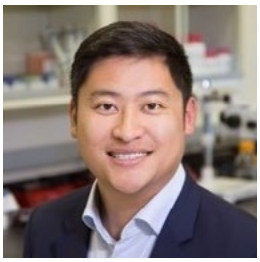
How the current pandemic will shape healthcare innovation for the next decade

Michael Pereira
President and COO



Brian Wong
Senior MedTech Research Analyst

The COVID-19 pandemic has thrust a number of emerging healthcare trends into the spotlight with a renewed sense of urgency. Memories of the current pandemic and its devastating impact is likely to drive healthcare innovations and investments for the next decade.

The COVID-19 pandemic has exposed gaps in the U.S. healthcare system and worldwide. Gaps not of technology or resource but rather systemic, communication, and information gaps. ***Addressing these will require a shift from patient-centric to system-centric innovation models built on scalability, connectivity, and usability.***

In a series of white papers and interviews to be published over the coming days and weeks, we discuss with our Ximedica diagnostics experts the development and scaling of high throughput and Point-of-Care (POC) diagnostics, globalization vs localization of a product pipeline with our research and strategy experts, and explore the rising need of system integration in a global healthcare economy. Finally, we bring together a panel of our experts to understand what a shift to system-centric innovation could mean for healthcare innovation and improving access.

Part 1. SARS-CoV-2: Gaps, impact, and opportunities

Since the first reported case sometime in November 2019, COVID-19 has now 300,000 confirmed cases worldwide, in excess of 210,000 cases outside China, and 12,000 deaths worldwide. With a higher transmission rate than the flu and anecdotal stories of asymptomatic individuals becoming super-spreaders at large gatherings, experts have projected eventually between 160 million and 214 million people in the United States could be infected over the course of the epidemic. Outside the U.S., the estimated number of infected people in India is projected to reach 800 million.

The scale and magnitude of the current response designed to “flatten the curve” of the fast-moving virus has highlighted structural shortcomings of the U.S. healthcare system and around the world. As part of the response, the Biotech and MedTech communities are focused on developing diagnostics, vaccines and treatment for SARS-CoV-2 (the virus) and COVID-19 (the disease).

The U.S. Department of Health and Human Services announced it will provide financial support to two companies developing rapid diagnostics for SARS-CoV-2. DiaSorin Molecular is developing the Simplexa COVID-19 Direct Assay, and Qiagen will use the funds to accelerate development of the QIAstat-Dx RPS2 test for COVID-19. The FDA also rapidly approved Abbott, Thermo Fisher, and Roche's high throughput coronavirus diagnostics within 24 hours of submission. Roche's test kit will run on the company's 6800/8800 molecular testing systems while Thermo Fisher test kit will run on Applied Biosystem's 7500 Fast Dx Real-time PCR instrument. As the situation continues to evolve, we expect a number of Point-of-Care (POC) platforms to announce new rt-PCR assays shortly.

Major government contracts such as those expected for COVID-19, have a precedent of accelerating product development into a large, well defined market, which becomes an important strategic advantage for the company to leverage future growth. A decade ago, Cepheid first rose to prominence when it developed an anthrax assay under the direction of the United States Postal Service (USPS) and was awarded subsequent contracts to test the U.S. mail for signs of biological warfare. They later leveraged rising TB awareness worldwide to launch their High Burden Developing Country (HBDC) program which helped Cephied place over 10,000 tools worldwide in 2016.

In February, BARDA announced it is accepting abstracts under AOI #4: 2019-nCoV, to advance an invitro diagnostics for the detection of 2019-nCOV in clinical samples, including upper and lower respiratory tract specimens.

Important issues that will need to be addressed beyond the scientific merits of any new assays are:

- **Scalability and quality of new POC tests**
- **Sample collection and sample management for global deployment**
- **Rapidly scaling R&D resources, designing for manufacturability, and quality management**

In the search for an effective vaccine or therapy, the Biotech community has been leveraging recent advances in machine learning to accelerate vaccine and drug discovery. By January 2020, multiple teams have reported targets of computation drug-repurposing therapies via a virtual screening of drug libraries to find suitable drug-target pairs. This strategy has previously proven effective for diseases such as Ebola, ZIKA, dengue, and influenza.

Similarly, for COVID-19, initial reports indicate that small molecule drugs Prulifloxacin, Bictegravir, Nelfinavir, and Tegobuvi exhibit high binding affinity against the main SARS-CoV protease and were likely candidates for SARS-CoV-2. Based on additional computational studies Nelfinavir, which is an approved HIV protease inhibitor, was identified as a primary candidate.

Insilico Medicine, a biotechnology company that is dedicated to "artificial intelligence for drug discovery, biomarker development, and aging research", caught the attention of worldwide news media when they released six novel drug candidates to treat COVID-19. The list was generated using a generative chemistry pipeline that represented a more "bottom up" approach than the repurposing attempts discussed above.

A number of small and large companies are spearheading an effort to develop a COVID2019 vaccine, including teams from GSK/CEPI, Johnson and Johnson/BARDA, Moderna, Clover Biopharmaceuticals, and many others. Current efforts are largely leveraging existing platforms as well as progress from the SARS-CoV efforts. Moderna reported the first patient trials of their novel vaccine in Seattle, Washington in March.

"A NUMBER OF SMALL AND LARGE COMPANIES ARE SPEARHEADING AN EFFORT TO DEVELOP A COVID2019 VACCINE, INCLUDING TEAMS FROM GSK/CEPI, JOHNSON AND JOHNSON/BARDA, MODERNA, CLOVER BIOPHARMACEUTICALS, AND MANY OTHERS."

It is important to remember that the earliest vaccine to reach the market will still take 12 – 18 months. In the meantime, the scale of the pandemic is unprecedented and the challenge of delivering the vaccine will be an equally formidable challenge. For example, the size and shape of a vaccine package can greatly affect supply chain operations as evidenced in 2006 when the initial packaging for rotavirus vaccines was too large for supply chains in Latin America to handle. Both Merck's RotaTeq and GlaxoSmithKline's Rotarix filled substantially greater cold chain volumes than other routine vaccines, creating and exacerbating bottlenecks that ultimately disrupted the flow of all vaccines.

The magnitude of delivering scalable and technology-driven healthcare in today's connected economy, poses a challenge that COVID-19 has acutely demonstrated we are not ready for. COVID-19 has shown that healthcare innovation will evolve beyond individual products, become more global, more integrated, and more connected.

So, what are the higher level questions we must consider as opposed to the constraints of a specific technology:

- **Who are the key stakeholders in the vaccine supply chain?**
- **There are a number of technologies that can replace the needle and syringe; what are bottlenecks restricting higher adoption?**
- **The worldwide demand for a COVID-19 vaccine and therapy could be unprecedented; what are key issues to address when viewed through a user centered lens (cultural, resource, language)?**

Please join us for Part 2 of this series, where we continue these discussions with the development and scaling of **high throughput and POC diagnostics, globalization vs localization** of a product pipeline and explore the rising need of system integration in a global healthcare economy.

> **"THE MAGNITUDE OF DELIVERING SCALABLE AND TECHNOLOGY-DRIVEN HEALTHCARE IN TODAY'S CONNECTED ECONOMY, POSES A CHALLENGE THAT COVID-19 HAS ACUTELY DEMONSTRATED WE ARE NOT READY FOR."**

A call to action – Leverage deep domain expertise and flexible manufacturing @ Ximedica

As American industry rise to the challenge of COVID-19, shortages of ventilators in hospitals have been identified as a key challenge. Companies from Medtronic to GM, Ford, and Tesla have all pledged resources to increasing the nation's supply of ventilators.

As part of our contribution to this effort, our medical device design and manufacturing teams have been sharing our expertise and insights with top academic teams, small business owners, venture partners, and entrepreneurs passionate about bringing innovative and timely solutions to address this crisis.

If you or your company are looking for partners, resources, or opportunities to bring innovative solutions to the pandemic, please join our conversation by reaching out to William Croisetiere, VP of Manufacturing (wcroisetiere@ximedica.com) or Melissa Bowley (mbowley@ximedica.com), VP of Strategic Development.

Ximedica was purpose built for flexibility with offices, engineering resources, and medical device manufacturing capacity in Rhode Island, San Francisco, and Minnesota. Our designers and engineers leverage deep domain expertise in respiratory assist devices, a unique innovation process, and a flexible quality system that balances speed with quality.

FDA REGISTERED ISO CERTIFIED NSAI CERTIFIED

Ximedica is a full-service ISO 13485-certified and FDA-registered product development firm. For 30 years Ximedica has provided a unique growth platform enabling organizations to successfully deploy medical technology products into the market.