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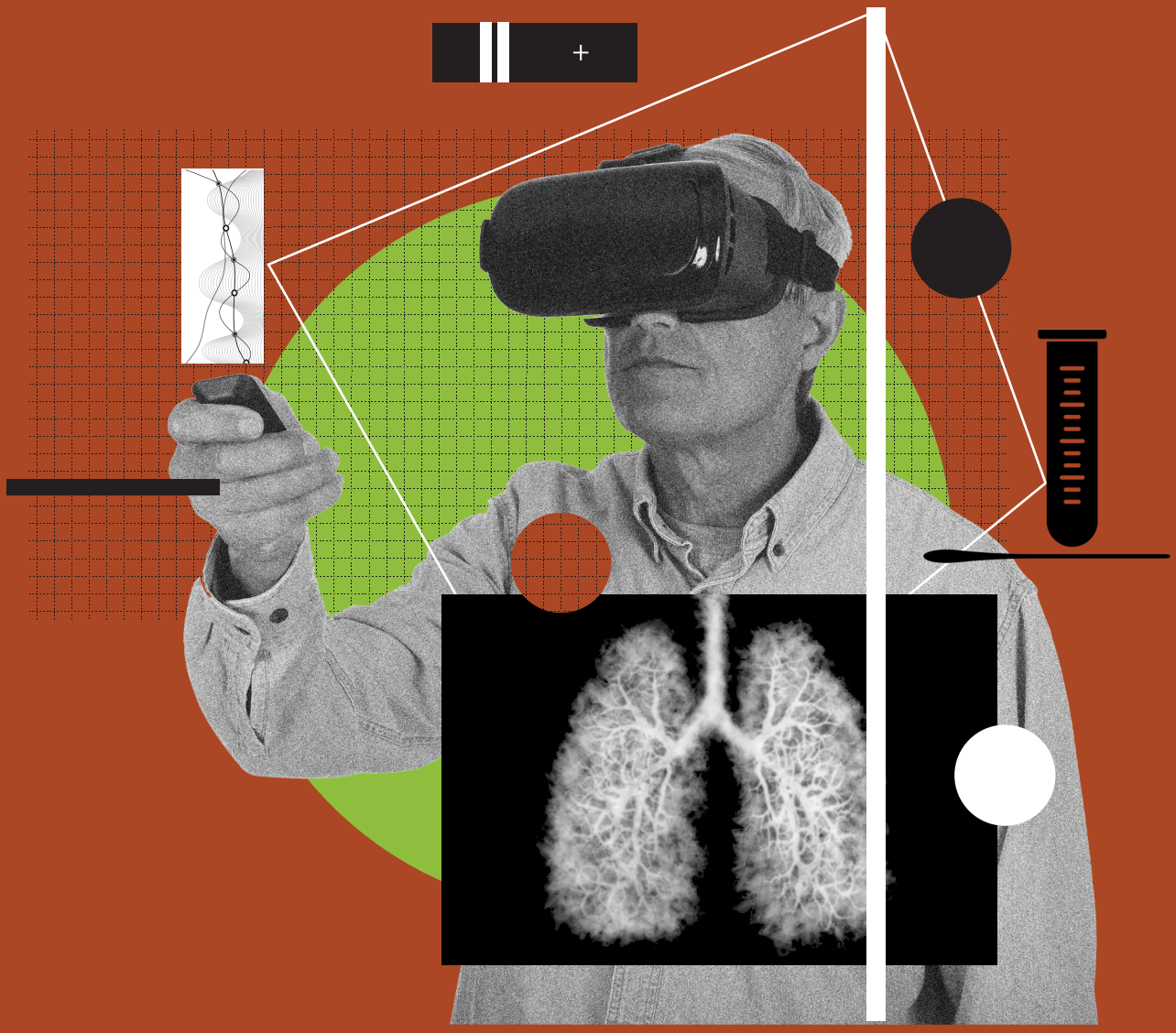

Preparing for tomorrow's diagnostics industry today

How the diagnostics industry can enable the shift from treatment to prevention and early detection—and help lower costs, boost returns, and improve outcomes.

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Executive summary

DIAGNOSTICS INDUSTRY LEADERS are taking note of major market forces, including pressure from payers to reduce costs and improve patient outcomes, changing patient, consumer, and provider behaviors, and real-world learnings from the COVID-19 pandemic. These forces are contributing to the birth of a new health care delivery system—one in which the focus will likely shift from reactionary, treatment-based care to prevention and well-being. Deloitte health actuaries project that embracing prevention and well-being will drastically reduce the rate of health care spending, with US$3.5 trillion in potential savings by 2040.[1]

The shift away from reactionary, treatment-based care is also helping drive record growth in the diagnostics market. And that's no surprise since diagnostics are not only an integral component in activating the transformation of health care delivery but also play a critical role in the clinical decision-making process, from screening and detection to treatment selection and monitoring. As a result, we're seeing an increasing demand for diagnostic technologies that are convenient, accessible, and affordable, and can provide actionable results quickly. Diagnostics companies could have an opportunity to shape the future of health care delivery—if they start planning now.

To understand the state of the diagnostics industry today and forecast where it is headed, we conducted interviews in the summer and fall of 2022 with 27 executives and investors covering a variety of diagnostic technologies globally, from labs and imaging to wearables and new market entrants.

The shift away from reactionary, treatment-based care is also helping drive record growth in the diagnostics market.

Based on these interviews, some of the most promising areas of development include:

1. **Convenience:** Rapid, point-of-care (POC), and at-home diagnostics for infectious diseases
2. **Miniaturization:** Miniaturized sensors, wearables, and microelectronics that facilitate noninvasive, continuous monitoring of conditions such as hypertension and blood glucose abnormalities
3. **Portability and connectivity:** Remote technologies that enable measurement and imaging opportunities outside of acute care settings, including those that leverage existing technologies such as smartphones
4. **Advanced precision:** Noninvasive biomarker tests, next-generation sequencing, and other molecular and in-vitro diagnostics to support early disease detection and personalized medicine
5. **Insights and analysis generated by artificial intelligence (AI):** AI-assisted detection and insight generation tools layered onto new and old technologies to improve predictability, adherence, and efficiency

Companies across the health care value chain should consider how diagnostics will continue to evolve to improve predictability, outcomes, and accuracy, and address new channels (e.g., at home and at the POC). Changing revenue and reimbursement patterns and regulatory expectations are also important considerations, along with data privacy and security dynamics weighed against the use of health information. The diagnostics industry leaders we spoke with are confident that innovation will continue at a rapid pace, but they also acknowledged the long and difficult pathway from ideation to commercialization. Incumbents and innovators alike should consider the following strategies to help minimize interruption along the way:

- **Advance data interoperability:** In addition to rendering data operable between systems and/or care teams, data conveners could help aggregate health care data from multiple sources and apply advanced analytical techniques to provide actionable insights for clinicians and patients.[2] Additionally, data conveners could provide an opportunity for data monetization.
- **Drive adoption across the health care system:** Clearly articulating the utility and value of diagnostic technologies across the value chain to help enable better outcomes for patients, reduce costs, and improve efficiencies in care delivery.
  - *Providers:* Consider the quality and actionability of the data generated by new technologies and their impact on workflow, as well as how to overcome potential resistance to change.
  - *Consumers:* Education on the availability and accessibility of certain technologies may be required, in addition to what kind of information new tests can provide and why that information is useful. Data inputs to algorithms should be representative.
  - *Payers and regulators:* Consider factors such as price and contribution to cost reduction. Partnering with end users, payers, and regulators from the outset may help mitigate challenges to approval.

Building tomorrow's diagnostics industry

THE YEAR IS 2030. Ben, a 58-year-old construction worker in Tulsa, Oklahoma, wakes up one morning with a sore throat and a nagging headache. Using his virtual reality headset, Ben connects with his local pharmacist. Based on his symptoms, the pharmacist orders a respiratory disease panel test kit and has it delivered via drone to his front door. Ben uses the swab provided to collect a sample of saliva and within 45 minutes of the appointment with his pharmacist, he tests positive for the flu and a novel respiratory virus. A few hours later, Ben's fever spikes and he starts to feel worse. From his bed, he asks his digital assistant to schedule a virtual appointment with his doctor, Dr. Murray.

Prior to the appointment, Ben receives a note reminding him to wear his haptic sensors—which mimic the sense of touch by applying forces, vibrations, or motions—during the exam. Dr. Murray uses the haptic sensors to capture a digital image of Ben's lungs. Dr. Murray's AI-enabled digital assistant reviews Ben's medical history via a cloud-based platform and compares the information with his intake description. Dr. Murray determines that Ben may be at risk for pneumonia and orders a smart vest to monitor Ben's lungs, breathing rate, and oxygen saturation at home. An additional sensor next to Ben's bed captures the sound of his cough. Data collected by the sensors is seamlessly integrated with an app on Ben's phone and shared with Dr. Murray in real time.

Dr. Murray continues to monitor Ben remotely. The real-time data allows her to provide an accurate and timely diagnosis using technologies that are

convenient, accessible, and affordable for both Dr. Murray and Ben. This is the future of health.

This example illustrates what may be possible as diagnostic and analytical technologies evolve and if data interoperability becomes a reality in health care. But without an advanced infrastructure that supports improved diagnostics data collection, better care delivery, and consistent payment policies, this future could be difficult to achieve. Diagnostics companies have an opportunity to leverage the changing health care landscape and become leaders in shaping the future of health care delivery.

Meanwhile, health care organizations are under unrelenting pressure from public and commercial payers to improve patient outcomes while controlling costs.[3] In 2019, health care spending in the United States topped approximately US$3.8

"The growth in diagnostics is not going to be limited by the technology. There's plenty of innovation happening there. The major market forces that will impact the industry have to do with regulation, reimbursement, clinical workflow, patient access, patient knowledge, and health literacy in general. Those sorts of things are the chief barriers to sustaining innovation and growth."

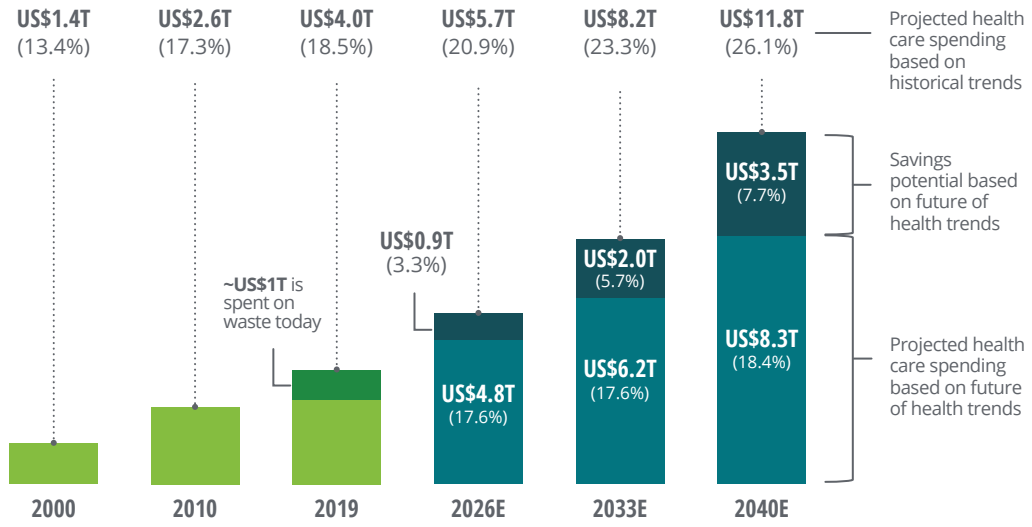
— *Mark Smedley, Senior Vice President, Genetic Sciences Group and China, Thermo Fisher Scientific*

trillion, with care and treatment accounting for nearly 80% of the total amount, according to Deloitte's Deloitte's *Breaking the cost curve* report. Diagnostic technologies can play a critical role in shifting the paradigm from acute sick care to prevention and wellness by facilitating disease screening, early detection, and monitoring. This, in turn, could help identify disease in its earliest stages, when care costs are typically lower and outcomes are better, and could also keep patients out of the hospital, where costs are high.

This could result in big savings for the broader health care industry. Deloitte health actuaries project that the shift to prevention and wellness will drastically reduce the rate of health care spending by 2040, with US$3.5 trillion in potential savings (figure 1). We expect that a significant portion of the US$3.5 trillion difference will likely be due to advancements in diagnostic technologies, including tools, systems, and protocols that help consumers take an active role in their health and well-being.

FIGURE 1

Health care spending in the United States will likely see a marked decline by 2040



Note: Numbers in parentheses are health care spending as a percentage of GDP.
Source: Deloitte analysis based on national health spending, Office of the Actuary estimates, CMS.

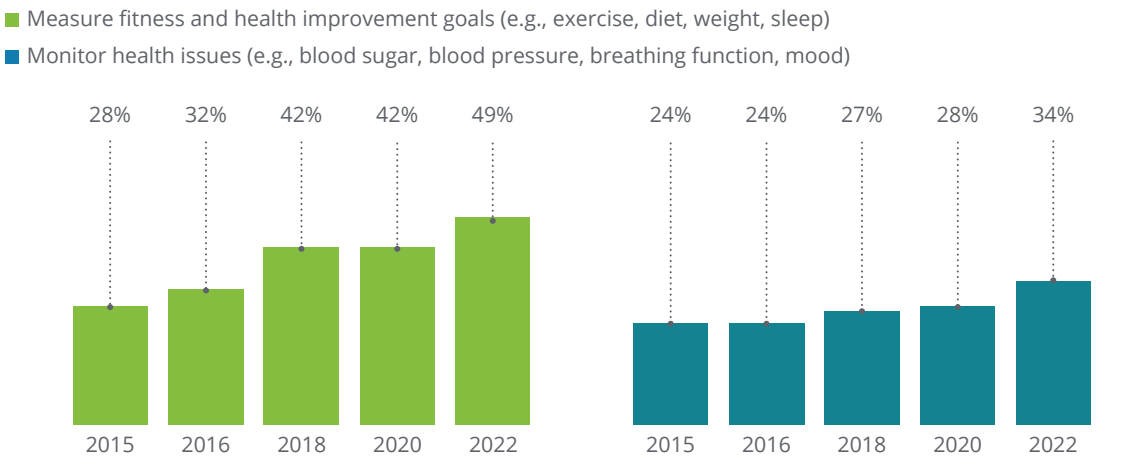
As the needs and behaviors of providers, patients, and consumers continue to change, we see an increasing demand for novel diagnostic technologies. According to the 2022 Deloitte Survey of US Health Care Consumers, nearly half (49%) of the 4,545 US adult health care consumers surveyed said they use wearables, digital assistants, or smart devices to measure fitness and health improvements—up from 28% in 2015 (figure 2). About one-third of consumers said they use a wearable device to monitor health issues (e.g., blood sugar, blood pressure, breathing function, mood), up from 24% in 2015. Consumers' increased interest in health-tracking devices could present an expanded market opportunity for diagnostics companies to explore multiple form factors, like wearables coupled with software and analytics to improve functionality and utility.

In addition, the COVID-19 pandemic pushed the health care system to the brink, driving unprecedented staffing shortages among an increasingly burned out, overworked, and unsatisfied clinical workforce. Nearly half (46%) of clinicians surveyed report high levels of burnout, according to a Deloitte report.[4] The diagnostics leaders we spoke with suggested that innovative diagnostic technologies have an opportunity to help automate tasks, improve efficiency, and potentially reduce clinician burnout while also improving outcomes for patients.

FIGURE 2

More consumers are using digital technologies to monitor health issues and measure wellness goals

Survey question: In the last 12 months, have you used any technologies including websites, smartphone/tablet apps, personal medical devices, or fitness monitors for any of the following health purposes?



Note: N = 4,545; percentages represent "yes" responses.
Source: 2022 Deloitte Survey of US Health Care Consumers.

Collectively, these forces—the need to control costs, the movement toward preventive care, and the changing behaviors of patients, consumers, and providers—are driving major growth in the diagnostics market. In 2021, the global diagnostic testing market size was valued at US$166 billion, with North America accounting for 40% of the revenue share. By 2030, the value is expected to increase to US$349 billion, with a compound annual growth rate of nearly 9%.[5] Analysis from Deloitte's medtech startups report shows that the average deal size of venture capital (VC) investments into novel in-vitro diagnostic (IVD) technologies and imaging doubled from US$13 million in 2019 to US$26 million in 2021.[6]

METHODOLOGY

The Deloitte Center for Health Solutions interviewed 27 C-suite executives and other senior leaders from global medtech incumbent and startup companies between May and December 2022. We also interviewed seasoned medtech-focused venture capitalists as well as diagnostics industry thought leaders. The leaders we spoke with represent various diagnostic technologies, including lab tests, imaging, software, and wearables. We spoke with them about key trends in the industry, where investments are being made, and what the biggest barriers to success are.

Technological advances shaping the future of diagnostics

FOR BEN'S JOURNEY through the health care system to be as seamless as described above, advanced technologies—those that are not only convenient, miniaturized, portable, and personalized but also less invasive—will be required. The industry leaders we interviewed were optimistic about the prospect of this future state, and outlined a few areas of active innovation, from rapid tests to diagnostic sensors, that could help transform health care delivery.

Rapid diagnostics are playing a larger role in disease control

Rapid diagnostic tests provide fast and accurate diagnosis at the POC, such as in a doctor's office or at home, arming patients and providers with important and actionable information within minutes. Industry leaders told us that this type of technology is of great interest, especially when one diagnostic platform can be used to detect an array of diseases including respiratory illnesses such as COVID-19 and influenza, common ailments like strep throat, and sexually transmitted infections.

The pandemic brought with it a crushing demand for quick diagnoses to meet public health guidelines, and the industry took notice. For example, Thermo Fisher acquired Mesa Biologics, which developed a 30-minute polymerase chain reaction (PCR) test for COVID-19 that enabled swift and reliable testing in various settings.[7] Abbott created BinaxNOW, a low-cost, 15-minute, rapid lateral flow test that combines telehealth services with diagnostic testing at scale.[8] Additionally, some large industry players are expanding their footprints in POC diagnostics through mergers and acquisitions. For example, Quidel acquired Ortho Clinical Diagnostics, one of the world's largest IVD companies to help expand access to diagnostic tests and POC diagnostic offerings.[9]

As consumers access health care in newer locations, including retail clinics, pharmacies, and workplaces, widely available and affordable tests will likely become more prevalent and more important in controlling communicable diseases. As such, this should be a continued area of focus for diagnostic companies' development efforts.

ROCHE'S SELF-SAMPLING FOR HPV SCREENING

Cervical cancer screening exams are typically performed in a clinician's office, but access issues, exam anxiety, and cultural influences can inhibit some patients from getting tested. Roche's cobas® solution can analyze self-collected samples with similar accuracy to clinician-collected samples. The solution, which was clinically validated and approved by the FDA, allows patients to collect the sample needed for human papilloma virus (HPV) screening privately. This can broaden access by removing barriers and enabling screening in additional health care environments.[10]

Are diagnostic sensors and wearables enabling better consumer health?

Eighty percent of what makes up someone's health is determined by what happens outside of the hospital or health clinic.[11] The digitalization of health care has transformed how we diagnose, manage, and monitor health conditions outside of routine provider visits. Multiple diagnostic form factors such as noninvasive sensors, wearables, and digestibles are collecting digital biomarkers and continuously monitoring conditions such as hypertension and blood glucose levels in real time. Miniaturized wearables, which could expand the applications and use of wearable products, are also being developed. Examples of miniaturized wearables include stickers, smart tattoos, and short-term implantable devices.

Data generated by wearable devices could eventually provide care teams with a more holistic view of their patients, particularly when that information is integrated with traditional clinical data.

Data generated by wearable devices could eventually provide care teams with a more holistic view of their patients, particularly when that information is integrated with traditional clinical data. Currently, there are many physician-prescribed devices that are well-integrated into care plans. But other devices are individually procured by consumers and can provide interesting and relevant data that may not be as easily shared with providers today. In the case of Ben, data was transmitted automatically from several monitoring devices to his provider continuously and in real time.

According to the 2022 Deloitte Survey of US Health Care Consumers, nearly 80% of the device-wearing respondents said the devices helped change their health behaviors (e.g., eating, sleeping, and fitness). Smartwatches, for example, can measure activity level and heart rhythm. When paired with remote patient monitoring (RPM) technologies, wearables can also facilitate direct and timely provider intervention. Dexcom has partnered with an RPM platform to transmit continuous glucose monitoring (CGM) data directly to care management teams for review. This increases convenience for patients and can also prevent more serious—and potentially more expensive—health outcomes.

Healthy consumers, or those in an unknowing predisease state, may also benefit from such monitors. One study, which compared CGM measurements between participants who have diabetes and those who do not, suggested that CGMs could help identify people who are at risk of diabetes and heart disease more accurately than standard tests.[12] People who do not have diabetes are also using these technologies to monitor and optimize blood sugar for ideal physical and mental performance, with varying degrees of skepticism about true effectiveness.[13] Technology that provides longitudinal data, in contrast to typical health snapshots, can equip providers with more data to help guide better diagnoses and treatment decisions.

Diagnostics companies should consider key factors to adoption, including convenience, ease of use, and affordability, when conceptualizing and developing diagnostic technologies. Additionally, companies should consider early on (e.g., during the design process) how data collected by wearables and sensors could be incorporated into a patient's health care journey.

Innovative imaging technologies could reduce the burden on the health care system

Diagnostic imaging technologies are becoming more portable and compact, which has increased adoption in nonacute care settings such as nursing homes, urgent care centers, and physician offices.[17]

TODAY'S SENSORS ARE SMALLER, SMARTER, AND MORE WEARABLE

- **Zimmer Biomet and Canary Health's Smart Knee, Persona IQ:** Persona IQ can measure patients' range of motion, step count, stride length, and walking distance from inside the human body. It is the first implantable device approved to collect data on an individual's progress after a total knee replacement. Data from the device is relayed to a cloud-based platform for the provider to review and monitor the patient's progress and recovery.[14]
- **Epitel's wearable, wireless electroencephalography monitoring platform, REMI:** REMI combines cloud-based data analytics and machine learning to provide, continuous, long-term monitoring for seizures. The company recently received FDA clearance to use REMI within hospital emergency rooms and critical care units, and it plans to expand into ambulatory and at-home care settings in the future.[15]
- **Riva Health's blood pressure measuring technology:** Riva Health has developed a medical-grade technology that measures blood pressure via a smartphone. Riva can track changes in blood pressure both within and outside of clinical settings and claims to bring blood pressure back under control within three weeks.[16]

Their portability and small size mean that they can be used at home, in emergency response situations, or in military zones. For example, Sonosite's portable ultrasound technology facilitates real-time imaging for soldiers in the battlefield, which can enhance the identification, speed, and accuracy of triage and treatment.[18]

The ability to conduct imaging at the POC can arm clinicians with timely data for making the most accurate diagnoses and determining the best treatment and care plans for their patients. A study published in the *British Medical Journal* found that POC ultrasounds altered clinical workflow and decision-making for nearly three out of four patients.[19]

The imaging leaders we interviewed expect the increased portability of imaging technologies and the expanded use of "remote imaging" to decrease the burden on the health care system. The Massachusetts Institute of Technology's miniaturized ultrasound patch, for example, provides continuous ultrasound imaging without the need for a clinician, and at a lower cost compared to conventional ultrasound technologies.[20] The patch can be synced with a smartphone, and AI algorithms can analyze the images on demand to provide actionable insight. Additionally, AI-based image analysis can be used to accelerate anomaly detection and improve predictive analytics using historical patient health data and other data sources.[21]

The ability to conduct imaging at the POC can arm clinicians with timely data for making the most accurate diagnoses and determining the best treatment and care plans for their patients.

The imaging leaders we spoke with said that increasing access to high-quality imaging outside of hospital settings continues to be a goal, both to create business opportunities and to advance health equity. While solving the logistics for imaging at home and in other settings is still underway, diagnostics companies could consider partnering with shipping services, telehealth companies, or visiting nurses to improve consumer access and reduce concerns about patients reading and interpreting their own imaging results.

PORTABLE TECHNOLOGIES ARE ENABLING TIMELY IMAGING AT THE POC

- **Pulsenmore™:**[22] A handheld ultrasound cradle that docks with the patient's smartphone to deliver ultrasound imaging at home. Once the smartphone is connected to the device, a mobile app is designed to guide the patient through a self-scan and enables online consultation with a clinician. With cloud-based software, clinicians are able to review scans and interact with patients remotely.
- **SOMATOM® On.Site:**[23] A portable CT scanner by Siemens Healthineers that is said to provide reliable and consistent imaging at the POC. The portability of this product can reduce the risk of complications associated with hospital transport to and from larger scanners for patients and provides timely results for faster treatment decisions. It can also reduce the physical burden of staff and increases streamlined utilization of stationary systems.
- **Swoop™ portable magnetic resonance imaging (MRI):**[24] Touted as the world's first MRI system that provides neuroimaging at the POC. The technology plugs directly into a patient's bedside and is controlled by an iPad. Its design and ability to complete a scan in less than three minutes enables neuroimaging in various care settings.

Sophisticated technologies are making personalized medicine a reality

The industry leaders we spoke with identified advanced molecular diagnostics, such as novel biomarker tests and next-generation sequencing (NGS), as one of the sector's biggest growth areas. Biomarker tests, including liquid biopsies, have the potential to become simpler, less invasive, more prevalent, and more accurate.[25] This is a large shift from traditional biopsies of solid tumors, for example, that require more costly (and sometimes unfeasible) surgical procedures to collect samples for testing. Biomarkers can indicate the presence of certain diseases in the body, and often show up early in the disease process.

Additionally, broad-panel NGS can enable fast and highly accurate analysis of thousands of genes at once—as opposed to single-gene sequencing—to understand the specific genetic makeup of tumors, for example. This information, in turn, allows clinicians to target treatments more precisely for the best possible outcome in a timelier manner. Several of the leaders we interviewed also highlighted the growing presence of companion diagnostics, which link biomarker tests to a specific therapeutic intervention. Collectively, advanced molecular diagnostics are enabling detection in earlier disease states and providing opportunities to tailor more personalized treatments.

"Next-generation sequencing tells you everything that's there (in terms of genetics). Yes, we are not ready to be inundated with all of this information but we're getting there. It's certainly the frontier to sequence everything which is driving down costs. AI will help process all of this information, enabling new fields like early cancer detection."

— ***Greg Yap, Partner, Menlo Ventures***

ADVANCED MOLECULAR DIAGNOSTICS ENABLE PERSONALIZED MEDICINE TO IMPROVE PATIENT OUTCOMES

- **DNA evaluation of fragments for early interception (DELFI):** A novel blood-based technology that uses AI to identify unique patterns in DNA fragments shed from circulating cancer cells to differentiate patients with cancer from those without cancer. This combination of NGS and deep learning could produce a more accurate, lower cost, easier-to-run lab test that can be expanded to include a range of cancer types. Delfi Diagnostics seeks to commercialize this noninvasive screening test for single cancer and multicancer detection, as well as treatment monitoring.[26]
- **Cologuard®:** Using advanced stool DNA technology, Cologuard is a noninvasive and convenient colon cancer screening test that can be done in the comfort and privacy of a patient's home. Unlike traditional colonoscopies, it does not require preparation or changes in diet or medication. Self-collected samples are shipped to a central lab.[27]
- **Gut microbiome testing:** Many companies, like Ombre™,[28] Thorne®,[29] and Verisana,[30] are offering at-home tests to assess gut health. While the utility of this information is less clear in today's clinical setting, many areas of medicine have become increasingly focused on how gut health affects other aspects of health.

Improving diagnostic technologies with AI

Model-based AI approaches are helping enhance clinical workflows, improving adherence to the standard of care, and providing more accurate images. However, our interviewees had differing views on the role of AI in diagnostics, both now and in the future. One thought leader said that AI could be reliably used to help identify errors and reduce misdiagnoses. A recent report estimates more than 7 million patients visiting emergency departments each year are misdiagnosed and approximately one-third experience adverse events as a result.[31] Other industry leaders told us that AI should be complementary to the clinical workforce, used to help enhance efficiency and productivity, and not as a replacement.

As AI-enabled diagnostic technologies become more prevalent, some interviewees said that modeling data and data quality should be continually reassessed to determine that it's used appropriately and to reduce bias that may exacerbate disparities. Deloitte's report, *Rethinking when and how to use race appropriately in care delivery*, discusses examples of how racism and bias in AI are negatively impacting and widening the disparity gap, particularly for Black and Brown Americans.

"People are going to live longer with more comorbidities, so more health care will be required. And there are fewer doctors graduating every year. We may be able to get by with fewer doctors because a lot of the diagnostic investigative work can be done with AI in the background, getting us to conclusions and actions faster."

— ***Joe Robinson, President, Robinson Healthcare Solutions***

AI AND MACHINE LEARNING ARE MAKING DIAGNOSTICS WORKFLOWS MORE EFFICIENT

- **Philips' AI-enabled solutions:** Philips recently launched an integrated suite of offerings which includes an AI-enabled automated radiology workflow suite, a vendor-neutral radiology operations command center, and an advanced visualization workspace. The system is designed to enable clinical collaboration in radiology and aids the decision-making process by providing access to a centralized dashboard that integrates patient information from various sources. It can also make it interoperable across departments for analysis, leading to clearer care pathways and predictable outcomes for every patient.[32]
- **LabWare Holdings and CompassRed's Laboratory Information Management Platform:** LabWare Holdings acquired CompassRed, a predictive analytics and insights company, to create a Data Analytics Innovations Center. Combined with LabWare's Laboratory Information Management platform, CompassRed is said to use AI and machine learning technologies to automatically and continuously study data, discover patterns, build predictive models, and develop analytical solutions.[33]
- **Becton, Dickinson and Company (BD) COR™ MX Instrument:** BD recently launched their MX instrument that performs molecular testing for infectious diseases. The FDA-cleared instrument is the third component of the BD COR™ system, which integrates and automates the complete molecular laboratory workflow for high-hroughput labs, delivering up to 1,000 sample results in 24 hours. The system also can use AI to automate labor intensive processes, such as sorting specimens, that reduce the workload for clinicians and laboratory staff.[34]

Paving the way to the future

THE DIAGNOSTICS INDUSTRY leaders we interviewed were confident that innovation will continue at a rapid pace and confirmed our hypothesis that current market forces are playing a role in this acceleration. But there are big questions about how new technologies will be integrated into existing clinical workflows and, perhaps more importantly, how they will be paid for.

"Without interoperability, we will not be able to apply digital diagnostics at scale; integrated patient data is necessary to improve outcomes."

— ***Margaret McMahon, Head Data Science, Roche Information Solutions***

We envision a future in which diagnostics are fast, reliable, affordable, and widely available, but achieving this vision will likely require the industry to break through significant barriers related to data interoperability, regulatory approval, and reimbursement. While our interviews focused predominantly on the US market, European markets are facing similar challenges, based on the findings shared in a report from our colleagues in the United Kingdom.[35] To achieve the future of diagnostics, here are a few strategies to consider based on what we've heard from today's industry leaders:

Advance data interoperability

Access to high-quality data is essential for clinicians to diagnose and treat patients appropriately. However, the lack of an interoperable infrastructure that connects data sources to electronic health record (EHR) systems is impeding the effective exchange of information. Old lab test results, images, and reports, for example, can be difficult for patients to track down and aggregate. This can make it more difficult for patients to communicate their full health history to new providers, and for providers to treat new patients with their complete history in mind. Sometimes, this can lead to repeat tests and potentially higher costs.

Some networked EHR systems today allow information to be exchanged across participating provider organizations. Epic's Care Everywhere and Share Everywhere features, for example, are a good start to enabling data-sharing between providers, and between providers and patients. But

"Information is a determinant of health."

— ***Alissa Hsu Lynch, former global lead, MedTech strategy and solutions, Google at The MedTech Conference 2022***

"Health plans can work with health care providers to help create an open architecture and allow for bidirectional access to data and provide transparency on costs and outcomes, so that members can make more informed decisions."

— *Liz Kwo, chief medical officer, Everly Health*

the offerings may not be dynamic enough to integrate data produced by novel diagnostics into the EHR—and into clinical workflows. Additional challenges might include standardization and inclusion of new data fields, both of which leave providers and patients with questions, including, where will the data go? How will it get there? How will continuous streams of data from technologies such as wearables be handled?

The industry leaders we interviewed said that unless industry stakeholders work together to create interoperable systems, the future of health will be difficult to achieve. It is incumbent upon innovators to consider the current infrastructure when developing digital components and platforms, while remaining forward-looking. In addition, they said that diagnostics companies and labs should develop capabilities that integrate, analyze, and interpret complex clinical datasets from unstructured sources of information to derive care-enabling insights (e.g., collection of real-world evidence from sources beyond controlled clinical trials such as wearables or smartphones).

As digital capabilities proliferate and medtech companies increase the connectivity of their products, vulnerability to cyberthreats is becoming an issue. Regulators in Europe have taken a strong approach to this vulnerability, and US regulators might follow. Medtech companies—both startups and strategic incumbents—should have a thoughtful approach to managing cyber risks as well as communicating privacy and safety to consumers and providers.[36]

Enable adoption across the health care system

Adoption of new diagnostic technologies could be a challenge, and the industry leaders we interviewed highlighted a few main reasons, including inertia or skepticism toward new technologies, lack of integration into clinical workflows, lack of ease-of-use and compliance, and disparate reimbursement policies. Industry leaders outlined the following opportunities to overcome these barriers and help enable increased adoption among providers, consumers, and payers and regulators:

PROVIDERS

Many providers are accustomed to the tools they were educated using and that have been standard in care delivery for decades. As such, they may be resistant to including novel technologies in their daily practice. Many also may not understand the value that new technologies bring to their patients or are skeptical of results. Despite these challenges, the industry leaders we interviewed said that newer clinicians may be more open to change and that medical curricula should also shift to reflect newer technologies. To increase adoption among entering and incumbent clinicians, diagnostics companies should articulate how their product helps to achieve the Quadruple Aim of improving access to

care, enhancing better outcomes, reducing costs, and taking care of the caregivers.

Diagnostics innovators should also consider questions such as, "does the diagnostic change the way that a clinician thinks about a patient?," and if so, "does the change in thinking alter the way the clinician manages the patient?," and if so, "does the change in patient management affect clinical outcomes?"[37] Finding the answers to these types of questions will be critical to gaining trust and enabling adoption among providers and consumers alike.

Innovative diagnostic technologies have an opportunity to help automate tasks and improve efficiency, and could potentially reduce clinician burnout, which has accelerated because of the pandemic. When clinicians were asked in a recent study to identify one aspect of their current job that has minimal clinical value and could be eliminated, 20% chose "work that could be done by others or automated." Some industry leaders pointed to AI model–based approaches as a means to create better workflows. But diagnostic technologies, especially those that can be used at the POC and that provide clear, actionable results, could be even more beneficial than AI models to create better workflows.

POC testing reduces the need for extraneous postvisit tasks such as providing referrals and reviewing results later, and thus improves efficiency. POC testing can often be managed by a nonphysician care team member, thus reducing burden. The introduction of novel technologies, including at-home tests and monitors, could also provide physicians with more data to use in treating patients than from traditional diagnostic tests which could lead to better patient outcomes.

"Diagnostics "wet-lab" technology has and will continue to advance. But wet lab technology is not enough - we need to integrate, analyze and use the information generated by our labs to improve patient and population diagnoses and monitoring. Providers, health systems, public health agencies and most importantly, patients, need tests that inform actionable decisions cost-effectively."

— ***Mara G. Aspinall, BlueStone Venture Partners***

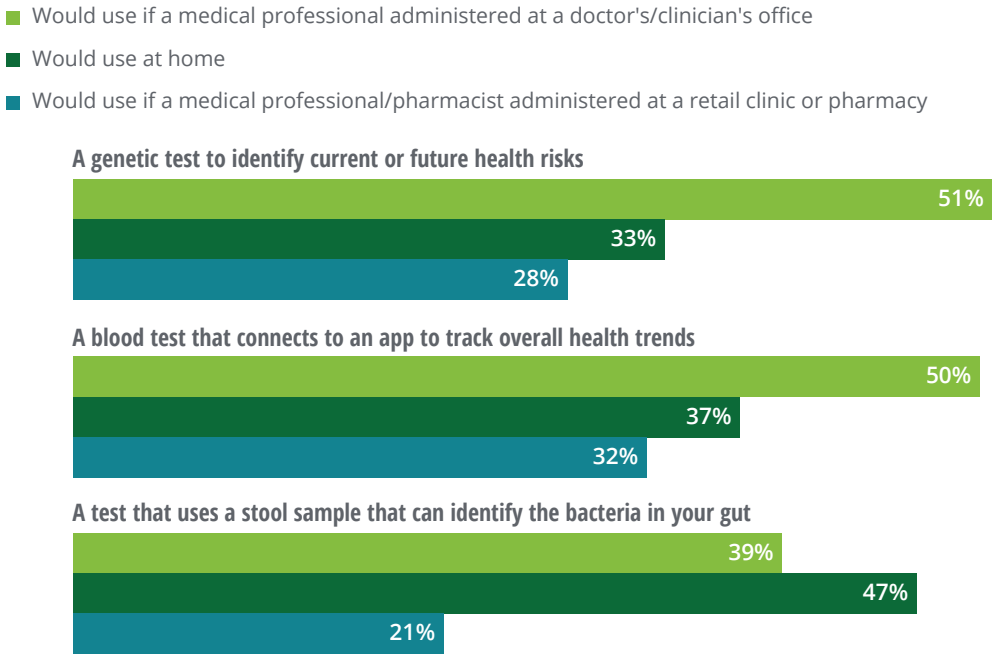
CONSUMERS

Consumers are becoming increasingly mindful about their health, and are demanding transparency, convenience, and holistic care solutions. According to Deloitte's 2022 Health Care Consumer Survey, 87% of respondents said they would be comfortable using novel diagnostic technologies in various settings for monitoring and tracking health and fitness. On average, 85% of those respondents reported they would use a genetic test to identify current or future health risks, 89% would use a blood test that connects to a tracking app, and 85% would use a stool sample that can identify gut bacteria (figure 3).

FIGURE 3

Consumers are willing to adopt novel diagnostic tests across various settings

Survey question: More and more tests are becoming available to help you diagnose various conditions, measure overall health, and identify genetic risks. How comfortable are you with potentially using the following at the locations specified? Select all that apply.



Note: N = 4, 545.
Source: 2022 Deloitte Survey of US Health Care Consumers.

While many consumers are using medical technologies and are interested in diagnostics specifically, they may not know the breadth of tests available to them and which ones are most appropriate or useful for them. The COVID-19 pandemic increased consumers' knowledge and understanding of the importance of diagnostics. Homes became personal testing centers and present an untapped market for diagnostic companies. One forecast suggests that direct-to-consumer testing will create a $2 billion market in 2025.[38]

The industry leaders we spoke with emphasized the need to educate consumers on the availability of diagnostic technologies, particularly those that are noninvasive. This education, in turn, could help consumers make decisions in collaboration with their personal care providers. Deloitte's 2022 Survey of US Health Care Consumers found that 42% of consumers used virtual visits for their health care needs in 2022, up from 17% in 2018.[39] These visits serve as additional, convenient connection points between providers and patients during which a variety of tasks could be completed, including disease education or virtual diagnostic tests. Retail clinics and other community-based sites could also increase access to and provide education for diagnostic technologies.[40]

Industry leaders also shared that while technological advances can increase access to diagnostic tests, the technologies themselves can also exacerbate disparities and cause harm to patients. For example, research has shown that pulse oximeters do not produce accurate readings for darker pigmented skin. One study found that Black patients were nearly three times more likely to have inaccurate pulse oximeter readings compared to white patients.[41] Despite this data, inaccuracies in pulse oximeters for Black and Brown patients went largely unnoticed.[42] As algorithms and AI become more relevant, industry leaders highlighted the importance of using appropriate data to feed models and of further validating diagnostic technologies using representative studies.

PAYERS AND REGULATORS

The industry leaders we spoke with highlighted the ongoing challenges around regulatory approval and reimbursement. While regulation is necessary to ensure validity and safety (see sidebar, "The case for regulating lab-developed tests," for more information), the findings from Deloitte's medtech startup strategies report suggest that the evidence required as part of the regulatory and reimbursement processes for new medtech products can be unclear and inconsistent. This is particularly true for nontraditional technologies that could require new coding or coverage policies, making the go-to-market process unpredictable and time-consuming. However, regulators recognize the need for flexibility when evaluating newer technologies—especially those that include digital components or Software as a Medical Device—and are formulating a revised process.

Reimbursement often isn't possible unless the product is both FDA-approved and available, and the economic models for making that determination are complicated. Payers look at a variety of factors when making coverage decisions, including the total addressable market, the cost of a device, the device's direct contribution to cost reduction or the product's ability to reduce high-cost care such as a cardiovascular event. Diagnostic product innovators should consider these factors in the discovery process—perhaps by partnering with both end users and payers from the outset—to mitigate challenges down the road and help ensure that products can be commercialized.

Tools such as AdvaMed's value framework can be useful in this endeavor.[43] One successful example is Rapid Acceleration of Diagnostics (RADx), which is an initiative created by the National Institutes of Health to accelerate innovation in the development, commercialization, and implementation of technologies for COVID-19 testing. One of their programs, called the RADx Mobile Application Reporting through Standards, seeks to standardize the capture, transmission, and reporting of COVID-19 self-test results, ensuring data uniformity and completeness.[44]

A healthy, early-stage medtech innovation ecosystem, including a constant flow of novel products from startups, can be critical to both bring new products to market and to sustain incumbent medtech company pipelines. According to our recent report, nearly half of medtech startup companies were focused on prevention, wellness, diagnosis, and/or detection of disease—not treatment. Investments into these kinds of technologies are essential to making preventive care a reality. Failure to achieve approvals on a large scale may impact investor and other funder interest and could pose a threat to the innovation ecosystem overall.

These challenges point to the need for diagnostics companies to develop clear business models that work within the constraints of our current health

care system, while also creating innovative revenue models for the future. The venture capitalists we interviewed told us that they prioritize investments into companies that could make money both now and in the future, and that the value of the diagnostic technology and what it brings to the patient (and payer) experience must be demonstrated.

Based on the information that was gathered during the interviews, we recommend that innovators think about these questions while developing diagnostic tools: Can users act on this information being generated? Will this information make a meaningful difference in how a patient is treated? Is it worth the cost? Innovators should consider generating extensive ROI-related evidence to help ensure commercial success. But some of the industry experts we interviewed warned that ROI is not enough: Innovators should also collect the *right* data, so that it tells a complete and representative impact story. This is relevant not only for equitable development and access, but also to safeguard against erroneous data being fed into algorithms.

"Whether it is actionable enough for a change in medical management, the percentage of positive test screens that can be found with it (sensitivity and specificity), and whether it is practical in terms of ROI to do universal screening without adjusted risk"

— ***Liz Kwo, Chief Medical Officer, Everly Health***

THE CASE FOR REGULATING LAB-DEVELOPED TESTS

Lab-developed tests (LDTs) are a type of IVD that is "designed, manufactured, and used within a single laboratory," according to the FDA.[45] Unlike other IVDs, which are regulated by the FDA and require premarket approval, LDTs are regulated by the Centers for Medicare and Medicaid Services under the Clinical Laboratory Improvement Amendment and do not require premarket approval or clinical validation.

The industry leaders we interviewed emphasized the need for additional regulation of the LDT market. As technological advances are made and business models continue to morph, companies are taking advantage of what was once a method for getting new technologies to the market quickly by largely bypassing FDA regulation via the LDT pathway.[46] Interviewees cited a few issues with this. LDTs that are used to detect high-risk diseases, such as Alzheimer's disease, can potentially cause serious harm to patients if erroneous.[47] Further, interviewees said the lack of clinical validation of many LDTs could cause skepticism and could impede adoption among physicians.

Efforts such as the Verifying Accurate Leading-edge IVCT Development Act of 2022 have been introduced to help codify the FDA's existing risk-based framework.[48] While these efforts have been unsuccessful thus far, interviewees highlighted the importance of assessing risk when developing regulatory guidance.

Diagnostics and the future of health

ADVANCEMENTS IN DIAGNOSTICS technologies—those that are making tools faster, better, and more affordable—are opening critical avenues to realizing the Future of Health™ by increasing access and identifying disease before it occurs. In theory, these factors alone should help increase adoption in the marketplace. But as we learned from industry leaders, that's not always the case.

In addition to advancing data interoperability and driving adoption across the health care diagnostic companies should also consider:

1. **Advancing health equity:** Studies show that 40,000 to 80,000 deaths occur annually due to preventable diagnostic errors, underscoring the need for more robust, more accurate, and more accessible diagnostic tools.[49] Innovators should consider partnering with academia, for example, to access quality, unbiased datasets to inform decision-making processes during the product development process. They could also evaluate accessibility and run diverse clinical trials to help ensure representativeness, help foster trust, and help ensure tools can reach the most people in the most equitable manner.[50]

2. **Addressing data privacy and security:** As data interoperability advances, diagnostics companies should pay closer attention to data privacy and take steps to modernize data protection standards. They could also face added pressure to establish better awareness, detection, and response capabilities for cybersecurity threats in health care.[51]

It may also be important to educate consumers on the importance of sharing the insights collected from wearables devices, for example, with their providers. Findings from Deloitte's 2022 US Health Care Consumer Survey show that more than half (54%) don't do this. The top two reasons were because they did not think their doctor would be interested in receiving this information (32%) and because they would rather keep the information private (31%). This underscores the need for diagnostics leaders to enhance the trustworthiness of their technologies to mitigate concerns among users.

Diagnostics companies have the potential to drive change in how health care is delivered and to advance health equity. While traditional diagnostic channels such as reference labs continue to serve an important role, diagnostics that are convenient, portable, and connected, are enabling diagnostic testing in nontraditional settings. These include long-term care facilities and schools as well as retail clinics, at home, and at the POC.

In the case of Ben, advanced sensors and wearable technologies facilitated seamless data-sharing and helped with the quick diagnosis of his ailment remotely. Not only did this reduce barriers to him accessing care, but it likely also limited potential disease spread, reduced his carbon footprint by not requiring travel, saved commuting time, and potentially saved money related to taking time off from work, higher copays, or other out-of-pocket costs. This scenario underscores the important role that diagnostics could play in the shift to a preventive care and wellness model—with the onset of quicker, more affordable, and increasingly accessible options to test and diagnose disease.

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