Title

The use of telemedicine in peripheral artery disease and limb salvage

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Authors

DiLosa, Kathryn

Gibson, Keenan

Humphries, Misty D

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ABSTRACT

Chronic limb threatening ischemia (CLT) represents the morbid end stage of severe peripheral arterial disease, with significant impact upon patient quality of life. Early diagnosis of arterial insufficiency and referral for vascular intervention is essential for successful limb salvage. Disparate outcomes have been demonstrated among patients residing in rural areas, due to decreased access to care.

Remote telemedicine outreach programs represent an opportunity to improve access to care among these rural communities. Establishment of a telehealth program requires identification of communities most in need of specialty care. After locating an ideal site, collaboration with local providers is necessary to develop a program that meets the specific needs of providers and patients.

Surgeon guidance in development of screening and management algorithms ensures that patients reliably obtain care, with adjustments as needed to suit the referring provider, the patient, and the specialist. Telehealth evaluations can limit the financial burden associated with travel, while ensuring access to higher levels of care than are available in the patients' immediate area.

Multiple barriers to telehealth exist. These include limited reimbursement, local provider resistance to new referral patterns, lack of in-person interaction and evaluation, and the inability to do a physical exam. Improved reimbursement models have made telehealth feasible, though care must be taken to ensure that practice patterns complement existing resources and are designed in a way that omits the need for in-person evaluation until the time of specialist intervention.

Telemedicine is an underutilized tool in the arsenal of vascular surgeons. Targeted telehealth programs aid in increasing patient access to expert level care, thereby improving health disparities that exist in rural populations.

Introduction

Chronic limb threatening ischemia (CLTI) describes the end stage of peripheral arterial disease (PAD) where severely diminished perfusion, often the result of multilevel arterial disease, becomes incapable of sustaining viable tissue.[1] In patients it can be characterized by pain at rest, gangrene, or non-healing ulcerations. CLTI arises in less than 20% of patients affected by PAD, and annually afflicts about 1.28% of the general population over the age of 40, representing 2 million people in the United States alone.[2,3] If left untreated, CLTI will eventually progress to amputation, an expensive and debilitating outcome that frequently results in poor functional status and a significantly reduced quality of life among affected patients.[4] Despite significant advances in available endovascular therapies, these end points have unfortunately persisted, boasting annual amputation rates as high as 20% and with 1 year mortality often exceeding 40% in those with CLTI.[4]

Overall rates of amputation are decreasing in the United States, suggesting improved outcomes with advancing treatments; however, amputation rates continue to increase within subgroups including rural communities, residents of southern geographical regions, Black and Native American populations, and persons of low socioeconomic status.[5] A recent study reviewing the 3-year outcomes following a peripheral vascular intervention, Black and Hispanic patients were found to have higher rates of amputation, reintervention, and 30-day major adverse limb events (MALE).[6] The disparities in outcomes among specific groups of patients has been observed within numerous studies deriving results from multiple data sources effectively confirming these observed trends in outcomes and thus identifying specific populations most in need of targeted efforts for limb salvage outreach.[7,8,9]

Though the disparities in these populations have been well documented, elucidating the specific source of the disparities has been more complex.[10] Prior studies propose that disparate outcomes in these populations arise due to increased rates of comorbidities such as hypertension, smoking, and diabetes.[10] For patients with evidence of CLTI, the Society for Vascular Surgery (SVS) Global Guidelines for the management of CLTI recommend initiation of best medical therapy for management of comorbid factors contributing to worsening peripheral arterial disease along with screening and prompt presentation to a vascular specialist for evaluation.[11] Unfortunately, presentation to a vascular specialist late in the progression of disease when gangrene or ulceration is present is common in the aforementioned-subgroups and is associated with higher rates of amputation than those who are evaluated sooner.[12] As health-related outcomes are often determined by access to care, improving access in person or remotely can provide patients with the specialty care required for limb salvage.[8,13] It is evident then that improving access to vascular care is essential for those at risk of limb loss related to CLTI. A targeted telehealth program represents a successful and underutilized modality to increase patient access to all types of vascular care through remote means.[14]

Defining Telehealth

For patients living in rural areas, remote consultation provides an alternate care pathway. Remote care can be achieved through telehealth services which have expanded dramatically

during the COVID-19 pandemic as a means of providing effective care to patients while minimizing the spread of disease.[15]

Telehealth comprises a spectrum of services that are offered to patients and referring providers. Figure 1. Determining the most appropriate style is dependent upon the referring provider or center, the patient, and the consulting vascular provider. Platforms can include live interactions with real time delivery of health information between a specialty provider and a patient (synchronous telemedicine) or stored and forwarded data with review and subsequent provision of care recommendations between provider and patient directly or provider to provider (asynchronous telehealth).[16] Synchronous telehealth describes models that support direct-to-consumer care through a telephone or video visit with a patient on a personal device, but can also include remote education programs in which a specialist discusses a care plan directly with a referring provider and patient. Alternatively, asynchronous telehealth includes the transfer of previously collected patient data with subsequent care recommendations offered after specialist review and can also include remote patient monitoring.

These modalities are quite effective in managing chronic health issues in patients lacking nearby care facilities. For example, the digital hypertension program through the Ochsner Health System achieved higher rates of target blood pressure control in its digital medicine program than traditional care patients at 90 days (71% vs 31%).[17] In CLTI, telehealth proves able to reach remote populations, alleviating barriers associated with cost and increased travel time to reach specialty vascular care. Furthermore, use of telehealth appears to improve visit completion with no significant differences based upon race, ethnicity, geography, or socioeconomic status.[18] Therefore, it is reasonable to conclude that telehealth services can be effective in addressing CLTI, while providing equal care across traditionally disparate populations. Though the disparities in care and resulting outcomes have been well described, the discussion of telehealth as a means of improving access and ameliorating the discrepancy in amputation rates is ongoing. The principal goal of this article was to describe the available literature and discuss our institutional experience with the use of remote telehealth outreach programs to improve access to care to lower amputation rates in disparate patient populations with CLTI.

Defining Access to Care—Targeting a site

Patients living in rural areas have long been burdened by worse outcomes in peripheral vascular disease. In unpacking the factors that specifically contribute to these disparate outcomes, it is observed that patients residing in rural locations are typically more elderly, and more likely to live in a state of poverty.[19] This population is unduly burdened by the need for travel to obtain care despite a higher rate of poverty limiting the financial resources for such travel. While experience and targeted research have both demonstrated worse outcomes in CLTI among racially and ethnically diverse patients, the populations in rural areas are overwhelmingly white and non-Hispanic, suggesting that other factors such as provider proximity may play a larger role in the adverse outcomes observed in rural populations.[19] Addressing outcomes in ethnically and racially diverse urban populations is beyond the scope of this work, though continues to be an area of ongoing research.

Ultimately, quantifying access to care is a complex challenge in vascular surgery, as access can be directly impacted through multiple factors such as location and insurance status simultaneously. In defining the role of telemedicine, the burden posed by a rural location and increasing distance from a specialty provider are the factors that can be most positively impacted. Identifying isolated regions that are most in need of targeted outreach programs is the crucial first step to establishing a telemedicine program that answers an unmet care need.

Multiple pathways have been utilized to identify rural areas that would benefit from targeted telemedicine programs. To distinguish those areas most at risk, statewide maps depicting rates of amputation have been reviewed. Alternative methods include review of Medicare databases to identify patients with a diagnosis or prior intervention for peripheral arterial diseases.
Initially, multiple sites with increased rates of amputation should be identified. In reaching out to primary care providers in the identified regions, it is possible to elicit knowledge of current practice patterns and referral pathways. It is important to appreciate that when establishing an outreach program, vascular providers are the drivers in this scenario—to successfully incorporate a telehealth practice into an existing practice paradigm, the vascular provider must assume the bulk of the effort required to establish that practice. Not all local providers are interested in adjusting their referral patterns that have been cultivated over many years of practice. In these scenarios, selecting another nearby site or fostering a better relationship with hesitant providers becomes necessary.

In addition to management of complex vascular care existing far beyond the scope of primary care providers, compensation for these primary providers is somewhat limited. The current telehealth model has seen improved reimbursements for remote services offered by the specialty provider and associated institution, but the referring provider typically obtains minimal financial benefit, if any, in this type of care model. Consequently, utilizing existing local resources becomes important to ensure local provider participation.

Establishing a Program

Once a site with decreased access to care and local provider interest has been identified, the next steps include seeking to understand the specific needs of the providers with whom a partnership is being established. This is best done with a needs assessment with stakeholders in the region. While some sites may have podiatrists or orthopedic surgeons available to manage mechanical deformities and need a partnership to provide only vascular intervention, others may lack any specialty surgical services and require the full spectrum care from initial screening and intervention to long-term wound care required for successful limb salvage. In our opinion, it falls to the limb salvage provider to evaluate the practice and offer services that complement the existing care model. In our case of UC Davis, this is headed by a vascular surgeon, but in some cases, this may be by other providers. Seeking to supplant the current local providers and model may be met with resistance. Instead, specialists should strive to collaborate with local providers toward a goal of creating a multidisciplinary care model that incorporates existing resources to best advantage. Collaboration between rural clinics and tertiary centers further creates

educational opportunities for rural providers to bring evidence-based guidelines to their communities.[20]

After ascertaining the needs and current resources of a facility, the next step is to identify a team able to provide the necessary services. Depending upon specific needs, a care team can include a wide range of possible providers, such as a dedicated wound care technician, a patient care coordinator, or a podiatrist. Some sites may employ suitable candidates, but in many cases, additional providers are needed to complete the team.

In addition to improving access to care in remote regions, telehealth can help to improve some of the financial burden associated with care for patients by limiting time off from work by decreasing time for travel and the associated costs.[21] This applies to both the patient, and the potential care giver who may also need to take time off. To limit unnecessary patient travel, it is important to design an algorithm for initial evaluation and referral that can be completed entirely remotely. At the very least a thorough history and surrogate physical exam including a vascular exam should be completed by the referring provider, along with an ankle brachial index (ABI). If there is concern about remote providers ability to perform a physical exam, then development of a surrogate testing algorithm can be used prior to any in-person specialist evaluation. It is reasonable and certainly possible to complete all encounters via phone or video prior to an intervention, limiting a patients travel needs to a single trip for surgical intervention with a specialist.

Prior experience and literature highlight the limited use of screening tools in CLTI among primary care providers. Rates of initial physical exam including a focused vascular exam are as low as 50%, and use of ABI testing as part of screening or identification of CLTI is even lower at 13%.[22] Training a team to adopt a new screening and triage algorithm may require a significant time investment initially, with ongoing refinement subsequently to meet the overall goals of the outreach program. Providers may even require specific training to support use of traditional screening tools, such as ABI testing. Many institutions do not have the ability to do toe pressures, and this should also be considered. Our own experience demonstrates that primary care providers have significant baseline knowledge deficits related to both performing and interpreting results from PAD screening tools, including ABI testing and the Wound Infection foot Ischemia (WIfI) criteria.[23] Do not assume that the providers collaborating in the establishment of a telehealth care program already have the relevant knowledge and tools in their arsenal, as this may limit the reliability of the patient data communicated during the referral process. A vital component of a successful remote telehealth program includes the ability to trust the objective data points being shared when forming a plan for care.

UC Davis Telehealth Program Experience

Establishing a successful telehealth program for limb salvage requires months or even years of time and effort from the lead provider. In our case, this is a vascular surgeon. Even once a partnership has been created, refinement of screening algorithms and treatment protocols require additional time and effort beyond the initial investment. The creation of a targeted program to provide care in the central valley of California required months/years of effort to

identify ideal sites, improve broken relationships, and additional time investments of multiple years to refine the programs into models that are feasible for providers and reliable for patients.

The process by which sites were identified included review of existing literature that described care outcomes in CLTI. These California care maps originally published in 2012 and 2013 by Goodney et al served as a guide to identify regions without adequate vascular specific care providers.[24, 25] (Figure 2) Given the lack of granularity with these, the work was replicated using California Office of Statewide Health Planning and Development (OSHPD) data. Amputation rates were mapped by patient zip code within California based Medical Service Study Areas (MSSAs). (Figure 3) Six areas were identified as possible target sites. Two sites were ultimately deemed feasible with primary care providers interested in collaborating with a new vascular surgeon to establish a targeted limb salvage outreach program for their patients. (Figure 4)

Establishment of a program starts with a complete needs assessment. For our programs, each had differing needs, ranging from the full scope of wound assessment and management to isolated revascularization and reconstructive efforts. One of our sites is a safety net hospital in a rural region of the state. For this group, an entire operations effort for wound care was created. This included development of local leadership, sharing best practice protocols, and guiding the establishment of a diagnostic algorithm, referral pathways for revascularization when indicated, and surgeon guided debridement and wound care long-term. The telehealth model here required both synchronous and asynchronous methods.

The second site included wound care providers on hand to support wound management and wanted to incorporate vascular specific interventions and foot reconstructive options to provide the full spectrum of recommended multidisciplinary care. Initial evaluation is performed by the wound care center and referral to a vascular surgeon follows appropriate screening according with an established algorithm. In those patients requiring revascularization, an elective outpatient intervention is scheduled, representing the single in-person encounter for many patients successfully managed through this pathway. Follow up is then completed remotely with telephone or video encounters and continued wound care at the patient's home care site. Tremendous success has been achieved with both models.

Barriers to Telehealth

A few significant barriers to implementation of a telehealth program have been described, including limited provider reimbursement, supplanting current referral patterns, specialist provider resistance, and patient-reported lack of personalization.

Limited opportunity for reimbursement for telehealth visits has been one of the most frequently cited barriers to use for many providers over time. Possibly one of the only benefits to come out of the recent COVID 19 pandemic, telehealth now enjoys a better rate of reimbursement than previously demonstrated. While rates still do not equal those of in-person evaluations for audio only visits, it is now feasible to establish and support a telehealth program as part of a comprehensive vascular care program that includes traditional in-person visits for local patients.

Part of establishing a successful telehealth program includes adjusting current practice patterns and referral patterns of local providers in accordance with the new pathway. Altering the existing structure can be met with resistance from the primary care and specialty providers involved. Over time, these providers have developed relationships with local specialists to whom they commonly refer their patients. In these cases, it is important to understand the provider goals to ensure that the program proposed meets the needs of both the providers and the target patient population. When encountering resistance, other sites may instead be targeted. It may also be possible to invest time interacting with the local providers to cultivate trust, which may facilitate the change in referral patterns.

The primary care providers involved may not represent the only possible source of provider resistance to a remote telehealth program. The patient relationship and developed rapport along with a physical exam continue to be a fundamental component of traditional patient encounters. Relinquishing control of the patient encounter to another provider can be disconcerting for many and trusting another provider to conduct a surrogate exam in their place leaves many surgeons feeling uncertain of the validity of that exam. Telehealth programs require a provider to more heavily rely upon non-objective measurements of disease to determine a treatment plan. However, even diagnostic studies from another facility may be subpar to the accredited vascular lab studies to which many vascular surgeons are accustomed. While this model does not represent the optimal evaluation that a surgeon might prefer, the objective data obtained is typically sufficient to design an appropriate care plan. Ongoing refinement of the diagnostic algorithm and referral process to better suit surgeon preferences can ameliorate some of these difficulties.

While some patients are comfortable with video-based interactions, many patients have cited the lack of personalization associated with telehealth encounters. While increased use of telephone and video visits to limit in-person interactions during the recent pandemic helped to dispel some of these opinions, providers are tasked with structuring interactions to reassure patients that their care is still personalized for their specific needs. It is imperative that a patient can develop trust in their surgeon even if their first in-person encounter is the day of the procedure. The telehealth model has replaced some in-person follow up in many institutions, and time may see a similar shift in initial visits to establish care. In the meantime, providers must take care to reassure a patient of the shared decision making and care goals.

While some barriers to telehealth programs may exist, all can be overcome. Flexibility and the ability to adapt as a program grows to suit the changing needs of involved parties is paramount. As vascular surgeons charged with the care of patients with CLTI, creative approaches to care to reach those outside of traditional care pathways are the next crucial steps to work towards better outcomes for these more isolated patient groups.

Conclusions

In his presidential address to the Western Vascular Society, Dr. Vincent Rowe urged all vascular surgeons to come together to consider novel and unique ways to address persistent disparities in outcomes in our patients.[26] While some technology has resulted in increasing physician

burnout, such as the electronic medical record, other tools with untapped potential exist. Telehealth is an underutilized tool in the arsenal of vascular surgeons that can bring specialty care into rural areas. Disparities in access to care and the resulting disparities in outcomes emphasize the urgent need for targeted telehealth programs to reach these isolated patient populations. The care model may differ dramatically from site to site, though the ultimate goal is the same—to improve outcomes among patients with CLTI.

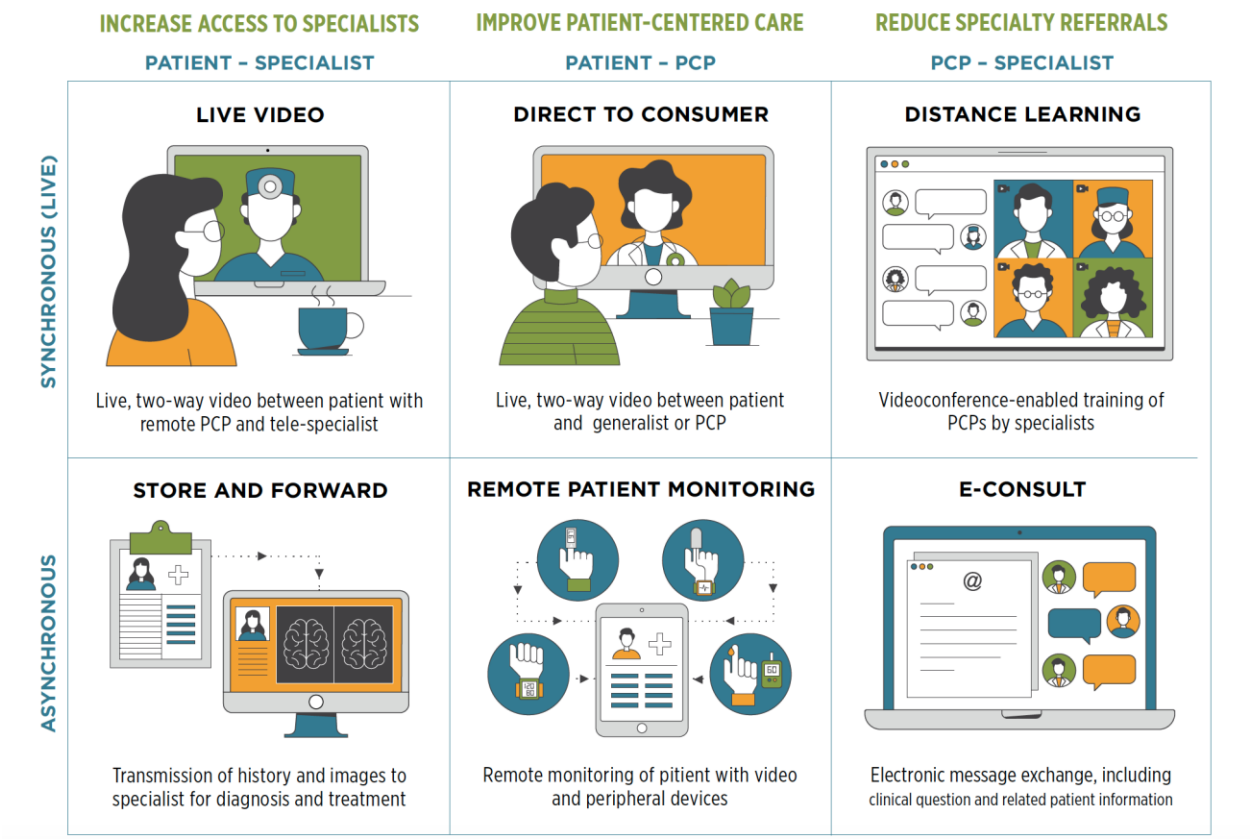

Figure 1. Center for Connected Health Policy. https://www.cchpca.org

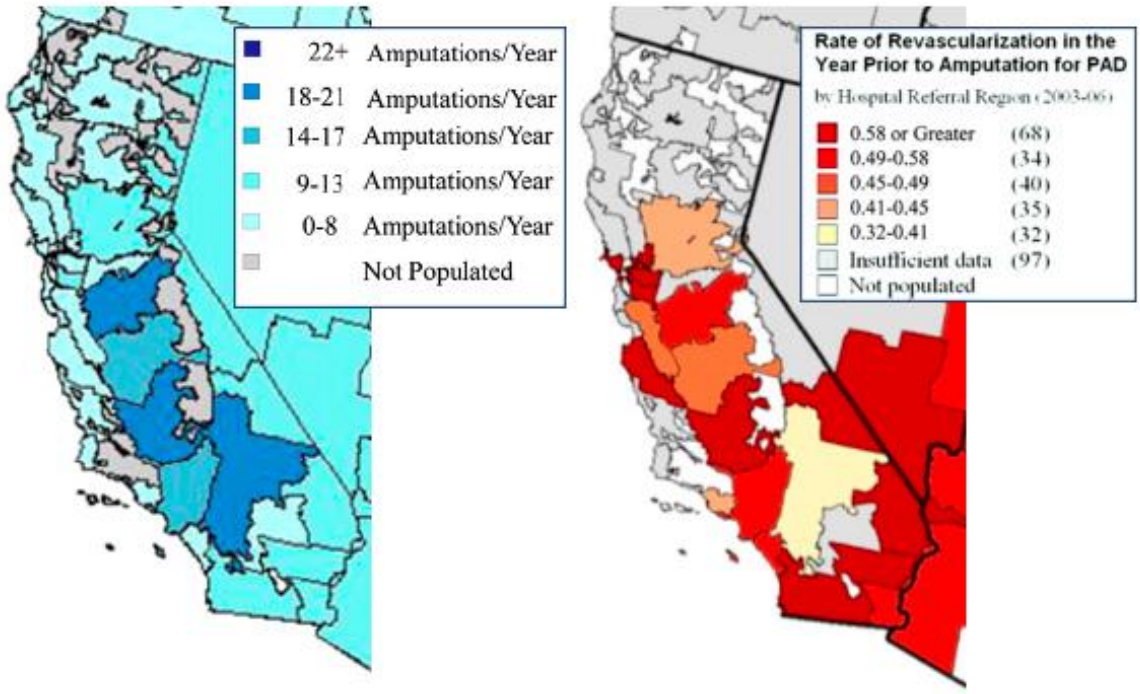

Figure 2: Amputation rates per year and rate of revascularization in the year prior to revascularization, as described by Goodney et all in 2012-2013.[24,25]

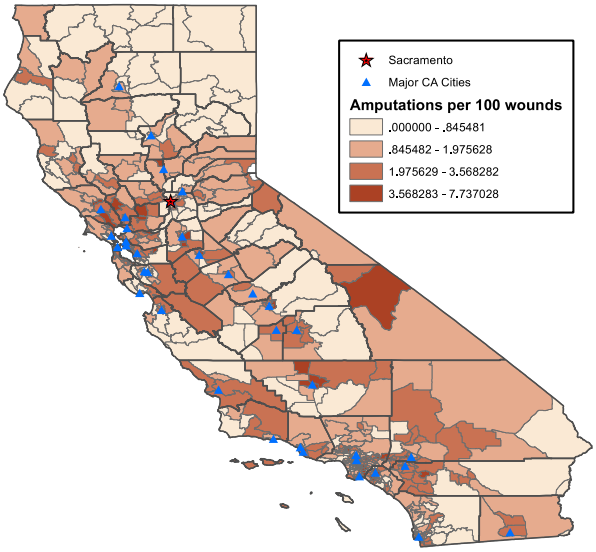

Figure 3: Amputations per 100 wounds in California Medical Service Study Areas. Unpublished, Humphries

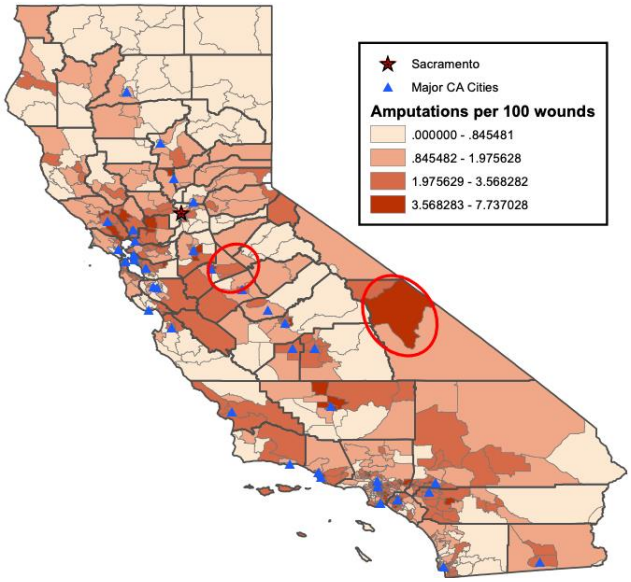

Figure 4: UC Davis telehealth partnership sites as identified by increased amputation rates within the relevant MSSA. Humphries unpublished data.

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