

Digital Diagnostics and Mobile Health in Laboratory Medicine: An International Federation of Clinical Chemistry and Laboratory Medicine Survey on Current Practice and Future Perspectives

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Background: A survey of IFCC members was conducted to determine current and future perspectives on digital innovations within laboratory medicine and healthcare sectors.

Methods: Questions focused on the relevance of digital diagnostic solutions, implementation and barriers to adopting digital technologies, and supplier roles in supporting innovation. Digital diagnostic market segments were defined by solution recipient (laboratory, clinician, patient/consumer, payor) and proximity to core laboratory operations.

Results: Digital solutions were of active interest for >90% of respondents. Although solutions to improve core operations were ranked as the most relevant currently, a future shift to technologies beyond core laboratory expertise is expected. A key area of potential differentiation for laboratory customers was clinical decision support. Currently, laboratories collaborate strongly with suppliers of laboratory integration software and information systems, with high expectations for future collaboration in clinical decision support, disease self-management, and population health management. Asia Pacific countries attributed greater importance to adopting digital solutions than those in other regions. Financial burden was the most commonly cited challenge in implementing digital solutions.

Conclusions: Specialists in laboratory medicine are proactively approaching digital innovations and transformation, and there is high enthusiasm and expectation for further collaboration with suppliers and healthcare professionals beyond current core laboratory expertise.

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IMPACT STATEMENT

This report describes the results of a survey of IFCC members to assess perspectives on digital innovation. We carefully defined user-centric market segments to effectively discuss digital technologies and solutions within the context of laboratory medicine. Digital diagnostic solutions were of interest and importance for most respondents; however, financial burden was the most common challenge to their implementation. The results indicate that specialists in laboratory medicine are proactively approaching innovative digital solutions proactively and welcome further collaboration with suppliers and healthcare professionals to better enable health management beyond the laboratory.

INTRODUCTION

In an increasingly connected world, digital innovations are rapidly changing healthcare delivery and the medical laboratory environment (1). There is growing consensus about the need for a strategy that combines medical and technological tools to provide us with a response at a scale that can outpace the speed and proliferation of a pandemic. The current COVID-19 pandemic and the consequent social distancing precautions adopted by many countries have highlighted the need for and usefulness of digital solutions (2, 3). The integration and adoption of such emerging technologies opens up new opportunities and offers several advantages to users. Advances in digital technologies can improve the speed, flexibility, quality assurance, and transparency of laboratory processes; they have the potential to increase healthcare delivery efficiency, to facilitate medical education, and to improve patient experiences and outcomes (4, 5). Nevertheless, digitalization may also create challenges and additional responsibilities for healthcare workforces and may require changes to practices and business models, as well as implementation of different workflows (6–9).

With the rapid increase in the development of digital health technologies, the WHO developed recommendations in 2019 to help ensure that new technologies are clinically effective and offer

medical outcomes and economic value (10). However, a vast array of digital health technologies are currently available, including electronic health records; patient self-monitoring of health using mobile phones and apps; cloud technology for data sharing and storage; use of advanced computing and artificial intelligence in diagnosis; telemedicine for remote consultations; digital approaches for monitoring and reporting inventory levels, consumption, and distribution of medical commodities; and transmission of customized health information for different target audiences (1). Consequently, it can be challenging to communicate and discuss these digital products and solutions in a meaningful way without a standardized approach to segmenting and defining different digital health technology markets.

We report the findings of a global survey of specialists in laboratory medicine conducted by the IFCC Committee on Mobile Health and Bioengineering in Laboratory Medicine (IFCC-C-MHBLM), which aimed to categorize and conceptualize current and future perceptions of digital innovations within the laboratory medicine and healthcare sectors.

METHODS

IFCC-C-MHBLM Questionnaire

The IFCC-C-MHBLM developed an online questionnaire on mobile health and digital diagnostics

that was distributed to 151 IFCC members (91 full, 16 affiliate, and 44 corporate members, as of December 31, 2018). The questionnaire was distributed on September 15, 2019, with a completion deadline of October 31, 2019. The survey included questions on the role of diagnostics suppliers in supporting digital innovations, the current and future relevance of digital diagnostic solutions in the laboratory environment, laboratory readiness and methods for implementing digital diagnostic solutions, barriers to their uptake, and respondent demographics ([Supplemental Table 1](#)). Respondents were grouped according to their geographic location into the following regions: Eastern Europe, Middle East, and Africa; Western Europe; Asia Pacific; North America; and Latin America.

Market Segments of the Digital Diagnostics Landscape

Respondents were asked for their opinions on the current and future states of digital diagnostic solutions in relation to 10 different market segments of the digital diagnostics landscape. These segments were defined by solution recipient (laboratory–data generation, clinician–clinical decisions, patient/consumer–disease self-management, and payor–health management) and proximity to the core laboratory environment (core business that directly affects the laboratory operation, adjacent business that may identify considerations for result analysis, and new business that focuses on population management rather than patient-specific details; [Supplemental Fig. 1](#)).

- Segment 1: Laboratory management software. Software solutions for the integration and connectivity of hardware and information technology platforms in both laboratory and point-of-care settings allow for automation, process control, and workflow streamlining between laboratories. These solutions aim to improve operational efficiency and productivity by improving data flow, process management, sample management, quality control, and validation workflows.
- Segment 2: Laboratory performance analytics. This segment includes operational or economic data analytics for generating laboratory performance insights. These analytics enable data-driven, strategic decision-making aimed at increasing efficiency through financial transparency and cost reduction and offer solutions for performance dashboards, laboratory benchmarking, operational optimizations, and inventory management.
- Segment 3: Laboratory information systems. These software systems support the coordination of various laboratory operations (e.g., workflow management, order entry, reporting, and billing) by recording, managing, and storing laboratory data.
- Segment 4: Digital after-sales services. Innovative digital interaction solutions after instrument purchase, such as the availability of a proactive remote service with skilled support personnel to aid with troubleshooting, aim to create a differentiating customer service experience.
- Segment 5: Clinical workflow automation. These digital tools promote clinician collaboration within or between disease specialties, enabling consolidation of patient data from multiple sources and standardization of clinical workflow and decision reporting. These digital tools aim to eliminate inefficiencies in patient data collection and facilitate patient-specific decision-making by clinicians, thus improving patient care and ensuring standardization of best practice.
- Segment 6: Clinical decision support (CDS). Digital data insight and recommendation tools help inform clinical decisions and thus provide direct medical value by offering solutions to assist physicians with diagnoses, clinical trial matching, patient-specific risk assessment, and patient-specific recommendations.
- Segment 7: Electronic health records. Digital collection of patient health information promotes collaboration between clinicians and other healthcare providers and offers solutions for sharing results and health data.
- Segment 8: Digital disease prevention. Digital, technology-based assistance tools for patient self-monitoring, such as health coaching for changing risky behaviors, aim to provide guidance in disease prevention until diagnosis by a clinician.
- Segment 9: Digital disease self-management. Digital patient self-testing solutions for disease monitoring, health coaching, and virtual assistance aid in self-management of a medical condition after diagnosis by a clinician.
- Segment 10: Population health management. Aggregation and analysis of patient data across multiple health information technology resources offer solutions for test utilization management, readmission avoidance, and patient stratification.

Two additional categories were included in the survey: telemedicine and artificial intelligence.

These categories were considered separately from the 10 market segments listed above, as they are focused on underlying technologies rather than solutions and may be the technology underlying or forming part of a number of solutions and segments.

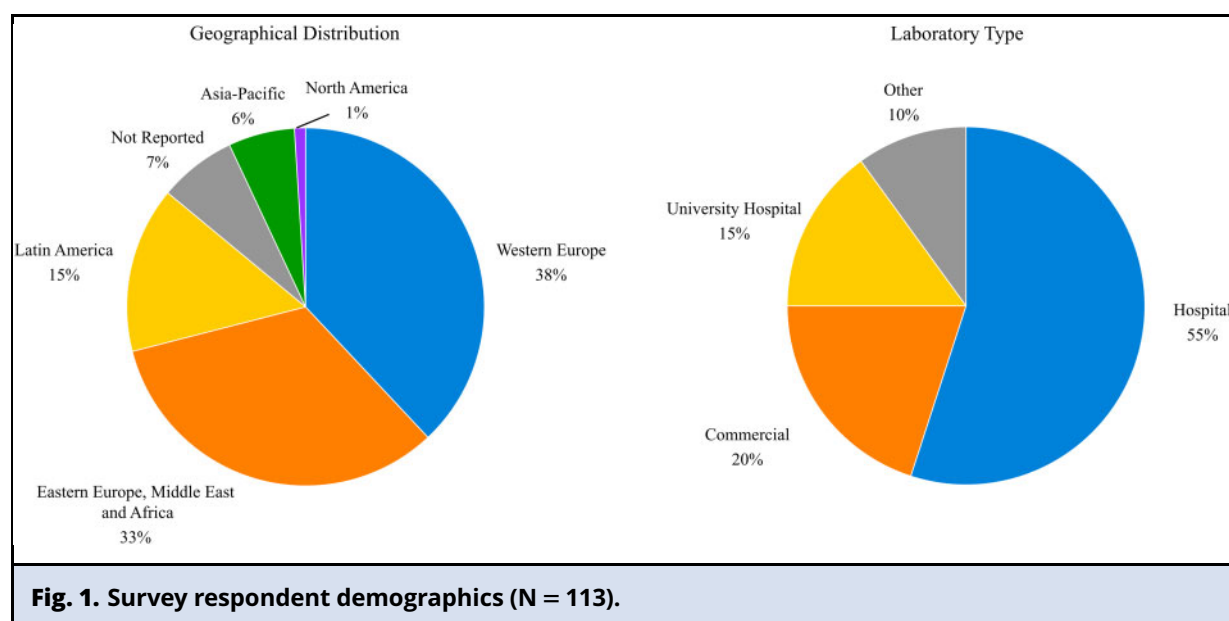
RESULTS

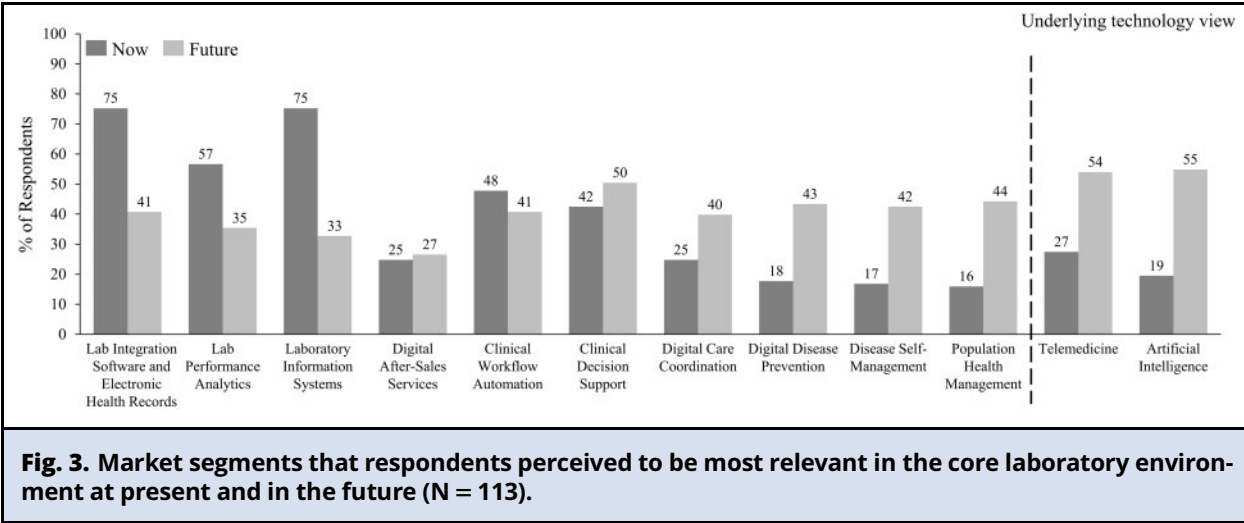
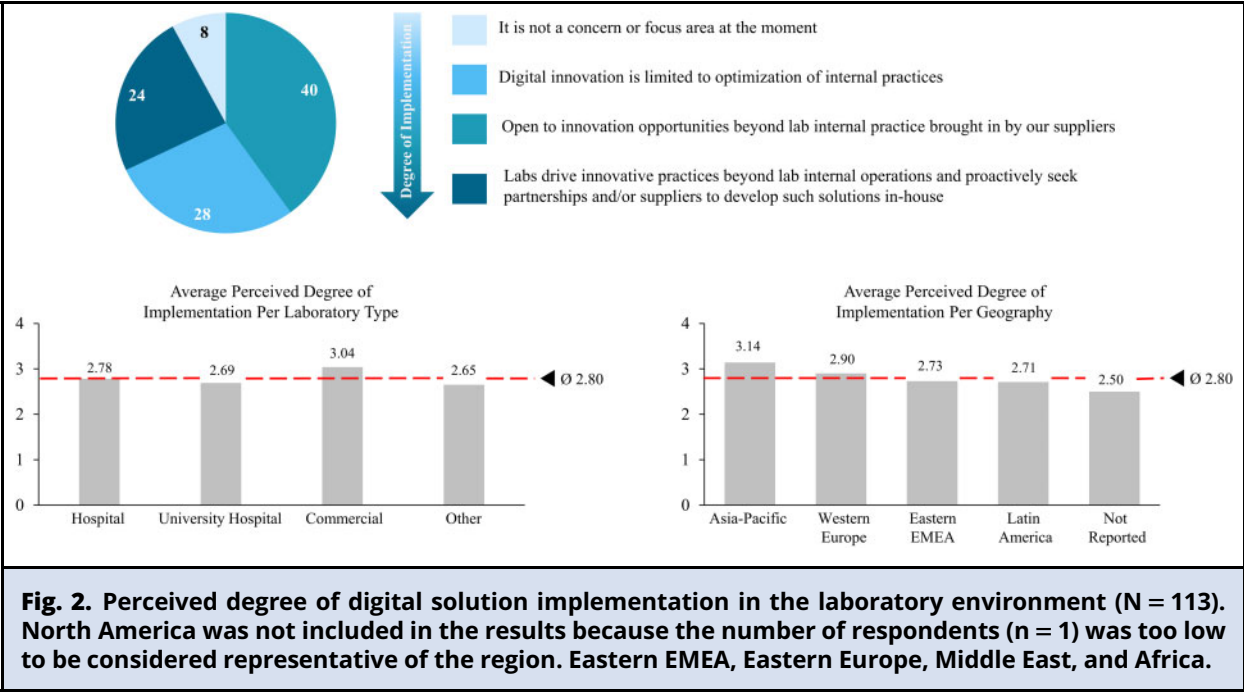
Respondent Demographics

A total of 113 IFCC members responded to the survey. Most respondents were from the IFCC regional federations of Europe, the Middle East, and Africa (Western Europe, 38%; Eastern Europe, the Middle East and Africa combined, 33%), and the main laboratory type was hospital laboratory (55%; Fig. 1). The complete list of countries with respondents within each region is provided in [Supplemental Table 2](#). A broad range of laboratory backgrounds and roles were represented by the survey respondents, including laboratory director, laboratory owner, laboratory doctor, clinical pathologist, in vitro diagnostics vendor, operations manager, and technical director.

Key Survey Findings

More than 90% of respondents agreed that digital solutions were an area of interest, and the average perceived degree of digital solution implementation in the laboratory environment was 2.8 (scale: 1 [low implementation] to 4 [high implementation]; Fig. 2). Digital solutions for improving laboratory operations (segments 1–3) were perceived to be the most relevant for the core laboratory environment at present, but a shift toward solutions in areas beyond core laboratory expertise is expected in the future, including telemedicine and artificial intelligence for CDS and workflow optimization (Fig. 3). Respondents perceived CDS (segment 6) as the biggest potential area for laboratory differentiation toward customers, followed by solutions for disease and care management (segments 7 and 8; Fig. 4). Although laboratories are generally perceived to strongly collaborate with suppliers in the areas of laboratory integration software and information systems at present (segments 1 and 3), there was a high expectation by laboratories for future collaboration with suppliers beyond laboratory optimization solutions, particularly in differentiating



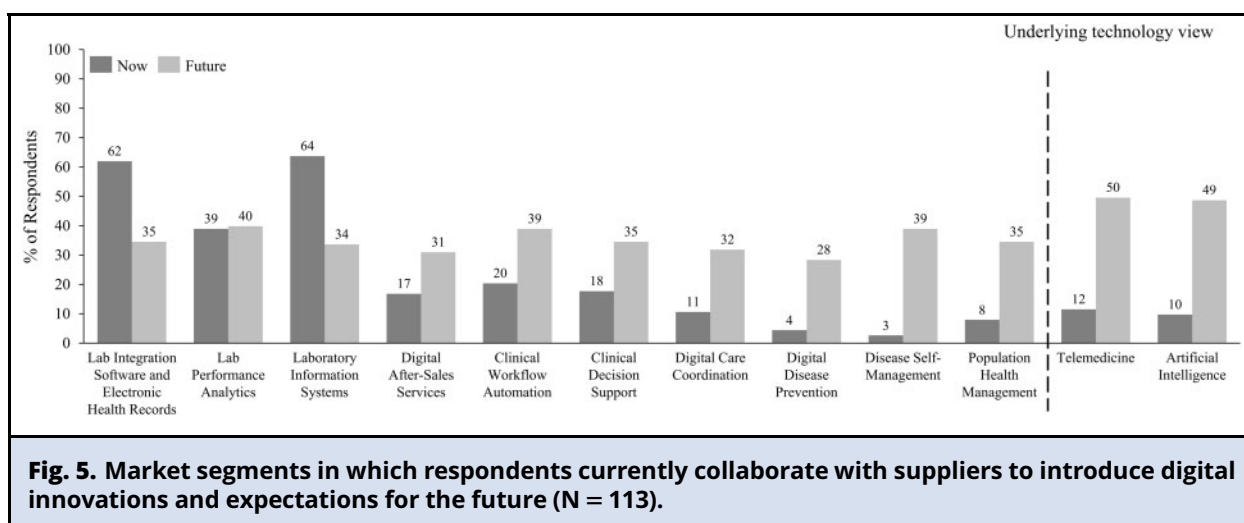
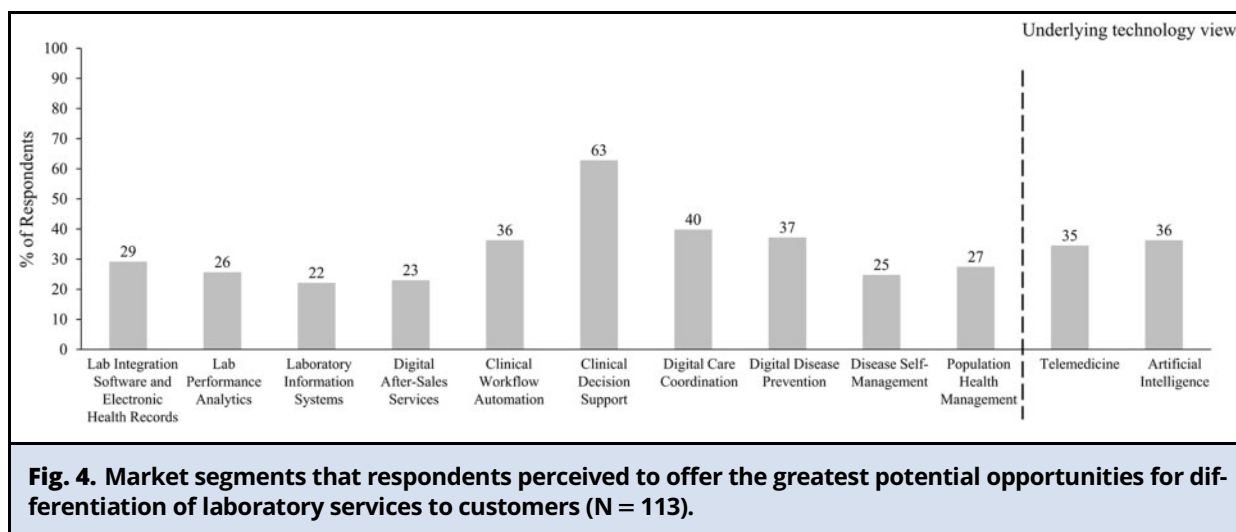


areas, such as CDS or population health management (Fig. 5).

There were some differences in responses between geographic regions (Figs. 3 and 6). In general, respondents from the Asia Pacific region attributed a higher importance to digital solutions, indicated a higher level of collaboration at present,

and had higher expectations for digital solutions in the future than respondents from other regions. Conversely, respondents from the Latin America region attributed the lowest importance to digital solutions both now and in the future.

Financial burden was the most commonly cited challenge in implementing digital solutions.

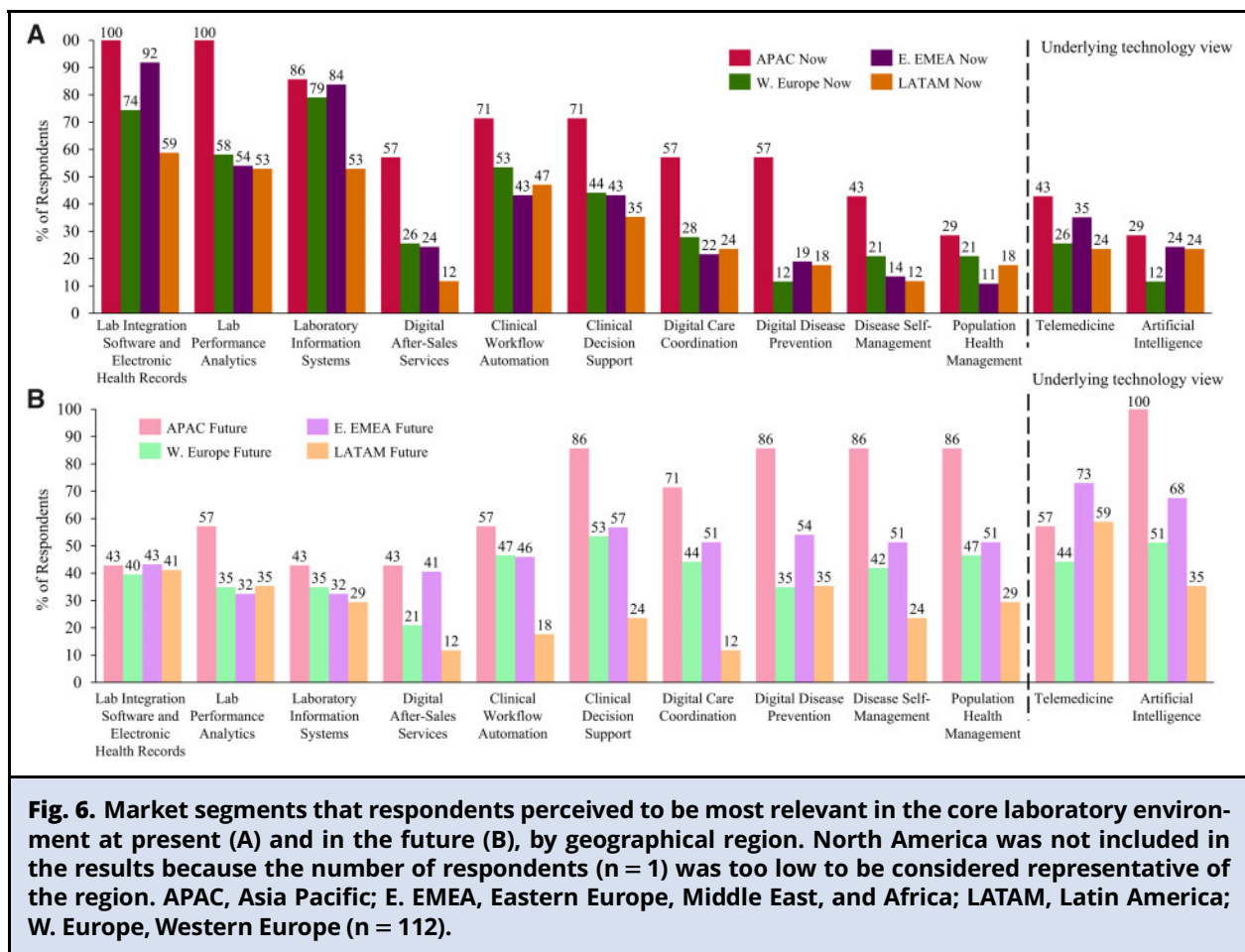


Other frequently raised obstacles included a lack of solutions fitting customer needs, issues with interoperability of information technology products, and concerns around data security (Supplemental Fig. 2).

DISCUSSION

The findings from the IFCC-C-MHBLM survey of laboratory medicine users' views on digital

technologies clearly show that digitalization in laboratory medicine is no longer a future expectation but rather is occurring now (1). Although IFCC members currently place the highest importance on digital solutions for improving core laboratory operations, a future shift is expected toward solutions in areas beyond core laboratory expertise. In particular, CDS is seen as the area of greatest potential for laboratory differentiation for customers, followed by solutions for disease and care management, which has subsequent implications for



increased demand on diagnostics providers. Importantly, laboratories cited financial burden as the most common challenge to implementing digital diagnostic solutions; other reported challenges were a lack of solutions designed to address specific customer needs, technical issues between different information technology systems, and potential data security issues. These challenges provide potential areas of focus for addressing gaps in the adoption of digital solutions, particularly when viewed as compounded challenges. There may be, for example, an increased financial burden to implementing high data security in individual organizations with low levels of digital

maturity, so personalized approaches are often required. In the current COVID-19 pandemic, it has become increasingly apparent that interoperability between healthcare institutions, aided by digital solutions, should be prioritized (11) and financial burden reduced. Although public health initiatives, such as the Promoting Interoperability Programs in the United States, may alleviate some of the financial burden facing laboratories in adopting these technologies (11), suppliers have a responsibility to help address potential financial obstacles. Several organizations may form buying groups or group purchasing organizations that allow smaller laboratories to negotiate as part of a

larger system, potentially reducing the cost of these technologies across the group.

It is possible that a number of specialists in laboratory medicine, outside of the IFCC membership, are not familiar with or anticipating the implementation of digital solutions as an important aspect of core laboratory practice. This observation emphasizes the responsibility of education providers to increase awareness of digital technologies that may address challenges and unmet needs for laboratory medicine. Education providers may also gather insights from specialists in laboratory medicine to improve current functioning and design of digital health solutions.

Recently, rapid advances have been made in the adoption and implementation of digital innovations in the laboratory medicine environment. The need for electronic healthcare delivery solutions is likely to increase with growing demand on healthcare systems in the context of constrained resources. Future developments that may enable digital technologies to further change healthcare delivery include global access to internet-based information, digital support for healthcare workers (i.e., for diagnosis, treatment, and training), provision of healthcare (including diagnostics) at home, and transformation of logistics management (12). The role of laboratory medicine in the future healthcare ecosystem is at a crucial turning point. Rather than being a sole commodity service provider, digital diagnostic solutions, particularly CDS, have the potential to transition laboratory medicine to a platform for generating patient-related actionable insights that are not currently available, thereby improving the clinical value of laboratory results. Digital technologies also offer the greatest opportunity to differentiate laboratory services for customers (e.g., healthcare professionals, hospitals, medical practices). The development of digital solutions will need to rely on cocreation and user experience to be fit for purpose, to respond to a clinical need, and to

integrate regulatory aspects (13). Strong interactions between healthcare workforces, in vitro diagnostic partners, and patients will be essential for this cocreation process.

Digital solution providers offer the product development capability, scale, and expertise to deploy and maintain digital diagnostic solutions that allow laboratory medicine to support clients, both physician and patient. Delivering good diagnostics services depends on providing an appropriate diagnosis. Digital solutions providers could play a pivotal role in the digitalization of the diagnostics process by extending artificial intelligence tools during the pre- and postanalytic phase, including selection of the right test for the right patient—the personalized medicine approach. Artificial intelligence may also streamline the processes for data interpretation, billing and reimbursement, and information gathering around population statistics. Digital solution providers may also bridge the gap between patients and laboratory medicine. An increase in health literacy and knowledge surrounding diagnosis processes and recommendations for other tests can allow patients to become active participants in their disease management. Although digital solution providers have the capability to research and develop new technologies to support laboratory medicine in delivering added value to clients, privacy and civil liberties must be preserved. Digital diagnostic solutions may provide benefits for every stage of the diagnostic process; however, secure methods that are respectful of privacy must be a priority.

When discussing digital technologies and solutions, it is important that the various market segments are carefully defined. Digital innovations can be difficult to explain to stakeholders without a common framework, and the full potential of these innovations may not be fully realized (14, 15). The WHO has developed a framework for the functions of digital technology in healthcare. This framework broadly comprises

provision of better and more direct information to people regarding health and illness, support of healthcare workers for diagnosis and treatment, and access to searchable databases and information across a broad spectrum of areas for healthcare managers (12, 14). In this report, we propose a different approach to market segmentation of the digital diagnostics landscape. Our approach incorporates more customer- or user-centric segmentation of digital solutions for the laboratory medicine environment. The market segmentation approach was validated using market research and aims to comprehensively cover activities in laboratory medicine and other medical organizations. It has been developed in a generic way so that the market can be described and quantified in the long term rather than focusing on the underlying technology. Such market segmentation allows for a more global vision and accounts for expectations from different areas of the world where clinical, operational, and economic constraints may differ. This approach has been used to describe other markets, such as the *in vitro* diagnostic landscape, which has been divided into well-defined segments (16). Market segmentation provides an educational framework for laboratory professionals in this new digital era and the future vision of laboratory medicine.

We provide a comprehensive survey of trends and priorities in digital diagnostics from laboratory medicine providers across different geographic regions and clearly defined digital diagnostic market segments within which to contextualize the results. The survey was validated within laboratory medicine communities through interviews with key opinion leaders in the field of digital diagnostics. Interviews were conducted by an external market research agency (Homburg & Partner, Mannheim, Germany), allowing for the collection of real-world evidence relating directly to the laboratory and diagnostic environment.

A limitation of our study is the potential for the data to be skewed by selecting only IFCC members to complete the survey. Although digital solutions affect all areas of laboratory medicine, hematology, coagulation, and microbiology, survey responders were primarily focused in clinical chemistry. A potential survey bias was the overrepresentation of respondents from Europe, the Middle East, and Africa (71% of respondents) and the low proportion of respondents from Latin America (15%), Asia Pacific (6%), and North America (1%). Other market segments of the digital diagnostics landscape were not included in our survey (e.g., digital therapeutics, robotics, digital trial management); however, the market segments that were included were considered to be the most relevant for the purposes of our survey, as determined through the key opinion leader interviews for validation of the survey, and thus were prioritized.

CONCLUSION

New digital technologies and regulations are supporting the laboratory digital transformation ahead. An array of digital technologies and tools are increasingly being used in laboratory medicine and could improve clinical decision-making, patient triage, and the exchange of information between healthcare professionals and patients. As the regulatory environment for digital technologies takes shape, emerging industry standards foster usability, compatibility, and interoperability to sustain growth of digital technology use in a safe environment before being widely adopted. Close collaboration among the industrial world, public health authorities, and digital communications operators will support effective solutions and implementation of best practices. As digital innovations are implemented, laboratory medicine providers are shifting their strategic focus from optimization of internal operations to novel offerings to customers. Digital diagnostic solutions are likely to facilitate this shift,

with CDS showing great potential for differentiation of laboratory services. Adopting digital technologies will require specialists of laboratory medicine not only to reimagine operational and clinical processes around care delivery but also to embed these technologies in new medical processes and concepts to reap the benefits. The IFCC-C-MHBLM survey highlighted that specialists in laboratory medicine are proactively approaching digital innovations and transformation. There are also high

expectations and enthusiasm for further collaboration with suppliers and healthcare professionals beyond current core laboratory expertise and traditional solutions.

SUPPLEMENTAL MATERIAL

Supplemental material is available at *The Journal of Applied Laboratory Medicine* online.

Author Contributions: All authors confirmed they have contributed to the intellectual content of this paper and have met the following 4 requirements: (a) significant contributions to the conception and design, acquisition of data, or analysis and interpretation of data; (b) drafting or revising the article for intellectual content; (c) final approval of the published article; and (d) agreement to be accountable for all aspects of the article thus ensuring that questions related to the accuracy or integrity of any part of the article are appropriately investigated and resolved.

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