



Leveraging Digital Technologies to Improve Health Care Outcomes: An opportunity for policy collaboration in the U.S.-Japan bilateral relationship

September 2020

Digital advancements in health care are propelling innovation and driving long-term structural changes in how health care is delivered—trends that the COVID-19 pandemic has only accelerated. From digital tools driving research and development of treatments and vaccines for COVID-19 to delivering health care remotely through telemedicine, both the response and recovery phases are heavily dependent on new technologies. We therefore urge governments around the world to embrace and facilitate these innovations by adopting new policies developed in partnership with the private sector and other key stakeholders.

Such innovations will ultimately bring about better patient outcomes, as well as cost savings for patients, care providers, and society. For these new technologies to be implemented successfully and responsibly, however, governments must grapple with emerging policy questions that require careful consideration. Governments will also need to take into account the views of the patients receiving these new services, together with those of the innovators delivering them.

The U.S. Chamber of Commerce, the U.S.-Japan Business Council (USJBC), and our member companies, which include the world's most innovative technology and health care companies, recognize the enormous policy considerations raised by ever-shifting public health care demands caused in part by aging populations, worsening public finances, and the fast-paced nature of the digital world, especially in Japan, which is known for its cutting-edge innovation and health care. These considerations include the following:

- **Health care as an investment.** Fundamentally, health care is an investment in the national and global economy. The health care sector continues to play a vital role in improving the health and welfare of people in the world—particularly in the midst of the COVID-19 pandemic—by driving economic growth and job creation, developing innovative health care solutions that support the lengthening of average healthy life spans, improving quality of life, and reducing the economic burden of disease.

At the same time though, the sustainability of health care systems remains a significant challenge to maintaining economic growth in rapidly aging societies

with a declining working-age population. While important progress has been made over the last several years in improving the competitiveness and attractiveness of Japan as a market and is critical to fueling continued innovation in the future, promoting these trends requires more to be done especially in the these digital-related areas:

- **Telemedicine.** Since the start of the pandemic, telemedicine usage has increased dramatically. The University of Pittsburgh Medical Center in the U.S., for instance, noted a 35-fold increase in telemedicine usage between early March and early April 2020. Japan, too, has begun to increasingly leverage telemedicine, with then Prime Minister Abe's administration temporarily loosening restrictions on online medical services effective April 13. Yet surveys have shown that a high percentage of hospitals are not offering the service, primarily due to health care professionals' (HCPs) distrust of telemedicine and their lack of knowledge in how to use it properly, in addition to the lack of infrastructure and uncertainty about reimbursement for these types of services.^{1,2} Furthermore, technological linkages among hospitals are virtually nonexistent, with no central control or oversight over them.

As is well recognized now, telemedicine could provide long-term, irrevocable benefits and convenience for Japanese society beyond COVID-19, not just to address the rising demands of a rapidly aging population but as a beneficial medical service for patients during public health crises.

- **Digital Therapeutics (DTx).** Digital therapeutics, a new category of digital medicine, have the potential to revolutionize health care as health systems evolve to incorporate new technology and promote the practice of personalized, evidence-based health care. DTx enable HCPs to provide individualized, simplified, and optimal care for patients. DTx take many forms, but one compelling example is sensor technology. The use of flexible, noninvasive personal sensors to detect, monitor, and evaluate disease are contributing to improved patient outcomes and enhancing our understanding of disease within the medical community. For example, electrophysiological sensors monitor muscle disorder changes in patients with neurological conditions (e.g., Parkinson's disease, multiple sclerosis, and epilepsy); tactile pressure sensors provide physicians with accurate, real-time information for

¹ See Eisaku Nitta and Yusuke Konishi, "Japan greenlights online doctor visits as outbreak hits hospitals," *Nikkei Asian Review*. <https://asia.nikkei.com/Business/Health-Care/Japan-greenlights-online-doctor-visits-as-outbreak-hits-hospitals>

² "Survey results regarding telephone and online medical care," Japan's Ministry of Health, Labour and Welfare. <https://www.mhlw.go.jp/content/10803000/000657038.pdf>

patients with cardiovascular disease, eye diseases, and lung diseases; and chemical sensors detect signals in the body associated with disease biomarkers, such as glucose and environmental contaminants.

The ability to detect and monitor diseases remotely provides a fourfold benefit: it (1) minimizes patient exposure to infectious environments and reduces patient burden with fewer doctor's office and hospital visits; (2) allows patients, caregivers, and physicians to communicate in real-time based on accurate, personalized data; (3) lowers total health care costs as a result of fewer hospitalizations and more personalized therapies; and (4) generates tremendous amounts of data that can be studied to advance medical science. Countries with regulatory policies and reimbursement schemes that enable DTx will attract more investment, lead global biomedical innovation, and foster a healthier, more productive population.

- **Artificial Intelligence (AI) and Data Enabled Research & Development (R&D).** Research in health care AI has been growing rapidly, even before the COVID-19 pandemic outbreak. One notable example is deep learning, a form of machine learning in which machines are trained to process and learn from high volumes of data. Deep learning is being used to identify diseases from glaucoma to cancer to great effect, with the added benefit of being able to be employed quickly and at large scale.

Yet launching real-world applications based on that research has proven challenging. Regulators have been leery of granting approvals for these newly developed technologies due to concerns about generalizability and bias, while concerns about compliance with data privacy laws have made it difficult to collect data for training algorithms. Hospitals' internal protocols and vetting processes provide another, albeit justifiable, hurdle to clear. Nevertheless, the COVID-19 pandemic may also reshape how patients themselves view data sharing to advance scientific research and access to innovative digitally enabled health care.

- **Cross-Border Data Flows and Privacy.** The COVID-19 pandemic has demonstrated the importance of rapidly sharing information across borders as companies work with governments to quickly identify and investigate potential treatments and vaccines. At the same time, policies enacted in third-party jurisdictions that are intended to protect privacy have impeded cross-border research and the effective deployment of technology, including AI tools. Some privacy regimes, for instance, unduly restrict the transfer of

health and genetic information across borders, greatly limiting innovation and cooperation.

One notable example is contact tracing. Countries like South Korea have successfully employed app-based contact tracing systems to combat the spread of coronavirus. The Japanese government has launched its own contact tracing app, which tracks users' proximity to other app users without storing geolocation data due to privacy concerns. In the U.S., the private sector has been collaborating in unprecedented ways that could provide large volumes of much-needed data to help stem the COVID-19 outbreak. Such private sector technologies and access to data could prove invaluable not only to Japan but around the world. Greater cooperation among the U.S., Japan, and likeminded countries on data privacy practices is therefore needed to ensure the free flow of data and data-driven innovations across borders.³

Though the COVID-19 pandemic will one day end, its impact and the trends it has accelerated will continue. The use of digital technology in health care delivery, research, and case management will no doubt be prominent among them. This presents an extraordinary opportunity for Japan to reconfigure its health care and regulatory frameworks to better support innovation and meet the evolving needs of its society, especially as it ages. Countless studies have shown the enormous financial burden that rising social security costs will impose on the government, combined with a shrinking workforce. Digital technologies can both significantly lower costs and raise capacity for health care, thus helping to lighten this burden and improve quality of life for millions in Japan.

Unfortunately, some governments have increased restrictions and controls on foreign investment that could negatively impact innovation in digital technologies. The Government of Japan, for example, recently added manufacturing industries related to pharmaceuticals for infectious diseases and manufacturing related to highly controlled medical devices to its list of “core industries” subject to its strictest foreign investment restrictions under the Foreign Exchange and Foreign Trade Act (FEFTA). At a time when the health care sector and specific digital technologies need additional investment to support innovation, initiatives that create additional costs or uncertainty risk hampering that investment without contributing to the overall reliability of supply chains.

In short, as the digital transformation of society as a whole progresses, it is important to accelerate digitalization in the health care field as well. The following

³ It should be noted that the U.S. and Japan have a shared interest in other third-country policies currently affecting digital trade, such as forced technology transfer and digital tariffs and taxes, which could also become impediments to health care-related digital innovation.

policy recommendations would help strengthen Japan’s ability to provide state-of-the-art health care alongside the private sector more effectively and efficiently, not only in the midst of the ongoing public health crisis but beyond. We also note that these recommendations should fundamentally be underpinned by a predictable and transparent public policy environment that allows stakeholders to meaningfully participate in the development of regulations and favors efficient processes to bring new technologies to market. We recommend the Japanese government and key stakeholders consider:

- **Embracing, enabling, and promoting digital technologies in Japanese health care** as an effective tool to care for and monitor patients, while also ensuring close coordination among the government agencies responsible for regulations, reimbursement, and oversight of telemedicine and government policy initiatives that aim to expand the scope and impact of telemedicine.
- **Conducting a thorough review of health care reimbursement in Japan** with the objective of adopting reimbursement policies that promote remote health care solutions.
- **Developing policies and a regulatory environment conducive to the monetization and reimbursement of digital solutions to accelerate the development of DTx** and their use in mainstream society in order to provide additional value for patients, HCPs, and the health care system. These technologies, to include temperature sensors and flexible physiological biochemical sensors, can lower costs and improve outcomes through evidence-based decision making in health care.^{4,5}
- **Developing an advanced health care IT infrastructure based on global standards** with a degree of flexibility and accessibility that substantially improves the delivery of health care for patients, including by facilitating responsible data collection and R&D, enhancing interoperability, and leveraging private sector technologies and capacity, such as AI.
- **Utilizing data and AI** to accelerate the development of drugs and functional foods and ensure safety.

⁴ See Alice Ravizza, et al., “Comprehensive Review on Current and Future Regulatory Requirements on Wearable Sensors in Preclinical and Clinical Testing,” *Frontiers in Bioengineering and Biotechnology*. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6857326>

⁵ See Yiding Gu, et al., “Mini Review on Flexible and Wearable Electronics for Monitoring Human Health Information,” *Frontiers in Bioengineering and Biotechnology*. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6675826>

- **Digitizing aspects of drug discovery and development**, such as virtual clinical trials and post-marketing surveillance, which will enable patients to access new therapies sooner and provide regulators with additional ways to assess the effectiveness of medicines and functional foods in real-world settings.
- **Ensuring that Japan’s legal and regulatory framework is up to date** and in line with the need for developing a broad health IT infrastructure, specifically regarding cross-border data flows, privacy considerations, and AI guidelines. (For reference, the U.S. Chamber of Commerce previously laid out recommended [Artificial Intelligence Principles](#).) We also urge the Japanese government to engage the Japanese public to promote trust and understanding about the value of using data to create new medicines and treatments.
- **Ensuring that any government initiatives intended to restrict foreign investment for national security reasons in the health care and related digital technology sectors are carefully calibrated** to facilitate legitimate trade and investment from trusted partners in order to lower health care costs and ultimately improve care and quality of life for millions in Japan.
- **Continuing to promote paperless operations, which are essential to digital transformation in all sectors but particularly affect health care**, through measures that include removing the requirement to create/submit physical documents; amending the regulations under the Electronic Signature Act to clarify the legal status of cloud-based digital signatures; ending the use of *hankeo* personal seals; relaxing the scanner storage requirement specified by the Electronic Books Maintenance Act; promoting digital government; and moving toward a national certification system for administrative time stamps.

The recommendations outlined in this document are not exhaustive, though we believe they address some of the most pressing needs in the Japanese health care space. The USJBC looks forward to collaborating with the Government of Japan on these issues and is eager to provide updates on the innovative health care solutions our companies are developing.