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TRANSPLANTABILITY IN BURDENED POPULATIONS:

A REGIONAL ANALYSIS OF THE ROBOT-ASSISTED KIDNEY TRANSPLANT ON ACCESS GIVEN SOCIOECONOMIC AND DEMOGRAPHIC FACTORS

A DISSERTATION SUBMITTED TO
THE GRADUATE SCHOOL IN PARTIAL FULFILLMENT OF
THE REQUIREMENTS FOR THE DEGREE

DOCTOR OF PHILOSOPHY

COMMUNITY PSYCHOLOGY DOCTORAL PROGRAM
IN THE COLLEGE OF PROFESSIONAL STUDIES AND ADVANCEMENT

BY
EARNEST DAVIS
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Chicago, Illinois

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Community Psychology Doctoral Program

Dissertation Notification of Completion

Doctoral Candidate: Earnest J. Davis Jr.

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A Regional Analysis of the Robot-Assisted Technique Impact in Kidney Transplantation Based On Socioeconomic and Demographic Factors

Certification: In accordance with the departmental and University policies, the above named candidate has satisfactorily completed a dissertation as required for attaining the Doctor of Philosophy degree in the Community Psychology Doctoral Program (College of Psychology and Behavioral Sciences) at National Louis University.

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ABSTRACT

Purpose. The study evaluates whether the robot-assisted kidney transplantation (RAKT) technique allows for patients with higher BMI and of burdened socioeconomic and sociodemographic status improved access to transplant compared to traditional open kidney transplant (OKT).

Background. The social contract of health (SCOH) in America governs healthcare interactions at individual, community, and systemic levels. The balance of this tacit agreement has listed toward provider organizations and away from the patient. End stage renal disease treatment provides an explicatory case to examine the current state of the SCOH.

Methods. The study set combined extant data from the Organ Procurement and Transplantation Network and the Chicago Area Patient Centered Outcomes Research Network for patients transplanted at Chicago kidney transplant programs. Investigators analyzed whether the robot-assisted kidney transplant (RAKT) technique allows for patients with higher body mass indices and of burdened socioeconomic and sociodemographic status improved access to transplant compared to the traditional open kidney transplant (OKT) approach.

Results. Patients transplanted through the robotic-assisted approach exhibited higher body mass index (BMI) values, lower glomerular filtration rates, reduced functional status, and higher rates of pre-transplant dialysis than the traditional transplant group. The RAKT group demonstrated higher proportions of Black recipients (a demographic historically marginalized by the healthcare system’s eGFR Black race modifier), recipients without a college degree, and lower median household income (based on ZIP code of residence). The RAKT cohort had a markedly lower wait time for kidney transplant (499.5 days vs 822.7 days in OKT). Patients with BMI over 40 in the two groups had no statistically significant difference in length of stay, graft function, or post-transplant outcomes.

Conclusions. Despite the myriad of disadvantages, the RAKT cohort clinical outcomes were equivalent to OKT in most respects. Robotic-assisted transplantation was superior in wait list duration, which literature has shown to be the primary variable in patient’s transplant decision-making. As rates of obesity and kidney disease increase in the U.S., wider proliferation of tools with demonstrated efficacy in treating this population support the social contract of health. Community psychology praxis can support communities in advocating for change in the American healthcare system.

Transplantability in Burdened Populations: A Regional Analysis of Robot-Assisted Kidney Transplantation's Impact on Socioeconomic and Demographic Factors

The social contract of health is often cited when discussing the ethical bearings of physicians or the inequalities of care delivery based on race and means. It is not a formal arrangement as much as a kind of democratic process based on negotiating and meeting mutual needs (Wells, 2004). The health of communities is the mutual need while the American society and organized medicine are parties in the agreement. E.H. Lewinski-Corwin, Director of the Hospital Information Bureau of the United States, laid out the Community Responsibility of Hospitals in the early-20th century. He posited that "a hospital's responsibilities to the community are as numerous as are its social ramifications, and they imply not only the obligations of the hospital to the community, but also the reciprocal relation of the community to the hospital" (Lewinski-Corwin, p. 605). He added "there exists a general tacit understanding on the part of the public that, on assuming their office, hospital trustees have accepted a moral obligation with respect to the community and those who come to the hospital for treatment" (p. 606).

History of the Social Contract of Health

On a grander scale social contract theory supposes an implicit understanding between people and society concerning how social order should be organized, how benefits are distributed, and how shared responsibilities are defined for all citizens (Breitbell, 2014). The original conceptualizers of social contract theory eschewed partition in favor of holistic understanding of the interplay between the public and those in power (Dienstag, 1996). The earliest pontifications on the subject by John Locke and Jean-Jacques Rousseau were born of politics and modern society, but all spotlighted the interaction between the population and institutions of power. So too in community psychology do we strive to understand the total ecology of a community and the anthropology of structural violence, both biological and historical (Farmer, 2004). Thus, understanding the social contract of health requires an understanding of the purpose of healthcare for individuals and society, and the historical contexts that cultivated it (Hill, 1996).

Physicians and the Social Contract of Health

Healthcare began as a one-to-one relationship between a medical provider and a person in need of their services. It was a simpler time that had capacity for an implicit or tacit understanding. For its part society granted physicians status, respect, autonomy in practice, the privilege of self-regulation, and financial rewards on the expectation that physicians would be competent, altruistic, moral, and would address the health care needs of individual patients and society (Cruess, 2004). In the late 1700's apprentice-trained providers without access to laboratories or clinical facilities were chiefly concerned with the health of American soldiers (National Institutes of Health, 1976). Thereafter healthcare in the American colonies was a rudimentary practice often provided on a one-to-one basis between the patient and the physician. Payment, if required at all, was only as great as the doctor felt reasonable for the patient; often payment was rendered in the form of barter with local farmers and tradesmen (McCulla, 2016). Over time this intimate relationship has evolved concurrently with society and the technological progression of medical care.

With the Industrial Revolution of the late 1800's came a need to provide medical services to the factory workers who had migrated to industrial centers. As the population centers grew and the industrial companies flourished, physicians were not only focused on serving the needs of the patient but ultimately ensuring that the company's investment in human capital was safe, secure, and most of all predictable (Hirschman, 2009). The physicians and medical researchers of the time began to move the science forward at an increasing rate by bringing more scientific approaches, rigorous training, standard practices, and more professional organization.

In 1847 the American Medical Association (AMA) drafted its first Code of Ethics, which included standards for ethical behavior for physicians and provisions addressing the obligations of patients and society (American Medical Association, No Date). This document memorialized the early underpinnings of the American healthcare social contract between the public and the established profession of medicine. By 1873 the AMA had formed a Judicial Council "to deal with medical ethical and constitutional controversies" (American Medical Association, p. 1). The controversies stemmed from the fact that scientific advancements were precipitating more effective medical care at higher costs, which restricted access to care for the elderly and unemployed (Hoffman, 2003). With 128,000 physicians licensed in the US and Canada by 1906 the AMA became regularly active in advocating for and protecting the livelihood of its physician professionals. They saw government contracting for healthcare as a less profitable payment arrangement than holding agreements with individual employers competing for their services. In 1948 the organization spent over $1 million ($10.7 million in 2020 dollars) on an "anti–health reform public relations blitz that included advertising, television and radio spots, telegram and letter-writing campaigns, and the lobbying of legislators by their own personal physicians" (p.

78). Many times, positions such as this put practitioners in direct conflict with government administrations striving to buttress the social contract of the health with legislation.

Government and the Social Contract of Health

As the American population grew, and the complexity of healthcare rose, the provision of healthcare became a cause for concern in many halls of government. The first wave of major health reforms in Europe came from Otto von Bismarck in 1883 Germany and Winston Churchill and Lloyd George in 1911 United Kingdom toward the end of World War II (Blanplain, 1994). The companies that had begun the trend of employer sponsored care in the U.S. during the Industrial Revolution had spared the federal government from having to tackle universal care movement which was springing up in other advanced societies (Palmer, 1999). Between the volunteer efforts sponsored by various religious and secular entities and employed individuals having access to care in case of infirmity, most of the country was ‘covered’. Labor unions became increasingly popular in the 1920s as workers sought representation that would secure safe working conditions and retain their existing benefits such as healthcare (Palmer, p. 4).

While Theodore Roosevelt is famously attributed the expression that no country could be strong whose people were sick and poor, most of the initiative for reform took place outside of government (Palmer, p. 6). In 1915 the American Association of Labor Legislation presented a bill that would reimburse medical expenses for the most vulnerable Americans relegated to the working class and below (Hoffman, p. 76). However, physicians and labor unions opposed universal care legislation through their powerful representative organizations. The AMA eventually contested the legislation for fear that it would affect physician payment and the

American Federation of Labor (AFL) believed a government-based insurance system would weaken unions by usurping their role in providing social benefits (Palmer, p. 6).

Throughout the 1900s more attempts at national healthcare were proposed during the Franklin Roosevelt and Harry Truman administrations. These too were thwarted either by labor unions, physician organizations, the insurance industry, or doomed by lack of social support (Hoffman, p. 78). This in no way stunted the expansion of the healthcare delivery system. After World War II hospitals transformed from charitable institutions that provided “a place to be sick and die” to technologically sophisticated institutions that offered “a place to live and get well” (Kisacky, 2019).

It is generally accepted that the profession of medicine is based on a shared set of tacit and explicit agreements about what patients, doctors, and society at large should be able to expect from each other; a social contract that defines the profession (Wynia, p. 565). The government, with its Lockean history and sizable purse strings, has implicated itself as a party to the institution of healthcare through multiple actions, laws, regulations, and funding decisions. Hospital-anchored health systems were a later appendage to the social contract but have swiftly become indispensable in its fulfilment.

Hospitals and the Social Contract of Health

American public hospitals are rooted in the tradition of aiding the poor and trace their origin to efforts by communities to provide shelter and care for the “ill, disabled, and deprived” (Owuor Otieno, 2019). The oldest hospital in the United States was established in 1736 but by 1820 there were still only ten facilities in the country. Gradually a call for more hospital facilities occurred with the desire that each hospital was a specific, locally determined enterprise to provide service to a perceived underserved community (Kisacky, 2019). Until this point, the social contract of health relied heavily on the physician-patient pact, but in the early 1900s the higher order hospital-community contract began to take hold. Many of the newly formed hospitals were incepted to care of a specific nationality, ethnicity, or religious affiliation (i.e., Jewish, Swedish, Catholic, Lutheran, etc.). Communities supported these institutions with the understanding that their cultural and religious beliefs would be cared for in addition to their medical needs.

In the first decades of the 20th century, hospitals became locations of collaborative, specialized scientific medicine (i.e., medicalized) and served all classes of patients, not just the poor (Kisacky, 2019). In a publication from 1926 Dr. E.H. Corwin, Public Health Consultant to the United States Public Health Service enumerated the fundamental obligations of nonprofit hospitals to the community including:

- Formulation of an adequate ‘community policy’ informed by the public health measures, knowledge of private and public health services available, and operational consequences of the previous both,
- The hospital will provide unincentivized, non-discriminatory, professionally sound care, as is the ‘general tacit understanding’ of the public, and
- Clinical excellence in accordance with physician professional organizations, broader access to diagnostic services and teaching for doctors, provision of physician support staff, provision for contagious disease isolation, provision of adequate study and care for chronic diseases (Lewinski-Corwin, 1926)

As illustrated above, the social contract of health remained a focal point of medical endeavors but the shift towards a physician-centered model for hospitals had taken root. The advocacy power of the hospital industry was multifaceted and derived from well-off physicians, the charitable and religious orders that founded many facilities, the ethnic communities with attachments to specific hospitals, and the scores of ill (both in affluent private rooms and indigent wards) who saw the facilities as their savior. The healthcare industry amassed political power locally and, eventually, was able to flex its political power nationally.

Financing and Cost Impacts the Social Contract of Health

Hospitals were the primary proponents of the 1946 Hospital Survey and Construction Act (Hill-Burton), which provided hospitals with grants to build new facilities in exchange for a certain amount of charity care (Shi, 2019). President Truman called for this expansion of the nation's hospital system, and it was a substantial accomplishment, even though a concession allowing for states to control disbursement of funds ensured the new facilities could be segregated depending on the political leanings of the region (Interlandi, 2019). This government action cemented the dominance of nonprofit hospitals in today's healthcare system, but only in so much as the hospitals formalized their social contract to care for all in the community. John Henning Schumann, a physician and president of the University of Oklahoma-Tulsa contends that 6,800 facilities in 4,000 communities and one-third of U.S. hospitals were constructed with Hill-Burton funds. However, the legislation stipulated those federal dollars were only made available if "hospitals receiving federal monies are obligated to provide free or subsidized care to a portion of their indigent patients" (Schumann, p. 2). Care delivery organizations received a grand windfall to enhance their physical assets, but the government also established an element of the social contract of health that still exists today. In exchange for nonprofit status, hospitals must provide a charitable benefit to the public which, ultimately, reduces the burden of government to care for citizens.

Not to be outdone in lobbying prowess, insurance companies had entered the fray and began to grow rapidly, adding another powerful player to the table of healthcare stakeholders and further crowding out individuals and communities. With the passing of the Stabilization Act of 1942 and several successive rulings, the government reinforced the efforts of insurance companies to link health insurance with employment and institutionalized the employment-based system of health insurance that exists today (Kelton, 2007). However, the insurance companies were intent on remaining financially viable. Taking care of the elderly, who logically require the most healthcare on average, was not profitable. The AMA again protested vehemently against any legislation including state-sponsored outpatient medical care coverage. The American Hospital Association (AHA), a new power player at the time, but today ensures that its 5000+ member hospital and health systems perspectives are addressed in national health policy, negotiated point by point until a palatable solution was identified (Gluck, 2001). The AHA hospital members feared a loss of revenue due to government payment rates just as the AMA did but saw some advantage to negotiating once it was clear that the political will existed to pass the bill.

In 1965 the Johnson Administration passed the Social Security Act (SSA) that included Medicare Part A, Part B, and Medicaid. Parts A and B provided seniors over sixty-five coverage for acute care (hospital, home health, hospice, etc.) and primary care (physician charges, outpatient services, etc.), respectively. Medicaid provided acute and primary care coverage for impoverished citizens of any age if they could prove their financial need (Everson, 2005). These programs speak directly to the general will of the public within the social contract of health in that the most vulnerable citizens (i.e., the elderly and poor) are provided access to the healthcare system. Title VI of the Civil Rights Act, passed only 12 months earlier, stated that all citizens have equal right to participate in federal programs. Until this point the majority of hospitals in the United States were still segregated, relegating non-white persons to a lower standard of care and poorer health outcomes. Thus, the passage of the Social Security Act paved the way for more equitable provision of treatment among marginalized populations.

The means-tested model that the AMA pushed for evolved into the Medicaid program as part of the SSA (Everson, 2005). This notably provided a new revenue stream to physicians – people who could not previously pay. One piece of legislation had effectively made healthcare accessible for elderly, minority, and underprivileged Americans even in the face of continued opposition from the AMA. Everson further noted that many felt this legislation would eventually eliminate the need for indigent care, a community benefit requirement imposed upon non-profit healthcare organizations to take care of the neediest Americans in exchange for tax-exempt status. However, the Internal Revenue Services had already begun work clarifying non-profit hospitals' social responsibility towards that end.

Introduction of Community Benefit Standard

The Federal Internal Revenue Services (IRS) published its first positions regarding hospitals in the 1950's. The rules included in the 1956 Tax Code recognized hospitals as "charitable organizations provided they accepted patients without regard for their ability to pay to the extent of the hospital's financial ability" (also referred to as indigent or charity care)and further defined charity beyond "relief of the poor" in 1959 (Everson, 2005). Healthcare industry representatives complained that the financial ability standard exposed hospitals to an undue amount of financial risk. Thus the “community benefit standard” was set forth in Rev. Rul. 69-545 of 1969 wherein acceptable activities went beyond charity care as long as the activities were “deemed beneficial to the community as a whole” (Rozier, 2020). The rule stated that in order to qualify as a 501(c)(3), “hospitals would no longer be required to provide a specific level of care to the poor in order to qualify for tax exemption, but instead must demonstrate that they benefit the community sufficiently” (Everson, p. 5).

Rule 69-545 has endured its share of challenges, including an unsuccessful Supreme Court challenge in the late 1970’s (Powell, 1975) and a revision to relax the emergency room provision in 1983 (IRS, 1969). The latter (Rev. Rul. 83-157) also opened the door for more services and activities not originally included in the 1969 version of the rule to become synonymous with community benefit. For instance, medical training and community health education were just as demonstrative to a hospital’s benevolence within a community as charity care and 24/7 emergency treatment. It can be reasoned that all of these activities provide community benefit in furtherance of the social contract of health, though a distinction exists between community benefit and community-building activities (Trocchio, 2011). Hospital expenditures on IRS-defined community benefits were $105 billion in 2018 (AHA, 2021).

Modernization of the Social Contract of Health

With the roots of the American healthcare delivery system firmly in place, the healthcare industry boomed with advancements. They included procedural developments like kidney transplants (1954), minimally invasive surgery (1961) and liver transplant (1963) as well as technological breakthroughs like pacemakers (1958), ultrasound (1965) and CT scanning (1971), all of which contributed to increasing healthcare costs as hospitals jockeyed to be more technologically advanced than their competitors (Bakalar, 2012). In 2007 Kelton asserted:

> During this Golden Age of American capitalism, the health care system survived rising costs and increasing out-of-pocket medical expenditures as the economy experienced historically low-levels of unemployment, rising real wages based on productivity gains, and strengthened collective-bargaining rights. Costs increased, but firms and their employees were able to absorb these expenses because revenues and wages kept pace (Kelton, p. 29).

Maintaining this lofty position long-term was untenable and the government eventually stepped in. In the early 1970s the Nixon Administration created Professional Standards Review Organizations, which were designed to limit the expansion of Medicare costs by increasing the oversight of physician practices, and the National Health Planning and Resources Development Act to limit the growth of hospitals and other health care facilities (Kelton, p. 19). Irrespective of these efforts, healthcare costs continued to rise. Later in the decade the Carter Administration proposed legislation to contain healthcare costs but was defeated in Congress, where the debate became contrasting the virtues of “competition” versus “regulation” (Kelton, p. 20). It is fitting that the social contract of health was under threat from profiteering in the healthcare system and a classic capitalistic protest was employed to prevent the government from stabilizing the situation.

Investor-owned hospital chains, emboldened by the prospects of remuneration in the climate of Medicare and Medicaid, became players in the provider industry in the early 1970’s (Everson, 2005). The government continued its defense of patients by enacting legislation that prevented for-profit and NFP hospitals alike from participating in adverse patient selection (i.e., cherry-picking patients based on their profitability). The Emergency Medical Treatment & Labor Act of 1986 (EMTALA) ensured public access to emergency services regardless of ability to pay (CMS, 2012). This was yet another steadying of the social contract of health as EMTALA and other changes in the health care industry mitigated factors specifically discussed in Rev. Rul. 69-545.

The 1980s brought a new proposed panacea for an uncontrolled healthcare system in the form of health maintenance organizations (HMOs). However, adding an additional level of management and profit (or retained earnings for nonprofit insurers) soon did more to add cost to the system than remove it (Mahar, 2006). The Clinton Administration’s attempt at a national healthcare program never made it out of Congress in the 1990’s as attempts to legislate the social contract of health again faced strong lobbyist challenges. Employers continued their own efforts to control costs including benefits restructuring, cost transfer, health resource accounts, and transitioning staff from full-time benefits eligible positions to part-time positions with no employer-sponsored health insurance (Kelton, 2007).

The Patient Protection and Accountable Care act of 2010 (ACA) eventually provided more citizens with access to care. Passed during the Obama administration it continued the governmental shepherding toward community interaction by requiring the community health needs assessments (CHNA) and community health improvement plans (CHIP), creating the Patient Centered Outcomes Resource Institute (PCORI), and expanding payment mechanisms for accountable care organizations (H.R.3590, 2010). The ACA attempted to direct patient investments toward community health enrichment and incentivization of those efforts through novel payment approaches. However, key elements of the law (e.g., the individual mandate and cost-sharing reduction payments to insurers) were vehemently opposed by capitalism-friendly state and federal Republicans and effectively repealed (Griffith, 2018). Without pricing standards, insurance companies were able to pass along increased cost burdens from cost-sharing cuts to the enrollee via higher premiums (BBC News, 2019). Absent an individual mandate that taxed persons who chose not to carry health insurance, the number of people on the exchange fell by 9.3% (The Kaiser Family Foundation, 2020) and the quantity of competitive insurance exchange markets fell by 57% (Griffith, p. 1681).

When viewed with the history of the American healthcare system as context, there is compelling evidence to suggest that the ACA has struggled to counteract the degrading social contract of health for three reasons:

- Its attempts to increase health industry investment in community health promotion resulted in a 0.5% increase in community benefit spending from 7.6 percent of their operating expenses in 2010 to 8.1 percent in 2014 (Young, 2018),
- The power imbalance of providers, financers, and corporation-friendly legislatures has become too great (Antos, 2020), and
- The primary intention of the program was to increase access to healthcare, not to improve the health of the community (CMS, 2020).

By the time the ACA was enacted, the possibility of reviving the social contract of health through the established healthcare system rooted in marginalization was fleeting at best. A review of the historical context that cultivated the American healthcare system provides some understanding of the purpose of healthcare for individuals and society, and the pillars of the system that propagate imbalance in the social contract of health. A more profound insight into that imbalance requires recognition of the macroeconomic ideals that also preserve the current state.

Evolution of Market Dynamics in American Healthcare

The healthcare sector currently accounts for 17.9% of the United States gross domestic product and the Office of the Actuary at the Centers for Medicare & Medicaid Services (CMS) estimated that number to grow to 19.4% by 2027 before the pandemic altered all assumptions of health industry spend (Sisko, 2019). In order for an industry to be that successful, it must be supported by both institutions and capitalistic ideologies (Kasser, 2007). The institutions in play for the healthcare industry, such as the AMA, AHA, AFL and others, have been discussed in this thesis. However, the ideologies of capitalism posed by Kasser bear note. They include the treatment of natural resources as private property, the primacy of self-interest, beliefs in the benefits of competition and the necessity of economic growth. The International Monetary Fund (IMF) similarly lists private property, self-interest, and competition as pillars of capitalism along with supply/demand pricing, freedom of choice and limited government intervention (Jahan, 2015). It is proposed herein that the healthcare industry has participated these ideologies of capitalism with examples including but not limited to:

- Treating human bodies as property, intentionally performing unnecessarily invasive or even unneeded procedures for chargeable units,
- Prioritizing self-interests by continually resisting reform of the healthcare system to protect autonomy and profit at the expense of outcomes,
- Leaning on competition to the detriment of transparency and interoperability, and

- Necessitating economic growth through merger and acquisition activities, purchase of ever-evolving technologies, and new construction even in the face of saturated markets.

In its earlier stages, healthcare operated in a less consumerist economic environment.

From Free Market Capitalism to Oligopoly

Changes to the healthcare landscape since the 1980s have challenged the free market economics of capitalism. Vertical integration of hospital systems has coalesced the continuum of care by aggregating small physician practices into wholly owned subsidiary mega-practices (Manning, 2018). Insurance companies have succumbed to the trend as well. In 2019 Optum, the health services subsidiary of UnitedHealth, added 10,000 physicians to provide care to its members in addition to its core business of health insurance (Ellison, 2019). With its physician network now estimated at 46,000 physicians, its yet another egress into industrialized medicine.

When merging non-acute services (immediate care, post-acute care, rehabilitation, etc.) into the same conglomerate structure the American healthcare system moves along the competitive continuum toward oligopolistic competition (McLaughlin, 2015). Compile that reality with the industry trend toward horizontal integration, where successful hospital systems can acquire the assets of competing providers, and the system looks much less like the classic capitalistic economic framework. Mega-systems create economies of scale in their supply chain, but rarely is this savings passed on to the consumer (Schwartz, 2020). Instead, hospitals have amassed more capital and more power, both in the ability to negotiate higher prices with private insurers and to politically fend off governmental interference. In contrast, Dr. Thomas Bodenheimer (1995) insisted that the “historic developments of the 1980’s have created a fundamental power shift in health care; away from the providers of care, to the payers and the insurers" (p. 30).

It would seem as though capitalism in healthcare has not realized many of the benefits expected of the theoretical application of its theories. Centuries ago, Adam Smith postured the presence of many buyers and many sellers competing with one another in the marketplace would weed out wasteful resource allocations (The Center on Capitalism and Society, 2019). Yet 30% of all healthcare costs are considered to be waste (Berwick, 2012) and some estimates extend that figure to 40% (McLaughlin, 2015). The median occupancy rate for staffed beds in Illinois was 57 percent overall and 67 percent in the six-county Chicago area in 2015 (Schorsch, 2015). In most industries that type of excess inventory would trigger investigations into wasteful spending, if not tank a company. In healthcare, it is somehow standard operating practice.

Another key concept in capitalism is that producers can only generate and charge what the market will bear (The Center on Capitalism and Society, 2019). In the United States the per capita healthcare spending nearly quadrupled from 1980 to 2018 (Nunn, 2020). The 67% rise in health insurance costs shouldered directly by families outstripped the growth in wages (31%) and inflation (21%) from 2008 to 2018 (Rae, 2019). Healthcare costs have routinely held to this trend, leading multiple federal administrations to attack the problem on a gross scale.

Further examples concerning the rise of oligopoly in healthcare involve the stringent opposition to the regulation of the healthcare industry. This has recently been illustrated by vehement resistance to the Trump administration's 2019 rules regarding price transparency and interoperability, both of which would further serve to depower oligopolies by providing information to communities.

Oligopolies Oppose De-Powering Actions

In response the Trump administration's *Improving Price and Quality Transparency in American Healthcare* executive order, price transparency proposed rules were released by the Departments of Treasury, Labor and Health and Human Services in 2019. They require hospitals to disclose their standard charges, including payer-specific negotiated rates for all items and services (Ellison, 2019), and force insurers to disclose negotiated rates for in-network providers and out-of-network care (King, 2020). In a statement released by the Department of Health & Human Services Press Office, CMS Administrator Seema Verma indicated that by implementing the rule the administration is "throwing open the shutters and bringing to light the price of care for American consumers. Kept secret, these prices are simply dollar amounts on a ledger; disclosed, they deliver fuel to the engines of competition among hospitals and insurers. Today's rules usher in a new era that upends the status quo to empower patients and put them first" (HHS, p. 1).

The Blue Cross Blue Shield Association (representing 36 state health plans), Association for Community Affiliated Plans (representing 67 nonprofit and community-based safety net plans), America's Health Insurance Plans (representing tens of thousands of insurance industry professionals) and the American Hospital Association criticized the rule to varying degrees as too costly for, too complex to implement or just too complicated for consumers to grasp (Ellison, 2019). The American Hospital Association, the Association of American Medical Colleges, the Children's Hospital Association, and the Federation of American Hospitals filed a lawsuit in the U.S. District Court claiming that, according to AHA President Rick Pollack, the rule would "lead to widespread confusion" among patients (King, 2020). It is established that price transparency, along with competition, is a core concept in capitalism yet the healthcare industry is using its considerable resources to obfuscate this principle.

Similarly, the Centers for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC) released *The Interoperability and Patient Access Proposed Rule* which “outlines opportunities to make patient data more useful and transferable through open, secure, standardized, and machine-readable formats while reducing restrictive burdens on healthcare providers” (CMS, p. 1). Dr. Don Rucker, National Coordinator for Health IT, argues the rule would “support patients accessing and sharing their electronic health information, while giving them the tools to shop for and coordinate their own health care” (HHS, p. 1).

Again, powerful interests have taken a stand against regulation in furtherance of the social contract. The rule would require the healthcare industry to implement information technology to help patients more easily access their health data. Epic, the fifth largest health IT company in America with $2.9 billion in annual revenues and boasting 54% of all medical records in the country, aligned with sixty health systems to oppose the interoperability rule (Drees, 2020). In addressing Health and Human Services Secretary Alex Azar, Epic CEO Judy Faulkner lamented that the rule would be “overly burdensome on our health system and will endanger patient privacy," and later adding “the scope of regulated data, the timeline for compliance, and the significant costs and penalties will make it extraordinarily difficult for us to comply”. While the language sounds altruistic, any moralistic reasoning behind this attempt to derail the rule was swiftly debunked. Former Health and Human Services Secretary and Wisconsin Gov. Tommy Thompson recently observed that the new interoperability rules would harm Epic’s business model by requiring cooperation with its competitors and "unfairly harm" Wisconsin’s economy. He acknowledged the interoperability rules would “compel Epic to give its trade secrets away to venture capitalists, Big Tech, Silicon Valley interests, and overseas competitors for little or no compensation” (Drees, p. 1). Rarely has the healthcare industry’s disregard for the fair practices in favor of business interests been so clearly stated: a profound indictment on the current state of the social contract of health.

Population Implications of the Current Social Contract of Health

The present social contract of health has been gone largely unchanged for fourteen years as it is one-dimensional, overly simplistic, and failing to sustain the public’s trust (Wynia, 2008). Higher income individuals, whether covered by employer-sponsored insurance plans or Obamacare exchanges, are seeing their premiums increase regularly. Similarly middle-class families pay the highest prices globally for health coverage without receiving the best outcomes internationally. The less fortunate struggle to gain access to the system because some providers refuse to accept Medicaid as a payor and avoid making investments in communities with a high proportion of Medicaid enrollees, which constrains access to quality healthcare. All the while reports of malpractice, provider fraud and discrimination in the provision of services continues to erode trust in the institution.

The federal government has failed to memorialize the social contract of health through universal coverage and state-level gains made during the Obama administration were reversed by the political leanings of the Trump administration. The healthcare provider industry embraced capitalism and evolved into oligopoly, forcing patients to adhere to *financial* contracts with powerful, mis-incentivized companies while the *social* contract of health devolves. The ramifications of these actions are evidenced in many facets of the healthcare industry, but three instances are highlighted here to illustrate the problem.

Financial Contract Versus the Social Contract

Technological advances have made early detection and early intervention pervasive across disease states, yet its proliferation within healthcare delivery organizations is scant. The American Cancer Society (2017) proclaimed the use of potentially lifesaving prevention and early detection measures is suboptimal and profoundly influenced by individual behaviors, as well as social, economic, and public policy factors. The National Kidney Foundation (2019) approximates 90% of those with chronic kidney disease do not know they have it even though the best survival rates are attributed to early diagnosis and intervention. Assuming that the case for profiteering in healthcare has been made, then it is reasonable to consider disease prevention and early detection (i.e., primary intervention) are peripheral endeavors because they are less profitable than traditional ‘illness-care’. It has been clear for decades that failure to provide these services results in loss of opportunity for potential improvement of health and prevention of disease, yet the problem persists (Davis, 1992).

There are some instances where disease prevention and early detection rates are superior in the United States. According to The Commonwealth Fund:

> The U.S. outperforms its peers in terms of preventive measures — it has one of the highest rates of breast cancer screening among women ages 50 to 69 [80% vs. 60% Organization for Economic Co-operation and Development (OECD) average] and the second-highest rate of flu vaccinations (68% vs. 44% OECD average) among people aged 65 and older (Tikkanen, 2020).

The cause of this encouraging trend is potentially profiteering in disguise. Breast cancer screening and flu vaccination are low intensity procedures with reliable payment rates, high usage rates and high recidivism rates, making them productive profit centers. Concurrently they are two of the most common quality indicators that integrated health systems are judged by. Processes and initiatives are often put in place to support high penetration of these services knowing that, depending on the reimbursement contract, the organization could gain or lose dollars if the indicators are not met. Thus, healthcare organizations can reap significant financial rewards from this prevention.

Other health issues that could equally benefit from uniform screening are less likely to be focal points of quality programs or outreach. The rates of screening for cervical cancer fall far below its prevalence of breast checks. A meta-analysis of social inequality and the risk of cervical cancer found consistent social class disparity in cervical cancer rates (Parikh, 2003). The results of the 2003 study emphasized the importance of cervical cancer prevention programs, including vaccination and screening, to be focused on “women from low socio-economic groups in order to ensure that those most at risk are also those who benefit”. Nearly twenty years later the United States still has the lowest five-year survival rate for cervical cancer compared to other first world countries (Tikkanen, 2020). By framing the social contract of health within the context of succession and interdependence, community and health professionals can critically analyze the effect financial motivation has had on the health of communities.

A companion example of financial contracts detracting for the social contract of health lies in the juxtaposition of prevention versus diagnosis and treatment in healthcare settings.

Researchers have calculated that it would require 7.4 hours per workday for a physician to fully satisfy the US Preventive Services Task Force (USPSTF) recommendations for preventive services (Yarnall, 2003). A great deal of work would need to be done to improve physician cognitive value of primary preventative services prior to its full integration into practices (Mirand, 2003) but most practices have decided it is more efficient to delegate the responsibility to various health educators. The expenses related to additional medical staff required to provide the preventive services have been deemed prohibitive by many of these practices.

Improving Margins Versus Improving Outcomes

The proposed solutions to the ills of the American health system further illustrate the tenuous social contract of health. The predominance of solutions posed by the provider system to combat substandard health outcomes are focused on providing more chargeable services rather than addressing fundamental issues. The Triple Aim was developed by the Institute for Healthcare Improvement in 2007 to focus provider organizations on improving the patient care experience, improving the health of a population, and reducing per capita health care costs (IHI, 2014). The IHI cautions that true Triple Aim improvement cannot be realized by health care systems acting alone, nor by solely delivering high-quality care at lower costs. However, many solution approaches in the health system arena have attempted to do just that through minor modifications of the status quo.

Two examples of healthcare’s misguided application of the Triple Aim framework lie in the superutilizer intervention concept and the CMS Shared Savings Programs from the Accountable Care Act. The superutilizer concept was born out of the widespread interest in ‘Triple Aim-lite’ programs aiming to reduce spending and improve health care quality. These factors led to health systems’ focus on patients with remarkably high use of health care services and flowing additional services to them. The Camden Coalition of Healthcare Providers created the “hotspotting” intervention, where a team of nurses, social workers, and community health workers visits enrolled patients to coordinate outpatient care and link them with social services in the months after hospital discharge (Finkelstein, 2020). With its wide proliferation across the United States, researchers performed a randomized controlled trial to assess the program’s real impact on the care of patients. Results of the studies showed the 180-day readmission rate was 62.3% in the intervention group and 61.7% in the control group indicating there was no beneficial effect on the cost of healthcare.

The Accountable Care Act was mainly focused on insuring more Americans but included a few clauses meant to improve coordination and communication within the healthcare industry. According to the Department of Health and Human Services:

> ACOs create incentives for health care providers to work together to treat an individual patient across care settings – including doctor’s offices, hospitals, and long-term care facilities. The Medicare Shared Savings Program will reward ACOs that lower health care costs while meeting performance standards on quality of care and putting patients first. Patient and provider participation in an ACO is purely voluntary (p.1, 2011).

On initial inspection the program failed to achieve its initially stated goals, achieving approximately 68% of its expected savings (CMS, 2020). However, researchers from Germany insinuate something more nefarious. Schulte et. al. compared ACOs to their German equivalents, noting that the German healthcare management company *Gesundes Kinzigtal* assessed the program based on regional populations while the American version only assessed patients, and only those patients treated mainly by providers participating in the ACO. Furthermore, examining the organizational structure in both models indicated “concerns about market power gained from consolidation and fears that providers shift costs instead of reducing them” (Schulte, p. 2). CMS touts savings of $983 million in 2018, but that accounts for .028% of total healthcare spending and does not consider the anticipated costs of operating the ACO. For instance, Bleser et. al. (2018) acknowledged that while CMS reported ACO savings of $799 million in 2017, only $313 million ($35 per participant) of that was actual savings to the bottom-line cost of care.

Victim Blaming Versus Empowerment

A great deal of work has been done over decades to define community benefit hoping to rebalance the social and financial contracts in American healthcare. However, material deficiency exists in aligning community benefit policy with a larger vision of community health. The concept of community benefit is widely accepted as essential to health system transformation by both public and private payers (Rosenbaum, 2016). Non-profit hospitals have contended that their burden relieving activities are improving the wellbeing of communities as stated in their mission/vision/values statements with any variances due to community factors beyond their control.

Communities deem the healthcare industry accountable for health beyond healthcare in large part because the social contract of health requires it. That prevention is preferable to treatment is a common and clinically agreed upon fact. However, primary interventions inevitably require the individual targeted by services and interventions to act on behalf of themselves or those within their auspices. Unlike healthcare delivery intercessions that take place at the policy or resource allocation level, health improvement requires an individual level of change subsequent to the personal reflection that brings critical awareness. Thus, adoption of new behaviors must be a core tenet of any prevention or promotion activity.

This is a delicate yet complex conceptualization that requires balance. Some physicians deem that the individual must share responsibility for prevention activities. Davis et al. believe “a more comprehensive approach to prevention should include strategies for activating patients to take responsibility for initiating requests for preventative services” (p. 386). This is a consummate victim-blaming approach to diverting responsibility away from the healthcare provider industry. Numerous research organizations, like the USPSTF noted above, have provided best practices for providing prevention education to patients as part of a doctor’s vocation. Requiring the individual to be trained on what to ask for, and to require access to the healthcare delivery system to receive preventative services, is not a fair and balanced application of social contract theory.

Beyond the assignment of ownership, biases in causation exist amongst the healthcare industry. A study of eighty-seven providers (80 physicians, 7 non-physician extenders such as nurse practitioners) within the Children's Hospital of Philadelphia network found that providers within the hospital system believed the patient was primarily at fault for their obesity. Over 90% of survey respondents placed more importance on perceived barriers for obesity prevention such as: parent is not motivated, child is not motivated, parents are overweight, families often have fast food, watch too much TV, and do not get enough exercise (Spivack, 2012). Practice limitations that may preclude adequate care provision, such as not enough nutritionists to help with overweight children, pediatricians lack sufficient training to help with overweight children, pediatricians have limited time to discuss nutrition, and pediatricians lack sufficient education materials to prevent or treat overweight children, all ranked lower. The impediments that speak to social determinants of health, such as health foods are too expensive (economic stability), healthy lifestyle habits too complicated to follow/published reports of research studies about diet and nutrition are too complicated (health literacy), were rated much lower in importance by the respondents. This study confirmed previous studies by Story and colleagues (2002), Price and colleagues (1989) and Rhodes and colleagues (2007) identifying lack of patient motivation and lack of parent motivation or involvement as the primary impediments to preventing and treating childhood obesity.

None of this research detracts from the fact that an activated potential patient is an empowered potential patient. A family that fully understands the near- and long-term impacts of obesity is more likely to take actions that stave off those detrimental effects (Greene, 2012). Providing the needed public health education and services to communities is only impactful if those communities own the responsibility for active change.

With the illustrated power of the healthcare industry, employers, and governmental interests thoroughly presented alongside a historical accounting of the healthcare system’s evolution, some constraint is necessary to holistically comprehend the current state of American healthcare delivery. In particular, one devastating chronic illness provides a laboratory to deeply explore the social contract of health and its impact of patients.

End Stage Renal Disease: The Case of Dialysis and Renal Transplant

Chronic kidney disease (CKD) is a medical condition impacting one of every seven Americans wherein the kidneys, which filter waste and excess fluid from the blood, have increasingly diminished function (CDC, 2020). Approximately one in three Americans with diabetes and one in five Americans with high blood pressure have kidney disease (NIDDK, 2021). There are multiple stages of chronic kidney disease based on the glomerular filtration rate (GFR) with Stage 5, or end-stage renal disease (ESRD), being the most severe. When a CKD patient reaches end-stage they require dialysis or a kidney transplant to survive (CDC, 2019). Approximately 786,000 Americans have ESRD with 71% on dialysis and 29% beneficiaries of one of over 20,000 kidney transplants per year (NIDDK, 2021).

History of ESRD Treatment

The ESRD population had been largely ignored by the healthcare industry with little or no access to a potentially life-saving treatment prior to federal government intervention in 1973 (Sullivan, 2010). A great deal of clinical scientific exploration in the field took place in the 1960s thanks to early adopters such as Kolff, Merrill, Schreiner, and Scribner coupled with funding from the National Institutes of Health (NIH). Dr. Christopher Blagg was part of Dr. Scribner's team and presented a metanalysis of historical documents, appended with his personal historical accounts, in 2007. Dr. Blagg details the difficulty they experienced trying to extend their research into the clinical field because hospital administrators were concerned about the unreimbursed costs associated with the treatment in excess of their (NIH) funding. Dr. Scribner was forced to open a non-profit community outpatient dialysis center in a basement in 1962 with funding from private donors. Care was meticulously rationed due to scarcity cause by hospital's refusal to support the treatment and a lay board was selected to decide who would have access to early dialysis treatment (Blagg, 2007).

The federal government took notice of the growing need for ESRD treatment and responded with thirty dialysis units in Veterans Administration (VA) hospitals in 1963 to treat eligible veterans. Various federal programs provided grants for dialysis research from 1963 to 1977 including a demonstration grant in 1965 to “examine the feasibility of providing dialysis on a larger scale” (Blagg, p. 492). The Kidney Disease Control Program awarded grants from 1965-66 to prove that dialysis was no longer experimental and should be covered under Medicare; a 1966-68 Chronic Kidney Disease committee appointed by the Bureau of the Budget eventually supported that claim (Rettig, 1981). Even during this time of less than superior noninvasive and surgical procedures, the science included in the resulting Burton and Gottschalk reports stipulated that kidney transplantation was preferable to dialysis and home dialysis was preferable to in-center dialysis (Blagg, 494). Furthermore, the committees declared that the prohibitive cost of treatment required federal financial assistance and that ESRD treatments be made universally available due to some core reasoning:

> The reasons for this decision are the irreversibility of the decision not to do so, as far as an individual is concerned; the existence for the first time of a technology capable of prolonging the lives of persons otherwise doomed to an early death; the relative youth of these persons; the prospects of further improvements in technology; and the fact that patients are known and identifiable, not members of a statistical distribution, enhances the community’s interest in doing something in their behalf (Rettig, p. 8).

The Gottschalk group eschewed the cost-benefit analysis that had kept the provider industry from adopting dialysis as a core service, refusing to put a cost on human life. The Burton group performed rigorous cost-effectiveness calculations but remained resolute in the need for readily available ESRD treatment facilities in the American healthcare system.

In 1969 the National Kidney Fund and National Association of Patients on Hemodialysis ramped up its lobbying efforts in Washington to take advantage of the public sentiment concerning CKD patients. One physician active in the petitioning effort pointed towards patient marginalization when he proclaimed, “chronic kidney failure was the only situation where money separated individuals from life or death” (Blagg, 2007) The Medicare End-Stage Renal Disease Program of 1972 amended the Social Security Act to provide coverage for ESRD patients under the existing Medicare legislature and allowed for proliferation of the life-affirming technologies.

From the passing of the ESRD amendment through the 1990s the dialysis service industry thrived. The now ubiquitous payment for a previously unprofitable service attracted nonprofit as well as for-profit providers, which hastened the adoption curve for new facilities. A provision in the law that allowed nephrologists to include their dialysis clinic as part of their practice turned renal physicians into businesspeople (Sullivan, 2010). Notably, Dr. Belding Scribner summarized the early work of he and his peers as “a noble experiment” but later lamented the care provided to patients in the United States as “dialysis became an industry dominated by for-profit organizations” (Blagg, 2007).

ESRD Industry Snapshot

Dr. Scribner foreshadowed the evolution of the dialysis provider sector. In 2017, 91% of Medicare recipient dialysis treatments were provided in a for-profit facility (MedPAC, 2019) and 73% of the total dialysis provider market was controlled by DaVita and Fresenius Medical Care, both for-profit providers (Hackethal, 2019). According to the 2019 Medicare Payment Advisory Commission report, these two companies dominate the entirety of dialysis market. Beyond operating dialysis centers Fresenius and DaVita operate ESRD-related labs, pharmacies, vascular access centers and ESRD-related disease management services (MedPAC, 2019). The two publicly traded companies booked more than $4 billion in profits in 2018 (Hostetter, 2020). As an added boon to its bottom line, Fresenius also makes and sells ESRD-specific drugs and is the principal maker of the very machines and dialyzers used in ESRD treatment to other dialysis companies (MedPAC, 2019). When placed on the continuum of market dynamics, these companies place the dialysis industry further from free market enterprise and closer to oligopoly.

The number of facilities that are freestanding and for-profit continues to grow annually while the number and capacity of hospital-based and nonprofit dialysis providers continues to erode (MedPAC, 2019). For a nonprofit hospital, selling a dialysis unit to a for-profit provider delivers a short-term infusion of capital that can help with their debt and, in the long term, divest a Medicare-heavy service line with low margins (Maidenburg, 2011). Nonprofit facilities purchased by for-profit chains achieve savings through volume purchasing, centralized clinical laboratories, and fixed cost allocation over more patients (Pozniak, 2010). Compared to nonprofit dialysis providers, for-profit clinics have been criticized for cutting patient treatment times, less use of home dialysis (i.e., peritoneal dialysis) and referring fewer patients for transplant evaluation, each of which improve profits and may lead to patient harm (Childers, 2019). The companies rely heavily on private insurance as a source of revenue and have charged them four times more for privately insured patients than those on government insurance (Hackenthal, 2019). For-profit dialysis providers, like DaVita in 2014 and American Renal

Associates in 2016, have been sued for kickback schemes aimed at migrating patients from Medicare and Medicaid to private insurers, even though those private plans exposed the patients to out-of-pocket expenses (Abelson, 2016).

Fresenius and DaVita have also been vigorous in their merger and acquisition (M&A) activities that further their vertical integration strategies, including software and life science companies that maximize efficiency and profitability. The most recent merger valued at $2.4 billion incorporated two companies under the Fresenius banner. Merging Fresenius Health Partners with Cricket Health eliminated a renal care market competitor with a promising technology-enabled care model and patient engagement platform, while integrating InterWell Health adds 1,600 nephrologists to the Fresenius portfolio (Landi, 2022). Less competing players in the healthcare market limits contract negotiation and increases healthcare spending for patients, employers, and insurers.

Horizontal integration is also a key strategy the hinders competition. Fresenius M&A activity has targeted the healthcare services sector in 75% of its transactions (mergr.com, 2022). DaVita has acquired twenty-six companies since 2005 targeting the healthcare services sector in 96% of those transactions (mergr.com, 2022). A Federal Trade Commission (FTC) lawsuit challenging a proposed acquisition of dialysis centers in Utah as anticompetitive ended in more than divestiture of three clinics; DaVita was additionally the first entity to be restricted from any M&A activity in the state in question for the next 10 years (FTC, 2021). The FTC made the following statement when announcing the settlement:

> “DaVita has a history of attempting to buy up competing dialysis clinics in an industry that is already highly concentrated,” and that the restriction on future

> acquisitions will “help the Commission quickly identify and ultimately prevent future facially anticompetitive deals by DaVita.” (Burns, 2021).

The FTC ruling and subsequent statement indict the dialysis industry for using oligarchical influence and financial wherewithal to stifle competition. Like the AMA and AHA before, the dialysis provider industry has also effectively lobbied against evolution in the industry. As an example, dialysis providers spent considerably to influence Californians as they voted on Proposition 8 in the November 2018 elections. Better known as the “Fair Pricing for Dialysis Act”, Proposition 8 aimed to cap dialysis clinic profits at 15% above the costs of patient care (Rowan, 2018). Dialysis provider industry players, concerned that the cap would take a bite out of their bottom line, spent $111 million in 2018 on an ad campaign to beat back the regulatory legislation (Rowan, 2019). The next year California legislative measure AB-290, which would limit the reimbursement rate that dialysis providers receive for patients who get assistance from groups such as the American Kidney Fund, was met with another $2.5 million in lobbying and campaign contributions from the dialysis industry (Rowan, 2019). Proposition 8 was defeated and AB-290 is still being adjudicated in federal court.

Payment mechanisms make it more profitable for nephrologists and dialysis centers to have patients receive their ESRD treatments in the center (hemodialysis or HD) rather than at home, most often through peritoneal dialysis (PD). One nephrologist compared the phenomenon to an airline filling empty seats on a flight (Bannow, 2019). Peritoneal dialysis is associated with similar mortality, higher quality of life, and lower costs compared with hemodialysis (Sloan, 2019) but only accounts for approximately 10% of dialysis patients nationally (Flanagin, 2020).

It is essential that patients are engaged in the selection between PD and HD and the ultimate choice should center on patient preference (Zee, 2018). However, research has shown that patients feel unprepared and ill-informed about the dialysis initiation as well as the different modalities available (Zee, p. 2). These lobbying efforts, market dynamics and deference to financial contracts in lieu of the social contract closely mimic the American healthcare system.

The federal government has taken notice of the current state of the ESRD treatment industry and issued new regulations to protect patients. The Advancing American Kidney Health initiative announced in 2019 aims to prevent kidney failure and improve access to person-centered care and transplantation (USRDS, 2021). Its objectives include increased uptake of PD and transplantation in ESRD patients through new payment models and incentives for providers. What this enhancements are and how they will impact the patient is yet to be seen.

ESRD Patient Snapshot

To compound the stressors of the ESRD treatment industry in whole, ESRD patients are very often undiagnosed. According to the website MDSave a complete metabolic panel (a blood test that estimates how well a person's metabolism functions) can provide a GFR value at cost of between $10 and $78 with the national average price around $48 (MDSave, 2021). While the disease is nationally prevalent, life-threatening, and comparatively inexpensive to diagnosis, it is estimated that only 1 in 10 people with CKD know that have the disease and only 48% of people with severely reduced kidney function and not on dialysis do not know they have the disease (CDC, 2019). Once diagnosed chronic illnesses can cause a wide range of personality and behavioral disorders, which can impact patient compliance with dietary restrictions, disease management and prescription drug regimen (Naqvi, 2015).

ESRD patients are further burdened by the physical, mental, economic, and social effects of dialysis treatment. The average dialysis treatment regimen is three sessions per week and 4 hours per session (USRDS, 2019), during which time the patient’s blood is pulled out of their body and cleaned by a dialyzer (essentially an artificial kidney). Patients often experience fatigue, loss of appetite, difficulty concentrating, edema in the extremities, muscle cramps, and itching, the combination of any of these leading to an increased stress load and impaired quality of life (Horigan, 2013). Patients receiving HD are especially prone to these side effects due to the frequency, intensity, and chronicity of their treatments, yet the symptoms are often under-recognized and undertreated by their providers (Horigan, p. 113)

Clinically, these patients are significantly ill. Data from the 2019 U.S. Renal Data System report indicate that patients from 2015-2017 had an average body mass index of 29.7 kg/m^2 (healthy goal is under 25 kg/m$^{2)}$ and a glomerular filtration rate of 9.7 mL/min (healthy adult values are over 60 mL/min). During the same time period, 87.5% had a history of hypertension, 59.8% were diabetic, and 47.4% were diagnosed with congestive heart failure or some other cardiac disease (USRDS, 2019). Socially, ESRD patients experience a medley of debilitating circumstances due to the disease. During the period 2015-2017, 13.4% required assistance with daily activities (USRDS, 2019). A recent study by Erickson et. al. spanning 17 years of ESRD registry data calculated a 76% unemployment rate among patients at the start of dialysis; of those that were employed, 38% were unemployed within 6 months of dialysis initiation (2018). Without employment, 26.4% of patients required Medicaid and 61.2 % received Medicare benefits in the period 2015-2017 (USRDS, 2019).

Chronic kidney disease and ESRD, as with healthcare in general, impacts the full diaspora of Americans. It does however exhibit the disparities across demographic and socioeconomic statuses that are indicative of the healthcare system. African American and Hispanic people are more likely to become unemployed at some point after starting dialysis than their white counterparts (Erickson, 2018). African Americans are three times more likely (Laster, 2018) and Hispanics are almost 50% more likely (Desai, 2019) to require ESRD treatment compared to their white compatriots. Laster et. al. and Desai et. al. partly attribute these differences in disease prevalence to clinical (high comorbid condition burden i.e., obesity, diabetes, cardiovascular disease, etc.) and socioeconomic (social determinants of health i.e., income, insurance, community-level assets, etc.) factors that impact chronic disease progression. The authors also touch upon important succession and adaptation factors that impact the evolution of ERSD in ethnic minorities, including

- Genetic factors (ancestral polymorphisms, epigenetic augmentation due to racial/social stresses, etc.)
- Institutional policies and practices that perpetuate social inequities (residential segregation, educational injustice, etc.)
- Discrimination (implicit and explicit biases, stereotyping, etc.)
- Patient beliefs and behaviors (lack of trust in healthcare systems, prevalent myths of CKD/ESRD, etc.)

Issues with Patient Care in Dialysis Treatment

In a February 2021 during a panel discussion for the Center for Healthcare Innovation, Dr. Deidra Crews, a nephrologist and Associate director for Research Development at the Johns

Hopkins Center for Health Equity was quoted as saying "ESRD is not a moral failure of the patient; it is a direct reflection of structural factors patients live with every day." Nevertheless, patients are frequently confronted with ardent struggles to receive unbiased, evidenced-based care for their renal condition. The barriers to quality, patient-centered care span the clinical spectrum from resistance to remediation.

Primary prevention and screening for chronic diseases like CKD are widely deemed to be most effective in limiting the prevalence of these diseases (Grunfeld, 2013). As Yarnall et al (2003) stipulated, the most common barriers to providing prevention services were inadequate insurance reimbursement, patient refusal to discuss or comply with recommendations, and lack of physician expertise in counseling techniques. Each of these shifts the onus of responsibility from the provider system because of profitability, patient compliance, or lack of training. More to the point, each places the patient in a position of diminished service due to provider resistance or victim blaming. Davis et al (1992) acknowledged that “failure to provide these services results in loss of opportunity for potential improvement of health and prevention of disease”.

Due to sociocultural factors, the dearth of preventative measures incorporated in the American healthcare system, and rising incidence of chronic disease, more patients are migrating through the stages of CKD and requiring dialysis to treat their ESRD. With so much data pointing to PD being equivalent or superior to HD, it would be appropriate to question why the 2019 USRDS Annual Report declares 89.6% of ESRD patients start receiving dialysis in-center. An editorial by Flanagin et. al. sprouting from a 2019 National Kidney Foundation (NKF) conference on home dialysis delineated several barriers to improving PD uptake in the ESRD community. The impediments included education factors (lack of awareness of CKD, failure to timely refer at-risk patients to a nephrologist, skepticism from their providers about the risks and benefits of PD, etc.) and social factors like poverty, housing instability, care partner limitations, and low health literacy (Flanagin, 2020). While there are clinical factors (e.g., loss of peritoneal function) that limit PD selection, research has shown many other previous contraindications can be overcome with provider education and skill development (Hathaway, 2014 and Corapi, 2019). Most pertinently, financial factors were among the factors that misincentivized patient steerage to HD over PD including:

- The monthly capitated payment for dialysis patient care is significantly less for PD vs HD
- The PD training fee from Medicare is inconsistently charged and a one-time payment
- Lack of sufficient insurance coverage prior to starting dialysis
- Moving a patient to from HD to PD make the clinician’s HD clinic less profitable
- Facilities with PD programs face higher risk for quality incentive program penalties
- The time it would take to educate patients in PD and care for their comorbidities may result in time with the patient that is unreimbursed (Flanagin, 2020)

Once again calling back to social contract theory, it should be considered that the financial disincentives are paramount among the listed PD impediments. As evidence, there is a direct connection between financial incentives for PD included in the Medicare Improvement for Patients and Providers Act of 2011 (i.e., the “dialysis bundle”) and a 68% increase in PD usage from 2009 to 2013 (Hathaway, 2014).

Erythropoiesis-stimulating agents, or ESAs, are a class of drug used to treat anemia in dialysis patients. They are reimbursable by Medicare and were identified as a source of untapped revenue in the 1990s (Sullivan, 2010). Side effects including adverse cardiovascular events were identified in literature in the late 1990s, yet a panel of experts used “observational data” to justify higher doses of the drug in CKD patients citing “potential improvement in the patients' quality of life” as its basis (Singh, 2009). It was not until large, controlled research programs such as the CHOIR and CREATE studies of 2006 that the harmful side effects of the drugs were revealed. These studies involving patients with pre–end-stage or end-stage renal disease showed either an increase in adverse cardiovascular events or no benefit from anemia treatment with ESAs (Singh, 2009). Anemia is still an issue in CKD patients and ESAs are still prescribed by nephrologists, but the percentage of CKD patients receiving the treatment has decreased from 33% at its mid-2000s height to 20% in 2017 (U.S. Renal Data System, 2020). The 29-52% reduction in use of ESA nationally is mostly attributable to the 2007 FDA black box warning resultant from the CHOIR and CREATE and the “dialysis bundle”, which changed ESAs from being separately billable to being rolled into one lump sum payment per treatment (Shen, 2016). The prescription and billing of ESAs without clinical trial evidence is further evidence of the healthcare industry treating patient bodies as property for chargeable units as previously mentioned in this paper.

Patients undergoing dialysis treatment are diverse in their presentation, both owing to ESRD impacting the range of sociocultural backgrounds and the multiple ways the disease ravages the body. Yet each dialysis provider has an analogous ‘code of conduct’ that requires patient adherence to a schedule, care regimen (i.e. take what is prescribed), and behavior norms. ‘Cherry picking’ is a process by with nephrologists and dialysis centers select patients that best conform to the center’s ideal patient construct (Parker, 2011) A national survey of renal clinicians found three-quarters of respondents believed ‘cherry picking’ occurred sometimes or frequently (Borges, 2013). On the back end, physicians ‘fire’ undesirable patients by way of involuntary discharge or convincing the patient that they are not/no longer a good candidate for dialysis (Parker, p. 6). When patients are involuntarily discharged, they are often instructed to "go to the nearest emergency room for dialysis care", a processed referred to as patient dumping (Borges, p. 19). Cherry picking, involuntary discharge, and patient dumping can each result in patient harm physically, emotionally, and financially.

Dialysis is only the first of two treatment options available to ESRD patients. Renal transplant has long been deemed the preferred therapy by most patients and physicians (Port, 1993). To become a transplant candidate, patients must be referred to a transplant center by their nephrologist, who is also the physician managing their dialysis regimen. This relationship creates a conflict of interest with a provider who has a financial interest in the patient receiving dialysis treatment. During the period 2015-2017, 86.4% of patients received some form of education concerning their transplant options but 38.6% were not assessed for transplant (USRDS, 2019). Patients report receiving little information about the listing process and feel it is unfair based on burdened status (Calestani, 2014). Studies have shown that race and ethnicity play a role in referral for transplant (Suliman, 2019). Research has established patients with longer duration on dialysis have progressively decreased graft and patient survival once they are transplanted (Aufhauser, 2018). Given the difference in quality of life and improved outcomes over dialysis it is no wonder patients prioritize waitlist duration over all other transplant outcomes (Husain, 2018) Unfortunately, concerns with quality of care often follow the patient in the transplant journey.

Issues of Patient Care in Transplant

If a patient is referred, assessed by a transplant center, and deemed a viable candidate, they are placed on the transplant waitlist managed by the federal government's Organ Procurement and Transplantation Network (OPTN). The assessment, however, presents its own cadre of hindrances beyond navigation from the dialysis nephrologists. A 2008 publication by Douglas Keith et. al. sums up the process, and how biases can impact the patient's ability to access renal transplantation:

> Access to the kidney transplant waiting list requires many steps, including identification of progressive renal disease; referral to a transplant center for medical, financial, and psychosocial evaluation of appropriateness for transplantation; approval; and placement on the waiting list. Minority race/ethnicity… has been shown to effect significantly the rates of early identification of renal disease, opportunities for referral, rates of completion of evaluation, and the likelihood of acceptance of patients as candidates for transplantation. The additive impact of these impediments at each step of the process likely profoundly affects disease outcomes in these populations… (p. 469)

Add to this quandary the fact that each transplant center has its own standards for accepting candidates. According to the United Network for Organ Sharing (UNOS), "each transplant center may view the same facts and information diverse ways and make different decisions about listing a person for a transplant. So, if one program is not willing to accept you as a candidate, a different program may accept you" (2021).

The psychosocial evaluation is especially bothersome because research has shown that the process is opaque, and providers are uncomfortable with its entirety. Researchers investigating the social support evaluation, the section of the psychosocial assessment which grades patients' ability to be buoyed by their social network during recovery, reported 86.3% of transplant centers used social support as a listing criteria even though only 67.6% believed it should be used in listing decisions (Ladin, 2019). In the same study 67.3% of respondents believed social support evaluations disproportionately impacted candidates of lower socioeconomic status and 69.2% supported revising the guidelines for use of social support evaluations. Study participants estimated 9.6% of patients, and as many as 21.7% in the most aggressive programs, were denied listing because they lacked or were unable to demonstrate adequate social support in the eyes of the transplant program (Ladin, p. 200). Other criteria, including pre-existing mental disorders (Cahn-Fuller, 2017), drug and alcohol abuse (Parker, 2013), mental capacity (Marcangelo, 2007), and even marital status (Marotta, 2019) have similarly been used to deny access to the transplant waiting list. Some of these vague practices have anecdotal or small but statistically significant evidence of increased risk, leading to them being challenged in court.

Given the current state of the social contract of health, it would be unreasonable to ignore financial considerations playing a part in the listing process. Patients with lower socioeconomic status are known to have extraordinary circumstances that delay transplant referral, evaluation, and listing (Axelrod, 2010). Even with the resources to navigate the referral and evaluation process, potential candidates can still be turned away prior to listing. Transplant candidates with Medicare as the only insurance payor have been shown to be 78% less likely to be pre-emptively listed for transplant compared to patients with private insurance, a practice known to increase morbidity and negatively impact the eventual success of the transplant (Axelrod, p. 2280).

The general lack of inter-program standard leaves patients wondering what the rules of the game are, which program is truly best for them, and often whether they were denied access to this resource due to cultural, societal, or financial biases. This is not to say that some of the factors used in assessing transplant candidates do not have clinical merit, such as higher risk of renal graft failure in patients with pre-transplant alcohol dependency (Gueye, 2007). Lack of transparency elicits mistrust, a precursor to deleterious effects on patient’s willingness to submit to the process (Mohottige, 2020). When coupled with the confounding barriers in the dialysis industry, the result is that only 13% of patients with ESRD join the waiting list or receive a live-donor transplant within 1 year, even though many are predicted to have excellent posttransplant outcomes (Kucirka, 2015).

ESRD patients are forced to navigate among transplant centers without full transparency into the parameters of selection. Unfortunately, clear and transparent data regarding transplant centers is not readily available either. For instance, the rate at which transplant programs operate on patients compared to their expected transplant rate, known as the transplant rate ratio, is significant for ESRD patients (Brett, 2018). The probability of being transplanted varies 16-fold between different centers across the United States and patients can experience up to a ten-fold variation between centers in their organ allocation region (King, 2020). Higher program-specific adjusted transplant rate ratios are associated with better transplant outcomes and lower mortality rates. The Scientific Registry of Transplant Recipients (SRTR) provides some comparative data on transplant programs (SRTR, 2022). That information happens to be derivative graphics illustrating approximations of 1-year transplant survival and waitlist duration quality metrics. Patients must make their decisions on where to *attempt* to be listed, one of the biggest decisions of their adult life, with only the snapshot of information the healthcare industry provides.

The Role of Sociodemographic Status in ESRD Treatment

For every one white person that matriculates to end-stage renal disease, three Black people develop ESRD. That ratio is 3:4 for Hispanic individuals (NIDDK, 2021). Black patients with CKD have poorer outcomes and a higher rate of end stage renal disease than other racial groups (Poff, 2021). A recent discourse among the quaternary care community is a pertinent exemplar for the detrimental role race has historically played in transplantability. Estimated glomerular filtration rate (eGFR) is used by physicians to diagnose chronic kidney disease and assign stages to those afflicted with the disease (Hirst, 2018). The date eGFR value is measured below 20 mL/min is used to initiate qualified waiting time on the transplant list, which "plays a significant role in the prioritization of kidney offers" (Poff, p. 3). The earlier a candidate starts to accrue waiting time, the faster they be able to access the pool of available organs. Commonly used eGFR equations include a Black race modifier (BRM), though research shows that there is limited evidence to support its use (Marzinke, 2021). Research suggests that use of eGFR formulas inclusive of the BRM overestimates renal function for Black individuals, which could delay referral to transplant, decrease waiting time on the transplant list, and have an overall deleterious effect on renal outcomes for this population (Poff, p. 2). In 2021 the American Society of Nephrology and National Kidney Foundation released a joint statement stating that "race modifiers should not be included in equations to estimate kidney function" (Delgado, 2021), though the managing body for the transplant system (the OPTN) is still in the process of mandating removal of the BRM nationally.

A 2016 study in Kidney International connected the intersectionality of ethnicity, low-income, and ESRD. Researchers found that Black and Hispanic patients, who are disproportionately represented at the lower end of the socioeconomic spectrum, face a tougher path to transplant due to the burden of costly non-renal related medical prerequisites, longer waits for an organ and fewer living donors (Taber, 2016). Black people are four times more likely to experience kidney failure, spend 2.5 months longer on the waitlist, and are less likely to be referred for evaluation than white people (Arnold, 2020). By the time they are transplanted, their bodies are more ravaged by the disease and more likely to experience rejection five years post-transplant (Taber, p. 878).

Racial disparities in transplant access have been corroborated through research. African Americans are 25% less likely to be waitlisted and have a lower rate of kidney transplantation compared to their white counterparts even when risk adjusted for medical factors and social determinants of health (Ng, 2020). Race has proven to be a significant barrier to access at the regional level, as Peng et. al. observed a 27% lower instance of waitlisting for African Americans in Chicago compared to whites when adjusted for clinical, socioeconomic, and sociodemographic characteristics (2018). In 2021 the US Renal Data Service reported that, while the average wait time is 51.6 months, Black patients endure 26.4 additional months on the wait list compared to White patients.

The disparities in transplantation along socioeconomic and sociodemographic lines, including age, education, income, neighborhood of residence, insurance status and other reasons, has gained attention of late. Researchers found the probability of waitlisting decreased based on “being older, having lower income, public insurance, more comorbidities, and being on dialysis” (Ng, 2020). Peng et. al. identified 78% of the racial disparities observed in kidney transplant waitlisting in Chicago were associated with neighborhood poverty and racial composition (Peng, 2018). Wesselman and colleagues recently reaffirmed these variables as associated with lower probability of kidney transplant, along with greater religiosity, less social support, less transplant knowledge, and fewer learning activities (2021).

The Role of Body Mass Index in ESRD Treatment

The final evaluation point assessing the state of the social contract of health in the transplant arena is a complex one. Obesity is clinically defined by body mass index (BMI). More than four in ten American adults are obese (BMI ≥ 30 kg/m^2), severely obese (BMI ≥ 35 kg/m^2) or extremely obese (BMI ≥ 40 kg/m^2) according to the Centers for Disease Control (CDC, 2021). If the overweight population (BMI 25-29.9 kg/m^2) were joined to the obesity statistics, a full two thirds of Americans would fall into these categories (Bryant, 2015).

As a chronic condition obesity has a detrimental impact on risk of CKD, risk of matriculating to ESRD, and on transplantability (Hales, 2020, Kramer, 2006, Diwan 2020, Kovesdy, 2020). Obese patients are also at greater risk of going undiagnosed for kidney disease, potentially missing critical intervention time during early states. There are multiple formulas used to calculate e(GFR), though each has a higher likelihood of inaccuracy in people “at extremes of body type e.g., patients with limb amputations, severely malnourished and morbidly obese individuals” (UKKA, 2022).

For years obese patients have faced impediments to listing and receiving kidney transplants as investigators associated recipient obesity with an increased risk of wound complications and delayed graft function (Gore, 2006). Segev et. al. pointed to disincentives more consistent with the current state of the social contract of health: performing surgical procedures on obese patients is more difficult, more time-consuming, impact the profitability of the surgery because of the likelihood of more complications and longer hospital stays (Segev, 2008). Whether clinical or financial, the transplant system's reticence to equitably service obese patients has led to arbitrary BMI listing restrictions at transplant programs ranging from 32 kg/m^2 – 40 kg/m^2 (Diwan, p. 281).

Segev and Glanton have studied the impact of high BMI in patients' ability to access transplant services. Their work was deftly summarized by Tzvetanov et. al. in their 2020 American Journal of Transplantation publication:

> "Despite an increasing prevalence of obesity, many transplant centers do not list obese candidates. Segev et al analyzed UNOS data and showed that 21% of transplant centers do not list morbidly obese patients, which may be an underestimation. Additionally, once listed, the median time to transplantation is greater than 50 months for patients with a $BMI \geq 35\ kg/m^2$ in comparison to 40 months for nonobese patients ($P < .001$)… Glanton's review of 7443 patients waitlisted for transplantation with a $BMI > 30\ kg/m^2$ from the United States Renal Data System revealed a 50% reduction in mortality risk (3.3 vs 6.6 deaths/100 patient-years) with transplantation. This finding highlights the benefits of

> transplantation in obese patients and emphasizes the need to provide equal opportunity to these patients (p. 437)."

This sentiment is slow to be operationalized in the transplant community. From 1995-2006 among all patients awaiting kidney transplantation, the likelihood of receiving a transplant decreased with increasing degree of obesity (Segev, 2008). Gore and colleagues found that obese patients were less likely to receive a living donor transplant compared to those with 'normal' BMI, even though obesity did not increase the likelihood of mortality posttransplant after adjusting for comorbidities (p. 357). Research has nevertheless found, despite a higher propensity for delayed graft function and wound infection, obese transplant recipients have only a slight increase in risk of graft loss and can expect similar outcomes to recipients with 'normal' BMI (Hill, 2015).

The impact of body mass index and sociodemographic status on transplantability are inextricably intertwined. Obesity is more prevalent in Black (49.6%) and Hispanic (44.8%) adults more often that White adults (42.2%) and more than the average of 42.4 % nationally (CDC, 2021). Women (11.5%) and non-Hispanic Black adults (13.8%) are more likely to be severely obese than the population as a whole (9.2%) according to the most recent CDC statistics. Reducing or managing chronic diseases like obesity among burdened populations is challenging given the impact of social determinants of health on lifestyle and health behaviors (Bryant, 2015). Thus, the lower prevalence of obesity in college educated adults and frequently in higher income brackets follows that trend (CDC, 2021). Ultimately, the same people who are burdened by the transplantation system due to their socioeconomic and sociodemographic characteristics are doubly injured by BMI restrictions in transplant evaluations

The USRDS reported the average BMI for Black (30.1) and Native American (30.5) ESRD patients was only slightly higher than White (29.7) and Hispanic (29.3) patients and the national average of 29.6 from 2016-2018 (USRDS, 2020). The disparities come into play when viewed in the transplant context where incremental escalations in BMI correspond to an increasing proportion of African American candidates and a declining proportion of other ethnicities (Gore, 2006). As study by Rachel Patzer and colleagues found as neighborhood poverty increased, the likelihood of waitlisting decreased for African Americans compared with their white counterparts and, in areas of highest poverty, African Americans were disadvantaged in waitlisting by as much as 57% (Patzer, 2009). In the Southeastern part of the country Black patients were 59% less likely to receive a transplant than members of the majority with socioeconomic status explaining 30.6% of the reduction in transplantability (Patzer, 2012).

Irrefutably, progress is being made on transplantation disparities. From 2000 to 2018, the percentage of total transplants allocated to patients sixty-five and older more than doubled from 8.4% to 20.1% and the growth in transplants for African Americans grew 23% faster than total transplant growth among dialysis patients (USRDS, 2020). Regrettably, the growth in Hispanic population transplants has not kept pace with the growth in transplants for the same period (39% vs.47%) and the representation of African Americans among total transplants for dialysis patients has barely moved from 22% in 2000 to 25% in 2018 (USRDS, 2020). Novel technologies, such as deceased donor organ profusion and 3D printed organoids, promise to increase the number of available organs in the years to come, but improving the odds of transplant waitlisting and subsequent transplantability would remain an issue.

Robot-assisted kidney transplant (RAKT) provides some promise to patients facing barriers to transplant. Rather than creating a wound near the waist where it is more likely to cause an infection, surgeons create an incision below the sternum where obese patients likely have less excess fat tissue. Patients benefit from smaller incisions, lower morbidity, shorter hospital stays, less pain, lower wound infection rates and superior cosmetic results (Spiers, 2022). Clinicians at the University of Illinois at Chicago (UIC) Medical Center were the first American transplant center to perform an RAKT procedure (Giulianotti, 2010). The UIC team published a single-center retrospective analysis of a RAKT cohort transplanted between January 2009 to December 2018 (Tzvetanov, 2020). While many centers have BMI caps in the thirties, the average patient in this cohort had a body mass index of 41.4 (range 25.2 – 62.6 kg/m^2). For the 239 RAKT patients included in the study transplant function and recipient survival were comparable to the UNOS population from the same time period (Tzvetanov, p. 437). The publication of the study results is considered to be the largest cohort to be reported over a 10-year period, though smaller studies from India (n=55), Germany (n=21), Turkey (n=40) and Italy (n=17) exist with research physicians reporting similar positive outcomes and significantly reduced post-operative patient-reported pain (Tugcu, 2018). To date, the impact of RAKT technology on access to transplant for burdened populations has not been studied.

Community Psychology and the Social Contract of Health

As a discipline community psychology is uniquely oriented to support study of the social contract of health with a population currently burdened by social determinants of health, multiple epidemics (e.g., COVID, obesity, gun violence, etc.) and the health system itself. The literature at the intersection of community psychology and healthcare mostly focuses on healthcare disparities among certain groups (LGBTQ, African Americans, the homeless, etc.) and specific ailments (HIV, mental illness, physical disability, etc.) but rarely broaches the existing power dynamic that facilitates the systemic complications of the American healthcare system. A review of community psychology values in the context of the social contract of health aids in connecting the discipline to the charge at hand.

Community psychology (CP) in praxis offers a framework that leads to self-aware social change with an emphasis on value-based, participatory work and forging of alliances (Burton, 2007). It is a relatively new discipline with its genesis most often associated with a meeting of clinical psychologists to discuss evolution of their profession in Swampscott, Massachusetts in 1965. The social revolutions of the 1960's were a catapult for change as described by proceedings from the Swampscott conference, but equally as influential on the development of the field was the treatment of mental health patients. Rudkin (2003) described the situation as follows:

> In the 1960's, questions abounded as to whether the established way of doing things was the best way. Activists exposed the overcrowding and abuses of state hospitals, objected to the overuse of drugs and surgery in treating inpatients, highlighted the discriminatory nature of service delivery, and questioned the ability of psychiatrists and psychologists to cure mental illness even under the most favorable conditions. The belief that the mental health system must change became widespread.

Julian Rappaport provided context for the logical connection of this social science to the current healthcare debate. First, similar to examples in the publication 'In Praise of Paradox', evaluation of the social contract of health has become ‘one-sided’ (Rappaport, 1981). When individual patients who have ill health receive a great deal of care, there is a tendency to blame the patient behaviors when the outcomes of the healthcare system fail to meet expectation. On the other hand, when patients do not utilize the traditional healthcare system due to costs, lack of convenient access or fear owing to previous injustices of the delivery system, they nevertheless bare the blame for not engaging with the system. Moreover, if attention were solely focused on the patient community, solutions would be ineffective in altering the public policies and procedures impacting outcomes. Yet to eschew the influence on care relationships in favor of policy change, one would be abjuring one basic tenet of the business: healthcare is local. Because community psychology has had the character of a social movement, it can contribute to the pursuit of paradox inherent to a redistribution of power, which is needed in the social contract of health.

A final bit of context can be found in Dalton and colleagues’ (2001) definition of CP. These authors suggest that through collaborative research and action, community psychologists seek to understand and to enhance quality of life for individuals, communities, and society (Nelson, 2010). The national healthcare system has the technological superiority and funding to be the best in the world, but a reckoning of the social contract of health at all individual, community and societal level is required to engender a structure that works for the people.

In that mold, this research seeks to understand the impact RAKT can have on transplantability of patient populations that have been harmed by the dialysis provider system, distanced from the optimal treatment of transplantation, and disregarded by an imbalanced social contract of health.

Purpose of the Study

The hypothesis evaluated states that the robot-assisted kidney transplant (RAKT) technique allows for patients with higher BMI and of burdened socioeconomic and sociodemographic status improved access to transplant compared to the traditional open kidney transplant (OKT) approach. The research questions addressed included:

a) Are the upper limits of BMI between the comparison (RAKT) and control (OKT) groups statistically different as to impact transplantability of end-stage renal disease patients?

b) Does the experimental group exhibit socioeconomic and sociodemographic characteristic proportions that are significantly different from the control group?

c) Are the predictors that are significantly associated with transplantability different between the traditional and robot-assisted groups?

The study was retrospective and concluded following statistical analysis and reporting. The primary endpoint was the change in predictors of transplantability, as defined by estimated post-transplant survival score, as BMI is extricated from the transplantability predictor set by the RAKT technique.

METHOD

Design of Study

The study was retrospective and designed to conduct a review of existing transplant patient information from two sources. First, this study used data from the Organ Procurement and Transplantation Network (OPTN). The OPTN data system includes data on all donor, wait-listed candidates, and transplant recipients in the US, submitted by the members of the Organ Procurement and Transplantation Network (OPTN). The U.S. Department of Health and Human

Services Health Resources and Services Administration (HRSA) provides oversight to the activities of the OPTN contractor. Second, data from the CAPriCORN clinical data network (CDN) was used. CAPriCORN is a partnership between healthcare and research institutions, patients, patient advocates, clinicians, community-based organizations (CBOs) and non-profits committed to enabling and delivering patient centered clinical research. CAPriCORN has erected the infrastructure and processes necessary to create data sets comprised of high-quality, de-duplicated patient information from participating institutions' electronic health records using a common data model. All CAPriCORN entities that performed kidney transplant during the study period agreed to respond to the query and are considered study sites. Both the OPTN and CAPriCORN are extant data sets with open and robotic-assisted kidney transplantation records. The variables requested from each data set include:

CAPriCORN Data	UNOS Data
Height	Body Mass Index (BMI) at Waitlisting
Weight	Body Mass Index (BMI) at Transplant
BMI	Glomerular Filtration Rate (GFR)
Race	Estimated Post Transplant Survival Score
Ethnicity	Total days on waitlist
Age	Survival 1-Year Post-transplant
Gender	Reported Transplant Complications
Insurance Payer	Recipient LOS Post-transplant

3-digit ZIP	Payment Source @ Registration
ZIP-to-income translation	Recipient Treated for Rejection
Transplant Procedure Codes	Work for Income at Registration
Serum Creatinine (mg/dL)	Work for Income at Transplant
	Recipient Highest Educational Level at Registration
	Total Days on Kidney Waiting List
	Graft Lifespan-Kidney

Figure 1. CAPriCORN and UNOS Requested Variables

Participants

The target population consisted of 5880 kidney transplant patients from Chicago transplant centers (UIC, RUSH, NMH, and UChicago). Patients who had records in the UNOS data set and were matched through hashing procedures to the CAPriCORN data set were included as a part of this study.

Women and all race groups were included. Children under age 18 were excluded because they are not candidates for the robotic assisted technique at the region’s only RAKT transplant center (UIC). The study did not actively target prisoners or pregnant women; however, datasets may include them incidentally. Indication of the patient's incarcerated or pregnancy status will not be included in the dataset.

Procedure

The study period is defined as January 1, 2009, to December 31, 2018. The University of Illinois Department of Surgery applied for access to a patient-identified STAR data file from UNOS and signed a data use agreement (DUA). The file included first name, last name, date of birth, social security number, and ZIP code for each transplant record in the time period. This step required approval from the United States Health Resources and Services Administration (HRSA) and the OPTN. The UIC Department of Surgery was invoiced $1,500.00 by UNOS for the preparation of the data set and remitted payment accordingly.

Rohith Vanam, a Biomedical Informatics Research Specialist at UIC's CCTS serving as the Honest Broker for this study, received the UNOS file including protected health information (PHI) to maintain security and privacy. Patient identifiers including first name, last name, date of birth, social security number, and ZIP code were used to create hash tokens for each UNOS patient record. The research team has not had access to the patient identifiers; only the Honest Broker manipulated the UNOS data set with PHI appended.

The previously denoted variables were collected from the CAPriCORN data mart according to an SQL query. The CAPriCORN data query was created by Dr. Howard Gordon's research team at UIC and reviewed with the Principal Investigator (Earnest Davis). Part 1 of the query requested that sites search for any patient records that included a kidney transplant based on charge codes. Part 1 was distributed to participating sites by the Medical Research Analytics and Informatics Alliance (MRAIA). From the responses hash tokens were created based on first name, last name, date of birth, social security number, and ZIP code. Part 2 of the query matched the UNOS and CAPriCORN patient records using the hash tokens. The research team had no access to the patient identifiers. A detailed accounting of study design is available upon request.

The Principal Investigator was able to access the resultant data set through a secured Box.com data folder. Charge analysis in the CAPriCORN data set confirmed that all robotic-assisted renal transplants during the study period occurred at one center. Procedures performed using the robotic-assisted approach were classified by the UIC Surgery teams charge records and matched to the UNOS data set by the Honest Broker.

The CAPriCORN query returned ZIP code entries for 2652 unique patient records at the five transplant centers. Code written into the SQL query assigned a median household income to each record as defined by the 2019 U.S. Census Bureau American Community Survey. Estimated post-transplant survival (EPTS) scores were added to the UNOS STAR data file May 27, 2014, which falls midway through the study period. The circumstance resulted in 1593 (27.1%) EPTS values at time of listing and 2562 (43.6%)values at time of transplant. CAPriCORN records were matched to the UNOS data set in Microsoft Excel using a lookup function keyed on the study ID (RAKT_ID). The resultant data file was uploaded to Microsoft SPSS statistical hardware for analysis.

Data Privacy

Data from UNOS was delivered via Box.com and uploaded to an ACER secure compute environment by the Honest Broker. All hash tokens were created in the Datavant software to be shared with MRAIA. After the RAKT query has been fulfilled by CAPriCORN sites and compiled by MRAIA it was transmitted electronically to the research team. Access to the resultant deidentified data set has been limited to Dr. Gordon, Dr. Benedetti, and Mr. Davis set for statistical analysis.

Each institution in CAPriCORN created a data mart (or equivalent database) conforming to the designated data model(s). The data mart was connected to a local PopMedNet client to execute CAPriCORN queries. Each resides behind an institutional firewall and is subject to normal local security protections. Each institution was free to choose the platform and the database software in which to implement its internal data mart (IDM), and consequently is responsible for ensuring that the local PopMedNet client interfaces with the IDM in such a way that queries can be run without modification. Protected health information in CAPriCORN will be held in IDMs and subject to the institution's normal systems, protections and protocols for security, patient privacy and confidentiality.

Data Analysis

Data analysis was performed using Microsoft SPSS statistical software. A univariate ANOVA compared groups like body mass index and GFR. Along with the ANOVA, frequencies and means for nominal and continuous variables assessed the similarity of the RAKT and OKT groups. Analysis of means (independent t-test) and frequencies were employed to define the differences in BMI within the two groups. A chi-square test was implemented to discern any differences in ethnicity, gender, age, or socioeconomic status (SES) between the groups (SES defined by census tract, insurance status, educational attainment, and employment status). A step-wise multiple linear regression analysis identified the predictors that are significantly associated with transplantability (transplantability defined by EPTS score).

The assessment centered on whether disparities in transplantation could be alleviated with RAKT proliferation.

Expected Risks and Benefits

There are no substantial psychological, physical, social, economic, or legal risks to patients in this retrospective study. There is a potential risk of loss of confidentiality if there was a data breach but this was mitigated by taking all steps as required by the DUA to protect the data including storage in a HIPAA compliant secure data storage location and use of an honest broker to create data linkages so the PI would not receive any identifiable data. There was no effort to reidentify any patients in the deidentified data set.

There are no direct benefits to patients anticipated in this study. As chronic conditions such as obesity, hypertension, and diabetes continue to become more prevalent in American society, the incidence of chronic kidney disease and ESRD is climbing along with them. The transplant network needs to adopt new ways to treat this population with the optimal therapy. Scientific evidence and voice of the patient points to transplant being superior to dialysis. Understanding the impact RAKT has on patient's ability to be waitlisted and to receive a transplant could lead to wider proliferation of the technique. Hence, indirectly, support for the hypothesis could benefit patients through wider proliferation of the robotic approach within the transplant industry, allowing for more patients from more diverse backgrounds to access the most efficacious therapy for ESRD.

RESULTS

The data reported here have been supplied by UNOS as the contractor for the Organ Procurement and Transplantation Network (OPTN). The interpretation and reporting of these data are the responsibility of the authors and in no way should be seen as an official policy of or interpretation by the OPTN or the U.S. Government.

The OPTN data set identified 5880 adult kidney transplants at Chicago hospitals during the study period. The robot assisted kidney transplant (RAKT) group consisted of 238 recipients. The remainder were performed through the traditional open kidney transplant (OKT) approach. All RAKT procedures identified took place at one transplant center (University of Illinois at Chicago Medical Center). The CAPriCORN data set identified 2908 adult kidney transplants (152 RAKT) during the study period and confirmed all RAKT procedures took place at UIC.

Clinical Indicators

To interpret whether the upper limits of BMI were statistically different as to impact transplantability of end-stage renal disease patients an independent *t*-test was conducted. Results found the RAKT group (n=238) exhibited a mean BMI at listing of 41.3 (SD 6.1) kg/m^2 versus the OKT group (n=5258) mean of 28.5 (SD 6.9) kg/m^2 ($p<.001$), indicating larger patients were listed for transplant through the RAKT program than traditional OKT sites. The comparison of means also demonstrated a higher mean GFR score at listing in the OKT group (12.8, SD 4.9 mL/min) versus the RAKT group (10.4, SD 4.8 mL/min), illustrating that patients transplanted via the robotic approach had lower renal functioning than the control group ($p<.001$). All RAKT (n=78) and OKT (n=2423) patients in the data set that possessed a glomerular filtration rate exhibited severely decreased renal function (GFR≤20 mL/min), though a higher proportion of the RAKT cohort (75.6%, n=59) fell into the kidney failure category (GFR<15) than the OKT group (60.8%, n=1474). These results are clinically relevant because authorities suggest symptomatic patients begin dialysis when GFR<15 (NKF, 2015) and dialysis duration is a negative indicator for transplant outcomes (Aufhauser, 2018). Of the cases with reported dialysis status (n=3908) more RAKT recipients were on dialysis at time of transplant with 77.6%

(n=149) receiving maintenance treatments compared to 69.7% (n=3759) of OKT patients (p=.019).

Recipients in the RAKT group benefited from living donation in 71.0% (n=169) of cases while living donation in the OKT group was much lower at 42.3% (n=2385) of transplants during the study period (p<.001). The difference in length of stay, which demonstrated a mean of 6.8 (SD 4.3) days for the RAKT group (n=237) and 6.1 (SD 8.6) days for the OKT group (n=5615) was not statistically significant (p=0.235). There was no significant difference between the status of the kidney graft post-transplant in the two groups as 86.2% (n=4864) of the OKT recipients and 85.3% (n=203) of the RAKT recipients benefited from functioning grafts post-surgery (p=.688).

Independent *t*-test analysis illustrated that once transplanted the RAKT group (n=230) demonstrated creatinine lab values that were not statistically different compared with creatinine values in the OKT cohort (n=5385). Post-transplant creatinine for the RAKT group exhibited a mean of 1.5 (SD 0.6) mg/dL after six months compared to 1.4 (SD 0.6) mg/dL for the OKT group (p=0.18). Similarly, post-transplant creatinine for the RAKT group showed a mean of 1.6 (SD 0.8) mg/dL after one year compared to 1.4 (SD 0.6) mg/dL for the OKT cohort (p=0.16). Neither six-month nor one-year mean creatinine was statistically significant among the two groups. A chi-square analysis investigated the proportion of patients with a functioning graft that returned to dialysis treatment following transplant. In the OKT group 20.0% (n=1130) of patients returned to dialysis while 21.8% (n=52) of RAKT patients returned to some type and frequency of dialysis, though the difference was not statistically significant (p=.615).

Recipients experienced graft failure in 13.8% (n=778) of open kidney transplant procedures compared to 14.7% (n=35) of robot assisted renal transplants. The difference in mean graft survival between the OKT group (68.9 months, n=5642) and the RAKT group (62.1 months, n=238) was statistically significant (p=.006), but not clinically relevant. A difference of 5.7 years in traditional transplant and 5.2 years via the robotic-assisted technique is not likely to sway physicians' listing or surgical decisions. A Kaplan-Meier Survival test was implemented to test the hazard associated with both surgical transplant techniques. The chi-square statistic (χ^2 =1.017) revealed no statistically significant difference between the two cohorts (p=.313). The hazard plot is displayed in Figure 2.

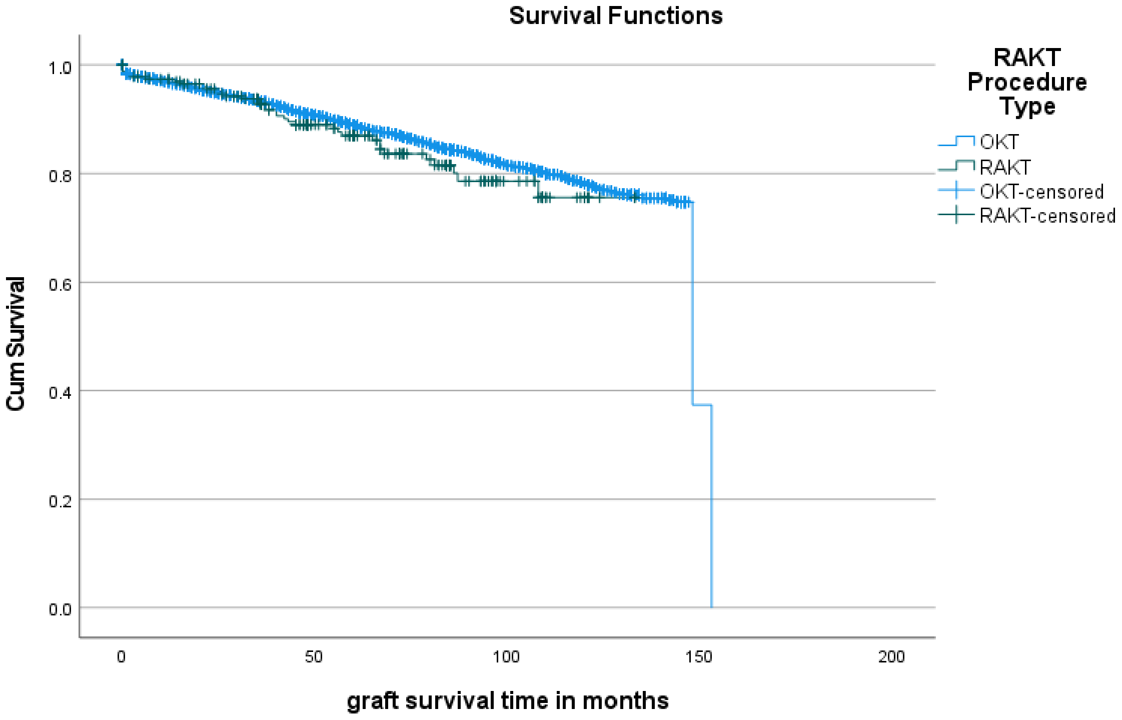


Figure 1. Kidney Graft Survival Hazard Plot

Sociodemographic Indicators

The second research question pertaining to whether socioeconomic and sociodemographic characteristic proportions are significantly different between the two groups was explored through a series of Chi-square tests. Demographic assessment included gender, age, ethnicity, and citizenship at the time of listing. The RAKT group exhibited a higher proportion of females (44.5%, n=106) than the OKT cohort (38.5%, n=2174), though not by a statistically significant margin (p=.063). Conversely, traditional OKT patients in Chicago exhibited more diversity based on non-US citizenship status (7.6%, n=430) than the RAKT (0.8%, n=2) group by a statistically significant margin (p<.001) though the low number of persons in the RAKT group violates the assumptions of the analysis. Traditional approach transplant patients in the 60-79 (31.5%, n=1804) age bracket constituted a higher proportion of their cohort compared to robotic-assisted approach recipients in the older adult age group (15.5%, n=37) at a statistically significant level (p<.001).

In terms of ethnicity, results were statistically significant (p<.001) and varied. The OKT group proportion of Hispanic individuals (23.4%, n=1322) was slightly higher than the RAKT cohort (21.4%, n=51). As well was the percentage of Asian OKT recipients (5.2%, n=292) compared to the RAKT group (1.3%, n=3). However, the proportion of Black candidates that received a kidney transplant was substantially higher than expected in the RAKT group (55.5%, n=132) compared to the OKT group (33.2%, n=1875). American Indians/Native Alaskans, Native Hawaiians/Pacific Islanders, and multiracial individuals each saw near their expected proportion in both groups.

Socioeconomic Indicators

Further exploration of the second research question was facilitated by chi-square tests that examined socioeconomic characteristics of the two groups. Patients without a college degree were more often transplanted through the RAKT approach (81.5%, n=194) compared to the 64.9% (n=3664) patients in the OKT group (p<.001). Variances in the frequency of unemployment at the time of listing were statistically significant (p=.006) in the OKT (69.7%, n=2909) and the RAKT (60.9%, n=160) groups. Both groups exhibited significantly higher percentages of unemployed candidates at the time of transplant with RAKT recipients (80.4%, n=185) again demonstrating a higher instance of unemployment than the OKT cohort (68.9%, n=3695) at a statistically significant level (p<.001).

Payment source at time of transplant is another harbinger of socioeconomic status. The RAKT cohort had a higher proportion (70.6%, n=168) of government sponsored programs as payors than the OKT group (63.9%, n=3604) during the study period (p<.001). A *t*-test and chi square analysis were employed to infer economic status based on the ZIP code of residence. The estimated median household income by ZIP code for the RAKT group was $59,024 (SD $23,343 ,p<.001) with 36.9% (p=.003 , n=72) living below the qualifying income maximum for food stamps in Illinois (currently positioned at 185% of the federal poverty line). OKT group members showed a median household income of $67,704 (SD $28,095 , p<.001) with 27.3% of (p=.003, n=673) classified as low income.

Transplantability Indicators

The final research question investigated the predictors that are significantly associated with transplantability and whether they differed between the traditional and robot-assisted groups. Transplantability indicators are operationalized as values that demonstrate the barriers patients face to receiving a transplant. They speak to individual patient presentations that are assessed during the candidate evaluation and impact a patient's access to transplant based on program norms, preferences, risk tolerance and biases. Some transplantability indicators tell the story of the patient, while some demonstrate the impact of system practices.

Functional status is a patient-reported estimate of disability due to their kidney failure and other comorbidities. It is best analyzed though a chi square test. Patients listed in the RAKT group reported they could perform 60% or less of the activities of daily living (ADL) in 38.7% of cases (n=92) while OKT group patients reported completing 60% or less on their own in 12.1% percent of cases (n=680) during the study period (p<.001). At transplant, patients in the RAKT group reported they could perform 60% or less of the activities of daily living (ADL) in 50.4% of cases (n=120) while 15.7 % of patients (n=888) in the OKT group reported completing 60% or less of ADLs without assistance (p<.001).

A series of *t*-tests evaluated EPTS score means at the time of listing and transplant. Values for 27.1% of cases were available in the data set including 71 RAKT and 1522 OKT cases. Means of 0.37 (SD 0.28) for the OKT and 0.38 for the RAKT (SD 0.27) groups were not statistically significant in the t-test (p=.660). At the time of transplant, 43.6% of cases included values for analysis including 106 RAKT and 2456 OKT cases. Means of 0.40 (SD 0.28) for the RAKT and 0.44 (SD 0.30) for the OKT groups were not statistically significant in the t-test (p=.231).

To further examine access to transplant among recipients, a series of analyses were performed with waiting list duration as the dependent variable. Wait times were available for

5390 OKT and 192 RAKT cases. Recipients in the OKT population had a calculated mean of 822.7 (SD 862.2) days (p<.001). The mean of the RAKT cohort was markedly lower at 499.5 (SD 654.4) days during the study period (p<.001).

Acknowledging that the OKT group was far more variable in BMI values, some attenuation of the data set was necessary to evaluate the RAKT impact on transplantability among its intended patient demographic. Among severely obese recipients (BMI>40), 132 (55.5%) received transplant by RAKT approach and 215 (3.8%) were transplanted using the OKT method during the study period. Some 16.7% (n=36) of OKT patients returned to dialysis follow transplant versus 16.6% (n=22) in the RAKT group with no statistical significance (p=.733). Some 14.4% (n=31) patients in the OKT cohort experienced nonfunctioning renal grafts against 16.7% (n=22) with no statistical difference (p=.572). Renal graft survival (1880.8 [SD 1143] days OKT versus 1776 [SD 956] days RAKT, p=.385) and length of hospital stay (8.67 [SD 14.86] days OKT versus 7.20 [SD 4.72] RAKT, p=.271) as well showed no statistically significant difference in their mean values.

Clinical indicators showed further similarity in clinical outcomes for the over 40 kg/m^2 subgroup. Creatinine values were available for the OKT (n=203) and RAKT (n=127) subgroup. Creatinine levels six months post-transplant (1.57 [SD 0.77] mg/dL OKT versus 1.56 [SD 0.52] mg/dL, p=.941) and one-year post-transplant (1.49 [SD 0.56] mg/dL OKT versus 1.56 (SD 0.74) mg/dL RAKT, p=.375) were similar.

Wait times were available for 207 OKT and 110 RAKT cases in the extremely obese subgroup. Patients in the OKT group received a transplant within 12 months of listing in 36.7% of cases (n=76) while RAKT recipients exhibited a 59.1% rate (n=65) though results were not statistically significant (p=.305). Comparison of frequencies in the RAKT group were statistically significant (p<.001), illustrating that 57.7% (n=124) of OKT participants who were severely obese saw their BMI fall between 40 and 43 kg/m^2 opposed to 27.3% (n=36) of patients in the RAKT group. A bivariate correlation analysis showed no significant relationship between BMI and waiting list time for the OKT group (r=.073) or the RAKT group (r=.063). Scatter plots reveal that almost none of variance in waiting time is explained by BMI at listing in the OKT group (R^2=.005) or the RAKT group (R^2=.004). However, when comparing the scatter plot for listing BMI (Figure 3) against the BMI at time of transplant (Figure 4), the visualization illustrates the difference in BMI from listing to transplant.

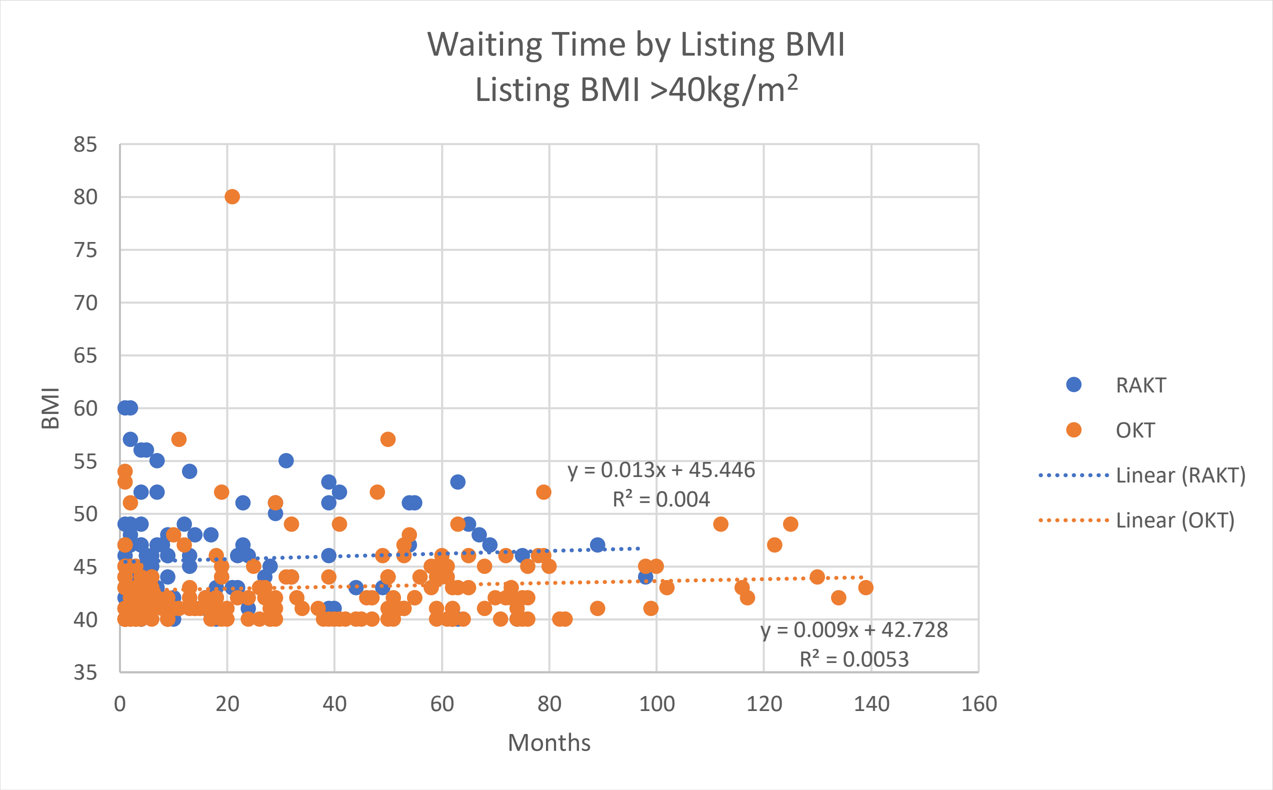


Figure 2. Waiting Time by Listing BMI for Candidates Over 40 kg/m^2 at Listing

The mean BMI at listing for the OKT subgroup (43.51 [SD 4.1] kg/m^2) and RAKT subgroup (46.29 [SD 4.6] kg/m^2) was significantly different from the OKT (39.83 [SD 5.7] kg/m^2) and RAKT (45.26 [SD 4.1] kg/m^2) cohort means at the time of transplantation (p<.001). The coefficients of determination for recipient BMI in the OKT group (R^2=.038) and RAKT group (R^2=.003) were negligible.

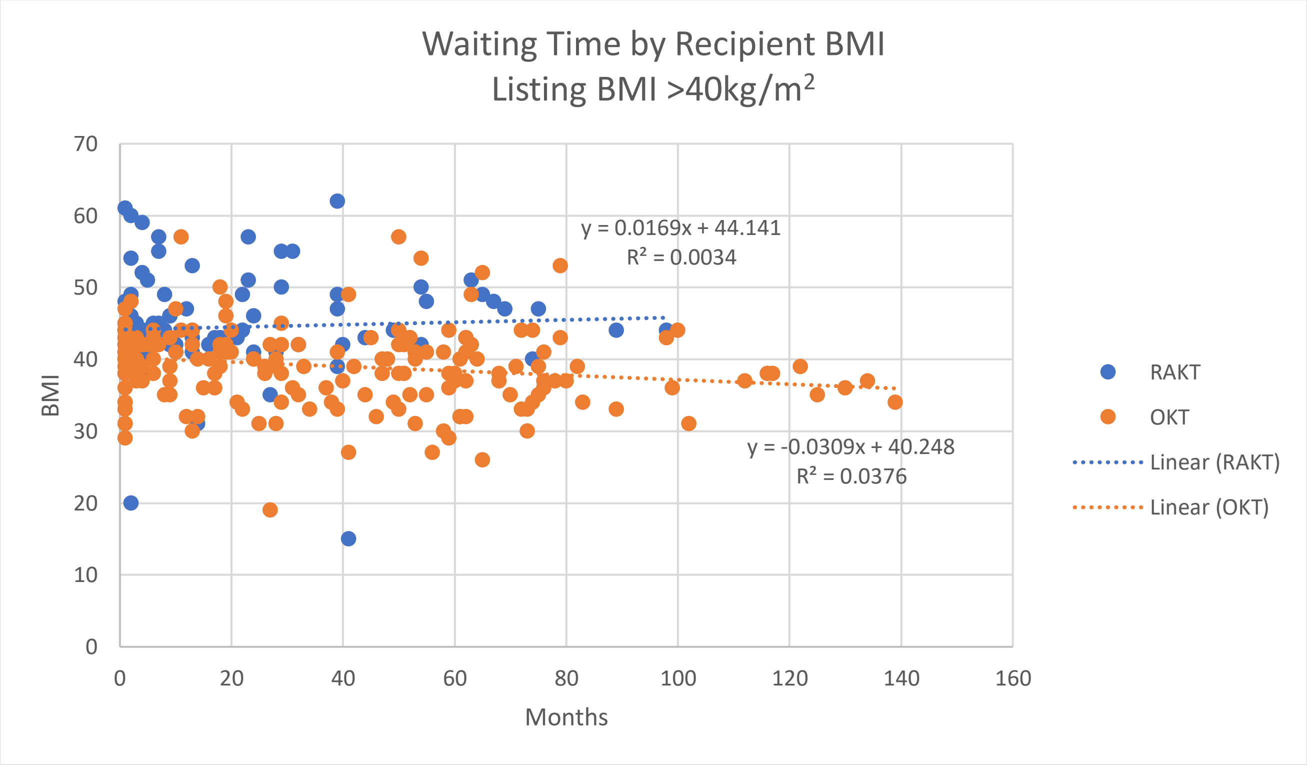


Figure 4. Waiting Time by Recipient BMI for Recipients Over 40 kg/m^2 at Listing

DISCUSSION

Results indicate the hypothesis was supported. Patients transplanted through the robotic assisted transplant program exhibited higher BMI values than OKT program recipients at the time of listing and even more so at the time of transplant. Patients in the RAKT group presented at transplant centers with more advanced disease when considering their functional status, glomerular filtration rate and history of dialysis. The estimated viability of both cohorts seemed to be similar, though not statistically significant. Patients at the robotic-assisted program suffered from more significant loss of functional ability and employment during their wait on the list.

Moreover, the RAKT group exhibited more diversity in terms of female and Black recipients, though non-U.S. citizens, persons over sixty years of age, and Hispanic individuals tended to be better represented in the OKT group. There is an important intersection to consider with the results for Black patients specifically. This demographic has been systemically marginalized throughout the renal specialty by the Black race coefficient in eGFR calculations that underdiagnoses Black people, only recently being viewed as racist and inequitable within the field (OPTN, 2021). Research has shown that with each successive BMI category, a greater proportion of recipients are African American (Gore, 2006). The propensity for robot-assisted transplant to broaden opportunities for the optimal renal failure therapy is reason enough to support its wider proliferation.

In terms of socioeconomic status, there were more recipients who were without a college degree in the RAKT group. Individuals that were transplanted at the robotic-assisted program exhibited higher levels of unemployment at listing and at the time of transplant, which may partially explain why a higher proportion of this group had Medicaid or Medicare as a primary payer. The RAKT cohort also carried the distinction of having lower median household income based on their ZIP code of residence when compared to the traditional renal transplant group.

With so many indicators to illustrate the burdened status of the RAKT group clinically and socioeconomically throughout the transplant experience, the cohort showed resilience when analyzing outcome indicators. Creatinine lab values at six- and twelve-months post-procedure were not significantly different. Length of stay in the hospital, post-surgical graft function, and incidence of returning to dialysis treatments post-transplant each exhibited variances that were not statistically significant between the OKT and RAKT approach. An analysis of time to event data illustrated that there was no statistical difference in the longevity of the renal graft between the two groups in patients who experienced graft failure. Importantly, a significantly higher percentage of patients in the RAKT group benefited from living donation, demonstrating strong support networks for individuals in the cohort.

A key observation of this research lies in the correlation analysis of waiting time compared to BMI in patients over 40 kg/m^2. Literature stipulates that the likelihood of receiving a transplant decreases with increasing degree of obesity (Segev, 2008), but the BMI threshold of 40 kg/m^2 was selected because it is the generally accepted upper limit of BMI cutoffs instituted by transplant centers (Reingard 2018, Chopra 2018). The analysis was initially performed utilizing BMI at listing data. A recent study indicates that people who lose >10% of their body weight prior to surgery are at increased risk of negative outcomes following deceased donor kidney transplant (Harhay, 2019) suggested BMI at transplant be used as a comparison.

The resulting analysis showed that while outcomes were similar across the board for the BMI>40 kg/m^2 subgroup, the patients in the OKT cohort lost a significant amount of weight (8.5% loss of BMI) prior to being transplanted while the RAKT group stayed close to their listing BMI (2.2% loss of BMI). Given that both patient groups are suffering from ESRD, it is to be inferred that center practices forced patients to meet an arbitrary BMI goal prior to receiving a transplant, even though their outcomes could have been similar had they received a transplant months sooner at a robotic-assisted transplant program.

Implications

Patients with high BMI are systematically restricted from transplant as a therapy at the community referral level due to provider biases and at the referral stage, then by arbitrary BMI cutoffs and weight loss requirements at the evaluation and listing stages. The hypothesis that the robot-assisted kidney transplant technique allows patients with higher BMI and of burdened socioeconomic and sociodemographic status improved access to transplant is accepted.

The high proportion of living donor transplantation in the RAKT population is illustrative of the fact that patients of higher BMI will not be a drain on the system. Clinical outcomes comparable to traditional transplant techniques, when analyzing the entire ten-year data set or censored for the severely obese, demonstrate persons of higher BMI will not be a waste of an organ owing to the transplantation itself. The patient in the midst of a myocardial infarction is not instructed to begin an insulin regimen before a stent can be placed. Transplant candidates of higher BMI, facing jeopardy just as acute if not immediate, should not be forced to endure additional procedures (e.g., lap band, gastric bypass, etc.) or years on a waiting list because of bias in transplant center practices.

Additionally, there is an ethical issue at play in this scenario. The social contract of health requires that patients have transparency and autonomy in their dealings with the healthcare system. Price transparency has received a partition of media scrutiny lately with new federal mandates being flaunted and legally opposed by the healthcare industry. However, transparency in procedure, and the procedural justice it engenders, is critical to proper alignment of individualized patient needs and center norms. While the optimal solution to arbitrary BMI cutoffs is to have every center trained and equipped to perform RAKT procedures, it is not a reasonable resolution. Transplant centers that do not transplant patients beyond a certain BMI comfort zone should make that cutoff known publicly and refer patients outside of that threshold to a center willing to provide immediate access to the waitlist.

Detractors of expanded access in this group express trepidation at the risk of co-morbidities cutting short the useful life of a transplanted kidney. The goal of an efficient transplant system should be to *increase* access, improve equity and minimize risk. This research postulates that technology and technique are better enhancements to an open and efficient transplant system than arbitrary restrictions. Any system enrichment that gives hope to terminally ill patients, be it behavioral, technical, clinical, or technological, should be the work that transplant centers throw themselves into. Resistance to innovation in a demographic of growing transplant demand is not ethically just and impedes the balancing of the social contract of health.

This research and other current publications have established through clinical, demographic, and socioeconomic indicators that patients of higher BMI can benefit from robotic-assisted kidney transplant. Patient survival is improved through transplantation irrespective of BMI or the innovation of RAKT (Krishnan, 2015). The fact that biases, systemic restrictions and opacity in the process continue to persist in the American transplant system implies that there is something even more troubling festering below the surface of this issue hindering an evolution beyond the status quo. We postulate that is indeed the treatment of natural resources as private property, the primacy of self-interest, beliefs in the benefits of competition and the necessity of economic growth maintaining the current state of transplant.

The transplant system is a microcosm of the healthcare system in America. Providers project a belief that the patient is at their disposal and all treatment decisions should benefit the system if not themselves. To that point, decisions made around who will and will not get a transplant must be made through the lens of risk aversion to protect personal clinical reputation (i.e., outcomes metrics), malpractice expense, and other items of self-interest. The opacity of the system ensures that competition is had based on marketing, referral relationships and insurance steerage rather than informed patient decision-making. Significantly, the additional cost of the robotic-assisted approach, including an equipped and devoted robotics lab, training of staff and providers, and additional supplies per procedure, is acknowledged. Yet the disenfranchisement of patients, in part due to the financial margins of a life-affirming procedure, stands starkly against the moral underpinnings of the healthcare practiced by women religious in the early days of the United States.

The case for marginalization of Americans in the social contract of health has been presented at macro, meso, and micro level. The evolution of market dynamics driving the American healthcare system have served to replace the social contract of health with financial agreements, though the tax benefits bolstering the retained earnings of nonprofit health organizations remain generous. Provider lobbying efforts locally and nationally have served to mold or even cull legislation for the benefit of the system rather than society. While the health of the population continues to lag behind other OECD countries spending less per capita on healthcare, the American system continues to be perpetuated by financial incentives for diagnostic and recuperative healthcare rather than a true commitment to community health. Though degradation of the social contract of health has led to marginalization of all populations, some communities are more impacted by disenfranchisement and thus serve as illustrative examples of a failed social contract of health.

The previously presented examples of diminished service among ESRD patients, coupled with this research study, illustrate how humans are treated as sources of capital by the dialysis system and negligible players in the transplant system. Generations of capitalism, succession and unfettered industrialization of the American healthcare system has led to an atmosphere in which communities, and especially the infirmed, have been marginalized. It is the primacy of non-clinical incentives, haphazard application of waitlisting assessments, and the assumption that certain ESRD patients do not have the wherewithal to properly care for the gift of life or weather their circumstance that creates a state of marginalization for the transplant candidate.

Community Psychology as Healthcare Praxis

It was previously mentioned that community psychology as a discipline is well positioned to support leveling of the social contract of health with a burdened populations. Yet much of the literature and findings of this research suggest that the entire population engaged with and by the American healthcare system is burdened by capitalistic and oligarchical influences. This research also shows that even when everyone is under foot, some groups suffer more under the weight of marginalization due to pre-existing social and clinical conditions. In total, whole-scale change is required to help American health and healthcare outcomes match the significant investment.

In addition to self-aware social change, community psychology offers a framework for working with those marginalized by systems (Burton, 2007). The struggles with the 1960’s mental health system are analogous to healthcare system issues in 2022. Increasing access to the very healthcare organizations that have produced sub-par results, as is the intent of the Accountable Care Act, should be questioned. Continuing to invest in a provider system that skews toward prescriptions and surgery rather than effective prevention of chronic disease and treatment of non-acute conditions should be questioned. Community psychology coalesced as a science behind mental health reform and other social justice movements, suggesting by its inception that the discipline can focus rebalancing of the social contract of health on justice rather than lessening the burden of government as is the goal of most health legislation (Schumman, 2016).

Yet herein lies the paradox Rappaport contextualized in his writings. Individual patients who have ESRD have no lack of care needs and options for fulfilling them. The face cherry picking, patient dumping, involuntary disenrollment, and worse based on their behaviors, presentation, or impacts of their social determinants of health fail to meet expectations. On the other hand, when chronic renal patients resist and refute the traditional healthcare system due to marginalization at the hands of the system, they nevertheless bare the blame for not embracing the system. Change agents in healthcare must be effective in altering the public policies and procedures impacting outcomes *and* collaborative in influencing care relationships for current patients. Either approach will require a blend of social movement, redistribution of power, regulation legislation, and retraining of the provider labor force to impact the social contract of health in the near and long term.

Rappaport also spoke of empowerment as a core value of community psychology practice. He combined the principle of community research with elevating the collective knowledge of the community researched to foster social policies that allow the community to gain control over their lives (Rappaport, pg. 15). Subsequent attempts to define CP have pointed to frameworks for working with those marginalized by the social system that leads to self-aware social change with an emphasis on value-based, participatory work and the forging of alliances (Burton, 2007). Burton et al stress that CP is pragmatic and reflexive, a necessary dichotomy for dealing with the paradox that exists in the modern social contract of health.

Limitations of Research

Access to transplant can be operationalized as the ability to be waitlisted or the opportunity to be transplanted efficiently once waitlisted. Both are important to patients and deserve to be gauged in furtherance of the social contract of health. This study centered on the latter by analyzing transplantability in waitlisted patients who received a renal transplant. Researchers were unable to ascertain the impact of the robot-assisted approach on potential candidates' ability to be waitlisted, *then* carry through to transplantation in a reasonable timeframe, without a complete data set of waitlisted candidates.

The research team intended to independently identify the robot-assisted kidney transplants using charge codes. However, the CAPriCORN data set only identified 147 using the syntax in the SQL query. All identified RAKT procedures among those records occurred at UIC. This information paired with market intelligence from Dr. Benedetti and internet searches led to the assumption that UIC was the only center in Chicago performing renal transplants utilizing the robot. Consequently, the Honest Broker used the list of UIC-reported RAKT patients to segregate the two groups. All 147 CAPriCORN RAKT records were accounted for in the UIC list but self-reporting by a member of the research team is a limitation.

When evaluating survival among the two groups, survival of the kidney graft was deemed a more demonstrative expression of transplant success than death alone. The ontology of the Principal Investigator as well as literature that suggests that kidney transplant patients consider returning to dialysis (i.e., graft failure) as a worse outcome than death, supported this selection. However, the industry standard outcome for kidney transplant is 1-year patient survival. Thus, outcomes of the current research may be less comparable to established industry literature.

While all transplant programs in the study were located in the city of Chicago, each hospital is known to attract different populations based on socioeconomic and ethnicity variables. The current research does not adjust for variances at the transplant center level. Some variances in the ethnicity and socioeconomic analyses could be attributable to the natural population of the hospitals.

Directions for Future Research

As stated in the limitations, the combined CAPriCORN-UNOS study data set was rich but included only transplanted patients. To gain a holistic understanding of transplant access for renal patients of higher BMI's, future research should analyze the impact of the RAKT approach on 'waitlistability' as a partner to the current research. Further, RAKT is recognized as a surgical enhancement for patients of higher BMI. If the robotic-assisted approach minimizes pain, risk of infection and hospital stay time for the patient, subsequent research should weigh the benefits of expanding the criteria to persons of lower BMI's. Literature suggests that unpredictability of transplant outcomes is a main reason for refusing kidney transplantation (Nizic-Kos, 2013); perhaps the risk reduction inherent in RAKT could open more minds to transplant evaluation.

There are many biases at play in healthcare. Transplant candidates with high BMI were the focus of the treatment in this research but individuals assessed as poor, morally undesirable (i.e., living with substance use disorder or a mental health issue), potentially frail, or highly sensitized have all faced limited access do to transplant programs' prioritizing self-preservation over the needs of individual patients. This research could be replicated regarding each of these patient presentations to define not only the clinical efficacy of technologies, but the cumulative impact of de-stigmatization on the efficacy and equity of the American transplant system.

Transplant, though heralded for eclipsing the 40,000 surgeries mark for the first time in 2021, is only a small proportion of the millions of surgical procedures performed annually in the United States. Medical care in clinics, physician practices, emergency rooms and throughout the healthcare system provide a grand laboratory for testing and challenging the social contract of health. The most foundational aspect of the social contract of health currently at play in all of these arenas is the issue of community benefit and community building activities. Publications topical to a comparison of community benefits to tax-exemption savings – a key concept in the social contract of health – have been frequent in recent years but only partially critique the matter. Applying the tenets of community psychology and the structure of this research, comparing the effectiveness of community benefit activities to community building activities' impact on community health is a possible direction for future research. Paired with a correlation of community benefit and community building activities to public affinity, the research would be a worthwhile extended examination of the social contract of health in the 21st century.

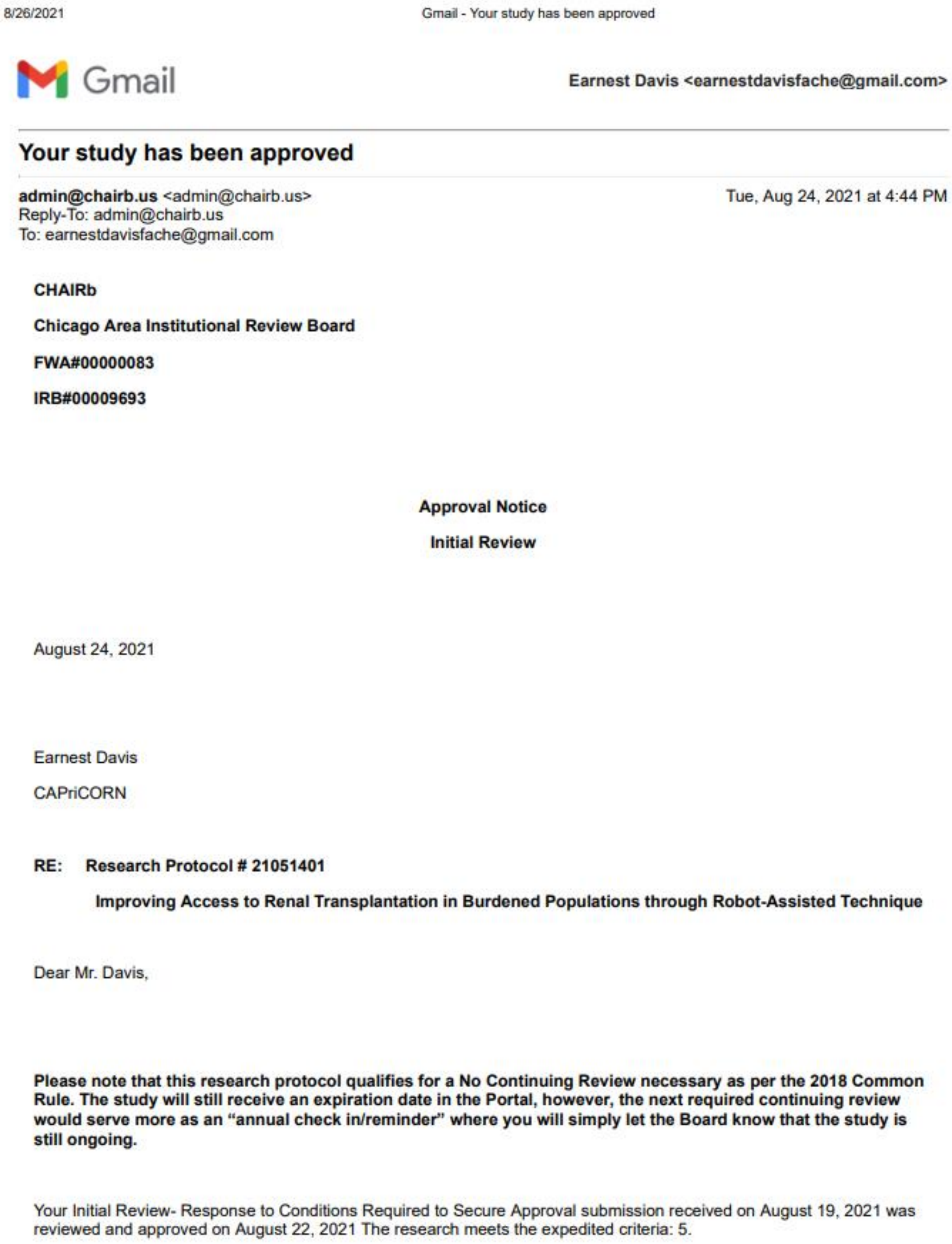
CONCLUSION

While for-profit dialysis companies received some rumination in weighing the social contract of health, the intention of this thesis has not been to prosecute them. Organizations that enter the healthcare arena and exacerbate the already imbalanced agreement certainly do not beget praise, however their motivations have been proclaimed. The presence of these players in the market dictates more action is needed on behalf of nonprofit healthcare providers and government entities with healthcare devoted charters. The marginalization of patients and systemic misincentivization that perpetuates the marginalization must be adjusted. The primacy of profit and self-interest in the healthcare industry must also be adjusted. Proliferation of robotic-assisted renal transplant is a step in the right direction for many ESRD patients and their loved ones. However, if the healthcare system continues to abdicate its liability in the social contract, communities must embrace their sovereign authority to facilitate second order change.

As a patient, I have experienced marginalization within the health delivery industry. Yet as a healthcare executive I have practiced and witnessed many others similarly embrace sound business principles with the intent of supporting the patient experience. This paradox is engrained in the healthcare industry and parcel to my reflexivity. The current research applies a critical lens to the healthcare field but advocates for change with communities and within the structure of the existing healthcare system. The core principles and values of community psychology positions the discipline as a capable partner for marginalized people intent on retaking their influence in the social contract of health through collaboration, advocacy, empowerment, and legislative action.

APPENDIX A:

CHAIRb APPROVAL LETTER



8/26/2021 Gmail - Your study has been approved

Gmail **Earnest Davis <earnestdavisfache@gmail.com>**

Your study has been approved

admin@chairb.us <admin@chairb.us> Tue, Aug 24, 2021 at 4:44 PM
Reply-To: admin@chairb.us
To: earnestdavisfache@gmail.com

CHAIRb

Chicago Area Institutional Review Board

FWA#00000083

IRB#00009693

Approval Notice

Initial Review

August 24, 2021

Earnest Davis

CAPriCORN

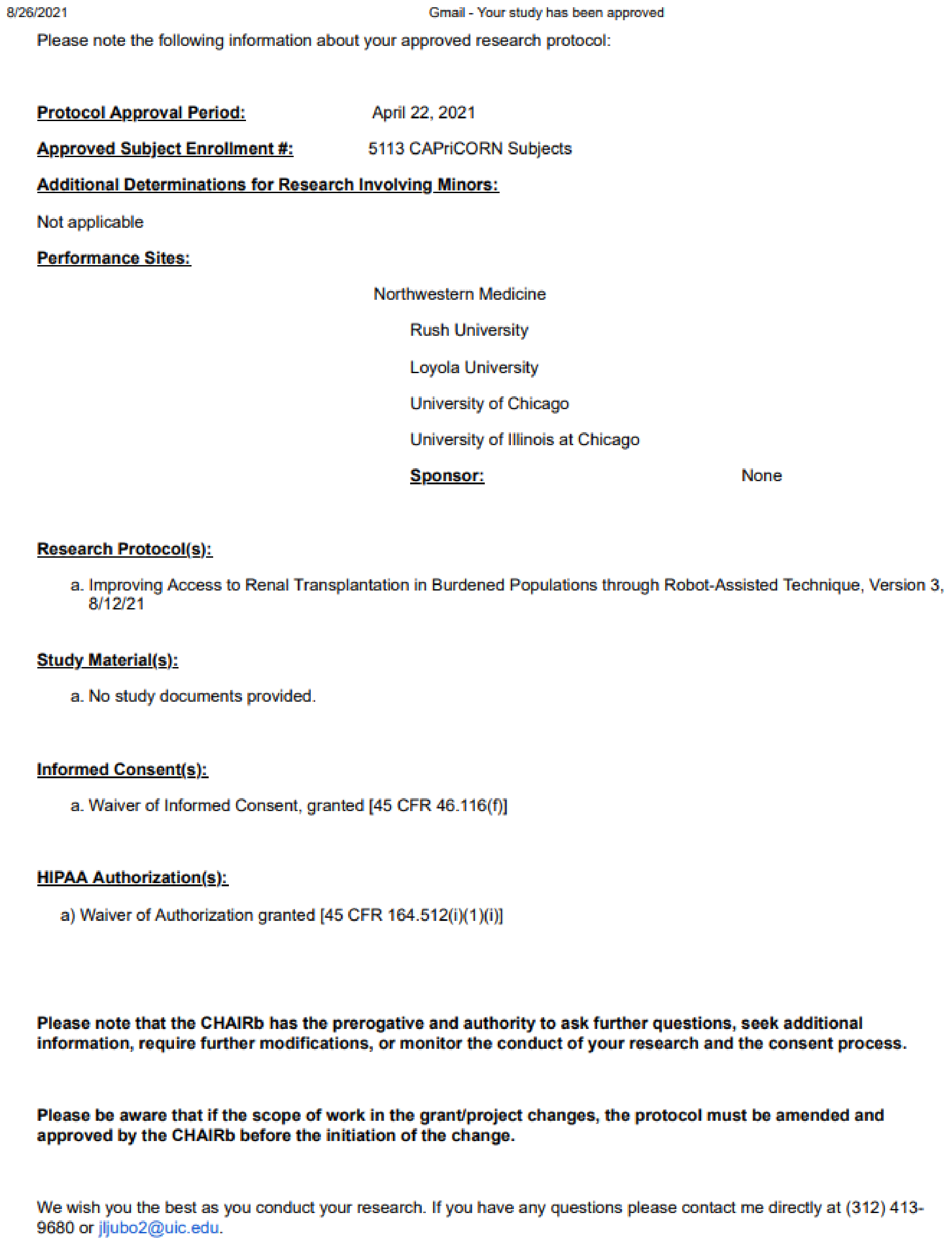
RE: Research Protocol # 21051401

Improving Access to Renal Transplantation in Burdened Populations through Robot-Assisted Technique

Dear Mr. Davis,

Please note that this research protocol qualifies for a No Continuing Review necessary as per the 2018 Common Rule. The study will still receive an expiration date in the Portal, however, the next required continuing review would serve more as an "annual check in/reminder" where you will simply let the Board know that the study is still ongoing.

Your Initial Review- Response to Conditions Required to Secure Approval submission received on August 19, 2021 was reviewed and approved on August 22, 2021 The research meets the expedited criteria: 5.



Please note the following information about your approved research protocol:

Protocol Approval Period: April 22, 2021

Approved Subject Enrollment #: 5113 CAPriCORN Subjects

Additional Determinations for Research Involving Minors:

Not applicable

Performance Sites:

Northwestern Medicine
Rush University
Loyola University
University of Chicago
University of Illinois at Chicago

Sponsor: None

Research Protocol(s):

a. Improving Access to Renal Transplantation in Burdened Populations through Robot-Assisted Technique, Version 3, 8/12/21

Study Material(s):

a. No study documents provided.

Informed Consent(s):

a. Waiver of Informed Consent, granted [45 CFR 46.116(f)]

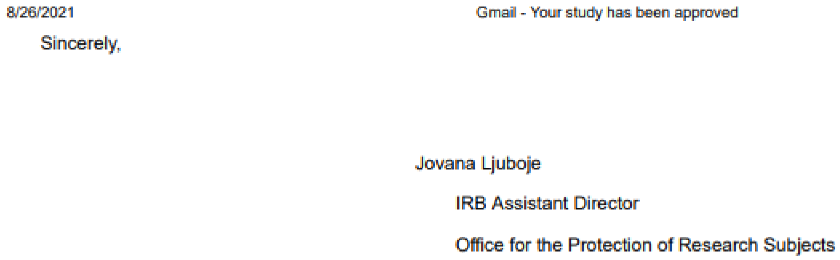
HIPAA Authorization(s):

a) Waiver of Authorization granted [45 CFR 164.512(i)(1)(i)]

Please note that the CHAIRb has the prerogative and authority to ask further questions, seek additional information, require further modifications, or monitor the conduct of your research and the consent process.

Please be aware that if the scope of work in the grant/project changes, the protocol must be amended and approved by the CHAIRb before the initiation of the change.

We wish you the best as you conduct your research. If you have any questions please contact me directly at (312) 413-9680 or jljubo2@uic.edu.



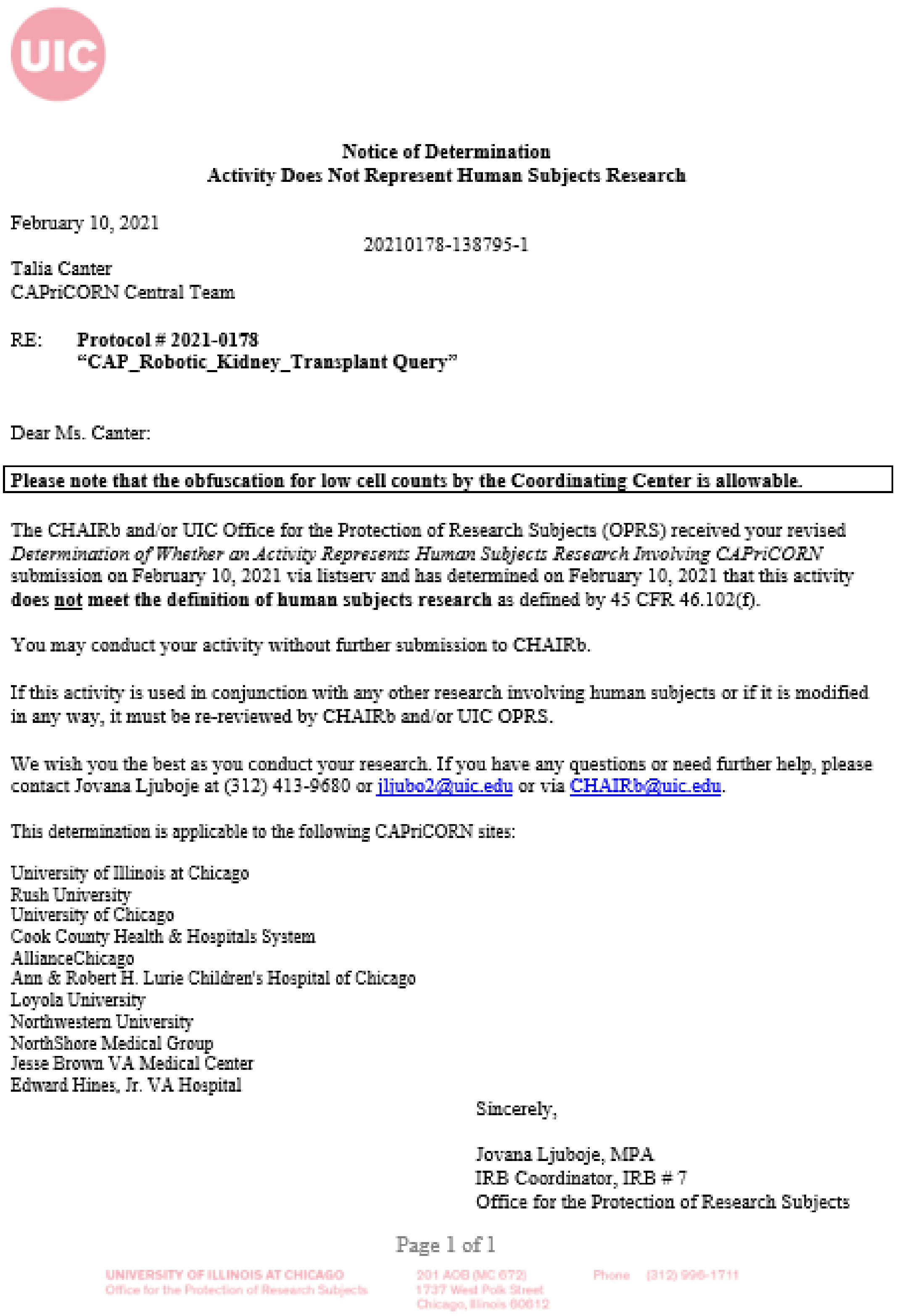
8/26/2021 Gmail - Your study has been approved

Sincerely,

Jovana Ljuboje

IRB Assistant Director

Office for the Protection of Research Subjects



Notice of Determination
Activity Does Not Represent Human Subjects Research

February 10, 2021

20210178-138795-1

Talia Canter
CAPriCORN Central Team

RE: **Protocol # 2021-0178**
"CAP_Robotic_Kidney_Transplant Query"

Dear Ms. Canter:

Please note that the obfuscation for low cell counts by the Coordinating Center is allowable.

The CHAIRb and/or UIC Office for the Protection of Research Subjects (OPRS) received your revised *Determination of Whether an Activity Represents Human Subjects Research Involving CAPriCORN* submission on February 10, 2021 via listserv and has determined on February 10, 2021 that this activity **does not meet the definition of human subjects research** as defined by 45 CFR 46.102(f).

You may conduct your activity without further submission to CHAIRb.

If this activity is used in conjunction with any other research involving human subjects or if it is modified in any way, it must be re-reviewed by CHAIRb and/or UIC OPRS.

We wish you the best as you conduct your research. If you have any questions or need further help, please contact Jovana Ljuboje at (312) 413-9680 or jljubo2@uic.edu or via CHAIRb@uic.edu.

This determination is applicable to the following CAPriCORN sites:

University of Illinois at Chicago
Rush University
University of Chicago
Cook County Health & Hospitals System
AllianceChicago
Ann & Robert H. Lurie Children's Hospital of Chicago
Loyola University
Northwestern University
NorthShore Medical Group
Jesse Brown VA Medical Center
Edward Hines, Jr. VA Hospital

Sincerely,

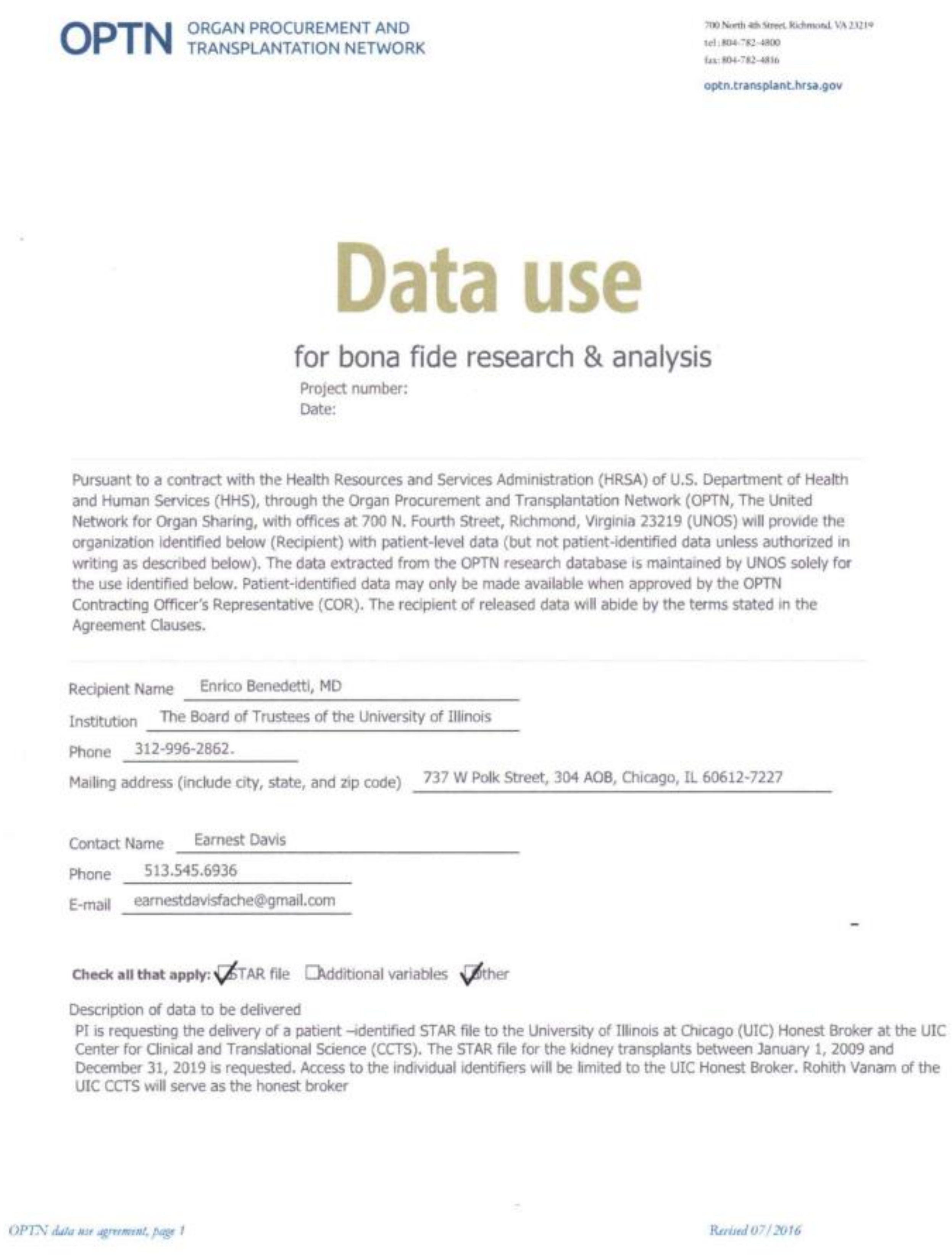
Jovana Ljuboje, MPA
IRB Coordinator, IRB # 7
Office for the Protection of Research Subjects

Page 1 of 1

UNIVERSITY OF ILLINOIS AT CHICAGO
Office for the Protection of Research Subjects
201 AOB (MC 672)
1737 West Polk Street
Chicago, Illinois 60612
Phone (312) 996-1711

APPENDIX B:

DATA USE AGREEMENT



OPTN ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

700 North 4th Street, Richmond, VA 23219
tel : 804-782-4800
fax: 804-782-4816

optn.transplant.hrsa.gov

Data use

for bona fide research & analysis

Project number:
Date:

Pursuant to a contract with the Health Resources and Services Administration (HRSA) of U.S. Department of Health and Human Services (HHS), through the Organ Procurement and Transplantation Network (OPTN, The United Network for Organ Sharing, with offices at 700 N. Fourth Street, Richmond, Virginia 23219 (UNOS) will provide the organization identified below (Recipient) with patient-level data (but not patient-identified data unless authorized in writing as described below). The data extracted from the OPTN research database is maintained by UNOS solely for the use identified below. Patient-identified data may only be made available when approved by the OPTN Contracting Officer's Representative (COR). The recipient of released data will abide by the terms stated in the Agreement Clauses.

Recipient Name Enrico Benedetti, MD
Institution The Board of Trustees of the University of Illinois
Phone 312-996-2862.
Mailing address (include city, state, and zip code) 737 W Polk Street, 304 AOB, Chicago, IL 60612-7227

Contact Name Earnest Davis
Phone 513.545.6936
E-mail earnestdavisfache@gmail.com

Check all that apply: ☑STAR file ☐Additional variables ☑Other

Description of data to be delivered

PI is requesting the delivery of a patient –identified STAR file to the University of Illinois at Chicago (UIC) Honest Broker at the UIC Center for Clinical and Translational Science (CCTS). The STAR file for the kidney transplants between January 1, 2009 and December 31, 2019 is requested. Access to the individual identifiers will be limited to the UIC Honest Broker. Rohith Vanam of the UIC CCTS will serve as the honest broker

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fax: 804-782-4816

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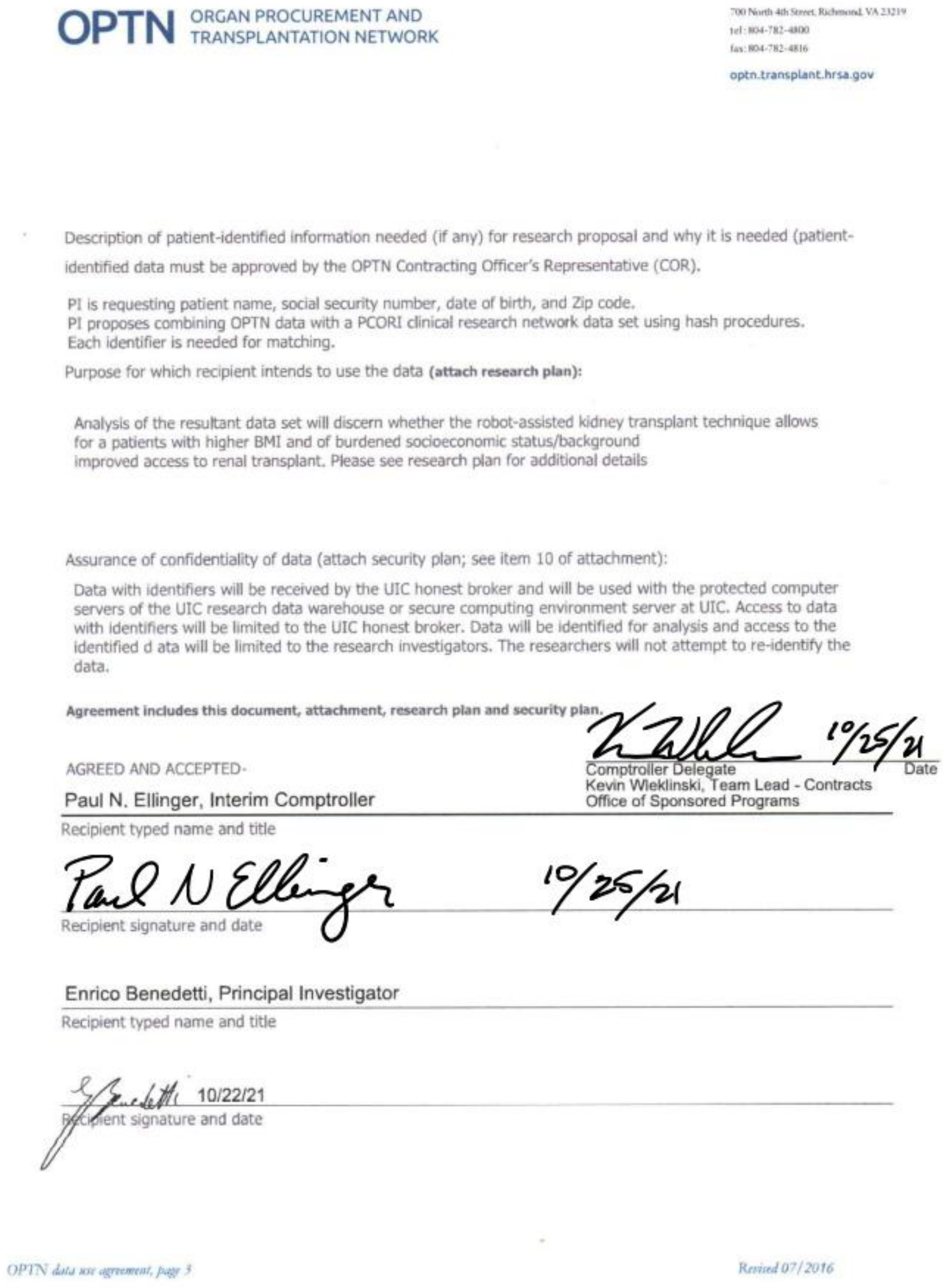
Date of Delivery 10.1.21 Format Box.com File



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Description of patient-identified information needed (if any) for research proposal and why it is needed (patient-identified data must be approved by the OPTN Contracting Officer's Representative (COR).

PI is requesting patient name, social security number, date of birth, and Zip code.
PI proposes combining OPTN data with a PCORI clinical research network data set using hash procedures.
Each identifier is needed for matching.

Purpose for which recipient intends to use the data **(attach research plan):**

Analysis of the resultant data set will discern whether the robot-assisted kidney transplant technique allows for a patients with higher BMI and of burdened socioeconomic status/background improved access to renal transplant. Please see research plan for additional details

Assurance of confidentiality of data (attach security plan; see item 10 of attachment):

Data with identifiers will be received by the UIC honest broker and will be used with the protected computer servers of the UIC research data warehouse or secure computing environment server at UIC. Access to data with identifiers will be limited to the UIC honest broker. Data will be identified for analysis and access to the identified d ata will be limited to the research investigators. The researchers will not attempt to re-identify the data.

Agreement includes this document, attachment, research plan and security plan.

10/25/21

Comptroller Delegate — Date
Kevin Wieklinski, Team Lead - Contracts
Office of Sponsored Programs

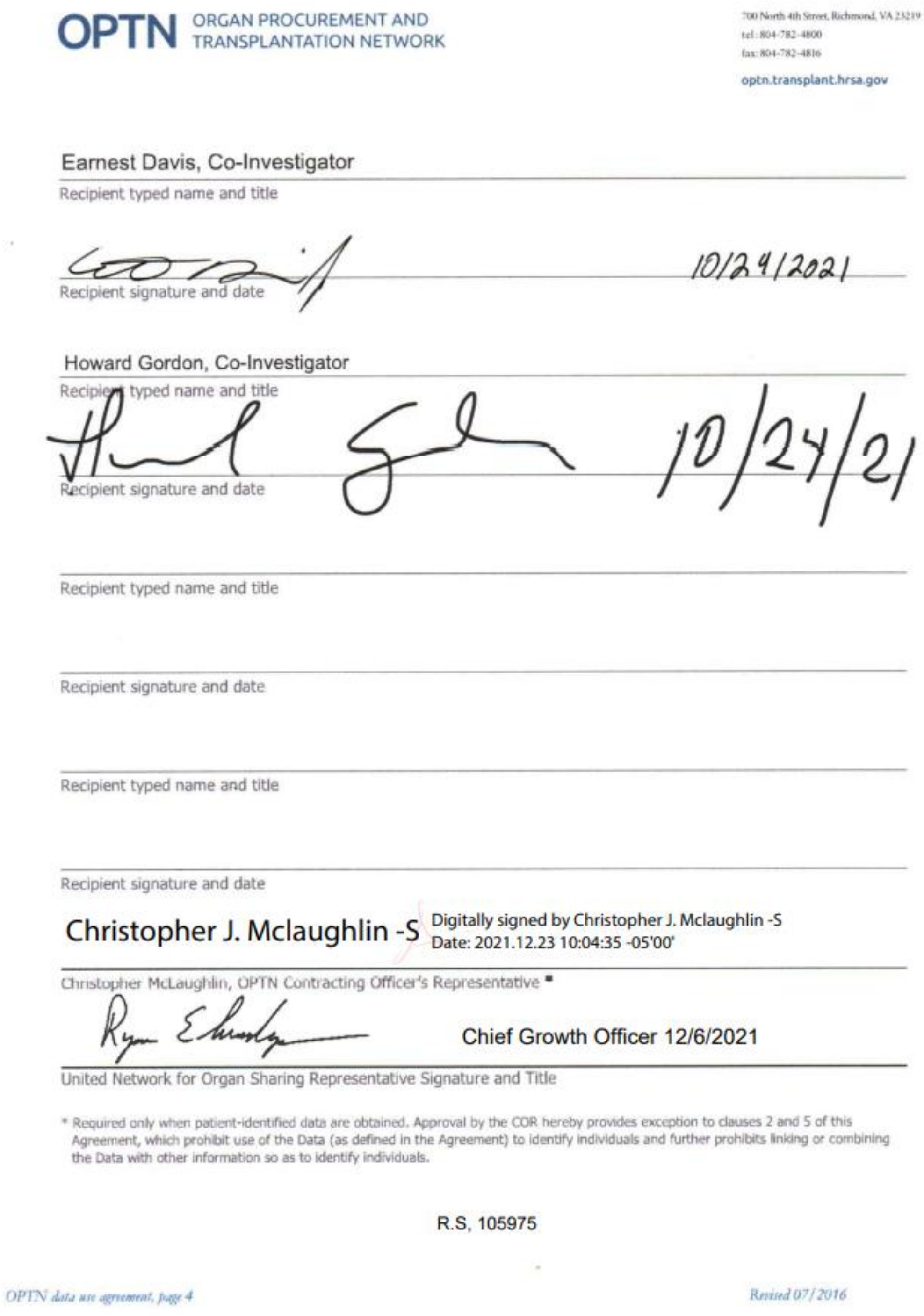
AGREED AND ACCEPTED-

Paul N. Ellinger, Interim Comptroller
Recipient typed name and title

Paul N Ellinger 10/25/21
Recipient signature and date

Enrico Benedetti, Principal Investigator
Recipient typed name and title

Benedetti 10/22/21
Recipient signature and date



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Earnest Davis, Co-Investigator

Recipient typed name and title

10/24/2021

Recipient signature and date

Howard Gordon, Co-Investigator

Recipient typed name and title

10/24/21

Recipient signature and date

Recipient typed name and title

Recipient signature and date

Recipient typed name and title

Recipient signature and date

Christopher J. Mclaughlin -S Digitally signed by Christopher J. Mclaughlin -S
Date: 2021.12.23 10:04:35 -05'00'

Christopher McLaughlin, OPTN Contracting Officer's Representative *

Chief Growth Officer 12/6/2021

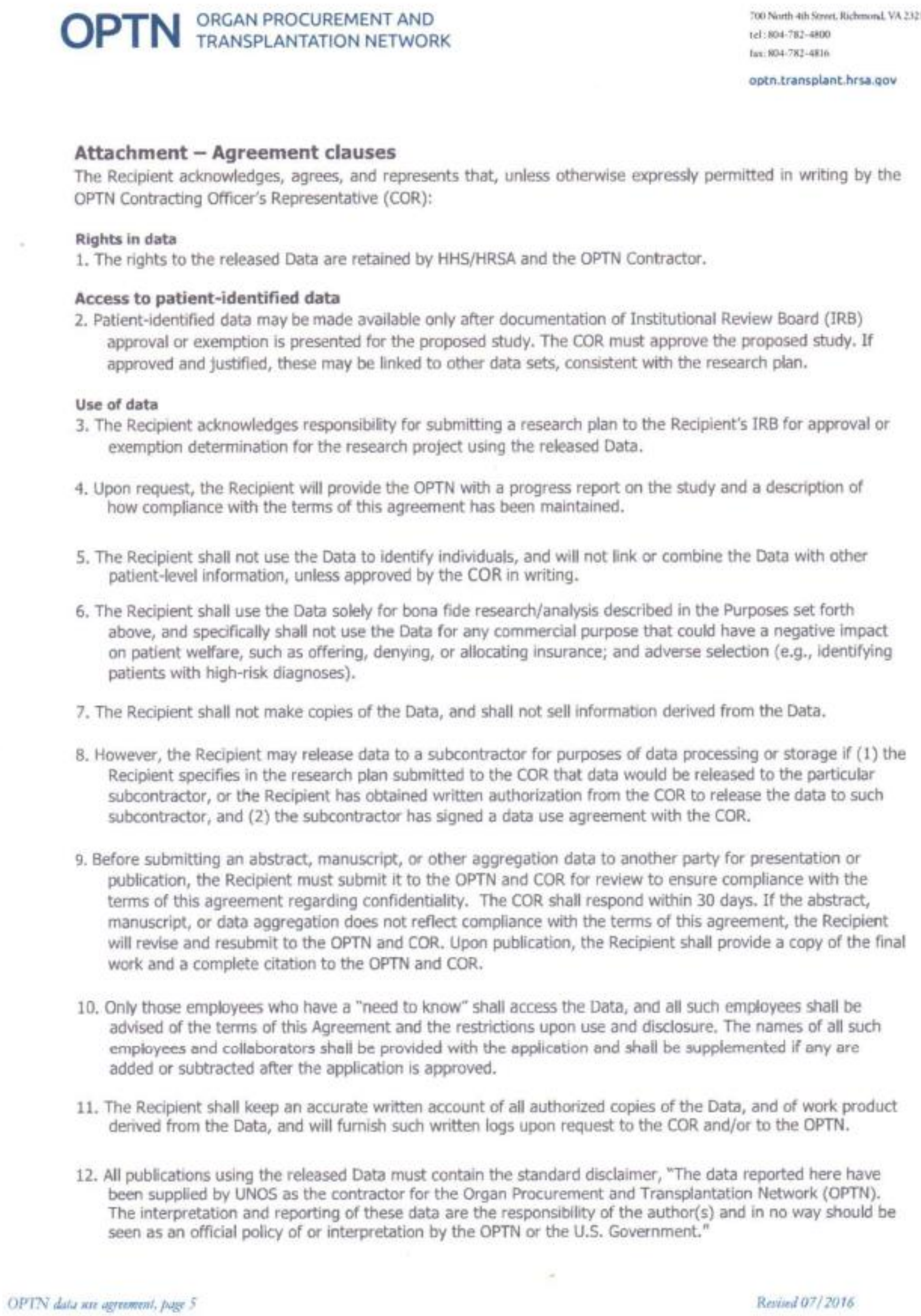
United Network for Organ Sharing Representative Signature and Title

* Required only when patient-identified data are obtained. Approval by the COR hereby provides exception to clauses 2 and 5 of this Agreement, which prohibit use of the Data (as defined in the Agreement) to identify individuals and further prohibits linking or combining the Data with other information so as to identify individuals.

R.S, 105975

OPTN data use agreement, page 4

Revised 07/2016



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Attachment – Agreement clauses

The Recipient acknowledges, agrees, and represents that, unless otherwise expressly permitted in writing by the OPTN Contracting Officer's Representative (COR):

Rights in data

1. The rights to the released Data are retained by HHS/HRSA and the OPTN Contractor.

Access to patient-identified data

2. Patient-identified data may be made available only after documentation of Institutional Review Board (IRB) approval or exemption is presented for the proposed study. The COR must approve the proposed study. If approved and justified, these may be linked to other data sets, consistent with the research plan.

Use of data

3. The Recipient acknowledges responsibility for submitting a research plan to the Recipient's IRB for approval or exemption determination for the research project using the released Data.

4. Upon request, the Recipient will provide the OPTN with a progress report on the study and a description of how compliance with the terms of this agreement has been maintained.

5. The Recipient shall not use the Data to identify individuals, and will not link or combine the Data with other patient-level information, unless approved by the COR in writing.

6. The Recipient shall use the Data solely for bona fide research/analysis described in the Purposes set forth above, and specifically shall not use the Data for any commercial purpose that could have a negative impact on patient welfare, such as offering, denying, or allocating insurance; and adverse selection (e.g., identifying patients with high-risk diagnoses).

7. The Recipient shall not make copies of the Data, and shall not sell information derived from the Data.

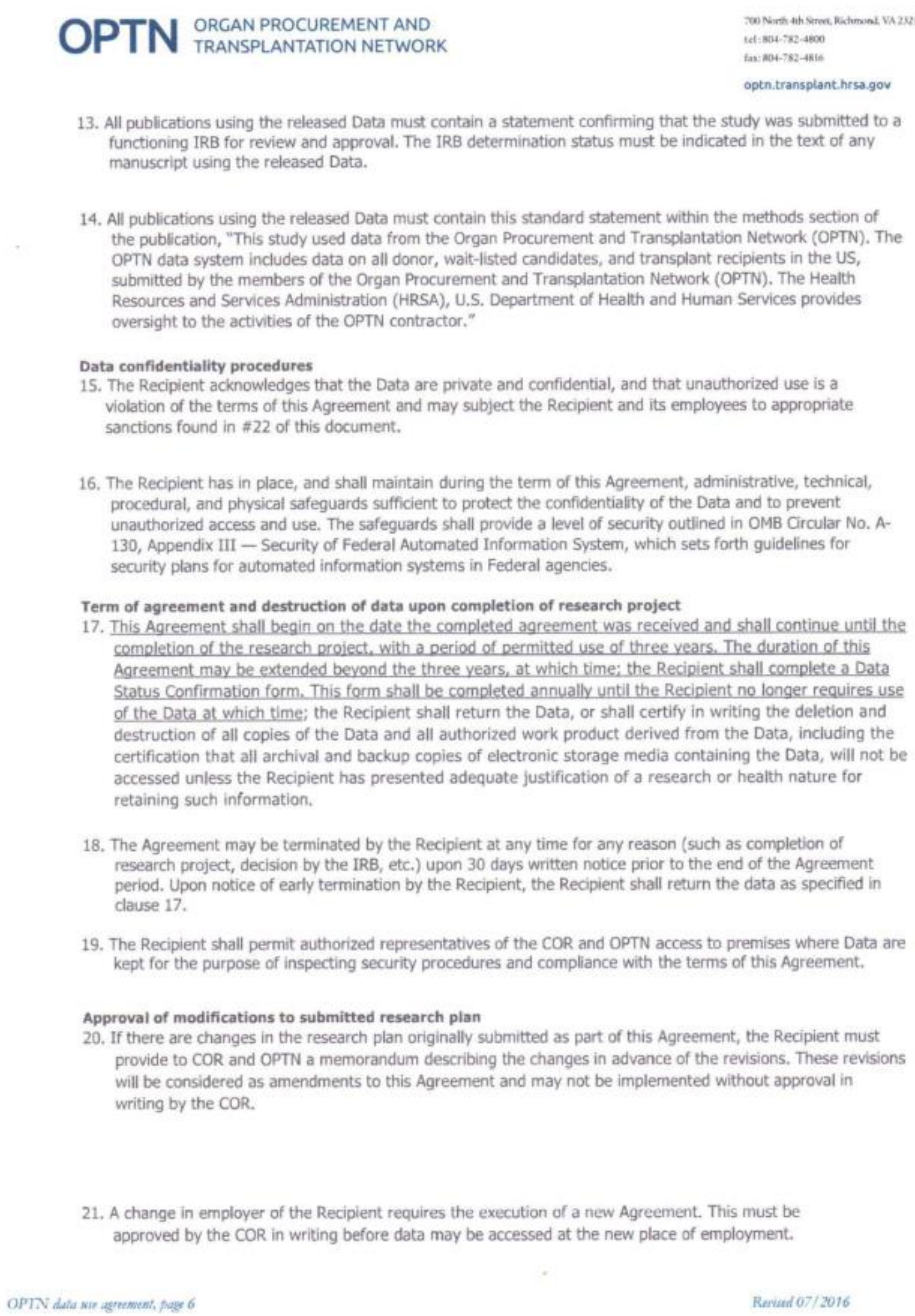
8. However, the Recipient may release data to a subcontractor for purposes of data processing or storage if (1) the Recipient specifies in the research plan submitted to the COR that data would be released to the particular subcontractor, or the Recipient has obtained written authorization from the COR to release the data to such subcontractor, and (2) the subcontractor has signed a data use agreement with the COR.

9. Before submitting an abstract, manuscript, or other aggregation data to another party for presentation or publication, the Recipient must submit it to the OPTN and COR for review to ensure compliance with the terms of this agreement regarding confidentiality. The COR shall respond within 30 days. If the abstract, manuscript, or data aggregation does not reflect compliance with the terms of this agreement, the Recipient will revise and resubmit to the OPTN and COR. Upon publication, the Recipient shall provide a copy of the final work and a complete citation to the OPTN and COR.

10. Only those employees who have a "need to know" shall access the Data, and all such employees shall be advised of the terms of this Agreement and the restrictions upon use and disclosure. The names of all such employees and collaborators shall be provided with the application and shall be supplemented if any are added or subtracted after the application is approved.

11. The Recipient shall keep an accurate written account of all authorized copies of the Data, and of work product derived from the Data, and will furnish such written logs upon request to the COR and/or to the OPTN.

12. All publications using the released Data must contain the standard disclaimer, "The data reported here have been supplied by UNOS as the contractor for the Organ Procurement and Transplantation Network (OPTN). The interpretation and reporting of these data are the responsibility of the author(s) and in no way should be seen as an official policy of or interpretation by the OPTN or the U.S. Government."



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13. All publications using the released Data must contain a statement confirming that the study was submitted to a functioning IRB for review and approval. The IRB determination status must be indicated in the text of any manuscript using the released Data.

14. All publications using the released Data must contain this standard statement within the methods section of the publication, "This study used data from the Organ Procurement and Transplantation Network (OPTN). The OPTN data system includes data on all donor, wait-listed candidates, and transplant recipients in the US, submitted by the members of the Organ Procurement and Transplantation Network (OPTN). The Health Resources and Services Administration (HRSA), U.S. Department of Health and Human Services provides oversight to the activities of the OPTN contractor."

Data confidentiality procedures

15. The Recipient acknowledges that the Data are private and confidential, and that unauthorized use is a violation of the terms of this Agreement and may subject the Recipient and its employees to appropriate sanctions found in #22 of this document.

16. The Recipient has in place, and shall maintain during the term of this Agreement, administrative, technical, procedural, and physical safeguards sufficient to protect the confidentiality of the Data and to prevent unauthorized access and use. The safeguards shall provide a level of security outlined in OMB Circular No. A-130, Appendix III — Security of Federal Automated Information System, which sets forth guidelines for security plans for automated information systems in Federal agencies.

Term of agreement and destruction of data upon completion of research project

17. This Agreement shall begin on the date the completed agreement was received and shall continue until the completion of the research project, with a period of permitted use of three years. The duration of this Agreement may be extended beyond the three years, at which time; the Recipient shall complete a Data Status Confirmation form. This form shall be completed annually until the Recipient no longer requires use of the Data at which time; the Recipient shall return the Data, or shall certify in writing the deletion and destruction of all copies of the Data and all authorized work product derived from the Data, including the certification that all archival and backup copies of electronic storage media containing the Data, will not be accessed unless the Recipient has presented adequate justification of a research or health nature for retaining such information.

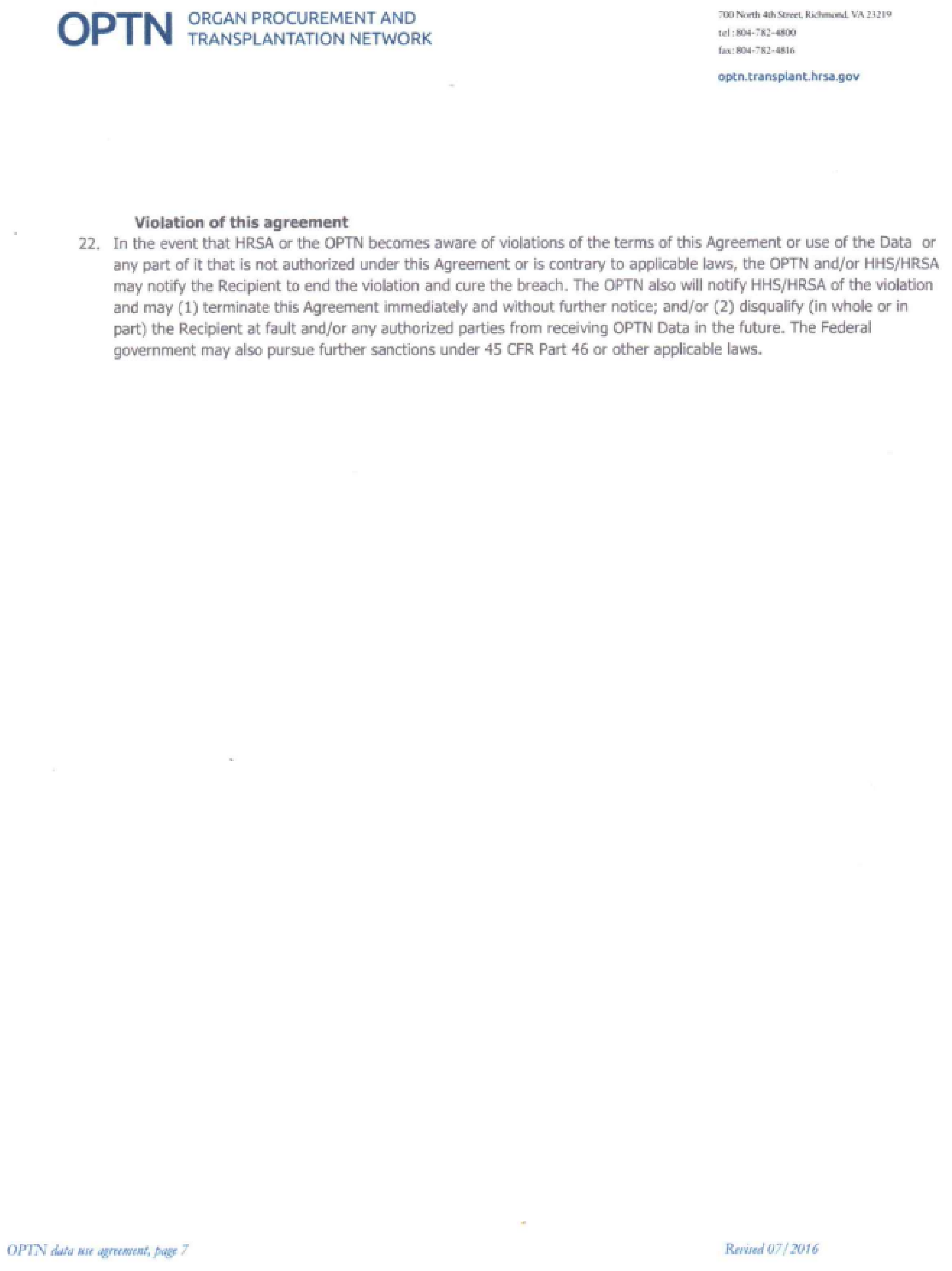
18. The Agreement may be terminated by the Recipient at any time for any reason (such as completion of research project, decision by the IRB, etc.) upon 30 days written notice prior to the end of the Agreement period. Upon notice of early termination by the Recipient, the Recipient shall return the data as specified in clause 17.

19. The Recipient shall permit authorized representatives of the COR and OPTN access to premises where Data are kept for the purpose of inspecting security procedures and compliance with the terms of this Agreement.

Approval of modifications to submitted research plan

20. If there are changes in the research plan originally submitted as part of this Agreement, the Recipient must provide to COR and OPTN a memorandum describing the changes in advance of the revisions. These revisions will be considered as amendments to this Agreement and may not be implemented without approval in writing by the COR.

21. A change in employer of the Recipient requires the execution of a new Agreement. This must be approved by the COR in writing before data may be accessed at the new place of employment.



Violation of this agreement

22. In the event that HRSA or the OPTN becomes aware of violations of the terms of this Agreement or use of the Data or any part of it that is not authorized under this Agreement or is contrary to applicable laws, the OPTN and/or HHS/HRSA may notify the Recipient to end the violation and cure the breach. The OPTN also will notify HHS/HRSA of the violation and may (1) terminate this Agreement immediately and without further notice; and/or (2) disqualify (in whole or in part) the Recipient at fault and/or any authorized parties from receiving OPTN Data in the future. The Federal government may also pursue further sanctions under 45 CFR Part 46 or other applicable laws.

APPENDIX C:

DETAILED ACCOUNT OF STUDY PROTOCOL

1. CCTS Honest Broker receives UNOS data.
2. CCTS Honest Broker Creates 2 data files:
    a. [UNOS_TOKEN.csv] Using PPRL software (Datavant), create a list of tokens using PHI in UNOS data mapped to serial ids (e.g., 0001, 0002, 0003, etc.)
    b. [UNOS_DATA.csv] Generate extract of UNOS data consisting of the following variables with the UNOSID replaced with the serial id.
3. CCTS (Honest Broker) provides research team with the [UNOS_DATA.csv] file.
4. CCTS Honest Broker provides MRAIA with the [UNOS_TOKEN.csv] file.
5. MRAIA asks each site to send CAP_ID, tokens file for all patients between 1/1/09 to 12/31/18.
6. MRAIA matches the UNOS hashes with the site hashes.
7. MRAIA sends CAPIDs from Step 5 back to sites, requesting the query be run on those patients only. Sites will only be sent their site CAPIDs.
8. Sites submit requested data for CAPIDs to MRAIA.
9. MRAIA removes all site identifiers and replaces the CAPIDs with the serial ids from the UNOS_TOKEN.csv file.
10. MRAIA sends CAPriCORN data to research team.
11. CCTS (Honest Broker) identifies RAKT patients in the data set via billing codes and transplant center records.

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