Application of Telehealth to Overcome Geographic Disparities in Liver Transplantation Within the Veterans Health Administration

HoChong Smith Ferguson, MS, RN, FNP-C

Midlothian, Virginia

Bachelor of Science in Nursing, Virginia Commonwealth University, 2007

Master of Science in Nursing, Virginia Commonwealth University, 2009

A Scholarly Practice Project presented to the Graduate Faculty of the University of Virginia in Candidacy for the Degree of Doctor of Nursing Practice

School of Nursing

University of Virginia

May, 2018

Kathryn Reid, PhD, RN, FNP-C, CNL

Patty Schweikert, DNP, APRN-BC

Michael Fuchs, MD, PhD

Abstract

Many centers within the Veterans Health Administration have limited access to hepatology and transplant specialists. Liver transplantation is centralized and performed at six approved VA transplant centers (VATC). Geographic disparities are associated with lower access to transplantation, decreased placement onto the national waitlist and poorer survival in Veterans residing over a hundred miles from a VATC. The aim of this study was to evaluate if telehealth (TH) can reduce the timeframe of performing liver transplant evaluations compared to usual care (UC) in Veterans referred for liver transplantation across vast geographic distances. A retrospective, descriptive, comparative analysis of electronic medical records of approximately 200 Veterans was conducted to evaluate for differences in time from referral to a listing decision using TH versus UC visits in Veterans referred for liver transplant consideration to a VATC from 10/01/2011- 9/30/2016. A total sample size (n=140) included 102 subjects in the TH group and 38 subjects in the UC group. The mean time from referral to initial evaluation in the TH group was 22 days (SD=7.0) and 23.4 days (SD=15.3) in the UC group. Mean time from referral to listing decision was 108 days (SD=55.8) in the TH group and 90 days (SD=94.6) in the UC group. The independent samples *t*-test revealed no significant differences in the mean times were detected at these specific time intervals conducted by TH or UC visits. Preliminary findings suggest that conducting transplant evaluations by TH were no different than UC. Telehealth has the potential to improve access to specialized transplant services, reduce travel burden for Veterans and increase the successful navigation across the complex transplant process in a timely manner, regardless of the site of care.

Keywords: Veterans, liver transplantation, telehealth, telemedicine

Acknowledgments

First, I would like to thank my most wonderful husband and family for their love, patience and support throughout my DNP program. I could not have done this without all of you. I would like to acknowledge the time and feedback offered by my capstone committee members: Dr. Kathryn Reid, Dr. Patty Schweickert and Dr. Michael Fuchs. To my advisor, Dr. Kathryn Reid, thank you for your generous time, support, encouragement and mentorship. I would like to express my sincerest appreciation and thanks to my practice mentor, Michael Fuchs, MD, PhD. Additional thanks to Dr. Jasmohan Bajaj, Dr. Binu John, Dr. Phillip Tarkington and my hepatology family at McGuire for their encouragement and support. Special thanks go to the numerous University School of Nursing faculty and staff that helped me throughout this program: Dr. Elizabeth Friberg, Dr. Regina DeGennaro, Dr. Ishan Williams, Dr. Ivy Hinton, Dr. Virginia Rovnyak, Dr. Christine Kennedy and Dr. Clareen Wienchek.

Lastly, I would like to express my deepest appreciation and thanks to my long-time mentor, Dr. Douglas Heuman. Dr. Heuman supported my education, practice and professional development for almost two decades. Foundation of the liver transplant program at McGuire is his legacy. Words can’t express how grateful I am for your guidance, mentorship and commitment to advance my career in hepatology. It has been a tremendous honor to serve our Veterans with you.

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Chronic liver disease resulting in cirrhosis is the twelfth leading cause of mortality and responsible for more than 34,000 deaths per year in the United States (Martin, DiMartini, Feng, Brown, & Fallon, 2014). Orthotopic liver transplantation is a procedure that replaces the entire liver either from a cadaveric or living donor. Liver transplant remains the primary curative treatment for decompensated cirrhosis, hepatocellular carcinoma, and acute liver failure (Martin et al., 2014). An estimated 13,000 to 15,000 are currently on the national wait list and approximately 4,000-6,000 receives a liver transplant per year (Mathur, Ashby, Fuller, Zhang, Merion, Leichtman, & Kalbfleisch, 2014). A current crisis exists due to the rising demand for liver transplantation exceeding the diminishing supply of organs. Veterans with cirrhosis are required to travel long distances to receive specialized access to transplantation services.

Section I: Introduction

Background of the Issue

The National Organ Transplant Act was passed in the United States to address shortages in organ donation and ensure equitable access to transplantation (U.S. Department of Health and Human Services, n.d.). The Organ Procurement and Transplantation Network (OPTN) strive to ensure equity and fairness; however, health disparities and barriers are well known to the transplant community and continue to impair access to liver transplantation. The United Network of Organ Sharing (UNOS) oversees the equitable allocation of organs and established a system to collect and analyze data related to national wait list trends, organ matching, and transplant outcomes (United Network of Organ Sharing, n.d.). The current liver allocation system is considered unequal due to the variability of organ availability within the 58 donor service areas (DSA), inconsistent listing practices, and organ utilization (Adler, Dong, Markmann, Schoenfeld, & Yeh, 2015a). A Federal mandate, "The Final Rule", requires that organ allocation should not be contingent on residence or location of the transplant center (Ladner & Mehrotra, 2016). Geographic disparities persist despite prioritizing organs by medical need under the current "sickest-first" allocation system (Schwartz, Schiano, Kim-Schluger, & Florman, 2014). Geographic disparities continue to affect access to transplantation despite attempts to address this issue at policy levels.

Patient factors related to social determinants of health play an increasingly important role in health access and outcomes before and after transplantation (Adler & Yeh, 2016). Individuals are influenced by members within their social environment, which include family, friends, and health care professionals (US Department of Health and Human Services, 2005). Key components of social determinants of health include economic, educational, social, health care, and environmental factors (Healthy People 2020, n.d.). Social support is necessary and required to qualify for liver transplantation. Various social barriers including poverty, racial discrimination, limited transportation, inadequate housing, and weak social network of friends and family are major barriers to transplant evaluation and listing (Flattau et al., 2011).

Social determinates of health such as low socioeconomic status (SES), decreased educational level, and inadequate social support adversely influence individuals' candidacy and are associated with increased mortality and poor health outcomes (Quillin et al., 2014). Environmental factors including geographic inaccessibility limit access and interactions with specialty providers, which contribute to poor health literacy resulting in decreased transplant opportunities. Poor health literacy has also been associated with nonadherence, graft failure, and poor outcomes after liver transplant (Adler & Yeh, 2016). Patients with adequate financial means can travel to different DSAs to improve their chances for liver transplantation. This clearly disadvantages patients within a lower socioeconomic status. A common perception that organ allocation is discriminatory limits organ donation rates in the U.S. (Yeh, Smoot, Schoenfeld, & Markmann, 2011).

Challenges within the Veterans Health Administration

The Veterans Health Administration (VHA) is the largest integrated health care system in the United States, and includes 153 medical centers and 1,400 community-based outpatient clinics and serves more than eight million Veterans yearly (U.S. Department of Veterans Affairs, n.d.). Centralization of specialized services is used by the VHA to increase efficiency, consolidate expertise, and minimize costs (Goldberg, French, Forde, Groeneveld, Bittermann, Backus, & Kaplan, 2014). Veterans needing a liver transplant are offered specialized hepatology and transplant services from one of the six transplant centers within the entire VHA. Veterans without other forms of secondary insurance are constrained to obtaining transplant care within one of these designated centers (Goldberg et al., 2014).

Expanding the geographic distances between individuals and facilities is an unintended consequence of centralizing specialized services. Veterans residing more than a hundred miles from a VA transplant center (VATC) were found to have decreased chance of waitlist placement, lower likelihood of transplant, and increased mortality (Goldberg et al., 2014). The Office of Inspection General (2015) conducted an inspection of another VATC due to allegations of inefficient processes and delays in care of Veterans referred for liver transplantation. Accusations of significant delays in primary health care services have additionally intensified debates and distrust beyond specialty care access to organ transplantation. The VHA reaffirmed its commitment to improving health care access. This included conceptualization of innovative models of health care delivery, including telehealth technology to provide Veterans health services within an appropriate timeframe (Kehle, Greer, Rutks, & Wilt, 2011).

Patients needing a transplant require successful navigation across a complicated system to fortunately undergo a liver transplant (Mathur, Sonnenday, & Merion, 2009). Steps include appropriate referral to a transplant center, comprehensive medical and surgical evaluation of suitability for transplantation, national waitlist registration, and survival until a donor liver becomes available (Mathur et al., 2014). Many centers within the VHA lack or have limited access to hepatology specialists. A single center VHA study revealed low referral rates in Veterans who otherwise met the American Association for the Study of Liver Diseases (AASLD) guidelines for liver transplant referral (Julapalli, Kramer, El-Serag, & American Association for the Study of Liver Diseases, 2005). Waitlist practices vary among transplant centers and transplant access remains elusive since many patients are never placed onto the national waitlist.

The VHA's National Surgery Office Director responded to findings of inequalities related to centralization of specialized services. The director stated that decreased transplant access exist across the nation, especially in rural areas and were not limited to the veteran population. Geographic disparities and mortality were similarly observed in nonveteran populations and patients listed at non-VATCs. Increasing the number of VATCs would not necessarily eliminate all issues surrounding distance. The VHA minimizes barriers caused by large distances to VATCs by offering travel and lodging benefits to Veterans and their caregivers. Goldberg and colleagues (2014) recommend the VHA leadership should explore alternatives to pay for transplant services locally through VA purchased care. This would require regulatory changes and significant amount of funding allocation from Congress. In the meantime, the VHA improved the transplant referral tracking system and expanded telehealth capabilities across the largest integrated health network to overcome the travel burden of Veterans needing transplantation.

Telehealth Clinical Application in Transplantation

New innovative approaches are needed to overcome current geographic disparities limiting transplant access and improve delays in care. Telehealth technology has rapidly transformed how providers connect with their patients in the delivery of health care. There is growing evidence describing the benefits of telehealth on healthcare access, quality, and costs (Bashshur et al., 2014). Telehealth is defined as sharing of information to provide various clinical, educational and administrative services using telecommunications and information technologies (IT) at a distance (Darkins, 2014). Strategies adopting health communication and IT are gaining momentum as a model of health care delivery beyond the traditional usual care visits. The application of telemedicine is currently used in numerous clinical settings to care for patients with various chronic health conditions (Bashshur et al., 2014a). The interactive use of this technology would allow the exchange of clinical data required to meet the rising demand of complexities associated with managing chronic disease conditions, including advanced liver disease.

The Richmond VA liver transplant program revitalized its use of telehealth to conduct initial triage of transplant referrals, counseling, and comprehensive evaluations to facilitate successful navigation through the complex, multi-tiered transplantation process. However, the program has yet to fully integrate the use of telehealth in all pre-transplant evaluations, waitlist monitoring and in the post-transplant setting. Use of telemedicine services could serve as a potential strategy to improve timely health access to specialized hepatology care and provide transplant expertise regardless of patient location and VHA site of care. The usefulness of telehealth to increase placement onto the national waitlist, survival and positive health outcomes in this Veteran population with advanced liver disease requires further exploration.

Purpose of Project

The aim of this project is to determine if the application of telehealth improves the timeframe of performing liver transplant evaluations across vast geographic distances in Veterans referred for liver transplantation.

Conceptual Framework

The theoretical foundation for this project is based upon Rogers' Diffusion of Innovations. This conceptual framework is well known for understanding the process by which a technology is or is not adopted within a population (Edberg, 2015). Rogers (1995) describes four main constructs of diffusion, which include *innovation, communication channels, time,* and *social system*. Rogers defined an *innovation* as "an idea, practice or object that is perceived as new by an individual or other unit of adoption" (1995, p.11). "*Diffusion* is the process by which an innovation is communicated through certain channels over time among the members of a social system" (Rogers, 1995, p. 5). The diffusion context refers to the interaction of complex factors related to the population targeted by the innovation and the dissemination may influence its adoption (Edberg, 2015). Technological innovations have increased the study and application of Rogers' Diffusion of Innovations Theory in telehealth interventions.

The VHA built a telehealth network which connects to over 1,700 hospitals and outpatient clinics and completed over 2 million telehealth encounters in 2016 (U.S. Department of Veterans Affairs, n.d.). Darkins (2014) article titled, "The Growth of Telehealth Services in the Veterans Health Administration Between 1994 and 2014: A Study in the Diffusion of

Innovation” examined the elements of diffusion and its dynamic interaction within the complex organizational environment during the development of telehealth services within the VHA over the past twenty years. The VHA initially encountered many organizational challenges and obstacles in disseminating the innovation of telehealth services. The VHA’s progressive uptake and dissemination of telehealth services address the main principles of Rogers’ diffusion of innovations in the adoption of telehealth over three distinct time periods and provided an understanding of attributes and factors influencing its adoption (Darkins, 2014). Transformational initiatives such as telehealth were later identified as representing a new model of care to combat existing issues surrounding access within the VHA (Darkins, 2014). The Diffusion of Innovation theory provides valuable insights into examining variety of concepts involved in developing and implementing telehealth programs along the continuum of virtual care.

Project Question

Does the use of telehealth reduce wait time from referral to listing decision in Veterans referred for liver transplantation compared to usual care visits at the Richmond Veterans Affairs Transplant center?

Section II: Review of the Literature

The OPTN strives to reduce existing disparities to improve organ donation and ensure the equitable distribution of scarce organs. Current geographic disparities continue to plague waitlist placement, variable organ transplant rates and decreased access to liver transplantation (Mathur et al., 2014; Rana, Riaz, Gruessner, & Gruessner, 2015). Racial and ethnic inequities have been implicated in reduced transplant referrals among minority Veterans within the VHA (Mathur et al., 2014). Low referral rates in Veterans who otherwise met criteria for transplant per national guidelines were also reported at a large VA transplant center (Julapalli et al., 2005). In a recent editorial, the VHA was repeatedly criticized for decreased rates of transplant referrals, low utilization of VA transplant centers due to long distances to obtain transplant care and delays in time to transplant listing (Pullen, 2017). Increased burden of travel among Veterans is required to overcome current disparities caused by geography resulting in limited access to specialized hepatology and transplant services across the VHA. These factors place an overwhelming burden on VATCs to explore strategies to minimize these barriers.

Telemedicine is currently used in various clinical settings. Application of telehealth technology can potentially reduce travel burden and expedite evaluation to expand access to liver transplantation across significant distances encountered by Veterans. Review of the existing evidence is required due to the lack of knowledge regarding the efficacy of health outcomes utilizing telemedicine in chronic disease management pertaining to end-stage liver disease and in pre-transplant settings. Despite the expanding body of evidence supporting the application of telehealth, there are gaps in the literature regarding the effectiveness of telemedicine and its impact on health outcomes in this target population. The review of literature will serve as the evidentiary support for this scholarly project.

Methods

A comprehensive review of the literature was conducted to assess the effectiveness of telehealth in adults with chronic health conditions as an alternative to usual care. The search was initiated by using the electronic databases CINAHL (Cumulative Index to Nursing and Allied Health Literature) and Ovid Medline from January 2007 to May 2017. Key words "telemedicine or telehealth" and "outcomes or treatment outcomes" with "chronic" were used in combination. The Cochrane Library was searched using key words "telemedicine or telehealth" and "chronic". Inclusion criteria were: 1) any study comparing telemedicine or telehealth intervention in addition to or as an alternative to usual care, and 2) any study comparing telemonitoring in addition to or as an alternative to usual care visits in adults (defined > 19 years of age) with chronic health conditions. Exclusion criteria were: 1) studies not written in English, 2) pilot or feasibility studies with very small sample sizes (n < 100), 3) studies using cognitive behavioral therapy, 4) studies employing telerehabilitation, teleradiology, or teledermatology, and 5) studies using only web-based portals or SMS texting. Only randomized controlled clinical trials (RCT) were included in this review. The ancestry was hand searched by inspecting reference lists to identify additional pertinent studies. Eleven studies meeting inclusion criteria and one Cochran systematic review were identified for the final review (see Table 1 and Figure 1).

Telehealth in Chronic Disease Management

The included studies provide analyses of the impact of telehealth in chronic disease management. There is growing evidence supporting its application in various disease conditions to address health care access, improve quality of care, and escalating costs associated with the rising prevalence of chronic diseases in the United States (Bashshur et al., 2014). The three main chronic disease conditions observed in the RCTs assessing the effectiveness of telehealth comparing to usual care (UC) were congestive failure, diabetes, and hypertension management. One RCT evaluated the impact of telemonitoring in elderly patients with multiple chronic conditions on hospitalizations and emergency department (ED) visits. There was only one study identified involving the use of telehealth in solid organ transplantation. A systematic review from the Cochrane library assessed numerous RTCs comparing telemedicine and usual care in any clinical condition but the summary of findings will be limited to the following chronic disease conditions.

Congestive Heart Failure.

Congestive heart failure (CHF) has been associated with poor survival, increased utilization of health care and escalating health care costs (Koehler et al., 2011). The authors illustrated the need for alternative strategies using telemanagement to improve health outcomes to improve compliance rates, optimization of therapy and early detection of clinical decompensation. This study examined the impact of remote telemedical management (RTM) in New York Heart Association (NYHA) functional class II or III ambulatory patients with heart failure compared to usual care. Primary outcome measure was overall mortality and the secondary endpoint was hospitalizations resulting from heart failure. There was no significant reduction in all-cause mortality or hospitalizations between the RTM and usual care groups in an ambulatory group of patients with CHF.

Blum & Gottlieb (2014) also reported findings in ambulatory patients with CHF within a community dwelling setting. The authors examined the effect of home telemonitoring (HT) on mortality, 30-day readmissions, health-related quality of life and medical costs compared to usual care over a four-year period. Subjects were recruited from an academic center and its affiliated VA Medical Center. Patients in the HT group were managed by an experienced nurse practitioner. There was no statistically significant decrease in overall mortality, health-related quality of life, and medical costs between the two groups. There was a reported difference in the 30-day readmissions in the HT group, but only within the first year.

Giordano and colleagues (2009) evaluated whether a home-based telemanagement (HBT) program decreased hospitalizations and costs compared to usual care in patients admitted with CHF. Subjects were randomized to either HBT or UC group just prior to discharge from a recent hospitalization. Subjects included had both moderate (NYHA II) and severe (NYHA III-IV) heart failure. All-cause hospital readmissions were reported to be lower in the HBT compared to the UC group. Mean costs of readmissions were also significantly lower in the HBT group. These findings suggest benefits of HBT in the reduction in all-cause readmissions and costs over a one-year period.

Another study included participants hospitalized with heart failure and enrolled prior to discharge (Ong et al., 2016). The better effectiveness after transition-heart failure (BEAT-HF) study randomized over 1,400 patients across six major academic centers to either a transition intervention using remote monitoring (RM) or usual care over a 180-day period. The primary outcome was all-cause readmissions within 180 days after discharge and secondary outcomes included: 1) all-cause readmissions within 30 days; 2) all-cause mortality at 30 days and 180 days; and 3) quality of life at 30 and 180 days. Overall, this study reported no significant differences in the primary endpoint. Additionally, there were no differences seen in the secondary end points of readmissions within 30 days and all-cause mortality within 30 days and 180 days. There were no differences reported in quality of life at 30 days, however, there was a difference seen at 180 days favoring the intervention group.

Chaudhry and colleagues (2010) also conducted a large, multi-center trial of 1653 subjects recently hospitalized for heart failure. This study examined the impact of telemonitoring (TM) in patients with heart failure compared to UC. The primary endpoint was all-cause readmissions or deaths within 180 days after study enrollment. Secondary end points consisted of hospitalization for heart failure, length of stay and number of hospitalizations. There was no significant difference seen in both the primary and secondary outcomes between these two groups.

Findings of these five RCTs revealed inconsistent findings as to the benefit of remote telemonitoring or telemedicine intervention in reduction of mortality, readmissions, costs, and quality of life in patients with chronic heart failure compared to usual care groups. These RCTs have several limitations including no blinding, Hawthorne effect, heterogeneity between trials, and concerns for generalizability due to specific target populations. Although results from these studies varied, a common theme emerged describing the need for future research to determine which specific target population or sub-populations with limited healthcare access would benefit from remote management.

Hypertension.

Self-monitoring of blood pressures (BP) is associated with improved treatment outcomes to reduce the largest risk factor for cardiovascular disease (Artinian et al., 2007). An alternative treatment strategy was explored in this study to evaluate the effects of nurse-managed telemonitoring in urban African-Americans with hypertension to improve blood pressure (BP) management over a one-year period. Participants in the intervention group received usual care plus nurse-managed TM compared to usual care only. Nurse-managed telemonitoring significantly reduced systolic blood pressure (SBP) over the study period. The article reported that the TM group also demonstrated the greatest reduction in diastolic blood pressure (DBP) between baseline and three-month follow-up period. However, the differences in DBP were not statistically significant.

Margolis and colleagues (2013) conducted a contrasting study using a different type of case management provider. This study evaluated a BP telemonitoring intervention using pharmacist case management in patients with uncontrolled hypertension compared to a usual care group. In the intervention group, BP data were transmitted to a pharmacist and if indicated, medications were adjusted. Primary outcome was the proportion of participants with controlled BP at the 6-month and 12-month visits. Secondary outcome was continued BP control at the 18-month post-intervention follow-up. Telemonitoring with pharmacist case management demonstrated statistically significant improvement in BP control. Reduction of BP from baseline compared to usual care group was sustained during the entire length of study period. Additionally, it was reported that BP control was significantly improved at the post-intervention 18-month follow-up in the telemonitoring group (Margolis et al., 2013).

Diabetes Mellitus.

The rising prevalence of diabetes and associated high costs of treatment continue to burden the healthcare system (Stone et al., 2010). The authors compared the efficacy of case management with home telemonitoring in Veterans with uncontrolled type 2 diabetes compared to usual care. Usual care in this study consisted of monthly care coordination conducted by telephone calls. The primary outcome was reduction in hemoglobin A1C, weight, blood pressure, and lipids at three and six- month visits. The article demonstrated greater glycemic control in the intervention group. There were no significant differences of the other primary outcomes reported during the study duration.

The informatics for diabetes education and telemedicine (IDEATel) study examined the effectiveness of telemedicine with nurse case management compared to usual care in patients with diabetes living in medically underserved areas (Shea et al., 2009). The IDEATel study was conducted over five years. Primary outcomes were hemoglobin A1C, low density lipoprotein (LDL) cholesterol and blood pressure. Telemedicine case management resulted in statistically significant improvement of all primary outcomes measured over the five years compared to the usual care group. The IDEATel study highlighted the potential of delivering health care using telemedicine to patients living in medically underserved areas to overcome geographic transportation and socio-economic barriers. Both studies showed improvement in glycemic control beyond six months in the intervention group, however, positive long-term clinical health outcomes are unknown.

Hospitalizations and Emergency Department Visits.

One multi-site study examined telemonitoring in frail, older adults with numerous chronic health conditions at risk for re-hospitalization compared to usual care (Takahashi et al., 2012). The usual care group had access to primary care, specialty care, urgent care and emergency department (ED). The primary outcome was a composite endpoint of hospitalizations and ED visits within 12 months after enrollment. The secondary outcomes included hospitalizations, ED visits, and length of stay per individual. The mean age of this study sample was 80.3 years. The results demonstrated no reduction in hospitalizations or ED visits. There were no significant differences in the secondary outcomes between the telemonitoring and usual care group.

Organ Transplantation.

There was only one longitudinal, prospective study examining the use of telehealth in the post-transplant population for six months (Leimig, Gower, Thompson, & Winsett, 2008). Participants were randomized to either the telehealth or standard care group. The main post-transplant outcomes include infection, rejection, and hospitalization in transplant recipients who lived far from the study transplant center. The majority of participants underwent renal transplantation. A small subset (n=11) of participants was comprised of liver transplant recipients. The small sample size was a major limitation of this study. The preliminary findings support the application of telehealth in providing specialized transplant services remotely for follow-up care after transplant. There were no RCTs identified in the literature review that explored the use of telehealth in the management of advanced liver disease and pre-transplant patients.

Cochran Systematic Review.

A recent Cochran systematic review included 93 eligible studies assessing the effectiveness of interactive telemedicine compared to usual care visits (Flodgren, Rachas, Farmer, Inzitari, & Shepperd, 2015). Results from few large studies outweighed the numerous studies evaluating a small number of participants were a limitation of this systematic review. The effectiveness of telemedicine varied based on factors including: 1) disease condition; 2) disease severity; 3) type of health care provider; and 4) different interventions.

In the management of CHF, the review illustrated no significant differences in re-admissions or mortality between participants receiving care with telemedicine intervention, suggesting equivalent health outcomes compared to usual care visits. There were inconsistent findings among studies in the literature. Differences in the severity of heart failure and settings likely contributed to this variation. Health-related quality of life favored the telemedicine group.

The authors also concluded that there was a greater reduction in blood pressures measurements in the telemedicine group. Telemedicine intervention showed sufficient evidence improving blood glucose control in patients with diabetes, but the effects varied across studies. The systematic review also specified no differences were found between the standard of care and telehealth groups in participants discharged after solid organ transplantation. Lastly, there were no unintended consequences of telemedicine intervention reported.

Implications for Nursing

Telehealth is used in a variety of clinical settings to care for patients with chronic health conditions. Telehealth is viewed as a potential solution for alternative delivery of healthcare in reducing heath disparities created by geographic location (Prinz, Cramer, & Englund, 2008). Numerous emerging applications of telehealth in various health conditions and settings have been reported in the literature. Telehealth models are exploring interventions to address limitations of efficiency, quality, and costs burdening our current healthcare system. Major barriers to conducting telehealth research include rapidly evolving technology and changing application across different settings complicates the interpretation of the evidence (Flodgren et al., 2015).

A lack of expert consensus in the evaluation of telemedicine exists due to the differences in study designs, variations in analytic methodology and outcome measures (Bashshur et al., 2014). Summary of the evidence from the literature provide an improved understanding of the potential use of telehealth as an alternative strategy to improve access to healthcare. Despite the heterogeneity described, there is growing support for the application of telehealth in chronic disease management. Telehealth has the potential to provide effective, frequent and timely health care to improve health outcomes equivalent to usual care across a distance.

Implications for Project

The changing landscape of our healthcare system, environmental factors and societal factors are all driving the wider adoption and use of telehealth (Doarn et al., 2008). Many telehealth models lack a theoretical foundation and focus only on one dimension (Nepal, Li, Jang-Jaccard, & Alem, 2014). Roger's Diffusion of Innovations Theory is among the most popular frameworks applied for studying the adoption and spread of health information technology within and between communities (Zhang, Yu, Yan, & Ton A M Spil, 2015). This theory is useful in the conceptualization of telehealth technology and examining factors affecting the innovation and its diffusion. The VHA's development of telehealth services also coincided with the rapid development of other clinical initiatives driven by the transforming need to expand health services to Veterans. Rogers' theory provides valuable insight in developing interventions using telehealth by understanding the determinants of success and feasibility of the application in a target population or health setting.

Tailoring interventions to address existing barriers of geography using telehealth has the potential to enhance VA transplant centers' ability to improve access and health outcomes in patients needing liver transplantation. There is supportive evidence of the interactive use of telehealth technology in other chronic disease conditions. Additionally, the VHA's prior successful expansion of telehealth services explained by Rogers' Diffusions of Innovations theory support the adoption of using this approach in managing decompensated cirrhosis to improve access across the virtual continuum from a distance. The evolving innovation of telehealth technology has transformed how providers connect and consult with patients in delivering high-quality health care. However, there is a need to clarify the effectiveness of telehealth in improving health outcomes in chronic disease management of advanced liver disease and in the transplant population and setting.

Project Question

Does the use of telehealth reduce wait time from referral to listing decision in Veterans referred for liver transplantation compared to usual care visits at the Richmond Veterans Affairs Transplant center?

Section III: Methods

Transplantation is complex and requires successful navigation through extensive medical and surgical evaluation (Ertel, Kaiser, & Shah, 2015). Proximity to a transplant center has been associated with the successful placement onto the national waitlist, which is a prerequisite to liver transplantation (Adler, Dong, Markmann, Schoenfeld, & Yeh, 2015). Many centers lack specialized hepatology expertise and transplantation is offered to Veterans at only six existing VATCs. Expanding telehealth capabilities can potentially increase utilization of limited specialty resources, reduce travel burden for the Veteran and his/her caregiver and minimize barriers to transplant access across large distances within the VHA.

Purpose of the Study

The aim of this project is to determine if the application of telehealth improves the timeframe of performing liver transplant evaluations across vast geographic distances in Veterans referred for liver transplantation.

Project Question

Does the use of telehealth reduce wait time from referral to listing decision in Veterans referred for liver transplantation compared to usual care visits at the Richmond Veterans Affairs Transplant center?

Definition of Terms

TRACER. The National Surgery Office (NSO) transitioned to a web-based electronic transplant referral system application called TRACER. The TRACER website link is available to referring centers and VATCs located on a secured VA transplant intranet site. The checklist along with clinical information and supportive documentation are submitted by uploading the information into TRACER for review by the VATC provider. Dates reflecting activity and workload are tracked and recorded in TRACER from the time of referral submission.

Referral. A medical center provider or designee completes the standardized laboratory and diagnostic assessments listed in the referral packet checklist (see Appendix A) to formally refer a Veteran for liver transplant consideration. The VATC then reviews the results of the clinical data from the referral checklist to render a preliminary decision of approval for further evaluation at the VATC. The VATC is required to provide feedback regarding referral submission to the referring center within 48 hours for emergency referrals or five business days for stable referrals. Once the Veteran is approved for further evaluation, the date for initial evaluation is negotiated with the Veteran.

MELD. The Model for End Stage Liver Disease (MELD) is a prognostic indicator based on the mathematical model calculated by bilirubin, international normalized ratio (INR) and creatinine to determine priority for organ allocation (Martin et al., 2014). Hyponatremia, low serum sodium, is an independent predictor of mortality in decompensated liver disease (Martin & O'Brien, 2015). Sodium was added to the MELD calculation in January 2016 (Organ Procurement and Transplantation Network, n.d.). The MELD-Na score replaced the MELD score in prioritizing organ allocation of recipients on the national waitlist for liver transplant. A higher score determines the priority of registrants on the national waitlist. The MELD-Na score remains capped at 40 points for organ allocation.

Telemedicine. The American Telemedicine Association (ATA) defines telemedicine as "the remote delivery of healthcare services and clinical information using telecommunications technology" (ATA, 2012). Flodgren and colleagues (2015) define telemedicine as a provision of clinical care using telecommunications for patients at a distance. The ATA considers telehealth and telemedicine as synonyms (ATA, 2012).

Initial evaluation. The initial evaluation is the *first* encounter that occurs either by telehealth or in-person (usual care) after the VATC confirms eligibility for further evaluation for liver transplant consideration. Veterans are offered the option of telehealth or usual care visit at the VATC for the initial evaluation upon referral assignment. A comprehensive review of all testing and evaluation is performed during this initial evaluation to determine appropriate timing of an in-person evaluation in Richmond. The most invasive testing such as cardiac catheterization or treatment for hepatocellular carcinoma, is often deferred until the initial evaluation. If no prohibitive findings are discovered at the initial evaluation, the VATC provider will recommend additional invasive testing or required repeat testing be performed prior to scheduling an in-person evaluation in Richmond.

In-person evaluation. The in-person evaluation is conducted on-site at the VATC located in Richmond, Virginia. This is scheduled after the initial evaluation is completed by either usual care or telehealth visit. The referring center, patient, and VATC mutually arrange an in-person evaluation once all necessary testing have been performed. The patient and his/her designated caregiver travel to the VATC for an evaluation that typically spans a week. The patient undergoes additional treatment, imaging and testing at the VATC if necessary. Some specific program testing is only available at the VATC. The patient typically meets with the transplant social worker, transplant psychologist, transplant clinical pharmacist, dietician, hepatology provider, and the surgical team at the academic affiliate during the in-person evaluation.

Decision for listing. The patient's comprehensive evaluation is presented at the combined selection committee. The transplant selection committee meets weekly. The listing decision results from a formal discussion at selection committee after completion of the in-person surgical evaluation. The committee considers the elements of the entire evaluation. A decision of the individual's candidacy for placement onto the national waitlist is formally recorded in the minutes. The three possibilities resulting from a listing decision are denial, deferral, or approval for liver transplant listing. The description of the entire transplant referral process flow is depicted in Figure 2.

Transplant List. UNOS developed a computer-based application called UNet SM, which contains names and clinical data of patients waiting for organ transplantation (UNOS, n.d.). The patient is officially registered in this computer network when deemed a candidate and accepted for liver transplant listing by the transplant program. The patient is formally notified upon placement on the national waitlist as required by UNOS.

Research Design

This study is a retrospective, descriptive comparative study of time from: 1) referral to initial evaluation; 2) initial evaluation to listing decision; and 3) referral to listing decision performed using telehealth or usual care.

Setting

The VHA is organized into twenty-one regional districts named Veterans Integrated Service Networks (VISN). The Hunter Holmes McGuire (HHM) Veterans Affairs Medical Center (VAMC) located in Richmond, Virginia is one of eight medical centers that manages care for veterans in the Mid-Atlantic Healthcare Network (VA Mid-Atlantic Health Care Network, n.d.). This 399-bed facility is a state-of-the art primary, secondary, and tertiary care center that provides comprehensive, cutting-edge diagnostic and health services for more than 200,000 veterans from central Virginia expanding down to the northern regions of North Carolina (Hunter Holmes McGuire VA Medical Center - Richmond, VA, n.d.). The HHM VAMC consists of a main campus and community-based outpatient clinics (CBOC) located in Fredericksburg, Charlottesville, and Emporia.

The HHM VAMC serves as one of the six approved national VATC for liver transplantation (see Figure 3). The Hepatology and Liver Transplant Program is a sub-specialty of the Gastroenterology division. The liver transplant program is a combined program with the academic affiliate, Virginia Commonwealth University. The program has a stable referring pool from numerous VA centers across the nation with a majority originating from the Northeast, extending down to the Southeast and San Juan, Puerto Rico. The transplant surgical event occurs at the university while the remaining care before and after the surgical event takes place primarily at the VAMC. Letter summarizing request for project access and support is provided in Appendix B.

Sample

The study sample consisted of a convenience sample of electronic medical chart reviews of Veterans referred for liver transplant consideration at the HHM VAMC from October 1, 2011 to September 30, 2016. VA Central Office (VACO) assigned a unique, de-identified case number at the time of referral submission that was used as the patient identification number. The two comparative groups consisted of initial evaluations conducted by either telehealth or usual care visits. Veterans determined eligible for further evaluation after stable referral submission during this timeframe were included in this study. Exclusion criteria consisted of: 1) referrals that originated from the Richmond VATC; 2) emergency status referrals, including patients with acute liver failure; 3) candidates that failed to meet VATC clinical or psychosocial criteria at time of referral; 4) patients that died after referral but prior to initial evaluation; 5) patients that no longer desired transplant after referral but prior to initial evaluation; and 6) those that pursued transplantation outside the VHA after referral but before the initial evaluation; and 7) Veterans that did not meet clinical or psychosocial criteria at the time of initial evaluation.

Procedures

Electronic medical record chart review of a convenience sample of approximately 200 Veterans referred for liver transplant consideration from October 1, 2011 to September 30, 2016 was conducted. Individuals that met both the inclusion and exclusion criteria were included in the data analysis. Data of sample characteristics and key measures using the unique identifiers were organized and recorded into an Excel spreadsheet.

The date of transplant referral placed into TRACER by the referring center was recorded as the date of referral. The evaluation that occurred after referral submission in those eligible for further evaluation was recorded as the date of initial evaluation. The type of evaluation was coded as “1” for telehealth visits or “2” for usual care visits. The first evaluation that was completed after the initial evaluation date in Richmond was recorded as the in-person evaluation date.

Formal review and discussion of transplant candidacy at the weekly selection committee or decisions conducted by electronic voting with majority ruling for urgent decisions was documented as the date of listing decision. The listing decision was categorized as “1” for approval, “2” for deferred, or “3” for denial. Distance between the subject residence zip code and VATC zip code was measured using ZipCodeAPI (ZipCodeAPI.com, n.d.). MELD scores and MELD Na scores at the time of referral and time of listing decision were calculated and entered. The major contributing condition to a diagnosis of cirrhosis was recorded as the primary etiology of liver disease. Veterans with a history of primary liver cancer were coded with a dual diagnosis of having primary hepatocellular carcinoma in addition to the primary cause of cirrhosis. Data collection of sample characteristics used the initial referral date as the index point.

Variables and Measures

Demographic data of sample characteristics obtained from the patient's electronic medical record and TRACER included: 1) gender; 2) age; 3) race; 4) marital status; 5) educational level; 6) other forms of insurance; 7) zip code; 8) name of referring center; 9) primary etiology of liver disease; and 10) blood group. MELD and MELD Na scores were calculated at times of referral and listing decision. The independent variables consisted of the telehealth or usual care groups conducted at the initial evaluation. The dependent variable was the length of time from: 1) referral to the initial evaluation; 2) initial evaluation to listing decision; and 3) referral to listing decision were computed. All dates and status changes of referrals were recorded and available in TRACER. The MELD score and MELD-Na score are both statistically validated mathematical models that estimate mortality in patients listed for liver transplant (Martin et al., 2014; Ahmed, Santhanam, & Rayyan, 2015; Kalra, Wedd, & Biggins, 2016). The MELD and MELD Na calculations were performed using a reliable calculator available on the Organ Procurement and Transplantation Network website (Organ Procurement and Transplantation Network, n.d.).

Data Analysis

The sample's demographic and descriptive data were analyzed using IBM's SPSS, version 25. Descriptive statistics were used to examine the baseline characteristics of subjects in the telehealth and usual care groups for comparison. Frequencies and percentages of categorical variables were tallied. Mean and standard deviation of continuous variables were calculated. The χ^2 test was used to evaluate the distribution of categorical variables. Independent t-tests were conducted to assess for significant differences of the mean wait-times from referral to initial evaluation, initial referral to listing decision and initial evaluation to listing decision in the telehealth and usual care groups. A p-value of <0.05 was considered significant.

Protection of Human Subjects

This project and proposal were reviewed and approved by the HHM VAMC's McGuire Research Institute (MRI) Institutional Review Board (IRB), which included a waiver of informed consent (see Appendix C). The University of Virginia Determination of Agent form was obtained after IRB approval at the study site (see Appendix D). Unique, de-identified identification numbers were used to maintain confidentiality of subjects. The minimal amount of protected health information was collected to meet the aims of this study. Data collected retrospectively was stored securely on VA servers behind the VA firewall and backed up on a hard drive maintained and secured in the liver transplant office. All data files were maintained in a password-protected environment.

Section IV: Results

The data were obtained from medical records of 295 Veterans referred for liver transplant consideration at the Richmond VATC spanning over five fiscal years. 211 stable referrals were deemed eligible for further evaluation. However, 25% of these referrals (n=53) were closed since candidates no longer met VATC clinical of psychosocial criteria after the initial evaluation by telehealth. Major reasons for exclusion other than failure to meet the VATC's criteria included deaths prior to evaluation, no longer desired transplantation or pursued transplant outside of the VHA. A total of 155 individuals were excluded from the data analysis. This left a total sample size of n=140 that met the predefined criteria, resulting in a cohort of 102 in the telehealth group and 38 in the usual care group. The Consort flow diagram illustrated the selection of subjects (see Figure 4). A large part of liver transplantation referrals came from centers outside VISN 6 (see Figure 5). Additionally, more than half of the total referrals received an approval for a listing decision (see Table 2).

Sample Characteristics

The majority of the participants were men with a mean age of 59 years (SD=6.9) in the telehealth group and 57 years (SD=7.1) in the usual care group. Over half were married and Caucasian. The leading etiology contributing to cirrhosis of the liver was attributed to chronic hepatitis C (HCV) infection in both groups. A detailed breakdown of the underlying primary etiology of liver disease is listed in Figure 6. Growing proportions were also diagnosed with primary hepatocellular carcinoma (TH=49%, UC=37%). More than half of Veterans referred for transplant did not have other forms of insurance coverage and resided between 101-500 miles from the VATC (TH M=549, SD=465; UC M=464, SD=420). Another quarter lived between 501-1000 miles from the VATC (see Table 3). The minimum distance travelled by Veterans was

86 miles and the maximum was 1,931 miles. The median distance was approximately 300 miles in each group. Additional demographic characteristics are listed in Table 4.

Categorical Variable Analysis

The exact 2-sided chi square test was performed on all categorical variables by telehealth and usual care groups (see Table 4). The proportion of participants in these two groups did not significantly differ by gender, race/ethnicity, marital status, educational level or blood group. There were no statistically significant differences by the primary etiology of liver disease or presence of primary hepatocellular carcinoma. No significant differences were revealed by insurance status or referrals from centers within or outside of VISN. However, there was a statistically significant difference of an approved listing decision between the two groups (p=0.007). Half of the subjects in the telehealth group were approved for listing compared to 75% of those in the usual care group who received an approval for listing.

Continuous Variable Analysis

There were no significant differences by age (p=.068) or distances (p=.306) between the two groups. The mean MELD and MELD Na scores were lower in the telehealth group (M=14.5, SD=4.7; M=15.3, SD= 5.2, respectively) compared to the usual care group (M=19.6, SD=8.9; M=20.9, SD=9.5, respectively). The MELD and MELD Na scores were also lower at the time of listing decision in the telehealth group. A two-tailed, independent samples *t*-test revealed a statistical difference in mean MELD and MELD Na scores between those in the telehealth and usual care groups at both referral (p=.002, p=.001) and time of listing decision (p=.005, p=.003). The mean time from referral to initial evaluation in the telehealth group was 22 days (SD=7.0) and 23.4 days (SD=15.3) in the usual care group. The average time from initial evaluation to listing decision in the telehealth group was 86 days (SD-55.5) and 66 days

(SD=92.5) in the usual care group. The mean time from referral to listing decision was 108 days (SD=55.8) in the telehealth group and 90 days (SD=94.6) in the usual care group (see Table 5). The independent samples *t*-test revealed no significant differences in mean times at these time intervals conducted by telehealth or usual care visits.

Section V: Discussion

The VHA has expanded telehealth capabilities as a potential solution to deliver timely care due to significant delays reported across the largest health care system. Geographic disparities due to centralization of specialized services have also fueled intense criticisms regarding decreased access to transplantation. Distance from a transplant center was adversely associated with poorer survival and decreased placement onto the national waitlist (Goldberg et al., 2014). Telehealth can potentially provide comprehensive pre-transplant evaluations and deliver high quality transplant services regardless of site of care. However, there were limited data regarding the use of telehealth to expedite transplant evaluations reported in the literature. The study's preliminary findings reported no statistically significant differences were associated with time from referral to an ultimate listing decision between the telehealth and usual care groups. This indicates that there was insufficient evidence that telehealth-based evaluations were different than usual care visits.

The study results suggest that initial telehealth evaluations were better at rendering a denial decision in those that failed to meet the VATC's clinical or psychosocial criteria earlier in the referral process. A decision of approval was more likely in the usual care group. However, if the VATC brought every referral to Richmond, as was done in the past with usual care visits, approximately 50% of referrals would have been denied or deferred during the in-person evaluation. Additionally, these denial or deferred decisions would occur much later into the transplant referral process. The mean times from referral to initial evaluation were similar by group. However, the average times from initial evaluation to listing decision were substantially longer, compared to the mean times from referral to initial evaluation in both groups. Understanding factors associated with delays from initial evaluation to listing decision contributed by Veterans, referring centers or the VATC should be integrated into continuous process and performance improvements.

The majority of Veterans referred had to travel far to the VATC, with over 90% living more than 100 miles from the VATC. Almost 40% of Veterans lived over 500 miles from the transplant center. Telehealth eliminates problems associated with distance and can offer the appropriate care at the right time, therefore, increasing access to transplant care and services. Additionally, telehealth can substantially reduce time and costs associated with lodging and travel to and from the transplant center. Potential benefits of utilizing telehealth in transplant evaluations include performing routine, non-specialty required care locally; reduction in travel burden and costs to veterans and their caregivers; and increasing early communication with potential candidates and referring center providers. Application of telehealth-based evaluations may enhance screening of non-candidates that do not meet VATC criteria and avoid futile transplant evaluations. This strategy can reduce health care associated costs, curtail unnecessary utilization of specialty care and decrease bottleneck of referrals. The potential benefits of telehealth application and its direct impact on costs and efficiency of the transplant program deserves further exploration.

The demographic profile of this study was consistent with the description of the general VA population examined in other studies in respect to age, gender, race/ethnicity, etiology of liver disease and presence of hepatocellular carcinoma (Kaplan, et al., 2018). In the analyses evaluating MELD and MELD Na scores at the time of referral and listing decision, there was a significant difference between the two groups. A higher MELD score, which reflects the severity of the underlying liver disease, may influence the type of initial evaluation desired by the patient and may explain the significant differences between the two groups. Factors associated with perceived barriers of telehealth adoption and rejection of initial transplant evaluations by telehealth in sicker patients warrants additional investigation.

Strengths and Weaknesses

A strength of the study design included an adequate sample size with a historical control group, under real-world conditions within the VHA health system. The VHA's large, integrated electronic medical record system permitted comprehensive data collection. This descriptive, comparative study illustrated patient characteristics of Veterans with end-stage liver disease referred for transplantation. Time from referral to a listing decision was analyzed to reflect the efficiency of conducting liver transplant evaluations by a VATC using telehealth. A major strength of this study also involved close evaluation of the decisional processes of the systematic implementation of telehealth in the pre-transplant setting. Findings from this study can contribute to the development of best practices for future applications for remote waitlist monitoring or post-transplant management. Program performance of completing liver transplant evaluations based on the study's results can be incorporated into continuous quality improvement initiatives to improve the efficiency of navigating referrals to a listing decision after referral.

Limitations of this retrospective study design include selection bias and reliance on the availability and accuracy of the data (Hess, 2004). A drawback of a descriptive study is the inability to draw any causal inferences (Grimes & Schulz, 2002). Another weakness identified was a small size within usual care group compared to the telehealth group. A convenience sample limits the generalizability to other disease conditions, patient populations, and health systems. Potential biases can result from the lack of randomization that can explain no significant differences in wait times between the telehealth or usual care groups. As with any observational study, there may be unmeasured confounding variables that can threaten the internal validity of the impact of telehealth intervention which include: 1) those with more advanced decompensation of liver disease reflected by higher MELD scores would readily opt for usual care visits; 2) changes in the patterns of transplant referral and listing; 3) changes in the epidemiology of liver disease; and 4) organ policies affecting organ allocation and prioritization.

Implications for Practice

Geographic inequity resulting in long-distance travel for Veterans needing a liver transplant at one of the six VATCs has been associated with discrepancies in transplant rates and poor health outcomes (Goldberg et al., 2014; Schwartz, Schiano, Kim-Schluger, & Florman, 2014; & Pullen, 2017). Veterans with decompensated cirrhosis would benefit from increased access to specialty care and life-saving transplantation. Specialty services such as liver transplantation are highly complex and resource intensive (Ertel, Kaiser, & Shah, 2015). Comprehensive counseling and initial evaluations conducted by telehealth can reduce the frequency of travel, which can be burdensome for the majority of Veterans living great distances away from the VATC. The initial findings of this study suggest that initial evaluations conducted by telehealth were not significantly different to usual care visits. Application of telehealth in chronic liver disease management within this target population is a novel approach to overcome disadvantages resulting from centralizing specialty services within the VHA. Expanding current telehealth capabilities to deliver specialized health services have the potential to improve Veterans' access and successful navigation across the multi-level transplant process in a timely manner.

Conclusion

Preliminary data suggests that it may be feasible to use telehealth-based evaluations for patients referred for liver transplant consideration across vast geographic distances. There were no differences detected in the telehealth group associated with time from referral to a listing decision compared to the usual care group. Veterans initially evaluated by telehealth were not disadvantaged in the transplant evaluation process. Additionally, telehealth may effectively identify non-candidates for liver transplant earlier into the current referral process and reduce unnecessary travel to the VATC. Telehealth has the potential to improve access to specialized transplant services, reduce travel requirements and improve the efficiency of conducting liver transplant evaluations across the complicated transplant process. Findings from this study on a larger scale can further clarify the role of telehealth in the transplant population and setting. The relationship between these findings and use of telehealth across the entire transplant process deserves further investigation.

Products of the Capstone

A report summarizing the findings from the Capstone will be shared with local staff, facility leadership, the National Surgery Office and VHA Telehealth Services. Preliminary findings from this project will be incorporated into quality and performance improvement initiatives demonstrating best clinical practices in expanding the program's use of telehealth in: 1) pre-transplant evaluation; 2) wait-list monitoring; and 3) post-transplant management of patients assigned to the Richmond VATC. Using Diffusion of Innovation concepts for improved program evaluation will be shared to influence adoption of telehealth across all VATCs. An abstract was submitted and accepted for poster presentation at the Virginia Council of Nurse Practitioner's 2108 Annual Conference (see Appendices E and F). Abstract submission for poster presentation at the Liver Meeting© of the American Association for the Study of Liver Diseases is in progress. A manuscript is in preparation for submission to the Federal Practitioner for publication (see Appendix G).

Disclaimer: The content in this scholarly project does not reflect the views or policies of the United States Department of Veterans Affairs.

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Table 1

Study Table of Literature Review

Study	Subjects and Setting	Design	Intervention and Comparison	Outcomes
Blum, K. & Gottlieb, S., 2014	N=206 Multicenter, heart failure services at the University of Maryland Medical Center, the Baltimore Veterans Administration Medical Center, and a number of private cardiology practices in the Baltimore/ Washington DC metropolitan area Systolic or diastolic dysfunction with a hospitalization within the past year 4-year study Power analysis reported	RCT	Subjects were randomized to monitored (telemonitored) or usual-care (control) group and all subjects were given written material about heart failure and self-management activities. Remote monitoring of daily weights, blood pressure, heart rate, and 15-second heart rhythm strip was performed with the use of the Philips Electronics E-care System. There were no specific protocols regarding the management decisions, and decisions were based on the nurse practitioner's experience and/or consultation with the subject's cardiologist.	**Hospitalizations and cost:** 154 were hospitalized with a total of 625 hospitalizations. 74 of the 101 in the usual-care group (312 hospitalizations) and 80 of the 103 in the monitored group (313 hospitalizations) were hospitalized at least once (P=.51). The average time to first hospitalization after randomization was 240 days (95% confidence interval [CI] 200-281) with a median of 138 days. There was no significant difference in the time to first hospitalization between the 2 groups. **30 Day Readmissions:** Readmissions= 203, 30-day readmissions in the total cohort, with an unadjusted readmission rate of 30% of total hospitalizations. The usual-care group had a total of 114 30-day readmissions resulting from 264 admissions (43%). The monitored group experienced 89 30-day readmissions resulting from 257 admissions (35%; $P < .05$) The lower readmission rate for the monitored group was only present in the first year of enrollment. Even though the 30-day readmission rate for the monitored group was significantly less in the 1st year, the cost to Medicare for inpatient care was not higher for patients in the monitored group. **Mortality:** Total of 94 deaths in the cohort over the course of the study. Forty subjects died within the 1st year of randomization and 31 within the 2nd year. There were no differences in the number of deaths or survival time between the monitored and usual-care groups. **Statistical Analysis:** t tests and repeated measures analysis of variance was used for comparing normally distributed continuous variables between the usual-care and monitored groups. Chi-square was used to compare the 2 groups according to categorical variables. The Mann-Whitney U test was used comparing the 2 groups regarding continuous variables that were

				not normally distributed. Kaplan-Meier curves were used for time-to-event analysis. **Limitations:** Used administrative database with some outlier data. No specific protocol.
Takahashi, et al., 2012	N= 205 multi-site, in four sites within Mayo Clinic's program of Employee and Community Health (ECH). Three of the sites were in Rochester, MN with one in rural Kasson, MN. Patients were > 60 years of age with a high-risk for re-hospitalization with a high score (>15) on the Elder Risk Assessment Index (ERA). Power analysis reported	RCT block randomization using blocks depending on site. The block size was randomly determined using computer generated allocation as 2–4 individuals in size. The analysis of the final results was performed in a blinded fashion.	Subjects were randomized to telemonitoring with daily input versus usual care. Telemonitoring was accomplished by daily biometrics, symptom reporting and videoconference.	**Hospitalization or ER visits:** The primary outcome of the percentage of patients with either hospitalization or an ER visit was 63.7% in the telemonitoring group, compared to 57.3% in the usual care group resulting in a 6.4% increased risk of the combined outcome (*P*=0.35). Each outcome did not reveal significant differences for hospitalizations, ER visits, number of ER visits, and hospital days. Mortality was different between the groups with 15 deaths (14.7%) in the telemonitoring group and 4 deaths (3.9%) in the usual care group (*P*=0.008). In a combined endpoint of time-to-event analysis of mortality, hospitalization, and ER visit, there was no difference noted between the telemonitoring group and the usual care group (*P*=0.499). **Statistical Analysis:** Intention-to-treat method. Wilcoxon rank sum tests, two-sample T tests, or chi-square analysis were used to compare baseline characteristics between the two groups. Kaplan-Meier time-to-event analysis was conducted with a combined endpoint for mortality, hospitalization, and ER visits. **Limitations:** Study was not blinded which could have led to the Hawthorne effect that states that the act of being monitored changes behavior. Limitations include generalizability since population is primarily Northern European descent. Usual care group had access to a tertiary care hospital and some case management for treatment of heart failure and diabetes. These services would bias the results to show no difference between the groups
Koehler, et al., 2010 TIM-HF study	N= 710 chronic HF were enrolled from 165 cardiology, internal medicine, or general medicine	RCT 1:1 ratio	Patients were randomly assigned to receive either remote telemedical management (RTM) or usual care. The following devices were part of the integrated sensor	**All-cause mortality:** The rate per 100 person-years of follow-up for the primary outcome of death for any cause was 8.4% in the RTM group compared with 8.7% in the usual care group (hazard ratio in the RTM group, 0.97; 95% confidence interval, 0.67 to 1.41; *P*=0.87) **Cardiovascular death or HF**

	practices Stable, ambulatory patients of with chronic HF, if at least 18 years of age, were in New York Heart Association (NYHA) class II or III, and had a left ventricular ejection fraction of ≤35%. Patients with a LVEF ≤25% must have had at least 1 HF decompensation episode that resulted in hospitalization or treatment with intravenous loop diuretics (> 40 mg furosemide per day) in the 24 months prior to randomization. Power analysis reported.		network: a 3-lead ECG, a blood pressure device, and a weighing scale. The 2 telemedical centers provided physician-led medical support 24 hours per day, 7 days per week for the entire study period with the use of standard operating procedures. The patient was contacted by the telemedical center physician in accordance with the standard operating procedures in place or when requested by the patient to verify measurements, to give consultation, or to institute treatment. The telemedical center contacted the patient's local physician at least every 3 months.	**hospitalization:** The rate per 100 person-years of follow-up was 14.7% in the RTM group compared with 16.5% in the usual care group (hazard ratio in the RTM group, 0.89; 95% confidence interval, 0.67 to 1.19; *P*=0.44). Compared with usual care, RTM had no significant effect on all-cause mortality or on cardiovascular death or HF hospitalization. **Study analysis:** Cumulative survival curves for the time-to-event analyses were constructed according to the Kaplan-Meier method, and the differences between curves were examined by the log-rank statistic. The Cox proportional hazards regression was used to estimate the hazard ratios, with treatment as the only covariate. **Limitations:** Low statistical power to detect a clinically relevant difference in mortality between the compared patient groups, as is evidenced by the wide 95% confidence intervals. No information was available concerning the number of patients who were prescreened and who were not enrolled in the trial. Only contacted to those who met the inclusion/exclusion criteria.
Giordano et al., 2009	N=460 Multi-center; 5 heart failure centers in Italy Patients hospitalized with confirmed CHF, LVEF < 40% and at least one hospitalization for acute HF in the previous year. Had to be	RCT Random permuted blocks for each center were used to allocate patients to treatment groups	Patients were randomly assigned to receive home-based telemanagement (HBT) or usual care (UC) program. The HBT pts received a portable device, transferring, by telephone, a one-lead trace to a receiving station where a nurse was available for	**Hospital readmission:** All-cause hospital readmissions occurred in 67 patients in HBT group and 96 patients in UC group (RR=0.57, 95% [CI]: 0.39–0.84; p=0.03). 55 patients (24%) in HBT group and 83 patients (36%) in the UC group had at least one readmission due to cardiovascular reasons (RR=0.56, 95% [CI]: 0.38, 0.82; p=0.003). The number of patients experiencing HF readmissions was 43 (19%) in HBT group and 73 in UC group (RR=0.49, 95% [CI]: 0.31–0.76; p=0.0001). Cardiovascular mortality was 8% (18 patients) in the HBT group and 13% (29 patients) in UC group (RR=0.44, 95%

	clinically stable with optimized oral therapy including maximally tolerated doses of both an angiotensin renin inhibitor and beta-blocker. Power analysis reported. 3% discontinuation rate		interactive teleconsultation. The UC pts were referred to their primary care physicians and cardiologists.	[CI]: 0.20–0.97; p=0.04). In multivariate Cox-proportional hazard models including baseline variables, the HBT group maintained a lower but not significant risk of cardiovascular death (HR=0.45, 95% [CI]: 0.19–1.03; p=0.06). **Costs:** Mean cost for hospital readmission was significantly lower in HBT group than in UC group (−35%, p<.001). Study suggests that one-year HBT program reduce hospital readmissions and costs in CHF patients. **Statistical analysis:** Characteristics of the two study groups were compared by the unpaired t test for the continuous variables and by chi-square test for categorical variables. Outcome measures (rate of readmission and cardiovascular mortality) were compared using Mantel–Haenszel chi-square. To assess the independent effects of management strategy on readmission-free survival and cardiovascular mortality we used Cox-proportional hazard model. **Limitations:** 2 groups were comparable with respect to demographic and clinical characteristics, although some differences were noted. Concern of generalizability of the results since patients enrolled in the study were selected among a population of CHF patients discharged to centers that have comprehensive HF management services. Cost analysis was limited to cost of hospital readmissions and did not evaluate costs for other health care services, direct nor indirect.
Ong, et al., 2016 BEAT-HF	N= 1437 Multi-center setting of 6 academic medical centers in California. Participants were hospitalized individuals 50 years or older, who received active treatment for decompensate	RTC Prospective2 arm (1:1) randomization	Compare usual care with a telehealth based care transition intervention for older patients who are discharged home after inpatient treatment for decompensated HF. The intervention consisted of 3 components conducted by registered nurses: pre- discharge HF	**180-day all-cause readmission:** The intervention and usual care groups did not differ significantly in readmissions for any cause 180 days after discharge, which occurred in 50.8% (363 of 715) and 49.2% (355 of 722) of patients, respectively (adjusted hazard ratio, 1.03; 95% CI, 0.88-1.20; *p* = .74). **Secondary outcomes:** There was no significant difference detected in unadjusted (p = .56) or adjusted (p = .63) analyses between the proportion of intervention participants (22.7% [162 of 715]) or usual care participants (21.6% [156 of 722]) with 30-day all-cause readmission. There were no significant differences in

	d HF (defined as HF with the initiation of or an increase in diuretic treatment) expected to be discharged home Power analysis reported.		education, regularly scheduled telephone coaching, and home telemonitoring of weight, blood pressure, heart rate, and symptoms. Usual care at the sites included robust pre-discharge education and often a post-discharge follow-up telephone call.	30-day readmission or 180-day mortality. **Statistical analysis:** Unadjusted intent-to-treat analyses were conducted. These multivariable analyses include logistic regression models for readmission and mortality analyses. **Limitations:** Could not extend enrollment which may have strengthened the 30-day mortality findings because the study was not powered for this specific outcome. The study sites are all academic centers in Ca. which could limit generalizability. The use of other types of personnel instead of registered nurses potentially could have affected study outcomes. Adherence to the BEAT-HF intervention appears to have been a critical factor. Despite deploying several strategies to promote patient engagement and foster adherence with the telemonitoring and telephone call center intervention, only 61.4% (439 of 715) and 55.4% (396 of 715) of patients randomized to the intervention were more than 50% adherent to telephone calls and telemonitoring, respectively, within the first 30 days.
Chaudhry et al., 2010 Tele-HF study	N= 1653 Multi-center; 33 cardiology practices across the U.S. Patients recently hospitalized for heart failure Power analysis reported	RCT Sequence of computer generated random numbers with stratification on the basis of the study site	Patients were either randomized to telemonitoring or usual care group. Telemonitoring group was instructed to make daily, toll-free calls to the system regarding general health and heart-failure symptoms. Internet site and was reviewed every weekday (except on holidays) by site coordinators. The protocol required the sites to contact any patient whose response generated variances and document their management of the	**Readmission for any reason and all-cause mortality:** No significant difference was seen between the two groups, 432 patients (52.3%) in the telemonitoring group and in 426 patients (51.5%) in the usual-care group (p= 0.75 by the chi-square test). Readmission for any cause occurred in 407 patients (49.3%) in the telemonitoring group and 392 patients (47.4%) in the usual care group (p = 0.45 by the chi-square test). A total of 92 patients (11.1%) in the telemonitoring group and 94 patients (11.4%) in the usual-care group died during the 180-day study period (p = 0.88 by the chi-square test). Readmissions for heart failure, the number of days in the hospital, and the number of readmissions were also similar in the two groups. Kaplan–Meier time-to-event curves for readmission or death from any cause, as well as for each component separately, did not reveal a significant difference between the two groups.

			variances.	**Statistical analysis:** tested the primary hypothesis using a chi-square test of independence. In secondary analyses, calculated the Kaplan–Meier time-to-event function for readmission or death from any cause. For each end point, estimated the corresponding hazard ratio and 95% confidence interval, using a Cox proportional-hazards model. Compared the numbers of readmissions and hospital days between the two groups using the Wilcoxon rank sum test. **Limitations:** 15% randomized never used the system. 55% adherence still using system by the final week of the study period. 21% of study patients did not complete final telephone interview at 6 months. Limited intervention between clinicians and patients since this study used telephone based system (IVRS).
Margolis, et al., 2013 Hyper Link	N= 450 Patients with uncontrolled BP recruited from 16 primary care clinics in an integrated health system in Minneapolis-St Paul, Minnesota, with 12 months of intervention and 6 months of post-intervention follow-up. Power analysis reported	RCT Cluster randomized clinical trial The16 study clinics were matched by size and clinic-level BP control at baseline and then randomly assigned to either the telemonitoring intervention (n = 8) or usual care (n = 8).	Clinics were randomized to receive either telemonitoring intervention or usual care. Each intervention patient received a home BP monitor (A&D Medical 767PC automated oscillometric) that stored and transmitted data to a secured website via modem. Pharmacists met with patients for a 1-hour, in-person visit. During telephone visits, pharmacists emphasized lifestyle changes and medication adherence. They assessed and adjusted antihypertensive drug therapy. Usual care patients worked with	**Outcomes:** At 6 months, BP was controlled in 71.8% (95% CI, 65.6%-77.3%) of the telemonitoring intervention group and 45.2% (95% CI, 39.2%-51.3%) of the usual care group (*P* < .001). At 12 months, BP was controlled in 71.2% (95% CI, 62.0 %-78.9 %) of the telemonitoring intervention group and 52.8% (95% CI, 45.4 %-60.2 %) of the usual care group (*P* = .005). At 18 months, BP was controlled in 71.8% (95% CI, 65.0 %-77.8 %) of the telemonitoring intervention group and 57.1% (95% CI, 51.5%-62.6%) of the usual care group (*P* = .003). Among the 362 patients attending all clinic visits at 6, 12, and 18 months, the proportions of patients with controlled BP at all visits were 50.9% (95% CI, 36.9%-64.8%) in the telemonitoring intervention group and 21.3%(95% CI, 14.4%-30.4%) in the usual care group (*P* = .002). Time points, BP was controlled at all visits in 40.9% (95% CI, 29.7% -53.1%) of the telemonitoring intervention group and17.2% (95% CI, 11.9%-24.3%) of the usual care group (*P* = .002). **Statistical analysis:** Generalized linear mixed models with a logit link and a random intercept for

			their PCPs as they had in the past.	clinic were used to test the effect of the intervention on the binary outcomes of BP control at 6, 12, and 18 months and at composite time points of 6 and 12 months, and 6, 12, and 18 months. **Limitations:** Not blinded. Multi-component intervention making it difficult to separate the intervention effect is attributed to telemonitoring or pharmacist case management. Generalizability, since population was well educated and about half used a home BP monitor during the year prior to the study. Cluster randomization of clinics rather than individuals have some limitations.
Artinian et al., 2007	N= 387 African Americans with hypertension were recruited through free BP screenings offered at community centers, thrift stores, drug stores, and grocery stores located on the east side of Detroit. Participants were screened for study eligibility three times. Inclusion criteria were SBP ≥ 140 mm Hg or DBP ≥ 90 mm Hg, unless self-identified as a diabetic or with a history of chronic kidney disease, then SBP ≥ 130 mm Hg or DBP ≥ 80 mm	RCT two-group, experimental, with block stratified randomization	Comparing treatment group of nurse-managed telemonitoring and the control group receiving enhanced usual care. Enhanced UC for participants included visits to their primary care provider scheduled at intervals requested by the PCP influenced by the participant's level of adherence to keeping appointments. Participants in the TM group received UC plus nurse managed TM. Once the intervention nurses received the BP reports, they telephoned each participant to provide feedback in relation to the target goals and to provide telecounseling about lifestyle modification and medication adherence in	**Outcomes:** Independent t tests show that 3-month BP values were lower in the TM group compared with the UC group (p = .05). Repeated measures ANOVA showed significant effects of treatment group, time, and group-by-time interaction on both SBP and DBP over the 12-month follow-up. Rates of BP control were generally similar for both the TM and UC groups at the 6- and 12-month follow-ups. **Statistical analysis:** Independent t tests and chi-square statistics were used to compare baseline characteristics between the TM and enhanced UC groups. Cross-tabs, repeated measures analysis of variance (ANOVA), and independent t tests were used. **Limitations:** Potential Hawthorne effect. Community-based rather than clinic- or hospital-based recruitment was conducted, which meant that TM reports were sent to providers who happened to be caring for participants. SBP and DBP in both groups lowering to about the same level at 12-month follow-up relates to the control group receiving enhanced UC rather than UC only.

	Hg Power analysis not reported		accordance with JNC-VII guidelines	
Stone, et al., 2010	N= 150 Veterans who received primary care at the VA Pittsburgh Healthcare System at one of the three main Pittsburgh campuses or five outlying community-based clinics. from June 2004 to December 2005, who were taking oral hypoglycemic agents and/or insulin for ≥ 1 year, and who had A1C ≥ 7.5% at enrollment Power analysis reported	RCT Statistician generated random sequences	Compared the short-term efficacy of home telemonitoring coupled with active medication care management by a nurse practitioner (ACM + HT) to a monthly care coordination (CC) telephone call Both groups received monthly calls for diabetes education and self-management review. ACM_HT group participants transmitted blood glucose, blood pressure, and weight to a nurse practitioner using the Viterion 100 TeleHealth Monitor; the nurse practitioner adjusted medications for glucose, blood pressure, and lipid control based on established ADA targets. Measures were obtained at baseline, 3-month, and 6-month visits.	**Outcomes:** A1C was significantly lower for ACM +HT than for CC participants at both 3 and 6 months (0.7% lower at each time point, *P* < 0.001 for each). Significantly greater decreases in A1C were observed in the ACM+HT group relative to the CC group at 3 months (1.7 vs. 0.7%) and 6 months (1.7 vs. 0.8%), corresponding to differential decreases of ~ 0.9% (*P* < 0.001 for each). Compared with the CC group, the ACM+HT group demonstrated significantly greater reductions in A1C by 3 and 6 months. However, both interventions improved glycemic control in primary care patients with previously inadequate control. **Statistical analysis:** Intent-to-treat approach included all randomly assigned participants to the extent possible. A modified multiple imputation approach was used to obtain unbiased estimates, appropriate variances, and valid tests, based on a chained equations algorithm. Mean A1C, weight, blood pressure, and lipid values were compared for the ACM+HT and CC groups at baseline, 3 months, and 6 months. The proportions of participants in each group who reached defined clinical target values at each time point were compared using Fisher's exact tests. **Limitations:** Not blinded. Generalizability given veteran population. Shorter duration of trial. Greater intensification of insulin therapy in the ACM + HT intervention group may have resulted in A1C decline compared to the CC group.
Shea, et al., 2009	N=1,665 Medicare recipients ≥ 55 with diabetes in designated underserved areas of NY State	RCT of 5 year results of the IDEATel Study; blinded outcome evaluation	Comparing home telemedicine unit with case management to usual care. The intervention group received a home telemedicine unit	**AIC:** Intervention group had net improvement in HgbA1c relative to usual care (p= 0.001). Statistically significant differences in HgbA1c level favoring the intervention group were found in years 4 and 5, with a net adjusted difference (95% CI) favoring telemedicine of 0.29 (0.12, 0.46) % at

	Power analysis not reported		(American Telecare, Inc, Eden Prairie, MN) consisting of a web-enabled computer with modem connection to an existing telephone line. The home telemedicine unit had a web camera that allowed video conferencing with nurse case managers, home glucose meter (One Touch Sure Step) and blood pressure cuff connected to the home telemedicine unit so that home finger stick glucose and blood pressure readings could be uploaded into a clinical database and access to a special educational web page created for the project by the ADA	year 5. The difference between baseline and 5 year adjusted means was 0.34% in the telemedicine group, compared to 0.07% in the usual care group. **LDL Cholesterol:** Intervention group experienced in net improvement in LDL (p<0.001) relative to usual care. Intervention group were found in years 1–4, reflecting progressive narrowing of the relatively greater improvement in the telemedicine group in the earlier years of follow-up. The difference between baseline and 5 year adjusted mean LDL-cholesterol was 15.51 mg/dL in the telemedicine group, compared to 13.14 mg/dL in the usual care group. **Blood pressure:** Reductions in systolic and diastolic blood pressure (p=0.024 and p<0.001, respectively) were significantly greater in the telemedicine group compared to the usual care group. Statistically significant differences favoring the intervention group were found in all five years for both systolic and diastolic blood pressure. **All-Cause Mortality and Adverse Effects:** Did not differ over the 5 years of follow-up between the intervention and usual care groups. There were no serious adverse events related to the intervention. **Statistical Analysis:** Intention-to-treat mixed models. A Cox proportional hazards model was used in an intention-to-treat analysis of all-cause mortality, adjusting for clustered randomization within PCP practices. **Limitations:** Potential Hawthorne effect since participants were randomized within primary care offices, no design to detect differences in clinical events or mortality, difficulty in carrying out 5-year longitudinal study; no cost-effectiveness analysis; and inability to estimate the effects of the intervention over five years. Intention to treat analysis with high attrition rate of 52% drop out rate adversely affects the generalizability of study outcomes. No power analysis.
Leimig, Gower, Thompson & Winsett, 2008	N= 106 Transplant clinic Sites were	Longitudinal prospective study	Randomized to telehealth or standard care	**Main outcomes:** Infections, rejections, and hospitalizations Collected from medical records 6 and 12 months from study entry. **Statistical analysis:** Chi-squared tests were used for univariate analysis

	located 19, 90, and120 miles from the standard care clinic Majority were renal transplant recipients. Small number of liver transplant recipients.			between categorical variables. No differences between the two groups were found. **Limitations:** Small sample size

Table 2

Overall Decision for Listing and Decision for Listing by Groups

Listing Decision	**Overall N (%)**	**Telehealth N (%)**	**Usual Care N (%)**	**P**
				0.007*
Approved	81 (57.9)	52 (51.0)	29 (76.3)	
Deferred	47 (33.6)	41 (40.2)	6 (15.8)	
Denied	12 (8.6)	9 (8.8)	3 (7.9)	

Note. * $p<0.05$ by Exact 2-sided chi-square test

Table 3

Distance by Categories

Distance (miles)	**Overall N (%)**	**Telehealth N (%)**	**Usual Care N (%)**
0 - 100	13 (9.3)	7 (6.9)	6 (15.8)
101 - 500	73 (52.1)	53 (52)	20 (52.6)
501 - 1000	36 (25.7)	28 (27.5)	8 (21.1)
1001 - 1500	13 (9.3)	10 (9.8)	3 (7.9)
>1501	5 (3.6)	4 (3.9)	1 (2.6)
Median		338	301

Table 4

Demographic Characteristics

Variable	**(Telehealth Group) N=102**		**(Usual Care Group) N=38**		***p***
	Mean (SD)	**N (%)**	**Mean (SD)**	**N (%)**	
Gender					.179[2]
Male		101 (99.0)		36 (94.7)	
Female		1 (1.0)		2 (5.3)	
Age (years)	59.4 (6.9)		56.9 (7.1)		.068[1]
Race /Ethnicity					.176[2]
White		59 (57.8)		27 (71.0)	
Black		27 (26.5)		5 (13.2)	
Hispanic		16 (15.7)		6 (15.8)	
Marital Status					1.0[2]
Married		72 (70.6)		27 (71.1)	
Never Married		13 (12.7)		1 (2.6)	
Divorced		13 (12.7)		10 (26.3)	
Separated		2 (2.0)			
Widowed		2 (2.0)			
Education					.571[2]
≤ High School Graduate		45 (44.1)		19 (50.0)	
> High School Graduate		57 (55.9)		19 (50.0)	
Insurance					.130[2]
None (VA Only)		52 (51.0)		25 (65.8)	
Medicare		34 (33.3)		8 (21.1)	
Private		16 (15.7)		5 (13.2)	
Referring Center					.487[2]
Within VISN		20 (19.6)		10 (26.3)	
Outside of VISN		82 (80.4)		28 (73.7)	
Etiology of Liver Disease					
HCV		65 (63.7)		26 (68.4)	.692[2]
ETOH		8 (7.8)		5 (13.2)	.339[2]
NASH		22 (21.6)		4 (10.5)	.152[2]
Other		7 (6.9)		3 (7.9)	1.0[2]
Primary HCC		50 (49.0)		14 (36.8)	.253[2]
Blood Group					.342[2]
A		37 (36.3)		8 (21.1)	
B		10 (9.8)		5 (13.2)	
AB		4 (3.9)		2 (5.3)	
O		51 (50.0)		23 (60.5)	
Distance (miles)	548.5 (464.7)		463.8 (420.1)		.306[1]

Note. SD= Standard Deviation; VA= Veterans Affairs; VISN= Veterans Integrated Service Network; HCV= Chronic Hepatitis C; ETOH= Alcohol; and HCC= Hepatocellular Carcinoma.
[1]Independent samples 2-sided t-test; [2]Exact 2-sided chi-square test.

Table 5

Analysis by MELD Score and Time

Variable	**(Telehealth Group) N=102**		**(Usual Care Group) N=38**		***p***
	Mean (SD)	**N (%)**	**Mean (SD)**	**N (%)**	
Referral MELD Score	14.5 (4.7)		19.6 (8.9)		.002[1]
Referral MELD Na Score	15.3 (5.2)		20.9 (9.5)		.001[1]
Decision MELD Score	16.4 (7.9)		21.3 (9.1)		.005[1]
Decision MELD Na Score	17.0 (8.2)		22.2 (9.2)		.003[1]
Time					
Referral to Initial Evaluation	22.0 (7.0)		23.4 (15.3)		.598[1]
Initial Evaluation to Listing Decision	86.3 (55.5)		66.4 (92.5)		.219[1]
Referral to Listing Decision	108.3 (55.8)		89.8 (94.6)		.262[1]

Note. SD= Standard Deviation; MELD= Model for End-Stage Liver Disease; Na= Sodium.
[1]Independent samples 2-sided t-test.

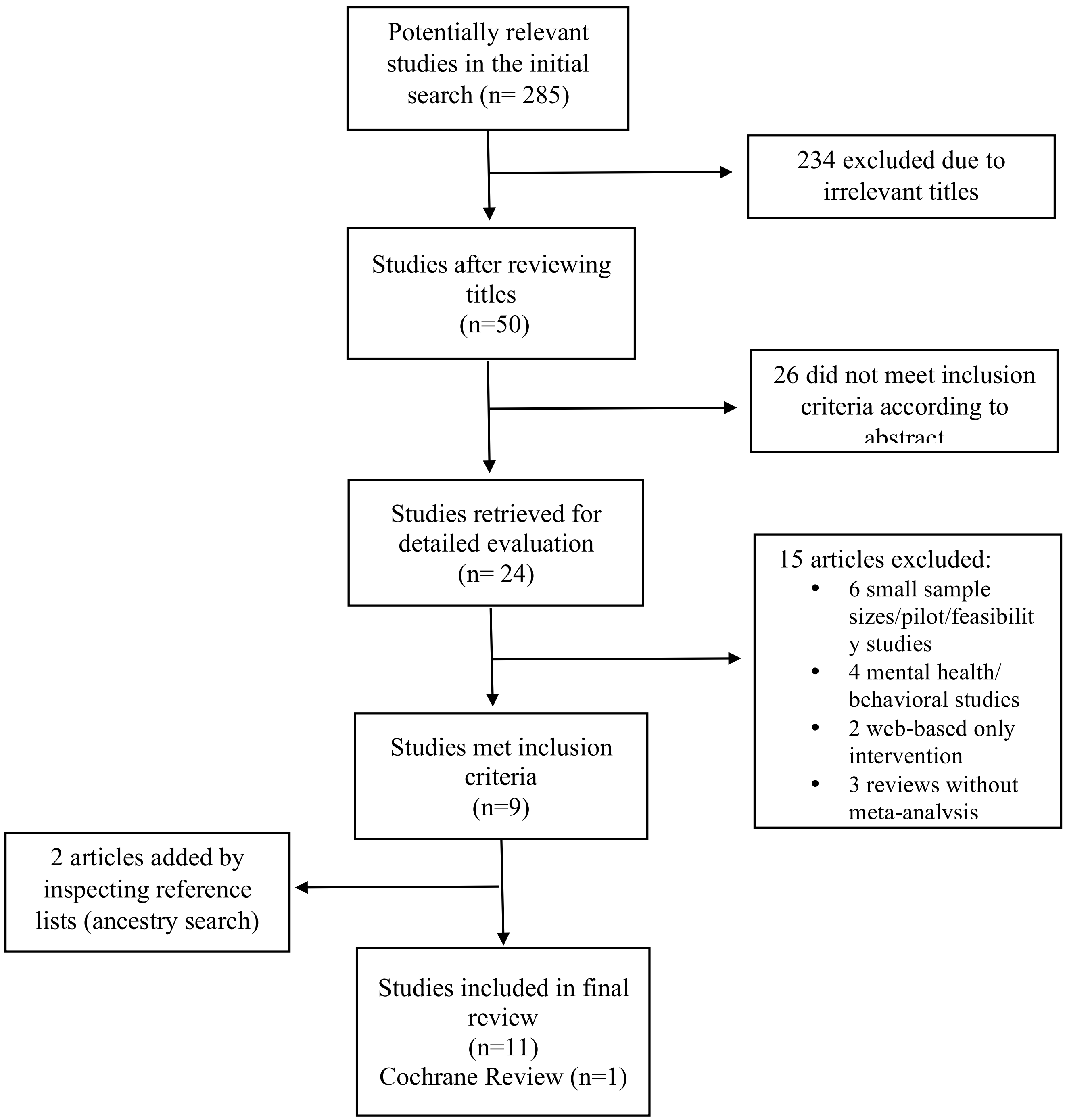

Figure 1. Systematic review of literature flow chart.

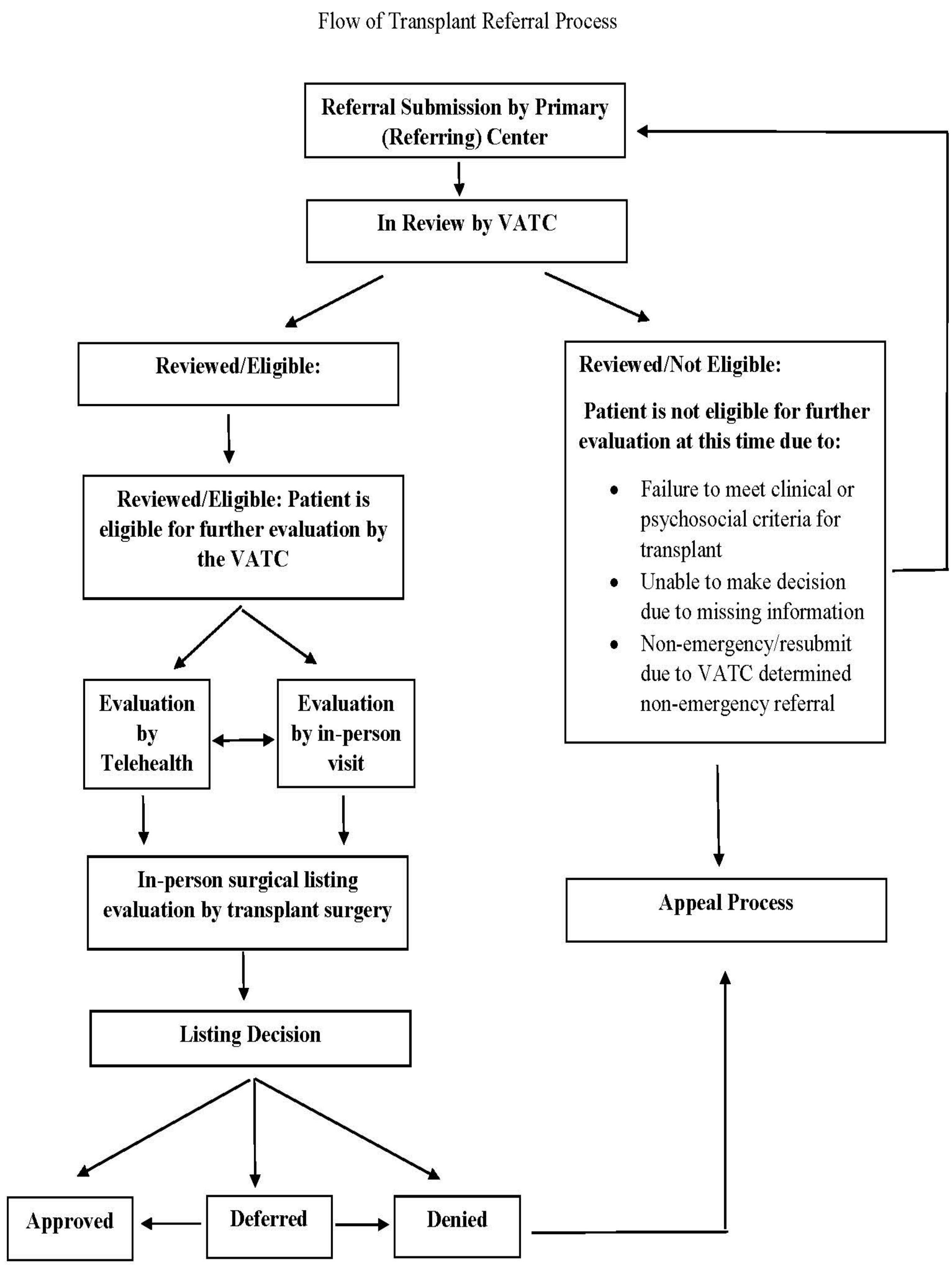

Figure 2. Liver transplant referral process within the Veterans Health Administration.

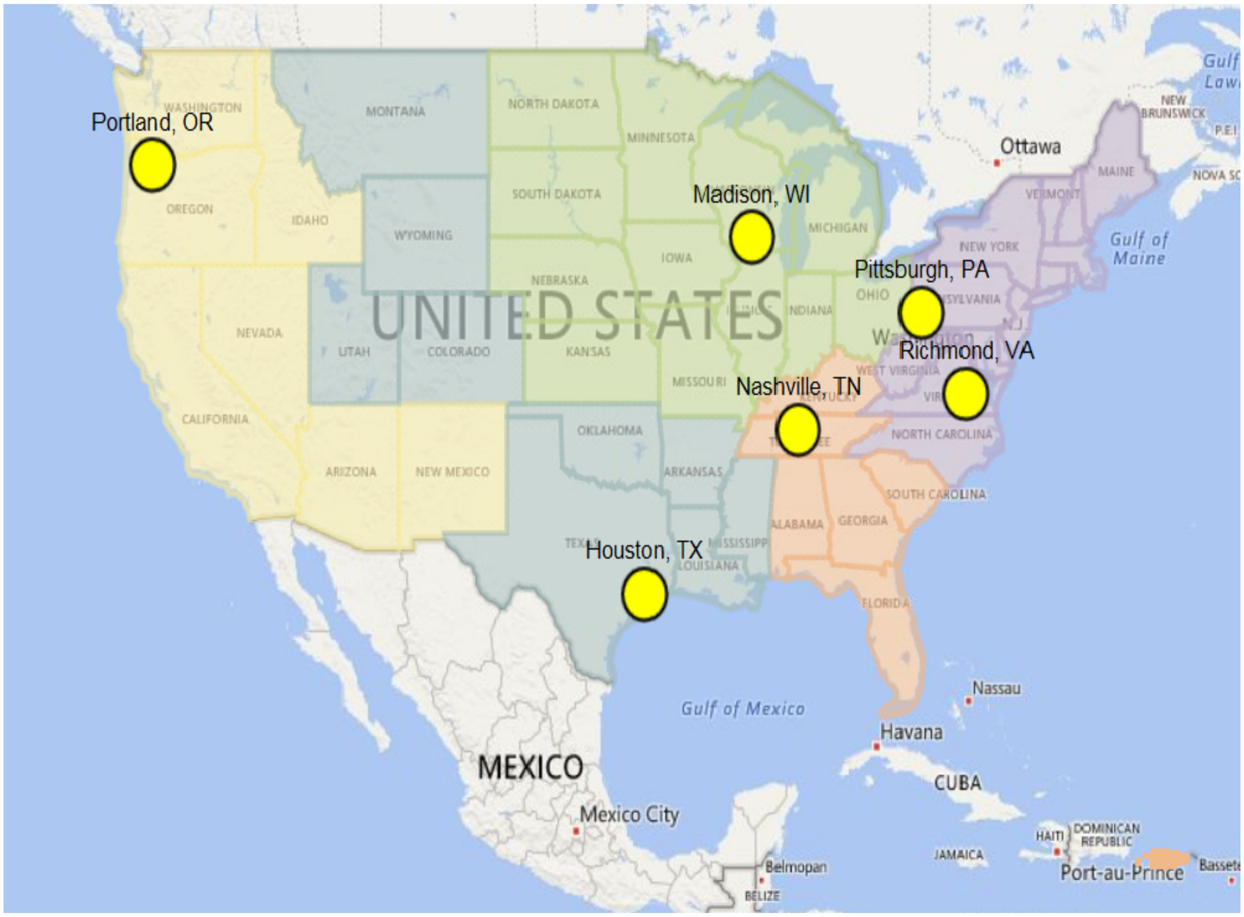

Figure 3. Map of the six liver transplant programs for the Veterans Health Administration. Retrieved from http://vaww.dushom.va.gov/ on June 23, 2017.

CONSORT Flow Diagram

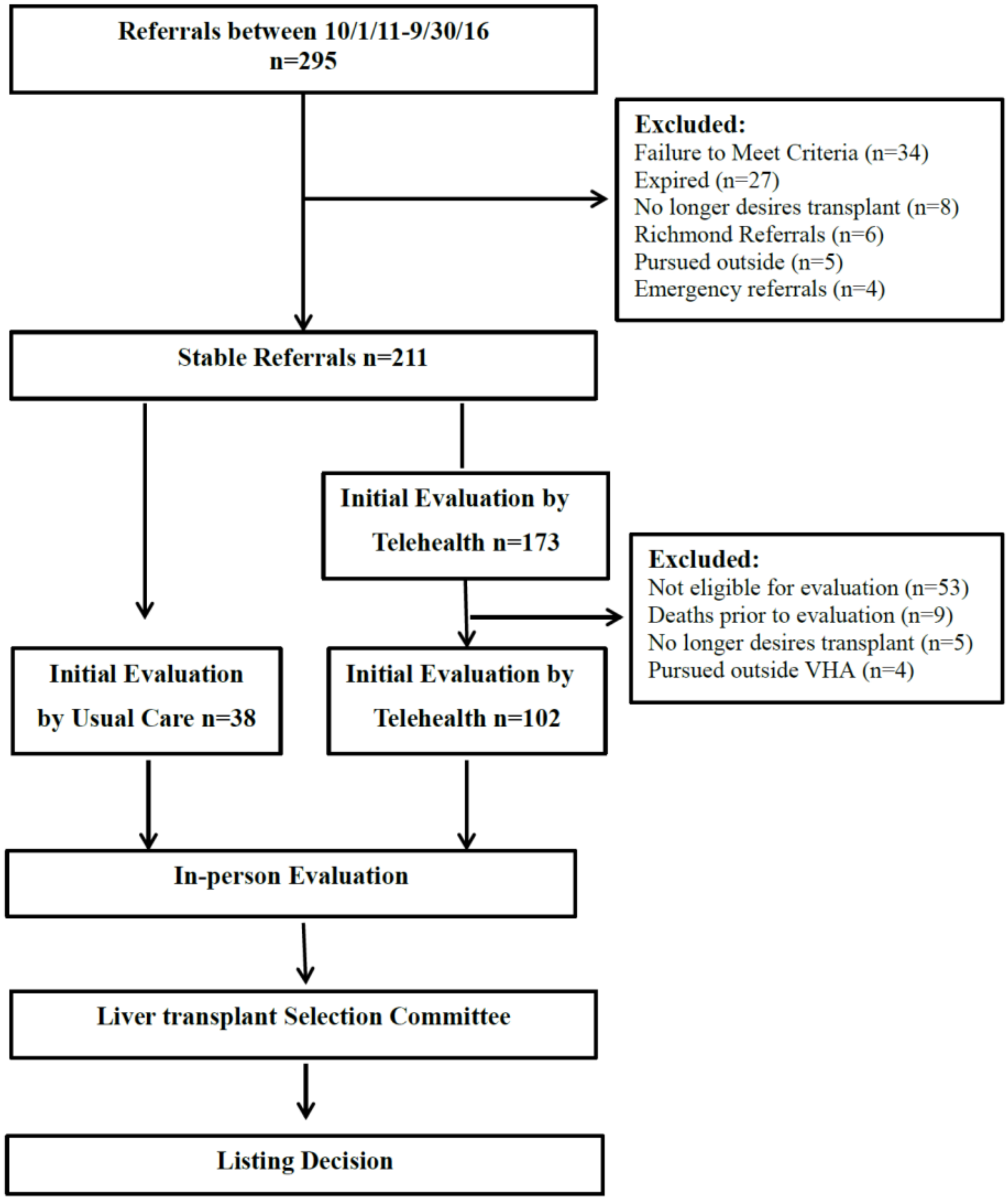

Figure 4. Flow diagram of study selection.

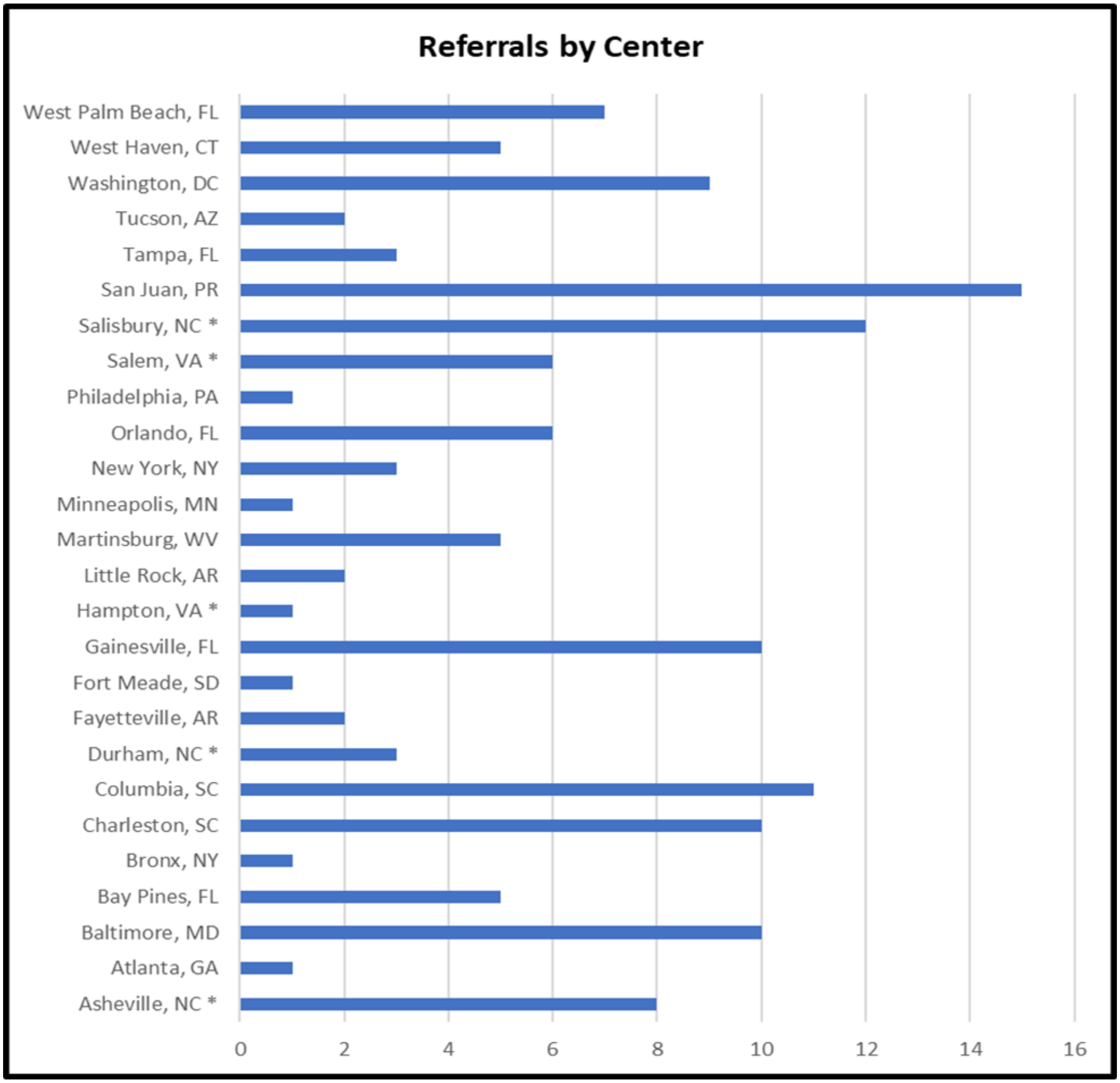

Figure 5. Location of referring centers. Centers within the Veterans Integrated Service Network (VISN) 6 of Richmond is denoted with *.

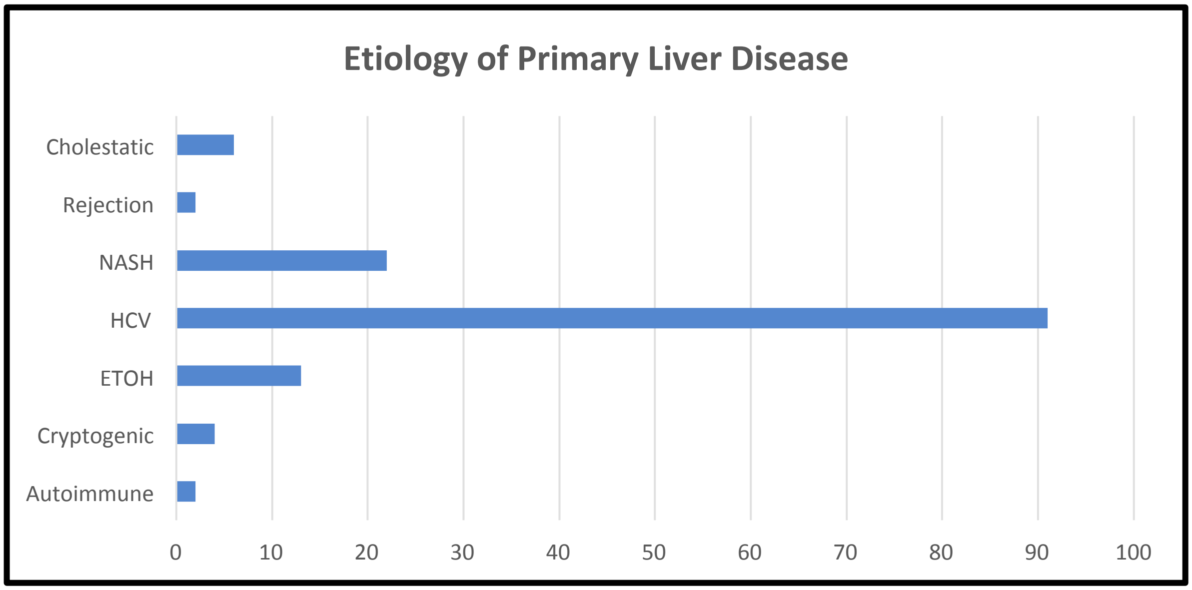

Figure 6. Etiology of primary liver disease. NASH= Non-alcoholic Steatohepatitis; HCV= Hepatitis C Virus; ETOH= Alcohol.

Appendix A

The required laboratory and diagnostic studies are summarized in the referral checklist. The referring center completes the necessary testing and submits the clinical data at the time of referral. The VATC will determine if the Veteran is eligible for further evaluation based on these results.

Liver Transplant Referral Packet Checklist

VACO Patient ID:	**Date**	**Comments**
VA Transplant Referral Form - VA Form 10-0390		
VA Physician Assessment/Summary (Use VACO Template)		
Discharge Summary (Latest Summary Only)		
Social Work Assessment (Use VACO Template)		
Mental Health Assessment (Use VACO Template)		
Dental Assessment (Treatment plan; use VACO Template)		
List of Current Medications (Consolidated)		
BMI (kg/m2)		
CXR		
EKG		
PFT/DLCO (N/A unless > 20 pack per yr smoking hx or lung disease)		
Echocardiogram		
Pharmacological Cardiac Stress Test w/ Estimated Ejection Fraction (Required if age > 50 or any cardiac risk factor, e.g., HTN, diabetes, extensive smoking history, obesity, etc.)		
Doppler US (to measure vessel patency)		
Abdominal CT or MRI		
If HCC suspected, need CT of Thorax, Abdomen and Pelvis		
Colonoscopy (If age >50; need latest report; include colon biopsy results if applicable)		
Pap smear and mammogram (for females)		
Path Report (any surgery)		
Liver Biopsy (if available)		
AFP		

PPD (If positive PPD, include status of INH Treatment in physician assessment)		
ABO/RH		
HAV		
HBsAg		
HBsAb		
HBcAb		
HbeAg (if HBs Ag positive)		
HbeAb (if HBs Ag positive)		
HBV DNA (if HBs Ag positive)		
HCV		
HIV Ab		
CMV IgG		
RPR/VDRL		
CBC		
UA (N/A if anuric)		
Chemistry Profile (Include LFT's, electrolytes, renal function, comprehensive metabolic profile)		
Coagulation studies		
TSH		
T4 (if TSH abnormal)		
24-Hour Creatinine Clearance or eGFR (ml/min)		
ETOH Screen (If history of abuse within past year, need at least 3 negative screens; if longer history of abstinence, 1 negative screen required)		
Toxicology Screen (Required for *all* referrals; must screen for amphetamines, barbiturates, benzoids, cannabinoids, cocaine, methadone, opiates, and propoxyphene. Blood acceptable if anuric) (Screening requirements same as ETOH above.)		
Smoking Screen (Screening requirements same as ETOH above.)		
Eligibility Information (Automated VA Form 10-10 or HINQ)		

Appendix B

Letter of Support

From: Fuchs, Michael RICVAMC
Sent: Tuesday, June 27, 2017 1:29 PM
To: Gilles, Hochong RICVAMC
Subject: Statement of Support

Dear Ms. Gilles,

this note is to express my greatest enthusiasm in support of your research project that will explore the use of telehealth to improve specialty access and timeliness of liver transplant referrals at McGuire VA Medical Center. With your medical expertise in taking care of liver transplant patients and patients with advanced liver disease in general, your diligence, attention to details as well as good organizational skills, I am confident that your project will be completed in time and will provide important insights that will have impact on how telehealth can be used by liver transplant centers such as the McGuire VA Medical Center.

I am looking forward to working with you on this exciting project.

Sincerely,

Michael Fuchs, MD, PhD, FAASLD, AGAF, FEBG
Professor of Medicine, Virginia Commonwealth University
Chief of Hepatology, Hunter Holmes McGuire VA Medical Center
Associate Editor, Digestive Diseases and Sciences

From: Gilles, Hochong RICVAMC
Sent: Saturday, June 24, 2017 3:02 PM
To: Fuchs, Michael RICVAMC
Subject: Statement of Support for

Dr. Fuchs,

As you know, I am a doctoral student at the University of Virginia. I am requesting a letter of support to conduct my DNP project at our setting as previously discussed. My project will be examining the use of telehealth to improve specialty access and timeliness of liver transplant referrals in our liver transplant program. This proposal will be submitted for ethical review through McGuire IRB and plan to complete the University of Virginia determination of agent form once I receive IRB approval from McGuire. Thank you for your ongoing mentorship and support.

Best,

HoChong Gilles

Appendix C

McGuire IRB Letter of Approval

McGuire Institutional Review Board (IRB)
McGuire VA Medical Center
1201 Broad Rock Blvd. (Room 3C-126) • Richmond, VA 23249 • 804-675-5676 • Fax: 804-675-5679

IRB APPROVAL - Initial Review

Date: September 21, 2017
From: Edward S. Wong, M.D., Acting Chairperson
Investigator: Michael Fuchs, M.D., Ph.D,FEBG, AGAF
Protocol: Expediting The Listing Process for Liver Transplantation Utilizing Telehealth
ID: 02358 Prom#: N/A Protocol#: N/A

The following items were reviewed at the 09/19/2017 meeting:

- Research Protocol (08/21/2017)
- Conflict of Interest Disclosure Form - Fuchs (08/23/2017)
- Conflict of Interest Disclosure Form - Gilles (08/21/2017)
- Initial Review Submission Form - Minimal Risk (08/23/2017)
- Project Data Sheet (08/23/2017)
- Waiver of HIPAA Authorization (08/23/2017)
- Facility Information Security Officer Review of Hu (08/29/2017)
- Privacy Officer Review of Human Subjects Research (09/07/2017)
- Study Personnel List (08/21/2017)
- Waiver or Alteration of Consent (08/23/2017)
- Privacy and Data Security Plan (08/21/2017)

Conditions of Approval are attached. These conditions are further detailed in the HHS, FDA, and VA regulations, which are available in the Research Office.

Approval is granted for a period of 12 months and will expire on 09/18/2018. Your Continuing Review is scheduled for 08/21/2018, and the requirements are attached.

Waiver of HIPAA - APPROVED

Waiver or Alteration of Consent - APPROVED

In the event that your employment at the Richmond VA Medical Center ends, you must:
1. Notify the IRB and take action to transition active and pending human research studies.
2. Notify Research Office staff and take action to archive paper and electronic research records.

Approval by each of the following is required prior to study initiation (unless Exempt):
McGuire Institutional Review Board (IRB)

Page 1 of 2

The McGuire VAMC IRB is not connected with, has no authority over, and is not responsible for human research conducted at any other institution, except where a Memorandum of Understanding specifies otherwise. Separate consent forms, initial reviews, continuing reviews, amendments, and reporting of serious adverse events are required if the same study is conducted at multiple institutions.

Research and Development Committee

Approval for study initiation is contingent upon your compliance with the requirements of the Research Service for the conduct of studies involving human subjects.

The McGuire VAMC IRB is not connected with, has no authority over, and is not responsible for human research conducted at any other institution, except where a Memorandum of Understanding specifies otherwise. Separate consent forms, initial reviews, continuing reviews, amendments, and reporting of serious adverse events are required if the same study is conducted at multiple institutions.

Appendix D

University of Virginia Determination of Agent Form

University of Virginia IRB-HSR — Institutional Review Board for Health Sciences Research

DETERMINATION OF UVa AGENT FORM

INFORMATION ABOUT THIS FORM

- This form is to determine if UVa personnel are or are not considered to be working as an Agent* for UVA on this project.
- If it is determined that UVA personnel are considered to be working as an Agent* for UVA the study, then your team will be required to provide an additional submission to the IRB-HSR, unless the project is determined to not involve human subject research. See Determination of Human Subject Research Form

****Agent-*** *all individuals (including students) performing institutionally designated activities or exercising institutionally delegated authority or responsibility.*

Enter responses electronically. Email the completed form to IRBHSR@virginia.edu for pre-review.

An IRB staff member will reply with any changes to be made.

Name of Individual to be Working on Project:	HoChong Gilles, RN, MS, FNP-C
Email:	hsg3mc
Phone:	804-301-8635
UVa Messenger Mail Box #	n/a
Project/Protocol Title if Known:	☐ Unknown or Title: Expediting the Listing Process for Liver Transplantation Using Telehealth
Explain your role in the project: (200 words or less)	DNP Project: Role is Sub-investigator (Student can't be Priniciple Investigator at Practice Site)
Explain the reason for traveling to the outside institution.	Employee at the Practice Site and DNP project will be conducted at this practice site (outside of UVA_

INSTRUCTIONS: Complete the applicable option below:

Option A: Typically used by UVA personnel who are asked to assist with a research study after arriving at the non- UVA institution. (e.g., resident doing rotation at another institution)

Answer the following questions:

☐**Yes** ☐**No** I was involved in the design of this research project.
☐**Yes** ☐**No** A UVA IRB has approved this research. IRB-HSR #
☐**Yes** ☐**No** Funding to conduct this research will come from or through UVa.
☐**Yes** ☐**No** The only reason I am traveling to this outside institution is to work on this research.
☐**Yes** ☐**No** Working on this research is required for my degree program.

I confirm that:

☐**Yes** ☐**No** I am a student, employee or faculty member of the University of Virginia.
☐**Yes** ☐**No** My work on this project will be overseen by the Principal Investigator and the IRB at the outside institution. This includes completing any training in human subject research protection or other training as required by the outside IRB.
☐**Yes** ☐**No** I will communicate with the UVA IRB and UVA Contracts Office for my school, to determine what approvals may be needed, prior to receiving any data from the outside institution

Option B: Typically used by graduate students conducting their research outside of UVA.

I confirm that:

☒Yes ☐No I designed this research.
☒Yes ☐No I am a student, employee or faculty member of UVa but am employed by another institution.
☒Yes ☐No All subjects will be enrolled at this outside institution.
☒Yes ☐No Only de-identified data may be brought to UVA. If data is brought to UVA it will be protected according to UVA Data Security Policies.
☒Yes ☐No The research will be overseen by their IRB and, if applicable, their HIPAA Privacy Board. This includes completing any training in human subject research protections or other training as required by the outside IRB.
☒Yes ☐No There is no funding for this study or if there is funding, it will be handled by the non-UVA institution at which I am employed.
☒Yes ☐No I have notified the outside IRB that a UVA IRB will not be overseeing my work. ATTACH COPY OF THE OUTSIDE IRB APPROVAL/DETERMINATION.

Option C: Typically used by a person who will continue working on their research at their previous institution after transferring to UVA. No research protocol will be opened to enroll additional subjects at UVA.

I confirm that:

☐Yes ☐No I am a student, employee or faculty member of UVa but I was employed by another institution when the research was begun.

☐Yes ☐No All subjects were or will be enrolled at this outside institution and all data will remain there.

☐Yes ☐No The research will be overseen by a non-UVA IRB and, if applicable, the HIPAA Privacy Board of my previous institution. This includes completing any training in human subject research protections or other training as required by the outside institution.

☐Yes ☐No There is no funding for this study or if there is funding, it will be handled by my previous institution.

☐Yes ☐No I have notified the IRB of Record that I have transferred to UVA and that a UVA IRB will not be overseeing my work on this research protocol.
ATTACH COPY OF THE OUTSIDE IRB APPROVAL/DETERMINATION.

Option D: Typically used by a UVa Faculty member who has an appointment or clinical privileges at another institution. Research to be conducted at outside institution. Research protocol will not be opened to enroll subjects at UVA facilities.

I confirm that:

☐Yes ☐No I am a faculty member of UVA and I have an appointment or clinical privileges at another institution.

☐Yes ☐No All subjects will be enrolled at the other institution and all data will remain there.

☐Yes ☐No The research will be overseen by a non-UVA IRB and, if applicable, the HIPAA Privacy Board of the other institution. This includes completing any training in human subject research protections or other training as required by the other institution.

☐Yes ☐No There is no funding for this study or if there is funding, it will be handled by the other institution.

☐Yes ☐No I have notified the IRB of Record that a UVA IRB will not be overseeing my work on this research protocol.
ATTACH COPY OF THE OUTSIDE IRB APPROVAL/DETERMINATION for this protocol.

FOR IRB-HSR OFFICE USE ONLY

☒ UVa personnel are not considered to be working as an Agent for UVa on this project.
No approvals from the UVa IRB-HSR are required.
UVA Tracking # 20192

☐ UVa personnel are considered to be working as an Agent for UVa on this project.
Submit a research application to the UVa IRB-HSR.

Joanna Faulconer — October 9, 2017
Signature of IRB Chair, Director or Designee — Date

Appendix E

Abstract Submitted to Virginia Council of Nurse Practitioners 2018 State Conference

Application of Telehealth to Overcome Geographic Disparities in Liver Transplantation within the Veterans Health Administration (VHA)

HoChong Gilles, MS, RN, FNP-C, Michael Fuchs, MD, PhD, Binu John, MD, MPH and Kathryn Reid, PhD, RN, FNP-C, CNL

Abstract

Background: Many centers within the VHA have limited access to hepatology and transplant specialists. Liver transplantation within the VHA is centralized and performed at one of only six approved VA transplant centers (VATC). Geographic disparities are associated with lower access to transplantation and poorer survival in Veterans residing over a hundred miles from a VATC.

Purpose: This study aims to evaluate if telehealth can improve the efficiency of performing transplant evaluations in Veterans referred for liver transplantation.

Methods: A retrospective, descriptive, comparative analysis of electronic medical records was conducted to evaluate the differences in time from referral to a listing decision using telehealth versus usual care visits **in Veterans referred for liver transplant consideration to a VATC from 10/01/2011- 9/30/2016.**

Findings/Results: Findings to be presented include: 1) demographic characteristics; 2) etiology and severity assessment of liver disease; 3) time measures from transplant referral to initial evaluation and listing decision; and 4) geographic distances to the VATC.

Implications/Conclusion: Application of telehealth is a novel approach to address disadvantages resulting from centralizing specialty services within the VHA. Telehealth has the potential to improve timely access to specialized health services in managing end-stage liver disease and successfully navigate through the complex transplantation process across vast geographic areas. Products from this study can clarify the utilization of telehealth in the pre-transplant population and contribute to best practices to improve quality and program performance in the transplant setting.

Keywords: liver transplantation, telehealth, telemedicine

Appendix F

Notification of Abstract Acceptance

From: Amy Sales [mailto:amy.sales@easterassociates.com]
Sent: Monday, February 12, 2018 4:38 PM
To: Gilles, Hochong RICVAMC
Subject: [EXTERNAL] VCNP: 2018 VCNP Annual Conference Poster Presentation

Dear HoChong Gilles,

Thank you for agreeing to present the following poster, "Application of Telehealth to Overcome Geographic Disparities in Liver Transplantation within the Veterans Health Administration (VHA)"

Thank you for submitting a poster presentation for the 2018 VCNP Annual Conference. The following poster, "Application of Telehealth to Overcome Geographic Disparities in Liver Transplantation within the Veterans Health Administration (VHA)" has been accepted by the Conference Committee. Congratulations! There are several important documents that are required for the accreditation of the conference, and it is important that they are completed in a timely fashion. Your attention to this matter is appreciated.

Here is a link to the poster presenter section of the conference website for your convenience:https://services.easterassociates.info/conference/poster/VCNP/14
Please use your email address (hochong.gilles@va.gov) as your user id, and your last name (Gilles) as your password.

Please complete the following areas:
Personal Information Incomplete
Presentation Incomplete
Agreement Incomplete

Thank you for your interest in presenting at the 2018 VCNP Annual Conference, and let us know if you have any questions.

Sincerely,

VCNP Conference Committee

Amy Sales, CMP
Associate Director
Virginia Council of Nurse Practitioners
250 West Main Street, Suite 100
Charlottesville, VA 22902
Phone: 434-906-1778
www.vcnp.net

Nurse Practitioners: Partners for a healthier tomorrow

Appendix G

Submission Guidelines for Federal Practitioner

Federal Practitioner expects its authors to abide by its stated policies for conflict of interest, human and animal rights, and informed consent. These policies can be found in the Editorial Policies section.

Federal Practitioner welcomes submission of manuscripts on subjects pertinent to physicians, clinical pharmacists, physician assistants, advanced practice nurses, and medical center administrators currently working within the VA, the DoD, IHS, and the PHS. Authored features include clinical review articles, original research, case reports, evidence-based treatment protocols, and program profiles. The journal also publishes bylined editorials and columns. Manuscript submissions will be considered for publication only if the author has certified that the work is original, has not been published previously, and is not under consideration for publication elsewhere. All manuscripts are subject to peer review.

Federal Practitioner uses Editorial Manager, a web-based manuscript submission and review system. All manuscripts must be submitted through this system; e-mail or standard mail submissions will not be accepted. The Editorial Manager website can be found at http://www.editorialmanager.com/fedprac.

STYLE

Federal Practitioner uses a straightforward style that balances scholarly discourse with a reader friendly, conversational tone. Contractions are not acceptable, and the narrative should be in the third person. Avoid excessive jargon and define all acronyms. Because the majority of *Federal Practitioner* readers are primary care providers, avoid terminology that is unique to a particular medical specialty. Be concise and use the active voice when possible.

The *Federal Practitioner* style is based on that established by the American Medical Association, with some modifications. When preparing your manuscript, therefore, it may be helpful to consult the 10th edition of the *AMA Manual of Style* (2007). If you have additional questions, e-mail fedprac@frontlinemedcom.com.

MANUSCRIPT PREPARATION

The manuscript should contain no author names anywhere in the document, including headers. Authors should be listed on a separate cover page. The manuscript document should begin with the title, followed by the introduction, body of the manuscript, acknowledgments (if applicable), references, figure legends (if applicable), and tables (if applicable). Tables and figures should be submitted as separate, 300 dpi high-resolution files (.jpg, .gif, etc).

Although abstracts are not published within the journal, the inclusion of an abstract with a submission assists in the review process and is required for certain manuscript types. **Keywords and manuscript classifications are similarly required**. It is not necessary that these components be included in the manuscript file, however, as you will be prompted to enter them separately as part of the Editorial Manager manuscript submission process. Before submission, review your manuscript for grammar, readability, and accuracy.

FEATURE ARTICLES

Manuscripts submitted for consideration as feature articles should be in a Word document of 4,000 words or less, excluding references. **We will not accept a .pdf format.** Also, if the manuscript's layout runs longer than 6 printed pages, some tables, figures, and appendixes may appear only on the website but citations to their appearance will be included in the print version.

The submission should begin with a strong introduction that catches the reader's attention, identifies the need for the article, and explains how the article adds to the literature on the topic. The preferred format for the introduction is 3 to 4 paragraphs that follow a "lead, need, sell" structure:

Lead: First paragraph is designed to catch the reader's attention. It may include relevant statistics that illustrate the importance of the information that will be presented in the article, an illustrative case (either hypothetical or actual), or some other eye-catching technique appropriate to the article's style and content.

Need: Second (and possibly third) paragraphs should clarify the specific focus of the article, identifying some problem or area of importance that will be addressed in the article.

Sell: Third or fourth paragraphs should explain how this article will address the problem or area of importance identified and how it will add to current health care literature on this topic.

Present background concepts early in the manuscript, followed by more complex ideas. Use subheads to differentiate major points of emphasis. For research articles, follow a standard organizational structure (introduction, background information, methods, results, discussion, conclusion).

SUBMISSION

To submit a manuscript, go to the *Federal Practitioner* Editorial Manager website (http://www.editorialmanager.com/fedprac). If you have not already done so, you must register for the site. (Note: If you have been registered for the site as a reviewer, you do not need to register again as an author. All reviewers have the ability to log in as an author should they choose to do so.) After you have registered, you may log in as an author and begin the submission process.

The submission process consists of several steps, which vary depending on the type of manuscript you are submitting. All submissions require you to enter a title, enter key words, **select classifications** (subject areas discussed in the manuscript), and answer several questions about the submission. Attach the following submission components:

1. cover page;

2. manuscript (with no author information); and

3. disclosure and copyright forms and corresponding author's release form.

The cover page should include the title of the manuscript, a byline listing all individuals and degrees who have served in authorship roles for the manuscript, and brief biographical information on the authors (professional and academic titles and affiliations). For criteria defining authorship roles, consult the 10th edition of the *AMA Manual of Style* (2007) or the ICMJE's *Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication*. In the byline, include each author's full name, highest relevant degrees and certifications, and military rank (when applicable). Do not include U.S. fellowships. It is also helpful to identify, on the cover page, which author will be serving as the corresponding author.

Authors must use the standard *Federal Practitioner* authors' form, available for download on the *Federal Practitioner* Editorial Manager website (on the Attach Files page that appears during manuscript submission).

You must also download the *Federal Practitioner* ReleaseForm.pdf, CopyrightTransferForm.pdf, and

Disclosure_Form.pdf
here once your article has been accepted for publication.
Certain types of manuscript submissions also require that an abstract be entered as part of the submission process. This should be typed (or copied and pasted) into the text box provided.

Once you have submitted a manuscript through the Editorial Manager system, you may check on its status at any time by logging in as an author.

PEER REVIEW AND EDITING

All manuscripts submitted to *Federal Practitioner* for consideration as feature articles, case reports, or columns are reviewed by at least 3 members of our peer-review committee. Peer reviews are conducted in a double-blind fashion, and the reviewers are asked to comment on the manuscript's importance, accuracy, relevance, clarity, timeliness, balance, and reference citation. Final decisions on all submitted manuscripts are made by the journal's editor-in-chief (or, in the event of a potential conflict of interest, a designated surrogate from the journal's Editorial Advisory Association).

Manuscripts that are accepted for publication in *Federal Practitioner* undergo editing for length, clarity, and journal style. Some material may be reworded or reordered to improve readability and eliminate redundancy, but we make every effort to retain the authors' voice and meaning. Edited manuscripts are returned to the corresponding author for approval prior to publication.

If you have any questions about the preparation or submission of your manuscript, wish to propose a specific topic, or have any other feedback, e-mail us at fedprac@frontlinemedcom.com.

Appendix H

Manuscript for submission to the *Federal Practitioner*

Application of Telehealth to Overcome Geographic Disparities in Liver Transplantation Within the Veterans Health Administration

HoChong Smith Ferguson, MS, RN, FNP-C

Michael Fuchs, MD, PhD

Kathryn Reid, PhD, RN, FNP-C, CNL

Abstract

Many centers within the Veterans Health Administration have limited access to hepatology and transplant specialists. Liver transplantation is centralized and performed at six approved VA transplant centers (VATC). Geographic disparities are associated with lower access to transplantation, decreased placement onto the national waitlist and poorer survival in Veterans residing over a hundred miles from a VATC. The aim of this study was to evaluate if telehealth (TH) can reduce the timeframe of performing liver transplant evaluations compared to usual care (UC) in Veterans referred for liver transplantation across vast geographic distances. A retrospective, descriptive, comparative analysis of electronic medical records of approximately 200 Veterans was conducted to evaluate for differences in time from referral to a listing decision using TH versus UC visits in Veterans referred for liver transplant consideration to a VATC from 10/01/2011- 9/30/2016. A total sample size (n=140) included 102 subjects in the TH group and 38 subjects in the UC group. The mean time from referral to initial evaluation in the TH group was 22 days (SD=7.0) and 23.4 days (SD=15.3) in the UC group. Mean time from referral to listing decision was 108 days (SD=55.8) in the TH group and 90 days (SD=94.6) in the UC group. The independent samples *t*-test revealed no significant differences in the mean times were detected at these specific time intervals conducted by TH or UC visits. Preliminary findings suggest that conducting transplant evaluations by TH were no different than UC. Telehealth has the potential to improve access to specialized transplant services, reduce travel burden for Veterans and increase the successful navigation across the complex transplant process in a timely manner, regardless of the site of care.

Keywords: Veterans, liver transplantation, telehealth, telemedicine

Chronic liver disease resulting in cirrhosis is the twelfth leading cause of mortality and responsible for more than 34,000 deaths per year in the United States.[1] Orthotopic liver transplantation is a procedure that replaces the entire liver either from a cadaveric or living donor. Liver transplant remains the primary curative treatment for decompensated cirrhosis, hepatocellular carcinoma, and acute liver failure.[1] An estimated 13,000 to 15,000 are currently on the national wait list and approximately 4,000-6,000 receives a liver transplant per year.[2] A current crisis exists due to the rising demand for liver transplantation exceeding the diminishing supply of organs. Veterans with cirrhosis are required to travel long distances to receive specialized access to transplantation services.

Background of the Issue

The National Organ Transplant Act was passed in the United States to address shortages in organ donation and ensure equitable access to transplantation.[3] The Organ Procurement and Transplantation Network (OPTN) strive to ensure equity and fairness; however, health disparities and barriers are well known to the transplant community and continue to impair access to liver transplantation. The United Network of Organ Sharing (UNOS) oversees the equitable allocation of organs and established a system to collect and analyze data related to national wait list trends, organ matching, and transplant outcomes.[4] The current liver allocation system is considered unequal due to the variability of organ availability within the 58 donor service areas (DSA), inconsistent listing practices, and organ utilization.[5] A Federal mandate, “The Final Rule”, requires that organ allocation should not be contingent on residence or location of the transplant center.[6] Geographic disparities persist despite prioritizing organs by medical need under the current “sickest-first” allocation system.[7] Geographic disparities continue to affect access to transplantation despite attempts to address this issue at policy levels.

Challenges within the Veterans Health Administration

The Veterans Health Administration (VHA) is the largest integrated health care system in the United States, and includes 153 medical centers and 1,400 community-based outpatient clinics and serves more than eight million Veterans yearly.[8] Centralization of specialized services is used by the VHA to increase efficiency, consolidate expertise, and minimize costs.[9] Veterans needing a liver transplant are offered specialized hepatology and transplant services from one of the six transplant centers within the entire VHA (see Figure 1). Veterans without other forms of secondary insurance are constrained to obtaining transplant care within one of these designated centers.[9]

Patients needing a transplant require successful navigation across a complicated system to fortunately undergo a liver transplant.[10] Steps include appropriate referral to a transplant center, comprehensive medical and surgical evaluation of suitability for transplantation, national waitlist registration, and survival until a donor liver becomes available.[2] Many centers within the VHA lack or have limited access to hepatology specialists. A single center VHA study revealed low referral rates in Veterans who otherwise met the American Association for the Study of Liver Diseases (AASLD) guidelines for liver transplant referral.[11] Waitlist practices vary among transplant centers and transplant access remains elusive since many patients are never placed onto the national waitlist.

Expanding the geographic distances between individuals and facilities is an unintended consequence of centralizing specialized services. Veterans residing more than a hundred miles from a VA transplant center (VATC) were found to have decreased chance of waitlist placement, lower likelihood of transplant, and increased mortality.[9] However, geographic disparities and mortality were similarly observed in nonveteran populations and patients listed at non-VATCs.

The Office of Inspection General conducted an inspection of another VATC due to allegations of inefficient processes and delays in care of Veterans referred for liver transplantation. Accusations of significant delays in primary health care services have additionally intensified debates and distrust beyond specialty care access to organ transplantation. The VHA reaffirmed its commitment to improving health care access. This included conceptualization of innovative models of health care delivery, including telehealth technology to provide Veterans health services within an appropriate timeframe.[12] Therefore, the VHA improved the transplant referral tracking system and expanded telehealth capabilities across the largest integrated health network to overcome the travel burden of Veterans needing transplantation.

Telehealth Application in Transplantation

New innovative approaches are needed to overcome current geographic disparities limiting transplant access and improve delays in care. Telehealth technology has rapidly transformed how providers connect with their patients in the delivery of health care. There is growing evidence describing the benefits of telehealth on healthcare access, quality, and costs.[13] Telehealth is defined as sharing of information to provide various clinical, educational and administrative services using telecommunications and information technologies (IT) at a distance.[14] Strategies adopting health communication and IT are gaining momentum as a model of health care delivery beyond the traditional usual care visits. The application of telemedicine is currently used in numerous clinical settings to care for patients with various chronic health conditions.[13] The interactive use of this technology would allow the exchange of clinical data required to meet the rising demand of complexities associated with managing chronic disease conditions, including advanced liver disease.

The Richmond VA liver transplant program revitalized its use of telehealth to conduct initial triage of transplant referrals, counseling, and comprehensive evaluations to facilitate successful navigation through the complex, multi-tiered transplantation process. However, the program has yet to fully integrate the use of telehealth in all pre-transplant evaluations, waitlist monitoring and in the post-transplant setting. Use of telemedicine services could serve as a potential strategy to improve timely health access to specialized hepatology care and provide transplant expertise regardless of patient location and VHA site of care. The usefulness of telehealth to increase placement onto the national waitlist, survival and positive health outcomes in this Veteran population with advanced liver disease requires further exploration.

Implications for Nursing

Telehealth is used in a variety of clinical settings to care for patients with chronic health conditions. Telehealth is viewed as a potential solution for alternative delivery of healthcare in reducing heath disparities created by geographic location.[15] There are numerous emerging applications of telehealth in various health conditions and settings reported in the literature. Telehealth models are exploring interventions to address limitations of efficiency, quality, and costs burdening our current healthcare system. Major barriers to conducting telehealth research include rapidly evolving technology and changing application across different settings complicates the interpretation of the evidence.[16] A lack of expert consensus in the evaluation of telemedicine exists due to the differences in study designs, variations in analytic methodology and outcome measures.[13] Summary of the evidence from the literature provide an improved understanding of the potential use of telehealth as an alternative strategy to improve access to healthcare. Despite the heterogeneity described, there is growing support for the application of telehealth in chronic disease management. Telehealth has the potential to provide effective, frequent and timely health care to improve health outcomes equivalent to usual care across a distance.

The changing landscape of our healthcare system, environmental factors and societal factors are all driving the wider adoption and use of telehealth.[17] The VHA's development of telehealth services also coincided with the rapid development of other clinical initiatives driven by the transforming need to expand health services to Veterans. Tailoring interventions to address existing barriers of geography using telehealth has the potential to enhance VA transplant centers to improve access and health outcomes in patients needing liver transplantation. There is supportive evidence of the interactive use of telehealth technology in other chronic disease conditions. Additionally, the VHA's prior successful expansion of telehealth services support the adoption of using this approach in managing decompensated cirrhosis to improve access across the virtual continuum from a distance. The evolving innovation of telehealth technology has transformed how providers connect and consult with patients in delivering high-quality health care. However, there is a need to clarify the effectiveness of telehealth in health outcomes in chronic disease management of advanced liver disease and in the transplant population and setting.

Methods

The study sample consisted of a convenience sample of electronic medical chart reviews of Veterans referred for liver transplant consideration at the HHM VAMC from October 1, 2011 to September 30, 2016. The National Surgery Office (NSO) transitioned to a web-based electronic transplant referral system application called TRACER. The TRACER website link is available to referring centers and VATCs located on a secured VA transplant intranet site. Dates reflecting activity and workload are tracked and recorded in TRACER from the time of referral submission. NSO assigns a unique, de-identified case number at the time of referral submission, which was used as the patient identification number. The two comparative groups consisted of initial evaluations conducted by either telehealth or usual care visits.

Veterans determined eligible for further evaluation after stable referral submission during this timeframe were included in this study. Exclusion criteria consisted of: 1) referrals that originated from the Richmond VATC; 2) emergency status referrals, including patients with acute liver failure; 3) candidates that failed to meet VATC clinical or psychosocial criteria at time of referral; 4) patients that died after referral but prior to initial evaluation; 5) patients that no longer desired transplant after referral but prior to initial evaluation; and 6) those that pursued transplantation outside the VHA after referral but before the initial evaluation; and 7) Veterans that did not meet clinical or psychosocial criteria at the time of initial evaluation. This study was approved by the McGuire Research Institutional Review Board, which included a waiver of informed consent.

Procedures

Individuals that met both the inclusion and exclusion criteria were included in the data analysis. The date of transplant referral placed into TRACER by the referring center was recorded as the date of referral. The evaluation that occurred after referral submission in those eligible for further evaluation was recorded as the date of initial evaluation. The first evaluation that was completed after the initial evaluation date in Richmond was recorded as the in-person evaluation date. Formal review and discussion of transplant candidacy occurred at the weekly selection committee. Committee decisions were documented and recorded in the minutes. This served as the date for listing decision. The listing decision was categorized as approved, deferred, or denied. Distance between the subject's residence and VATC was calculated by zip codes using the ZipCodeAPI application.[18] MELD scores and MELD Na scores at the time of referral and time of listing decision were calculated. The major contributing condition to a diagnosis of cirrhosis was recorded as the primary etiology of liver disease. Veterans with a history of primary liver cancer were coded with a dual diagnosis of having primary hepatocellular carcinoma in addition to the primary cause of cirrhosis. Data collection of sample characteristics used the initial referral date as the index point.

Variables and Measures

Demographic data of sample characteristics obtained from the patient's electronic medical record and TRACER included: 1) gender; 2) age; 3) race; 4) marital status; 5) educational level; 6) other forms of insurance; 7) zip code; 8) name of referring center; 9) primary etiology of liver disease; and 10) blood group. MELD and MELD Na scores were calculated at times of referral and listing decision. The independent variables consisted of the telehealth or usual care groups conducted at the initial evaluation. The dependent variable was the length of time from: 1) referral to the initial evaluation; 2) initial evaluation to listing decision; and 3) referral to listing decision were computed. All dates and status changes of referrals were recorded and available in TRACER. The MELD score and MELD-Na score are both statistically validated mathematical models that estimate mortality in patients listed for liver transplant.[1.19.20] The MELD and MELD Na calculations were performed using a reliable calculator available on the Organ Procurement and Transplantation Network website.[4]

Data Analysis

The sample's demographic and descriptive data were analyzed using IBM's SPSS, version 25. Descriptive statistics were used to examine the baseline characteristics of subjects in the telehealth and usual care groups for comparison. Frequencies and percentages of categorical variables were tallied. Mean and standard deviation of continuous variables were calculated. The χ^2 test was used to evaluate the distribution of categorical variables. Independent t-tests were conducted to assess for significant differences of the mean wait-times from referral to initial evaluation, initial referral to listing decision and initial evaluation to listing decision in the telehealth and usual care groups. A p-value of <0.05 was considered significant.

Results

The data were obtained from medical records of 295 Veterans referred for liver transplant consideration at the Richmond VATC spanning over five fiscal years. 211 stable referrals were deemed eligible for further evaluation. However, 25% of these referrals (n=53) were closed since candidates no longer met VATC clinical of psychosocial criteria after the initial evaluation by telehealth. Major reasons for exclusion other than failure to meet the VATC's criteria included deaths prior to evaluation, no longer desired transplantation or pursued transplant outside of the VHA. A total of 155 individuals were excluded from the data analysis. This left a total sample size of n=140 that met the predefined criteria, resulting in a cohort of 102 in the telehealth group and 38 in the usual care group. The Consort flow diagram illustrated the selection of subjects (see Figure 2). A large part of liver transplantation referrals came from centers outside VISN 6 (see Figure 3). Additionally, more than half of the total referrals received an approval for a listing decision (see Table 1).

Sample Characteristics

The majority of the participants were men with a mean age of 59 years (SD=6.9) in the telehealth group and 57 years (SD=7.1) in the usual care group. Over half were married and Caucasian. The leading etiology contributing to cirrhosis of the liver was attributed to chronic hepatitis C (HCV) infection in both groups. A detailed breakdown of the underlying primary etiology of liver disease is listed in Figure 4. Growing proportions were also diagnosed with primary hepatocellular carcinoma (TH=49%, UC=37%). More than half of Veterans referred for transplant did not have other forms of insurance coverage and resided between 101-500 miles from the VATC (TH M=549, SD=465; UC M=464, SD=420). Another quarter lived between 501-1000 miles from the VATC (see Table 2). The minimum distance travelled by Veterans was 86 miles and the maximum was 1,931 miles. The median distance was approximately 300 miles in each group. Additional demographic characteristics are listed in Table 3.

Categorical Variable Analysis

The exact 2-sided chi square test was performed on all categorical variables by telehealth and usual care groups (see Table 3). The proportion of participants in these two groups did not significantly differ by gender, race/ethnicity, marital status, educational level or blood group. There were no statistically significant differences by the primary etiology of liver disease or presence of primary hepatocellular carcinoma. No significant differences were revealed by insurance status or referrals from centers within or outside of VISN. However, there was a statistically significant difference of an approved listing decision between the two groups (p=0.007). Half of the subjects in the telehealth group were approved for listing compared to 75% of those in the usual care group who received an approval for listing.

Continuous Variable Analysis

There were no significant differences by age (p=.068) or distances (p=.306) between the two groups. The mean MELD and MELD Na scores were lower in the telehealth group (M=14.5, SD=4.7; M=15.3, SD= 5.2, respectively) compared to the usual care group (M=19.6, SD=8.9; M=20.9, SD=9.5, respectively). The MELD and MELD Na scores were also lower at the time of listing decision in the telehealth group. A two-tailed, independent samples *t*-test revealed a statistical difference in mean MELD and MELD Na scores between those in the telehealth and usual care groups at both referral (p=.002, p=.001) and time of listing decision (p=.005, p=.003). The mean time from referral to initial evaluation in the telehealth group was 22 days (SD=7.0) and 23.4 days (SD=15.3) in the usual care group. The average time from initial evaluation to listing decision in the telehealth group was 86 days (SD-55.5) and 66 days (SD=92.5) in the usual care group. The mean time from referral to listing decision was 108 days (SD=55.8) in the telehealth group and 90 days (SD=94.6) in the usual care group (see Table 4). The independent samples *t*-test revealed no significant differences in mean times at these time intervals conducted by telehealth or usual care visits.

Discussion

The VHA has expanded telehealth capabilities as a potential solution to deliver timely care due to significant delays reported across the largest health care system. Geographic disparities due to centralization of specialized services have also fueled intense criticisms regarding decreased access to transplantation. Distance from a transplant center was adversely associated with poorer survival and decreased placement onto the national waitlist.[9] Telehealth can potentially provide comprehensive pre-transplant evaluations and deliver high quality transplant services regardless of site of care. However, there were limited data regarding the use of telehealth to expedite transplant evaluations reported in the literature. The study's preliminary findings reported no statistically significant differences were associated with time from referral to an ultimate listing decision between the telehealth and usual care groups. There was insufficient evidence that evaluations conducted by telehealth were different than usual care visits.

The study results suggest that initial telehealth evaluations were better at rendering a denial decision in those that failed to meet the VATC's clinical or psychosocial criteria earlier into the referral process. A decision of approval was more likely in the usual care group. However, if the VATC brought every referral to Richmond, as was done in the past with usual care visits, approximately 50% of referrals would have been denied or deferred during the in-person evaluation. Additionally, these denial or deferred decisions would occur much later into the transplant referral process. The mean times from referral to initial evaluation were similar by group. However, the average times from initial evaluation to listing decision were substantially longer, compared to the mean times from referral to initial evaluation in both groups. Understanding factors associated with delays from initial evaluation to listing decision contributed by Veterans, referring centers or the VATC should be integrated into continuous process and performance improvements.

The majority of Veterans referred had to travel far to the VATC, with over 90% living more than 100 miles from the VATC. Almost 40% of Veterans lived over 500 miles from the transplant center. Telehealth eliminates problems associated with distance and can offer the appropriate care at the right time, therefore, increasing access to transplant care and services. Additionally, telehealth can substantially reduce time and costs associated with lodging and travel to and from the transplant center. Potential benefits of utilizing telehealth in transplant evaluations include performing routine, non-specialty required care locally; reduction in travel burden and costs to veterans and their caregivers; and increasing early communication with potential candidates and referring center providers. Application of telehealth-based evaluations may enhance screening of non-candidates that do not meet VATC criteria and avoid futile transplant evaluations. This strategy can reduce health care associated costs, curtail unnecessary utilization of specialty care and decrease bottleneck of referrals. The potential benefits of telehealth application and its direct impact on costs and efficiency of the transplant program deserves further exploration.

The demographic profile of this study was consistent with the description of the general VA population examined in other studies in respect to age, gender, race/ethnicity, etiology of liver disease and presence of hepatocellular carcinoma.[21] In the analyses evaluating MELD and MELD Na scores at the time of referral and listing decision, there was a significant difference between the two groups. A higher MELD score, which reflects the severity of the underlying liver disease, may influence the type of initial evaluation desired by the patient and may explain the significant differences between the two groups. Factors associated with perceived barriers of telehealth adoption and rejection of initial transplant evaluations by telehealth in sicker patients warrants additional investigation.

A strength of the study design included an adequate sample size with a historical control group, under real-world conditions within the VHA health system. The VHA's large, integrated electronic medical record system permitted comprehensive data collection. This descriptive, comparative study illustrated patient characteristics of Veterans with end-stage liver disease referred for transplantation. Time from referral to a listing decision was analyzed to reflect the efficiency of conducting liver transplant evaluations by a VATC using telehealth. A major strength of this study also involved close evaluation of the decisional processes of the systematic implementation of telehealth in the pre-transplant setting. Findings from this study can contribute to the development of best practices for future applications for remote waitlist monitoring or post-transplant management. Program performance of completing liver transplant evaluations based on the study's results can be incorporated into continuous quality improvement initiatives to improve the efficiency of navigating referrals to a listing decision after referral.

Limitations of this retrospective study design include selection bias and reliance on the availability and accuracy of the data.[22] A drawback of a descriptive study is the inability to draw any causal inferences.[23] Another weakness identified was a small size within usual care group compared to the telehealth group. A convenience sample limits the generalizability to other disease conditions, patient populations, and health systems. Potential biases can result from the lack of randomization that can explain no significant differences in wait times between the telehealth or usual care groups. As with any observational study, there may be unmeasured confounding variables that can threaten the internal validity of the impact of telehealth intervention which include: 1) those with more advanced decompensation of liver disease reflected by higher MELD scores would readily opt for usual care visits; 2) changes in the patterns of transplant referral and listing; 3) changes in the epidemiology of liver disease; and 4) organ policies affecting organ allocation and prioritization.

Implications for Practice

Geographic inequity resulting in long-distance travel for Veterans needing a liver transplant at one of the six VATCs has been associated with discrepancies in transplant rates and poor health outcomes.[7,9,24] Veterans with decompensated cirrhosis would benefit from increased access to specialty care and life-saving transplantation. Specialty services such as liver transplantation are highly complex and resource intensive.[25] Comprehensive counseling and initial evaluations conducted by telehealth can reduce the frequency of travel, which can be burdensome for the majority of Veterans living great distances away from the VATC. The initial findings of this study suggest that initial evaluations conducted by telehealth were not significantly different to usual care visits. Application of telehealth in chronic liver disease management within this target population is a novel approach to overcome disadvantages resulting from centralizing specialty services within the VHA. Expanding current telehealth capabilities to deliver specialized health services have the potential to improve Veterans' access and successful navigation across the multi-level transplant process in a timely manner.

Conclusion

Preliminary data suggests that it may be feasible to use telehealth-based evaluations for patients referred for liver transplant consideration across vast geographic distances. There were no differences detected in the telehealth group associated with time from referral to a listing decision compared to the usual care group. Veterans initially evaluated by telehealth were not disadvantaged in the transplant evaluation process. Additionally, telehealth may effectively identify non-candidates for liver transplant earlier into the current referral process and reduce unnecessary travel to the VATC. Telehealth has the potential to improve access to specialized transplant services, reduce travel requirements and improve the efficiency of conducting liver transplant evaluations across the complicated transplant process. Findings from this study on a larger scale can further clarify the role of telehealth in the transplant population and setting. The relationship between these findings and use of telehealth across the entire transplant process deserves further investigation.

Disclaimer: The content in this scholarly project does not reflect the views or policies of the United States Department of Veterans Affairs.

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Tables and Figures

Table 1

Overall Decision for Listing and Decision for Listing by Groups

Listing Decision	Overall N (%)	Telehealth N (%)	Usual Care N (%)	P
				0.007*
Approved	81 (57.9)	52 (51.0)	29 (76.3)	
Deferred	47 (33.6)	41 (40.2)	6 (15.8)	
Denied	12 (8.6)	9 (8.8)	3 (7.9)	

Note. * $p<0.05$ by Exact 2-sided chi-square test

Table 2

Distance by Categories

Distance (miles)	**Overall N (%)**	**Telehealth N (%)**	**Usual Care N (%)**
0 - 100	13 (9.3)	7 (6.9)	6 (15.8)
101 - 500	73 (52.1)	53 (52)	20 (52.6)
501 - 1000	36 (25.7)	28 (27.5)	8 (21.1)
1001 - 1500	13 (9.3)	10 (9.8)	3 (7.9)
>1501	5 (3.6)	4 (3.9)	1 (2.6)
Median		338	301

Table 3

Demographic Characteristics

Variable	(Telehealth Group) N=102		(Usual Care Group) N=38		*p*
	Mean (SD)	N (%)	Mean (SD)	N (%)	
Gender					.179[2]
Male		101 (99.0)		36 (94.7)	
Female		1 (1.0)		2 (5.3)	
Age (years)	59.4 (6.9)		56.9 (7.1)		.068[1]
Race /Ethnicity					.176[2]
White		59 (57.8)		27 (71.0)	
Black		27 (26.5)		5 (13.2)	
Hispanic		16 (15.7)		6 (15.8)	
Marital Status					1.0[2]
Married		72 (70.6)		27 (71.1)	
Never Married		13 (12.7)		1 (2.6)	
Divorced		13 (12.7)		10 (26.3)	
Separated		2 (2.0)			
Widowed		2 (2.0)			
Education					.571[2]
≤ High School Graduate		45 (44.1)		19 (50.0)	
> High School Graduate		57 (55.9)		19 (50.0)	
Insurance					.130[2]
None (VA Only)		52 (51.0)		25 (65.8)	
Medicare		34 (33.3)		8 (21.1)	
Private		16 (15.7)		5 (13.2)	
Referring Center					.487[2]
Within VISN		20 (19.6)		10 (26.3)	
Outside of VISN		82 (80.4)		28 (73.7)	
Etiology of Liver Disease					
HCV		65 (63.7)		26 (68.4)	.692[2]
ETOH		8 (7.8)		5 (13.2)	.339[2]
NASH		22 (21.6)		4 (10.5)	.152[2]
Other		7 (6.9)		3 (7.9)	1.0[2]
Primary HCC		50 (49.0)		14 (36.8)	.253[2]
Blood Group					.342[2]
A		37 (36.3)		8 (21.1)	
B		10 (9.8)		5 (13.2)	
AB		4 (3.9)		2 (5.3)	
O		51 (50.0)		23 (60.5)	
Distance (miles)	548.5 (464.7)		463.8 (420.1)		.306[1]

Note. SD= Standard Deviation; VA= Veterans Affairs; VISN= Veterans Integrated Service Network; HCV= Chronic Hepatitis C; ETOH= Alcohol; and HCC= Hepatocellular Carcinoma. [1]Independent samples 2-sided t-test; [2]Exact 2-sided chi-square test.

Table 4

Analysis by MELD Score and Time

Variable	**(Telehealth Group) N=102**		**(Usual Care Group) N=38**		***p***
	Mean (SD)	**N (%)**	**Mean (SD)**	**N (%)**	
Referral MELD Score	14.5 (4.7)		19.6 (8.9)		.002[1]
Referral MELD Na Score	15.3 (5.2)		20.9 (9.5)		.001[1]
Decision MELD Score	16.4 (7.9)		21.3 (9.1)		.005[1]
Decision MELD Na Score	17.0 (8.2)		22.2 (9.2)		.003[1]
Time					
Referral to Initial Evaluation	22.0 (7.0)		23.4 (15.3)		.598[1]
Initial Evaluation to Listing Decision	86.3 (55.5)		66.4 (92.5)		.219[1]
Referral to Listing Decision	108.3 (55.8)		89.8 (94.6)		.262[1]

Note. SD= Standard Deviation; MELD= Model for End-Stage Liver Disease; Na= Sodium.
[1]Independent samples 2-sided t-test.

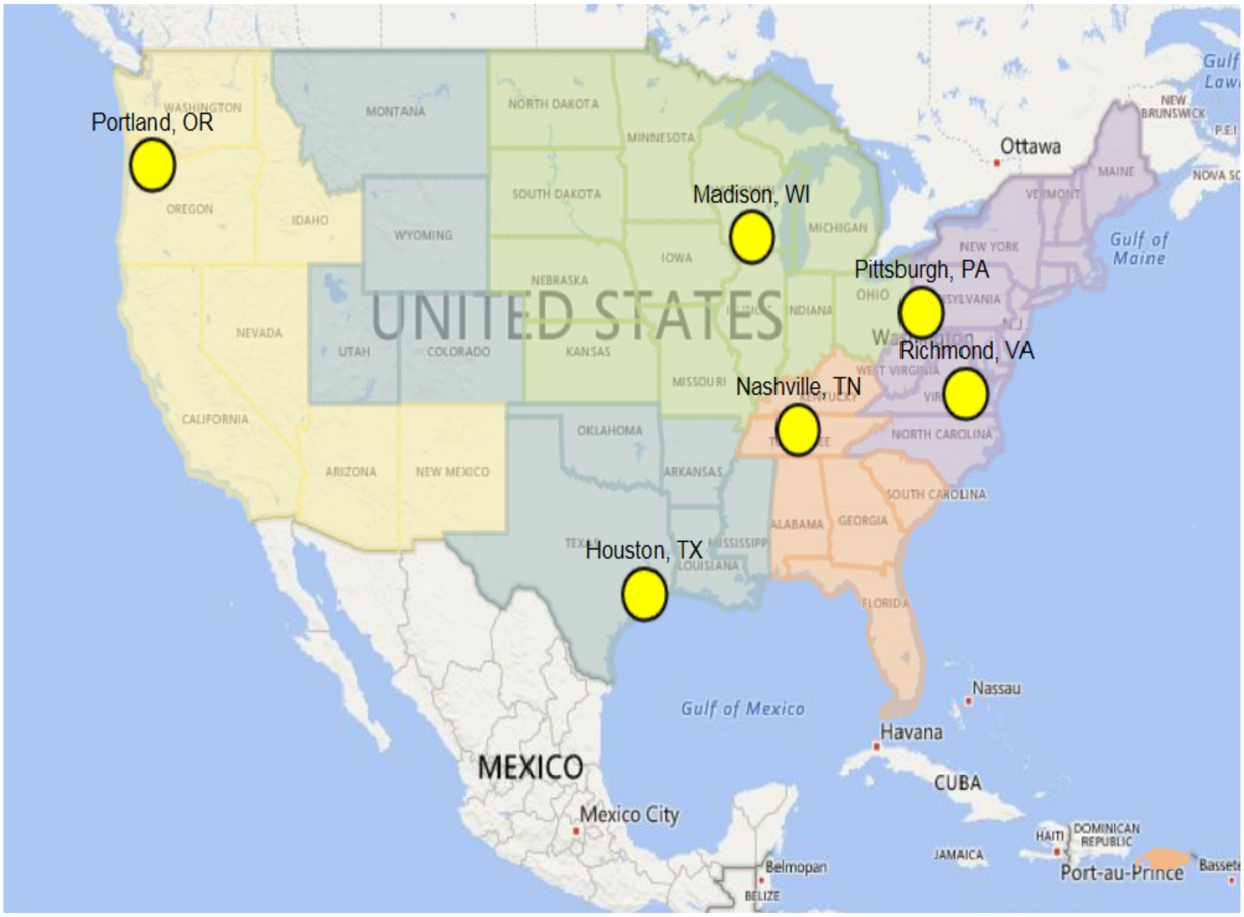

Figure 1. Map of the six liver transplant programs for the Veterans Health Administration. Retrieved from http://vaww.dushom.va.gov/ on June 23, 2017.

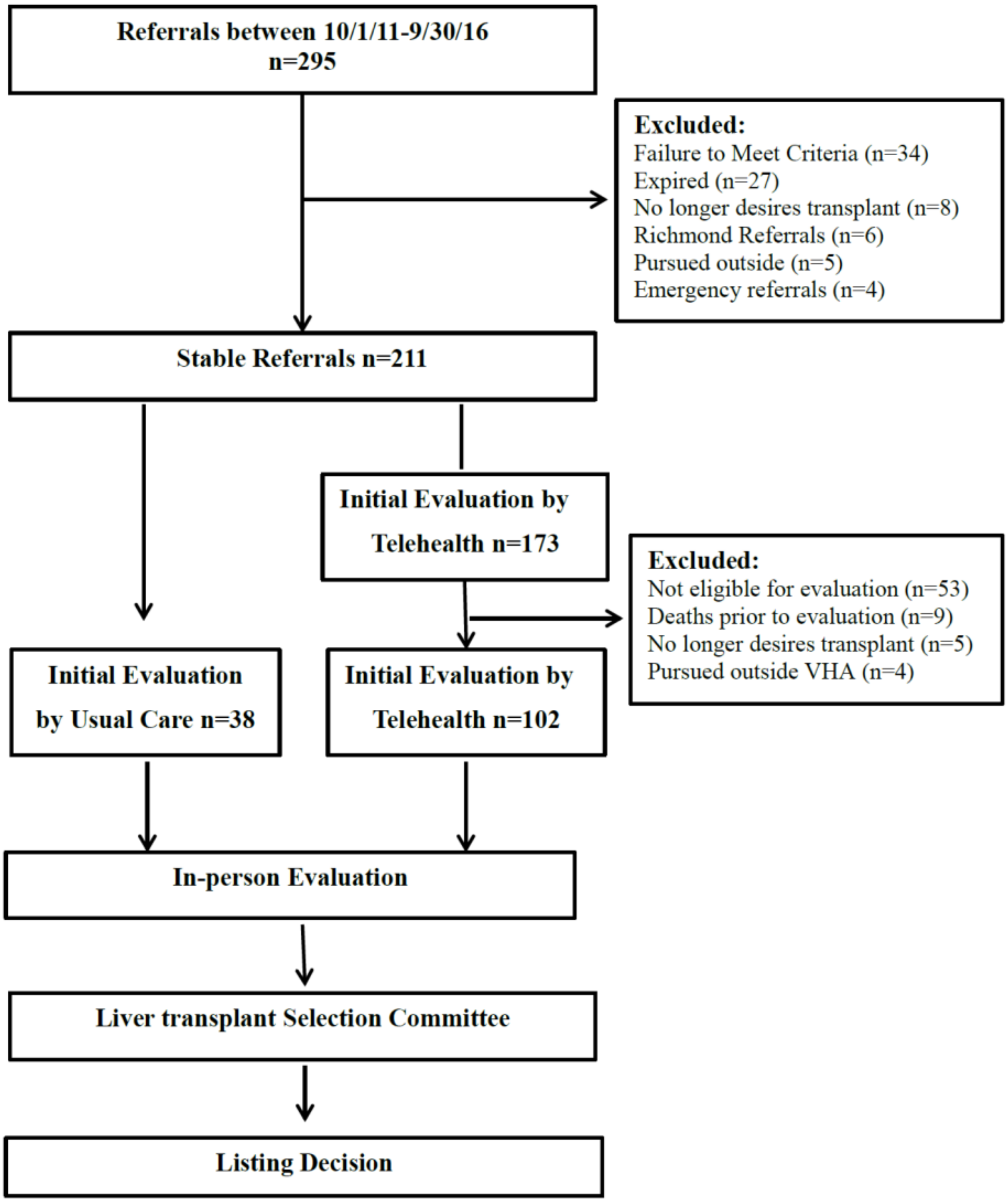

Figure 2. Flow diagram of study selection.

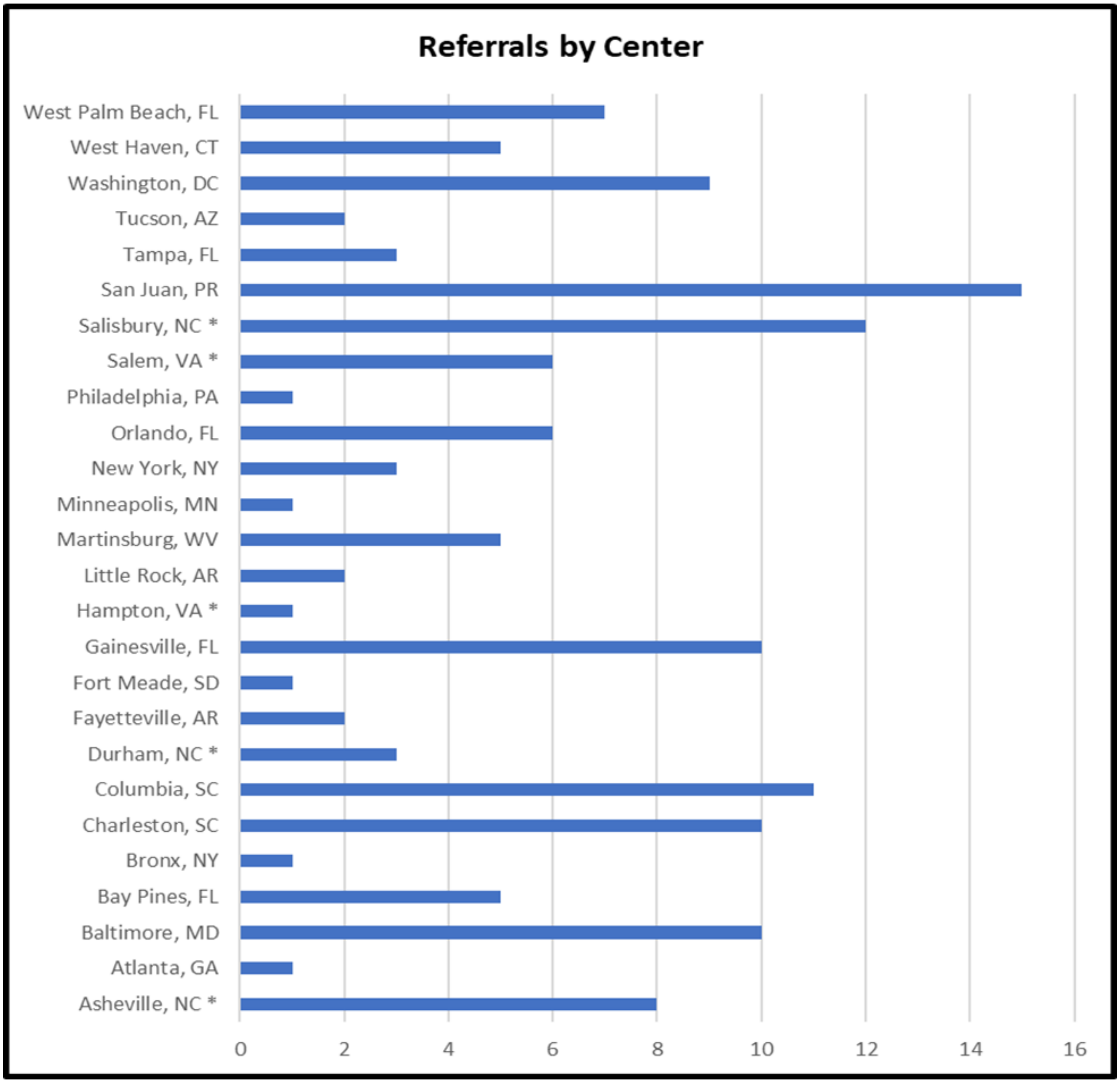

Figure 3. Location of referring centers. Centers within the Veterans Integrated Service Network (VISN) 6 of Richmond is denoted with *.

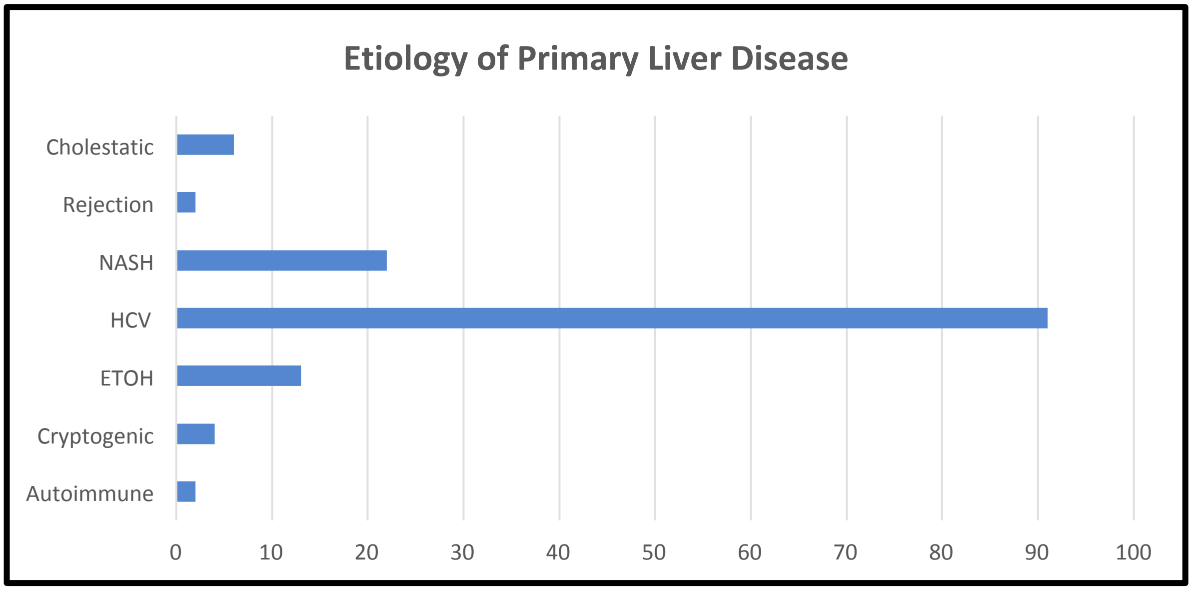

Figure 4. Etiology of primary liver disease. NASH= Non-alcoholic Steatohepatitis; HCV= Hepatitis C Virus; ETOH= Alcohol.