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Title: Telemedicine in Liver Disease and Beyond: Can the COVID-19 Crisis Lead to Action?

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Abbreviations:

COVID-19 – Coronavirus Disease 2019

CMS – Centers for Medicare & Medicaid Services

ECHO - Extension for Community Healthcare Outcomes

HCV – Hepatitis C Virus

HHS – Health and Human Services

NPS – Net Promoter Score

SARS-CoV-2 - severe acute respiratory syndrome coronavirus 2

SD - Standard Deviations

ABSTRACT

Evidence strongly supports that access to specialty gastroenterology or hepatology care in cirrhosis is associated with higher adherence to guideline-recommended care and improves clinical outcomes. Presently, only about one half of acute care hospitalizations for cirrhosis-related complications result in inpatient specialty care and the current hepatology workforce cannot meet the demand of patients with liver disease nationwide, particularly in less densely populated areas and in community-based practices not affiliated with academic centers. Telemedicine, defined as the delivery of health care services at a distance using electronic means for diagnosis and treatment, holds tremendous promise to increase access to broadly specialty care. The technology is cheap and easy to use, however, is presently limited in scale by interstate licensing restrictions and reimbursement barriers. The outbreak of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and Coronavirus Disease 2019 (COVID-19) has, in the short-term, accelerated the growth of telemedicine delivery as a public health and social distancing measure. Herein, we examine whether this public health crisis can accelerate the national conversation about broader adoption of telemedicine for routine medical care in non-crisis situations using a case series from our telehepatology program as a pragmatic example.

The outbreak of SARS-CoV-2 Coronavirus Disease 2019 (COVID-19), which began in December 2019 has been declared a public health emergency by the Department of Health and Human Services.⁽¹⁾ Widespread transmission of the virus has reached pandemic proportions and is now beginning to cause disruptions in daily life in the United States. As part of the public health response, the Center for Medicare & Medicaid Services (CMS) and private payers are lifting restrictions on telemedicine reimbursement to facilitate healthcare access while minimizing the spread of infection.

As part of a social distancing and containment strategy, multiple experts and tertiary care centers are rapidly adopting telephone- and video-based appointments to assist with triage of symptomatic patients and conduct routine visits to prevent the spread of infection. This crisis situation, however, additionally presents an opportunity to more broadly examine telemedicine, its promise and barriers to implementation.

Telemedicine, a term often used interchangeably with telehealth, is defined as the delivery of health care services at a distance using electronic means for “the diagnosis of, treatment, and prevention of disease and injuries, research and evaluation, education of health care providers” to improve health.(2) Despite the potential of telemedicine to improve access to care, its uptake has been variable due to inadequate reimbursement, interstate licensing barriers, and to a lesser extent lack of infrastructure and resistance to change. (2, 3) We describe a case study of a “telehepatology” (telemedicine for advanced liver disease) between a tertiary-care center and community-based gastroenterology practice, its success and challenges, in order to help inform a conversation about its utility in a public health crisis and beyond.

TELEHEPATOLOGY PROGRAM

Background

In the Fall of 2017, our team embarked upon a project with the Penn Medicine Center for Health Care Innovation seeking to improve access to liver disease specialists by leveraging telemedicine for patients with advanced liver disease. The motivating factor to use telemedicine as the care delivery innovation was that there is a dearth of liver disease specialists nationally with the majority concentrated in heavily populated urban areas and transplant centers.(4, 5) Multiple studies in liver disease have shown that access to specialty care improves adherence to guideline-recommended care for liver disease and clinical outcomes such as readmissions and mortality.(6-8) Rooted in this prior research, the goal of our program was to improve access to care for advanced liver disease,

which has a comparable morbidity and mortality to end stage congestive heart failure and chronic obstructive pulmonary disease.(9)

The tertiary care team partnered with a large, community-based gastroenterology (GI) practice of 23 healthcare providers located in Lancaster, Pennsylvania about 60 miles from the downtown University Hospital. Serendipitously, a physician who cared for many of the complex liver disease cases retired from the community-based GI practice as the partnership began, and so the case for the telemedicine program was based on the mutual desire for innovation, efficiency, and clinical need. Due to the lack of reimbursement parity by most commercial payers in Pennsylvania, the service was provided on a one-time basis “in-kind” under a research grant. Patients were not billed for the service and providers were not reimbursed.

Project Set-Up and Execution

After several planning phone calls, in-person meetings, and staff introductions, VidyoConnect™ was installed at the referring site (Lancaster Pennsylvania) and tertiary care site (Philadelphia Pennsylvania). The University hospital has a license for the technology, which is HIPAA compliant and encrypted. The staff training was seamless, and the scheduling workflows were developed within 2 weeks. The technology startup costs for the clinical departments were minimal – two extra monitors, two cameras, two microphones, a small amount of overhead, and scheduling staff time.

Objectives

The immediate goals of the project were to assess program feasibility as measured by the team’s ability to deliver live video visits at a distance, acceptability for patients and providers, and fidelity, i.e. was the program delivered as originally intended. The ultimate goal was to develop a scalable and sustainable program to improve patient access to subspecialty care for liver disease without compromising the quality of clinical care.

Workflow

All telehepatology program participants were established patients in the referring community-based practice located about 60 miles from Philadelphia. The patients were identified in two ways: 1) if they had a hospitalization for decompensated cirrhosis and were offered a post-hospitalization telehepatology appointment, 2) if they were referred by their gastroenterologist for a second opinion for the diagnosis of or management of any liver disease. This was a pragmatic study whereby the hepatology consultant delivered telemedicine to any patient determined to be clinically appropriate by the referring community-based practice and were sequentially included. Patients verbally consented to the appointment and subsequently verbally consented to answering surveys.

The appointment process was simple: a hepatologist at the University Hospital site (MS) received liver disease referrals and scheduled patients at a time convenient for them and for the provider. The patient attended a scheduled appointment in the office of the referring community-based GI practice in a dedicated clinic exam room. The hepatologist conducted one live video visit using Vidyo™ desktop technology between the Penn Medicine and the referring GI practice. The medical assistant at the referring site in Lancaster Pennsylvania obtained patient vital signs and medications and recorded immediate or urgent physician recommendations after the visit. As both practices use Epic MyChart with the CareEverywhere interoperability options, clinical records from the distant site were readily available to the hepatology provider prior to and during the appointment. All other routine communication took place via letters sent by the specialist to the referring providers as conducted in routine clinical care.

Outcomes

Feasibility and Fidelity

From March 2018 through December 2019, a total of 67 patients were referred to the telehepatology program, 57 (85%) had clinical appointments, 5 (7%) had electronic consultations, and 4 (6%) patients were not able to be scheduled due to patient preferences or clinical issues. Patients were referred for 3 main reasons: 1) after a cirrhosis-related hospitalization, 2) second opinion consultation on the clinical management of advanced liver disease, 3) consideration of liver transplantation. The mean age was 52 (standard deviation 11.5), 27 (47%) were female; 26 (46%) had decompensated

cirrhosis, and 31 (54%) were referred for a second opinion for other diagnostic or treatment challenges in liver disease. On average, the new patient visits lasted 31 minutes in-person with 30-45 minutes of reviewing patient records and charting before and after the visits. Two visits had technical issues due to software upgrades resulting in one delayed visit on the same day and one visit requiring rescheduling.

Actionable Clinical Recommendations

A total of 26 (45%) individual patient visits resulted in new tests being ordered, 26 (45%) resulted in medication changes, and 10 (18%) led to subsequent liver transplant referrals. Among the 10 patients referred for transplantation, 8 underwent subsequent liver transplant evaluation. Among those 8, 2 are actively waitlisted, 3 have completed testing and are early for transplantation, 1 is in evaluation, and 2 have been determined to not be transplant candidates.

Patient-Rated Acceptability

The team calculated a Net Promoter Score (NPS), measuring patient likelihood to recommend the telehepatology service to a friend or colleague, considered a gold standard customer satisfaction tool. (10) Patients were asked on a scale of 0 to 10 to rate the likelihood of recommending the telemedicine service to a colleague or friend. The NPS was then calculated as an index from -100 to 100. NPS above 70 indicates a very positive experience and a high likelihood of a positive word of mouth. A total of 38 of 57 (65%) patients who had video appointments agreed to being contacted for surveys and 37 of 38 (97%) of those contacted responded. Among the responders, the mean NPS was 92, indicating they had an excellent experience and high satisfaction, well above levels typically seen in health care settings. A total of 4 patients (11%) thought the audiovisual quality of the video visit could be improved and 4 (11%) felt that provider communication with referring providers could be improved.

Provider-Rated Acceptability

Referring providers were asked to give verbal and written open-ended feedback to study staff about their experience with the telemedicine program. The feedback was uniformly positive, citing the

hepatology provider as “excellent to work with”, “helpful”, and “quick to provide recommendations and arrange for all of the services that were needed to ensure a positive outcome”. The program was seen as “convenient”, “seamless”, “helpful with difficult cases”, and “allowed us to obtain expert consultation efficiently and quickly”. Another provider thought the telemedicine service was “a valuable service to providers and the community”.

The Challenge: How Can a Pilot Become a Program?

Despite a highly efficient program with actionable clinical recommendations, high ratings from patients and referring providers, and perceived benefit to the community, there are multiple barriers in bringing the telehepatology pilot to scale.

The key challenges are legislative barriers and payer variability. These are commonly inter-related: reimbursement is needed to financially support the program and at this time, payer reimbursement policies are highly variable and most payers do not provide telemedicine parity with in-person visits. In our state (Pennsylvania), there is limited reimbursement for telemedicine in both rural and non-rural settings. Telemedicine programs cannot legally provide “in-kind” new patient consultations, outside of the limited context of research, due to the potential for referral inducement and the federal Anti-Kickback Statute, which considers “in-kind visits” a form of referral inducement.⁽¹¹⁾ In the absence of payer reimbursement, several different models of telemedicine would have been legal and sustainable, however, not necessarily financially viable. The first model could have been a ‘physician to physician’ business agreement from the referring practice to the tertiary care practice and the second ‘direct to consumer’ whereby the patient would pay a fee to the referring provider. Both models were considered, but neither was deemed suitable or financially sustainable by referring providers.

Finally, our program is headquartered in a city, Philadelphia, in close proximity to a tri-state area encompassing Pennsylvania, Delaware, and New Jersey. Unfortunately, the practice of medicine and telemedicine being no exception is subject to state-specific licensing regulations and cannot be delivered across state lines by a practitioner in Pennsylvania if they are not licensed in those other states. State licensing laws were originally enacted to prevent incompetent physicians from practicing and to control entry into the practice of medicine in the Civil War Era. ⁽¹²⁾ However, these

historical reasons for state licensing restrictions are no longer valid and hamper providers' ability to deliver care as they limit patients' ability to access it. These rules especially antiquated as medical licensing for physicians must adhere to national clinical training standards and competencies set by the Accreditation Council for Graduate Medical Education, the Centers for Medicare and Medicaid Services' Graduate Medical Education standards, and the Liaison Committee on Medical Education. Licensing board exams are national and not state-specific. (13) Unfortunately, telemedicine which in its promise is supposed to bridge distances and improve access particularly suffers from the deleterious impact of these outdated laws.

Key Takeaways from the Local Pilot

After piloting the telehepatology program, there were multiple key takeaways imparted on us by the experience. Firstly, partnerships between academic and community-based practices are strengthened by increased communication and additional face-to-face time. By becoming a virtual hepatology provider in a community-based clinic, the hepatologist was incorporated into treatment team greatly facilitating open communication with medical assistants, nurses, physicians, and advanced practice providers in the referring practice. These relationships were built in a short period of time, and perhaps surprisingly did not require in-person contact. Multiple patients remarked how thankful they were to receive an expert opinion whether it was reassurance or clinical concern resulting in further testing or transplant evaluation. Referring providers felt the program was efficient and valuable, however, did not see a business case for it that could help bring the program to scale in the current reimbursement climate. Least expected, however, was the general lack of inertia when piloting the new care delivery model. There was little hesitation on the part of our patients in adopting a new way to communicate with a referring provider they had never met as long as the procedure was explained to them ahead of the appointment. Perhaps, this reflects the ubiquity of technology and enhanced uptake among all age groups.

The positive experience of our program must be placed into context as telemedicine for liver disease has been successful in other healthcare settings, particularly in integrated systems of care.

Telemedicine has been successfully used for many years for Hepatitis C therapy in incarcerated and rural populations.(2) One of the most durable and scalable examples of telemedicine for liver disease has been for hepatitis C virus (HCV) treatment as part of the Extension for Community Healthcare Outcomes (ECHO), or Project ECHO program.(14) ECHO targets front-line primary care providers to enhance expertise and enable problem-based learning via live video teleconferencing with subspecialty experts. Among other factors, part of the success of Project ECHO is that it does not rely on billing or reimbursement as a 'provider-to-provider' model. Innovative extensions of PROJECT ECHO spearheaded by Price and colleagues, such as the University of California, San Francisco's 'DeLIVER Care' mobile HCV screening van equipped with point-of-care HCV testing and liver stiffness assessment, have successfully expanded HCV care to the community.(3) As an early adopter of telemedicine and after the success of Project ECHO in 2011, the Veteran Affairs developed and implemented the Specialty Care Access Network–ECHO to increase access, training, and provide real-time expert consultation for primary care physicians for multiple chronic conditions, including HCV and chronic liver disease. Recent VA data from Su and colleagues support that the SCAN-ECHO program improves survival in liver disease. (15) Several recent VA studies by Konjeti and John and colleagues showed that telemedicine enhanced the efficiency of liver transplant evaluations. (16, 17) Unfortunately, currently such programs cannot readily be implemented outside of integrated systems of care or accountable care organizations given the regulatory and financial barriers described above.

We are now faced with a public health emergency due to the COVID-19 virus. Multiple stakeholders are temporarily increasing telemedicine video visits in aiding symptom screening and diagnosis in ways that are convenient, scalable and efficient. Although convenience may sound simply like something that's a nice bonus for the sake of experience, however, we also know that eliminating friction and effort increase desirable behaviors. For example, convenience may facilitate a patient with relevant symptoms and health concerns seeking care earlier rather than putting it off and may lead to higher engagement and better outcomes. Minimizing spread, based on human proximity and contact, also reinforces telemedicine's advantages for safety. Delivering urgent and routine care for those who are infected and for populations who may be more vulnerable to infection, such as the elderly or people who are immunocompromised, in a remote manner limiting exposure frames this second layer of opportunity and simply makes common sense.

The Current State of Telemedicine Emergency Coverage under COVID-19

On February 28th, key telemedicine interest groups (The American Telemedicine Association, eHealth Initiative, Health Innovation Alliance, Healthcare Information and Management Systems Society (HIMSS), Personal Connected Health Alliance (PCHAlliance) sent a letter to congress to expand access to telemedicine. (1) On March 4th, 2020 U.S. Congress approved an \$8.3 billion package novel coronavirus (COVID-19) spending package, which includes an emergency telehealth waiver allowing the Department of Health and Human Services (DHHS) Secretary to waive certain Medicare telehealth restrictions during the coronavirus public health emergency. (18) On March 24th, 2020, the Coronavirus Preparedness and Response Supplemental Appropriations Act (H.R.6074) was signed into law (19). This law temporarily lifts previous telehealth/telemedicine restrictions, namely: 1) patients do not have live in rural areas to receive telemedicine, 2) there is no restriction on the type of site where telemedicine can be delivered and patients may receive telemedicine from home. HHS has issues a notice relaxing requirement to use Health Insurance Portability and Accountability Act (HIPAA)-compliant software to communicate with patients remotely as long as the technology is used in good faith. (18)

Following the passing of federal legislation, many private payers have lifted telemedicine restrictions temporarily, made provisions for 'parity', i.e. the same levels of reimbursement as for in-person visits, several have eliminated cost-sharing for telemedicine services.(20) The legal and regulatory landscape continues to evolve rapidly with up-to-date federal and state specific information on regulatory and billing compliance available on the websites for the Department of Health and Human Services, (1), CMS (21), and the Center for Connected Health Policy.(22)

The Path Forward

Despite the promising developments to rapidly remove telemedicine barriers in addressing the COVID-19 virus, multiple challenges remain when thinking about integrating telemedicine into routine clinical care. Integrated health-systems such as the Veterans Affairs and Kaiser have invested in telemedicine infrastructure, however, other health-systems do not yet have the capability to bring these services to scale. Interstate licensing issues and variable reimbursement policies will continue

to be barriers before widespread adoption will be possible as evidenced from our examples and many others that are unpublished.

CONCLUSIONS

Telemedicine technology is low-cost, widely available, and accepted by patients and providers. We highlight a case study in telehepatology whereby providing care to patients with complex advanced liver disease is feasible, acceptable, efficient, and does not compromise clinical care. The unprecedented COVID-19 public health emergency provides us with an opportunity to leverage this technology not just in times of crisis, but to improve access, safety and efficiency for primary and specialty care. In order to achieve this, we need to change our payer reimbursement policies and inter-state licensing regulations to better serve the healthcare needs of our community.

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