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Telehealth: Exploring the Ethical Issues

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I. INTRODUCTION

A. History

For more than a century, telephones and radio-enabled devices have been used to transmit medical information, particularly in times of war. In the 1960s, when embarking on the new era of space exploration, the National Aeronautics and Space Administration (NASA) began to see the need to address acute medical issues remotely using telecommunication technologies.[1] Methods were developed to monitor vital signs, triage complaints, and diagnose and treat the ailments of American astronauts who were miles above the Earth's surface. Thus, telehealth was born. As the Internet became more widely accessible and utilized, new dollars were invested in

[1] Rashid R. Bashshur & Jacqueline Lovett, *Assessment of Telemedicine: Results of the Initial Experience*, 48 AVIATION, SPACE & ENVTL. MED. 65 (1977); *see also* Charles R. Doarn, *Development of Telemedicine and NASA's Contribution*, 86 AEROSPACE MED. & HUMAN PERFORMANCE 504 (2015).

researching and developing telemedicine for the terrestrial care of remote populations.[2] Limited studies of telemedicine suggested efficient and reliable communication capabilities, but funding expired and further program development floundered. However, the 1990s and early 2000s saw a reinvigoration of interest in telehealth due to diminishing costs and greater availability of Internet connectivity and encryption software. Over the past two decades, telehealth programs have flourished across the United States and the globe.[3]The establishment of the American Telemedicine Association (ATA) in 1993 provided an organizational foundation for the growth of technology in medicine.[4]

The use of telehealth is an increasingly common avenue for providing clinical care and consultation, performing research and conducting public health interventions in the Twenty-First Century. Telehealth's expanding role has been spurred on by advancements in technology, widespread availability of the Internet and public/provider demand. Connecting with providers via Internet-based communication technologies is particularly gaining favor as a way of increasing access to remote or underserved populations, such as those living in rural areas, nursing homes or correctional facilities and those with impaired mobility. Indeed, the technologies used in telehealth and mobile health (mHealth) are evolving rapidly, allowing for improved access to medical care for many in need, and expanded options for the doctor-patient relationship.

Questions regarding the ethical practice of medicine in the telehealth era are evolving as quickly as the available technologies. At a minimum, there have been changes in how we should apply basic medical ethics when using the virtual space of the Internet as a setting for medical care. With the growth and availability of telecommunication technologies, healthcare professionals have encountered an emerging new set of ethical issues relating to the doctor-patient relationship, economics, privacy, cost and liability. Being cognizant of these issues will help providers and healthcare organizations avoid some of the common pitfalls in establishing and conducting a telehealth program for patient management, research and education.

B. Definitions

The terms "telehealth" and "telemedicine" have often been used interchangeably, including by the ATA. While we will also use these terms somewhat interchangeably, the difference in how they are often used is important to note. In addition, defining some other basic terminology can be very helpful in an informed discussion of telehealth, mHealth and virtual medicine.

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[2] Karen M. Zundel, *Telemedicine: History, Applications, and Impact on Librarianship*, 84 BULLETIN OF THE MED. LIBR. ASS'N 71 (1996).
[3] Pamela Whitten & Beverly Davenport Sypher, *Evolution of Telemedicine from an Applied Communication Perspective in the United States*, 12 TELEMEDICINE & E-HEALTH 590 (2006).
[4] Jonathan Linkous, *Telemedicine: An Overview*, 18 J. MED. PRACTICE MGMT. 24 (2002).

•*Telehealth and Telemedicine* – Telehealth is the broadest term. It refers to the use of technology in medicine and, although often used interchangeably with telemedicine, includes nearly any health information exchange via telecommunication. The definitional scope of telehealth includes synchronous management of patients, patient or provider advice and consultation, review of records, education and distance learning, home monitoring, public health investigations, health data management and integration of healthcare systems.[5] The administrative, research, educational and public health applications of technology are generally included under this broader term of "telehealth." The larger scope telehealth implies makes it the more preferred general term in the modern era. Telemedicine tends to be more narrowly defined, with the scope only including direct clinical services, including preventative, diagnostic and treatment delivery, such as synchronous and asynchronous clinics.[6]

•*mHealth and Remote Monitoring* – mHealth refers to the use of mobile technologies, such as smartphones, to monitor patients remotely or as a means of communication between patients and providers.[7] Examples include text messaging and collection of data, such as blood glucose, telemetry, sphygmomanometer readings or pulse oximetry, often via wearable body sensors, into mobile phone applications for organization, analysis and presentation to a clinician.[8] Remote monitoring is typically considered to be a form of mHealth, and can provide a more complete temporal picture of a patient's overall condition, giving more data points at a wider range of times during daily life, assisting in medical management.

•*Synchronous and Asynchronous* – Synchronous telemedicine involves a live, real-time, two-way video and audio connection between either a patient and provider or multiple providers. This method of telehealth most closely resembles the in-person interaction of an inpatient or outpatient visit, allowing clinicians to directly obtain a history, perform a limited physical exam and tailor questions to patient complaints. Also known as "store-and-forward," asynchronous telemedicine involves the digital recording of patient data, such as previously documented histories, medication administration records, photos, radiographic studies and laboratory analyses, for provider evaluation at a later time. A common application would be for non-urgent medical issues, such as teledermatology or radiology, and often involves the contribution of a sub-specialist consultant.

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[5] *Telehealth Programs*, HEALTH RES. & SERV. ADMIN., https://www.hrsa.gov/ruralhealth/telehealth/index.html (last visited June 16, 2017).
[6] Maria A. Loane & Richard Wootton, *A Review of Guidelines and Standards for Telemedicine*, 8 J. TELEMEDICINE & TELECARE 63 (2002).
[7] Karin Källander et al., *Mobile Health (mHealth) Approaches and Lessons for Increased Performance and Retention of Community Health Workers in Low- and Middle-Income Countries: A Review* 15 J. MED. INTERNET RESEARCH 1 (2013).
[8] Geoff Appelboom et al., *Smart Wearable Body Sensors for Patient Self-Assessment and Monitoring*, 72 ARCHIVES OF PUB. HEALTH 28 (2014).

•*Originating and Distant Site* – In all forms of telehealth, the location of the patient is referred to as the originating site. The distant site is the location of the healthcare provider or organization. These are important terms to recognize as they relate to licensure, scope of practice and liability.

At this point, we should explore the old and new ethical issues as they apply to telehealth and the practice of telemedicine. In the future, new ethical hurdles are certain to arise as practice catches up with the evolution of technology. Therefore, it is always important to keep the foundational principles in mind while simultaneously being open to addressing new issues as they emerge. Throughout, practitioners should be patient-focused in applying the science of technology in medicine.

II. THE DEPERSONALIZATION OF MEDICINE

The practice of medicine has a tradition of establishing trusting, and often emotionally intimate, relationships with patients. These relationships are vital because a patient's honest account of their symptoms and exposure history, including psychosocial issues, sexual activity and drug use, frequently help the clinician diagnose and treat often complex conditions. Patient trust of, and relationship with, the healthcare provider can significantly affect one's outcomes and quality of life.[9] Perceptions that the use of technology in healthcare lacks privacy and is innately "cold" in nature poses a risk of depersonalizing the doctor-patient relationship, potentially damaging it irrevocably. Some have been reluctant to broaden their scope of practice to include telehealth due to valid concerns about shifting this traditionally in-person relationship to the Internet. This requires and honest assessment of when, and why, one is using telehealth.

Knowing the limitations – not just technical limitations – are important when harnessing technology in medicine. The clinician should recognize when it may not be appropriate to use telehealth for communication, given the natural lack of intimacy involved. For example, telehealth may be perfect for evaluating a patient with symptoms of an upper respiratory tract infection, but inappropriate for discussing more serious diagnoses or end-of-life issues. There should never be a "one size fits all" presumption. Also, it behooves the clinician to recognize that the perception of depersonalization with technology can be heavily influenced by a patient's previous experiences, knowledge, trust of Western medicine and technology, socioeconomic status, beliefs and culture.[10]

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[9] Nicole Ernstmann et al., *Patients' Trust in Physician, Patient Enablement, and Health-Related Quality of Life During Colon Cancer Treatment*, 32 J. CANCER EDUC. 571 (2017); *see also* Steven A. Farmer et al., *Patient, Caregiver, and Physician Work in Heart Failure Disease Management: A Qualitative Study of Issues that Undermine Wellness*, 91 MAYO CLINIC PROC. 1056 (2016).

[10] Jane Chung et al., *Examining Korean and Korean American Older Adults' Perceived Acceptability of Home-Based Monitoring Technologies in the Context of Culture*, 42 J. INFORMATICS FOR HEALTH & SOCIAL CARE 61 (2017).

Therefore, having a practice solely utilizing telehealth technology has its limitations. Many experts recommend solutions such as having all initial visits be in-person with an opt-in approach to the future use of telemedicine. Technology should enable and enhance the doctor-patient relationship by making communication more open, accessible and convenient. A purely telemedicine-driven practice can be alienating to some, and practitioners should be cognizant of this fact. A combined approach, with the option to opt-in to any such alternative methods of care, is ideal for use with a broad and diverse patient base. Having an open dialogue with patients regarding issues of depersonalization and changes to the traditional doctor-patient relationship may be helpful in managing expectations and improve patient satisfaction.

III. PRIORITIZING EFFICIENCY & ECONOMICS ABOVE QUALITY CARE

Scheduling, clinic flow and reimbursement in healthcare have changed dramatically over the past decade. The old fee-for-service model is less relevant than ever, with the new goals focused on efficiency of care and clinical outcomes, such as hospital length-of-stay and readmission rates.[11] The Patient Protection and Affordable Care Act (ACA) along with Medicare bundled payments are driving this shift toward value-based care, with the financial risk being transferred from commercial insurers and government payers to hospital systems and independent physician groups.[12] This has led providers and medical centers to focus on efficiency, time management and reduction of overhead. Technology-based solutions, such as telehealth and electronic health records (EHR), are reasonable approaches with proven benefits. However, many patients and providers are concerned that these advancements may lead to reductions in the quality of care.

Internet prescribing, often issuing a large volume of potentially addictive narcotic medications via "pill mills," is the most obvious and impactful misuse of technology in medicine, and has undoubtedly contributed to the opioid epidemic in the US.[13] The US Department of Health and Human Services (DHHS), Department of Justice (DOJ) and state medical boards have pursued legal action, including loss of professional licensure, fines and jail time, for such offenders. Prescribing any controlled substances without a proper evaluation of a patient is irresponsible, professionally unethical and potentially dangerous. While an extreme example, Internet prescribing of pharmaceuticals highlights the need for a proper evaluation of patients. Telehealth

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[11] Richard Bruch, *A Sea Change in Medicine: Current Shifts in the Delivery and Payment of Medical Care*, 77 N.C. MED. J. 261 (2016); *see also* Mark I. Froimson et al., *Bundled Payments for Care Improvement Initiative: The Next Evolution of Payment Formulations. AAHKS Bundled Payment Task Force*, 28 J. ARTHROPLASTY 157 (2013); *see also* William B. Weeks, *Medicare's Bundled Payment Program and Health Care Utilization*, 315 JAMA 2470 (2016).

[12] Basit Chaudhry et al., *Systematic Review: Impact of Health Information Technology on Quality, Efficiency, and Costs of Medical Care*, 144 ANNALS OF INTERNAL MED. 742 (2006).

[13] Khary K. Rigg et al., *Prescription Drug Abuse & Diversion: Role of the Pain Clinic*, 40 J. DRUG ISSUES 681 (2010); *see also* James A. Inciardi et al., *Prescription Opioid Abuse and Diversion in an Urban Community: The Results of an Ultrarapid Assessment*, 10 PAIN MED. 537 (2009).

technologies may present a temptation for clinicians to perform more cursory evaluations, but the added efficiency afforded by telemedicine should not take away from high quality, patient-centered care. Technology should complement care, not prove to be a barrier.

IV. PRIVACY & CONFIDENTIALITY

As a baseline, healthcare professionals need to follow the Healthcare Portability and Accountability Act of 1996 (HIPAA)[14] rules and regulations regarding the handling of protected health information (PHI). Keeping sensitive and identifiable information confidential is ethically sound and legally required. In addition to basic non-maleficence, fines of more than $50,000 per breach, with a maximum penalty of $1.5 million, can be assessed to culpable providers for HIPAA privacy violations.[15] Whether the discussion is of social media, online banking, public data collection or healthcare, privacy can be complicated in the Internet age, and telehealth practitioners need to remain vigilant about their duty to protect PHI during visits and when storing PHI at the distant site.

A. The HIPAA Privacy Rule

Under HIPAA and the DHHS, the Privacy Rule was established in August, 2002.[16] The rule attempts to strike a balance between allowing the appropriate flow of information needed to provide high quality healthcare and assuring that an individual's health information is appropriately protected. It protects all "individually identifiable health information" held or transmitted by a covered entity or its business associates, in any form or media, whether electronic, in print or verbally.[17] As defined by the Privacy Rule, PHI includes data that would allow an outside party to identify an individual, including demographic data relating to: 1) an individual's past, present or future physical or mental health; 2) the provision of healthcare to an individual; or 3) past, present or future payment for the provision of healthcare to an individual.[18] PHI includes common identifiers, such as name, address, date of birth, email address, Social Security Number and, depending on the incidence and prevalence of a given condition, data as broad as zip code.[19]

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[14] *Summary of the HIPAA Privacy Rule*, U.S. Dep't of Health & Human Servs., https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html (last visited June 23, 2017).
[15],*HITECH Act Enforcement Interim Final Rule*, U.S. Dep't of Health and Human Servs., https://www.hhs.gov/hipaa/for-professionals/special-topics/HITECH-act-enforcement-interim-final-rule/index.html (last visited June 23, 2017).
[16] *Summary of the HIPAA Privacy Rule*, *supra* note 14.
[17] *Id.*
[18] *Id.*
[19] *Id.*

Responsible covered entities include health plans, healthcare providers, health information clearinghouses and business associates.[20] Any uses or disclosures of PHI must be authorized by the individual and only used in very limited settings, such as treatment, referral, payment and internal healthcare operations.[21] Some disclosures are allowed without consent when necessary for public health and safety, judicial and administrative proceedings, law enforcement purposes, cadaveric tissue donation, essential government functions or in cases of abuse.[22]

B. Current Standards in Telehealth

To meet these standards, telehealth interactions must be appropriately encrypted, firewalls maintained and updated, and any video, audio and PHI stored securely.[23] Databases used for program evaluation, external reporting or research should be approved by an accredited Institutional Review Board (IRB).[24] When utilizing telemedicine, the burden lies with the practitioner or organization at the distant site to ensure proper connectivity and encryption, update firewalls, enter records properly into a secure and password-protected EHR, recognize that stored data contains PHI, and practice the standard of non-maleficence.

The US Federal Food and Drug Administration (FDA) plays the critical regulatory role in ensuring the safety, security and effectiveness of hardware, medical devices and software used in the delivery of telemedicine, with the Center for Devices and Radiological Health (CDRH) acting as the lead agency.[25] The FDA and CDRH perform pre-market device reviews, post-market surveillance, quality monitoring, and assessing the standards and science of telehealth in general.[26] The agency's focus is on the intended use of any equipment, medical device or software.[27] They take into account medical condition, type of clinic, diagnosis and real-world treatment standards.[28] The FDA provides guidance regarding minimum standards, processing,

[20] *Health information privacy*, NAT'L INST. OF HEALTH, https://www.hhs.gov/hipaa/for-professionals/special-topics/research/index.html (last visited May 7, 2018).
[21] *Summary of the HIPAA Privacy Rule*, *supra* note 14.
[22] 45 C.F.R. § 164.512.
[23] *HIPAA Guidelines on Telemedicine,* HIPAA JOURNAL, https://www.hipaajournal.com/hipaa-guidelines-on-telemedicine/ (last visited May 7, 2017).
[24] Lisa A. Eckenwiler, *Moral reasoning and the review of research involving human subjects*, 11 KENNEDY INST. ETHICS J. 30 (2001).
[25] *FDA Radiological Health Program*, FDA, https://www.fda.gov/Radiation-EmittingProducts/FDARadiologicalHealthProgram/default.htm (last visited May 7, 2018).
[26] Nathan G. Cortez et al., *FDA Regulation of Mobile Health Technologies*, 371 THE NEW ENG. J. MED. 372 (2014).
[27] *Unique Device Identifiers (UDIs): A Roadmap for Effective Implementation*, ENGELBERG CTR. FOR HEALTH CARE REFORM AT BROOKINGS (Dec. 2014), https://www.fda.gov/downloads/MedicalDevices/UCM445330.pdf.
[28] *Id.*

display, encryption and storage of images for use in healthcare.[29] In 2015, the FDA issued guidance to provide clarity for mHealth application manufacturers as well, clarifying the standards for hardware, modem speed and connectivity, digital interfaces and communications portals.[30]

In addition to the basic ethical standards of privacy and confidentiality, practitioners must be cognizant of potential pitfalls encountered with the use of Internet connections for often sensitive health-related information. Several professional societies, including the ATA, can function as excellent resources when practice-specific questions arise. When storing PHI, utilizing password-protected, fully encrypted EHR, following IRB standards and de-identifying data when appropriate are outstanding starting points.

V. TECHNOLOGY AS AN ADDED BURDEN TO PATIENTS

For many Americans, technology has made the activities of daily living easier and more efficient. Overall, patient satisfaction surveys regarding the use of telemedicine have been exceptionally positive.[31] However, it is also clear that a digital divide exists between urban and rural populations[32] and poor access within some cultures such as Native American reservations.[33] Age-based differences in comfort and familiarity with modern technology can also act as barriers to equitable application of modern telemedicine technologies. Indeed, more than a decade of Pew polling has shown that about 85% of American adults use the Internet, but older adults have significantly lagged behind, with only 58% of senior citizens online.[34] The same polls have

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[29] Christopher J. Roth et al., *The Current State and Path Forward For Enterprise Image Viewing: HIMSS-SIIM Collaborative White Paper*, 29 J. DIG. IMAGING 567 (2016).
[30] *Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff*, FDA, http://www.fda.gov/downloads/medicaldevices (last visited June 19, 2017). *see also Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communication Devices: Guidance for Industry and Food and Drug Administration Staff*, FDA, https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm401996.pdf (last visited June 19, 2017).
[31] James D. Robinson et al., *Patient Perceptions of Acute Care Telemedicine: A Pilot Investigation*, 30 J. HEALTH COMMC'N 1269 (2015); *see also* Rhea E. Powell et al., *Patient Perceptions of Telehealth Primary Care Video Visits*, 15 THE ANNALS OF FAM. MED. 225 (2017); *see also* Pat Sevean et al., *Patients and Families Experiences with Video Telehealth in Rural/Remote Communities in Northern Canada*, 18 J. CLINICAL NURSING 2573 (2009).
[32] Alexandra J. Greenberg et al., *Differences in Access to and Use of Electronic Personal Health Information Between Rural and Urban Residents in the United States*, 132 J. RURAL HEALTH 27 (2016).
[33] Christine M. Markham et al., *Internet-Based Delivery of Evidence-Based Health Promotion Programs Among American Indian and Alaska Native Youth: A Case Study*, 5 JMIR RES. PROTOCOLS e225 (2016).
[34] Aaron Smith, *Older Adults and Technology Use*, PEW RES. CTR. (Apr. 3, 2014), http://www.pewinternet.org/2014/04/03/older-adults-and-technology-use/.

found racial and socioeconomic differences, with African-Americans, Hispanics, lower-income persons and those without a college education less likely to utilize the Internet.[35]

To harness new technologies, one must have the financial resources to purchase equipment, access to high-speed Internet and the education for proper use. Even simple mHealth interventions often require patients at the originating site to have smartphones, email and texting capabilities. The vast majority of Americans do own a cell phone, but only 80% of persons over 65 years-of-age own a cell phone with a mere 42% owning a smartphone.[36] Even though the socioeconomic and racial disparities in cell phone utilization are less pronounced, they stillexist. When designing a telehealth intervention, one must be cognizant of the age, educational, geographic and socioeconomic barriers that may be in place for patients. In fact, most telehealth programs are often specifically targeted towards traditionally underserved populations, composed of persons who may have poor access to, and education regarding, the use of technology.[37] Grant funding, bulk purchase and incorporation into distant site overhead are some options to increase access, and short, simple training regarding the use of hardware and software for patients could certainly remove some apprehension at the originating site. The ongoing issues with access to care represent an issue of medical ethics that must be addressed in telemedicine and mHealth.

VI. SHIFTING JURISDICTIONS OF PRACTICE & LIABILITY

Telehealth technologies allow healthcare professionals to see and manage patients without geographical barriers. However, increasing a practitioner's catchment area across state borders is often complicated by the restrictive nature of licensure and credentialing as well as concerns regarding liability. It may also thwart the longstanding concept in medicine of "patient care ownership." That is, taking responsibility as a provider for patient advocacy, autonomy, effective communication, follow-through, education and teamwork.[38] Depersonalization of the provider-patient relationship with technology and geographic divides, never meeting in-person, may reduce a physician's sense of patient care ownership. Shifting and widening jurisdictions of practice also tends to de-emphasize the broader community when the provider resides hundreds or thousands of miles away from his or her patient.

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[35] Andrew Perrin & Maeve Duggan, *Americans' Internet Access: 2000-2015*, PEW RES. CTR. (June 26, 2015), http://www.pewinternet.org/2015/06/26/americans-internet-access-2000-2015/.
[36] *Mobile Fact Sheet*, PEW RES. CTR., http://www.pewinternet.org/fact-sheet/mobile/ (last visited June 26, 2017).
[37] Eric S. Munsert et al., *Enhancing the quality of life and preserving independence for target needs populations through integration of assistive technology devices,* 17 TELEMEDICINE & E-HEALTH 478 (2011).
[38] Kimberly McLaren et al., *Ownership of Patient Care: A Behavioural Definition and Stepwise Approach to Diagnosing Problems in Trainees,* 2 PERSPS. MED. EDUC. 72 (2013).

Currently, any physician must be licensed to practice on a state-by-state basis, either as a temporary practitioner, visiting professor, visiting physician, visiting resident or fully licensed clinician. This restriction clearly limits the ability of clinicians to actually manage patients using telemedicine across state lines, with medical licensure required in the state of the originating site. There have been high-level discussions of federal licensure, telehealth-specific licensure or reciprocal licensure (as in the Veterans Affairs system),[39] but these options have been opposed by policymakers and some professional societies, including the Federation of State Medical Boards (FSMB) and American Medical Association (AMA),[40] who have significant lobbying power. The Interstate Medical Licensure Compact (IMLC) offers a new pathway for physicians to practice in multiple states,[41] but how this applies to telemedicine remains an evolving issue.

The ATA supports the implementation of a federal, even if telehealth-specific, license or medical license portability, stating "…these state-by-state approaches prevent people from receiving critical, often life-saving medical services that may be available to their neighbors living just across the state line. They also create economic trade barriers, restricting access to medical services and artificially protecting markets from competition."[42] Such ethical considerations in medical licensure have only just begun to receive serious and thoughtful discussion at the legislative leadership level, putting interstate practice of telemedicine on somewhat precarious legal ground. Medical malpractice insurers also need to enter the discussion with regard to liability in telehealth, particularly when considering out-of-state or international applications. Healthcare laws relating to telemedicine, remote monitoring and mHealth are clearly in their infancy and will continue to evolve over the upcoming decade.

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[39] Kacie Blackman, *Telehealth and Licensing Interstate Providers*, 24 NCSL Legisbrief 1 (2016). *See also* John K. Iglehart, *The Veterans Administration Medical Care System and the Private Sector*, 313 THE NEW ENG. J. MED. 1552 (1985).

[40] *Policy Statement H-480.969 and D-480.999*, AMA, https://www.ama-assn.org/sites/default/files/media-browser/public/about-ama/councils/Council%20Reports/council-on-medical-education/a10-cme-telemedicine-medical-licensure.pdf (last visited June 26, 2017).

[41] Interstate Medical Licensure Compact (IMLC), http://www.imlcc.org/ (last visited June 26, 2017).

[42] *Statement on Federal Licensure*, AM. TELEMEDICINE ASS'N, http://www.americantelemed.org/main/policy-page/federal-policy/medical-licensure (last visited June 26, 2017).

VII. EFFICACY

The whole of the published literature overwhelmingly concludes that telemedicine has the potential to increase access to care,[43] improve key health outcomes and reduce costs.[44] The American College of Physicians (ACP), AMA and many other professional organizations support the expanded role of telehealth strategies in healthcare delivery, as long as an appropriate provider-patient relationship is established.[45] It is clear that clinicians can effectively manage patients with multiple medical conditions using telemedicine, but should we? It is important to provide the best quality, up-to-date medical care for patients, but what do the data show regarding the actual efficacy and usefulness of technology as a replacement for in-person care?

Telepsychiatry is now more than fifty years old, and has a rich literature showing its efficacy in several patient populations.[46] In 1956, Cecil Wittson of the Nebraska Psychiatric Institute (NPI) began using one-way, closed circuit television transmission to provide psychiatric training to medical students at the Medical College of Nebraska.[47] In 1957, this instructional network was expanded to several surrounding states, and began using live, two-way video and audio.[48] By 1959, patient- and group-centered telepsychiatry was being used at NPI in Omaha to manage patients at Norfolk State Hospital, 112 miles away.[49] Psychiatry has formed the basis for

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[43] Roxanne Nelson, *Telemedicine and Telehealth: The Potential to Improve Rural Access to Care*, 117 THE AM. J. NURSING 17 (2017). *see also* Kristin N. Ray et al., *Optimizing Telehealth Strategies for Subspecialty Care: Recommendations from Rural Pediatricians*, 21 TELEMEDICINE AND E-HEALTH 622 (2015); *see also* Isabelle Ellis, *Is Telehealth the Right Tool for Remote Communities? Improving Health Status in Rural Australia*, 16 CONTEMP. NURSE 163 (2004).

[44] Shu-Lin Uei et al., *The Effect of Telehealth Systems and Satisfaction with Health Expenditure among Patients with Metabolic Syndrome*, 24 TECH. HEALTH CARE S527 (2016). *see also* Centaine Snoswell et al., *Cost-Effectiveness of Store-and-Forward Teledermatology: A Systematic Review*, 152 JAMA DERMATOLOGY 702 (2016).

[45] Hilary Daniel et al., *Policy Recommendations to Guide the Use of Telemedicine in Primary Care Settings: an American College of Physicians Position Paper*, 163 ANNALS OF INTERNAL MED. 787 (2015); *see also Coverage and Payment for Telemedicine*, AMA, http://mb.cision.com/Public/373/9600400/99c2f1db96d7fec3.pdf (last visited June 20, 2017).

[46] Kelly P. Maieritsch et al., *Randomized Controlled Equivalence Trial Comparing Videoconference and in Person Delivery of Cognitive Processing Therapy for PTSD*, 22 J. TELEMEDICINE & TELECARE 238 (2016); *see also* Jessica Abrams et al., *Practical Issues in Delivery of Clinician-to-Patient Telemental Health in an Academic Medical Center*, 25 HARV. REV. PSYCHIATRY 135 (2017); *see also* Sam Hubley et al, *Review of Key Telepsychiatry Outcomes*, 6 WORLD J. PSYCHIATRY 269 (2016).

[47] *The History of Telemental Health*, JSA HEALTH, http://jsahealthmd.com/the-history-of-telemental-health/ (last visited May 7, 2018).

[48] CL Wittson et al., *Two-way television in group therapy*, 12 MENTAL HOSP. 22, 22-23 (1961).

[49] William J. Crump & Timo Pfeil, *A Telemedicine Primer. An Introduction to the Technology and an Overview of the Literature*, 4 ARCHIVES FAM. MED. 796 (1995).

synchronous telemedicine as it requires a simple connection and no peripheral hardware, such as a telephonic stethoscope, to assist with the physical exam.

With expansion of its use to various medical and surgical specialties, telemedicine programs have been shown to improve clinically significant patient outcomes in the management of diabetes mellitus,[50] coronary artery disease and hypertension,[51] preventive medicine,[52] stroke,[53] chronic obstructive pulmonary disease (COPD),[54] triage and consultation in emergency departments,[55] critical care,[56] dermatologic and ophthalmologic care,[57] and many other acute and chronic conditions. Our own large study of the impact of a synchronous telehealth program in corrections showed improved outcomes in key measures of human immunodeficiency virus

[50] Shawn W.H. Lee et al., *Telemedicine for the Management of Glycemic Control and Clinical Outcomes of Type 1 Diabetes Mellitus: A Systematic Review and Meta-Analysis of Randomized Controlled Studies*, 8 FRONTIERS IN PHARMACOLOGY 330 (2017).
[51] Brodie M. Sakakibara et al., *Using Mobile-Health to Connect Women with Cardiovascular Disease and Improve Self-Management*, 23 TELEMEDICINE & E-HEALTH 233 (2017); *see also* Kaisen Huang et al., *Telehealth Interventions Versus Center-Based Cardiac Rehabilitation of Coronary Artery Disease: A Systematic Review and Meta-Analysis* 22 EUR. J. PREVENTIVE CARDIOLOGY 959 (2015). *See also* Lorraine Buis et al., *Text Messaging to Improve Hypertension Medication Adherence in African Americans from Primary Care and Emergency Department Settings: Results from Two Randomized Feasibility Studies*, 5 JMIR mHealth & uHealth e9 (2017); *see also* Richard V. Milani et al., *Improving Hypertension Control and Patient Engagement Using Digital Tools*, 130(1) THE AM. J. MED. 14 (2017).
[52] Andre Matthias Müller et al., *The Effectiveness of e- & m-Health Interventions to Promote Physical Activity and Healthy Diets in Developing Countries: A Systematic Review*, 13 INT'L J. BEHAV. NUTRITION & PHYSICAL ACTIVITY 109 (2016).
[53] Lawrence R. Weschler et al., *Telemedicine Quality and Outcomes in Stroke: a Scientific Statement for Healthcare Professionals from the American Heart Association/American Stroke Association*, 48 Stroke e3 (2017).
[54] Pernille Heyckendorff Lilholt et al., *Telehealthcare for Patients Suffering from Chronic Obstructive Pulmonary Disease: Effects on Health-Related Quality of Life: Results from the Danish "TeleCare North" Cluster-Randomised Trial*, 7 BMJ Open e014578 (2017).
[55] Yael Harris et al., *Building the Evidence Base for Tele-Emergency Care: Efforts to Identify a Standardized Set of Outcome Measures*, 23 Telemedicine & e-Health e1 (2017).
[56] Jeanette L. Morrison et al., *Clinical and Economic Outcomes of the Electronic Intensive Care Unit: Results from Two Community Hospitals*, 38 CRITICAL CARE MED. 2 (2010).
[57] Malcolm Creighton-Smith et al., *Incidence of Melanoma and Keratinocytic Carcinomas in Patients Evaluated by Store-and-Forward Teledermatology vs. Dermatology Clinic*, 56 INT'L. J. DERMATOLOGY 1026 (2017); *see also* Jennifer L. Hsiao & Dennis H. Oh, *The Impact of Store-and-Forward Teledermatology on Skin Cancer Diagnosis and Treatment*, 59 J. AM. ACAD. DERMATOLOGY 260 (2008); *see also* Siddarth Rathi et al., *The Current State of Teleophthalmology in the United States*, 124 OPHTHALMOLOGY 1729 (2017).

(HIV) care.[58] These outcomes in HIV have been associated with reductions in morbidity, mortality and transmission.[59]

Project Extension for Community Healthcare Outcomes (ECHO), based at the University of New Mexico, is an asynchronous, provider education-based telehealth model that has been successfully used to triage and treat patients with hepatitis C infection.[60] The Project ECHO model has shown to improve outcomes for patients with several chronic diseases, most notably hepatitis C and HIV, when applied in rural areas with relative shortages of subspecialty providers.[61] As an educational and practical consultative model, Project ECHO has great potential to increase access to subspecialist care in rural areas, nursing homes, correctional facilities and other remote, underserved areas.

In limited studies, the use of mHealth applications for home monitoring has been demonstrated to improve the quality of care in persons with cardiovascular disease,[62] including hypertension and congestive heart failure,[63] management of diabetes and mental health care.[64] However, many clinicians are unclear regarding how to correctly pool, analyze and act upon such a large number of data points. Studies are promising, but have not led to clear and high-quality, evidence-based guidelines for the use of mHealth. The use of cellular phone apps and text messaging appears to be most promising for very remote populations in the developing world who may have no

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[58] Jeremy D. Young et al., *Improved Virologic Suppression with HIV Subspecialty Care in a Large Prison System Using Telemedicine: an Observational Study with Historical Controls*, 59 CLINICAL INFECTIOUS DISEASES 123 (2014).
[59] Thomas C. Quinn et al., *Viral Load and Heterosexual Transmission of Human Immunodeficiency Virus Type 1*, 342 THE NEW ENGL. J. MED. 921 (2000); *see also* Myron S. Cohen et al., *Prevention of HIV Infection with Early Antiretroviral Therapy*, 365 THE NEW ENGL. J. MED. 493 (2011); *see also* Suzanna Attia et al., *Sexual Transmission of HIV According to Viral Load and Antiretroviral Therapy: Systematic Review and Meta-Analysis*, 23 AIDS 1431 (2009); *see also* Mari M. Kitahata et al., *Effect of Early Versus Deferred Antiretroviral Therapy for HIV on Survival*, 360 THE NEW ENGL. J. MED. 1815 (2009).
[60] Sanjeev Arora et al., *Academic Health Center Management of Chronic Diseases Through Knowledge Networks: Project ECHO*, 82 ACAD. MED. J. OF THE ASS'N OF AMER. MED. COLLEGES 154 (2007).
[61] Sanjeev Arora et al., *Outcomes of Treatment for Hepatitis C Virus Infection by Primary Care Providers*, 364 THE NEW ENGL. J. MED. 2199 (2011); *see also* John D. Scott et al., *Project ECHO: a Model for Complex, Chronic Care in the Pacific Northwest Region of the United States*, 18 J. TELEMEDICINE & TELECARE 481 (2012).
[62] Vikram Chandrasekara, *Measuring Vital Signs Using Smart Phones* (2010) (published dissertation, University of North Texas), https://pdfs.semanticscholar.org/7883/0cf36262f92049a7b4348813b3a7734f5287.pdf.
[63] Marie Chan et al., *Smart Wearable Systems: Current Status and Future Challenges*, 56 ARTIFICIAL INTELLIGENCE MED. 137 (2012).
[64] Lisa Marzano et al., *The Application of mHealth to Mental Health: Opportunities and Challenges*, 2 THE LANCET PSYCHIATRY 942 (2015).

feasible means of transportation. A review of the literature suggests that for many chronic conditions mHealth will likely be a key component of care in the future, although likely not a method of comprehensive medical care.

Currently, the FDA offers regulatory oversight or guidance for the use of smart phone apps, wearables or telemedicine peripherals, such as telephonic stethoscopes, otoscopes and ophthalmoscopes.[65] In the modern era, peripheral hardware components can provide accurate and reliable video, photos, audio, imaging and electrocardiography to assist the clinician in conducting a real-time physical examination. However, more high-quality studies are needed to clarify the appropriate applications of equipment and software for use in the day-to-day of telemedicine.

VIII. TELEHEALTH IN RESEARCH & EDUCATION

A. Research

Standards of practice are important in medicine, and this concept applies to clinical research as well. As with any research involving human subjects, instituting ethical research practices, prioritizing the protection of subjects and PHI, and thorough examination of protocols by IRBs should be applied to clinical trials in telehealth. The use of modern technology does not change any ethical standards of research, and investigators should remain particularly cognizant of video and audio encryption, updating of firewall protections and storage of video, audio and PHI.

The emergence of new ethical issues in performing digital age research has led to the launching of the Connected and Open Research Ethics (CORE) initiative.[66] The CORE is a free, Internet-based resource that convenes key stakeholders in the telehealth and mHealth arena to dynamically shape, and respond to, questions regarding ethical and responsible research practices. Focus groups and experts were convened with IRB representatives to launch a platform in 2016, representing a global network of more than 200 individuals with expertise in privacy, technology, bioethics, research ethics and regulatory issues. The goal is to assist researchers using synchronous telehealth, mHealth, social media, and other Internet-enabled methods of data collection to construct appropriate study methods and consent language when designing clinical research studies.

B. Medical Education

With the emergence of telehealth, several institutions of higher medical education worldwide have successfully designed and implemented specific educational courses and modules for

[65] FDA, *supra* note 30.
[66] John Torous & Camille Nebeker, *Navigating Ethics in the Digital Age: Introducing Connected and Open Research Ethics (CORE), a Tool for Researchers and Institutional Review Boards*, 19 J. MED. INT. RES. 38 (2017).

students.[67] It is clear that telehealth – both synchronous and asynchronous – will play a major role in the future of medicine. Whether providing one-on-one care, consulting via the ECHO model, reviewing bulk data trends using mHealth applications or connecting the "internet of things" to improve public health policy, the foundations of healthcare are shifting. Given these changes, we call upon institutions of medical education and post-graduate clinical training programs to incorporate these, and other, ethical principles into their instruction regarding telemedicine. Telehealth is more than an Internet-assisted conversation akin to a conference call. Indeed, future healthcare professionals must keep the basic tenets of ethical practice in mind while keeping apace of new methods of care.

IX. CONCLUSIONS

The adoption of telehealth, telemedicine, remote monitoring and mHealth is increasing, and this may benefit patients and practitioners in myriad ways. Technology allows us to improve healthcare access to many underserved populations, including those living in rural areas, nursing homes, correctional facilities and the developing world. However, as we move forward, it is vital to consider the need to adhere to established principles of medical ethics, adapt old concepts to new forms of communication and address the unique ethical issues one may encounter with the use of technology in healthcare. Clinicians must always be cognizant of risks and implement ethical safeguards, all while nurturing the therapeutic relationship, insuring confidentiality, maintaining patient satisfaction and appropriately utilizing technology to provide evidence-based care and clinical benefits.

The AMA has clearly acknowledged that telehealth is really just a method of providing healthcare, using a different, technology-based format. At its annual meeting in Chicago, the AMA Board of Delegates agreed upon a public position statement on Ethical Practice in Telemedicine.[68] The policy affirms that physicians providing care via technology have the same ethical responsibilities as those providing care in brick and mortar environments.[69] These responsibilities include providing competent care, respecting patient privacy and confidentiality, taking appropriate steps to ensure continuity of care and following best practice guidelines.[70]

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[67] Christiane Brockes et al., *Evaluation of the Educational "Clinical Telemedicine/e-Health" in the Curriculum of Medical Students at the University of Zurich,* 23 TELEMEDICINE & E-HEALTH e1 (2017); *see also* Rafael Oliveira Chaves et al., *An Innovative Streaming Video System with a Point-of-View Head Camera Transmission of Surgeries to Smartphones and Tablets: An Educational Utility,* 24 SURGICAL INNOVATION 462 (2017).

[68] *AMA Adopts New Guidance for Ethical Practice in Telemedicine,* AMA, https://www.ama-assn.org/ama-adopts-new-guidance-ethical-practice-telemedicine (last visited June 26, 2017).

[69] *Id.*

[70] *Id.*