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Digital Connectivity: The Sixth Vital Sign

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Abstract

Digital health and telehealth connectivity have become important aspects of clinical care. Connected devices, including continuous glucose monitors and automated insulin delivery systems for diabetes, are being used increasingly to support personalized clinical decisions based on automatically collected data. Furthermore, the development, demand, and coverage for telehealth have all recently expanded, as a result of the COVID-19 pandemic. Medical care, and especially diabetes care, are therefore becoming more digital through the use of both connected digital health devices and telehealth communication. It has therefore become necessary to integrate digital data into the electronic health record and maintain personal data confidentiality, integrity, and availability. Connected digital monitoring combined with telehealth communication is known as virtual health. For this virtual care paradigm to be successful, patients must have proper skills, training, and equipment. We propose that along with the five current vital signs of blood pressure, pulse, respiratory rate, temperature, and pain, at this time, digital connectivity should be considered as the sixth vital sign. In this article, we present a scale to assess digital connectivity.

Keywords

connectivity, digital health, telehealth, virtual health, vital sign

Introduction

Connectivity of wireless devices and communication tools for medical care is allowing a better understanding of an individual's unique physiology and behavior. Networks of devices now contain embedded sensors, software, and transmitters that can collect, exchange, and wirelessly transmit data to each other and to people with diabetes and other long-term medical conditions by way of monitors and the Internet. This paradigm of continuous automatic data collection by wearable devices and data analysis by software contained in smartphones and the cloud is known as digital health. A second paradigm that permits remote real-time communication to provide health services by way of telecommunication technologies is also becoming established. This paradigm is known as telehealth. Together digital health and telehealth offer the potential for unprecedented benefits to monitor and respond to fluctuations of data that are inherent in diabetes and other common long-term conditions. Together, digital health based on monitoring devices combined with telehealth based on communication tools are known as virtual health. For patients to benefit from virtual health, they must have good connectivity with a secure broadband internet connection as well as resources to pay for the hardware and software that are needed to provide this care. Connectivity is becoming so important for healthcare that we believe connectivity will soon become recognized as an important prognostic factor for outcomes, because connectivity is a determinant of health.

The vital signs of blood pressure, pulse, respiratory rate, and temperature are traditionally the four most important measurements to assess health. On November 11, 1996, in his presidential address to the American Pain Society, James Campbell, MD introduced the concept of treating pain as a vital sign.[1,2] Soon afterward the concept of, "pain as the fifth vital sign" became widely adopted with the development of a 0 to 10 scale for this fifth vital sign.[1] Given the increasing importance of connectivity to permit people to tap into digital health and telehealth systems, we hereby propose that (1) connectivity be quantitatively assessed and (2) the degree of connectivity should be considered as the sixth vital sign.

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Benefits of Digital Health Connectivity

Connectivity between humans and technology in disease management has been introduced as an essential tool.[3] This past decade ushered in many new technologies that gained significant momentum after the introduction of real-time, indirect measurement of blood glucose levels using continuous glucose monitors (CGM). Traditional stand-alone insulin pumps have been gradually replaced by interconnected systems with smart insulin pumps that are equipped with insulin delivery decision-making algorithms augmented by CGM trends. The new-generation smart insulin delivery devices go beyond merely having a memory function. Modern insulin pens with a smart phone application interface offer a practical method to track each insulin dose, calculate an insulin bolus, and generate meaningful insulin and glycemic reports by also connecting with CGM devices. There is growing evidence to prioritize the use of interconnected technology treatment over conventional care for many diseases.[4] Diabetes is particularly well suited to the use of connected digital tools, as shown by significant reduction in hypoglycemia and increase in time in target glycemic range during automated insulin delivery clinical trials and real-life observational studies.[5-7]

The highly anticipated next generation automated insulin delivery systems are expected to improve insulin dosing decisions by tracking multiple sensor-detected factors that have an impact on blood glucose control to drive better glycemic outcomes.[8] Such systems will open new avenues for personalized treatment, known as precision diabetes,[9] but will only be possible if there is dependable digital connectivity of each system element to support immediate decisions.[10] Assessing the capacity of individuals to be connected and to use these digital connected devices by way of quantitative metrics will be crucial to fully exploit opportunities to deploy these tools.

Benefits of Telehealth Connectivity

An unforeseen consequence of the coronavirus disease 2019 (COVID-19) pandemic has been the marked acceleration in the use of telehealth.[11] In general, four platforms have been used to deliver telehealth: (1) information and communication technologies, such as text messaging, telephone calls, and video meetings; (2) social media, including using open access and private online communities; (3) patient portals allowing access to medical records, appointment scheduling, and refill requests; and (4) m-Health, which consists of monitoring and sharing health information via mobile technology, such as wearables and health tracking apps that can transmit data and provide recommendations.[12] Telehealth communication usually consists of: (1) real-time video with synchronous face-to-face video enabled consultations; (2) real-time audio with telephone consultations including coaching and support; (3) asynchronous communication involving email, text-messaging, and other methods of non-real-time communication; and (4) combined approaches which can involve both synchronous and asynchronous communications as well as video education.[13] The use of telehealth for diabetes has been associated with improvements in glycemic control[13] and is acceptable especially if supported by physicians.[12] A major benefit from telehealth is the potential to improve pharmacoadherence.[14]

Barriers to Adopting Digital Technologies

The switch to a predominantly telehealth-based system for delivering care for chronic diseases like diabetes, however, has highlighted challenges related to access to digital technologies, digital literacy, and the digital divide leading to an amplification of existing health disparities.[15] The complexity of device connectivity creates a barrier to adoption of technology and widens the digital gap for disadvantaged populations and people who are not tech savvy. If our goal is to improve healthcare by using technology-driven systems where machines do all the tracking, observation, estimating, and planning automatically and passively, then reliable and efficient digital connectivity is essential.

Human to Machine Connectivity

The pressure point is most notable at the "human to machine connectivity" component of telehealth and is distinct from the established concepts of machine to machine and machine to human connectivity. In other words, the digital connectivity fault line is most acute at the connections between digital health devices and with people living with a disease. At present, most digital health technologies are wearable devices worn externally to be connected to the Internet, although implantable, inserted, and ingestible devices are likely to become more widespread with miniaturization.[16]

Human to machine digital connectivity can be viewed in three ways, all of which matter to people with diabetes and their clinicians.

(1) The ability to connect in the first instance,
(2) The ability to maintain a connection, and
(3) The consequences if connectivity is lost.

Assessing the Level of Digital Connectivity

Digital health technologies are now the keystone of every digital health ecosystem. Given the existing inequities in telehealth laid bare by the recent pandemic, there is now a need to consider a novel scoring system by which the capability to use various connected devices and systems can be evaluated from the perspective of different human stakeholders. We propose a ten-part yes-no questionnaire to assess the

Table 1. Questionnaire for Assessing the Level of Digital Connectivity and Determining the Score Corresponding to the Sixth Vital Sign.

1. Is virtual care affordable? Yes___No___
2. Does the user have a smartphone, tablet, or computer? Yes___No___
3. Does the user have access to video capability? Yes___No___
4. Does the user have adequate health literacy and numeracy to effectively use and benefit from the technology? Yes___ No___
5. Does the user have broadband connectivity? Yes___No___
6. Is training a time or financial burden? Yes___No___
7. Is the data collected automatically? Yes___No___
8. Is the data integrated with the electronic health record? Yes___No___
9. Is the data secure? Yes___No___
10. Is the data private? Yes___No___
Total score (Number of Yes responses) _____

level of digital connectivity. The number of questions to which there is an affirmative response represents the connectivity score on a 0 to 10 point scale of increasing connectivity. Each affirmative response would be worth one point (Table 1). Each characteristic is given an individual score like an Apgar score that summarizes the health of a newborn child. The questionnaire should be administered face-to-face, rather than electronically, to avoid bias because individuals without a connected capability would be excluded. Because this questionnaire is currently a proposal, it should be validated through future studies and clinical work.

Electronic Health Data and Connectivity

With the adoption of electronic health records (EHRs), it is important to seamlessly integrate data in the EHR within the bigger picture of connected healthcare. Patients now have access to their own EHR and are also able to collect their own data by use of various mobile applications linked to smart phones, smart watches, tablets, and computers. Various levels of digital connectivity to the EHR include access to: (1) an individual's own medical records, including assessments, lab and imaging results, and other clinical information; (2) scheduling platforms; (3) billing platforms; and (4) communication with healthcare teams by way of telemedicine, texts, and secure emails. It is also preferable if EHRs can share data between healthcare organizations.

Health Insurance Coverage for Telehealth

The widespread adoption of telehealth from the COVID-19 pandemic necessitated an increase in health insurance policies for both governmental and private payers, expanding coverage to meet the growing needs of the public. This expanded coverage has improved the affordability of telehealth, and subsequently, has allowed for greater digital connectivity for many people, including those with diabetes.

Government

In 2019, prior to the pandemic, the United States (US) Federal Government began making plans to expand existing limited coverage for telehealth services. Once the pandemic began, these plans were fast-tracked with Medicare, Medicaid, and TRICARE (the healthcare program for the US Department of Defense Military Health System) increasing coverage for telehealth services in the past year (Table 2).

In December 2020, the US Federal Government finalized the permanent expansion of Medicare telehealth coverage to cover 144 telehealth services during the COVID-19 pandemic, and 60 of these newly added telehealth services have become permanent additions to the Medicare coverage plans. These additional telehealth services benefit people living in rural areas, although permanent expansions of telehealth services for those not living in rural areas are currently unavailable.[20] In February 2021, the House and Senate reintroduced the Telehealth Modernization Act, which would permanently remove Medicare restrictions on geographic sites for telehealth services and would expand the type of healthcare workers that would be able to provide telehealth services.[21]

Private Payers

Before the COVID-19 pandemic, private health insurance companies in the US were already making progress toward expanding telehealth coverage. In March 2020, at the beginning of the COVID-19 pandemic, many health insurance companies started waiving out-of-pocket payments for tests and treatment for COVID-19, including telehealth visits. Shortly after, acts were established to expand private payer coverage of telehealth visits during the COVID-19 pandemic (Table 3).

Since the pandemic began, many insurance companies have also voluntarily adopted policies temporarily expanding telehealth coverage.[23] As of October 2020, there were private payer laws related to coverage of telehealth services in at least 43 states and the District of Columbia.[23,24] However, there is no federal regulation for private payer policy for telehealth services, so these policies are not standardized from state to state.

As of January 2021, only seven states have mandated that telehealth services must be reimbursed at the in-person rate by private payers. However, the Center for Connected Health Policy found that most insurance companies were covering telehealth services at an in-person rate regardless of state policy.[23] With the availability of data on the widespread utilization of telehealth and consumer preferences, private payers may choose to expand telehealth coverage permanently.

Table 2. Changes to Medicare, Medicaid, and TRICARE Telehealth Coverage in 2020.

Healthcare program	Telehealth coverage changes in 2020
Medicare	Telehealth services at renal dialysis facilities and at home Telehealth services for Emergency department visits at home Certain physical and occupational therapy services at home Some services through audio-only devices Virtual check-ins E-visits[17]
Medicaid and Children's Health Insurance Program (CHIP)	Changes are state dependent. The Centers for Medicare and Medicaid services (CMS) has released a Medicaid and CHIP toolkit and a supplemental guide to help states looking to expand their telehealth coverage for their Medicaid and CHIP programs during the COVID-19 pandemic.[18]
TRICARE	Medically-necessary audio-only telehealth Can use telehealth services from physicians that practice across state or county lines Co-payments suspended[19]

Table 3. Acts Established in 2020 to Expand Private Payer Coverage of Telehealth Visits During COVID-19 Pandemic.

Act name	Act description
Families First Coronavirus Response Act	Mandates that out-of-pocket payments for COVID-19 tests and any additional COVID-19 related appointments are waived, including all telehealth visits[22]
Coronavirus Aid, Relief, and Economic Security Act	Provides a safe harbor for insurance companies to cover pre-deductible COVID-19 services for those with high deductible health plans[22]

Table 4. Examples of Vendors That Have Informed the OCR (as of January 20, 2021) That They Provide HIPAA-Compliant Video Communication Products.[27]

Skype for Business/Microsoft Teams
Updox
VSee
Zoom for Healthcare
Doxy.me
Google G Suite Hangouts Meet
Cisco Webex Meetings/Webex Teams
Amazon Chime
GoToMeeting
Spruce Health Care Messenger

Cybersecurity of Virtual Health Systems

Successful implementation of telehealth and digital health solutions requires sound cybersecurity and privacy protections. Trust by patients and healthcare professionals (HCPs) in telehealth requires that the confidentiality, integrity, and availability of the patients' data must be ensured. Three pillars of medical device cybersecurity that can support secure data protection are people, processes, and technology.[25]

All users of virtual health must practice physical security and not leave communication tools unattended where they might be used by an intruder to hack into the healthcare system. Processes which will promote security include two-factor authentication, strong passwords, regular patching, and frequent backing up of data. A diabetes connected device can demonstrate cybersecurity by adhering to DTSec and DTMoSt which are (respectively) a standard and a guideline for diabetes devices that were developed in a consensus process by Diabetes Technology Society.[26] Both are currently being adopted in a similar format by the Institute of Electrical and Electronics Engineers (IEEE) and Underwriter Laboratories, and by the end of 2021, they will likely be officially known as IEEE 2621 ("Standards for Wireless Diabetes Device Security Assurance").

The Office for Civil Rights (OCR) at the Department of Health and Human Services (HHS) is responsible for enforcing regulations to protect the privacy and security of protected health information, namely the HIPAA Privacy, Security and Breach Notification Rules (the HIPAA Rules). The OCR has announced that during the current public health emergency, HCPs may use popular video conferencing software without penalties for noncompliance with rules about the Health Insurance Portability and Accountability Act of 1996 (HIPAA).[27] The OCR has published a list of HIPAA-compliant video communication products as of January 20, 2021 (Table 4).[27] Once the COVID-19 pandemic is over, then the OCR will likely become stricter and resume requiring deliverers of healthcare to: (1) demonstrate having safeguards to protect the confidentiality, integrity, and availability of electronic protected health information, and (2) perform a formal risk assessment to ensure compliance with these safeguards.[28]

Conclusions

Connectivity to digital health tools, telehealth, and the EHR are the key components of virtual healthcare. Furthermore,

like genetic, biological, behavioral, psychological, and environmental factors, connectivity is a determinant of health. As such, an individual's health will be significantly affected by their connectivity or lack thereof. Therefore, it is now time to quantitatively define connectivity to healthcare systems and apply this metric as the sixth vital sign.

Abbreviations

CGM, continuous glucose monitor; COVID-19, coronavirus disease 2019; EHR, electronic health record; HCPs, healthcare professionals; HHS, Department of Health and Human Services; HIPAA, Health Insurance Portability and Accountability Act of 1996; IEEE, Institute of Electrical and Electronics Engineers; OCR, Office of Civil Rights; US, United States.

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