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Rethinking the in vitro diagnostic testing model in Europe

European health systems used in vitro diagnostic testing in new ways to tackle COVID-19. Now leaders can apply these tactics more broadly.

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There is no denying that the COVID-19 pandemic fundamentally changed the in vitro diagnostic (IVD) testing[1] market. Huge investment and rapid innovation across Europe were critical in coping with the considerable demand for testing.

Health systems have a distinct opportunity to unlock the full potential of testing by identifying where diagnostics can have the greatest positive impact on health outcomes, better embedding data and digital solutions into the testing pathway, and using partnerships and novel delivery models to sustain innovation and improve access to care. IVD testing suppliers and other stakeholders will play an important role in supporting the transition to a new diagnostic testing construct and could start to consider how best to bring innovative technology, services, and partnership models to their customers.

A revolution: The impact of COVID-19 on in vitro diagnostic testing

Throughout the pandemic, Europe saw massive investment in IVD testing to scale up capacity, as well as an urgency to innovate quickly to cope with historic demand. The first diagnostic COVID-19 test was developed by researchers in Germany in mid-January 2020,[2] and the first test with a CE (Conformité Européenne) mark[3] was launched only one month later for commercial distribution.[4] For comparison, the typical development timeline is more than four years.[5] By the end of 2021, nearly 2.9 billion COVID-19 tests had been performed across Europe.[6]

The rapid growth in testing during the pandemic led to innovation across the healthcare services value chain. New testing sites were developed in the community, and many tests were taken at home, signifying a major shift in how many individuals had access to testing. New testing technologies were introduced, such as CRISPR[7] and rapid breath testers,[8] in addition to the first at-scale use of sequencing at the point of care.[9] Health systems enhanced their integration of (and access to) diagnostic data, and public and private organizations collaborated more closely than ever.

Testing for COVID-19 has provided a blueprint for sampling and testing at home that has the potential to enable wider screening for (and monitoring of) chronic diseases. Recently, for example, pharmaceutical companies have worked to produce self-administered blood tests to test for chronic kidney disease and heart failure.[10] COVID-19 testing has also demonstrated the potential value of other testing use cases, such as population-level screening to understand the evolution of infectious disease. Last, the experience of IVD testing for COVID-19 has shifted the mindset of physicians and patients about the purpose of testing from solely the diagnosis and stratification of illness to the confirmation of wellness.

Navigating the pandemic has caused many health systems to ask the same question: "How do we build from this experience?"

Challenges to the revolution

A broader testing transformation faces many hurdles. Health systems are confronting persistent workforce shortages and substantial financial pressure exacerbated by the pandemic and inflation.[11] For example, 90 percent of hospitals in the Netherlands are at risk of recording losses in 2023.[12] In addition, competing issues, such as the

[1] Tests done on samples taken from the human body, such as blood or tissue, to detect, diagnose, or monitor diseases or other conditions.
[2] "Researchers develop first diagnostic test for novel coronavirus in China," German Center for Infection Research (DZIF), January 16, 2020.
[3] CE marking signifies that products sold in the European Economic Area have been assessed to meet high safety, health, and environmental-protection requirements.
[4] "Coronavirus stock hype proves infectious," Evaluate Vantage, February 27, 2020.
[5] "Device approval analyzer," GlobalData, accessed June 7, 2023.
[6] "Archive of historical data on the testing volume for COVID-19," European Centre for Disease Prevention and Control, September 20, 2022.
[7] "United PPE America's CRISPR SARS-CoV-2 test kit gets CE mark," FDAnews, January 18, 2022.
[8] Nick Flaherty, "Breath tester for Covid-19 gets CE approval," eeNews Europe, January 20, 2022.
[9] "Roll-out of 2 new rapid coronavirus tests ahead of winter," UK Department of Health and Social Care, August 3, 2020.
[10] "Jana Care to enter collaboration with Roche to develop and distribute blood testing platform to improve remote care for patients with chronic kidney and heart disease," Jana Care, January 30, 2023.
[11] *The future of healthcare*, McKinsey, accessed June 12, 2023.
[12] "Report: More than 90% of hospitals are at risk of falling into the red," Nederlandse Vereniging van Ziekenhuizen (NVZ), November 25, 2022.

care backlog, may take priority over a long-term diagnostics redesign. The established prepandemic approach to testing is also deeply entrenched in health systems, making any large-scale changes even more daunting.

Alternatively, many health systems may take the view that, given the severity and urgency of COVID-19, the approach to IVD testing during the pandemic was necessary at the time but need not be expanded to other use cases. Although there is some variation among healthcare systems in Europe in testing practices and requirements, the levels of spending by governments on IVD testing during the pandemic far exceeded historic spend. In the United Kingdom, for instance, NHS Test and Trace (NHST&T) spent £10.4 billion on IVD testing in 2020 and 2021,[13] substantially exceeding previous levels: in 2017, for example, NHS IVD testing spend was an estimated £850 million.[14] Denmark, meanwhile, spent 0.5 percent of its GDP on testing in 2021.[15]

By rethinking the testing model in its entirety and applying many of the lessons learned through the pandemic, health systems could increase the efficiency, effectiveness, and affordability of IVD testing and alleviate many of the stresses they are experiencing today.

Five priorities to help health systems sustain progress

Health systems have a window of opportunity to align their strategic aspirations with the changing needs and expectations of clinicians and patients. In parallel, they could establish an operating model that embeds these changes for the coming decades and creates more use cases for diagnostic testing. Below, we outline five main priorities healthcare leaders can consider to achieve this broader goal.

Ensure that investments have long-term impact by maintaining and repurposing testing capacity

As demand for COVID-19 testing decreases, health leaders could repurpose existing testing capacity to address key priorities in healthcare and improve patient outcomes. At the same time, when responding to demand, it will be crucial to use the lessons learned from the pandemic and flex resources (including facilities that have been shut down since pandemic demand receded) up or down to ensure sufficient capacity within the overall system.

Understanding where IVD testing can drive the most value for health systems is vital for maximizing the use of existing facilities. Identifying local health priorities will be necessary to determine how different technologies could best be redeployed. These goals could be accomplished in three main ways:

Identify disease areas that would benefit most from increased, improved, or earlier testing. Research has suggested that two-thirds of the health improvement opportunity in Europe lies in disease prevention and earlier intervention. As such, improved access to diagnostics plays a crucial role in improving health outcomes and economic prosperity in the region.[16]

For example, a potential focus in many systems may be ischemic heart disease, which is the number-one cause of death in every European country apart from North Macedonia, Montenegro, and Portugal.[17] Early diagnosis and treatment of often asymptomatic conditions such as type 2 diabetes, hypertension, and hyperlipidemia, which predispose individuals to ischemic heart disease, can have a meaningful, long-term impact on population health outcomes.

[13] *Test and trace in England—progress update, UK National Audit Office*, June 25, 2021.
[14] "The value of IVDs: The contribution of the *in vitro* diagnostics industry to patients, the NHS and the UK economy," British In Vitro Diagnostics Association, 2017.
[15] Christian Wienberg, "Denmark spent 0.5% of its GDP on Covid-19 testing last year," Bloomberg, June 16, 2022.
[16] "How keeping health a priority is a prescription for European prosperity," McKinsey Global Institute, May 19, 2021.
[17] "GBD compare," Global Burden of Disease, Institute for Health Metrics and Evaluation, accessed June 13, 2023.

Alternatively, widespread biomarker analyses in areas such as oncology and immunology could enable risk stratification and the development of personalized treatment plans. These approaches are used to inform the treatment of lung cancer, a top five killer in every European country other than Portugal and Moldova. In Austria, for example, allele-specific PCR[18] or next-generation sequencing is recommended to test for key lung cancer markers.

Finally, identifying and tracing infectious diseases, such as respiratory and sexually transmitted infections, within a population could help leaders to better plan and target public health responses through tailored educational or immunization campaigns.

Pinpoint critical decision makers in primary care. These decision makers can assess current infrastructure and ensure a balance between national strategic aims and local testing needs. Engaging primary care leaders will become increasingly important in understanding specific testing requirements as well as the optimal modalities of testing delivery to address unmet needs within a local population. In turn, frontline clinicians in these settings of care could identify disease earlier and with greater precision to intervene appropriately.

For example, primary-care leaders could initiate programs to screen for and identify diseases that disproportionately affect specific groups, such as cardiovascular disease in South Asian communities within European countries.[19] This approach focuses on the leading driver of disease burden while targeting interventions on higher-risk groups in the population, thereby optimizing investment.

Determine the best deployment of different testing modalities, such as immunoassay, PCR, and sequencing, to meet population diagnostic priorities. Testing modalities carry different advantages and disadvantages, which must be considered when addressing public health priorities. Modalities can be deployed in different ways depending on specific population health needs within a community and can be rapidly adjusted to address emerging healthcare challenges, such as disease outbreaks. For example, to guide oncology treatments, nanopore sequencing could be used to identify key mutations in tumors and would allow the detection of rare but clinically significant mutations. The same technology could also be deployed to detect infectious disease. Compared to traditional nucleic acid testing, the speed and portability of nanopore sequencing could assist in rapidly mapping outbreaks and help health systems proactively recognize and manage public health threats.

Tailor access to testing to align with target groups

Easy access to testing was commonplace during the pandemic. Near-patient and at-home sampling and testing could have much broader applications beyond COVID-19, improving access and turnaround times. For example, in the United Kingdom, about 90 percent of results processed through NHST&T were reported within 72 hours, and patients had direct access to results. Maintaining improved access to diagnostic testing could also have a profound impact on reducing morbidity and health inequities. It would involve two main steps.

[18] Polymerase chain reaction (PCR) tests detect genetic material from a specific organism, such as a virus. Endpoint PCR can be used to increase testing throughput compared to real-time PCR, though testing performance may be sacrificed.

[19] Cameron Razieh et al., "Differences in the risk of cardiovascular disease across ethnic groups: UK Biobank observational study," *Nutrition, Metabolism and Cardiovascular Diseases*, November 2022, Volume 32, Number 11.

First, health systems would need to design an integrated ecosystem of point-of-care technologies that overcomes the logistical complexity of decentralized testing to ensure that patient care history is uninterrupted. For instance, whether a prescribed test is taken in a primary-care facility, in a pharmacy, or at home, a standardized system would be required for different stakeholders to access results regardless of which approach was used.

Second, health systems would need to identify the disease areas and patient groups that would benefit most from improved access to testing. Then they could provide more equitable care access and address health inequities by developing specific programs for underrepresented groups that have historically not engaged with health systems. For example, they could perform localized population screening in high-risk groups, as has proven successful for Q fever within high-risk groups in the Netherlands.[20]

Innovate on technology, digital, and service in parallel to maximize impact

Physical distancing during the COVID-19 pandemic made it necessary for health systems to look for new ways to reach people quickly, leading to swift and substantial innovation across the value chain, including the use of new assay types, telemedicine, test-result apps, and at-home testing-kit delivery. Although the pandemic has subsided, health systems could continue to prioritize innovation to benefit both patients and physicians and to help address persistent challenges, such as a pathology workforce shortage.[21] Three opportunities are particularly relevant to health systems following the many lessons learned during the pandemic. They can be most adequately addressed through both digital and service improvements.

First, health systems could deploy new diagnostic modalities (LAMP[22] and long-read sequencing,[23] for example) and previously underused diagnostic modalities, such as endpoint PCR testing. During the pandemic, these testing methods had an important complementary role to real-time PCR tests, typically enabling higher volumes, faster turnaround times, and improved access. These methods could also be employed in situations not related to COVID-19: LAMP, for instance, could be used for near-patient molecular testing for influenza.

Second, along with new diagnostic testing options, digital technologies were also crucial for healthcare delivery throughout the pandemic, with telemedicine and app-based engagement scaling substantially.[24] Health systems could continue to evolve their thinking on how the diagnostic workflow can be digitalized to help them more effectively share data and improve clinical decision making as patients travel among care delivery organizations (from primary to secondary to tertiary care, for instance).

Third, delivering new diagnostic tests and digital solutions will require models of service to evolve beyond those developed during COVID-19 testing. This continued evolution of service models could help increase the efficiency and efficacy of IVD testing for patients by reducing barriers to access, such as long waiting times to access primary care.

Strengthen the integration and use of diagnostic data to improve clinical and operational performance

Many health systems saw a step change in their ability to report data because of increased coordination and sharing of testing data. These data helped improve the robustness of testing systems and informed strategic decision making.

[20] Daphne F.M. Reukers et al., "Targeted screening for chronic Q fever, the Netherlands," *Emerging Infectious Diseases*, July 2022, Volume 28, Number 7.

[21] A workforce census by the Royal College of Pathologists in 2018 indicated that only 3 percent of NHS histopathology departments in the United Kingdom have enough staff to meet clinical demand, and a quarter of all histopathologists are aged 55 or older; in Germany, only one in 200 physicians is a pathologist, the lowest ratio in Europe. See "College report finds UK wide histopathology staff shortages," The Royal College of Pathologists, September 16, 2018; Bruno Märkl et al., "Number of pathologists in Germany: Comparison with European countries, USA, and Canada," *Virchows Archiv (European Journal of Pathology)*, February 2021, Volume 478, Number 2.

[22] Loop-mediated isothermal amplification testing provides a quicker and cheaper alternative to PCR because it uses a constant temperature.

[23] Long-read sequencing allows larger parts of the genome to be sequenced, reading more than 10,000 base pairs versus 75 to 300 base pairs for short-read sequencing. Emma Johnson and Sobia Raza, "What is long read sequencing?," PHG Foundation, accessed June 7, 2023.

[24] Oleg Bestsennyy, Greg Gilbert, Alex Harris, and Jennifer Rost, "Telehealth: A quarter-trillion-dollar post-COVID-19 reality?," McKinsey, July 9, 2021.

For example, in the United Kingdom, the availability of daily testing data at the local-authority level informed the deployment of mobile testing units in places such as Blackburn.[25]

Going forward, to increase patients' engagement with their own health, health systems could empower patients to take ownership of their healthcare data by making it available through apps or other digital tools. Systems could use those data to ensure that services address specific patient requirements and drive higher standards. For example, some leading imaging companies have created platforms that integrate data (including imaging data) to rapidly generate patient-specific insights.[26] These platforms enable healthcare systems to build their own apps or use third-party apps that can work directly within the platform to allow patients and healthcare clinicians to monitor health statuses. Health systems could couple IVD testing with similar platforms to better monitor patient health.

Through patient interactions with these apps and digital tools, health systems could also capture and integrate patient-reported outcomes to produce distinctive data sets that could inform better diagnosis, treatment planning, and patient management for chronic diseases such as diabetes. Furthermore, data could be leveraged to improve healthcare research and clinical decision making, which would, in turn, allow for a deeper understanding of diseases at both the patient and the population level.

Finally, health systems could embed real-time data into strategic planning and drive operational improvement across regional and national networks. During the early stages of the COVID-19 pandemic, data about testing and positivity rates were used to inform decisions about the interventions required in many countries, such as confinement restrictions to control the spread of infection.[27] This same approach could be employed for other communicable diseases to limit the spread of disease.

Embrace partnerships across the value chain

Strong partnerships have been at the heart of the COVID-19 response across Europe, enabling testing at scale in ways that would have been even more challenging if done in isolation. This experience provides opportunities to sustain innovation.

[25] John Fitzpatrick, "Blackburn facing 'rising tide' of coronavirus cases as extra restrictions are imposed," *Telegraph*, July 15, 2020.
[26] "Teamplay digital health platform," Siemens Healthineers, accessed June 13, 2023.
[27] *Testing for COVID-19: A way to lift confinement restrictions*, OECD, May 4, 2020.

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Strategic partnerships could help maintain the pace of technological advancements by developing new tests and technologies that are aligned with national priorities. In the Netherlands, for example, the STRIP consortium developed an optimized robotics testing platform that enabled an increase in testing capacity.[28] Public bodies may support efficient testing and trials to deliver more robust, detailed evidence bases for new approaches.

Partnerships could also help improve data utilization to inform healthcare planning. Physicians and researchers could deploy new analytics capabilities developed in the commercial sector to support improvements in population-wide healthcare delivery. Finally, partnerships with companies outside the healthcare sector could help enhance lab processes and boost operational productivity by refining standards and setting ambitious goals. For example, much of the at-home testing in the United Kingdom was underpinned by logistics and delivery support from several organizations, including Amazon, DHL, and Royal Mail.[29]

European health systems have an opportunity to build on the progress made throughout the pandemic to develop an in vitro diagnostic testing model fit for the increasingly engaged, digitally sophisticated population we see today. As health systems grapple with myriad challenges affecting their ability to deliver high-quality care in a sustainable way, a more effective and efficient diagnostic service could play a crucial role in improving patient outcomes while avoiding costs associated with delayed diagnosis and treatment.

[28] Peter H. L. Krijger et al., "A public–private partnership model for COVID-19 diagnostics," *Nature Biotechnology*, October 2021, Volume 39.
[29] *Test and Trace: Overarching privacy notice*, UK Health Security Agency, December 14, 2021.

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