opinions of clinicians and patients on the topic of DPA via online portals.[8-13] A systematic review and meta-analysis of the impact of DPA on health records found that access improved overall patient safety and efficacy measures.[14] However, in this review only 1 of the included papers asked about the use of personal EHR data in helping patients understand tests.[15] Another study focused on access to CLTRs documented that 82.7% of patients found the test feature useful but thought the information about abnormal results should be better explained to address patient anxiety and be actionable.[12] On the provider side, while one study found physicians who had personally missed addressing an abnormal test result with their patients welcomed DPA, another study reported that 54% of emergency room physicians disagreed with patients receiving abnormal test results directly, suggesting "patients lacked the necessary expertise or knowledge to interpret test results."[8,10]

EHR systems with DPA have created an expectation for the availability of complex information, potentially

increasing the pressure on the personnel who generate this data to adjust their protocols and satisfy regulatory requirements. While access to laboratory test results is a central area impacted by policy and regulatory changes, little is known about the practice and perceptions of MLPs regarding patient DPA, with no current published studies, to our knowledge, reporting MLPs' point of view. This qualitative study aimed to understand current laboratory connectivity with patients through the EHR, document MLPs' perspectives regarding DPA to CLTRs through web portals, and explore how DPA may influence laboratory professionals' practice in order to improve patient safety.

MATERIALS AND METHODS

This study was qualitative and descriptive, using grounded theory to design and implement a semistructured interview guide for data collection.[16,17] Qualitative methodology is appropriate for topics like these, wherein there is little published knowledge and salient factors and theories have not been developed.[18] Following the tenants of the constant comparative method, data collection and transcription took place simultaneously, which allowed an iterative development of the study instrument, informing subsequent interviews as new data emerged.[19,20] The semistructured interview assessed 3 main domain areas: (1) knowledge of how laboratory systems report results to patients; (2) MLPs' opinions, perceptions, and attitudes regarding DPA; and (3) implications of DPA for patients and laboratory professionals. At the end of the interviews, respondents answered a short demographic survey. The institutional review board at our institution approved this project.

Eligible respondents were adults 18 years or older who were employees of a clinical laboratory conducting tests using human samples and approving results to be reported to the EHR. Initially, theoretical sampling was used to recruit respondents through professional contacts, through which 5 individuals were recruited and completed in-person interviews. Subsequently, a recruitment survey was shared through a national laboratory professionals' society listserv seeking additional respondents that would allow us to capture further variation in laboratory type, size, and practice setting. We received 31 responses to our online query, but 10 of these individuals did not meet inclusion criteria or provide complete contact information. Of the remaining 21, we were able to reach19 via email with a copy of the informed consent letter, but only 10 (52%) scheduled and completed a telephone interview by the time data collection ended, which brought our total sample to 15 respondents.

Interviews were conducted between March and December of 2019. Verbal, electronic, or physical informed consent was obtained for each participant. Interviews lasted an average of 25 minutes and were recorded with a digital recorder. All interviewed respondents received a $5 gift card. Interviews were transcribed verbatim, and the transcripts were coded by L.N.A., in frequent consultation with J.V.B. Interviewees were designated aliases for anonymization (randomly selected names of colors), which were used for quote identification. Data analysis using thematic analysis and grounded theory techniques was conducted, allowing subthemes to be identified inductively within the 3 interview domains.[21-24] NVivo qualitative analysis software was used to manage the data analysis process.[25] Demographic information was summarized using basic descriptive statistics.

RESULTS

Table 1 shows respondent characteristics ($N = 15$). Over one-third of MLPs reported working as generalists, which involves working across multiple laboratory areas. Geographically, respondents were distributed as follows: 10 from the Central United States region, 3 from the Eastern region, 1 from the Western region, and 1 from the Mountain region. Our findings are organized according to the 3 domains from our interview guide into 7 themes (see Table 2).

Knowledge of How Laboratory Systems Report Results to Patients

Autoverification versus manual entry of results

Respondents explained that technological advances have made MLPs' work safer for patients and allowed faster turnaround times for result reporting. The changing laboratory environment "requires for laboratorians to be more computer savvy" (MAGENTA) and enables them to focus their scientific and critical skills on complicated laboratory processes. Reflective of most current laboratory operations, MLPs classified test result reporting depending on whether results were relayed through automated algorithms (autoverification) or entered manually. One participant, INDIGO, explained, "the 2 reasons autoverification works is, one, [the patient's test] values are normal, [. . .] within reference range, and the second reason is, they agree with previous history."

According to MLPs frequently working with these automated processes, the results do not transfer automatically to the EHR if a patient sample produces values that do not comply with autoverification rules. The CLTRs are reviewed or even entered manually into the system either because the results are abnormal and flagged for review or because the test's specialized nature requires entry or confirmation by an MLP. Some differences in test result entry were associated with an area of the clinical laboratory and are listed in Table 3.

Information systems and patient portals

Most respondents knew how CLTRs transferred from the laboratory to patient portals. "[T]he lab uses [software name] as its LIS [laboratory information system], and it uses Epic or [software platform] as its EHR. [. . .] Epic

Table 1. Characteristics of interviewed medical laboratory professionals ($N = 15$)

Variable	*N* (Mean)	% (SD | Min | Max)
Sex		
Male	4	26.7
Female	11	73.3
Mean age (years)	(38.4)	(11.8 | 26 | 63)
Education		
Highest degree completed		
Associate	1	6.7
Graduate	11	73.3
Bachelor	3	20.0
National certifications*		
CLT(NCA)	1	67.7
MLS(ASCP)	11	73.3
MT(ASCP)	3	20.0
Other (ASCP)	3	20.0
Professional practice information		
Mean time in practice (years)	(12.3)	(11.4 | 1 | 41)
Current position information		
Mean length in this position (years)	(5.9)	(6.3 | 1 | 25)
Mean shift (hours)	(9.0)	(1.4 | 8 | 12)
Shift type		
Days	10	66.7
Evenings	3	20.0
Nights	2	13.3
Position title		
MLS	11	73.3
Laboratory manager/director	2	13.3
Specialty supervisor/coordinator	2	13.3
Area of the laboratory worked		
Blood bank	2	13.3
Core: chemistry and hematology	3	20.0
Generalist	6	40.0
Microbiology	2	13.3
Other specialty	5	13.3
Laboratory setting		
Hospital (medium/large >100 beds)	10	66.7
Hospital (small <100 beds)	3	20.0
Reference/independent	2	13.3

Notes: ASCP, American Society for Clinical Pathology; CLT, clinical laboratory technician; MLS, medical laboratory scientist; MT, medical technologist; NCA, National Credentialing Agency for Laboratory Personnel; SD, standard deviation.
*Percentages do not total 100% because some MLPs hold >1 certification.

Table 2. Domains and categories describing MLPs' knowledge and perceptions of patient direct access to laboratory test results via web portals

Domains	Themes
Knowledge of how the laboratory's systems report results to patients	• Autoverification versus manual entry of results • Information systems and patient portals
MLPs' opinions, perceptions, and attitudes about DPA	• Tests that can and cannot go straight to patients • Perceptions of patient understanding of CLTRs • MLPs and other health professionals as patients
Implications of DPA for the patient–laboratory relationship	• DPA and differences in patient–laboratory communication practices • DPA and changes to visibility of the laboratory profession

Notes: CLTR, clinical laboratory test result; DPA, direct patient access; MLP, medical laboratory professional.

has their own software MyChart, [. . .] the patient web portal," explained GRAY. More than half of respondents reported Epic Systems software (Verona, WI) as the EHR at their facility, with MyChart as the patient interface. They also indicated the need to use middleware to communicate with various EHR systems. MAGENTA mentioned, "We have partnerships with several other hospital systems, and they all run on different medical record software. So, we have to use a lot of middleware to communicate laboratory results." In 2 instances, MLPs said their workplace did not have an EHR system.

Knowledge of patient portals varied among MLPs, with some learning about these systems because they were patient-users themselves. In contrast, others had become familiar with the EHR through employer-provided education. KHAKI explained, "I was first exposed to [the patient portal] because like when we had our HIPPA training [. . .] one of those things that violate HIPAA is if you look up your own results" (HIPAA is the Health Insurance Portability and Accountability Act, which protects patient health information from disclosure without patient consent). All MLPs reported they enjoyed seeing their CLTRs as users of patient portals, although they could not always provide precise details about what results look like on the patient side. ORANGE disclosed, "I can't remember [. . .] you can see your test results and you can see like the past results, and I think it has a reference range."

Opinions, Perceptions, and Attitudes About DPA

Tests that can and cannot go directly to patients

MLPs reported mixed perspectives about DPA to CLTRs, explaining that certain kinds of tests were appropriate

Table 3. Variation in laboratory systems' result reporting

Differences in Result Entry by Area of the Clinical Laboratory	
Core (chemistry/hematology)/generalist	Blood bank/microbiology/molecular

• Process a large number of automated tests
  ○ "We aren't manually doing a lot of things anymore, so I mean technology has changed [. . .] the ability to quickly produce results within a timelier manner because of the automation" ~RED.
• Driven by autoverification
  ○ "70%–75% of the samples" (INDIGO) have their results autoverified into the EHR.
  ○ "if it is nonreactive it goes directly to the LIS and into the patient's result and gets autoverified. But if it's you know if it's a reactive, there's a hard stop on it and doesn't get sent out" ~BURGUNDY.
	• Autoverification was minimally or not at all implemented
	  ○ "[E]very result is entered into the patient's medical record number not necessarily manually but somebody has to look at it so it might transition from the instrument into the LIS [. . .] before the results are saved and then further moved into the electronic health record" ~GRAY.
	• Tests can have serious implications for patients, were diagnostic or complex in nature, or required pathology review
	  ○ "we have numerous complicated testing, we do FISH, we do flow cytometry and we do next generation sequencing testing, and all of those results are given to a pathologist for their interpretation" ~MAGENTA.

Notes: LIS, laboratory information system.

while others were not. Table 4 includes a list of characteristics and examples illustrating why some tests were considered appropriate or inappropriate. Interviewed participants expressed concern about possible errors or technical issues in test results. They highlighted the need for ample time for the results to be confirmed by clinicians before patients gained access to them. INDIGO explained:

> *you have a super critically low sodium [. . .] and then we find out an hour later that the [chemistry] instrument has a cloggage in the electrode or something like that, and we correct it [. . .] we notify the doctor or nurse when we correct a result, and hopefully that information hasn't yet got to the patient.*

MLPs also raised concerns about DPA to CLTRs based on situations they had experienced in their career. One respondent, BLUE, shared that test results for infectious and sexually transmitted diseases, which are monitored by the public health authorities, had in the past led to unexpected news for patients. For example, BLUE said, "We've had cases where the result crossed the interface [. . .] and the State called the patient . . . the patient wasn't aware the testing was being performed on them."

Perceptions of patient understanding of CLTRs

Although all MLPs believed ready access to test results could be positive for patients, they gave multiple reasons in favor of and against the practice of providing CLTRs directly to patients. These examples had emphasized perceived patient knowledge of medical history and the potential to create unnecessary worry and anxiety (see Table 4). All MLPs agreed that one of the more negative aspects of DPA was that viewing abnormal results may lead patients to look up the information online, which could be at best inappropriate and at worst detrimental. GRAY illustrated this: "Nowadays when social media and other nonconfirmable sources do put out articles or clickbait . . . . it can be very dangerous for patients to see their test results and try to interpret them themselves."

MLPs and other health professionals as patients

In contrast, MLPs reported they would not personally have these same concerns when receiving CLTR information as patients themselves, since their specialized training would enable them to comprehend what they were seeing. The same was not the case for healthcare professionals with training that did not focus on laboratory testing. Examples respondents provided to illustrate these points are listed in Table 4. When MLPs were asked about sources of information they commonly utilized for themselves or that they would recommend for patients to help provide additional understanding about test results, only 2 MLPs mentioned the patient portals. In addition, only half of the participants volunteered names of websites they considered contained reliable information, including LabTestsOnline.org, WebMD, and United States government sites such as those managed by the Centers for Disease Control and Prevention.

Implications of DPA for the Patient–Laboratory Relationship

DPA and differences in laboratory communication practices

When asked about the relationship between MLPs and patients, most MLPs described a natural barrier between them and patients, which they believed exists for several reasons. One is related to their purported role. Overall, respondents felt that communication with patients is not the laboratory's role, and they consistently voiced their support for clinicians communicating test results directly to patients. Also, MLPs considered a separation between their work and patients was necessary to avoid having to answer questions outside of their scope of practice. One respondent, YELLOW, indicated that patients should

Table 4. Variation in MLPs opinions, perceptions, and attitudes about direct patient access

Characteristics of Tests That Can and Cannot Go Straight to Patients

Appropriate	Not appropriate

• Normal/routine
  ○ "Tests as a part of either a yearly physical or periodic follow-up for conditions are acceptable or in cases where the patient is well aware of his or her clinical condition and has the ability to take steps in order to rectify the situation" ~GRAY.
• Comply with rules of autoverification
  ○ "if the values are all very agreeable [. . .] I feel like the majority of those samples should be able to go to the patient chart right away." ~BLUE
• Examples of tests: complete blood counts, blood types, chemistry panels, renal panels, creatinine clearance.
	• Abnormal, esoteric results; complex testing; tests that are not frequently performed or not in the common vernacular; critical values
	  ○ "HIV, hepatitis . . . probably would be better if you know the doctor told them [. . .] a drug test, I suppose that would be another one . . . so that they don't interpret the results incorrectly" ~CYAN.
	• Results that could understandably cause distress for patients
	  ○ "if it's like a cancer antigen that may be high [but] they haven't got a diagnosis of cancer" ~AMBER.
	• Examples of tests: bacterial susceptibilities to drugs, blood crossmatch results, anatomic pathology, STD tests.

Perceptions of Patients' Understanding of CLTRs

Patients are knowledgeable	Patients are not knowledgeable

• If the patient has adequate understanding of their disease and can use the information that they find in the portal
  ○ "let's say you have a patient that is a known diabetic they try their best to manage their diabetes [. . .] if they are well aware of their condition [. . .] those results are fine to release to the patient" ~GRAY.
  ○ "the patients are able to like see [. . .] right away before they see the doctor and they can gather up information and ask their provider beforehand" ~GREEN.
• If seeing test results could have a positive impact in the timeliness and quality of their care
  ○ "I mean we do our rapid test for our Biofire this have, you know, respiratory panels and stuff like that. I don't think it would hurt for a patient to know that they have a cold right away" ~RED.
	• Concerns with emotional response to laboratory test results
	  ○ "[W]hat if the patient saw the critical value before the physician [. . .] they'd be freaking out [. . .] things that could I guess really put fear in a patient's heart [. . .] because they don't understand what some of those tests really mean" ~JADE.
	  ○ "I guess it would freak them out if they don't understand what they're reading" ~GREEN.
	• A clinician should always be available to explain the results
	  ○ "they are able to add information about whether they saw a high or low . . . something flagged the results, rather than just the result without any interpretation." ~BLUE.
	  ○ "Any life-changing experience like a very serious diagnosis we should intercept the patient first" ~FUCHSIA.

Healthcare Personnel's Understanding of CLTRs

MLPs as patients	Other health professionals as patients

• Some MLPs said that their specialized knowledge allows them to better understand test results
  ○ "I had an incident recently where I had some blood work drawn and they called me 2 days later to let me know that my glucose was abnormally high [. . .] I recognized that it's literally one number over their top range but I also knew that I had forgotten to fast . . . so I knew that my glucose levels were fine" ~MAGENTA.
• MLPs who disagreed, said they do not know everything
  ○ "I feel like with the profession I'd then be able to know [. . .] not necessarily that I can interpret all the different lab reports from all the areas I definitely cannot" ~BLUE.
  ○ "I think that [MLPs] should be treated like maybe someone who doesn't have medical experience [. . .] because you don't know how much they know and how much they don't" ~ORANGE.
	• Depending on their scope of practice, some healthcare professionals can comprehend and use CLTRs
	  ○ "So like nurses, you know, they should be able to get it and understand what's going on; dieticians yeah maybe they should too [. . .] but it kind of just depends on . . . on the patient . . . you know? and how active they are in . . . in their health care" ~CYAN.
	• Some MLPs were more skeptical about other healthcare professionals being able to use the test information
	  ○ "I would say that they are more like regular patients [. . .] They just lack that understanding and knowledge base" ~MAROON.
	  ○ "I don't know if they are aware exactly what everything represents because they're really the only people who can interpret lab tests are supposed to be doctors" ~YELLOW

rely on established relationships with clinicians for information about their tests, explaining "[a] doctor is the one who's going to interpret those results and make a diagnosis based on those results and the treatment plan, which we are not trained to do."

In addition to scope of practice concerns, some MLPs reported an affinity for the built-in separation and anonymity afforded by their role. Remaining anonymous, however, was not always easy. MLPs conveyed that whether to communicate an interpretation of test results was not always straightforward, with several laboratorians sharing personal or family experiences that highlighted these tensions (see Table 5).

DPA and changes in the visibility of the laboratory profession

When asked how DPA impacts communication with patients, MLPs revealed a range of practices that varied by practice setting (see Table 5). MLPs recognized that the separation between the laboratory and patients creates challenges for the visibility of their role as critical

Table 5. Opinions about implications of DPA for the patient–laboratory relationship

Sharing Information With Patients

Relationship

- Name of patient is familiar, someone they see frequently, may take added significance
  - "even if I don't know the patient. I think in blood bank particularly you know we see names so . . . and we work on everyone individually and so we're preparing something for that patient in addition to just testing so I think it takes on a little added significance" ~MAROON
- Knowing the impact of a result for someone they know
  - "so, there is someone that I know that gets urine cultures done quite often I have never talked to the person about it. I don't know why but I just happened to see their name quite often" ~ORANGE.
  - "Mom was in dad's chart. Dad's cancer spread. She was worried. I told her I didn't know what it meant, but I did" ~FUCHSIA.

No relationship

- Contact with patients is outside of the laboratory's role
  - "[T]here is no relationship between the lab worker and the patient other than the lab worker receives the patient sample, they perform the testing, they result the testing" ~GRAY.
- Patients are deidentified
  - "it doesn't register for me it's not important really what the name is. How you usually go with not with the patient's name you know I go for the identifiers I look for the numbers [. . .] the date of birth and the MR numbers and all that" ~BURGUNDY
- No time to form a connection
  - "I mean if you see the patient a lot it makes you like 'oh I know this patient' but then it's so busy [. . .] you move on [. . .] there is no time to wallow" ~GREEN.

Contact

- Participating in procedures at the bedside
  - "I have direct contact with [patients] especially if I go up on a bone marrow and ended up crying inside the room because you know their story" ~GREEN
- Knowing the likely implication of a test result for a patient
  - "I was fairly confident with my own observation that the patient probably had leukemia and they were wanting a copy of their results and [. . .] I really didn't want to give them the results [. . .] they could tell from my apprehension that there was a problem" ~AMBER.

No contact

- Desire to remain anonymous
  - "lab people—their personalities tend to be that kind of person they just want to be in the background [. . .] they don't want anybody to notice them" ~CYAN
  - "[W]e need to remain anonymous, that way [patients] don't like ask us [. . .] questions because that might affect the professionalism" ~GREEN

Practice Setting and Communication

Medium/large hospital

- Get phone calls from patients but usually redirect them and try not to communicate about results
  - "we do sometimes get calls from patients; we direct them to MyChart for example [. . .] it's not a direct communicative relationship" ~KHAKI.
- Specific laboratory policies prevent verbal communication of laboratory results to patients
  - "I can't give you results over the phone directly. I'm not a clinician, so please contact either your clinician or medical records at this number" ~INDIGO.
  - "so, for us we essentially have to tell them that unfortunately we can't give out test results directly we can't even give them to outside hospitals" ~ORANGE.

Small hospital/independent

- Interacted with patients constantly
  - "I have some patients that do come in and pick up copies of the results" ~CYAN.
  - "I actually enjoy it when . . . um patients come in and say explain this to me and I always have to say "you know I can't interpret it. I can't tell you what you can do about it, but I can tell you that an AST is related to your liver" or just some of those facts of what the lab test is" ~JADE.
- These individuals were confident in their ability to speak with patients.
  - "[W]e're so small and everybody knows everybody [. . .] I don't mind discussing with them or trying to figure out [as patient] 'well why did the doctor order this for me?' is like [as self] 'well do you have this going on?' [. . .] they trust us to give them the right information" ~AMBER.

Implications for Visibility of the Laboratory

DPA impact on visibility for MLPs

- Some MLPs believe that patients being able to see their test results directly can be positive for increasing visibility of their profession
  - "I think it would increase visibility because patients would know that we're actually the ones doing the tests, right? [. . .] We have no visibility because any results to patients come through a doctor or clinician, right? And so, I think it would increase the visibility to lab" ~INDIGO.
  - "[W]ith a patient seeing all those different results and seeing how many there are and how many different results are . . . I think that could definitely spark someone's interest to wonder how they all got there and who did them" ~BLUE.
- Others said DPA alone would not make much of a difference
  - "I use the portal as a . . . as a patient I don't think about the people who are running the test. I just see it myself and I'm curious to talk to the physician about it I mean the although I'm in that profession I don't think about the people who are running the tests as a patient" ~BURGUNDY.

Other efforts that can increase visibility of MLPs

- MLPs should engage in other efforts that can help them gain visibility
  - "I think the visibility has more to do with the legislation I think . . . because nurses . . . nurses are more visible they have more unions and stuff like that, and we don't have any of that you know? I mean we don't get that kind of exposure I don't think this would be one way to do it." ~BURGUNDY.
  - "it comes down to just promoting ourselves [. . .] nobody's going to promote the lab except us, and we have to do that whether it's taking the time to explain to a patient what their test involves. Simple things like giving tours of the lab . . . just getting us out there because nobody will get us out there but us. [. . .] And let them see what the lab actually is" ~JADE.

healthcare team members. Participant MAGENTA provided an example:

> *[Patients] don't even recognize that we exist you know? You watch television shows of hospitals and whatnot and it's the provider orders the tests, the phlebotomist comes in, or the nurse and takes a sample and the next thing you know the results are in the physicians' hands. So, the laboratory testing itself is like this magic black box that is faceless and unrecognized."*

MLPs provided several arguments as to how DPA to CLTRs may or may not aid in increasing the visibility of laboratorians (see Table 5). For example, the ability to see test results without the intervention of a physician may help patients think about testing as a process separate from clinical consultation done by professionals trained for this purpose.

DISCUSSION

This interview study is the first to investigate the individual and professional attitudes of MLPs toward implementing DPA to CLTRs. Through this qualitative approach, we better appreciated the current landscape of DPA information from a laboratory practitioner's lens. Overall, MLPs know of the technological systems currently in place to facilitate DPA. They reported mixed attitudes about DPA, with most highlighting vital differences between reporting CLTRs for common tests versus uncommon or unexpected ones. Finally, respondents shared that DPA to CLTRs might help improve the visibility of the laboratory profession, bringing direct attention to their typically overlooked role. While some thought this was positive, others worried about the scope of practice and professionalism considerations.

Like other healthcare professionals in previously reported studies, MLPs were apprehensive about the implications of DPA and patients' ability to interpret test results.[8,10] These concerns are not without merit. Prior research assessing patients' aptitudes to interpret laboratory test values found low levels of health literacy and the potential for unnecessary stress and anxiety in patients.[12,26-28] MLPs agree that when patients access CLTRs directly, they can exert self-advocacy but only when there is enough understanding about the test's meaning in the context of their overall health. The perceptions voiced in our study suggest what other researchers have found, that in order for DPA to become an effective healthcare tool that has a meaningful impact on patient safety, additional work is needed to provide adequate linkage to care.[12,29,30]

MLPs viewed DPA as an opportunity to increase the visibility of the laboratory by providing patients with tangible evidence of what happens inside the "magic black box" of healthcare. There have been some attempts to expand the reach of laboratory medicine in the direction of patient-centered care, particularly by pathologists, through initiatives such as Pathology Explanation Clinics and data management interventions.[31,32] Currently, most of these communication strategies are designed for personnel trained as physicians and do not include laboratory technologists and technicians, a combined workforce in the United States of over 344 000 individuals, compared with approximately 29 000 pathologists.[31-35] In addition, based on our respondents' statements, there is no consensus on how laboratorians should participate in the DPA process, which may speak to MLPs' perception of themselves as generators, but not necessarily communicators of healthcare data. The entry-level MLP scope of practice and physical location of the laboratory may also limit their involvement in patient safety initiatives that utilize DPA to CLTRs.

With additional experience, training, and admittance to spaces that facilitate patient contact, like those reported by respondents working in small healthcare settings, MLPs' level of comfort communicating with patients may increase. Areas of opportunity included improved awareness of EHR web portals as places where MLPs can refer patients for viewing of their test results, increased understanding by MLPs of what test results look like as they are displayed through patient portals, and establishing consensus on authentic online resources MLPs can share with patients. Issues of trust and appropriate communication by the laboratory are critical. They must be addressed, particularly in the context of health emergencies, such as the COVID-19 pandemic, because these situations lead to increased scrutiny of the laboratory profession and pressure to provide fast turnaround times on testing.[36,37]

This study has several limitations. While we were able to include opinions from respondents with diverse clinical backgrounds, age groups, and work experience in the profession, MLPs from small facilities, rural settings, and the coastal regions of the United States were underrepresented. By design, this is a qualitative study, and the number of participants was low. Although this is typical of the nascent field research archetype wherein the aim of the study is pattern identification of theories that will invite further research, we acknowledge that our small sample is not representative of MLPs at large. Also, this study did not include perspectives of employees within the clinical laboratory who share resulting and reporting duties, such as cytologists, pathologists, and others, who may have different opinions than those expressed by the MLPs who were interviewed. Additional quantitative survey studies and qualitative studies focusing on these populations of MLPs are needed.

In their current position, MLPs, "the silent heroes in lab coats who also serve as detectives of disease," are limited in their ability to impact patient safety through increased access to laboratory data.[38] But, policy and regulatory changes requiring direct communication of CLTRs have set the stage for a potential increase in the scope of

practice of laboratory-trained health professionals. This research provides insight into laboratory processes and reporting practices and highlights the tensions around DPA for MLPs. Given the established concerns with DPA, a key opportunity exists for training and integration of MLPs into the clinical team, as they could contribute to implementation efforts in DPA through evidence-based practice use of EHR-based informatics and analytics.[4,39]

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