THE ROLE OF DECENTRALIZED DIAGNOSTICS IN HEALTHCARE DELIVERY

Executive Summary

The COVID-19 pandemic exposed weaknesses in the traditional healthcare delivery system and forced us to change how we think about patient care. Existing disparities in care for underserved communities widened, and the limitations and weaknesses in the broader system became more acute and evident.

Patients, providers, and government entities became more comfortable with telemedicine, consequently, telehealth claim volumes rose significantly in early 2020 and then stabilized at about forty times the volume of pre-COVID levels. It is the premise of this document that technological advancements and societal acceptance of telemedicine have opened the door for the uberization of diagnostic testing. COVID-19 has taught us that decentralized testing, specifically a combination of point-of-care (POC), over-the-counter (OTC), and home Rx solutions, can provide essential missing elements to enable the expansion, increased utility, and adoption of novel healthcare models.

We propose utilizing the proven POCTRN and RADx methodologies, processes, and infrastructure to further expand decentralized diagnostic testing and accelerate next-generation POC and at-home-testing technologies. Selecting promising testing platforms to fund will require balancing a number of priorities: affordability, accuracy, ease of use, ability to scale, and more importantly, designs that offer flexibility to diagnose a range of diseases or conditions.

Participation for this program should be on a continuum that can support early-stage high-risk, high-reward projects and lower-risk more mature development efforts. The goal of this program will be to accelerate promising technologies through proof of concept, development, follow-on funding, regulatory approval, scale-up, and market launch.

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Healthcare Trends, Challenges, and the Impact of COVID-19

The importance of improving healthcare outcomes, cost efficiencies, and accessibility has become critical as expenditures for acute and chronic conditions have increased to unsustainable levels.

The COVID-19 pandemic created enormous demand for resources—from critical care rooms to ventilators and nurses—to treat an unprecedented number of patients. Routine healthcare came to a standstill; chronic disease management and even acute disease cases were left untreated. The pandemic revealed gaps and deficiencies in the broader healthcare system, including distance to care, supply chain constraints for essential products, clinician shortages, and a lack of good alternatives for patient management.

This new and sudden reality made tools like telemedicine more essential and spurred regulators to adjust rules to expand access to care and medication, driving utilization and expansion of new care models that had been slow in gaining adoption prior to the pandemic.

One of the key shortcomings of our healthcare system was the overreliance on centralized lab-based diagnostics, in both the hospital and outpatient care settings. The need for distributed diagnostic capability and capacity was acutely felt during this pandemic and will be essential for future pandemic preparedness.

Moving forward, employers, start-ups, and non-traditional healthcare players like Amazon, Apple, and Walmart will be an increasingly potent force driving the transformation of the healthcare experience. (See Table 2b)

Healthcare Access

The COVID-19 pandemic had an immense impact on access to healthcare. By May 2020, 1,954 health centers nationwide had temporarily closed their doors to in-person patients and patient visits dropped by 43%[4]. Decentralization of healthcare included rapid adoption of virtual technologies and growth of alternative testing locations. A greater emphasis was placed on POC and at-home testing, as it decreased patients' exposure to COVID-19. In-vitro diagnostic businesses quickly scaled up assay production and deployed tests closer to the point of use in airports, schools, and workplaces.

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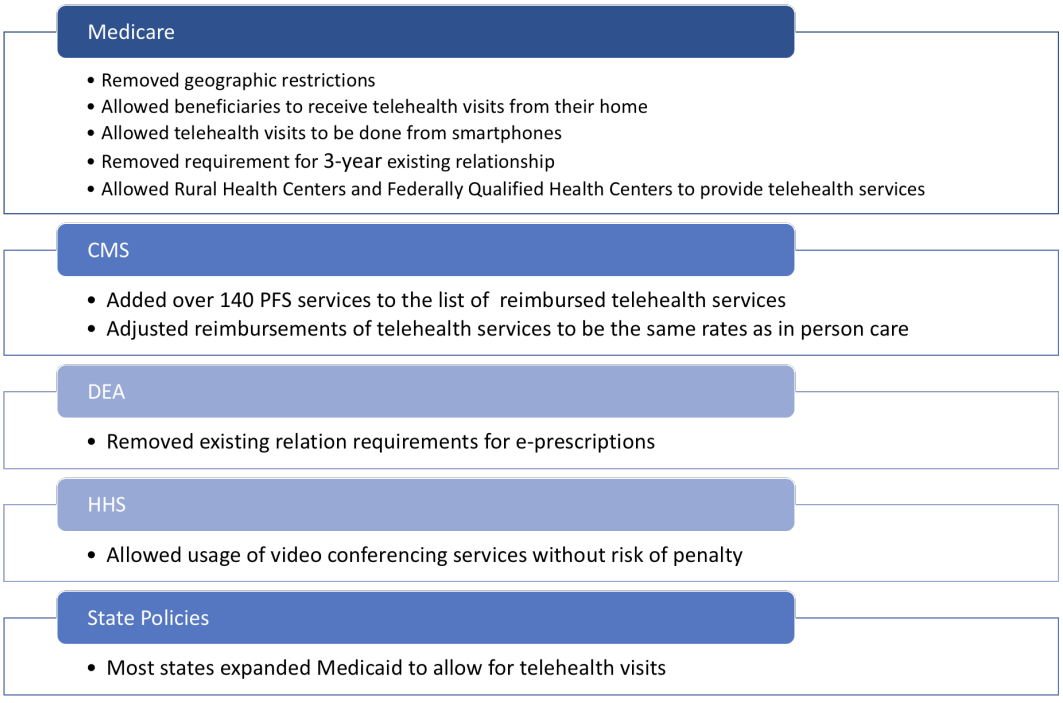
Exacerbated Healthcare Disparities in Underserved Populations

The adverse effects of COVID-19 have disproportionately affected the underserved populations. According to a study conducted by the Kaiser Family Foundation, COVID-19 hospitalization rates per 1000, were 24.6 for Black patients, 30.4 for Hispanic patients, 15.9 for Asian patients, and 7.4 for white patients[1]. This reflects reports that underserved communities are more likely to exhibit lifestyles that place them at greater risk of transmission, due to living conditions, jobs that cannot be done remotely, and utilization of public transportation. Initiation of treatment often lags due to poor access to healthcare infrastructure. Additionally, these communities have an increased prevalence of pre-existing conditions (such as obesity, diabetes, and hypertension) further widening outcome disparities.

Telemedicine

As facilities closed and fear of COVID-19 spread, the need for greater healthcare accessibility became apparent. In response, modifications to legislation and regulations paved the way for telemedicine expansion. These changes came from Medicare, Medicaid, DEA, CMS, and HHS, and quickly addressed obstacles that had limited adoption for years[10].



As a result of these policy changes, telehealth claim volumes rose significantly in early 2020 and then stabilized at a almost 40x of pre-COVID-19 levels. Additionally, consumer

and provider attitudes have evolved with increasing telehealth utilization. Recent studies found that patients interest in telehealth for upcoming care increased by 65% since COVID-19[3], and that 82% would be willing to use telehealth again after trying it at least once. 57% of providers view telehealth more favorably than they did before COVID and 64% are more comfortable with telehealth use[6].

Telemedicine can increase the accessibility of healthcare as it allows medical care to be transferred to more adaptable settings. For example, AMD Global Telemedicine created portable TeleClinics that can be brought to non-traditional healthcare settings[22]. Telemedicine can also be deployed through smartphones such as Amwell's mobile application[15]. Many telemedicine companies are available 24 hours a day, further increasing patient access.

Telemedicine reduces costs for patients and the healthcare system. On average, virtual appointments are $62 less expensive than in-person physician visits and $932 less expensive than emergency department visits[14]. Additional cost savings are also realized by eliminating travel time, minimizing wage loss, and reducing unnecessary hospital visits and readmissions.

Future Opportunities in Diagnostic Development

A combination of POC, OTC and home Rx testing solutions will be essential for the successful implementation of emerging healthcare models.

In the future, a combination of remote patient monitoring, telemedicine, and technology platforms/solutions supported by accurate, cost-appropriate, decentralized diagnostics can support a significant share of healthcare needs. These models will not replace specialists and inpatient care, but will increase the overall effectiveness of the system by improving speed of diagnosis for simple conditions and appropriate escalation of care based on acuity.

Innovators are rapidly creating and expanding models that combine technology and digital patient interactions to improve diagnosis of simple conditions (ear infections, flu, strep, STIs), manage chronic diseases effectively, and avoid repeated/unnecessary visits to emergency rooms and hospital admissions.

It is important to note, while this whitepaper focuses on how decentralized diagnostic testing will amplify technological changes and improvements in care, with some modifications these more comprehensive solutions have the potential to democratize access to healthcare across all communities.

To consider the role of decentralized diagnostics in healthcare, we discuss three areas of impact: 1) prevention and screening, 2) non-emergent acute care, and 3) chronic disease management.

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1) Prevention and Screening

Earlier diagnosis presents a clear opportunity to enable longer, healthier lives.

There is a strong push on a global level to detect and identify diseases earlier in order to optimize healthy living. This trend is observed in patients, with increased interest in healthy living and self-care, as well as in health policy, with a growing focus is on prevention.

POC and OTC tests that report blood counts, lipid profiles, sexual health, and other biomarkers of importance are able to provide patients with faster and more accurate diagnoses. These areas continue to expand in scope and interest, including tremendous opportunities to improve oncology, neurology, and metabolic health, among other areas.

2) Non-Emergent Acute Care (Physical and Virtual "Walk-In" Clinics)

Acute, non-emergency medical care is a rising need, particularly in medically underserved locations, and is the most common telehealth use case today among payers.

An increasing number of consumers are opting for convenience and cost over credentials and provider continuity. Walk-in clinics, telehealth services, neighborhood pharmacies, mobile labs, home delivery, and telemedicine will combine to create a future healthcare model to reduce barriers and expand the spectrum of services available.

Current Testing Offerings	Potential Testing Additions
• A1C, Blood Glucose, Cholesterol • Covid, Flu, Strep • Urinary Tract Infection • Colorectal Cancer • Marijuana, Nicotine, Drug tests • Paternity and Ancestry • Menopause and Testosterone • Allergy test • HIV	• STIs • Respiratory Tract Infections • Diarrheal Infection • Acute Febrile Illness • H. Pylori • Infection Severity • Stroke • Anemia • Myocardial Infarction

3) Chronic Disease Management

Although walk-in clinics can be helpful for those who temporarily lack access to a family doctor, they are not a substitute for longitudinal care with a personal provider.

The use of remote care and digital strategies for chronic disease management supports equitable access to health services across broad geographies, increases patients' self-care management, and reduces the patient's time away from daily life.

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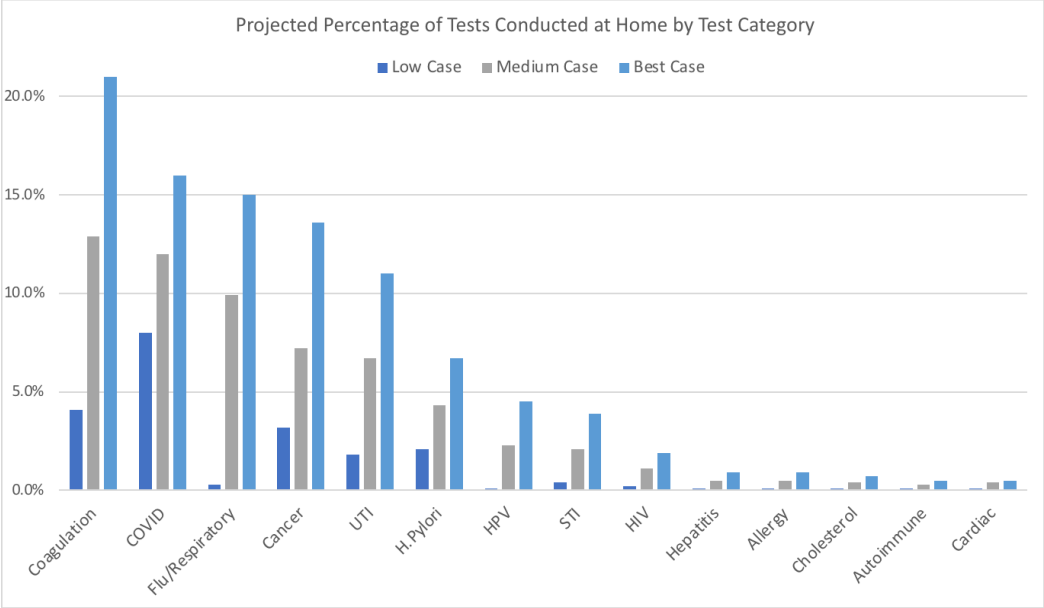
Although a variety of telehealth strategies have been used successfully to deliver lifestyle interventions for weight reduction and improvements in metabolic risk factors, their translation into clinical practice is complex due to the need to monitor outcomes remotely.

Expanding decentralized diagnostics creates opportunities to develop individualized clinical pathways and expands the patient's role in managing their conditions, likely leading to better treatment adherence and improving health outcomes. The success of these at-home and community clinic techniques has been evident within diabetes and anticoagulation populations for years, and it is in these populations that POC and home testing devices serve as the pivotal link to the development of sustainable patient-driven engagement.

Accelerated POC testing tools enhance work-up and diagnosis of conditions such as diabetes, asthma, and chronic obstructive pulmonary disease. Several conditions will benefit from improved access, accuracy, and decentralization of diagnostics,[8] including:

- Metabolic & Hormone Levels
- Cardiac Function
- Antibiotic Resistance
- Chronic Kidney Disease



Challenges to Expanding Decentralized Diagnostics

While there are significant opportunities to expand home and POC diagnostic utilization to improve health care, there are also some foundational challenges.

Diagnostic safety and errors affect millions of patients in the United States each year. Reports have estimated that one in three patients has first-hand experience with a diagnostic error[13]. As diagnostics expand in the home and POC setting, we must ensure proper use, correct and timely reporting of results, appropriate follow-up care, and safe use of the diagnostic tools themselves.

Reporting capabilities and fluid integration to EHR/LIS systems are essential to capture the full benefit of home and POC diagnostics. Ensuring security and privacy have become increasingly complex and challenging due to cybersecurity threats and interconnectivity.

Good patient outcomes hinge on accurate and timely diagnoses. However, sole reliance on electronic tools to deliver health services may limit the patient's ability to obtain and understand relevant health information. Awareness and education are pivotal to expanding access and increasing the positive impact to patients, especially those in underserved communities.

Future Funding Programs

Given the critical role that decentralized diagnostics will play in future pandemic preparedness and healthcare models, innovative funding programs, as typified by RADx, should be leveraged to accelerate their development and adoption.

Funding should be focused on testing platforms that combine:

- Affordability
- Accuracy
- Ease of use
- Expanded reach
- Designs with flexibility to diagnose a broad range of factors

Advanced Research Projects Agency for Health (ARPA-H) and pandemic preparedness initiatives provide the opportunity to reconceptualize the role of the government as an engine for the transformation of healthcare and, in our case, diagnostic testing where emergency-fostered interagency collaboration and public partnerships demonstrated the possibilities for meaningful change.

Funding

We see the funding opportunities targeted to various levels of technology maturity:

Early Stage: Projects that exhibit a strong business case and solid proof of concept. These projects will be incubated and receive mentoring and limited funding for up to one year to achieve proof of feasibility. Funding recommendation: Up to $150K

Validation Stage: More mature projects with strong business opportunities and completed proof of feasibility should be funded based on the remaining milestones necessary to remove technological risk and achieve external validation and design freeze. Funding recommendation: Up to $2M.

Scale-up and Pilot Demonstration Stage: Projects seeking pilot implementation of technologies in targeted settings and populations. These will be provided the opportunity

to showcase results and refine the technology and deployment model, to improve speed and efficiency to scale. Funding recommendation: $5M+

Projects that achieve successful outcomes in the early-stage program may enter the technology validation program. Successful validation will lead to either professional funding, license to industry and to a lesser extent SBIR phase 2 funding, or other governmental funding opportunities. Pilot demonstrations could be employed on a selective basis.

Process

The process would begin with many applications meeting minimum qualification requirements. Following an initial triage process, applicants would be separated into categories based upon their advancements in two dimensions: Business Opportunity and Technology Readiness.

- **Business Opportunity** incorporates problem identification, stakeholder validation, development of an unmet need, key product attributes, and proof of value. In addition to these traditional needs definition and market validation elements, a clear understanding of how the technology integrates into the continuum of care and the health economics of incorporating the technology is essential.
- **Technology Readiness** incorporates idea generation, proof of concept, and proof of feasibility. Only projects with a well-validated business opportunity have high technology readiness groups. The initial stages will be an idea or concept of how to solve the unmet need, and more advanced stages will include proof of concept and proof of feasibility.

Deep Dive (2-4 weeks)**:**

RADx demonstrated an efficient process for quick assessment of proposals using what is called “Deep Dive”. It consists of a validation assessment of applicants through a written submission. At the end of the Deep Dive, the team will present their risk assessment to a multidisciplinary panel of experts (MPE), based on a clear standardized set of criteria along with a proposed path forward, including milestones and a budget with funding needs. After the presentation, the panel will concur or disagree with the team’s recommendation.

Work Package (several months)**:**

Those projects that are deemed meritorious by the selection panel will receive tranche funding commensurate with the milestones proposed by the team during Deep Dive. During this phase, the team works with the applicant and presents progress reports to the MPE with recommendations on how to proceed.

Completion:

A project that has completed a work package should be ready to obtain new sources of funding, either professional or governmental, commensurate with requirements for market entry.

Project Resources

Multidisciplinary Panel of Experts: Members should include clinicians, regulatory, manufacturing, validation cores, business, technologists, NIH.

Team Members: A team leader and a program manager. The team leader would be a senior-level professional, preferably within an IVD or medical device company. Program manager with program management experience preferably in the medical industry.

Ad Hoc Technical Experts: To complement expertise on the teams and for specific projects as needed.

Regulatory Consultants: To help teams develop an achievable regulatory strategy.

Work Plan Review Panel: Group of experts in IVD, technical, and business that help teams maximize the impact of their presentations to the MPE. Serve as a dry run opportunity for the teams.

Clinical Advisory Board: Group of clinical experts in laboratory medicine that can aid teams in understanding the possible issues with their products in applicable community segments and the usability of their devices.

Core Centers: Institution with the laboratory, personnel, and equipment capabilities to validate tests, to store samples, with BSL 3/4 capabilities and ability to adapt quickly to changing equipment, type of samples, test, and speed to provide assessments.

Coordination Center: Entity with the systems, accounting, and personnel capable of centralizing and managing all the activities required to issue solicitations, administer multi-stage selection processes, and manage awards.

Personnel Contracting Entities: Organizations with experience and proven networks of experts that can quickly adapt to the needs of the program

APPENDIX

POCTRN

The NIBIB created POCTRN in 2007 after a NIH workshop and the subsequent article, "Improving Healthcare Accessibility through Point-of-Care Technologies", published in *Clinical Chemistry* that same year. The goals of its creation were:

- To facilitate the development of a pipeline of point-of-care technologies with commercialization potential
- To utilize a center structure in order to enable incorporation of clinical and user needs in the development process
- To provide expertise and resources to address early barriers to commercialization and implementation

Independent centers called for proposals, based on clear thematic areas of interest. They then selected and managed the project teams. CIMIT acts as a coordination center providing resources, training courses, solicitation software (COLAB), tracking tools (GAITS), meetings, and business expertise.

Table 1: **POCTRN AWARDEES**

2007 Award Recipients	
Point-of-Care Center for Emerging Neurotechnologies	*University of Cincinnati*
Center for Point-of-Care Technologies Research for Sexually Transmitted Diseases	*Johns Hopkins University*
Center for Point-of-Care Technologies for Disaster Readiness	*University of California, Davis*
Center to Advance POC Diagnostics for Global Health	*Program for Appropriate Technology in Health (PATH)*
2012 Award Recipients	
Center for Point-of-Care Technologies Research for Sexually Transmitted Diseases	*Johns Hopkins University*
Center for Innovation in Point of Care Technologies for the Future of Cancer Care	*Boston University*
Point of Care Technology Research Center in Primary Care	*CIMIT*
2018 Award Recipients	
Atlanta Center for Microsystems Engineered Point-of-Care Technologies	*Emory University*
Center for Point-of-Care Technologies Research for Sexually Transmitted Diseases	*Johns Hopkins University*
Center for Innovation in Point of Care Technologies for HIV/AIDS at Northwestern	*Northwestern University*
Center for Advancing Point of Care in Heart, Lung, Blood, and Sleep Diseases	*UMass Medical School*

RADx(SM)

The Rapid Acceleration of Diagnostics initiative was launched in response to the COVID-19 pandemic. It's goals were to accelerate the development, validation, and commercialization of innovative point-of-care and home-based tests, as well as improvements to clinical laboratory tests. The existing POCTRN cores were utilized and expanded to support all phases of the product development pipeline from conceptualization and design to reduction-to-practice, performance evaluation, clinical validation, and scale-up of manufacturing. The program was divided into 3 stages.

- Deep Dive: Two week rapid assessment to identify key risks and determine resources necessary to mitigate risks
- Work Package 1: One month to mitigate high-risk barriers to success
- Work Package 2: Full range of activities needed to distribute a viable product to the public at scale

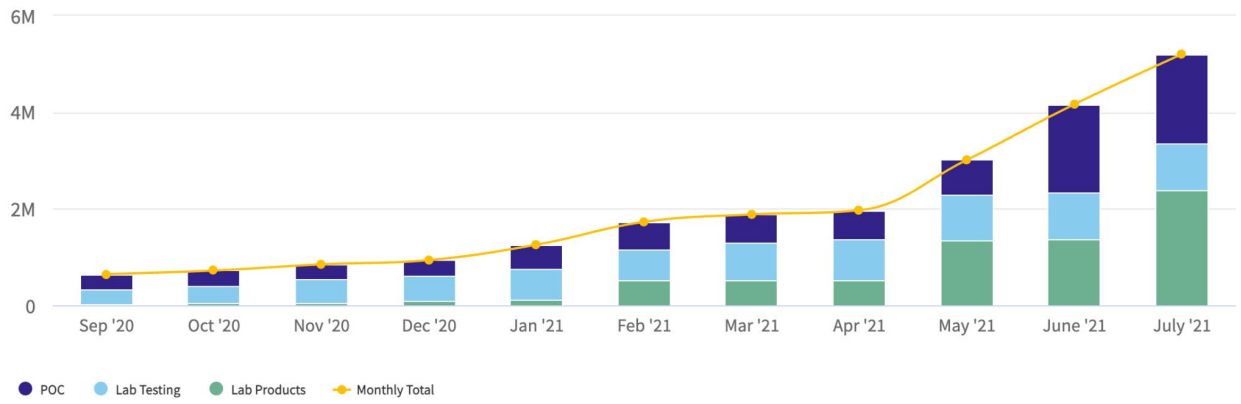
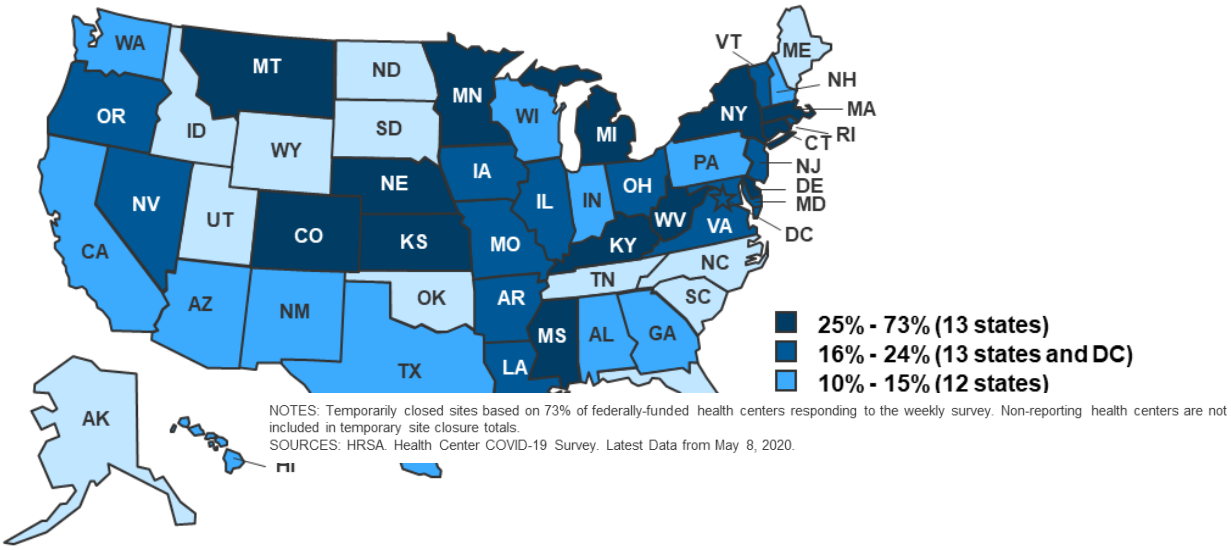


Figure 1: **More than 30 projects reached the Work Package 2 stage, resulting in an increased test production capacity of millions of tests per day[23].**

Percent of Health Center Service Delivery Sites Temporarily Closed due to Coronavirus, as of May 8, 2020

Figure 2: The COVID-19 pandemic stressed existing healthcare systems, reducing availability of in-person care[4].



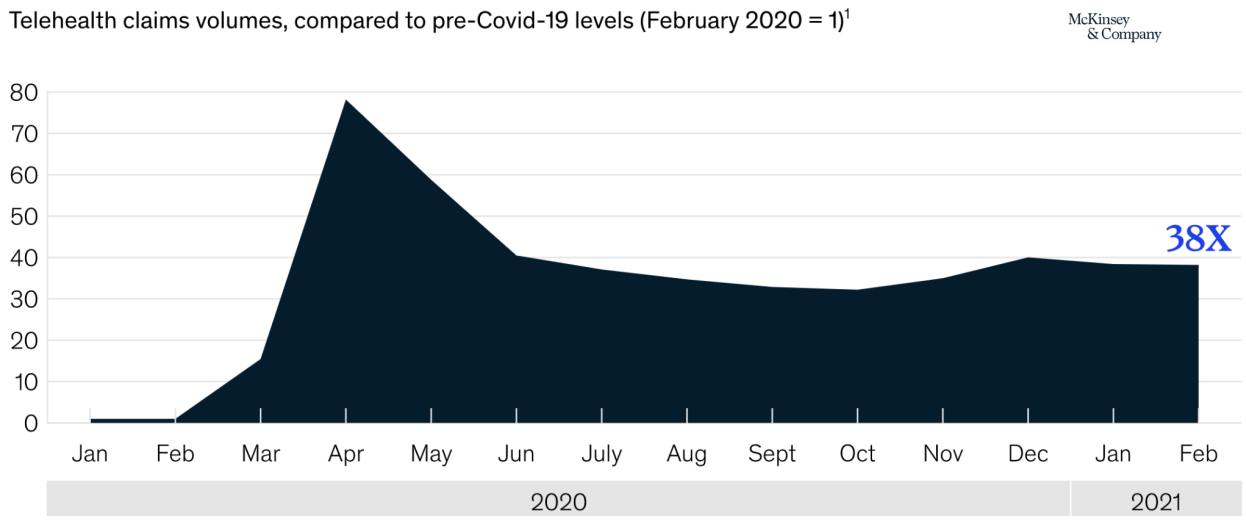


Figure 3: **During the pandemic, telehealth utilization volumes peaked at 80x pre-pandemic levels, and have since stabilized at nearly 40x[3].**

Tables 2a & 2b: **Industry Activity and Innovation with Remote & Alternative Care Models**

2a. Telemedicine Companies

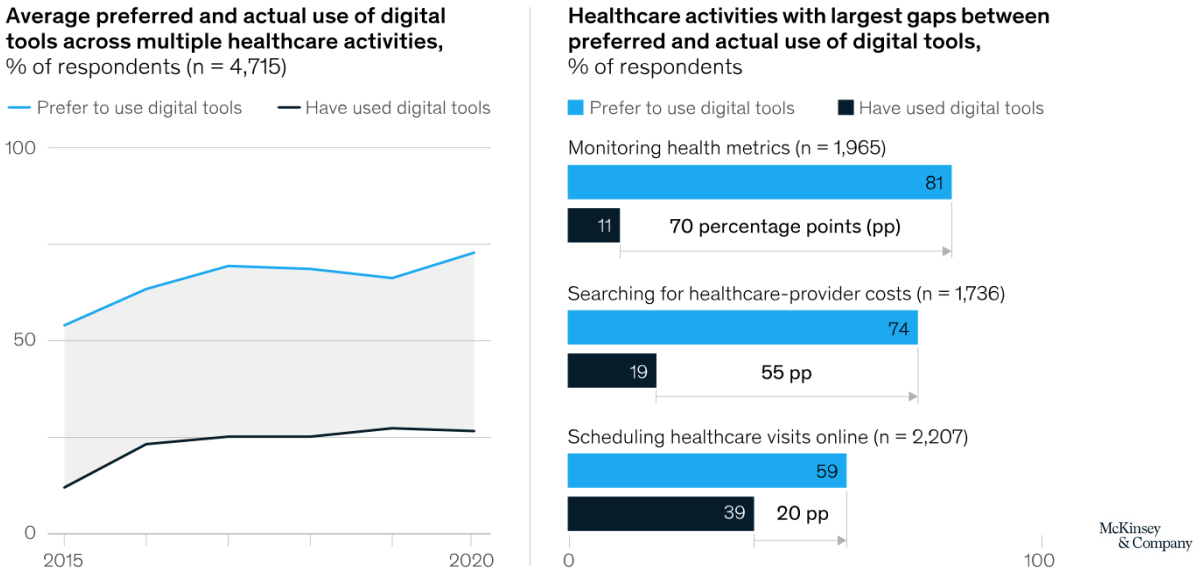
Company	Services	Impact and Utilization
AMD Global Telemedicine	➢ Video Consultations ➢ Remote Monitoring (Hardware) ➢ Portable TeleClinic	Delivers telehealth services in over 100 countries worldwide. Enables remote treatment of cardiac patients. +33% (as of 2020)[22]
Amwell	➢ Hardware Devices ➢ Mobile Application	Offers 24-hr teleconference service to HCPs. In 2020, over 40,000 providers used the platform. +120% (as of 2021)[15]
Azova	➢ Video Consults ➢ Diagnostic Testing	Enabling proctored tests to be employed to meet air travel requirements
Doctolib	➢ Video consultation	Global offering with more than 135,000 practitioners and over 100,000 virtual consultations a day.

		+100% (as of 2020)[9]
eMed	➢ At-Home Diagnostic Testing	Providing remote identity verified testing for high stakes situations
iCliniq	➢ Second Opinion Video Consultation ➢ Virtual Hospital	A medical second opinion platform with a network of doctors in India, UK, US, Singapore, UAE, and Germany. +8-9% (as of 2020)[11]
MDLive	➢ Video consultation with optional physical followup	Offers therapists, pediatricians, and doctors to over 40 million global members. +300% total bookings (as of 2020)[20]
Oscar	➢ Health Insurance Connection Platform	Health insurance company that focuses on telemedicine, technological interfaces, and transparent claims pricing systems 1.34% (Quarter 2:1 of 2020)[2]
Teladoc Health	➢ Video Consultations ➢ AI Analytics ➢ Devices & Licensable Platform Services	180 million visits in 2020. Operates in 130 countries. +203% (2020)[12]
2nd.MD	➢ Second Opinion Video Consultation	Partnered with Boston Children's Hospital to provide millions of people across US virtual access to specialist

2b. Non-Traditional Healthcare Players

Company	Services	Impact and Acquisitions
Amazon	➢ Employee Health Clinics ➢ Pharmaceutical Delivery ➢ In-house Laboratories & Diagnostic Testing ➢ AWS Cloud & Health Lake ➢ AI Analytics ➢ Wearable Patient Monitoring	- Expanded employee health clinics, dubbed Amazon Care, and acquired PillPack to expand into the prescription pharmacy business. - Extremely well positioned to provide logistical support to digital health companies that require diagnostics, monitoring and medication delivery. - AWS is also a growing component in healthcare delivery, integrating AI capabilities into cloud storage and processing solutions.
Apple	➢ Wearable Patient Monitoring ➢ Health Record Storage	- Positioned to enable wearable & smartphone platforms to monitor an increasing number of health data points, vital signs and activity. - Proprietary health records give customers direct access to their health info on their iPhones. - Strategic approach to overcoming regulatory barriers for health products by directing users to seek medical attention, instead of providing a conclusive diagnosis. (i.e. ECG function on Apple Watch)

Google	➢ AI Analytics	-Strategic focus on Artificial Intelligence - Developing machine learning tools to analyze medical records and publishing academic research out of its research group, Google Brain. -Working on a consumer-facing medical records tool to make it easier for patients to see, organise and share their health data.
Walmart	➢ Walmart Health Centers ➢ Video Consultations	- Expanding access to Walmart Health Centers providing preventive care, chronic disease management and minute clinic style care. - The purchase of telehealth provider MeMD will add the ability to offer specialty consults nationwide. - For many Americans, Walmart could become the go-to option for basic healthcare services.



Source: McKinsey Consumer Health Insights Survey, 2020

Figure 4: **Consumer preference for use of digital tools in healthcare is outpacing availability of solutions, especially those focused on monitoring and cost reduction[3].**

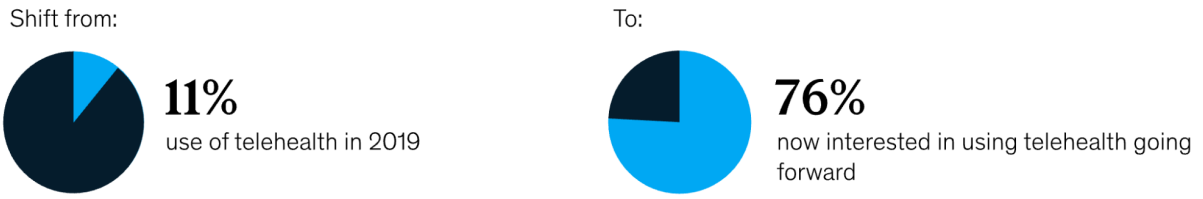


Figure 5: **Prior to the COVID-19 pandemic only 11% of the population used telehealth, but now as a result of the pandemic 76% of the population are interested in future use[3].**

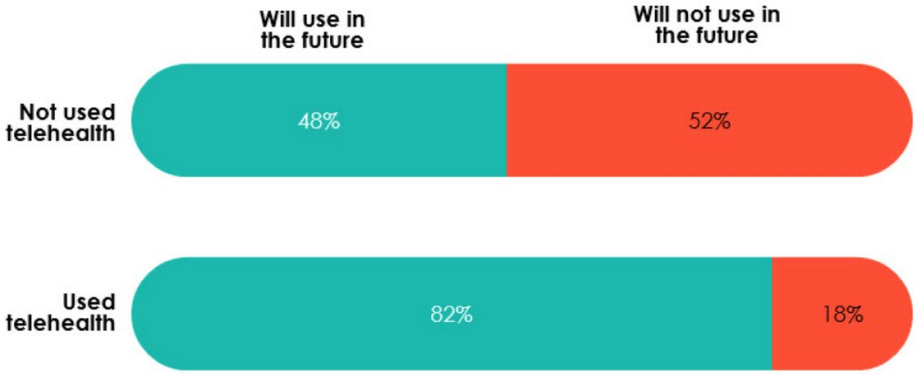


Figure 6: **Patients who have used telehealth are more likely to use it again in the future compared to those who have never tried it[6].**

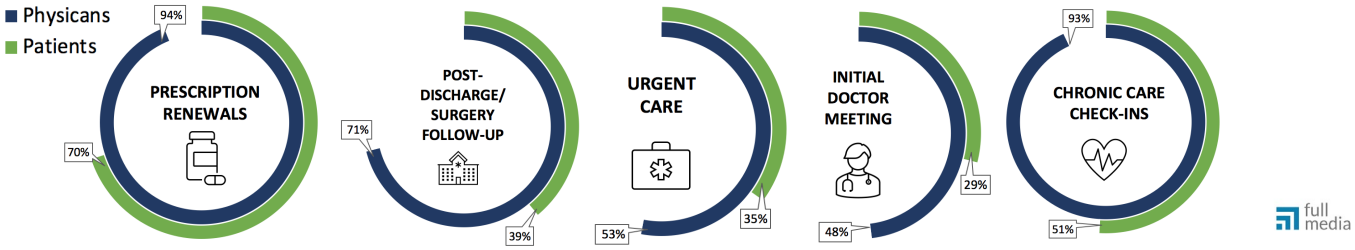
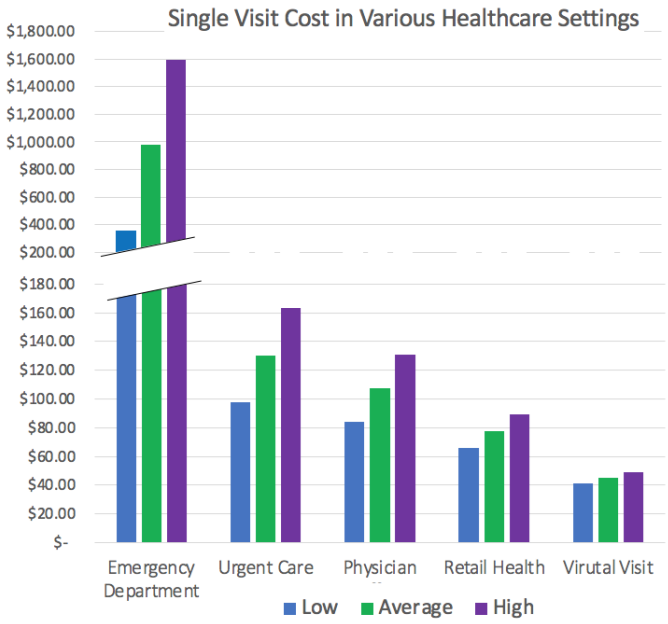


Figure 7: **Willingness to utilize telemedicine is highest for prescription renewals and lowest for initial doctor meetings. Overall, providers are more willing to utilize telemedicine than patients[7].**



American Journal of Emergency Medicine

Figure 8: **Virtual care allows for significant cost savings per visit, across various healthcare settings[14].**

Figure 9: **Comfort with use of at home diagnostics, especially those to diagnose current infections, is increasing with successive generations[17].**

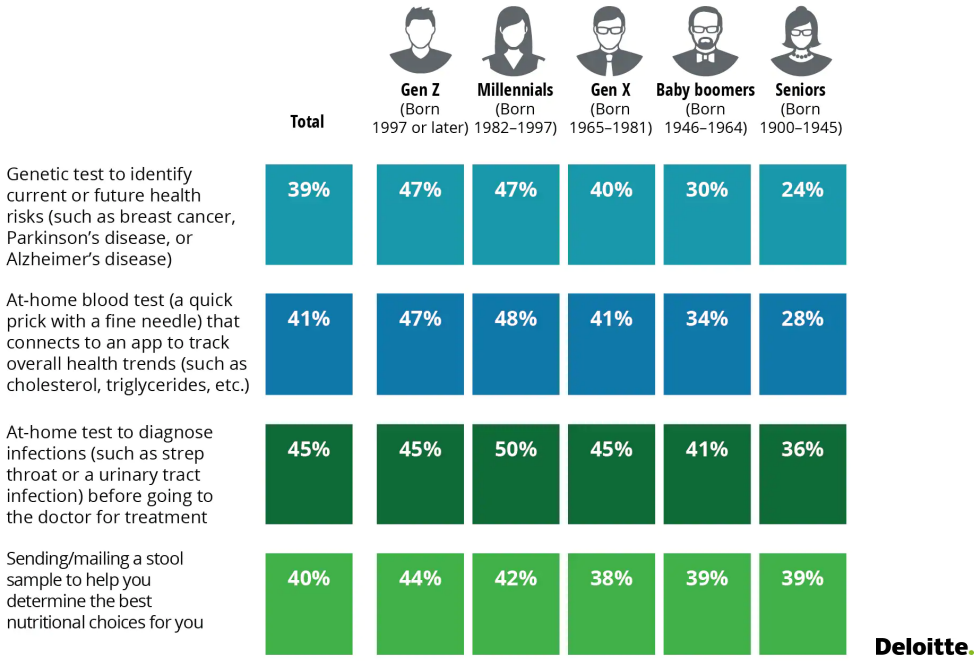


Figure 10: **Consumer trust in institutions' handling of health information varies widely, with trust in government and tech companies being lowest[18].**

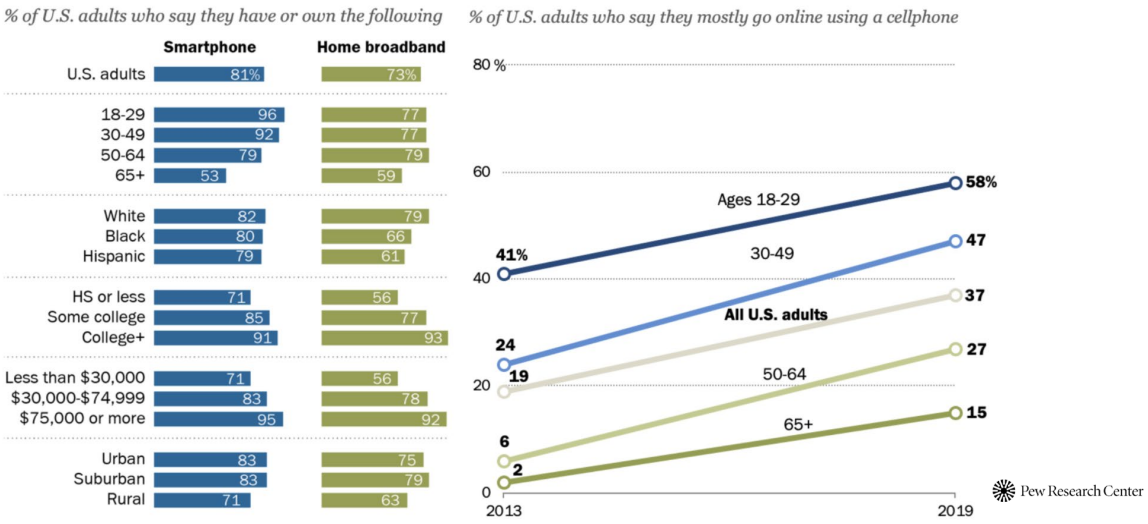


Figure 11: **Internet access has become more widespread, especially through smartphone proliferation. Although some demographic groups lag behind[16].**

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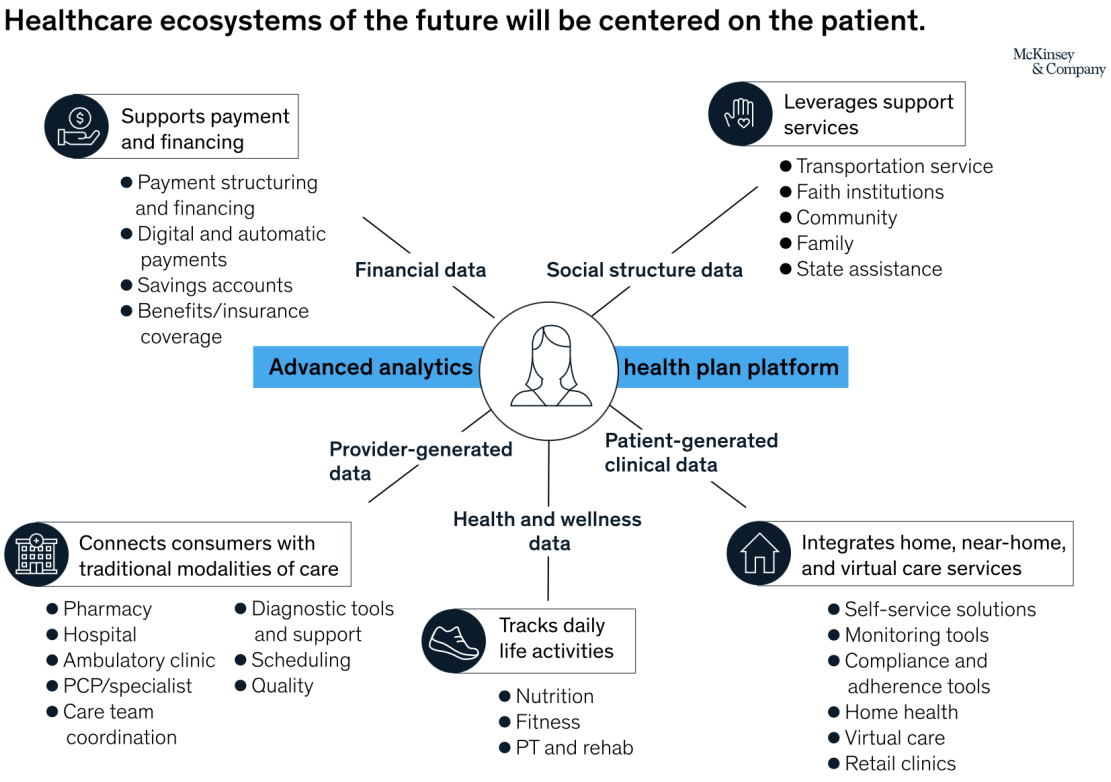

Figure 12: **Technology is just one facet of the health industry transformation. It must be integrated within the whole system, in conjunction with the other elements such as data analytics, payer involvement, and patient-centered models[21].**

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