Health Care Policy and Regulatory Challenges for Adoption of Telemedicine in Kidney Transplantation

Fawaz Al Ammary, Carolyn Sidoti, Dorry L. Segev, and Macey L. Henderson

Telemedicine practice has surged dramatically across US transplant centers during the coronavirus disease 2019 (COVID-19) pandemic in efforts to sustain access to kidney transplantation and maintain continuity of care with heightened public health consciousness.¹,² Telemedicine by synchronous video visits integrated with electronic medical records has the potential to have a lasting impact on the field of kidney transplantation beyond the pandemic. Telemedicine may help reduce kidney transplantation disparities by supporting pretransplantation evaluations of potential kidney transplant recipients and live kidney donors who have challenges to come to a transplantation center for their initial in-person evaluations due to geographic, financial, or logistical issues. Telemedicine also facilitates posttransplantation follow-up care for both the recipient and donor.

Regulatory and financial burdens to the spread of telemedicine have been lifted temporarily due to the public health emergency (PHE).³⁻⁶ These changes have been critical to expanding telemedicine services nationwide. However, many kidney transplant recipients and live donors will lose access to telemedicine and many institutions will stop receiving reimbursements for telemedicine services after expiration of the PHE. Permanent legislative and regulatory actions are needed to sustain and enhance the practice of telemedicine in kidney transplantation. We review the shift in telemedicine practice before and during the pandemic, discuss health care policy and regulatory challenges related to telemedicine practice in kidney transplantation, and propose solutions for beyond the pandemic.

Telemedicine Lagging Before COVID-19

Telemedicine adoption was slowly growing before the COVID-19 pandemic. In 2016, the US Department of Health and Human Services reported that >60% of health care institutions were using some form of telemedicine.⁷ Cost and reimbursements are the most frequent barriers to telemedicine implementation. The Federal Communications Commission piloted a program to increase access to telemedicine for low-income patients, veterans, and patients residing in areas lacking access to sufficient health care.⁹ Additionally, the Bipartisan Budget Act of 2018 expanded coverage of telemedicine for certain patients, including home dialysis patients.¹⁰,¹¹ Although these efforts were important, they failed to address key regulatory burdens such as payor reimbursements and state licensure restrictions. Notably, telemedicine adoption lagged in the field of kidney transplantation.¹²

Telemedicine Practice During COVID-19

The pandemic accelerated the adoption of telemedicine by US transplant centers, creating a unique opportunity to leverage existing telecommunications technology and nationally mandated electronic medical records. In a national survey of transplant centers, 96.8% implemented telemedicine. However, on a follow-up survey, 81% reported telemedicine challenges.¹ Telemedicine has allowed transplant centers to sustain pretransplantation evaluations of patients with kidney failure and potential live kidney donors and post-transplantation continuity of care for both the recipient and donor.¹³

Moreover, telemedicine provides a prompt and safe approach to assess patients with COVID-19 symptoms. We have developed a practical workflow process using telemedicine to evaluate, triage, and manage kidney transplant recipients with COVID-19 infection while avoiding emergency department or clinic visits, which is especially important for such immunosuppressed patients who may have prolonged viral shedding.²
The CARES Act Funding for Telemedicine

Congress has appropriated funding for nationwide telemedicine expansion on March 6, 2020, as part of the Coronavirus Aid, Relief, and Economic Security (CARES) Act. However, health care system incentives and technology infrastructure support to advance telemedicine practice beyond the pandemic remain undefined.

Medicare Regulations Shift

Medicare made an intentional decision to pay for only limited circumstances with respect to telemedicine services before the COVID-19 pandemic. The beneficiary must be in a rural area and travel to specific types of originating sites, such as a physician’s office, skilled nursing facility, or hospital, to receive telemedicine services from a provider in a remote location. The originating site must be in a Health Professional Shortage Area or a county that is outside any Metropolitan Statistical Area. Remarkably, the beneficiary could not receive telemedicine services in their home.

Beginning in 2019, there were some exceptions made for both geographic and originating site requirements when using telemedicine for dialysis services, treatment of acute stroke, and treatment of substance use disorder and co-occurring mental health conditions. Under the Bipartisan Budget Act, Medicare will pay for telemedicine visits without geographic restrictions for patients receiving home dialysis who choose to receive monthly kidney failure clinical assessments by telemedicine.

Under the Coronavirus Preparedness and Response Supplemental Appropriations Act and Section 1135 waiver authority, the Centers for Medicare & Medicaid Services (CMS) has broadened access to Medicare telemedicine services. Patients outside of rural areas and in their homes were made eligible for telemedicine services beginning on March 6, 2020. Medicare now reimburses office, hospital, and other visits furnished by telemedicine across the states and at the same rate as if these visits were in person regardless of patient location and prior existing relationship with the provider (new or established patient). Although these policy changes have been impactful, they will no longer be in place after expiration of the PHE.

We urge that telemedicine geographic restrictions and reimbursement policies should be exempt for kidney transplantation services, expanding on the Medicare exemption made for home dialysis.

Private Payors Adoption

Private insurance coverage of telemedicine varies due to state laws and insurer policies. Since the pandemic, several private payors have adopted a similar policy as CMS. These coverage policies are still temporary and requirements for telemedicine coverage vary by state. It is important to establish permanent policies for private payors to support telemedicine practice for kidney transplantation services beyond the pandemic.

State License Restrictions

State licensing restrictions are a major barrier to expanding telemedicine both before and during the COVID-19 pandemic. Distinctly, the CMS waivers to expand telemedicine across the states do not override the individual state’s licensing requirements. Securing national licensing for providers remains a challenge. Although many states have issued waivers with respect to telemedicine for out-of-state licensed providers under the PHE, these efforts remain limited and temporary. Some states limit out-of-state providers to practice telemedicine for established patients only, while others still do not allow any out-of-state providers to practice telemedicine regardless of prior relationship with the patient.

These restrictions place kidney transplantation at a disadvantage. Potential kidney transplant recipients and live kidney donors may come from different states and it is critical to expedite their evaluation process to reduce the risk for mortality on the waiting list for patients with kidney failure. In our experience, we were not able to evaluate many out-of-state potential live kidney donors due to state barriers to out-of-state providers or restrictions using telemedicine for established patients only even though these potential donors could be related to their intended established potential transplant recipients. State licensing restrictions must be removed to allow out-of-state providers to practice telemedicine, expanding kidney transplantation services to the recipient and donor. This helps increase access to live donor kidney transplantation in a timely fashion, especially with the limited number of available live donors.

Legal and Ethical Considerations

Patient privacy must be protected in accordance with the Health Insurance Portability and Accountability Act (HIPAA). While the Office for Civil Rights waived several HIPAA requirements for telemedicine during the COVID-19 pandemic, this waiver is temporary and providers should use HIPAA-compliant telemedicine platforms.

Access to a reliable internet connection and a sufficient electronic device must be supported for patients with low incomes or in rural areas. Telemedicine establishment for these patients helps improve their access to transplant centers. We propose offering public internet hotspots by the state for patients with limited internet access and establishing satellite facilities in which patients can be connected with providers at a transplant center remotely. Telephone visits are an alternative option if video visits are not accessible.

Other Considerations

Patients must be educated with a simple guide regarding the limitations of telemedicine versus in-person visits and how they can receive follow-up care if necessary. Patients will still need an in-person physical examination before kidney transplantation surgery. Financial
agreements between institutions may be needed to accommodate patients (especially those out of state) undergoing a virtual examination. Moreover, patients with language barriers may be disadvantaged by telemedicine and special accommodations must be made.

Providers must be supported with infrastructure, personnel staffing, and training to ensure high-quality care and satisfaction.\(^1,18,19\) Providers from different generations may have varying levels of comfort with this technology.

**Conclusions and Implications**

Relaxed regulations to expanding telemedicine during the PHE should be made permanent with respect to kidney transplantation services (Table 1).\(^3-6\) This includes pretransplantation evaluations and postransplantation follow-up care for both the recipient and donor, aligning with the Advancing American Kidney Health initiative to increase access to kidney transplantation.\(^20\) We advocate that telemedicine for kidney transplantation services should be exempt from geographic and originating site requirements, expanding on the Medicare exemption made for home dialysis.\(^10,11\) Payment models should be adjusted, ensuring that public and private payors reimburse telemedicine visits for kidney transplantation services at the same amount as in-person visits permanently. At the state level, policies should be adopted to support transplantation providers to practice telemedicine across state lines permanently because this should remain an available option for in- and out-of-state patients. Research studies to advance the use of telemedicine in the field of kidney transplantation are needed. These proposed solutions are generalizable to other solid-organ transplants. If these changes are made, telemedicine has the potential to reduce transplantation disparities.

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