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The World Health Organization Collaborating Center for Emergency and Trauma (WHO-CCET) in South East Asia, The World Academic Council of Emergency Medicine (WACEM), and The American College of Academic International Medicine (ACAAM) 2021 Framework for using Telemedicine Technology at Healthcare Institutions

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Abstract

The coronavirus disease 2019 crisis has forced the world to integrate telemedicine into health delivery systems in an unprecedented way. To deliver essential care, lawmakers, physicians, patients, payers, and health systems have all adopted telemedicine and redesigned delivery processes with accelerated speed and coordination in a fragmented way without a long-term vision or uniformed standards. There is an opportunity to learn from the experiences gained by this pandemic to help shape a better health-care system that standardizes telemedicine to optimize the overall efficiency of remote health-care delivery. This collaboration focuses on four pillars of telemedicine that will serve as a framework to enable a uniformed, standardized process that allows for remote data capture and quality, aiming to improve ongoing management outside the hospital. In this collaboration, we recommend learning from this experience by proposing a telemedicine framework built on the following four pillars-patient safety and confidentiality; metrics, analytics, and reform; recording of audio-visual data as a health record; and reimbursement and accountability.

Keywords: Coronavirus disease 2019, pillars of telemedicine, telehealth, telemedicine, virtual care

INTRODUCTION

The coronavirus disease 2019 (COVID-19) pandemic has transformed the landscape of health care, and telemedicine has emerged as one of the key drivers of this change.^[1,2] Since February 2020, the COVID-19 pandemic has been associated

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with more than 30 million cases and over 600,000 deaths in the United States (US), as well as widespread social and economic changes.^[3] Worldwide, we have seen over 180 million cases with over 4 million deaths.^[4] The ability of our health-care system to adapt with extraordinary speed under crisis has never been more evident as we endured the ongoing pandemic. Early on in the US experience, substantial increases in telemedicine and remote clinical services were required by health systems due to the concern for workplace transmission of COVID-19, the implementation of social-distancing policies, and the redeployment of health-care personnel.^[5] Telemedicine has proven to be both safe and effective during the times of crisis.^[6] Hospital footprints are shrinking due to shifts to outpatient care, changing demographics, and new interventions. As this trend continues, more diagnosis and care (as well as efforts to avoid treatment through prevention) will take place in the outpatient setting. A telemedicine visit can be conducted without exposing staff to infections during outbreaks.^[7] Telemedicine practice can prevent the transmission of infectious diseases, reducing risks to both health-care workers and patients. A growing number of patients are forgoing face-to-face visits and instead calling, texting, and video conferencing with their clinicians. This rapid change has proven clear benefits, making health care more convenient and seamless.

The development of guidelines and standards for telemedicine are an important and valuable process to help ensure safe and effective delivery of quality health care. Some organizations, such as the American Telemedicine Association,^[8] have made the development of standards and guidelines a priority. Guidelines have been created and tailored by specialty such as psychiatry,^[9] dermatology,^[10] ophthalmology,^[11] neurology/stroke,^[12] rehabilitation,^[13] sleep medicine,^[14] and gastroenterology.^[15]

In general, health-care delivery is complex and heterogeneous, which leads to the risk of fragmentation and increased

inefficiencies. The options for health-care delivery are quickly moving outside hospitals due to the advances in diagnostics, medical, and clinical services. More specifically, telemedicine is delivered through different modalities such as remote care in a patient's home, telemedicine centers operated by a hospital or third party, care delivery through mobile vehicles, and care outside of a formal hospital setting using information and communication technologies (ICT) or digital technologies. Telemedicine is a constantly evolving science, as it incorporates new advancements in technology and responds and adapts to changing health needs and contexts of societies.^[16] Telemedicine helps in improving access to care in resource-constrained settings and remote areas. Telemedicine has grown significantly during the last two decades due to increases in emergencies, pandemics, and natural disasters.^[16] Technological advances in transport systems, ICT, data sciences, and medicine have contributed significantly to the growth of telemedicine from high-income regions and low-and-middle-income regions. Figure 1 illustrates the telemedicine ecosystem.

Many successful organizations such as the Virginia Clinic, Cleveland Clinic, Aravind Eye Hospital, pharmaceutical companies, and medical equipment and device manufacturers have adopted telemedicine for better coordination among various stakeholders of care delivery while being able to improve care and reduce cost simultaneously. Recent advancements include the use of drones for the delivery of supplies to remote areas and use of artificial intelligence to improve care. Currently, medical drones have been used by DHL, DJI, Matternet, and Zipline for new product launches, delivering medical samples, drugs, and vaccines.^[17] According to Global Market insights,^[17] the medical drones' market is expected to grow from \$88 million to nearly \$400 million by 2025.

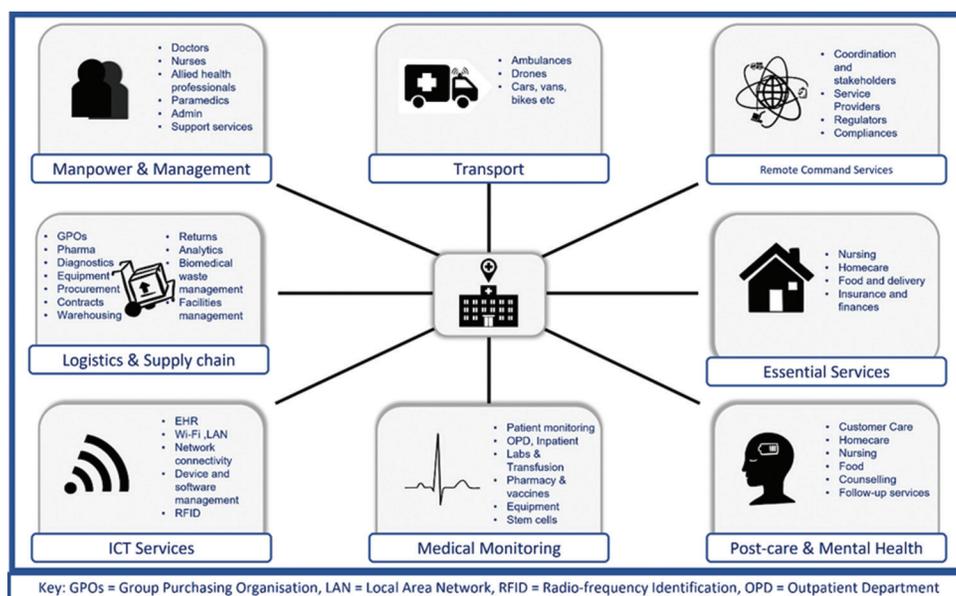


Figure 1: Telemedicine ecosystem

The World Health Organization Collaborating Center for Emergency and Trauma (WHO-CCET) in South East Asia constituted a group of experts from The World Academic Council of Emergency Medicine (WACEM) and The American College of Academic International Medicine (ACAAM). The World Academic Council of Emergency Medicine-American College of Academic International Medicine (WACEM-ACAAM) represents a collaboration of professional societies committed to advancing academic international medicine and providing clinicians with evidence-based strategies for improving health care. WACEM-ACAAM has previously characterized how telemedicine has been leveraged to optimize care while protecting health-care workers and the communities they serve.^[17] This current consensus aims to create a scientific basis for the use of telemedicine in health care. This collaboration discusses the four pillars of telemedicine [Figure 2], which are:

1. Patient safety and confidentiality
2. Metrics, analytics, and reform
3. Recording of audio-visual data as a health record
4. Reimbursements and accountability.

PILLAR 1: PATIENT SAFETY AND CONFIDENTIALITY

Patient safety by the way of confidentiality and privacy protection is a serious concern with telemedicine. Patient privacy in telemedicine has largely been studied on the macro level with a focus on Internet connection, mobile and app-based technologies, and protection of data.^[18,19] However, these macrolevel approaches are not patient-centric and often do not align with micro level challenges using telemedicine where front line care is provided. Protected health information (PHI) is always at risk for inappropriately being shared. The creation, storage, and transfer of PHI through telemedicine networks remain vulnerable to breaches in safety, privacy, and confidentiality of patient information.^[19]

The International Standards Organization (ISO) has laid the foundation for the protection of PHI in telemedicine. The key is that PHI should only be accessed by accountable individuals who can ensure information security as required by ISO Standards. In addition, the standard provides guidelines for the entire life cycle of patient data, from the creation to the destruction of the data. Adherence with standards is becoming more challenging with advances in technology.^[18] The

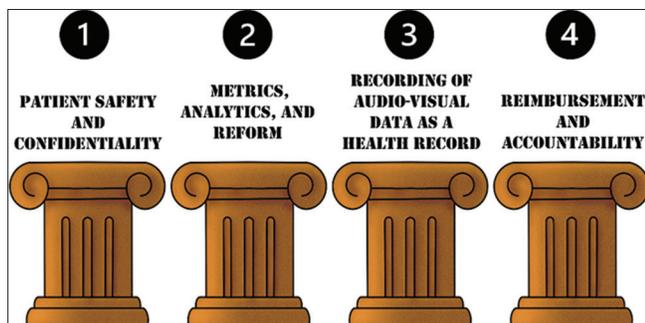


Figure 2: Four pillars of telemedicine

biggest challenge for the guidelines is to ensure compliance. Cloud-based systems pose another level of complexity to this challenge where an information breach is at higher risk.

Since telemedicine involves the transmission of patient data, maintaining patient privacy through cyber-security is important.^[20] The US Health Insurance Portability and Accountability Act (HIPAA) provides guidance around entities and PHI, along with privacy and security rules. However, telemedicine poses unique challenges^[21,22] such as how to distribute the Notice of Privacy Practice to patients or have all involved parties sign a Business Associate Agreement to provide services. In the European Union (EU) and United Kingdom (UK), telemedicine is governed by the General Data Protection Regulation, where processing and holding health data relies on seven defined principles and legal principles of explicit and not implied consent.^[23]

HIPAA (Health Insurance Portability and Accountability Act of 1996)

ISO rules are set across international territories. However, local rules in the different parts of the world vary on how they are viewed and valued. Privacy standards are perceived and accepted differently as well. In the US, HIPAA is strictly monitored and complied with to ensure that PHI is protected, not just in terms of technology, but also in terms of availability to insurance providers.

Cyber-security: The threat of hackers

When providing health care through telemedicine, there are multiple privacy issues at risk. Potential privacy issues include leaking or hacking of PHI to unwanted parties, accessing PHI beyond what is necessary, the security or lack thereof of electronic health record (EHR) systems, and the inappropriate sharing of data by patients.^[24] For example, privacy and cybersecurity issues remain in cases of automatic implantable cardioverter defibrillators, insulin pumps, and informatics.^[25] In addition, there has been a noticeable shift toward using online platforms and social media websites to exchange PHI. The US Office for Civil Rights has temporarily allowed for telehealth communications to occur over applications such as Zoom, Google Hangouts, and Facebook Messenger Video Chat--all of which have a potential for security breaches.^[26]

Smart phones and applications

In telemedicine, smartphones have many advantages in terms of addressing the diversity of needs for stakeholders including doctors, nurses, business administrators, and patients themselves.^[27] Health professionals can utilize smart phones to conduct teleconsultations to manage health-care records, prescribe medications, and view examination results.^[28] Smartphones can act as a remote access tool for health records for physicians and as a means for patients to access their own portal with relevant health information.^[29]

The risk of disclosure and breach is even higher for these apps as adequate cybersecurity measures are still not in place.^[27]

Even if the proper safeguards are in place, it is often difficult to verify the user. In addition, PHI is viewed to have a higher value than other online personal information such as credit card data, making it more attractive to hackers.^[27,30]

Due consideration should be given to assisting patients and physicians with technology setup, providing technical support, and responding to questions and concerns.^[31]

Consent forms

Consent forms are required to protect patients and physicians. They ensure that both patient and physicians understand how PHI will be accessed and used. Consent forms are legal documents completed by people involved in the transfer of sensitive information. They also explain how PHI will be accessed and the safeguards in place to protect PHI.^[32] Consent forms also limit what information is shared because the document controls what PHI is released when signed by both parties.

Clinical safety during teleconsultation

Telemedicine is limited by the inability to evaluate the certain aspects of the physical examination and may be unsuitable for conditions that are acute or life-threatening. Some data such as history, weight, and height can be provided using the tools available in the telemedicine platform. To ensure patient safety, teleconsultations should be used as a diagnostic and follow-up platform. If a person's condition worsens or if time sensitive symptoms develop during the teleconsultation, the physician should recommend that the patient present immediately to a hospital.^[33,34] A shared decision-making model that allows the patient and physician to communicate with each other while weighing the risks and benefits of certain treatments or need to go to an acute facility for follow-up is recommended.^[35]

PILLAR 2: METRICS, ANALYTICS, AND REFORM

While the COVID-19 pandemic has impacted health-care delivery in many ways, little is known regarding how the volume, site, and content of telemedicine in the US have changed. Despite the increased use of telemedicine, its uptake has varied across the US and has not been correlated, at a regional level, with COVID-19 burden. These findings are notable because little is known about the association between telemedicine utilization in primary care delivery during the pandemic.^[36]

This is largely due to the fact that telemedicine currently lacks standardized metrics and evidence-based professional performance standards that allow for measurable outcomes and associated reimbursement schedules. A retrospective study from January 2016 to December 2017 with a manual review of 390 encounters emphasized the need for CPT codes to perform telemedicine research in the administrative data.^[37] However, to have CPT codes, there must be standardized metrics that all telemedicine encounters use to ensure all required data elements are captured. This will allow for accurate Levels 1–5 billing, further discussed in Pillar 4.

An explicit understanding of the specific mechanisms by which telemedicine contributes to optimal quality of care needs to be delineated, then analyzed and perfected. The potential contributions of telemedicine to achieving optimal health status in the community needs to be demonstrated to establish telemedicine as a permanent modality of patient care after the COVID-19 pandemic. This implies an inclusive focus on a continuum of care management focused on patients rather than diseases, ranging from preventive services to therapeutic and rehabilitative services to humane and dignified end-of-life support strategies. The examples of metrics to include are first contact resolution (or ability to manage a patient's chief complaint during the telemedicine encounter), 72-h return (i.e., to the emergency department, urgent care, primary care physician, or telemedicine encounter), and phone versus video encounters (since video telemedicine encounters are generally preferred over telephone). The institutional operation team should review the relevant metric data and ensure it improves through an iterative process to meet accepted benchmarks (when available).

PILLAR 3: RECORDING OF AUDIO-VISUAL DATA AS A HEALTH RECORD

Since telemedicine is already on a potentially recordable platform, capturing the physician-patient encounter can have several advantages, namely including a clear visual record. Unfortunately, our current telemedicine system has limited protections to the physician-patient interaction other than electronic documentation. Although it is true that face-to-face visits are not recorded as part of a classic patient visit, telemedicine is vulnerable. Unless the patient has equipment or can provide verifiable findings, there are limited prescriptive vital signs and physical examination findings to support a physician's recommendations. Our recommendation is that telemedicine encounters should be recorded. The challenge of this call to action will be the necessary digital library/database space to house these encounters. Having a recording of the encounter allows the physician and patient a way of capturing the encounter to detail what was capable for evaluation and what follow-up visits are necessary. This process protects both parties from medico-legal entanglements that can result from this limited encounter. This recording essentially becomes a case file in the patient's chart that can be accessed later.

HIPAA and privacy regulations do not prevent a patient from recording their own health-care encounters. These laws and regulations are designed to protect the patient's health information from accidental or intentional disclosure by health-care workers and related entities. These regulations do not, however, prohibit patients from disclosing their own PHI. If the patient records and possesses a sole copy of their patient encounter, the patient can do nearly anything with the information so long as it does not violate another party's privacy rights. It is thus recommended to instruct patients

about rules related to personal recordings like one would with smartphone recordings during an in-person clinical encounter. If an instructed patient makes a surreptitious recording and posts it online, for example, and it can be established that it was disclosed by the patient, the physician should not have exposure for HIPAA or privacy law violations.

PILLAR 4: REIMBURSEMENTS AND ACCOUNTABILITY

The final pillar of a successful telemedicine system is commensurate reimbursement for care provided. One interaction, particularly, is the typically positive relationship between information technology and cost. However, this relationship has not been consistently demonstrated in telemedicine. Indeed, the capabilities and quality (or clinical effectiveness) of the underlying technology continue to advance at pace without a commensurate increase in price. Consequently, we may never be able to ascertain definitively the cost-effectiveness of this electronic information technology-based care or get a stationary assessment of its economic and clinical merit or its ultimate contribution to society.^[38]

In the US, Medicare coverage applies across the country, but reimbursement rules vary for private payers.^[39,40] Per existing law, private payers are required by state law to reimburse a telemedicine encounter at the same rate as a comparable in-person visit. In the EU, countries such as the UK, Italy, Belgium, France, Portugal, Sweden, and Germany pay at par with a physical visit.^[41]

In the US, handling medical malpractice^[42] and complying with federal anti-kickback statutes are two additional hurdles physicians need to consider. Special insurance coverage for telemedicine practitioners and stringent guidelines have been published to stay compliant with the anti-kickback statute.^[43]

As telemedicine becomes a more mainstream modality for delivery of healthcare, governments are working toward laws and policies to incorporate and normalize telemedicine. China's health authority issued rules regarding telemedicine in 2018 that included measures for the administration of internet-based diagnosis and treatment, internet hospitals and telemedicine.^[44] In 2015, as part of its 20-year plan "2035 Health Care," the Japanese government considered "the development of a health-care database to support telemedicine applications such as remote diagnosis, remote treatment, and telesurgery."^[45] The Government of India recently stipulated guidelines and criteria regarding practicing telemedicine where doctor's responsibilities in ensuring data privacy, ethics and maintaining records were highlighted.^[46,47] In the UK, remote health consultations are regulated by the Care Quality Commission and need approval before they can be commissioned.

SPECIAL CONSIDERATIONS

Standardization

As stated above, ISO and HIPAA regulate the safety issues

regarding telemedicine. In *Crossing the Quality Chasm*, the National Academy of Medicine (formally the Institute of Medicine) has defined six domains for the quality of care: Safe, timely, effective, efficient, equitable, and patient-centered.

Benefits of telemedicine include a reduction in the cost of health care and a focus on value-based care. Telemedicine also allows improved patient participation and engagement. Patient satisfaction and engagement are higher with fewer in person clinic visits, which also saves both the patient and the physician time. The clinician also feels more satisfied due to easy access and monitoring of patients. As an example, in high-risk pregnancies, remote monitoring devices and frequent telemedicine meetings lead to better outcomes, reduced visits, and better patient compliance.^[48]

Each specialty using telemedicine should have their standardized safety plans on what can and cannot be handled on telemedicine platforms. It is important that physicians, while understanding the benefits, also understand the limitations of telemedicine where in-person visits are safer and warranted.

Liability issues

There are several liability issues surrounding telemedicine. In the US, licensing and state medical boards are a prerequisite for licensing where the physician is providing telemedicine. Practicing telemedicine across state lines is illegal. While there is an increasing rise in the number of physicians providing telemedicine, especially with the rise of the COVID-19 pandemic, insurance carriers have been inconsistent with coverage.^[2] Medical liability remains a challenge. It is often not clear to the physician if their malpractice covers telemedicine visits. Telemedicine is a new platform of focused care that may leave room for litigation in terms of depth of evaluation. Recently, the American Heart Association has encouraged physicians to touch base with their institutions to make sure they are covered for telemedicine.^[49] Conventionally, a separate form must be completed for physicians to be covered for telemedicine. This will encourage physicians to adopt new technology. Furthermore, efforts by the Centers for Medicare and Medicaid Services to reimburse for telemedicine have also been positive in this direction.^[49]

Digital divide

The limitations to the use of telemedicine include crossing the digital divide where not all patients have access to quality telemedicine equipment, broadband/internet, or good cameras. Similarly, patients with mental or physical disabilities will require necessary accommodations.^[50] In addition, there may be issues with safeguarding clinical encounters where vulnerable patients may not have the privacy in their own homes to have an open conversation (i.e., abuse) and would benefit greatly from a face-to-face consultation.

Recommendations

Outline pathways

Each specialty needs to develop clearly defined clinical processes and procedures for evaluating patients while

ensuring patient safety. This may include situations where home or community-based professionals are conducting face-to-face patient encounters under direction of a specialist through telemedicine or remote monitoring devices.

Data storage mandates

These will be required to secure the record of data collected, whether audio-visual recordings, written records, or shared picture files as part of the EHR. Storage and security protocols should be delineated to mirror in-hospital data security processes.

Administrative records

Usage of various available telemedicine platforms will require differential data process management. Administrative forms, payment data, consent forms, and other patient encounter forms will require an outlined process for completion and storage while still following confidentiality and data security procedures.

Reimbursement

Each specialty will be required to develop standard reimbursement rates to optimize billing procedures (i.e., first visit, follow-up visit, visual clinical examination, etc.) and should have predefined reimbursement rates.

Telemedicine metrics

Development of clinical metrics may allow for optimal use of technology in the betterment of patient care (i.e., door to balloon time in myocardial infarction).

Patient encounter records

Telemedicine encounter records allow the patient and physician to capture the encounter for follow-up visits. They enable better record keeping in case of potential review because of such limited encounters, by acting as a case file.

Physician-led

We recommend a revision of current laws to mandate that telemedicine be availed only by certified physicians. This is important, particularly as telemedicine is still in its nascent stage, to keep examination and management limitations in mind and patient safety at the forefront.

SUMMARY

This collaboration proposes a framework for telemedicine to establish national roots with an emphasis on standardization across systems to allow for quality patient care, data collection, and accurate reimbursements. While telemedicine has established its value during the COVID-19 pandemic more than ever before, there remains significant opportunity for growth in ensuring it is uniformly performed with standardized note templates, recordings, and coding that will allow for consistent reimbursement despite patient location. Telemedicine remains very vulnerable and is on the brink of being ground-breaking as the new approach to patient care or a questionable modality for health-care delivery that will cause every health system to re-imagine virtual visits. If set up correctly, telemedicine provides significant opportunity to patients and physicians

alike. This collaboration attempts to elucidate four pillars needed for a systemically sound telemedicine system.

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Conflicts of interest

There are no conflicts of interest.

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