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Editorial: Global Initiatives Support the Use and Regulation of Digital Health Technology During the COVID-19 Pandemic

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Abstract The development and use of digital health technology have increased during the global COVID-19 pandemic. Artificial intelligence (AI)-powered digital tools have been increasingly used to diagnose and screen for SARS-CoV-2 infection. Digital technology, in the form of mobile phone applications (apps), has been adopted by several countries to track infected individuals as infection prevention and surveillance measures. Global best practice guidelines, technology approvals, and patient care models have only recently begun to catch up with the developments in digital technology. In 2021, the WHO published a global strategy on digital health (eHealth) and mobile health (mHealth) for 2020 to 2025. The US Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) now evaluates software as a medical device (SaMD) and software that is in a medical device (SiMD) through the International Medical Device Regulators Forum (IMDRF). This Editorial aims to discuss how the COVID-19 pandemic has driven global initiatives to support the use and regulation of digital health technology and the requirements for digital health evidence frameworks and new approaches to regulatory approvals.

Keywords: **Digital Technology • Digital Health • COVID-19 • SARS-CoV-2 • Regulation • eHealth • Pandemic • Editorial**

Digital health software and technologies that assist in patient diagnosis, treatment, storing and sharing medical health records, and managing clinical workflow have been established for more than two decades in healthcare settings [1-3]. Clinical studies and population studies support that digital health technology has improved the efficiency of clinical practice and patient care [3,4]. In the past decade, personal digital health technology has undergone rapid developments [1-3]. Digital health and well-being devices are now commercially available [1-3]. These devices are experiencing rapid growth and availability. Digital health technology empowers the healthy to remain healthy and provides early diagnosis of potentially life-threatening diseases [1-3]. Patients with common chronic medical conditions, including diabetes and heart failure, increasingly use the new digital health technology outside traditional healthcare settings [1-3]. Digital health products undergo frequent updates and modifications and are now accessible even across international boundaries and can improve the health of millions of people [2].

When the COVID-19 pandemic began at the end of 2019, digital technology in healthcare in developed countries was at a stage that favored its use in infection control and monitoring [4]. During 2020 and 2021, healthcare organizations responded to the first phase of the pandemic by rapidly adopting digital solutions supported by advanced technology tools [4,5]. A recent systematic review of the published medical literature during these stages of the COVID-19 pandemic has shown that digital technology has mitigated the impact of COVID-19 for individuals and healthcare systems, with use in the surveillance and prevention of SARS-CoV-2 infection [4]. Artificial intelligence (AI)-powered digital tools have been increasingly used to diagnose and screen for SARS-CoV-2 infection [4,5]. Digital technology, in the form of mobile phone applications (apps), has been adopted by several countries to track and trace infected individuals as infection prevention and surveillance measures [6]. Contact-tracing apps, patient engagement and information apps, and well-being apps have also been increasingly used [6]. The most recent developments in digital technologies in COVID-19 have been supported by studies on the diagnosis of SARS-CoV-2 infection and infection surveillance [6,7].

There have been rapid developments in diagnosing COVID-19 using digital technology that integrates with traditional diagnostic methods, such as AI-based imaging and laboratory diagnostic algorithms [5,6]. Infection surveillance is particularly amenable to the use of digital apps [6]. However, this approach has had varied success in different countries, possibly due to differences in societal attitudes to the use of new technology and privacy concerns [7-9]. With the need for social distancing during the COVID-19 pandemic, telehealth tools and telemedicine for clinical

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interactions between physician and patient, and pharmacist and patient, are increasingly used [7,8]. The COVID-19 pandemic has given new impetus to digital technology in healthcare. The rapid responses of digital technology during the COVID-19 pandemic have dramatically increased the use of mobile phones, online databases, electronic devices and networks, computing resources and have advanced and adapted machine learning methods to infection control [7,10]. However, the rapid development of digital technology, driven by the COVID-19 pandemic, has several legal, ethical, and privacy limitations and workforce and organizational boundaries [7,10].

Best practice guidelines, technology approvals, and patient care models have only recently begun to catch up with the developments in digital technology [7,8,10]. As with traditional medical devices, these products must be reliable and of high quality [9]. Therefore, a risk-based approach is required to regulate digital health technology to foster continued innovation of digital health products [7,10]. Because the global COVID-19 pandemic is ongoing, most digital technologies have not yet been evaluated, tested, or integrated into public health systems [7]. For example, apps for contact tracing for COVID-19 are currently used in at least 40 countries [7]. However, there is no evidence to support their effectiveness in cost, identified cases, contact compliance with advice, reduction in the R-value, or data to compare their use with traditional public health methods [7]. There is still an urgent need for international coordinated digital public health strategies to evaluate the effectiveness of emerging digital technology during the COVID-19 pandemic [7].

The concept of digital health evidence frameworks is relatively new [7]. In 2015, a joint document from the United States Agency for International Development (USAID), the World Bank Group, and the World Health Organization (WHO) supported the use of digital technology to advance health interventions and engage society in public health measures [11]. In May 2018, the World Health Assembly Resolution on Digital Health was approved by the WHO Member States in recognition of the value of digital technology to advancing universal health coverage and the aims of the Sustainable Development Goals (SDGs) by increasing the availability and use of digital health technology worldwide [12]. In 2019, the WHO published guideline recommendations on digital interventions in health and introduced the concept of digital health (eHealth) to include mobile health (mHealth) [13]. In 2021, the WHO published a global strategy on digital health (eHealth) for 2020 to 2025 [14]. The current WHO definition of eHealth includes the secure and cost-effective use of information and communication technology to support health, healthcare services, surveillance, publications, health education, and research [14].

One of the first national evidence standards frameworks for digital health technologies was developed in the UK by the National Institute for Health and Care Excellence (NICE) [15]. The aim of the 2021 update of the NICE framework is to provide technology developers and healthcare commissioners with an understanding of the evidence for digital health technology based on cost, methods of use, and effectiveness [15]. Since April 2020, the European Union (EU) has recommended a pan-European approach to using apps and mobile data specifically for COVID-19 [16]. A common approach for EU Member States recommends using digital technology during the COVID-19 pandemic, including apps, for targeted social distancing, contact tracing, and modeling virus transmission, supported by data security, privacy, and data protection [16].

Traditional approaches to evaluating and approving medical devices are not applicable for new digital health technology that requires rapid design and modifications of both the devices and the software [7]. For the past five years, the US FDA Center for Devices and Radiological Health (CDRH) has followed the Digital Health Innovation Action Plan to allow timely patient access to safe, effective, and high-quality digital medical technology [17]. The FDA has launched a pilot pre-certification program to facilitate digital health technology oversight, or the FDA Pre-Cert for Software [17]. This new regulatory approach evaluates software as a medical device (SaMD), and software that is in a medical device (SiMD) [17]. During the past five years, the FDA has evaluated new SaMD and SiMD digital technology using an approach that balances the benefits and risks to patients [18.19]. This evaluation approach is supported by the Food and Drug Administration Safety and Innovation Act (FDASIA) Health IT report and the framework for Health IT through the International Medical Device Regulators Forum (IMDRF) [18,19]. The IMDRF includes medical device regulators from Australia, Brazil, Canada, China, the European Union (EU), Japan, Russia, Singapore, and the US [19]. The IMDRF Strategic Plan for 2021 to 2025 was published in 2020 and includes recommendations for accessibility, cybersecurity, interoperability, data security, and data integrity [19]. The development of this regulatory approach to digital health technology has been welcome during the COVID-19 pandemic and represents a global preparedness approach for future viral pandemics.

A limitation of the use of global technology includes a lack of availability or access to digital systems and equipment. In 2018, the World Health Assembly Resolution on Digital Health identified the importance of digital technology in advancing global healthcare and proposed several Sustainable Development Goals [18]. The global 'digital divide' was also acknowledged, as at least half of the world population does not access the internet [18]. Therefore, preparedness during the ongoing COVID-19 pandemic and for future pandemics of infectious diseases requires adaptations for specific disease risks in people with different languages, cultures, and economies.

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Conclusions

The COVID-19 pandemic has driven global initiatives to support the use and development of digital health technology. Because the pandemic is ongoing, the value of digital health technology to the pandemic response has yet to be determined. However, the COVID-19 pandemic has also driven digital health evidence frameworks and new approaches to regulatory approvals.

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