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The VA Telederm Study: Protocol for a Stepped-Wedge Cluster Randomized Trial to Compare Access to Care for a Mobile App versus a Workstation-Based Store-and-Forward Teledermatology Process

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The VA Telederm Study: Protocol for a Stepped-Wedge Cluster Randomized Trial to Compare Access to Care for a Mobile App versus a Workstation-Based Store-and-Forward Teledermatology Process

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DHO, MW and JCP initiated the study design and specified the trial access outcomes.

DHO and MW are leading the implementation of the intervention

ND provided statistical expertise in clinical trial design and analysis, conducted power calculations, and
designed and performed the constrained randomization

GLJ and HAK conceptualized the formative evaluation and the trial implementation framework

JDW, SBP, and ARE provided expertise with implementation and study design

DHO, MW, and JCP are grant holders

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Competing Interests
JDW declares that he receives royalties based on sales as co-editor of “Teledermatology: a User’s Guide”, Cambridge University Press 2008. GLJ reports receiving grants from the Department of Veterans Affairs, Health Services Research & Development Service, during the conduct of the study. No other authors declare any conflict of interest.
## World Health Organization data set

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<td>Volume of total dermatology encounters (instances of care) Volume and relative proportion of teledermatology consults among all dermatology encounters at the health care facility level</td>
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Abstract

Introduction. Teledermatology has emerged as an important strategy to enhance access to high quality skin care. VA Telederm is a provider-facing, web-based mobile app designed to integrate into the existing teledermatology workflow in the United States Veterans Health Administration (VHA). In this study, we will conduct a systematic evaluation of VA Telederm on access outcomes in VHA facilities using a pragmatic trial guided by clinical and operational leaders.

Methods and analysis. The study is a prospective, stepped-wedge cluster randomized trial (SW-CRT) with cross-sectional exposure and outcome measurement via retrospective database analysis of administrative records. Each cluster is a VHA facility deemed eligible for the trial. We assign the intervention using a cluster-level balanced randomization scheme based on facility size, baseline teledermatology uptake, and geographic location. The trial will test whether patients receiving dermatological care at participating facilities will have better access compared with patients receiving care through the current standard process. The primary outcomes proxy for patient-level access to dermatology services, including (1) consult completion time; (2) appointment completion time for new patients; and (3) travel distance for dermatology services. As secondary outcomes, we will assess facility-level adoption outcomes, i.e. the number of dermatology encounters and the proportion of teledermatology consults out of all dermatology encounters. To account for secular trends in outcomes and for correlation across individuals within clusters, we will assess the impact of the intervention using generalized linear mixed regression models.

Discussion: Streamlining the current practice for store-and-forward teledermatology in the VHA has the potential to improve access to expert dermatological care for thousands of Veterans. The lessons learned in this trial could validate the use of mobile technology for consultative store-and-forward dermatology in a large health care organization. The results may also be of interest to other medical specialties assessing the merits of implementing mobile telehealth.

Strengths

- stepped-wedge cluster-randomized design allows for strong causal inference
- national coverage ensures diversity of geographic settings and organizational cultures
- close partnership with clinical and operational leaders will maximize implementation

Limitations

- may not be fully generalizable to other populations and health care delivery systems
- complex process requiring buy-in from multiple stakeholders may produce variations in implementation
Introduction

Background and Rationale

With the dermatology workforce facing a persistent shortage\textsuperscript{1,2} and maldistribution of providers and services across the country,\textsuperscript{3} access to dermatology services in the United States is severely lacking. Teledermatology has emerged as an important strategy to enhance access to dermatologic care. Asynchronous or store-and-forward telehealth (SFT) teledermatology transmits still digital photographs and textual information to dermatologists who need not be present at the same time and place, while live-interactive teledermatology uses real-time video interactions to exchange medical data and skin exams. SFT teledermatology has been shown to improve access to care in diverse populations and settings, enhancing patients’ ability to receive care\textsuperscript{4,5} and increasing service timeliness.\textsuperscript{6} Besides making care more accessible, SF teledermatology may increase efficiency, thus allowing dermatologists time to provide more in-person visits to patients with more severe conditions.\textsuperscript{5,7} Teledermatology may also improve access for underserved populations, particularly by allowing providers in safety-net settings to prioritize patients with the most urgent and severe conditions.\textsuperscript{8} The few studies which have been conducted on the impact of mobile devices in provider-to-provider SFT teledermatology show significant decreases in wait times.\textsuperscript{9,10} However, these studies are limited by small sample sizes recruited from single, urban clinic locations.

Access to health services is a key priority for the Veterans Health Administration (VHA), both in terms of geographic proximity and timeliness of care.\textsuperscript{11,12} Veterans disproportionately live in rural areas, thus accentuating the problem of geographic access to specialty care,\textsuperscript{13} particularly for patients seeking care from specialty providers such as dermatologists who tend to cluster in urban metropolitan areas.\textsuperscript{2} SFT teledermatology has grown rapidly in the VHA\textsuperscript{14} resulting in enhanced access of both rural and non-rural Veterans to skin care and more timely skin disease treatment.\textsuperscript{15–17}

Despite recent improvements in overall wait times, access to dermatology remains challenging, in part due to inconsistent implementation of teledermatology in the VHA. Data from fiscal year (FY) 2016 shows wide variation in the uptake of SF teledermatology consult use, from zero to about 50 percent of all consults in a given facility. One important impediment to the adoption of teledermatology by primary care clinics may be the inefficiency of the current workstation-based process, which involves several steps performed by VHA-trained imagers before the image can be reviewed by a dermatologist.

The convenience and capability of smart mobile devices (e.g., tablet computers) to combine data acquisition (i.e., photographs) with efficient communication strategies creates significant opportunities for the VHA to streamline teledermatology practice and expand it more widely. Capitalizing on these opportunities, the VHA Office of Connected Care (OCC) developed a mobile app, VA Telederm, as a more facile option to increase SF teledermatology use among providers. VA Telederm is designed to integrate into the existing teledermatology workflow and is interchangeable with the conventional workstation-based process. Its target users are primary care providers (PCPs) and imagers, and it recapitulates the same steps that are performed by these users on workstations, but using a streamlined graphical user interface, and permits dictation of patient histories. Importantly, imagers are able to obtain or automatically transfer patient histories as well as capture skin images, and seamlessly upload images to the electronic health record using the app, instead of using a separate camera. Since no images reside on the mobile device, there is no need for imagers to perform the extra step of deleting camera images.

In this study, we will conduct a systematic evaluation of VA Telederm impact on dermatology access outcomes in VHA facilities using a clinically-driven, pragmatic trial with a stepped-wedge cluster-
randomized design (SW-CRT). To our knowledge, this is the first systematic study of teledermatology roll-out nationally, encompassing rural and urban facilities across the United States. The SW-CRT design allows for rigorous assessment of the causal impact of the VA Telederm app implementation on providers’ adoption of SF teledermatology and the associated change in patients’ access to care in a large, integrated health care delivery system. This trial will help expand the evidence base for the effectiveness of provider-facing mobile apps in improving adoption and access to care by introducing subtle to moderate gains in user-friendliness and process efficiency. The comparator in our study is the current standard of care in the VHA facilities selected for the trial, which includes regular in-person dermatology visits and workstation-based SFT teledermatology.

This paper provides the trial protocol following the SPIRIT guidelines.\textsuperscript{18,19} Given the absence of specific items in the SPIRIT guidelines for SW-CRTs, we also include more detailed items proposed in recent methodological papers on SW-CRT design, analysis, and reporting.\textsuperscript{20–22}

Primary Objective
Our primary objective is to assess the impact of the VA Telederm mobile app on consult and appointment completion times, and travel distance in Veterans seen in outpatient dermatology practice.

Secondary Objectives
Our secondary objective is to determine if the VA Telederm App affects the number of dermatology encounters (instances of care) and adoption rates of teledermatology consults in outpatient dermatology practice in the VHA.

Specific Hypotheses
The study will test two specific hypotheses:

1) The VA Telederm mobile app improves access to dermatology services among VHA patients, as measured by reduced consult completion time, appointment completion times for new patients, and travel distance for dermatology services. In addition, we measure exposure to dermatologic care by the total dermatology encounters (instances of care).

2) The VA Telederm mobile app increases the adoption of teledermatology consults in VHA dermatology clinics.

Trial Design and Study Organization
This study is a prospective, stepped-wedge cluster randomized superiority trial. VHA facilities are randomized to receive the intervention according to a constrained randomization scheme that also ensures balance in key facility-level characteristics across the study steps. Patients’ exposure to the intervention will be cross-sectional (i.e., patients are exposed when they visit a VHA facility for dermatology care) and outcome measurement will be done via retrospective database analysis of administrative records. The trial involves a partnership between VHA telehealth clinical operations, research, and implementation scientists in the VHA.
Methods and Analysis

Participants and setting
Each cluster participating in the trial is a VHA facility deemed eligible for participation, defined as having patients with at least one in-person outpatient visit for dermatology or teledermatology encounter in the VA during the course of the study. Each facility represents a VHA Medical Center providing care for a variable number of associated medical centers or clinics. The individuals receiving dermatological care at the eligible facilities, i.e. patients with at least one in-person outpatient dermatology or teledermatology encounter in the VHA during the course of the study, will be automatically included in the study and have their outcomes evaluated by retrospective, automated statistical analysis.

Eligibility Criteria
We selected 36 eligible facilities using the inclusion and exclusion criteria presented in Table 1, with the rationale for each criterion.

The Current Standard of Care
Teledermatology services are currently provided in VHA facilities using a workstation-based SFT process. This process is consultative and consists of several stages, depicted schematically in Figure 1. When a patient or the provider has a skin concern, a referring provider (typically a PCP) initiates the consult request for skin imaging in the electronic medical record, known as the Computerized Patient Record System (CPRS), which also prompts the PCP for pertinent medical history. Upon receipt of the imaging consult request, an imager trained in the VHA protocol schedules the patient for imaging and transmits information from the PCP’s consult request or, and if necessary, obtains further medical history from the patient according to a scripted set of questions that are recorded in a templated CPRS note. The imager captures images of the patient’s skin using a standard digital camera and must then manually upload the photos and link them with the patient’s CPRS record. Finally, the imager then generates a new consult request to a teledermatology reader, typically a board-certified dermatologist. This imager must then manually delete the images to ensure that the patient’s privacy is protected. The reader reviews the history and images and writes a CPRS note that includes an impression and recommendations for the PCP, who is then responsible for enacting them. A face-to-face visit may also be recommended as follow-up.

The Intervention
The intervention studied in this trial consists of three elements, deployed under the umbrella of the Replicating Effective Programs (REP) framework: 23–25

1. The VA Telederm app is the key technology at the core of the intervention. The app has been developed by a Federal contractor to be in strict compliance with VHA standards and regulations and is anticipated to be ready for national release by April 2018 by the OCC. Clinics within the participating facilities will be provided with mobile devices (i.e., tablets) which can be used to download the app and perform the new imaging process. Teledermatology leads at each facility will provide guidance on how to test it prior to use, and each provider will first have to enroll their device with the VHA Mobile Health Services. The app will be implemented at the facility level (up to five tablets will be made available at no cost to each facility, though facilities may have additional tablets due to prior inventory or purchase) and will be available to dermatology providers in a participating facility after adoption during the corresponding trial step. However, use of the app will be at the discretion of providers and imagers, and thus not all patients may have the opportunity to receive care using the new app. Screenshots of the app’s interface are included in the Appendix.
The VA Telederm app is intended to improve the existing teledermatology workflow by seamlessly integrating image capture and upload into the VHA electronic records system. The app’s target users are referring providers and imagers. The app will allow referring providers to submit consults using touch screen entries and will permit dictation of patient histories. Imagers will be able to process those consults without transcribing or copying/pasting histories and to capture and upload images to the CPRS using the app, instead of using a separate camera. Thus, while it recapitulates the various steps that are performed by these users on workstations, the app will have a streamlined graphical user interface integrating these steps for an improved workflow. Since no images reside on the mobile device, there is no need for imagers to perform the extra step of deleting camera images.

(2) Education programs and resources specifically targeted to providers involved in the teledermatology process (PCPs, imagers, and dermatologists) have been streamlined by the study team in collaboration with OCC. OCC will conduct training sessions for Telehealth Leads in each VHA Integrated Service Network (VISN) and the Facility Telehealth Coordinators (FTCs) at each facility, who will then be responsible for training teledermatology providers. These sessions will be conducted using the existing process in the VHA by which new processes of care and guidelines are introduced. The core materials used for training are included in the Appendix.

(3) Continuing support will be made available to the participating facilities to assist them with the adoption of the new process. Technical support will be provided via a 24/7 telephone hotline to assist with any app- or device-related problems encountered by the providers. Implementation support will be provided by the VISN leads during monthly calls and via email by designated OCC staff. During these calls, providers will be able to share their experiences with the new app and will receive help to address any issues they have with the new care process.

Technical Field Testing
Before national release, the app will be field-tested at the pilot VHA facilities in San Francisco, CA, Providence, RI, and Denver, CO. During this process, the VA Telederm app will be used by providers with the goal of identifying their perceptions and evaluate how they adapt to the new process. Any issues identified with either the technology deployment or the implementation at this stage will inform any modifications necessary for the national rollout of the intervention.

Formative Evaluation
To complement and inform the randomized trial, we will also conduct a mixed-methods formative evaluation in the same facilities involved in the technical pilot field-testing (i.e. San Francisco, Providence, and Denver). The evaluation will be guided by the Organizational Theory of Implementation Effectiveness (OTIE), which is based on the work of Klein and Sorra as modified by Weiner and colleagues. The goal of this evaluation will be to understand the factors that may impact the organizational readiness for change (ORC) and process of implementation, how these factors change over time, and how they are associated to successful implementation and sustainability of the app. The findings of the formative evaluation will inform the process of implementing the teledermatology apps during the randomized implementation nationally as well as the implementation of future mobile clinical applications.

Baseline Assessment. We will first identify baseline characteristics of each organization and provider teams that may impact implementation. This will be followed by an assessment of readiness to
implement teledermatology; monitoring of the implementation process and progress through bi-monthly site reports; qualitative interviews addressing implementation factors suggested by the OTIE at baseline and at 6 months following initial implementation of the teledermatology app; and qualitative and quantitative evaluation of program sustainability 1 year after the first use of the teledermatology application.

In addition to their initial roles in field-testing, the three pilot sites—San Francisco, Denver and Providence—are appropriate for evaluation since the teledermatology leadership are located at San Francisco and Providence VHA Medical Centers and Dermatology Field Advisory Council is located in Denver. These sites may have specific qualities that impact implementation. However, since they vary in terms of both organization and location, lessons learned will likely translate to the mix of other VHA facilities with dermatology programs. Differences among the three sites include: 1) San Francisco and Denver have Dermatology Services, whereas Providence has Dermatology as a section of the Medicine service; 2) San Francisco and Denver do not use dermoscopy, whereas Providence does; and 3) each facility is in a different VHA information technology (IT) administrative region.

The three sites will be asked to identify individuals directly involved in planning and execution of app implementation, whose work or clinical decision-making may change as a result of app implementation. These sites will be asked to submit information on these core implementation team members and processes and size and composition of the medical centers and impacted clinical services.

Organization Readiness for Implementing Change. Core implementation team members and clinical staff from impacted services will be surveyed using the validated Organization Readiness for Implementing Change instrument, a computer-based survey developed specifically to measure aspects of the Weiner Theory of ORC. This instrument examines perceptions of organizational-level change efficacy and commitment to newly implemented interventions. In addition, we will conduct semi-structured qualitative telephone interviews of the core implementation team and clinical staff at each site to assess ORC and factors that are hypothesized to predict ORC.

Stages of Implementation Completion. We will also measure the implementation process by monthly reports from the three sites. Implementation progress will be assessed utilizing the Stages of Implementation Completion (SIC). SIC enumerates key pre-implementation, implementation and sustainability milestones. Dates by which specific implementation milestones are reached will be identified. This information will also enable us to examine if the degree of ORC is associated with the rapidity with which sites go through implementation steps. Bi-monthly (every other month) reports will also include assessment of barriers and facilitators identified through the ORC measurement process. Bi-monthly information will be fed back to project and OCC leadership so that program adjustments can be made.

Program Sustainability. At 6-8 months following the start of the implementation process at the 3 early adopter sites, we will conduct semi-structured qualitative telephone interviews, ideally with the same individuals interviewed at baseline. The goal is to understand changes in the process of utilizing the teledermatology app and the degree of implementation over time. At one year, we will assess the sustainability of use of the mobile apps, using the Mancini & Marek Model of Community-based Program Sustainability as a conceptual guide. Specifically, we will measure the six elements essential for sustainability (leadership competence, effective collaboration, demonstrating program results, strategic funding, staff involvement and integration, and program responsivity) using a modification of the validated Program Sustainability Index (PSI).
To inform the national rollout, we will continually analyze results and provide feedback to stakeholders. Rapid analysis approaches will generate preliminary findings to share among the research team, followed by in-depth content analysis.

**Intervention Timeline**

Figure 2 illustrates the main features of our stepped-wedge design for the national rollout, using the terminology proposed by Copas et al.\(^{20}\) For national rollout, the app is targeted to sites that are clinically appropriate and best positioned to benefit from the app. The evaluation of the app will be structured as a prospective, stepped-wedge cluster randomized trial, a form of randomized incomplete block design which delivers the intervention to all participants in a staggered fashion over time. This design has a long history in statistical research\(^{36}\) but has only more recently been used for program evaluation.\(^{37,38}\) In brief, as detailed below, all participating facilities (or clusters of patients) will be randomly assigned to receive the intervention sequentially in groups of 6 facilities at the beginning of each trial step. Starting April 2018, one group will be exposed to the app, and at subsequent 3-month intervals an additional group will join the intervention until all groups are exposed starting July 2019. Unexposed cohorts at any given time will serve as controls.

**Outcomes**

The primary study outcomes serve as proxies for access to dermatology services at the *patient* level, and will be used to test specific hypothesis 1) above. Table 2 specifies the outcome measures, the sources of data, and other important variables used in the study. Specifically, using statistical techniques (presented in the Statistical methods section below) we will assess changes in:

1. Consult completion time (continuous) – the interval between the time when a dermatology consult is requested by a PCP until and when the dermatologist completes a note in the health record with his or her medical assessment.
2. Appointment completion time for new patients (continuous) – the interval between the time when a dermatology appointment is requested and when it is completed.
3. Travel distance for dermatology services (continuous) – the distance between the centroid of the patient’s ZIP code of residence and the VHA facility to which he/she is receiving care.

We will also examine measures of teledermatology adoption at the *facility* level over time, such as the number and relative proportion of teledermatology consults among all dermatology encounters. These measures will be used to test specific hypothesis 2) above.

Outcomes will be extracted from the VHA’s Corporate Data Warehouse (CDW), which is regularly updated with information from individual electronic patient records at each clinic. Data on clinical full-time equivalents (FTEs) employed in dermatology will also be extracted from the VHA’s Office of Productivity, Efficiency and Staffing (OPES) in order to monitor changes in the supply of dermatologists at the study facilities. We hypothesize the teledermatology apps will have a larger impact on Veterans who live in rural areas. Consequently, models will also be secondarily stratified on urban/rural/highly rural status based on the Rural Urban Codes assigned to the ZIP code of residence for each patient.

**Sample Size**

Our intended sample size is 16,000 individuals receiving care at the study facilities. We conducted power analyses separately for binary and continuous outcome measures under the parameters characterizing trial design. We used a level of precision $\alpha = 0.05$ (probability of a Type I error) and a minimum power level of 0.80, corresponding to probability of a Type II error $\beta = 0.20$. Our base analysis assumed
parameter values that are reasonable given preliminary exploration of data from eligible sites for FY2016.

In addition to the base analysis, we conducted sensitivity and threshold analyses in which we varied the values of the parameters of interest for which there is uncertainty, in order to determine at what combinations of parameter values we might be underpowered. Specifically, we assumed a total number of clusters $I = 36$, an average cluster size $K = 2,500$, the number of baseline measurements $B = 2$ (since we will measure two pre-rollout quarters), and an effect size $\Delta$ of 10% of the baseline mean for continuous outcomes and 10% of the baseline odds for binary outcomes, which is considered clinically meaningful but also conservative for the analysis (this effect size was varied from 5% to 30% in the sensitivity analyses). We estimated an intraclass correlation coefficient (ICC) $\rho \approx 0.1$ in the eligible sites by performing a post-estimation procedure after estimating a model with cluster-level random effects on baseline data. We used this as the base ICC value for our power calculations and varied it from 0.05 to 0.20 in our sensitivity analyses. As base values for the probability of having a teledermatology encounter we used $p_3 = 0.03$ (varied from 0.02 to 0.05). In multi-way analyses, we varied multiple parameters simultaneously in order to examine how the power to detect a treatment effect changes with more conservative assumptions. Table 3 shows the power calculated under base assumptions and selected variations in parameters.

Recruitment
The eligible facilities were contacted by the operations partner (i.e., OCC) in November 2017 to confirm their participation in the trial and to identify staff, including the Clinical Applications Coordinators (CACs) and providers, who will need training in order to implement the intervention. Moreover, each facility’s FTC and the associated overseeing VISN telehealth lead will be notified by email of the mobile app’s implementation 1-3 months prior to the implementation date assigned to their specific site. These have been and will continue to be supplemented by announcements of the app and trial during weekly national VISN lead and FTC conference calls with OCC, and monthly conference calls by OCC’s teledermatology leads with the field. The FTC, supported by the VISN leads, will be responsible for disseminating information about the app to all clinical and allied support staff and recruiting their support, including informatics and information technology staff. One month prior to implementation, a conference call will be held with the FTC and VISN telehealth leads to review the app and its implementation.

Assignment of Intervention
We used a constrained randomization procedure to assign the order in which the facilities will receive the intervention. Given the small number of clusters included in the trial, this procedure avoids the potential imbalance in critical facility characteristics across the trial steps simply due to chance. In these situations, constrained randomization has been shown to perform better in achieving baseline balance on several potential confounders than simple randomization, matching, or stratification. This procedure is described briefly below and more detail is provided in the Appendix.

We followed a two-stage procedure in a similar vein to the approach proposed by Bertsimas et al., which entails first an allocation of study units (facilities) to groups such that the difference between the groups is minimized (the optimization stage) followed by random assignment of the order in which the groups will receive the intervention (the randomization stage). Bertsimas et al. developed their procedure in the context of a parallel randomized controlled trial with multiple treatments and a small number of units in each treatment arm. To our knowledge, this is the first time this procedure is adapted to a SW-CRT. Besides balancing cluster characteristics, we also randomize clusters to the order in which they receive (the same) treatment, as opposed to different treatments. Either way, the goal of
systematically decreasing the differences between groups while preserving the random component is achieved.

Site characteristics used for the optimization stage consisted of two continuous variables and one categorical variable. Specifically, the two continuous variables were the size of dermatology practice (measured by the number of dermatology encounters in the baseline year) and the level of teledermatology activity (measured by the percentage of teledermatology consults of all dermatology appointments in the baseline year). The categorical variable was the geographic location (determined by one of the five VHA administrative regions encompassing each facility). These characteristics were chosen as they are likely to affect the implementation of the intervention and its impact on outcomes.

For example, larger facilities may have more resources for implementation and stronger incentives to increase efficiency. Similarly, facilities that are already extensively providing teledermatology may be more effective in implementing it compared to facilities with lower uptake. Finally, facilities in different geographic areas differ in their practice patterns and constraints and may have systematic differences in pre-intervention outcome trends. We also considered balancing on facility complexity level, a VHA-specific measure that indicates the relative size and complexity of clinical services and administrative structures of a given VHA treatment facility. However, because this measure is highly correlated with the number of dermatology practices at each facility, we did not end up using this measure for balancing. Nevertheless, data provided in the Appendix shows that the procedure achieved reasonable balance on this measure by virtue of balancing on dermatology practice size.

Blinding
The health care professionals (PCPs and imagers) involved in the study will not be blinded to the intervention, as it is impossible to conceal the use of the app on a mobile device compared to the current workstation workflow. The Veteran patient experiences a different imaging device depending on whether the VA Telederm app is used versus a traditional workstation and auxiliary camera, so they are also not blinded to the process. However, other than the imaging technique the consult generation process is relatively transparent to the Veteran. Furthermore, data collection will be performed passively from patient records.

Data Collection and Management
Outcomes data will be collected by the research team via automated extraction from the CDW. Data will be stored on the Department of Veterans Affairs Informatics and Computing Infrastructure (VINCI) and only accessible by the research team. VINCI is a VA Health Services Research & Development (HSR&D) resource center that provides a secure, central analytic platform for performing research and supporting clinical operations activities. The platform includes a cluster of services for securely hosting suites of databases integrated from national data sources (such as the VHA CDW). VINCI servers for data, applications and virtual sessions are physically located at the VA Austin Information Technology Center (AITC) located in Austin, Texas. AITC hosts a secure enclave of high-performance servers and high-speed storage and has multiple layers of security and disaster recovery to prevent data loss.

VINCI maintains compliance with the guidelines established by the VHA policies and regulations. VA-credentialed research staff will be granted access to the study data along with tools for analysis and reporting in the secure virtual working environment through a certified VHA network computer. This computing environment will enable uniform security standards for access, a common point of entry for all investigators who use the data, and consistent control of data quality.
Study data will be kept in accordance with the Department of Veterans Affairs Record Control Schedule 10-1. Storage and transfer of any Personally Identifiable Information (PII) or Protected Health Information (PHI) will be performed in accordance with applicable VA policies and directives, state and federal regulations, and applicable statutes including the Health Insurance Portability and Accountability Act (HIPAA). Standard data quality checks such as examination of outliers or significant changes over time will be conducted to identify potential problems with the data extracted from CDW. Analytical files will be built in the VINCI secure environment and will be analyzed on the VINCI servers. Upon completion of the research project, the study principal investigators and the VA Information Security Officer will insure that data containing sensitive, confidential information will be returned to the VA and removed from all servers, desktops, removable storage devices, etc.

Statistical Methods
We will employ data analysis strategies that account for the causal structure implied by our trial design and mitigate its potential shortcomings. Two related issues which may confound the treatment effect are the within-cluster correlation and potentially significant secular trends in the outcomes of interest given the long duration of the trial (2.5 years). In fact, the exposure of each cluster to both the control and intervention allows us to partially exploit the within-cluster variance towards estimation, which renders this type of trial less sensitive to the intra-cluster correlation coefficient. To ensure that these confounding factors are properly handled, we will analyze the data using several model specifications. This will also allow us to explicitly test some of the assumptions underlying our empirical model.

Our first analysis relies on an intent-to-treat approach, in which we will directly assess the impact of being randomized to implement the VA Telederm app on the following specialty care access outcomes: consult completion time, appointment completion time, and travel distance for VHA care. This model yields an estimate of the average effect of being randomized to receive the VA Telederm app (average treatment effect). From a policy perspective, this effect can be interpreted as the efficacy of deploying an app in real-world outpatient clinics, where overall uptake to clinical practice is likely less than 100%.

Specifically, we will estimate generalized linear mixed models of the form:

$$Y_{iqt} = F(\mu + \alpha_q + \beta_t + \theta V_{qt} + X_{iq}) + e_{iqt}$$

where

$Y_{iqt}$ is the outcome for patient $i$ in cluster $q$ treated in quarter $t$;

$\mu$ is the outcome in the first observation;

$\alpha_q \sim N(0, \phi^2)$ is the random effect for clusters (VHA facilities);

$\beta_t$ is a fixed effect adjusting for being in quarter $t$;

$V_{qt}$ is a fixed effect for whether or not facility $q$ was randomized to the intervention in quarter $t$;

$\theta$, the coefficient of interest, is the effect of the being randomized to receive the intervention on the outcome;

$X_{iq}$ are fixed effects adjusting for demographic characteristics of patient $i$ in cluster $q$, i.e. age, gender, ethnicity, and rurality; and
\( e_{iqt} \sim N(0, \sigma^2) \) is the error term for each dermatology encounter.

Depending on the distribution of the outcome variable, the function \( F(.) \) is either the identity function (for continuous, normally distributed outcomes like travel distance) or inverse gamma distribution (for highly skewed and always positive outcomes like completion times for appointments and consults and time to follow-up).

This type of model, proposed for the analysis of SW-CRTs by Hussey and Hughes, clearly involves several important underlying assumptions, such as a common underlying piece-wise secular trend across all clusters, a constant change in this common trend as a result of the intervention, and an identical correlation between two observations in a cluster irrespective of treatment and time duration between the observations. In additional models, we will relax these assumptions in order to assess whether they impact the results. For example, we will allow the secular trends to vary by strata of clusters, such as VHA administrative regions or VHA Integrated Service Networks (VISNs) (using a fixed-effect interaction between time and stratum), or even by clusters (by adding a random interaction between time and cluster, and thus allowing intracluster correlation to vary by time period). Similarly, we will test models allowing for treatment effect heterogeneity across strata of clusters or across time (using either fixed or random effects), with the important caveat that some of these models will be estimable only on data collected in time periods in which there are both treated and control clusters.

In addition to the intent-to-treat analysis, we will also assess the impact of the intervention using an instrumental variable (IV)-based two-stage residual inclusion (2SRI) procedure. In this approach, we will estimate two parameters of interest. First, we are concerned with the effect of the randomization on uptake of the apps, as a factor leading to teledermatology adoption in the sites receiving the intervention. This effect can be obtained by estimating the following first-stage model:

\[
(1) \quad \text{App}_{iqt} = \text{Logit}^{-1}(\mu + \alpha_q + \beta_t + \theta V_{qt} + X_{iqt}) + e_{iqt}
\]

Second, we are interested in the average effect of the treatment among compliers (patients who only receive the treatment as a direct result of their exposure to the intervention), referred to as the Local Average Treatment Effect (LATE). This effect better reflects the efficacy of teledermatology compared to regular practice and can be estimated using the following second-stage model:

\[
(2) \quad Y_{iqt} = F(\nu + \alpha_q + \delta_t + \text{App}_{iqt} + X_{iqt} + \hat{e}_{iqt}) + e_{iqt}
\]

where \( \hat{e}_{iqt} \) is the predicted residual from estimating equation (1).

Continuous monitoring of implementation

Implementation will also be assessed at all participating sites by monitoring intermediate milestones and quantitative indicators of implementation that are available in CDW as well as from OCC’s own telehealth database and WMS mobile device procurement program. Randomized sites, in addition to the three sites in the formative evaluation, will be asked to complete a bi-monthly implementation site report monitoring key milestones, collected electronically via the VHA intranet. Sites will be sent email reminders two weeks and one week prior to, and one week after the due date, with follow up via phone call, if necessary. Collection of these data will be descriptively summarized every quarter (3 months) to understand how rapidly sites meet key milestones as a result of the OCC implementation process, correlate the milestones to the number of patients serviced via the apps (i.e., reach), and allow for stratified analyses of main quantitative study results by degree of implementation based on reaching milestones to determine if the apps are more effective among sites that have reached more
implementation milestones. The study will not have a separate data monitoring committee, due to the low risk of the intervention and its minimal interference with patient care. Since we do not anticipate any adverse effects to be reported, a data monitoring committee is not necessary.

**Ethics and Dissemination**

**Research Ethics Approval**

The research has been approved by the Institutional Review Board (IRB) at VHA Boston (IRB Project #3069). The research components of the formative evaluation have been approved by the IRB at the VHA Durham, San Francisco, and Providence facilities. The data collected in the trial will be deidentified and since the app will be implemented within the process of care in the VHA, there will be no consent required for the participating patients.

**Protocol Amendments**

Any modifications to the protocol which may impact on the conduct of the study, including study objectives, design, patient population, sample sizes, study procedures, or significant administrative aspects will require a formal amendment to the protocol. All such amendments will be agreed upon by the study investigators and approved by the institutional review board prior to implementation and notified to the VHA OCC and HSR&D. Administrative changes of the protocol, such as minor corrections that have no effect on the way the study is conducted, will be agreed upon by the study investigators and documented in a memorandum. The IRB may be notified of these administrative changes at the discretion of the study investigators.

**Dissemination Policy**

The project team is comprised of specialist clinicians, academic researchers, and experts in implementation science. This provides the project with access to a wide range of channels for results dissemination to policy makers, researchers, and system stakeholders. The results of the study will be published in academic peer-reviewed journals and presented at professional conferences. Additionally, VHA leadership will be briefed on the study findings in order to inform future VHA policy regarding teledermatology. Communications with VHA leadership will be facilitated by two members of the research team who also serve as the clinical leads for teledermatology in OCC (DHO and MAW). No use of professional writers will be made. Only investigators involved in the study planning, design, or analysis will be eligible for authorship of study communications.

Participant level data will not be made available to the public due to privacy and confidentiality concerns, but statistical code may be shared by request from the study authors. Study investigators and approved study personnel will be the only individuals who can access the final trial dataset.

**Discussion**

**Study Impact and Importance**

At the end of the study period, the trial will document the effectiveness of mobile store-and-forward teledermatology in enhancing Veterans’ access to dermatology services. Moreover, it will produce a comprehensive understanding of the factors that lead to successful mobile telehealth implementation and adoption. The results will be of significance to the VHA as it develops and implements other mobile telehealth programs, and more generally to other healthcare organizations planning for large-scale telehealth interventions.
In particular, the study will allow us to assess whether web-based mobile teledermatology apps improve access to expert dermatology services by decreasing consult times, reducing appointment completion times for new patients, increasing instances of dermatologic care, and reducing the distance traveled by patients to receive dermatology services.

Strengths
This study has several important strengths. First, the stepped-wedge design of the trial will allow us to assess with increased confidence the causal impact of the new teledermatology intervention, by assigning the order of the intervention in a randomized fashion. Stepped-wedge designs allow clusters to be compared to other sites and to also serve partially as their own control, thus permitting us to account for outcome time-trends for each participating facility. Second, the constrained randomization scheme will ensure that imbalance in measured facility characteristics due to sheer chance will not bias the findings. This bias is an important concern in trials in which randomization is performed for a small number of clusters. Third, in contrast with previous studies which were mainly conducted on small and relatively homogeneous samples, our study includes individuals accessing care in facilities throughout the US. This includes rural and urban facilities serving patients characterized by geographic and socioeconomic diversity.

Fourth, the close partnership with clinical and operations leaders will ensure that all eligible sites receive the intervention and that clinician buy-in, which is crucial for the success of the intervention, is maximized.

Finally, the pilot testing and formative evaluation will ensure that implementation issues are addressed early by learning from the early test sites. In this way, any early issues with on-the-ground implementation can be mitigated.

Limitations
The study also has several limitations. First, implementation will likely vary by facility depending on the local culture, resources, efficacy and engagement of local leadership. Although we will conduct a formative evaluation in three facilities in order to inform the national roll-out of the intervention, it is likely that we cannot ensure uniform implementation across facilities. For example, some of the participating sites will use dermatoscopes that attach to imaging devices in order to collect high-quality photos. Since the cost of dermatoscopes is not covered by OCC or the VHA Mobile Health Services office, there will likely be some variation in the quality of the images across sites.

Second, the impact of the app will depend on the effectiveness of the education and support provided to providers and to the extent to which the providers find the new process more intuitive and easy to use. Although we have adapted previously used training materials developed by OCC, there is still potential for inconsistent dissemination and support for the app.

Finally, the implementation requires the cooperation of multiple stakeholders at the national, regional, and local level in order to ensure proper training, education, and support for providers in their adoption process. It is inevitable that some confusion or improper deployment will occur at least initially, which may affect the implementation process. Moreover, although we have allowed for three months for implementation in each facility, the possibility for longer delays still exists.
Generalizability
The study findings may not be generalizable outside the VHA, which has a different institutional structure from most other practices in the United States. The findings may also not be generalizable to health care systems outside the United States or other teledermatology mobile apps.

Acknowledgments
The authors would like to acknowledge superb administrative support from Rebecca Lamkin at VHA Boston, Andrea Grenga at VHA Providence, and Jennifer Chapman at VHA Durham. The authors would also like to acknowledge Junius Lewis for excellent facilitation of contact with the VHA Facility Telehealth Coordinators and VISN leads.
References


Figure legends

Figure 1. Current workstation-based teledermatology process in the VHA.
Figure 2. Timeline and design features for the VA Telederm SW-CRT.
Table 1. Inclusion and exclusion criteria used for selecting the participating facilities and rationale for each.

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inclusion</td>
<td></td>
</tr>
<tr>
<td>1. Located within the continental United States</td>
<td>VA facilities outside the continental US do not reliably report electronic medical record data to the CDW and/or do not have dermatology clinics</td>
</tr>
<tr>
<td>2. Greater than zero provider full-time equivalents practicing dermatology</td>
<td>Have a dermatology clinic on-site</td>
</tr>
<tr>
<td>3. Higher than 0.1% and at most 8.8% of total FY2016 dermatology encounters at the facility were for teledermatology readings</td>
<td>Already performing some teledermatology consults at baseline using the existing store-and-forward technology, but their total teledermatology encounter rates were below the median; based on prior experience, these sites were judged to be good candidates for implementing the new mobile app</td>
</tr>
<tr>
<td>Exclusion</td>
<td></td>
</tr>
<tr>
<td>Participating in pre-trial mixed-methods formative evaluation</td>
<td>Three facilities will participate in the formative evaluation, which will be conducted to inform the implementation of the mobile app; these facilities are located in Providence, RI, San Francisco, CA, and Denver, CO.</td>
</tr>
</tbody>
</table>
Table 2. Study outcome measures and data sources

<table>
<thead>
<tr>
<th>Measure/Variable</th>
<th>Data Sources</th>
<th>Coding Notes</th>
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<tbody>
<tr>
<td>Consult completion time</td>
<td>VHA CDW</td>
<td>Total time in days from consult request date to consult completed date following Pizer et al.¹</td>
</tr>
<tr>
<td>Appointment completion time for new patients</td>
<td>VHA CDW</td>
<td>Total time in days from appointment create date to appointment completed date following Prentice et al.²</td>
</tr>
<tr>
<td>Travel distance for VA care</td>
<td>VHA CDW</td>
<td>Average driving distance from the centroid of the patient’s ZIP code of residence</td>
</tr>
<tr>
<td>Number of dermatologic encounters by type (in-person vs. teledermatology)</td>
<td>VHA CDW</td>
<td>Volume of total dermatology visits, both in-person and via teledermatology (total and %); coded at facility level</td>
</tr>
<tr>
<td>Percentage of dermatology encounters by type (in-person vs. teledermatology)</td>
<td>VHA CDW</td>
<td>Volume of total dermatology visits, both in-person and via teledermatology (total and %); coded at facility level</td>
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Table 3. Key results of power calculations under base assumptions

<table>
<thead>
<tr>
<th>Number of clusters</th>
<th>Average cluster size</th>
<th>Treatment effect</th>
<th>ICC</th>
<th>Power</th>
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</thead>
<tbody>
<tr>
<td>36</td>
<td>2,500</td>
<td>OR = 1.10; p1 = 0.03</td>
<td>0.10</td>
<td>0.92</td>
</tr>
<tr>
<td>36</td>
<td>2,000</td>
<td>OR = 1.10; p1 = 0.03</td>
<td>0.10</td>
<td>0.86</td>
</tr>
<tr>
<td>36</td>
<td>1,600</td>
<td>OR = 1.10; p1 = 0.03</td>
<td>0.10</td>
<td>0.79</td>
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<tr>
<td>36</td>
<td>500</td>
<td>OR = 1.20; p1 = 0.03</td>
<td>0.10</td>
<td>0.80</td>
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Figure 1. Current workstation-based teledermatology process in the VHA.

1007x744mm (72 x 72 DPI)
Figure 2. Timeline and design features for the VA Telederm SW-CRT.

1278x625mm (72 x 72 DPI)
A. Sample Screen Shots of the VA Telederm App

1. **Initial Login**: Imager may also get an introduction and overview of the app by touching the “Tour the App” button.

2. **Pending consults list**: Imager selects patient of interest and touches “Complete Consult” button to process consult request.

3. **Imaging consent**: Imager documents patients consent to be imaged.

4. **Reader consult request order**: Imager orders request for teledermatology reader. History from PCP is automatically inserted.

5. **Photography prompt**: Imager is guided to obtain skin images.

6. **Image review**: Imager reviews photos, signs and submits consult request.
B. Full Constrained Randomization Algorithm

1. The first stage of the procedure involved an optimization method that evaluated the potential combinations in group assignments and ranked these combinations according to balance in site characteristics. Since evaluating the full set of combinations is prohibitive in terms of time and computing power (the number of combinations is \( N = \binom{36}{6} \binom{30}{6} \binom{24}{6} \binom{18}{6} \binom{12}{6} \approx 2.67 \times 10^{24} \)), we performed a simplified step-wise procedure instead, relying on the assumption that if at each iteration a group of 6 facilities is chosen that is similar to the ones that are left, then the procedure will produce 6 groups of facilities that are similar to each other.

Starting with the full set of 36 sites, we chose 6 facilities at a time, compared their characteristics with the rest of the facilities, chose the most balanced combination, and then repeated these steps an additional 4 iterations on a progressively restricted subset of the facilities obtained by excluding the facilities already selected in the previous iteration. In the last iteration, 6 sites were chosen out of the 12 remaining sites and the most balanced combination of site allocations was chosen. This method produced 6 groups of sites that were balanced in baseline characteristics.

The quantitative measures were standardized, and their means were calculated, squared, and summed to create a continuous balancing score. A regional score was also calculated at each iteration as the sum of two subscores. The first subscore was calculated from the facilities selected in that iteration as the maximum number of facilities selected from any given region minus the minimum number of facilities selected from any given region. To illustrate, if a combination selected 6 facilities from region A but zero facilities from region B, it was assigned a subscore of 6. This subscore was higher than a combination that chose 3 facilities from region A and 3 facilities from region B, which received a subscore of 0. The same subscore was calculated for the left-over facilities at that iteration to ensure that the set of combinations was not restricted too much for the following iteration. The overall regional score was first minimized, and the combination with the lowest continuous score was chosen out of all the combinations with the lowest regional score before proceeding to the next iteration.

2. The second stage involved obtaining a computer-generated list of random allocation numbers using the Stata program version 14.1 (StataCorp, LLC). These numbers were assigned to the groups of facilities allocated in stage (1). Since this involved randomly assigning an order to 6 groups of facilities, we randomly chose one order out of a total of 6! = 720 potential orderings.
C. Facilities in order of implementation step and relevant facility characteristics

<table>
<thead>
<tr>
<th>Step</th>
<th>Facility</th>
<th>Facility Name</th>
<th>District</th>
<th>Complexity</th>
<th>Visits</th>
<th>% Telederm</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>523</td>
<td>(V01) (523) VA Boston, MA</td>
<td>North Atlantic</td>
<td>1a</td>
<td>15057</td>
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<tr>
<td></td>
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<td>1.9</td>
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<td>558</td>
<td>(V06) (558) Durham, NC</td>
<td>North Atlantic</td>
<td>1a</td>
<td>19603</td>
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F. Training materials for VA providers and telehealth leads

The below description, once approved, will be posted to the Beta App Store: mobile.va.gov/app/beta/va-telederm

The Department of Veterans Affairs VA TeleDerm mobile application (app) allows VA care teams to capture and store digital images and associated clinical data to provide safe, appropriate and cost-effective teledermatology services to Veterans. The app seamlessly integrates with current Veterans Affairs consultative store-and-forward teledermatology workflow practices by packaging all the necessary teledermatology tasks for referring clinicians and imagers into a single workflow app. The app enables users to conveniently and wirelessly upload clinical history and captured images to Veterans Health Information Systems and Technology Architecture (VistA), ensuring that all members of the health care team have access to the most up-to-date records and that images will be correctly associated with the appropriate patients.

Features:

- Create and complete Computerized Patient Record System (CPRS) consults for teledermatology
- Capture and upload images to VistA Imaging. No images are stored on the mobile device.
- Verify image upload and assess image quality
- View images that have been uploaded to patients' files
- Automatically transfer information from imaging consult request to reader consult request
- Use native mobile device dictation capabilities
Overview
The Department of Veterans Affairs VA TeleDerm mobile application (app) allows VA care teams to capture and store digital images and associated clinical data to provide safe, appropriate and cost-effective teledermatology services to Veterans. The app seamlessly integrates with current Veterans Affairs consultative store-and-forward teledermatology workflow practices by packaging all the necessary teledermatology tasks for referring clinicians and imagers into a single workflow app. The app enables users to conveniently and wirelessly upload clinical history and captured images to Veterans Health Information Systems and Technology Architecture (VistA), ensuring that all members of the health care team have access to the most up-to-date records and that images will be correctly associated with the appropriate patients.

Prerequisites
To use the VA TeleDerm App, you must be a VA health care professional with credentials for the Veterans Health Information Systems and Technology Architecture (VistA). To use VA Telederm on a mobile device, you must use a government-furnished mobile device and have PIV-exemption. The intended users of the app are clinicians who refer patients for teledermatology consultation, and imagers.

Getting Oriented
Using the “Menu” and “Patient Search” functions
When you log into the VA TeleDerm App, the “Select a Patient” screen will appear, displaying a Patient Search box above a list of the names of patients you recently searched for and a list of all patients in your facility’s Computerized Patient Record System (CPRS). There are also two icons in the upper left of your screen to help you navigate the app:
- Menu (three-line icon in upper left corner)
- Search for or Select a Patient (magnifying glass icon in upper left corner) – Quickly find patients to see their consults and dermatology information.

Menu functions

- Consults: The Consults option will only appear if you are currently viewing a specific patient’s details screen. It will return you to the “Select a Patient” screen
• Notifications: The Notifications option alerts you to notifications on your patients, e.g., completed consults that you have submitted. You can make sure you are viewing the most current list of notifications by tapping **Refresh** in the upper right corner. If any new notifications have come in, they will then appear in the list. **NOTE:** To follow up on any of the notifications, you will have to search for and select the patient in the patient search function.

• Tour the App: You can view app features and screenshots in more detail

• About: A brief summary of the app

• Logout: Exits the app. All unsaved work and images will be lost.
Getting Started

FOR REFERRING CLINICIANS/PRIMARY CARE PROVIDERS – CREATING A TELEDERMATOLOGY IMAGING REQUEST

1. Select your patient
   a) In the “Select a Patient” screen, enter your patient name into the Patient Search field and tap Search. A list of patients matching your search criteria will appear below.
   b) Tap the name of the patient you would like to view. A pop-up box with the patient’s identifying information will appear.
   c) Tap Confirm Patient to go to the “Dermatology Consults” screen.

You can also search for a different patient anywhere in the app by tapping Search for or Select a Patient (magnifying glass icon).

2. Create an imaging consult request
   a) In the “Dermatology Consults” screen, tap New Imager Consult + at the upper right.
   b) The Provider & Location for Current Activities screen appears. Select Clinic Appointments or New Visit radio buttons as appropriate. If you select New Visit, scroll through and tap the appropriate clinic location.
   c) Tap Create New Visit at the bottom of the screen to go to the “Create New Consult” screen.
   d) The “Create New Consult” screen is generally self-explanatory and is similar to VA’s standardized CPRS teledermatology templates.
      o General History: The Imaging Instructions and Chief Complaint fields, and any asterisked (*) questions must be answered to submit a consult. Use Imaging Instructions to specify all anatomic sites you wish to be photographed.
      o Problem A: The Locations and How Long Ago Did This Problem Begin? must be answered to submit a consult.
      o + Add Problem: Allows you to specify additional distinct skin problems. If you add a problem in error, you can tap Remove Problem at the bottom of each problem’s history questions.
      o When entering information into a free text field, you may use your mobile device’s microphone to dictate if you want to convey a lot of history or details. The app is not specifically trained to recognize medical jargon.
   a) Once all history is entered, tap Create Consult at the bottom of the screen. You may need to scroll down to see it.
   b) In the “Sign Order” screen, review the history. If you need to revise the history, you can use the mobile device’s “Back” button to return to the “Create New Consult” screen, but you will need to re-enter all information. If the history is acceptable, enter your signature code, and tap Sign.
   c) You will return to the “Dermatology Consults” screen where you can view the pending imaging consult request you just created.
VA Telederm App

Quick Start Guide

01.08.18

FOR IMAGERS – PROCESSING A TELEDERMATOLOGY IMAGING REQUEST

1. Identify and select pending imaging consults
   a) Select the patient you wish to image
   b) In the “Dermatology Consults” screen, tap the consult that you wish to process. It will expand, and you can scroll through the consult request in the grey box. When ready, tap Complete Consult button on the right side to go to the “Provider & Location for Current Activities” screen
   c) The Provider & Location for Current Activities screen appears. Select Clinic Appointments or New Visit radio buttons as appropriate. If you select New Visit, scroll through and tap the appropriate clinic location. Tap the date and either 1) type in the date in the form MM/DD/YYYY or 2) tap the date from the pop-up calendar that appears.
   d) Tap Create New Visit at the bottom of the screen to go to the “Consult Note Properties” screen.

2. Complete the imaging consult
   a) Enter a Level of understanding – selecting Poor will not allow the consult to be submitted.
   b) Answer the “Patient understands and consents…” question. Selecting Yes will expand the template. Answer the additional questions that are part of VA’s standardized teledermatology template.

---

Consult Note Properties

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Author

Author Results

Education: The Patient Understands that:

1. Images will be placed in the VA computer system to be remotely viewed by a dermatology provider and that recommendations will be conveyed to the patient’s provider.
2. Recommendations are based solely on a review of the patient’s submitted history and photographic images.
3. A conventional in-person dermatology referral is an option, but may require additional travel and time.

Level of understanding

Comment

Yes: Patient consents to the above. No: Primary Case Provider to discuss other options with patient.

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml
c) Review the history in the Consult Reason for Request box. If any fields are blank or if you have additional information to add, you may edit the history.

d) Tap Finish at the bottom of the form. You may need to scroll down to see it.

e) In the “Sign Note” screen, review the history. If you need to revise the history, you can use the mobile device’s “Back” button to return to the “Create New Consult” screen, but you will need to re-enter all information. If the history is acceptable, enter your signature code, and tap Sign. This will generate an imager note in CPRS and complete the imaging consult.

f) You will return to the “Dermatology Consults” screen where you can view the completed imaging consult request.

3. Create the Reader Consult

a) In the “Dermatology Consults” screen, tap the consult that you just completed. It will expand to show the consult details. Tap the Create Reader Consult button. The “Create New Reader Consult” screen appears.

b) In the “Create New Reader Consult” screen, enter information as requested
c) Tap the Create Consult button at the bottom.

d) In the “Sign Order” screen, you can review the history. Enter your signature code, and tap Sign.

e) The “Reader Consults” screen appears showing the pending Reader consult request that you just created. The pending Reader consult request should also show in CPRS.

4. Capture photos of the skin

a) In the “Reader Consults” screen, tap the pending consult request that you just created. It will expand.

b) Tap Select on the right hand side of the expanded consult request. The “Capture Images” screen appears.
c) To take photos, tap the green **Take Picture** button and select Take Photo. The camera view will appear.

d) Orient the mobile device and take a photo by pressing the shutter button on the mobile device. The photo is displayed. If it is acceptable, tap **Use Photo** at the bottom right. If it is unacceptable, tap Retake at the bottom left.

e) Once you return to the “Capture Images” screen you can continue to tap **Take Picture** and repeat steps (d) and (e) as often as required.

f) In “Capture Images” screen, you can review the images as follows

   o Tap `<Previous` or `>Next` to move through the images. You can also swipe the images forward or backward.

   o Tap **Zoom in** or **Zoom Out** to adjust the size of the photo or look at an area in detail.

   o Type notes into the comment box. If you have typed in more than one comment, you can tap `<Move Forwards` or `→Move Backwards` to move through the entered comments.

   o Tap **Remove** to delete the image and comments that are currently selected.

g) Tap **Capture Image**, and a pop-up Images Uploaded box will appear, verifying that the number of images you have selected have been stored in VistA Imaging. The pending Reader consult request should now also appear in VistA Imaging TeleReader.

![Image of thumbnail list]

h) To view the thumbnails you have just uploaded, tap **View Patient Studies**.
Help and Additional Information

Additional Training Materials for the VA TeleDerm App
More resources, such as a User Manual, FAQ and Slideshow, are available at mobile.va.gov/appstore, and search for the app to access the resources.

Help Desk Information
If you need help with the VA TeleDerm App, dial 1-844-482-6624 to speak with a VA representative. The Help Desk is open weekdays from 7 a.m. to 7 p.m. CT. For TTY assistance, dial 711.

Emergencies
If you feel your information may have been compromised, contact your local VA facility to obtain the contact information for your Privacy Officer. To locate your local VA facility, visit VA’s Facility Locator: http://www.va.gov/directory/guide/home.asp?isflash=1. Note that you should never use this app in an emergency. If you encounter an emergency, call your local medical center or dial 911.
# VA Telederm User Manual

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Overview
The Department of Veterans Affairs VA TeleDerm mobile application (app) allows VA care teams to capture and store digital images and associated clinical data to provide safe, appropriate and cost-effective teledermatology services to Veterans. The app seamlessly integrates with current Veterans Affairs consultative store-and-forward teledermatology workflow practices by packaging all the necessary teledermatology tasks for referring clinicians and imagers into a single workflow app. The app enables users to conveniently and wirelessly upload clinical history and captured images to Veterans Health Information Systems and Technology Architecture (VistA), ensuring that all members of the health care team have access to the most up-to-date records and that images will be correctly associated with the appropriate patients.

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- Verify image upload and assess image quality
- View images that have been uploaded to patients’ files
- Automatically transfer information from imaging consult request to reader consult request
- Use native mobile device dictation capabilities

VA TeleDerm is available for iOS, Android and Windows operating systems, and is supported by these Internet browsers:
1. Internet Explorer 10 and higher
2. Safari 7 and higher
3. Firefox 24 and higher
4. Google Chrome 30 and higher

The app is optimized for an Apple iPad, though it will run on a variety of mobile devices.

This user manual provides an in-depth, step-by-step guide for using the VA TeleDerm App.

The Basics
How VA TeleDerm integrates with teledermatology: VA TeleDerm is an app designed to allow mobile devices to function within the framework of VA’s existing consultative multi-step store-and-forward teledermatology process that involves referring clinicians, teledermatology imagers and teledermatology readers.
1. **Initiation of teledermatology consultation:** Referring clinician identifies a patient who needs dermatologic consultation, and orders a teledermatology imaging consult request in CPRS that directs the imager what areas of skin to photograph, and that provides relevant clinical history.

2. **Completion of teledermatology imaging consult.** Imager receives the teledermatology imaging consult request, and completes the consult by responding to some imager-specific questions, and also recording the clinical history from the referring clinician. This is recorded as an imaging note in CPRS.

3. **Creation of reader consult request:** Imager orders in CPRS a teledermatology reader consult request that automatically extracts relative information from the imaging note.

4. **Image capture:** Imager photographs skin according to instructions in the referring clinician’s original imaging consult request. Images are then uploaded into VistA using VistAImaging Capture to be associated with the reader consult request; this enables the reader consult to appear on the “Read” list of VistAImaging TeleReader, visible to the reading teledermatologist. Once the imager confirms successful upload, the images must be deleted from the camera.

5. **Scheduling appointments:** Appointments for teledermatology imaging and for teledermatology reading must be separately entered in order to correctly record encounters. These are done by various staff, often Imagers.

6. **Reading:** The Teledermatology Reader views the reader consult through VistAImaging TeleReader, including clinical history and images, and writes a consult note in CPRS including impression and recommendations to the referring clinician, completing the teledermatology reader consult.

7. **Patient care:** The original referring clinician receives a view alert when the reader consult is completed, views the reader’s note in CPRS, and executes any recommendations as appropriate.

**VA Telederm limitations**

- **VA Telederm** is an app that, in its current version, is intended only to be used by referring clinicians and imagers. Therefore, **VA Telederm** enables steps 1-4 above to be performed on a mobile device. Step 5 must likely still be done on CPRS separately. The device may also assist with 6, but this has not been validated. Future versions may allow for scheduling, and for dermatologists to view consults and images as well as respond and complete reader consults.

- The use of **VA Telederm** currently necessitates separately logging in to a different program/app than CPRS. As the use of mobile devices becomes more prevalent in VA’s clinical care, separate login may not be as significant an issue.

**VA Telederm advantages**

- **VA Telederm** is also interchangeable with CPRS for steps 1-4, and possibly step 6. That is, a referring clinician may use **VA Telederm** to create an imaging consult, and
an imager may use CPRS to process that imaging consult. Conversely, a referring clinician may use CPRS to create an imaging consult request, and an imager may use VA Telederm to process that request, including capturing images. Finally, both clinicians and imagers may use VA Telederm to participate in the teledermatology process for a patient.

- When entering information in free text fields of VA Telederm, the mobile device’s built-in microphone can be used to dictate text. This can improve the efficiency of entering data, particularly for referring clinicians, when entering in detailed symptoms and other clinical history. The app is not specially designed to understand medical terminology.
- VA Telederm uses the mobile device’s built-in camera to capture images and allows the imager to complete all imaging steps with a single device. Because the app wirelessly communicates with the facility’s VistA Imaging server, there is no need for the imager to physically connect a separate camera or a camera’s storage card to a workstation to upload images.
- VA Telederm does not store images on the mobile device. All images are automatically deleted from memory when exiting the app. Thus, imagers do not need to delete images following an imaging session to ensure privacy and security of imaging data.

**Prerequisites:** To use the VA Telederm App, you must be a VA health care professional with credentials for the Veterans Health Information Systems and Technology Architecture (VistA). To use VA Telederm on a mobile device, you must use a government-furnished mobile device and have PIV-exemption. The intended users of the app are: 1) Clinicians who refer patients for teledermatology consultation, and 2) imagers.

**Touring the app** Get to know the app before you log in by taking a tour, which provides a bulleted overview of the app’s features as well as screenshots. On the bottom left of your screen, tap **Tour the App** > You will go to the first screen of the tour > To move through the tour, tap the circles at the bottom of the screen. To close the tour, tap the X in the upper right corner of your screen. **NOTE:** The app tour will still be available after you log into the app. To get to the tour after you have logged in, tap **menu** (three-line icon in the upper left corner) > A drop-down menu will appear > Tap **Tour the App**.
Designer Change all names under Recent Results, Results, Patient Orders and “Awarb, George” in the white box and on the top blue bar to “MobileAppVeteran, One” “MobileAppVeteran, Two” etc.

Change the SSN to either five leading zero’s or five leading six’s (000-00-1234 or 666-66-1234)

Change the DOB year to “1900”

Logging in Enter your VistA Username > Enter your VistA Password > Begin typing in a VA Hospital Location > A list of matching facilities will appear in a drop-down menu > Tap your VA facility > Tap Sign In > You will proceed into the app.
Getting to know the screen  When you log into the VA TeleDerm App, you will see a Patient Search feature as well as a list of patients whose records you have recently viewed. There are two icons in the upper left of your screen to help you navigate the app:

- Menu (three-line icon in upper left corner) – Access Consults, Notifications, Tour the App, About and Logout. **NOTE:** The consults option will only appear if you are currently viewing a specific patient’s details screen.
- Search for or Select a Patient (magnifying glass icon in upper left corner) – Quickly find patients to see their consults and dermatology information.
Learning about the app Tap menu (three-line icon in upper left corner) > A drop-down menu will appear > Tap About > You will go to an About screen that provides you with a brief overview of the app, its main features and the version number.

Logging out Tap menu (three-link icon in upper left corner) > A drop-down menu will appear > Tap Logout > You will be logged out of the app.

Notifications
Review notifications related to your patients’ teledermatology consults.
Viewing your notifications  Notifications are triggered when a consult is created for your patient. Tap menu (three-line icon in upper left corner) > A drop-down menu will appear > Tap Notifications > You will see a list of notifications you have received related to your patients’ teledermatology consults. The notifications show you:

- Patient Name – Patients’ last and first name and the last initial and last 4 SSN digits.
- Location
- Urgency – This will default to routine. To change, tap the bar under the heading > A drop-down menu will appear > Tap the level or deadline you would like to select.
- Alert Date/Time – Date and time the alert was created.
- Message – Notes on the status of the consult.
- Forwarded By/When – Name of provider/reader/imager, if the message was forwarded.

You can make sure you are viewing the most current list of notifications by tapping Refresh in the upper right corner. If any new notifications have come in, they will then appear in the list.

**NOTE:** To follow up on any of the notifications, you will have to search for and select the patient in the patient search function.

**Search for or Select Patients**

Quickly find and select patients to view their dermatology information.
Searching for and selecting patients When you log into the VA TeleDerm App, you will arrive at the Select a Patient screen. You can also get to the search and select feature at any time by tapping Search for or Select a Patient (magnifying glass icon). NOTE: If you are already viewing a patient’s records, you can select a new patient at any time by tapping the magnifying glass icon > You will see a Patient Search box, and underneath you will see the names of patients you recently searched for and a list of all patients in CPRS at your facility. If you immediately see the name of the patient whose records you will like to view, you can tap the name of the patient. If you need to search for the patient you would like to view, type in the patient’s first and/or last name in the bar underneath the Patient Search heading > Tap Search > A list of patients matching your search criteria will appear below > Tap the name of the patient you would like to view > A pop-up box with the patient’s identifying information will appear > Tap Confirm Patient to go to the patient’s Dermatology Consults screen.

Understanding a patient's screen After you search for a patient, you will first arrive at the patient’s Dermatology Consults list screen. In the upper left corner, you will see the patient’s identifying information including patient name, date of birth (DOB), age, gender and social security number (SSN).
The screen is divided into two panes. On the left pane, you will see the total number of consults in parenthesis next to Results, a Refreshed button and a list of filters to help you narrow down or expand your search. On the right pane, you will see a list of dermatology consults. To change the type of list you would like to view, tap the List heading > A drop-down menu will appear > Tap one of the following lists:

- **Dermatology Consults** – View a list of complete or in-progress teledermatology consults for providers and imagers, complete a consult, create a new imager consult or create a reader consult.
- **Reader Consults** – View a list of reader consults, and capture and upload images.
- **Patient Orders** – View a list of patient orders, and edit or sign orders that have not yet been released.
- **Patient Studies** – View images that have been uploaded to VistA Imaging.

**Dermatology Consults**

See or complete a patient’s dermatology consults and create a new imager or reader consult.

**Accessing and filtering a patient’s dermatology consults** First search for and select a patient. If not already selected, tap the List heading > A drop-down menu will appear > Tap **Dermatology Consults**. The Dermatology Consults screen will be divided into two panes: status filter options on the left and the list of consults on the right. To use the status filters, tap the checkbox(es) next to any or all of the following statuses:
Tap **Refreshed** (circle with two arrows), and the list of consults in the right pane will adjust based upon the criteria you selected. The list provides you with an overview of the consult information:

- **Date** – Date consult was created.
- **Description** – Type of consult.
- **Status** – Current status of the dermatology consult.
- **IEN** – Internal entry number assigned to the consult request.

**Creating a new imager consult**

This is the first step in the teledermatology process. Referring clinicians/primary care providers can create new consults and send them to imagers. First search for and select a patient. On a patient’s Dermatology Consults screen, tap **New Imager Consult+** > Enter the following information:

- **Encountered Provider Results** – The name will default to the provider who requested the consult. To change the name, tap the bar under the heading > A drop-down menu will appear > Tap the name of the provider you would like to select.

- **Select Location Type** - Tap the circle next to the location type:
  - **Clinic Appointments** – Under Select a Clinic Appointment, tap on the specific clinic appointment you would like to complete > The selected hospital admission will have a checkmark next to it and the background will be light blue > Tap **Select Clinic Appointment**.
  - **Hospital Admissions** – A list of hospital admissions will appear > Tap the specific hospital admission you would like to complete > The selected hospital admission will have a checkmark next to it and the background will be light blue > Tap **Select Hospital Admission**.
  - **New Visit** – Under Visit Location, tap the specific type of appointment you would like to complete > Under Date of Visit, tap the date, and either 1) type in the date in the form MM/DD/YYYY or 2) tap the date from the pop-up calendar that appears > Tap **Create New Visit**.
You will go to the Create New Consult screen where you will see logistical information, general history and problems. Fill out the following information:

- **Consult to Service/Specialty** – The service/specialty will default to the title chosen when the clinician created the original consult. To change it, tap the bar under the heading > A drop-down menu will appear > Tap the service/specialty you would like to select.
- **Patient Will Be Seen** – Tap the circle next to either Outpatient or Inpatient.
- **Attention Results** – Tap the bar under the heading > A drop-down menu will appear > Tap the name of the person who should be alerted as to the results of the consult.
- **Clinically Indicated Date** – The date will default to the current date. To change it, tap the date and type in the form MM/DD/YYYY.
- **Urgency** – This will default to routine. To change, tap the bar under the heading > A drop-down menu will appear > Tap the level or deadline you would like to select.
- **Place of Consultation** – This will default to the location that was chosen when the consult was created. To change it, tap the bar under the heading > A drop-down menu will appear > Tap either Consultant’s Choice or Emergency Room.

For General History, you are required to fill out the first section of the patient’s health history. Enter information by:

- Typing in your comment. You may also dictate by tapping on the microphone symbol on the keyboard.
- Tapping a circle or checkbox next to the information that corresponds to your patient.
- Tapping the image of a family member on a family tree.

For Problems, you are required to enter at least one problem and its location on your patient’s body. Enter information by:

- Typing in your comments or by dictating if the mobile device has a built-in microphone.
- Tapping a circle or checkbox next to the information that corresponds to your patient.
- To add another problem, tap **+Add Problem**, and a new field will appear where you can enter the additional information.
- To edit problem information, tap the problem you want to edit (e.g., **Problem A**, **Problem B**, etc.) > The problem will appear below, and edit as you would normally.
- To remove a problem, tap the problem you want to delete (e.g., **Problem A**, **Problem B**, etc.) > The problem will appear below > Tap **Remove Problem**.

Tap **Create Consult** > Review the order information > Under the Electronic Signature Code, type in your name > Tap **Sign**.
Completing a teledermatology imaging consult

Teledermatology imaging consult requests from clinicians are processed by imagers who have been trained according to protocols established by Office of Connected Care / Office of Health Informatics. The section is intended to be used during an appointment with a patient.

First search for and select a patient. From the Dermatology Consults screen, tap a pending consult in the Dermatology Consult list > Full details about the consult will expand below > Tap Complete Consult > You will go to a Provider & Location for Current Activities screen > You will see a list of clinic appointments > Enter xxx

- Encounter Provider – Type in the first or last name of a provider > Tap Search
- Encountered Provider Results – The name will default to the provider who requested the consult. To change the name, tap the bar under the heading > A drop-down menu will appear with a list of names > Tap the name of the provider you would like to select.
- Select Location Type - Tap the circle next to the location type:
  - Clinic Appointments – Under Select a Clinic Appointment, tap on the specific clinic appointment you would like to complete > The selected clinic appointment will have a checkmark next to it and the background will be light blue > Tap Select Clinic Appointment.
  - Hospital Admissions – A list of hospital admissions will appear > Tap the specific hospital admission you would like to complete > The selected hospital admission will have a checkmark next to it and the background will be light blue > Tap Select Hospital Admission.
  - New Visit – Under Visit Location, tap the specific type of appointment you would like to complete > Under Date of Visit, tap the date, and either 1) type in the date in the form MM/DD/YYYY or 2) tap the date from the pop-up calendar that appears > Tap Create New Visit.
You will go to a Consult Note Properties screen > Fill out the form to create the appointment:

- **Progress Note Title** – The note title will default to the one chosen when the consult was created. To change it, tap the bar under the heading > A drop-down menu will appear > Tap the title you would like to select.
- **Date of Note** – The date will default to the current date. To change it, tap the date, and type the date in the form MM/DD/YYYY.
- **Author** – Type in the first or last name of a provider > Tap Search > XXX
- **Author Results** – The name will default to the provider who requested the consult. However, you can change the name by tapping the bar under the heading > A drop-down menu will appear with a list of names > Tap the name of the provider you would like to select.

Read the education section to your patient to inform him or her about the background and process of teledermatology care > Record your patient’s understanding by:

- **Level of understanding** – Tap the bar under the heading > A drop-down menu will appear > Tap the applicable description.
- **Comment** – If desired, type in any information about your interaction with the patient.
- **Patient consent** – Tap the circle next to either Yes or No. If you selected yes, a drop-down survey will appear > Ask your patient the questions, and record the answers by either tapping a checkbox or circle or typing in comments.

Tap **Finish** > Review the note > Under the Electronic Signature Code, type in your name > Tap **Sign**.
Creating a reader consult  Imagers can create a consult to send to readers. First search for and select a patient. From the Dermatology Consults screen, tap a completed consult in the Dermatology Consult list > Full details about the consult will expand below > Tap Create Reader Consult > You will go to a Create New Reader Consult screen > Fill out the form to create the appointment:

- Consult to Service/Specialty – The service/specialty will default to the title chosen when the clinician created the original consult. To change it, tap the bar under the heading > A drop-down menu will appear > Tap the service/specialty you would like to select.
- Patient Will Be Seen – Tap the circle next to either Outpatient or Inpatient.
- Attention Results – Tap the bar under the heading > A drop-down menu will appear > Tap the name of the person who should be alerted as to the results of the consult.
- Clinically Indicated Date – The date will default to the current date. To change it, tap the date, and type in the form MM/DD/YYYY.
- Urgency – This will default to routine. To change it, tap the bar under the heading > A drop-down menu will appear > Tap the level or deadline you would like to select.
- Place of Consultation – This will default to the location that was chosen when the consult was created. To change it, tap the bar under the heading > A drop-down menu will appear > Tap either Consultant’s Choice or Emergency Room.
- Provisional Diagnosis – > Tap Lexicon

Tap Create Consult > Review the order information > Under the Electronic Signature Code, type in your name > Tap Sign > You will go to a Reader Consults screen where you can view the consults sent to readers and capture and upload images. (For detailed instructions, visit the Reader Consults section.)

Reader Consults
Imagers can create consults for readers, and take and upload photos.
For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml
• Specialty  
• Proc/Event  
• Image Description  
• Controlled Image  

Tap Take Picture > Depending on the device you are using, choose and upload an image file saved on the device you are using to access the VA TeleDerm App > The selected image will appear in a preview within the Capture Image screen > If desired, you can:

• Tap Take Picture again to upload more photos > If you have uploaded more than one image, you can tap <Previous or >Next to move through the uploaded images.
• Tap Zoom In or Zoom Out to adjust the size of the photo or look at an area in detail.
• Type notes into the comment box. If you have typed in more than one comment, you can tap Move Forwards or Move Backwards to move through the entered comments.
• Tap Remove to delete the image and comments that are currently selected.

Tap Capture Image > A pop-up Images Uploaded box will appear, verifying that the number of images you have selected have been stored in VistA. To close the pop-up box and remain on the Capture Images screen, tap Close. To view the thumbnails you uploaded, tap View Patient Studies.
Patient Orders

Review, sign and edit patient orders.
Viewing patient orders

First search for and select a patient. From the Dermatology Consults screen, tap the List heading > A drop-down menu will appear > Tap Patient Orders > You will see a list of orders with the following information:

- Order Date – Date the order was created.
- Order – Description of the order.
- Provider – Name of the provider who created the order.
- Status – Current status of the dermatology consult.
- Location – Area of medicine.

Tap on the consult you would like to view > The details for the order will expand below.

Signing patient orders

First search for and select a patient. From the Dermatology Consults screen, tap the List heading > A drop-down menu will appear > Tap Patient Orders > You will see a list of orders > Tap the order you would like to sign, and the details for the order will expand below > Tap Sign Order > Review the order information > Under the Electronic Signature Code, type in your name > Tap Sign or tap Cancel to return to the Patient Orders screen.

Editing patient orders

First search for and select a patient. From the Dermatology Consults screen, tap the List heading > A drop-down menu will appear > Tap Patient Orders > You will see a list of orders > Tap the order you would like to edit, and the details for the order will
expand below > Tap **Edit Order** > You will go to a Provider & Location for Current Activities screen > Edit the following information as needed:

- **Encounter Provider** – Type in the first or last name of a provider > Tap **Search**
- **Encountered Provider Results** – The name will default to the provider who requested the consult. To change the name, tap the bar under the heading > A drop-down menu will appear with a list of names > Tap the name of the provider you would like to select.
- **Select Location Type** - Tap the circle next to the location type:
  - Clinic Appointments – Under Select a Clinic Appointment, tap on the specific clinic appointment you would like to complete > The selected hospital admission will have a checkmark next to it and the background will be light blue > Tap **Select Clinic Appointment**.
  - Hospital Admissions – A list of hospital admissions will appear > Tap the specific hospital admission you would like to complete > The selected hospital admission will have a checkmark next to it and the background will be light blue > Tap **Select Hospital Admission**.
  - New Visit – Under Visit Location, tap the specific type of appointment you would like to complete > Under Date of Visit, tap the date, and either 1) type in the date in the form DD/MM/YYYY or 2) tap the date from the pop-up calendar that appears > Tap **Create New Visit**.

You will go to an Edit Order screen > Type in any additional notes into the order box > Tap one of the following

- **Cancel** - Return to the Patient Orders screen.
- **Save Changes** - A pop-up Order Updated box will appear > Tap **Close** to return to the Patient Orders screen, or tap **Sign** to continue and sign the order.
- **Sign Order** - Complete the order. Under the Electronic Signature Code, type in your name > Tap **Sign**, or tap **Cancel** to return to the Patient Orders screen without signing.

**Patient Studies**

See images that have been uploaded to patients’ files.
Viewing patient studies Currently, the target users for VA Telederm are referring clinicians/primary care providers and certified imagers in VA. While dermatologists can also use the app to view which consults are pending or completed, the app does not permit a review of the submitted images, and VA Telederm should not be used to complete teledermatology reader consult requests. Reading and completion of teledermatology reader consult requests should continue to be done using VistA Imaging TeleReader until further notice.

Help and Additional Information

Additional Training Materials for the VA TeleDerm App More resources, such as a Quick Start Guide, Slideshow and FAQs, are available at mobile.va.gov/appstore, and search for the app to access the resources.

Help Desk Information If you need help with the VA TeleDerm App, dial 1-844-482-6624 to speak with a VA representative. The Help Desk is open weekdays from 7 a.m. to 7 p.m. CT. For TTY assistance, dial 711.

Emergencies If you feel your information may have been compromised, contact your local VA facility to obtain the contact information for your Privacy Officer. To locate your local VA facility, visit VA’s Facility Locator: http://www.va.gov/directory/guide/home.asp?isflash=1. Note that you should never use this app in an emergency. If you encounter an emergency, call your local medical center or dial 911.
Appendices

Appendix #1: Project References
This app was developed according to an approved concept paper. The app was tested in a demo environment to ensure optimal functionality.

Appendix #2: Glossary
App – An application, or software program, that can be accessed through a website or mobile device and is designed to fulfill a particular purpose.

CPRS – Computerized Patient Record System

DoD – Department of Defense

DS Logon (Department of Defense Self-Service Logon) – A secure logon ID, created by the Department of Defense (DoD), that verifies the identities of individuals affiliated with DoD or the Department of Veterans Affairs (VA) and allows them to access secure websites and digital resources across DoD and VA using a single username and password.

**DS Logon Level 1 (Basic) Account:** Provides limited access to website features

**DS Logon Level 2 (Premium) Account:** Offers the highest level of access to website features. (NOTE: You must have a DS Logon Level 2 (Premium) Account to use VA’s Mobile Apps.)

IEN – Internal entry number

VA – Department of Veterans Affairs

**VA Mobile Health** – An initiative that aims to improve Veterans’ health by providing technologies to expand care beyond the traditional office visit and that includes the creation of secure mobile apps to leverage the popularity of wireless technologies to support Veterans, Caregivers and VA care teams [More at: mobilehealth.va.gov]

VHA – Veteran Health Administration

VistA – Veterans Health Information Systems and Technology Architecture) - VA’s computerized patient record system.
### SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents

<table>
<thead>
<tr>
<th>Section/item</th>
<th>Item No</th>
<th>Description</th>
<th>Addressed on page number</th>
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<td>Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym</td>
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<td>Trial registration</td>
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<td>Trial identifier and registry name. If not yet registered, name of intended registry</td>
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<tr>
<td></td>
<td>2b</td>
<td>All items from the World Health Organization Trial Registration Data Set</td>
<td>3</td>
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<tr>
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<td>Date and version identifier</td>
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<td>Sources and types of financial, material, and other support</td>
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<td>Roles and responsibilities</td>
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<td>Names, affiliations, and roles of protocol contributors</td>
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<tr>
<td></td>
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<td>Name and contact information for the trial sponsor</td>
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<td></td>
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<td>Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities</td>
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<tr>
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<td>5d</td>
<td>Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)</td>
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Introduction

Background and rationale 6a Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention

6b Explanation for choice of comparators

Objectives 7 Specific objectives or hypotheses

Trial design 8 Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)

Methods: Participants, interventions, and outcomes

Study setting 9 Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained

Eligibility criteria 10 Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)

Interventions 11a Interventions for each group with sufficient detail to allow replication, including how and when they will be administered

11b Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)

11c Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)

11d Relevant concomitant care and interventions that are permitted or prohibited during the trial

Outcomes 12 Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended

Participant timeline 13 Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)
<table>
<thead>
<tr>
<th>Component</th>
<th>Code</th>
<th>Description</th>
<th>Code</th>
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<td>Sample size</td>
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<td>Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations</td>
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<td>Recruitment</td>
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<td>Strategies for achieving adequate participant enrolment to reach target sample size</td>
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<td>Methods: Assignment of interventions (for controlled trials)</td>
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<td>Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions</td>
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<td>Allocation concealment mechanism</td>
<td>16b</td>
<td>Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned</td>
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<td>Implementation</td>
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<td>Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions</td>
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<td>Blinding (masking)</td>
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<td>Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how</td>
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<td>17b</td>
<td>If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant’s allocated intervention during the trial</td>
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<td>Data collection methods</td>
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<td>Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol</td>
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<td>Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols</td>
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<td>Data management</td>
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<tr>
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<td>Methods for any additional analyses (eg, subgroup and adjusted analyses)</td>
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<tr>
<td></td>
<td>20c</td>
<td>Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)</td>
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<tr>
<td>Methods: Monitoring</td>
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<td>Data monitoring</td>
<td>21a</td>
<td>Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed</td>
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<td>21b</td>
<td>Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial</td>
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<td>Harms</td>
<td>22</td>
<td>Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct</td>
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<td>Auditing</td>
<td>23</td>
<td>Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor</td>
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<td>Ethics and dissemination</td>
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<td>Research ethics approval</td>
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<td>Plans for seeking research ethics committee/institutional review board (REC/IRB) approval</td>
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<td>Protocol amendments</td>
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<td>Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)</td>
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<td>26a</td>
<td>Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)</td>
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<td>26b</td>
<td>Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable</td>
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<td>27</td>
<td>How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial</td>
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<td>28</td>
<td>Financial and other competing interests for principal investigators for the overall trial and each study site</td>
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<td>29</td>
<td>Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators</td>
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<td>30</td>
<td>Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation</td>
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<td>31a</td>
<td>Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions</td>
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<td>31b</td>
<td>Authorship eligibility guidelines and any intended use of professional writers</td>
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<td>31c</td>
<td>Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code</td>
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<td>32</td>
<td>Model consent form and other related documentation given to participants and authorised surrogates</td>
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<td>33</td>
<td>Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable</td>
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*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons “Attribution-NonCommercial-NoDerivs 3.0 Unported” license.*
The VA Telederm Study: Protocol for a Stepped-Wedge Cluster Randomized Trial to Compare Access to Care for a Mobile App versus a Workstation-Based Store-and-Forward Teledermatology Process

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The VA Telederm Study: Protocol for a Stepped-Wedge Cluster Randomized Trial to Compare Access to Care for a Mobile App versus a Workstation-Based Store-and-Forward Teledermatology Process

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DHO, MW and JCP initiated the study design and specified the trial access outcomes.

DHO and MW are leading the implementation of the intervention

ND provided statistical expertise in clinical trial design and analysis, conducted power calculations, and designed and performed the constrained randomization

GLJ and HAK conceptualized the formative evaluation and the trial implementation framework

JDW, SBP, and ARE provided expertise with implementation and study design

DHO, MW, and JCP are grant holders

All authors contributed to the refinement of the study protocol and approved the final manuscript

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Competing Interests
Abstract

Introduction. Teledermatology has emerged as an important strategy to enhance access to high quality skin care. VA Telederm is a provider-facing, web-based mobile app designed to integrate into the existing teledermatology workflow in the United States Veterans Health Administration (VHA). In this study, we will conduct a systematic evaluation of VA Telederm on access outcomes in VHA facilities using a pragmatic trial guided by clinical and operational leaders.

Methods and analysis. The study is a prospective, stepped-wedge cluster randomized trial (SW-CRT) with cross-sectional exposure and outcome measurement via retrospective database analysis of administrative records. Each cluster is a VHA facility deemed eligible for the trial. We assign the intervention using a cluster-level balanced randomization scheme based on facility size, baseline teledermatology uptake, and geographic location. The trial will test whether patients receiving dermatological care at participating facilities will have better access compared with patients receiving care through the current standard process. The primary outcomes proxy for patient-level access to dermatology services, including (1) consult completion time for teledermatology consults; (2) appointment completion time for new dermatology consults; and (3) travel distance for dermatology services. As secondary outcomes, we will assess facility-level adoption outcomes, i.e. the number of dermatology encounters and the proportion of teledermatology consults out of all dermatology encounters. To account for secular trends in outcomes and for correlation across individuals within clusters, we will assess the impact of the intervention using generalized linear mixed regression models.

Discussion: Streamlining the current practice for store-and-forward teledermatology in the VHA can improve access to expert dermatological care for US Veterans. The lessons learned in this trial could validate the use of mobile technology for consultative store-and-forward dermatology in a large health care organization. The results may also be of interest to other medical specialties assessing the merits of implementing mobile telehealth.

Strengths

- stepped-wedge cluster-randomized design allows for strong causal inference
- national coverage ensures diversity of geographic settings and organizational cultures
- close partnership with clinical and operational leaders will maximize implementation

Limitations

- may not be fully generalizable to other populations and health care delivery systems
- complex process requiring buy-in from multiple stakeholders may produce variations in implementation
Introduction

Background and Rationale

With the dermatology workforce facing a persistent shortage and maldistribution of providers and services across the country, access to dermatology services in the United States is severely lacking. Teledermatology has emerged as an important strategy to enhance access to dermatologic care. Asynchronous or store-and-forward telehealth (SFT) teledermatology transmits still digital photographs and textual information to dermatologists who need not be present at the same time and place, while live-interactive teledermatology uses real-time video interactions to exchange medical data and skin exams. SFT teledermatology has been shown to improve access to care in diverse populations and settings, enhancing patients’ ability to receive care and increasing service timeliness. Besides making care more accessible, SFT teledermatology may increase efficiency, thus allowing dermatologists time to provide more in-person visits to patients with more severe conditions. Teledermatology may also improve access for underserved populations, particularly by allowing providers in safety-net settings to prioritize patients with the most urgent and severe conditions. The few studies which have been conducted on the impact of mobile devices in provider-to-provider SFT teledermatology show significant decreases in wait times. However, these studies are limited by small sample sizes recruited from single, urban clinic locations.

Access to health services is a key priority for the Veterans Health Administration (VHA), both in terms of geographic proximity and timeliness of care. Veterans disproportionately live in rural areas, thus accentuating the problem of geographic access to specialty care, particularly for patients seeking care from specialty providers such as dermatologists who tend to cluster in urban metropolitan areas. SFT teledermatology has grown rapidly in the VHA resulting in enhanced access of both rural and non-rural Veterans to skin care and more timely skin disease treatment.

Despite recent improvements in overall wait times, access to dermatology remains challenging, in part due to inconsistent implementation of teledermatology in the VHA. Data from fiscal year (FY) 2016 shows wide variation in the uptake of SF teledermatology consult use, from zero to about 50 percent of all consults in a given facility. One important impediment to the adoption of teledermatology by primary care clinics may be the inefficiency of the current workstation-based process, which involves several steps performed by VHA-trained imagers before the image can be reviewed by a dermatologist.

The convenience and capability of smart mobile devices (e.g., tablet computers) to combine data acquisition (i.e., photographs) with efficient communication strategies creates significant opportunities for the VHA to streamline teledermatology practice and expand it more widely. Capitalizing on these opportunities, the VHA Office of Connected Care (OCC) developed a mobile app, VA Telederm, as a more facile option to increase SF teledermatology use among providers. VA Telederm is designed to integrate into the existing teledermatology workflow and is interchangeable with the conventional workstation-based process. Its target users are primary care providers (PCPs) and imagers, and it recapitulates the same steps that are performed by these users on workstations, but using a streamlined graphical user interface, and permits dictation of patient histories. Importantly, imagers are able to obtain or automatically transfer patient histories as well as capture skin images, and seamlessly upload images to the electronic health record using the app, instead of using a separate camera. Since no images reside on the mobile device, there is no need for imagers to perform the extra step of deleting camera images.

In this study, we will conduct a systematic evaluation of VA Telederm impact on dermatology access outcomes in VHA facilities using a clinically-driven, pragmatic trial with a stepped-wedge cluster-
randomized design (SW-CRT). To our knowledge, this is the first systematic study of teledermatology roll-out nationally, encompassing rural and urban facilities across the United States. The SW-CRT design allows for rigorous assessment of the causal impact of the VA Telederm app implementation on providers’ adoption of SF teledermatology and the associated change in patients’ access to care in a large, integrated health care delivery system. This trial will help expand the evidence base for the effectiveness of provider-facing mobile apps in improving adoption and access to care by introducing subtle to moderate gains in user-friendliness and process efficiency. The comparator in our study is the current standard of care in the VHA facilities selected for the trial, which includes regular in-person dermatology visits and workstation-based SFT teledermatology.

The rationale for the study design evolved from the combination of several scientific and pragmatic considerations. Scientifically, the requirement for randomization stems from the VHA leadership desire to produce the most rigorous evidence on which to base system policy. Thus, the pilot tests proposed initially were redesigned as a fully randomized trial. Pragmatically however, the OCC’s operational need to begin disseminating and testing the app as quickly as possible to sites that were ready for implementation brought the stepped-wedge design to the forefront as a more feasible way of rolling out the highly anticipated apps to providers. It became apparent that this design would allow evaluation of the app while gradually releasing it in the field, thus using the system’s limited capacity to solve the inevitable implementation challenges in a small number of facilities at any given time.

This paper provides the trial protocol following the SPIRIT statement, which provides recommendations for a minimum set of scientific, ethical, and administrative elements that should be addressed in a trial protocol. The WHO dataset as required by the SPIRIT statement is included in the Supplementary File. Given the absence of specific items in the SPIRIT statement for SW-CRTs, we also include more detailed items proposed in recent methodological papers on SW-CRT design, analysis, and reporting.

Primary Objective
Our primary objective is to assess the impact of the VA Telederm mobile app on teledermatology consult completion times, dermatology appointment completion times, and travel distance in Veterans seen in outpatient dermatology practice.

Secondary Objectives
Our secondary objective is to determine if the VA Telederm App affects the number of dermatology encounters (instances of care) and adoption rates of teledermatology consults in outpatient dermatology practice in the VHA.

Specific Hypotheses
The study will test two specific hypotheses:

1) The VA Telederm mobile app improves access to dermatology services among VHA patients, as measured by reduced teledermatology consult completion time, appointment completion times for new dermatology consults, and travel distance for dermatology services. In addition, we measure exposure to dermatologic care by the total dermatology encounters (instances of care).

2) The VA Telederm mobile app increases the adoption of teledermatology consults in VHA dermatology clinics.
Trial Design and Study Organization
This study is a prospective, stepped-wedge cluster randomized superiority trial. VHA facilities are
randomized to receive the intervention according to a constrained randomization scheme that also
ensures balance in key facility-level characteristics across the study sequences. Patients’ exposure to the
intervention will be cross-sectional (i.e., patients are exposed when they visit a VHA facility for
dermatology care) and outcome measurement will be done via retrospective database analysis of
administrative records. The trial involves a partnership between VHA telehealth clinical operations,
research, and implementation scientists in the VHA.

Methods and Analysis
Participants and setting
Each cluster participating in the trial is a VHA facility deemed eligible for participation, defined as having
patients with at least one in-person outpatient visit for dermatology or teledermatology encounter in
the VA during the course of the study. Each facility represents a VHA Medical Center providing care for a
variable number of associated medical centers or clinics. The individuals receiving dermatological care at
the eligible facilities, i.e. patients with at least one in-person outpatient dermatology or teledermatology
encounter in the VHA during the course of the study, will be automatically included in the study and
have their outcomes evaluated by retrospective, automated statistical analysis.

Eligibility Criteria
We selected 36 eligible facilities using the inclusion and exclusion criteria presented in Table 1, with the
rationale for each criterion. Specifically, we included facilities located within the continental United
States which had a dermatology clinic on-site (thus able to implement the intervention) and which only
had a moderate penetration of SFT teledermatology. We excluded three facilities participating in a
mixed-methods formative evaluation of the implementation to avoid contamination of the intervention.

The Current Standard of Care
Teledermatology services are currently provided in VHA facilities using a workstation-based SFT process.
This process is consultative and consists of several stages, depicted schematically in Figure 1. When a
patient or the provider has a skin concern, a referring provider (typically a PCP) initiates the consult
request for skin imaging in the electronic medical record, known as the Computerized Patient Record
System (CPRS), which also prompts the PCP for pertinent medical history. Upon receipt of the imaging
consult request, an imager trained in the VHA protocol schedules the patient for imaging and transmits
information from the PCP’s consult request or, and if necessary, obtains further medical history from the
patient according to a scripted set of questions that are recorded in a templated CPRS note. Usually
imaging appointments are made for the same day when the imaging consult is placed, though in some
situations the patient or the clinic may delay the appointment to a different day. The imager captures
images of the patient’s skin using a standard digital camera and must then manually upload the photos
and link them with the patient’s CPRS record. Finally, the imager then generates a new consult request
to a teledermatology reader, typically a board-certified dermatologist. This imager must then manually
delete the images to ensure that the patient’s privacy is protected. The reader reviews the history and
images and writes a CPRS note that includes an impression and recommendations for the PCP, who is
then responsible for enacting them. A face-to-face visit may also be recommended as follow-up.
The Intervention
The intervention studied in this trial consists of three elements, deployed under the umbrella of the Replicating Effective Programs (REP) framework:26–28

(1) The VA Telederm app is the key technology at the core of the intervention. The app has been developed by a Federal contractor to be in strict compliance with VHA standards and regulations and is anticipated to be ready for national release by January 2019 by the OCC. Clinics within the participating facilities will be provided with mobile devices (i.e., tablets) which can be used to download the app and perform the new imaging process. The app will not be available for download or use on any personal mobile devices, either of the physician or the patient, as the app is intended to be used only on secure government-issued devices. Teledermatology leads at each facility will provide guidance on how to test it prior to use, and each provider will first have to enroll their device with the VHA Mobile Health Services. The app will be implemented at the facility level (up to five tablets will be made available at no cost to each facility, though facilities may have additional tablets due to prior inventory or purchase) and will be available to referring providers in a participating facility after adoption during the corresponding trial step. However, use of the app will be at the discretion of providers and imagers, and thus not all patients may have the opportunity to receive care using the new app. Screenshots of the app’s interface are included in Appendix A.

The VA Telederm app is intended to improve the existing teledermatology workflow by seamlessly integrating image capture and upload into the VHA electronic records system. The app’s target users are both referring providers and imagers. The app will allow referring providers to submit consults using touch screen entries and will permit dictation of patient histories. Imagers will be able to process those consults without transcribing or copying/pasting histories and to capture and upload images to the CPRS using the app, instead of using a separate camera. Thus, while it recapitulates the various steps that are performed by these users on workstations, the app will have a streamlined graphical user interface integrating these steps for an improved workflow. Since no images reside on the mobile device, there is no need for imagers to perform the extra step of deleting camera images.

(2) Education programs and resources specifically targeted to providers involved in the teledermatology process (PCPs, imagers, and dermatologists) have been streamlined by the study team in collaboration with OCC. OCC will conduct training sessions for Telehealth Leads in each VHA Veterans Integrated Service Network (VISN) and the Facility Telehealth Coordinators (FTCs) at each facility, who will then be responsible for training teledermatology providers. These sessions will be conducted using the existing process in the VHA by which new processes of care and guidelines are introduced. The core materials used for training are included in Appendix B.

(3) Continuing support will be made available to the participating facilities to assist them with the adoption of the new process. Technical support will be provided via a 24/7 telephone hotline to assist with any app- or device-related problems encountered by the providers. Implementation support will be provided by the VISN leads during monthly calls and via email by designated OCC staff. During these calls, providers will be able to share their experiences with the new app and will receive help to address any issues they have with the new care process.
Technical Field Testing
Before national release, the app will be field-tested at the pilot VHA facilities in San Francisco, CA, Providence, RI, and Denver, CO. During this process, the VA Telederm app will be used by providers with the goal of identifying any technical issues with the mobile app or the new clinical process it requires. Any issues identified at this stage, such as software bugs, incompatibilities with the existing systems, or security vulnerabilities will inform any modifications necessary for the national rollout of the intervention.

Formative Evaluation
To complement and inform the randomized trial, we will also conduct a mixed-methods formative evaluation in the same facilities involved in the technical pilot field-testing (i.e. San Francisco, Providence, and Denver). The evaluation will be guided by the Organizational Theory of Implementation Effectiveness, which is based on the work of Klein and Sorra as modified by Weiner and colleagues. The goal of this evaluation will be to understand the factors that may impact the organizational readiness for change (ORC) and process of implementation, how these factors change over time, and how they are associated with successful implementation and sustainability of the app. The findings of the formative evaluation will inform the process of implementing the teledermatology apps during the randomized implementation nationally as well as the implementation of future mobile clinical applications.

In addition to their initial roles in field-testing, the three pilot sites—San Francisco, Denver and Providence—are appropriate for evaluation since the teledermatology leadership are located at San Francisco and Providence VHA Medical Centers and Dermatology Field Advisory Council is located in Denver. These sites may have specific qualities that impact implementation. However, since they vary in terms of both organization and location, lessons learned will likely translate to the mix of other VHA facilities with dermatology programs. Differences among the three sites include: 1) San Francisco and Denver have Dermatology Services, whereas Providence has Dermatology as a section of the Medicine service; 2) San Francisco and Denver do not use dermoscopy, whereas Providence does; and 3) each facility is in a different VHA information technology (IT) administrative region.

We will first identify baseline characteristics of each organization and implementation teams that may impact implementation process and success. This will be followed by a qualitative and quantitative assessment of readiness to implement teledermatology; monitoring of the implementation process and progress through bi-monthly site reports; as well as qualitative interviews approximately 6-8 months following initial implementation of the teledermatology app; and qualitative and quantitative evaluation of program sustainability 1 year after the first use of the teledermatology application.

**Baseline Assessment.** The three sites will be asked to identify individuals directly involved in planning and execution of app implementation, whose work or clinical decision-making may change as a result of app implementation. These sites will be asked to submit information on these core implementation team members and processes and size and composition of the medical centers and impacted clinical services. For each separate facility, individuals representing the core implementation team will participate in a group conference call with the goal of providing detail on the planned process of implementing the app. Written bi-monthly (every other month) updates of the process will be provided by the sites.

**Organization Readiness for Change (ORC).** Core implementation team members and clinical staff from impacted services will be surveyed using the validated Organization Readiness for Implementing Change instrument, a computer-based survey developed specifically to measure aspects of the Weiner Theory of
This instrument examines perceptions of organizational-level change efficacy and commitment to newly implemented interventions. In addition, we will conduct semi-structured qualitative telephone interviews of the core implementation team and clinical staff at each site to assess ORC and factors that are hypothesized to predict ORC.

**Stages of Implementation Completion.** We will also measure the advancement of the implementation process through monthly reports from the three sites. Implementation progress will be assessed utilizing the Stages of Implementation Completion (SIC). SIC enumerates key pre-implementation, implementation and sustainability milestones. Dates by which specific implementation milestones are reached will be identified. This information will also enable us to examine if the degree of ORC is associated with the rapidity with which sites go through implementation steps. Bi-monthly (every other month) reports will also include assessment of barriers and facilitators identified through the ORC measurement process. Bi-monthly information will be fed back to project and OCC leadership so that program adjustments can be made.

**Program Sustainability.** At 6-8 months following the start of the implementation process at the 3 early adopter sites, we will conduct semi-structured qualitative telephone interviews, ideally with the same individuals interviewed at baseline. The goal is to understand changes in the process of utilizing the teledermatology app and the degree of implementation over time. At approximately one year, we will assess the sustainability of use of the mobile apps, using the Mancini & Marek Model of Community-based Program Sustainability as a conceptual guide. Specifically, we will measure the six elements essential for sustainability (leadership competence, effective collaboration, demonstrating program results, strategic funding, staff involvement and integration, and program responsivity) using a modification of the validated Program Sustainability Index (PSI). At this stage, we will again conduct qualitative interviews with the individuals involved in planning and implementation.

To inform the national rollout, we will continually analyze results and provide feedback to stakeholders. Rapid analysis approaches will generate preliminary findings to share among the research team, followed by in-depth content analysis.

**Intervention Timeline**

Figure 2 illustrates the main features of our stepped-wedge design for the national rollout, using the terminology proposed by Copas et al. For national rollout, the app is targeted to sites that are clinically appropriate and best positioned to benefit from the app. The evaluation of the app will be structured as a prospective, stepped-wedge cluster randomized trial, a form of randomized design which delivers the intervention to all participants in a staggered fashion over time. This design has a long history in statistical research but has only more recently been used for program evaluation. In brief, as detailed below, 36 participating facilities (or clusters of patients) will be randomly assigned to receive the intervention successively in sequences of 6 facilities each at the beginning of each trial step. Starting January 2019, one sequence will be exposed to the app, and at subsequent 3-month intervals an additional sequence will join the intervention until all groups are exposed starting April 2020. Therefore, the trial will consist of 6 steps, each one quarter apart. Unexposed cohorts in the sequences that have not yet crossed over at any given time will serve as controls. Measurements of outcomes will be performed every quarter after the start of the trial, with the exception of the quarters reserved for implementation in each sequence commencing rollout of the intervention. Additional measurements will be performed for two baseline quarters and two post-rollout quarters.
Outcomes

The primary study outcomes serve as proxies for access to dermatology services at the patient level, and will be used to test specific hypothesis 1) above. Table 2 specifies the outcome measures, the sources of data, and other important variables used in the study. Specifically, using statistical techniques (presented in the Statistical methods section below) we will assess changes in:

1. Consult completion time (continuous) – the interval between the time when a teledermatology consult is requested by a PCP until and when the dermatologist completes a note in the health record with his or her medical assessment.
2. Appointment completion time for new dermatology consults (continuous) – the interval between the time when a dermatology appointment (either in-person or teledermatology imaging) is requested and when it is completed.
3. Travel distance for dermatology services (continuous) – the distance between the centroid of the patient’s ZIP code of residence and the VHA facility to which he/she is receiving care.

We will also examine measures of teledermatology adoption at the facility level over time, such as the number and relative proportion of teledermatology consults among all dermatology encounters. These measures will be used to test specific hypothesis 2) above.

Outcomes will be extracted from the VHA’s Corporate Data Warehouse (CDW), which is regularly updated with information from individual electronic patient records at each clinic. Data on clinical full-time equivalents (FTEs) employed in dermatology will also be extracted from the VHA’s Office of Productivity, Efficiency and Staffing (OPES) in order to monitor changes in the supply of dermatologists at the study facilities. We hypothesize the teledermatology apps will have a larger impact on Veterans who live in rural areas. Consequently, models will also be secondarily stratified on urban/rural/highly rural status based on the Rural Urban Codes assigned to the ZIP code of residence for each patient.

Sample Size and Power Analyses

Our intended sample size is 16,000 individuals receiving care at the study facilities. We conducted power analyses separately for binary and continuous outcome measures under the parameters characterizing trial design. We conducted all power analyses in Stata using the user-written package steppedwedge following the authors’ guidance. We implemented the power analyses by using an incomplete design matrix with a three-month transition period with no outcome measurement, consistent with our proposed rollout. We verified our power analyses with analytical calculations performed using an alternative package written for the R statistical software and found the two methods to be highly consistent with each other. However, because the Stata package allowed for a user-specified design matrix with a 3-month transition period, which more closely reflects our intended rollout approach, we chose it as our preferred power analysis method. We provide the full code for the power analysis in Appendix C.

We used a level of precision $\alpha = 0.05$ (probability of a Type I error) and a minimum power level of 0.80, corresponding to probability of a Type II error $\beta = 0.20$. We also assumed a total number of clusters $I = 36$ as per the study design and the number of baseline measurements $B=2$ (since we will measure two pre-rollout quarters). Table 3 shows other key parameters used for selected power calculations and the corresponding statistical power level calculated with the steppedwedge commands. Because of the number of values the parameters can take leads to quite a large number of combinations, in multi-way sensitivity analyses we allowed the parameters to vary within certain ranges we consider reasonable. For brevity we show calculations that are at or near the predetermined limit of desired power (i.e., 0.80) illustrate potential cut-off values for our parameters.
The average cluster size per measurement occasion $K$ (this represents the number of relevant encounters in a measured period of time, i.e. quarterly) was varied depending on the outcome, with the base value estimated using encounter data extracted from the VHA CDW. Specifically, for continuous outcomes the values are shown in the first three panels of Table 3. We estimated reasonable baseline values via preliminary exploration of data from eligible sites for FY2016. We estimated an intraclass correlation coefficient (ICC) $\rho = 0.268$ (CI = [0.071-0.427]) for continuous outcomes in the eligible sites by performing a post-estimation procedure after estimating a mixed model with cluster-level random effects on baseline data on consult completion times (we used full year data with $i=36$ and total number of observations $N = 589,901$). We used $\rho \cong 0.25$ as the base ICC value for our power calculations and varied it from 0.10 to 0.30 in our sensitivity analyses. The effect size $\Delta \mu$ was varied between -0.03% and -0.15% for the continuous outcomes (representing the percent change in the baseline mean).

For the binary outcomes we assumed an average cluster size $K = 500$ and found upper and lower values of between 150 and 1,700 depending on other key parameter values (fourth panel). Using FY2016 data, we estimated an average proportion of teledermatology encounters of $p_0 = 0.03$ (varied up to 0.20 to allow for the possibility of increasing teledermatology before the intervention begins rollout). We estimated an ICC of $\rho = 0.136$ (CI = [0.091-0.190]) for the binary outcome, and we used a baseline value $\rho \cong 0.10$ and varied it between 0.05 and 0.20 in the sensitivity analyses. The effect size was expressed as an odds ratio for the binary outcome and was varied between 1.10 and 1.30, which was considered clinically meaningful but also conservative for the analysis.

Recruitment
The eligible facilities were contacted by the operations partner (i.e., OCC) in November 2017 to confirm their participation in the trial and to identify staff, including the Clinical Applications Coordinators (CACs) and providers, who will need training in order to implement the intervention. Moreover, each facility’s FTC and the associated overseeing VISN telehealth lead will be notified by email of the mobile app’s implementation 1-3 months prior to the implementation date assigned to their specific site. These have been and will continue to be supplemented by announcements of the app and trial during weekly national VISN lead and FTC conference calls with OCC, and monthly conference calls by OCC’s teledermatology leads with the field. The FTC, supported by the VISN leads, will be responsible for disseminating information about the app to all clinical and allied support staff and recruiting their support, including informatics and information technology staff. One month prior to implementation, a conference call will be held with the FTC and VISN telehealth leads to review the app and its implementation.

Assignment of Intervention
We used a constrained randomization procedure to assign the order in which the facilities will receive the intervention. Given the small number of clusters included in the trial, this procedure avoids the potential imbalance in critical facility characteristics across the trial sequences simply due to chance. In these situations, constrained randomization has been shown to perform better in achieving baseline balance on several potential confounders than simple randomization, matching, or stratification.\textsuperscript{44,45} This procedure is described briefly below and more detail is provided in Appendix D.

We followed a two-stage procedure in a similar vein to the approach proposed by Bertsimas \textit{et al.},\textsuperscript{44} which entails first an allocation of study units (facilities) to sequences such that the difference between the sequences is minimized (the optimization stage) followed by random assignment of the order in which the sequences will receive the intervention (the randomization stage). Bertsimas \textit{et al.} developed their procedure in the context of a parallel randomized controlled trial with multiple treatments and a small number of units in each treatment arm. To our knowledge, this is the first time this procedure is
adapted to a SW-CRT. Besides balancing sequence characteristics, we also randomize sequence to the order in which they receive (the same) treatment, as opposed to different treatments. Either way, the goal of systematically decreasing the differences between sequences while preserving the random component is achieved.

Site characteristics used for the optimization stage consisted of two continuous variables and one categorical variable. Specifically, the two continuous variables were the size of dermatology practice (measured by the number of dermatology encounters in the baseline year) and the level of teledermatology activity (measured by the percentage of teledermatology consults of all dermatology appointments in the baseline year). The categorical variable was the geographic location (determined by one of the five VHA administrative regions encompassing each facility). These characteristics were chosen as they are likely to affect the implementation of the intervention and its impact on outcomes. For example, larger facilities may have more resources for implementation and stronger incentives to increase efficiency. Similarly, facilities that are already extensively providing teledermatology may be more effective in implementing it compared to facilities with lower uptake. Finally, facilities in different geographic areas differ in their practice patterns and constraints and may have systematic differences in pre-intervention outcome trends.

The sequences of facilities in order of implementation are shown in Appendix E. Balance across sequences in the number of visits and the percentage of teledermatology encounters is shown in Appendix F, while balance in geographic location is shown in Appendix G. We also considered balancing on facility complexity level, a VHA-specific measure that indicates the relative size and complexity of clinical services and administrative structures of a given VHA treatment facility. However, because this measure is highly correlated with the number of dermatology practices at each facility, we did not end up using this measure for balancing. Nevertheless, this procedure achieved reasonable balance on this measure by virtue of balancing on dermatology practice size (data not shown).

Blinding
The health care professionals (PCPs and imagers) involved in the study will not be blinded to the intervention, as it is impossible to conceal the use of the app on a mobile device compared to the current workstation workflow. The Veteran patient experiences a different imaging device depending on whether the VA Telederm app is used versus a traditional workstation and auxiliary camera, so they are also not blinded to the process. However, other than the imaging technique the consult generation process is relatively transparent to the Veteran. Furthermore, data collection will be performed passively from patient records.

Data Collection and Management
Outcomes data will be collected by the research team via automated extraction from the CDW. Data will be stored on the Department of Veterans Affairs Informatics and Computing Infrastructure (VINCI) and only accessible by the research team. VINCI is a VA Health Services Research & Development (HSR&D) resource center that provides a secure, central analytic platform for performing research and supporting clinical operations activities. The platform includes a cluster of services for securely hosting suites of databases integrated from national data sources (such as the VHA CDW). VINCI servers for data, applications and virtual sessions are physically located at the VA Austin Information Technology Center (AITC) located in Austin, Texas. AITC hosts a secure enclave of high-performance servers and high-speed storage and has multiple layers of security and disaster recovery to prevent data loss.

VINCI maintains compliance with the guidelines established by the VHA policies and regulations. VA-credentialed research staff will be granted access to the study data along with tools for analysis and
reporting in the secure virtual working environment through a certified VHA network computer. This computing environment will enable uniform security standards for access, a common point of entry for all investigators who use the data, and consistent control of data quality.

Study data will be kept in accordance with the Department of Veterans Affairs Record Control Schedule 10-1. Storage and transfer of any Personally Identifiable Information (PII) or Protected Health Information (PHI) will be performed in accordance with applicable VA policies and directives, state and federal regulations, and applicable statutes including the Health Insurance Portability and Accountability Act (HIPAA). Standard data quality checks such as examination of outliers or significant changes over time will be conducted to identify potential problems with the data extracted from CDW. Analytical files will be built in the VINCI secure environment and will be analyzed on the VINCI servers. Upon completion of the research project, the study principal investigators and the VA Information Security Officer will insure that data containing sensitive, confidential information will be returned to the VA and removed from all servers, desktops, removable storage devices, etc.

Statistical Methods
We will employ data analysis strategies that account for the causal structure implied by our trial design and mitigate its potential shortcomings. Two related issues which may confound the treatment effect are the within-cluster correlation and potentially significant secular trends in the outcomes of interest given the long duration of the trial (2.5 years). In fact, the exposure of each cluster to both the control and intervention allows us to partially exploit the within-cluster variance towards estimation, which renders this type of trial less sensitive to the intra-cluster correlation coefficient. To ensure that these confounding factors are properly handled, we will analyze the data using several model specifications. This will also allow us to explicitly test some of the assumptions underlying our empirical model.

Our first analysis relies on an intent-to-treat approach, in which we will directly assess the impact of being randomized to implement the VA Telederm app on the following specialty care access outcomes: consult completion time, appointment completion time, and travel distance for VHA care. This model yields an estimate of the average effect of being randomized to receive the VA Telederm app (average treatment effect). From a policy perspective, this effect can be interpreted as the efficacy of deploying an app in real-world outpatient clinics, where overall uptake to clinical practice is likely less than 100%.

Specifically, we will estimate generalized linear mixed models of the form:

\[ Y_{iqt} = F(\mu + \alpha_q + \beta_t + \theta V_{qt} + X_{iq}) + e_{iqt} \]

where

- \( Y_{iqt} \) is the outcome for patient \( i \) in cluster \( q \) treated in quarter \( t \);
- \( \mu \) is the outcome in the first observation;
- \( \alpha_q \sim N(0, \phi^2) \) is the random effect for clusters (VHA facilities);
- \( \beta_t \) is a fixed effect adjusting for being in quarter \( t \);
- \( V_{qt} \) is a fixed effect for whether or not facility \( q \) was randomized to the intervention in quarter \( t \);
- \( \theta \), the coefficient of interest, is the effect of the being randomized to receive the intervention on the outcome;
\( X_{iq} \) are fixed effects adjusting for demographic characteristics of patient \( i \) in cluster \( q \), i.e. age, gender, ethnicity, and rurality; and

\[ e_{iqt} \sim N(0, \sigma^2) \] is the error term for each dermatology encounter.

Depending on the distribution of the outcome variable, the function \( F(.) \) is either the identity function (for continuous, normally distributed outcomes like travel distance) or inverse gamma distribution (for highly skewed and always positive outcomes like completion times for appointments and consults and time to follow-up).

This type of model, proposed for the analysis of SW-CRTs by Hussey and Hughes,\(^ {41} \) clearly involves several important underlying assumptions, such as a common underlying piece-wise secular trend across all clusters, a constant change in this common trend as a result of the intervention, and an identical correlation between two observations in a cluster irrespective of treatment and time duration between the observations.\(^ {25} \) In secondary analyses, we will relax these assumptions in order to assess whether they impact the results. For example, we will allow the secular trends to vary by strata of clusters, such as VHA administrative regions or VHA Integrated Service Networks (VISNs) (using a fixed-effect interaction between time and stratum), or even by clusters (by adding a random interaction between time and cluster, and thus allowing intracluster correlation to vary by time period). Similarly, we will test models allowing for treatment effect heterogeneity across strata of clusters or across time (using either fixed or random effects), with the important caveat that some of these models will be estimable only on data collected in time periods in which there are both treated and control clusters.\(^ {25} \)

In addition to the intent-to-treat analysis, we will also assess the impact of the intervention using an instrumental variable (IV)-based two-stage residual inclusion (2SRI) procedure. In this approach, we will estimate two parameters of interest. First, we are concerned with the effect of the randomization on uptake of the apps, as a factor leading to teledermatology adoption in the sites receiving the intervention. This effect can be obtained by estimating the following first-stage model:

\[
\text{(1)} \quad \text{App}_{iqt} = \text{Logit}^{-1}(\mu + \alpha_q + \beta_t + \theta V_{qt} + X_{iq}) + e_{iqt}
\]

Second, we are interested in the average effect of the treatment among compliers (patients who only receive the treatment as a direct result of their exposure to the intervention), referred to as the Local Average Treatment Effect (LATE). This effect better reflects the efficacy of teledermatology compared to regular practice and can be estimated using the following second-stage model:

\[
\text{(2)} \quad Y_{iqt} = F(v + \alpha_q + \delta_t + \text{App}_{iqt} + X_{iq} + \hat{e}_{iqt}) + e_{iqt}
\]

where \( \hat{e}_{iqt} \) is the predicted residual from estimating equation (1). Estimating this effect would allow future work to investigate why the intervention works and why uptake of the intervention varies across facilities. Pointing out that, for example, access can be improved significantly provided that the leadership of a health care system can ensure uptake of the app, would be important for future policy decisions.

Continuous monitoring of implementation
Implementation will also be assessed at all participating sites by monitoring intermediate milestones and quantitative indicators of implementation that are available in CDW as well as from OCC's own telehealth database and WMS mobile device procurement program. Randomized sites, in addition to the three sites in the formative evaluation, will be asked to complete a bi-monthly implementation site
report monitoring key milestones, collected electronically via the VHA intranet. Sites will be sent email reminders two weeks and one week prior to, and one week after the due date, with follow up via phone call, if necessary. Collection of these data will be descriptively summarized every quarter (3 months) to understand how rapidly sites meet key milestones as a result of the OCC implementation process, correlate the milestones to the number of patients serviced via the apps (i.e., reach), and allow for stratified analyses of main quantitative study results by degree of implementation based on reaching milestones to determine if the apps are more effective among sites that have reached more implementation milestones. The study will not have a separate data monitoring committee, due to the low risk of the intervention and its minimal interference with patient care. Since we do not anticipate any adverse effects to be reported, a data monitoring committee is not necessary.

Patient and Public Involvement
The VA Telederm mobile app is designed to be used by primary health care providers and by imaging staff respectively to order and to process teledermatology consults prior to being read by a dermatology reader. The app interchangeably substitutes for these steps in VHA’s existing teledermatology process using its electronic health record. While the app is intended to make teledermatology services available to more patients, patients are not the actual users of the app. For all of these reasons, it is anticipated that the patient experience itself will not be affected by the use of the VA Telederm app, and no patients or patient advocacy groups were consulted in the design of the app or this trial. The development of the research questions and outcome measures was informed by prior scientific literature (including work published by the authors) on the impact of teledermatology on access and on patient wait time measures for primary and specialty care services. For similar reasons, there are no plans to disseminate the results of this trial directly to patients or patient groups, and the burden of the intervention was not assessed by patients.

Ethics and Dissemination
Research Ethics Approval
The research has been approved by the Institutional Review Board (IRB) at VHA Boston (IRB Project #3069), which has designated the study as exempt since it involves collection and analysis of data in a way that subjects cannot be identified, either directly or through identifiers linked to the subjects. Specifically, since the app will be implemented within the process of care in the VHA, the data in the cluster-randomized trial will be deidentified and collected retrospectively in the administrative database. The research team will query the relevant database tables and extract the data necessary for the proposed analyses and will conduct the research in a secure environment following all required procedures for protection of privacy and confidentiality. For the purposes of the Ottawa statement, the research participants in this study are the patients receiving dermatology care at the eligible facilities, since they will be affected by the change in the health care delivery process. However, the study interventions and data collection procedures pose no more than minimal risk.

The research components of the formative evaluation have been approved by the IRBs at the VHA Durham, San Francisco, and Providence facilities, respectively. In this study component, the research participants are the VHA employees involved in the implementation, from whom consent will be obtained before being interviewed or surveyed.
Protocol Amendments

Any modifications to the protocol which may impact on the conduct of the study, including study objectives, design, patient population, sample sizes, study procedures, or significant administrative aspects will require a formal amendment to the protocol. All such amendments will be agreed upon by the study investigators and approved by the institutional review board prior to implementation and notified to the VHA OCC and HSR&D. Administrative changes of the protocol, such as minor corrections that have no effect on the way the study is conducted, will be agreed upon by the study investigators and documented in a memorandum. The IRB may be notified of these administrative changes at the discretion of the study investigators.

Dissemination Policy

The project team is comprised of specialist clinicians, academic researchers, and experts in implementation science. This provides the project with access to a wide range of channels for results dissemination to policy makers, researchers, and system stakeholders. The results of the study will be published in academic peer-reviewed journals and presented at professional conferences. Additionally, VHA leadership will be briefed on the preliminary as well as final study findings in order to inform future VHA policy regarding teledermatology. Communications with VHA leadership will be facilitated by two members of the research team who also serve as the clinical leads for teledermatology in OCC (DHO and MAW). No use of professional writers will be made. Only investigators involved in the study planning, design, or analysis will be eligible for authorship of study communications.

Participant level data will not be made available to the public due to privacy and confidentiality concerns, but statistical code may be shared by request from the study authors. Study investigators and approved study personnel will be the only individuals who can access the final trial dataset.

Patient and Public Involvement

Patients were not involved in the development of the research question or the outcome measures.

Discussion

Study Impact and Importance

At the end of the study period, the trial will document the effectiveness of mobile store-and-forward teledermatology in enhancing Veterans’ access to dermatology services. Moreover, it will produce a comprehensive understanding of the factors that lead to successful mobile telehealth implementation and adoption. The results will be of significance to the VHA as it develops and implements other mobile telehealth programs, and more generally to other healthcare organizations planning for large-scale telehealth interventions.

In particular, the study will allow us to assess whether web-based mobile teledermatology apps improve access to expert dermatology services by decreasing consult times, reducing appointment completion times for new patients, increasing instances of dermatologic care, and reducing the distance traveled by patients to receive dermatology services.

Strengths

This study has several important strengths. First, the stepped-wedge design of the trial will allow us to assess with increased confidence the causal impact of the new teledermatology intervention, by assigning the order of the intervention in a randomized fashion. Stepped-wedge designs allow clusters to be compared to other sites and to also serve partially as their own control, thus permitting us to
account for outcome time-trends for each participating facility. Second, the constrained randomization scheme will ensure that imbalance in measured facility characteristics due to sheer chance will not bias the findings. This bias is an important concern in trials in which randomization is performed for a small number of clusters. Third, in contrast with previous studies which were mainly conducted on small and relatively homogeneous samples, our study includes individuals accessing care in facilities throughout the US. This includes rural and urban facilities serving patients characterized by geographic and socioeconomic diversity.

Fourth, the close partnership with clinical and operations leaders will ensure that all eligible sites receive the intervention and that clinician buy-in, which is crucial for the success of the intervention, is maximized.

Finally, the pilot testing and formative evaluation will ensure that implementation issues are addressed early by learning from the early test sites. In this way, any early issues with on-the-ground implementation can be mitigated.

Limitations
The study also has several limitations. First, implementation will likely vary by facility depending on the local culture, resources, efficacy and engagement of local leadership. Although we will conduct a formative evaluation in three facilities in order to inform the national roll-out of the intervention, it is likely that we cannot ensure uniform implementation across facilities. For example, some of the participating sites will use dermatoscopes that attach to imaging devices in order to collect high-quality photos. Since the cost of dermatoscopes is not covered by OCC or the VHA Mobile Health Services office, there will likely be some variation in the quality of the images across sites.

Second, the impact of the app will depend on the effectiveness of the education and support provided to providers and to the extent to which the providers find the new process more intuitive and easy to use. Although we have adapted previously used training materials developed by OCC, there is still potential for inconsistent dissemination and support for the app.

Finally, the implementation requires the cooperation of multiple stakeholders at the national, regional, and local level in order to ensure proper training, education, and support for providers in their adoption process. It is inevitable that some confusion or improper deployment will occur at least initially, which may affect the implementation process. Moreover, although we have allowed for three months for implementation in each facility, the possibility for longer delays still exists.

Generalizability
The study findings may not be generalizable outside the VHA, which has a different institutional structure from most other practices in the United States. The findings may also not be generalizable to health care systems outside the United States or other teledermatology mobile apps.

Acknowledgments
The authors would like to acknowledge superb administrative support from Rebecca Lamkin at VHA Boston, MA, Andrea Grenga at VHA Providence, RI, and Jennifer Chapman at VHA Durham, NC. The authors would also like to acknowledge Junius Lewis for excellent facilitation of contact with the VHA Facility Telehealth Coordinators and VISN leads.
References


Figure legends

Figure 1. Current workstation-based teledermatology process in the VHA.
Figure 2. Timeline and design features for the VA Telederm SW-CRT.
Table 1. Inclusion and exclusion criteria used for selecting the participating facilities and rationale for each

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Located within the continental United States</td>
<td>VHA facilities outside the continental US do not reliably report electronic medical record data to the CDW and/or do not have dermatology clinics</td>
</tr>
<tr>
<td>2. Greater than zero provider full-time equivalents practicing dermatology</td>
<td>Have a dermatology clinic on-site</td>
</tr>
<tr>
<td>3. Higher than 0.1% and at most 8.8% of total FY2016 dermatology encounters at the facility were for teledermatology readings</td>
<td>Already performing some teledermatology consults at baseline using the existing store-and-forward technology, but their total teledermatology encounter rates were below the median; based on prior experience, these sites were judged to be good candidates for implementing the new mobile app</td>
</tr>
<tr>
<td>Exclusion</td>
<td></td>
</tr>
<tr>
<td>Participating in pre-trial mixed-methods formative evaluation</td>
<td>Three facilities will participate in the formative evaluation, which will be conducted to inform the implementation of the mobile app; these facilities are located in Providence, RI, San Francisco, CA, and Denver, CO.</td>
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## Table 2. Study outcome measures and data sources

<table>
<thead>
<tr>
<th>Measure/Variable</th>
<th>Data Sources</th>
<th>Coding Notes</th>
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<tbody>
<tr>
<td>Consult completion time</td>
<td>VHA CDW</td>
<td>Total time in days from consult request date to consult completed date following Pizer et al. (^{48})</td>
</tr>
<tr>
<td>Appointment completion time for new patients</td>
<td>VHA CDW</td>
<td>Total time in days from appointment create date to appointment completed date following Prentice et al. (^{49})</td>
</tr>
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<td>Travel distance for VA care</td>
<td>VHA CDW, OPES</td>
<td>Average driving distance from the centroid of the patient’s ZIP code of residence</td>
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<td>Number of dermatologic encounters by type (in-person vs. teledermatology)</td>
<td>VHA CDW</td>
<td>Volume of total dermatology visits, both in-person and via teledermatology (total and %); coded at facility level</td>
</tr>
<tr>
<td>Percentage of dermatology encounters by type (in-person vs. teledermatology)</td>
<td>VHA CDW</td>
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### Table 3. Key results of power calculations under base assumptions

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Average cluster size (per measurement occasion)</th>
<th>Treatment effect (Δμ or OR)</th>
<th>Parameter in control group (SD)</th>
<th>Parameter in treatment group (SD)</th>
<th>ICC</th>
<th>Power</th>
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<tr>
<td>Consult completion time</td>
<td>120 Δμ=0.10</td>
<td>μ₀=27.8 (44.3)</td>
<td>μ₁=25.0 (44.3)</td>
<td>0.25</td>
<td>0.800</td>
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<td></td>
<td>120 Δμ=0.10</td>
<td>μ₀=27.8 (44.3)</td>
<td>μ₁=25.0 (44.3)</td>
<td></td>
<td>0.30</td>
<td>0.800</td>
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<td>120 Δμ=0.15</td>
<td>μ₀=27.8 (44.3)</td>
<td>μ₁=23.6 (44.3)</td>
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<td></td>
<td>120 Δμ=0.15</td>
<td>μ₀=27.8 (44.3)</td>
<td>μ₁=23.6 (44.3)</td>
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<td>0.25</td>
<td>0.775</td>
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<td>Appointment completion time</td>
<td>200 Δμ=0.10</td>
<td>μ₀=60.0 (50.0)</td>
<td>μ₁=57.0 (50.0)</td>
<td>0.20</td>
<td>0.930</td>
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<tr>
<td></td>
<td>140 Δμ=0.10</td>
<td>μ₀=60.0 (50.0)</td>
<td>μ₁=57.0 (50.0)</td>
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<td>0.20</td>
<td>0.820</td>
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<td>μ₀=60.0 (75.0)</td>
<td>μ₁=57.0 (75.0)</td>
<td>0.20</td>
<td>0.800</td>
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<tr>
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<td>110 Δμ=0.05</td>
<td>μ₀=60.0 (50.0)</td>
<td>μ₁=57.0 (40.0)</td>
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<td>240 Δμ=0.05</td>
<td>μ₀=50.0 (50.0)</td>
<td>μ₁=47.5 (60.0)</td>
<td>0.10</td>
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<td>400 Δμ=0.03</td>
<td>μ₀=60.0 (50.0)</td>
<td>μ₁=58.2 (50.0)</td>
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<td>0.830</td>
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<td>Travel distance (miles)</td>
<td>550 Δμ=0.03</td>
<td>μ₀=13.0 (13.0)</td>
<td>μ₁=12.61 (13.0)</td>
<td>0.20</td>
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<td>300 Δμ=0.04</td>
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<td>μ₁=12.48 (13.0)</td>
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<td>300 Δμ=0.04</td>
<td>μ₀=13.0 (13.0)</td>
<td>μ₁=12.48 (13.0)</td>
<td></td>
<td>0.30</td>
<td>0.800</td>
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<tr>
<td></td>
<td>500 Δμ=0.04</td>
<td>μ₀=13.0 (13.0)</td>
<td>μ₁=12.48 (20.0)</td>
<td>0.20</td>
<td>0.814</td>
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<tr>
<td></td>
<td>1,000 Δμ=0.03</td>
<td>μ₀=10.0 (12.0)</td>
<td>μ₁=9.70 (15.0)</td>
<td>0.10</td>
<td>0.812</td>
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<tr>
<td>Proportion of teledermatology encounters</td>
<td>1,700 OR=1.10</td>
<td>p₀=0.03</td>
<td>p₁=0.0329</td>
<td>0.05</td>
<td>0.809</td>
<td></td>
</tr>
<tr>
<td></td>
<td>500 OR=1.10</td>
<td>p₀=0.20</td>
<td>p₁=0.2157</td>
<td>0.05</td>
<td>0.844</td>
<td></td>
</tr>
<tr>
<td></td>
<td>500 OR=1.10</td>
<td>p₀=0.03</td>
<td>p₁=0.1089</td>
<td>0.25</td>
<td>0.837</td>
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<tr>
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<td>450 OR=1.20</td>
<td>p₀=0.03</td>
<td>p₁=0.0358</td>
<td>0.05</td>
<td>0.830</td>
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<td>150 OR=1.20</td>
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<td>p₁=0.0386</td>
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</table>

Notes: μ₀ = is the mean of the outcome variable in the control group; μ₁ = is the mean of the outcome variable in the treatment group; p₀ = is the proportion of interest in the control group; p₁ = is the proportion of interest in the treatment group; Δμ = is the difference in means between the treatment and control arms, i.e. the expected treatment effect to be detected for continuous outcomes; OR = the odds ratio between the treatment and control arms, i.e. the expected treatment effect to be detected for the binary outcome; ICC = intracluster correlation coefficient; SD = standard deviation.
For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

Figure 1. Current workstation-based teledermatology process in the VHA.

254x190mm (300 x 300 DPI)
Figure 2. Timeline and design features for the VA Telederm SW-CRT.

338x190mm (300 x 300 DPI)
A. Sample Screen Shots of the VA Telederm App

1. **Initial Login**: Imager may also get an introduction and overview of the app by touching the “Tour the App” button.

2. **Pending consults list**: Imager selects patient of interest and touches “Complete Consult” button to process consult request.

3. **Imaging consent**: Imager documents patients consent to be imaged.

4. **Reader consult request order**: Imager orders request for teledermatology reader. History from PCP is automatically inserted.

5. **Photography prompt**: Imager is guided to obtain skin images.

6. **Image review**: Imager reviews photos, signs and submits consult request.
B. Training materials for VA providers and telehealth leads

The below description, once approved, will be posted to the Beta App Store: mobile.va.gov/app/beta/va-telederm

The Department of Veterans Affairs VA TeleDerm mobile application (app) allows VA care teams to capture and store digital images and associated clinical data to provide safe, appropriate and cost-effective teledermatology services to Veterans. The app seamlessly integrates with current Veterans Affairs consultative store-and-forward teledermatology workflow practices by packaging all the necessary teledermatology tasks for referring clinicians and imagers into a single workflow app. The app enables users to conveniently and wirelessly upload clinical history and captured images to Veterans Health Information Systems and Technology Architecture (VistA), ensuring that all members of the health care team have access to the most up-to-date records and that images will be correctly associated with the appropriate patients.

Features:

- Create and complete Computerized Patient Record System (CPRS) consults for teledermatology
- Capture and upload images to VistA Imaging. No images are stored on the mobile device.
- Verify image upload and assess image quality
- View images that have been uploaded to patients’ files
- Automatically transfer information from imaging consult request to reader consult request
- Use native mobile device dictation capabilities
Overview
The Department of Veterans Affairs VA TeleDerm mobile application (app) allows VA care teams to capture and store digital images and associated clinical data to provide safe, appropriate and cost-effective teledermatology services to Veterans. The app seamlessly integrates with current Veterans Affairs consultative store-and-forward teledermatology workflow practices by packaging all the necessary teledermatology tasks for referring clinicians and imagers into a single workflow app. The app enables users to conveniently and wirelessly upload clinical history and captured images to Veterans Health Information Systems and Technology Architecture (VistA), ensuring that all members of the health care team have access to the most up-to-date records and that images will be correctly associated with the appropriate patients.

Prerequisites
To use the VA TeleDerm App, you must be a VA health care professional with credentials for the Veterans Health Information Systems and Technology Architecture (VistA). To use VA Telederm on a mobile device, you must use a government-furnished mobile device and have PIV-exemption. The intended users of the app are clinicians who refer patients for teledermatology consultation, and imagers.

Getting Oriented
Using the “Menu” and “Patient Search” functions
When you log into the VA TeleDerm App, the “Select a Patient” screen will appear, displaying a Patient Search box above a list of the names of patients you recently searched for and a list of all patients in your facility’s Computerized Patient Record System (CPRS). There are also two icons in the upper left of your screen to help you navigate the app:
• Menu (three-line icon in upper left corner)
• Search for or Select a Patient (magnifying glass icon in upper left corner) – Quickly find patients to see their consults and dermatology information.

Menu functions

- Consults: The Consults option will only appear if you are currently viewing a specific patient’s details screen. It will return you to the “Select a Patient” screen
• Notifications: The Notifications option alerts you to notifications on your patients, e.g., completed consults that you have submitted. You can make sure you are viewing the most current list of notifications by tapping Refresh in the upper right corner. If any new notifications have come in, they will then appear in the list. NOTE: To follow up on any of the notifications, you will have to search for and select the patient in the patient search function.

• Tour the App: You can view app features and screenshots in more detail

• About: A brief summary of the app

• Logout: Exits the app. All unsaved work and images will be lost.
Getting Started

FOR REFERRING CLINICIANS/PRIMARY CARE PROVIDERS – CREATING A TELEDERMATOLOGY IMAGING REQUEST

1. Select your patient
   a) In the “Select a Patient” screen, enter your patient name into the Patient Search field and tap Search. A list of patients matching your search criteria will appear below.
   b) Tap the name of the patient you would like to view. A pop-up box with the patient’s identifying information will appear.
   c) Tap Confirm Patient to go to the “Dermatology Consults” screen.

You can also search for a different patient anywhere in the app by tapping Search for or Select a Patient (magnifying glass icon).

2. Create an imaging consult request
   a) In the “Dermatology Consults” screen, tap New Imager Consult + at the upper right.
   b) The Provider & Location for Current Activities screen appears. Select Clinic Appointments or New Visit radio buttons as appropriate. If you select New Visit, scroll through and tap the appropriate clinic location.
   c) Tap Create New Visit at the bottom of the screen to go to the “Create New Consult” screen.
   d) The “Create New Consult” screen is generally self-explanatory and is similar to VA’s standardized CPRS teledermatology templates.
      o General History: The Imaging Instructions and Chief Complaint fields, and any asterisked (*) questions must be answered to submit a consult. Use Imaging Instructions to specify all anatomic sites you wish to be photographed.
      o Problem A: The Locations and How Long Ago Did This Problem Begin? must be answered to submit a consult.
      o + Add Problem: Allows you to specify additional distinct skin problems. If you add a problem in error, you can tap Remove Problem at the bottom of each problem’s history questions.
      o When entering information into a free text field, you may use your mobile device’s microphone to dictate if you want to convey a lot of history or details. The app is not specifically trained to recognize medical jargon.
   a) Once all history is entered, tap Create Consult at the bottom of the screen. You may need to scroll down to see it.
   b) In the “Sign Order” screen, review the history. If you need to revise the history, you can use the mobile device’s “Back” button to return to the “Create New Consult” screen, but you will need to re-enter all information. If the history is acceptable, enter your signature code, and tap Sign.
   c) You will return to the “Dermatology Consults” screen where you can view the pending imaging consult request you just created.
VA Telederm App
Quick Start Guide
01.08.18

FOR IMAGERS – PROCESSING A TELEDERMATOLOGY IMAGING REQUEST

1. Identify and select pending imaging consults
   a) Select the patient you wish to image
   b) In the “Dermatology Consults” screen, tap the consult that you wish to process. It will expand, and you can scroll through the consult request in the grey box. When ready, tap Complete Consult button on the right side to go to the “Provider & Location for Current Activities” screen
   c) The Provider & Location for Current Activities screen appears. Select Clinic Appointments or New Visit radio buttons as appropriate. If you select New Visit, scroll through and tap the appropriate clinic location. Tap the date and either 1) type in the date in the form MM/DD/YYYY or 2) tap the date from the pop-up calendar that appears.
   d) Tap Create New Visit at the bottom of the screen to go to the “Consult Note Properties” screen.

2. Complete the imaging consult
   a) Enter a Level of understanding – selecting Poor will not allow the consult to be submitted.
   b) Answer the “Patient understands and consents...” question. Selecting Yes will expand the template. Answer the additional questions that are part of VA’s standardized teledermatology template.
c) Review the history in the Consult Reason for Request box. If any fields are blank or if you have additional information to add, you may edit the history.

d) Tap Finish at the bottom of the form. You may need to scroll down to see it.

e) In the “Sign Note” screen, review the history. If you need to revise the history, you can use the mobile device’s “Back” button to return to the “Create New Consult” screen, but you will need to re-enter all information. If the history is acceptable, enter your signature code, and tap Sign. This will generate an imager note in CPRS and complete the imaging consult.

f) You will return to the “Dermatology Consults” screen where you can view the completed imaging consult request.

3. Create the Reader Consult
a) In the “Dermatology Consults” screen, tap the consult that you just completed. It will expand to show the consult details. Tap the Create Reader Consult button. The “Create New Reader Consult” screen appears.

b) In the “Create New Reader Consult” screen, enter information as requested

c) Tap the Create Consult button at the bottom.

d) In the “Sign Order” screen, you can review the history. Enter your signature code, and tap Sign.

e) The “Reader Consults” screen appears showing the pending Reader consult request that you just created. The pending Reader consult request should also show in CPRS.

4. Capture photos of the skin
a) In the “Reader Consults” screen, tap the pending consult request that you just created. It will expand.

b) Tap Select on the right hand side of the expanded consult request. The “Capture Images” screen appears.
c) To take photos, tap the green **Take Picture** button and select Take Photo. The camera view will appear.

d) Orient the mobile device and take a photo by pressing the shutter button on the mobile device. The photo is displayed. If it is acceptable, tap **Use Photo** at the bottom right. If it is unacceptable, tap Retake at the bottom left.

e) Once you return to the “Capture Images” screen you can continue to tap **Take Picture** and repeat steps (d) and (e) as often as required.

f) In “Capture Images” screen, you can review the images as follows

   o Tap **<Previous** or **>Next** to move through the images. You can also swipe the images forward or backward.

   o Tap **Zoom In** or **Zoom Out** to adjust the size of the photo or look at an area in detail.

   o Type notes into the comment box. If you have typed in more than one comment, you can tap **<Move Forwards** or **>Move Backwards** to move through the entered comments.

   o Tap **Remove** to delete the image and comments that are currently selected.

g) Tap **Capture Image**, and a pop-up Images Uploaded box will appear, verifying that the number of images you have selected have been stored in VistA Imaging. The pending Reader consult request should now also appear in VistA Imaging TeleReader.

h) To view the thumbnails you have just uploaded, tap **View Patient Studies**.
Help and Additional Information

Additional Training Materials for the VA TeleDerm App
More resources, such as a User Manual, FAQ and Slideshow, are available at mobile.va.gov/appstore, and search for the app to access the resources.

Help Desk Information
If you need help with the VA TeleDerm App, dial 1-844-482-6624 to speak with a VA representative. The Help Desk is open weekdays from 7 a.m. to 7 p.m. CT. For TTY assistance, dial 711.

Emergencies
If you feel your information may have been compromised, contact your local VA facility to obtain the contact information for your Privacy Officer. To locate your local VA facility, visit VA’s Facility Locator: http://www.va.gov/directory/guide/home.asp?isflash=1. Note that you should never use this app in an emergency. If you encounter an emergency, call your local medical center or dial 911.
# VA Telederm User Manual

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Overview
The Department of Veterans Affairs VA TeleDerm mobile application (app) allows VA care teams to capture and store digital images and associated clinical data to provide safe, appropriate and cost-effective teledermatology services to Veterans. The app seamlessly integrates with current Veterans Affairs consultative store-and-forward teledermatology workflow practices by packaging all the necessary teledermatology tasks for referring clinicians and imagers into a single workflow app. The app enables users to conveniently and wirelessly upload clinical history and captured images to Veterans Health Information Systems and Technology Architecture (VistA), ensuring that all members of the health care team have access to the most up-to-date records and that images will be correctly associated with the appropriate patients.

Features:
- Create and complete Computerized Patient Record System (CPRS) consults for teledermatology
- Capture and upload images to VistA Imaging. No images are stored on the mobile device.
- Verify image upload and assess image quality
- View images that have been uploaded to patients’ files
- Automatically transfer information from imaging consult request to reader consult request
- Use native mobile device dictation capabilities

VA TeleDerm is available for iOS, Android and Windows operating systems, and is supported by these Internet browsers:
1. Internet Explorer 10 and higher
2. Safari 7 and higher
3. Firefox 24 and higher
4. Google Chrome 30 and higher

The app is optimized for an Apple iPad, though it will run on a variety of mobile devices.

This user manual provides an in-depth, step-by-step guide for using the VA TeleDerm App.

The Basics

How VA TeleDerm integrates with teledermatology: VA TeleDerm is an app designed to allow mobile devices to function within the framework of VA’s existing consultative multi-step store-and-forward teledermatology process that involves referring clinicians, teledermatology imagers and teledermatology readers.
1. **Initiation of teledermatology consultation**: Referring clinician identifies a patient who needs dermatologic consultation, and orders a teledermatology imaging consult request in CPRS that directs the imager what areas of skin to photograph, and that provides relevant clinical history.

2. **Completion of teledermatology imaging consult. Imager** receives the teledermatology imaging consult request, and completes the consult by responding to some imager-specific questions, and also recording the clinical history from the referring clinician. This is recorded as an imaging note in CPRS.

3. **Creation of reader consult request**: Imager orders in CPRS a teledermatology reader consult request that automatically extracts relative information from the imaging note.

4. **Image capture**: Imager photographs skin according to instructions in the referring clinician’s original imaging consult request. Images are then uploaded into VistA using VistAImaging Capture to be associated with the reader consult request; this enables the reader consult to appear on the “Read” list of VistAImaging TeleReader, visible to the reading teledermatologist. Once the imager confirms successful upload, the images must be deleted from the camera.

5. **Scheduling appointments**: Appointments for teledermatology imaging and for teledermatology reading must be separately entered in order to correctly record encounters. These are done by various staff, often Imagers.

6. **Reading: The Teledermatology Reader** views the reader consult through VistAImaging TeleReader, including clinical history and images, and writes a consult note in CPRS including impression and recommendations to the referring clinician, completing the teledermatology reader consult.

7. **Patient care**: The original referring clinician receives a view alert when the reader consult is completed, views the reader’s note in CPRS, and executes any recommendations as appropriate.

**VA Telederm limitations**

- **VA Telederm** is an app that, in its current version, is intended only to be used by referring clinicians and imagers. Therefore, **VA Telederm** enables steps 1-4 above to be performed on a mobile device. Step 5 must likely still be done on CPRS separately. The device may also assist with 6, but this has not been validated. Future versions may allow for scheduling, and for dermatologists to view consults and images as well as respond and complete reader consults.

- The use of **VA Telederm** currently necessitates separately logging in to a different program/app than CPRS. As the use of mobile devices becomes more prevalent in VA’s clinical care, separate login may not be as significant an issue.

**VA Telederm advantages**
VA Telederm is also interchangeable with CPRS for steps 1-4, and possibly step 6. That is, a referring clinician may use VA Telederm to create an imaging consult, and an imager may use CPRS to process that imaging consult. Conversely, a referring clinician may use CPRS to create an imaging consult request, and an imager may use VA Telederm to process that request, including capturing images. Finally, both clinicians and imagers may use VA Telederm to participate in the teledermatology process for a patient.

When entering information in free text fields of VA Telederm, the mobile device’s built-in microphone can be used to dictate text. This can improve the efficiency of entering data, particularly for referring clinicians, when entering in detailed symptoms and other clinical history. The app is not specially designed to understand medical terminology.

VA Telederm uses the mobile device’s built-in camera to capture images and allows the imager to complete all imaging steps with a single device. Because the app wirelessly communicates with the facility’s VistA Imaging server, there is no need for the imager to physically connect a separate camera or a camera’s storage card to a workstation to upload images.

VA Telederm does not store images on the mobile device. All images are automatically deleted from memory when exiting the app. Thus, imagers do not need to delete images following an imaging session to ensure privacy and security of imaging data.

Prerequisites: To use the VA TeleDerm App, you must be a VA health care professional with credentials for the Veterans Health Information Systems and Technology Architecture (VistA). To use VA Telederm on a mobile device, you must use a government-furnished mobile device and have PIV-exemption. The intended users of the app are: 1) Clinicians who refer patients for teledermatology consultation, and 2) imagers.

Touring the app Get to know the app before you log in by taking a tour, which provides a bulleted overview of the app’s features as well as screenshots. On the bottom left of your screen, tap Tour the App > You will go to the first screen of the tour > To move through the tour, tap the circles at the bottom of the screen. To close the tour, tap the X in the upper right corner of your screen. NOTE: The app tour will still be available after you log into the app. To get to the tour after you have logged in, tap menu (three-line icon in the upper left corner) > A drop-down menu will appear > Tap Tour the App.
Designer Change all names under Recent Results, Results, Patient Orders and “Awarb, George” in the white box and on the top blue bar to “MobileAppVeteran, One” “MobileAppVeteran, Two” ect.

Change the SSN to either five leading zero’s or five leading six’s (000-00-1234 or 666-66-1234)

Change the DOB year to “1900”

**Logging in** Enter your VistA Username > Enter your VistA Password > Begin typing in a VA Hospital Location > A list of matching facilities will appear in a drop-down menu > Tap your VA facility > Tap **Sign In** > You will proceed into the app.
Getting to know the screen

When you log into the VA TeleDerm App, you will see a Patient Search feature as well as a list of patients whose records you have recently viewed. There are two icons in the upper left of your screen to help you navigate the app:

- **Menu (three-line icon in upper left corner)** – Access Consults, Notifications, Tour the App, About and Logout. **NOTE:** The consults option will only appear if you are currently viewing a specific patient’s details screen.
- **Search for or Select a Patient (magnifying glass icon in upper left corner)** – Quickly find patients to see their consults and dermatology information.
Learning about the app Tap menu (three-line icon in upper left corner) > A drop-down menu will appear > Tap About > You will go to an About screen that provides you with a brief overview of the app, its main features and the version number.

Logging out Tap menu (three-link icon in upper left corner) > A drop-down menu will appear > Tap Logout > You will be logged out of the app.

Notifications
Review notifications related to your patients’ teledermatology consults.
Viewing your notifications

Notifications are triggered when a consult is created for your patient. Tap menu (three-line icon in upper left corner) > A drop-down menu will appear > Tap Notifications > You will see a list of notifications you have received related to your patients’ teledermatology consults. The notifications show you:

- Patient Name – Patients’ last and first name and the last initial and last 4 SSN digits.
- Location
- Urgency – This will default to routine. To change, tap the bar under the heading > A drop-down menu will appear > Tap the level or deadline you would like to select.
- Alert Date/Time – Date and time the alert was created.
- Message – Notes on the status of the consult.
- Forwarded By/When – Name of provider/reader/imager, if the message was forwarded.

You can make sure you are viewing the most current list of notifications by tapping Refresh in the upper right corner. If any new notifications have come in, they will then appear in the list.

NOTE: To follow up on any of the notifications, you will have to search for and select the patient in the patient search function.

Search for or Select Patients

Quickly find and select patients to view their dermatology information.
Searching for and selecting patients When you log into the VA TeleDerm App, you will arrive at the Select a Patient screen. You can also get to the search and select feature at any time by tapping Search for or Select a Patient (magnifying glass icon). NOTE: If you are already viewing a patient’s records, you can select a new patient at any time by tapping the magnifying glass icon > You will see a Patient Search box, and underneath you will see the names of patients you recently searched for and a list of all patients in CPRS at your facility. If you immediately see the name of the patient whose records you will like to view, you can tap the name of the patient. If you need to search for the patient you would like to view, type in the patient’s first and/or last name in the bar underneath the Patient Search heading > Tap Search > A list of patients matching your search criteria will appear below > Tap the name of the patient you would like to view > A pop-up box with the patient’s identifying information will appear > Tap Confirm Patient to go to the patient’s Dermatology Consults screen.

Understanding a patient’s screen After you search for a patient, you will first arrive at the patient’s Dermatology Consults list screen. In the upper left corner, you will see the patient’s identifying information including patient name, date of birth (DOB), age, gender and social security number (SSN).
The screen is divided into two panes. On the left pane, you will see the total number of consults in parenthesis next to Results, a Refreshed button and a list of filters to help you narrow down or expand your search. On the right pane, you will see a list of dermatology consults. To change the type of list you would like to view, tap the List heading > A drop-down menu will appear > Tap one of the following lists:

- **Dermatology Consults** – View a list of complete or in-progress teledermatology consults for providers and imagers, complete a consult, create a new imager consult or create a reader consult.
- **Reader Consults** – View a list of reader consults, and capture and upload images.
- **Patient Orders** – View a list of patient orders, and edit or sign orders that have not yet been released.
- **Patient Studies** – View images that have been uploaded to VistA Imaging.

**Dermatology Consults**

See or complete a patient’s dermatology consults and create a new imager or reader consult.

**Accessing and filtering a patient’s dermatology consults** First search for and select a patient. If not already selected, tap the List heading > A drop-down menu will appear > Tap **Dermatology Consults**. The Dermatology Consults screen will be divided into two panes: status filter options on the left and the list of consults on the right. To use the status filters, tap the checkbox(es) next to any or all of the following statuses:
• Active  
• Cancelled  
• Complete  
• Discontinued  
• No status  
• Other  
• Partial results  
• Pending  
• Scheduled

Tap Refreshed (circle with two arrows), and the list of consults in the right pane will adjust based upon the criteria you selected. The list provides you with an overview of the consult information:

• Date – Date consult was created.  
• Description – Type of consult.  
• Status – Current status of the dermatology consult.  
• IEN – Internal entry number assigned to the consult request.

Creating a new imager consult This is the first step in the teledermatology process. Referring clinicians/primary care providers can create new consults and send them to imagers. First search for and select a patient. On a patient’s Dermatology Consults screen, tap New Imager Consult+ > Enter the following information:

• Encountered Provider Results – The name will default to the provider who requested the consult. To change the name, tap the bar under the heading > A drop-down menu will appear > Tap the name of the provider you would like to select.  
• Select Location Type - Tap the circle next to the location type:
  o Clinic Appointments – Under Select a Clinic Appointment, tap on the specific clinic appointment you would like to complete > The selected hospital admission will have a checkmark next to it and the background will be light blue > Tap Select Clinic Appointment.  
  o Hospital Admissions – A list of hospital admissions will appear > Tap the specific hospital admission you would like to complete > The selected hospital admission will have a checkmark next to it and the background will be light blue > Tap Select Hospital Admission.  
  o New Visit – Under Visit Location, tap the specific type of appointment you would like to complete > Under Date of Visit, tap the date, and either 1) type in the date in the form MM/DD/YYYY or 2) tap the date from the pop-up calendar that appears > Tap Create New Visit.
You will go to the Create New Consult screen where you will see logistical information, general history and problems. Fill out the following information:

- **Consult to Service/Specialty** – The service/specialty will default to the title chosen when the clinician created the original consult. To change it, tap the bar under the heading > A drop-down menu will appear > Tap the service/specialty you would like to select.

- **Patient Will Be Seen** – Tap the circle next to either Outpatient or Inpatient.

- **Attention Results** – Tap the bar under the heading > A drop-down menu will appear > Tap the name of the person who should be alerted as to the results of the consult.

- **Clinically Indicated Date** – The date will default to the current date. To change it, tap the date and type in the form MM/DD/YYYY.

- **Urgency** – This will default to routine. To change, tap the bar under the heading > A drop-down menu will appear > Tap the level or deadline you would like to select.

- **Place of Consultation** – This will default to the location that was chosen when the consult was created. To change it, tap the bar under the heading > A drop-down menu will appear > Tap either Consultant’s Choice or Emergency Room.

For **General History**, you are required to fill out the first section of the patient’s health history. Enter information by:

- Typing in your comment. You may also dictate by tapping on the microphone symbol on the keyboard.

- Tapping a circle or checkbox next to the information that corresponds to your patient.

- Tapping the image of a family member on a family tree.

For **Problems**, you are required to enter at least one problem and its location on your patient’s body. Enter information by:

- Typing in your comments or by dictating if the mobile device has a built-in microphone.

- Tapping a circle or checkbox next to the information that corresponds to your patient.

- To add another problem, tap +Add Problem, and a new field will appear where you can enter the additional information.

- To edit problem information, tap the problem you want to edit (e.g., Problem A, Problem B, etc.) > The problem will appear below, and edit as you would normally.

- To remove a problem, tap the problem you want to delete (e.g., Problem A, Problem B, etc.) > The problem will appear below > Tap Remove Problem.

Tap **Create Consult** > Review the order information > Under the Electronic Signature Code, type in your name > Tap **Sign**.
Completing a teledermatology imaging consult

Teledermatology imaging consult requests from clinicians are processed by imagers who have been trained according to protocols established by Office of Connected Care / Office of Health Informatics. The section is intended to be used during an appointment with a patient.

First search for and select a patient. From the Dermatology Consults screen, tap a pending consult in the Dermatology Consult list > Full details about the consult will expand below > Tap Complete Consult > You will go to a Provider & Location for Current Activities screen > You will see a list of clinic appointments > Enter xxx

- Encounter Provider – Type in the first or last name of a provider > Tap Search
- Encountered Provider Results – The name will default to the provider who requested the consult. To change the name, tap the bar under the heading > A drop-down menu will appear with a list of names > Tap the name of the provider you would like to select.
- Select Location Type - Tap the circle next to the location type:
  - Clinic Appointments – Under Select a Clinic Appointment, tap on the specific clinic appointment you would like to complete > The selected clinic appointment will have a checkmark next to it and the background will be light blue > Tap Select Clinic Appointment.
  - Hospital Admissions – A list of hospital admissions will appear > Tap the specific hospital admission you would like to complete > The selected hospital admission will have a checkmark next to it and the background will be light blue > Tap Select Hospital Admission.
  - New Visit – Under Visit Location, tap the specific type of appointment you would like to complete > Under Date of Visit, tap the date, and either 1) type in the date in the form MM/DD/YYYY or 2) tap the date from the pop-up calendar that appears > Tap Create New Visit.
You will go to a Consult Note Properties screen > Fill out the form to create the appointment:

- **Progress Note Title** – The note title will default to the one chosen when the consult was created. To change it, tap the bar under the heading > A drop-down menu will appear > Tap the title you would like to select.
- **Date of Note** – The date will default to the current date. To change it, tap the date, and type the date in the form MM/DD/YYYY.
- **Author** – Type in the first or last name of a provider > Tap Search > XXX
- **Author Results** – The name will default to the provider who requested the consult. However, you can change the name by tapping the bar under the heading > A drop-down menu will appear with a list of names > Tap the name of the provider you would like to select.

Read the education section to your patient to inform him or her about the background and process of teledermatology care > Record your patient’s understanding by:

- **Level of understanding** – Tap the bar under the heading > A drop-down menu will appear > Tap the applicable description.
- **Comment** – If desired, type in any information about your interaction with the patient.
- **Patient consent** – Tap the circle next to either Yes or No. If you selected yes, a drop-down survey will appear > Ask your patient the questions, and record the answers by either tapping a checkbox or circle or typing in comments.

Tap **Finish** > Review the note > Under the Electronic Signature Code, type in your name > Tap **Sign**.
Creating a reader consult
Imagers can create a consult to send to readers. First search for and select a patient. From the Dermatology Consults screen, tap a completed consult in the Dermatology Consult list > Full details about the consult will expand below > Tap **Create Reader Consult** > You will go to a Create New Reader Consult screen > **Fill out the form to create the appointment:**

- **Consult to Service/Specialty** – The service/specialty will default to the title chosen when the clinician created the original consult. To change it, tap the bar under the heading > A drop-down menu will appear > Tap the service/specialty you would like to select.
- **Patient Will Be Seen** – Tap the circle next to either Outpatient or Inpatient.
- **Attention Results** – Tap the bar under the heading > A drop-down menu will appear > Tap the name of the person who should be alerted as to the results of the consult.
- **Clinically Indicated Date** – The date will default to the current date. To change it, tap the date, and type in the form MM/DD/YYYY.
- **Urgency** – This will default to routine. To change it, tap the bar under the heading > A drop-down menu will appear > Tap the level or deadline you would like to select.
- **Place of Consultation** – This will default to the location that was chosen when the consult was created. To change it, tap the bar under the heading > A drop-down menu will appear > Tap either **Consultant’s Choice** or **Emergency Room**.
- **Provisional Diagnosis** – > Tap **Lexicon**

**Tap Create Consult** > Review the order information > Under the Electronic Signature Code, type in your name > **Tap Sign** > You will go to a Reader Consults screen where you can view the consults sent to readers and capture and upload images. (For detailed instructions, visit the Reader Consults section.)

Reader Consults
Imagers can create consults for readers, and take and upload photos.
Accessing and completing reader consults First search for and select a patient. From the Dermatology Consults screen, tap the List heading > A drop-down menu will appear > Tap Reader Consults > You will go to a Reader Consults screen where you will see a list of the consults > The list provides you with an overview of the consult information:

- Date – Date consult was created.
- Service
- Procedure
- Sending Provider – Provider who created the original consult request.
- Status – Current status of the dermatology consult.
- IEN – Internal entry number assigned to the consult request.

Tap on the consult you would like to view > The details for the consult will expand below > Tap Select > You will go to a Capture Images screen > Details about the image will automate based on the information clinicians and imagers entered about the requested image, but you can change these by typing in information, tapping options from drop-down menus or tapping to check/uncheck boxes:

- Document/Image Date
- Origin
- Document/Image Type
• Specialty
• Proc/Event
• Image Description
• Controlled Image

Tap Take Picture > Depending on the device you are using, choose and upload an image file saved on the device you are using to access the VA TeleDerm App > The selected image will appear in a preview within the Capture Image screen > If desired, you can:
• Tap Take Picture again to upload more photos > If you have uploaded more than one image, you can tap <Previous or >Next to move through the uploaded images.
• Tap Zoom In or Zoom Out to adjust the size of the photo or look at an area in detail.
• Type notes into the comment box. If you have typed in more than one comment, you can tap \Move Forwards or \Move Backwards to move through the entered comments.
• Tap Remove to delete the image and comments that are currently selected.

Tap Capture Image > A pop-up Images Uploaded box will appear, verifying that the number of images you have selected have been stored in VistA. To close the pop-up box and remain on the Capture Images screen, tap Close. To view the thumbnails you uploaded, tap View Patient Studies.
Capture Images

TELEDERMATOLOGY READER REQUEST WF - 3/29/17 3:41 PM

- Document/Image Date: 2018-01-02
- Origin: VA
- Document/Image Type: CONSULT
- Specialty: DERMATOLOGY
- Proc/Event: PHOTOGRAPHY
- Image Description: Imaging Dermatology Consult

Capture the following image views:
- Identifier View w/Measure
- Forest View
- Oblique View
- Macro View
- Identifier View
- Dermoscopic View (optional)
- Other View

Patient Orders
Review, sign and edit patient orders.
Viewing patient orders First search for and select a patient. From the Dermatology Consults screen, tap the List heading > A drop-down menu will appear > Tap Patient Orders > You will see a list of orders with the following information:

- Order Date – Date the order was created.
- Order – Description of the order.
- Provider – Name of the provider who created the order.
- Status – Current status of the dermatology consult.
- Location – Area of medicine.

Tap on the consult you would like to view > The details for the order will expand below.

Signing patient orders First search for and select a patient. From the Dermatology Consults screen, tap the List heading > A drop-down menu will appear > Tap Patient Orders > You will see a list of orders > Tap the order you would like to sign, and the details for the order will expand below > Tap Sign Order > Review the order information > Under the Electronic Signature Code, type in your name > Tap Sign or tap Cancel to return to the Patient Orders screen.

Editing patient orders First search for and select a patient. From the Dermatology Consults screen, tap the List heading > A drop-down menu will appear > Tap Patient Orders > You will see a list of orders > Tap the order you would like to edit, and the details for the order will
expand below > Tap **Edit Order** > You will go to a Provider & Location for Current Activities screen > Edit the following information as needed:

- **Encounter Provider** – Type in the first or last name of a provider > Tap **Search**
- **Encountered Provider Results** – The name will default to the provider who requested the consult. To change the name, tap the bar under the heading > A drop-down menu will appear with a list of names > Tap the name of the provider you would like to select.
- **Select Location Type** - Tap the circle next to the location type:
  - **Clinic Appointments** – Under Select a Clinic Appointment, tap on the specific clinic appointment you would like to complete > The selected hospital admission will have a checkmark next to it and the background will be light blue > Tap **Select Clinic Appointment**.
  - **Hospital Admissions** – A list of hospital admissions will appear > Tap the specific hospital admission you would like to complete > The selected hospital admission will have a checkmark next to it and the background will be light blue > Tap **Select Hospital Admission**.
  - **New Visit** – Under Visit Location, tap the specific type of appointment you would like to complete > Under Date of Visit, tap the date, and either 1) type in the date in the form DD/MM/YYYY or 2) tap the date from the pop-up calendar that appears > Tap **Create New Visit**.

You will go to an **Edit Order** screen > Type in any additional notes into the order box > Tap one of the following

- **Cancel** - Return to the Patient Orders screen.
- **Save Changes** - A pop-up Order Updated box will appear > Tap **Close** to return to the Patient Orders screen, or tap **Sign** to continue and sign the order.
- **Sign Order** - Complete the order. Under the Electronic Signature Code, type in your name > Tap **Sign**, or tap **Cancel** to return to the Patient Orders screen without signing.

### Patient Studies

See images that have been uploaded to patients’ files.
Viewing patient studies: Currently, the target users for VA Telederm are referring clinicians/primary care providers and certified imagers in VA. While dermatologists can also use the app to view which consults are pending or completed, the app does not permit a review of the submitted images, and VA Telederm should not be used to complete teledermatology reader consult requests. Reading and completion of teledermatology reader consult requests should continue to be done using VistA Imaging TeleReader until further notice.

Help and Additional Information

Additional Training Materials for the VA TeleDerm App: More resources, such as a Quick Start Guide, Slideshow and FAQs, are available at mobile.va.gov/appstore, and search for the app to access the resources.

Help Desk Information: If you need help with the VA TeleDerm App, dial 1-844-482-6624 to speak with a VA representative. The Help Desk is open weekdays from 7 a.m. to 7 p.m. CT. For TTY assistance, dial 711.

Emergencies: If you feel your information may have been compromised, contact your local VA facility to obtain the contact information for your Privacy Officer. To locate your local VA facility, visit VA’s Facility Locator: http://www.va.gov/directory/guide/home.asp?isflash=1. Note that you should never use this app in an emergency. If you encounter an emergency, call your local medical center or dial 911.
Appendices

Appendix #1: Project References
This app was developed according to an approved concept paper. The app was tested in a demo environment to ensure optimal functionality.

Appendix #2: Glossary

**App** – An application, or software program, that can be accessed through a website or mobile device and is designed to fulfill a particular purpose

**CPRS** – Computerized Patient Record System

**DoD** – Department of Defense

**DS Logon** (Department of Defense Self-Service Logon) – A secure logon ID, created by the Department of Defense (DoD), that verifies the identities of individuals affiliated with DoD or the Department of Veterans Affairs (VA) and allows them to access secure websites and digital resources across DoD and VA using a single username and password.

- **DS Logon Level 1 (Basic) Account:** Provides limited access to website features
- **DS Logon Level 2 (Premium) Account:** Offers the highest level of access to website features. (NOTE: You must have a DS Logon Level 2 (Premium) Account to use VA’s Mobile Apps.)

**IEN** – Internal entry number

**VA** – Department of Veterans Affairs

**VA Mobile Health** – An initiative that aims to improve Veterans’ health by providing technologies to expand care beyond the traditional office visit and that includes the creation of secure mobile apps to leverage the popularity of wireless technologies to support Veterans, Caregivers and VA care teams [More at: mobilehealth.va.gov]

**VHA** – Veteran Health Administration

**VistA** – Veterans Health Information Systems and Technology Architecture) - VA’s computerized patient record system.
C. Stata code for the power analyses

*First need to create a design-pattern matrix in a replicable way
clear all
set obs 36 //this is the number of clusters
gen base1 = 0
gen base2 = 0

gen step1 = 0
replace step1 = . in 1/6

gen step2 = 0
replace step2 = 1 in 1/6
replace step2 = . in 7/12

gen step3 = 0
replace step3 = 1 in 1/12
replace step3 = . in 13/18

gen step4 = 0
replace step4 = 1 in 1/18
replace step4 = . in 19/24

gen step5 = 0
replace step5 = 1 in 1/24
replace step5 = . in 25/30

gen step6 = 0
replace step6 = 1 in 1/30
replace step6 = . in 31/36

gen step7 = 1
gen step8 = 1

cd "Y:\CAPER\Nicolae\Telederm\Analyses\Power calculations"
save design_va_telederm, replace

*CALCULATE POWER USING THE DESIGN MATRIX
clear all
cd "Y:\CAPER\Nicolae\Telederm\Analyses\Power calculations"
use design_va_telederm, clear

**Consult completion time
steppedwedge, power alpha(0.05) beta(0.8) incomplete(1) vartotal(0) m(120) mu1(27.8) mu2(25.0) sd1(44.3) sd2(44.3) rho(0.25)
steppedwedge, power alpha(0.05) beta(0.8) incomplete(1) vartotal(0) m(120) mu1(27.8) mu2(25.0) sd1(44.3) sd2(44.3) rho(0.30)
steppedwedge, power alpha(0.05) beta(0.8) incomplete(1) vartotal(0) m(60) mu1(27.8) mu2(23.6) sd1(44.3) sd2(44.3) rho(0.25)
steppedwedge, power alpha(0.05) beta(0.8) incomplete(1) vartotal(0) m(60) mu1(27.8) mu2(23.6) sd1(44.3) sd2(44.3) rho(0.25)
steppedwedge, power alpha(0.05) beta(0.8) incomplete(1) vartotal(0) m(50) mu1(27.8) mu2(23.6) sd1(44.3) sd2(50.0) rho(0.25)
steppedwedge, power alpha(0.05) beta(0.8) incomplete(1) vartotal(0) m(70) mu1(27.8) mu2(23.6) sd1(50.0) sd2(50.0) rho(0.25)
**Appointment completion time**
steppedwedge, power alpha(0.05) beta(0.8) incomplete(1) vartotal(0) m(200) mu1(60.0) mu2(57) sd1(50.0) sd2(50.0) rho(0.2)
steppedwedge, power alpha(0.05) beta(0.8) incomplete(1) vartotal(0) m(140) mu1(60.0) mu2(57) sd1(50.0) sd2(50.0) rho(0.2)
steppedwedge, power alpha(0.05) beta(0.8) incomplete(1) vartotal(0) m(300) mu1(60.0) mu2(57) sd1(75) sd2(75) rho(0.2)
steppedwedge, power alpha(0.05) beta(0.8) incomplete(1) vartotal(0) m(110) mu1(60.0) mu2(57) sd1(50.0) sd2(40.0) rho(0.1)
steppedwedge, power alpha(0.05) beta(0.8) incomplete(1) vartotal(0) m(240) mu1(50.0) mu2(47.5) sd1(50.0) sd2(60.0) rho(0.1)
steppedwedge, power alpha(0.05) beta(0.8) incomplete(1) vartotal(0) m(400) mu1(60.0) mu2(58.2) sd1(50.0) sd2(50.0) rho(0.3)

**Travel distance**
steppedwedge, power alpha(0.05) beta(0.8) incomplete(1) vartotal(0) m(550) mu1(13.0) mu2(12.61) sd1(13) sd2(13) rho(0.2)
steppedwedge, power alpha(0.05) beta(0.8) incomplete(1) vartotal(0) m(300) mu1(13.0) mu2(12.48) sd1(13) sd2(13) rho(0.2)
steinpedwedge, power alpha(0.05) beta(0.8) incomplete(1) vartotal(0) m(300) mu1(13.0) mu2(12.48) sd1(13) sd2(13) rho(0.1)
steppedwedge, power alpha(0.05) beta(0.8) incomplete(1) vartotal(0) m(500) mu1(13.0) mu2(12.48) sd1(13) sd2(13) rho(0.3)
steppedwedge, power alpha(0.05) beta(0.8) incomplete(1) vartotal(0) m(1000) mu1(10.0) mu2(9.7) sd1(12) sd2(15) rho(0.1)

**Proportion of telederm encounters**
steppedwedge, power binomial alpha(0.05) beta(0.8) incomplete(1) vartotal(0) m(1700) p1(0.03) p2(0.0329) rho(0.05)
steppedwedge, power binomial alpha(0.05) beta(0.8) incomplete(1) vartotal(0) m(450) p1(0.03) p2(0.035785) rho(0.05)
steppedwedge, power binomial alpha(0.05) beta(0.8) incomplete(1) vartotal(0) m(200) p1(0.03) p2(0.038652) rho(0.1)
steppedwedge, power binomial alpha(0.05) beta(0.8) incomplete(1) vartotal(0) m(150) p1(0.1) p2(0.117647) rho(0.1)
steppedwedge, power binomial alpha(0.05) beta(0.8) incomplete(1) vartotal(0) m(350) p1(0.2) p2(0.215686) rho(0.05)
steppedwedge, power binomial alpha(0.05) beta(0.8) incomplete(1) vartotal(0) m(600) p1(0.10) p2(0.108911) rho(0.25)
D. Full Constrained Randomization Algorithm

1. The first stage of the procedure involved an optimization method that evaluated the potential combinations in sequence assignments and ranked these combinations according to balance in site characteristics. Since evaluating the full set of combinations is prohibitive in terms of time and computing power (the total number of combinations is \( N = \binom{36}{6} \binom{30}{6} \binom{24}{6} \binom{18}{6} \binom{12}{6} \approx 2.67 \times 10^{24} \)), we performed a simplified step-wise procedure instead, relying on the assumption that if at each iteration a group of 6 facilities is chosen that is similar to the ones that are left, then the procedure will produce 6 groups of facilities that are similar to each other. We implemented this procedure in the SAS statistical software.

Thus, starting with the full set of \( K = 36 \) sites, we selected an allocation of 6 facilities at a time, compared their characteristics with the rest of the unselected facilities, chose the most balanced combination, and then repeated these steps an additional 4 iterations on a progressively restricted subset of the facilities obtained by excluding the facilities already selected in the previous iteration. In the last iteration, 6 sites were chosen out of the 12 remaining sites and the most balanced combination of site allocations was chosen. This method produced 6 groups of sites that were balanced in baseline characteristics. In more detail:

1.1. We first created a 0/1 matrix of all the possible combinations of 6 facilities to be chosen in the first group (group A). The total number of rows in this matrix was equal to the total number of ways of choosing exactly 6 elements out of a group of 36 when the order of the elements does not matter, meaning \( \binom{36}{6} = \frac{36!}{30!6!} = 1,947,792 \). The number of columns of this matrix was 6.

1.2. A continuous score was created for each possible combination of 6 facilities by standardizing the quantitative variables being balanced, calculating the means of each variable in each combination, and then squaring the means and summing the squared means.

1.3. Since our only categorical variable to balance is the region, a regional score was also calculated for each combination of 6 elements as the sum of two subscores. The first subscore was calculated as the maximum number of facilities selected from any given region minus the minimum number of facilities selected from any given region. To illustrate, if a combination selected 6 facilities from region A but zero facilities from region B, it was assigned a regional subscore of 6. This subscore was higher than a combination that chose 3 facilities from region A and 3 facilities from region B, which received a regional subscore of 3-3=0. The same subscore was then calculated for the left-over facilities after subtracting the selected combination to ensure that the set of combinations was not restricted too much for the following iteration.

1.4. In the next step, the overall regional score was first minimized, and the sequence with the lowest continuous score was chosen out of all the combinations with the lowest regional score.

1.5. The sequence of facilities selected with the lowest continuous score and lowest regional score was selected and excluded from the set, thus leaving \( K-6 \) facilities.

1.6. Steps 1.1 through 1.4 were then repeated for the \( K-6 \) facilities another 4 times, until a sequence of 6 facilities was left. Ultimately, the first stage resulted in 6 sequences of 6 facilities each, balanced on geographic composition, size, and percentage of teledermatology consults.
2. The second stage involved obtaining a computer-generated list of random allocation numbers using the Stata program version 14.1 (StataCorp, LLC). These numbers were assigned to the sequences of facilities allocated in stage (1). Since this involved randomly assigning an order to 6 sequences of facilities, we randomly chose one order out of a total of $6! = 720$ potential orderings.

The full SAS and Stata code for conducting the constrained randomization procedure is provided below.

**SAS Code for Selecting a Balanced Combination of Groups**

```sas
libname dt "Y:\Nicolae\Telederm\Analyses\Work";
proc import
datafile="Y:\Nicolae\Telederm\Analyses\Work\sites_vaderm_for_sas_fy16.csv" dbms=csv out=dt.vaderm replace;
proc contents data=dt.vaderm; run;
proc freq data=dt.vaderm; tables districtnumberfy17; run;
*RESTRICT THE TELEDERM DATA TO THE VARIABLES AND OBSERVATIONS NEEDED;
data dt.vaderm_rest(keep=id sta3n totvis pctd695_6 districtnumberfy17);
set dt.vaderm;
  id=_N_; run;
data dt.vaderm_rest; set dt.vaderm_rest; run;
*STANDARDIZE THE CONTINUOUS VARIABLE DATA;
proc standard data=dt.vaderm_rest mean=0 std=1 out=dt.vaderm_st print;
var pctd695_6 totvis;
run;
```

```sas
*MACRO THAT SELECTS A NUMBER Nsel of observations out of a total of Nfac;
* trial provides which study we are conducting the analysis for and can be either "va" or "my"
* group provides the group that we are selecting (=A, B, C, D, or E since F is selected at the same time as E by elimination);
* Nblk is a number equal to the number of combinations for the step, equal to (Nfac choose Nsel);
%macro procstep(trial,group,Nblk,Nfac,Nsel);
  *CREATE A DATASET THAT CONTAINS ALLOCATIONS WITH ID OF UNITS CHOSEN;
  proc plan seed=123;
    factors block=&Nblk ordered station=&Nsel of &Nfac comb;
    ods output plan=dt.&trial.derm_comb_&group;
  run;
  *CREATE A DATASET THAT CONTAINS ALL THE ALLOCATIONS AS 0/1 MATRIX;
data dt.&trial.derm_comb2_&group (drop=station);
  set dt.&trial.derm_comb_&group;
  array c (*) c1-c&Nfac;
  array stations (*) station1-station&Nfac;
```

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml
do i=1 to &Nfac;
    do j=1 to &Nsel;
        if stations(j)=i then c(i)=1;
    end;
    if c(i)=. then c(i)=0;
end;
drop i j;
run;
*COPY THE FACILITY DATA C TIMES AND MERGE WITH THE ALLOCATION MATRIX;
*if there are n facilities total and C total allocations there will be nXC total records;
data dt.&trial.derm_z_&group;
    set dt.&trial.derm_st_&group;
    do block = 1 to &Nblk;
        output;
    end;
run;
proc sort data=dt.&trial.derm_z_&group; by block id;
run;
*MERGE FACILITY DATA WITH ALL POSSIBLE ALLOCATIONS;
data dt.&trial.derm_z2_&group;
    merge dt.&trial.derm_comb2_&group
dt.&trial.derm_z_&group;
    by block;
run;
*ASSIGN EACH FACILITY TO EITHER CONTROL OR INTERVENTION ACCORDING TO THE POSSIBLE COMBINATIONS;
data dt.&trial.derm_z3_&group;
    set dt.&trial.derm_z2_&group;
    array c(*) c1-c&Nfac;
    do i=1 to dim(c);
        group=(c(i) ^= c(id));
    end;
run;
*SAVE A MATRIX WITH WHAT THE BLOCKS LOOK LIKE - SO I CAN MERGE LATER WITH THE SCORES AND KEEP TRACK OF WHAT FACILITIES GET PICKED;
data dt.&trial.derm_blocks1_&group (keep=block c:);
    set dt.&trial.derm_z3_&group;
    by block;
    if first.block then output;
run;
*CREATE VARIABLES WITH THE SCORES FOR EACH DISTRICT;
data dt.&trial.derm_z4reg_&group;
    set dt.&trial.derm_z3_&group;
    dis1=0; dis2=0; dis3=0; dis4=0; dis5=0;
    array d(*) dis1-dis5;
    do i = 1 to 5;
        d(i) = (districtnumberfyl7=i);
    end;
run;
*ADD UP REGION SCORES BY BLOCK AND GROUP;
proc means data=dt.&trial.derm_z4reg_&group sum;
class block group;
var dis1--dis5;
ods output summary=dt.&trial.derm_z5reg_&group;
run;

data dt.&trial.derm_regscores_&group;
set dt.&trial.derm_z5reg_&group;
reg_score =
(max(dis1_Sum,dis2_Sum,dis3_Sum,dis4_Sum,dis5_Sum) -
min(dis1_Sum,dis2_Sum,dis3_Sum,dis4_Sum,dis5_Sum));
run;

proc means data=dt.&trial.derm_regscores_&group mean;
class block;
var reg_score;
ods output summary=dt.&trial.derm_regscores2_&group;
run;

*GET A SORTED DATASET WITH REGION SCORE FOR EACH BLOCK;
proc sort data=dt.&trial.derm_regscores2_&group; by reg_score_Mean;
run;  
*****AT THIS POINT THE DATASET HAS THE REGION SCORES FOR EACH BLOCK

*CREATE THE MEAN VALUES BY GROUP OF ALL POSSIBLE COMBINATIONS OF FACILITIES;
proc means data=dt.&trial.derm_z3_&group mean;
class block group;
var totvis pctd695_6;
ods output summary=dt.&trial.derm_s1_&group;
run;

*CALCULATE SUM OF SQUARES DIFFS BETWEEN CONTROL AND INTERVENTION GROUPS OF FACILITIES;
proc sort data=dt.&trial.derm_s1_&group; by block group;
run;
data dt.&trial.derm_s2_&group(keep= block totalssq);
set dt.&trial.derm_s1_&group;
by block;
retain fvis fpct;
array f(*) fvis fpct;
array z(*) totvis_Mean pctd695_6_Mean;
array sqdiff(*) dvis dpct;
if first.block then do i=1 to dim(f);
f(i)=z(i);
end;
else if last.block then do;
do i=1 to dim(f);
sqdiff(i)=(f(i)-z(i))**2;
end;
totalssq=sum(dvis, dpct);
output;
end;
run;
proc sort data=dt.&trial.derm_s2_&group; by totalssq;
run;
****AT THIS POINT THE DATASET CONTAINS THE CONTINUOUS
SCORES AND IS SORTED IN ASCENDING ORDER;
proc sort data=dt.&trial.derm_s2_&group; by block;
run;
proc sort data=dt.&trial.derm_regscores2_&group; by block; run;
data dt.&trial.derm_step_&group;
merge dt.&trial.derm_blocks1_&group
dt.&trial.derm_s2_&group dt.&trial.derm_regscores2_&group;
by block;
run;
proc sort data=dt.&trial.derm_step_&group; by reg_score_mean totalssq; run;

*GET TOP PERCENT OF BLOCKS;
proc univariate data=dt.&trial.derm_s2_&group;
var totalssq;
id block;
ods output quantiles=dt.&trial.derm_q_&group
(drop=varname);
run;

*SET INITIAL DATA ONE MORE TIME TO IDENTIFY SELECTED
OBSERVATIONS;
data dt.&trial.derm_st_&group; set
dt.&trial.derm_step_&group; run;
%mend procstep;

*=====================================================================
*=====================================================================
*RUNNING PROCEDURE MACRO FOR THE VA TELEDERM TRIAL;
*=====================================================================

*RUN THE MACRO 5 TIMES WITH THE APPROPRIATE SUBSETTING AFTER EACH RUN
TO ELIMINATE THE FACILITIES THAT WERE JUST SELECTED;
data dt.vaderm_st_A; set dt.vaderm_st; run;
%procstep(va,A,1947792,36,6)
data vaderm_st_Bt(drop=id); set dt.vaderm_st; if id
NOTIN(1,6,7,10,35,36) then output; run;
data vaderm_st_B; set vaderm_st_Bt; id=_N_; run;
%procstep(va,B,593775,30,6)
data vaderm_st_Ct(drop=id); set dt.vaderm_st_B; if id
NOTIN(4,6,13,15,21,25) then output; run;
data dt.vaderm_st_C; set vaderm_st_Ct; id=_N_; run;
%procstep(va,C,134596,24,6)

data vaderm_st_Dt(drop=id); set dt.vaderm_st_C; if id NOTIN(1,5,8,18,19,22) then output; run;
data dt.vaderm_st_D; set vaderm_st_Dt; id=_N_; run;
%procstep(va,D,18564,18,6)

data vaderm_st_Et(drop=id); set dt.vaderm_st_D; if id NOTIN(2,4,5,6,10,12) then output; run;
data dt.vaderm_st_E; set vaderm_st_Et; id=_N_; run;
%procstep(va,E,924,12,6)

Stata Code for Selecting a Random Ordering
*****VA TELEDERM
cd "Y:\Nicolae\Telederm\Analyses\Work"
use sites_vaderm_group_fy16, replace

*PERFORM RANDOMIZATION OF ORDER IN WHICH GROUPS RECEIVE INTERVENTION
preserve
  set seed 123
  sort vatd_group
  by vatd_group: gen _keep=(_n==1)
  keep if _keep==1
  keep vatd_group
  list, clean noobs
  generate u = runiform()
  sort u
  gen vatd_step = _n
  list, clean noobs
  cd "Y:\Nicolae\Telederm\Analyses\Work"
  save vatd_order, replace
restore

*MERGE GROUPS WITH THE ORDER IN WHICH THEY WILL RECEIVE INTERVENTION
cd "Y:\Nicolae\Telederm\Analyses\Work"
use sites_vaderm_group_fy16, clear
merge m:1 vatd_group using vatd_order_fy16
drop _merge

label var vatd_step "VA Telederm Step"

cd "Y:\Nicolae\Telederm\Analyses\Work"
save sites_vaderm_randomized_fy16, replace
## E. Facilities in order of implementation sequence and relevant facility characteristics

<table>
<thead>
<tr>
<th>Sequence</th>
<th>Facility</th>
<th>Facility Name</th>
<th>District</th>
<th>Complexity</th>
<th>Visits</th>
<th>Percent Telederm</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>523 (V01) (523) VA Boston, MA</td>
<td>North Atlantic</td>
<td>1a</td>
<td>15057</td>
<td>2.7</td>
<td></td>
</tr>
<tr>
<td></td>
<td>688 (V05) (688) Washington, DC</td>
<td>North Atlantic</td>
<td>1a</td>
<td>14110</td>
<td>1.4</td>
<td></td>
</tr>
<tr>
<td></td>
<td>548 (V08) (548) West Palm Beach, FL</td>
<td>Southeast</td>
<td>1c</td>
<td>17945</td>
<td>7.1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>636 (V23) (636) Iowa City, IA</td>
<td>Midwest</td>
<td>1b</td>
<td>22938</td>
<td>0.3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>598 (V16) (598) Little Rock, AR</td>
<td>Continental</td>
<td>1a</td>
<td>15846</td>
<td>0.2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>654 (V21) (654) Reno, NV</td>
<td>Pacific</td>
<td>1c</td>
<td>4076</td>
<td>8.1</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>689 (V01) (689) VA Connecticut HCS, CT</td>
<td>North Atlantic</td>
<td>1a</td>
<td>15713</td>
<td>0.7</td>
<td></td>
</tr>
<tr>
<td></td>
<td>620 (V03) (620) VA Hudson Valley HCS, NY</td>
<td>North Atlantic</td>
<td>3</td>
<td>2870</td>
<td>0.1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>626 (V09) (626) Middle Tennessee HCS, TN</td>
<td>Southeast</td>
<td>1a</td>
<td>15396</td>
<td>0.1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>673 (V08) (673) Tampa, FL</td>
<td>Southeast</td>
<td>1a</td>
<td>32575</td>
<td>6.3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>610 (V11) (610) Northern Indiana HCS, IN</td>
<td>Midwest</td>
<td>2</td>
<td>5391</td>
<td>8.2</td>
<td></td>
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<tr>
<td></td>
<td>674 (V17) (674) Temple, TX</td>
<td>Continental</td>
<td>1b</td>
<td>21827</td>
<td>6.9</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>405 (V01) (405) White River Junction, VT</td>
<td>North Atlantic</td>
<td>2</td>
<td>4784</td>
<td>1.9</td>
<td></td>
</tr>
<tr>
<td></td>
<td>558 (V06) (558) Durham, NC</td>
<td>North Atlantic</td>
<td>1a</td>
<td>19603</td>
<td>5.2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>546 (V08) (546) Miami, FL</td>
<td>Southeast</td>
<td>1a</td>
<td>21553</td>
<td>1.1</td>
<td></td>
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<tr>
<td></td>
<td>695 (V12) (695) Milwaukee, WI</td>
<td>Midwest</td>
<td>1a</td>
<td>13747</td>
<td>6.9</td>
<td></td>
</tr>
<tr>
<td></td>
<td>539 (V10) (539) Cincinnati, OH</td>
<td>Midwest</td>
<td>1b</td>
<td>9926</td>
<td>4.1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>691 (V22) (691) Greater Los Angeles, CA</td>
<td>Pacific</td>
<td>1a</td>
<td>15053</td>
<td>1.9</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>528 (V02) (528) Western New York, NY</td>
<td>North Atlantic</td>
<td>3</td>
<td>26258</td>
<td>7.3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>637 (V06) (637) Asheville, NC</td>
<td>North Atlantic</td>
<td>1c</td>
<td>4845</td>
<td>0.7</td>
<td></td>
</tr>
<tr>
<td></td>
<td>614 (V09) (614) Memphis, TN</td>
<td>Southeast</td>
<td>1a</td>
<td>8486</td>
<td>0.3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>552 (V10) (552) Dayton, OH</td>
<td>Midwest</td>
<td>1c</td>
<td>9389</td>
<td>6.0</td>
<td></td>
</tr>
<tr>
<td></td>
<td>671 (V17) (671) San Antonio, TX</td>
<td>Continental</td>
<td>1a</td>
<td>18555</td>
<td>4.9</td>
<td></td>
</tr>
<tr>
<td></td>
<td>605 (V22) (605) Loma Linda, CA</td>
<td>Pacific</td>
<td>1b</td>
<td>17135</td>
<td>1.8</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>630 (V03) (630) New York Harbor HCS, NY</td>
<td>North Atlantic</td>
<td>1a</td>
<td>24641</td>
<td>1.5</td>
<td></td>
</tr>
<tr>
<td></td>
<td>526 (V03) (526) Bronx, NY</td>
<td>North Atlantic</td>
<td>1b</td>
<td>8615</td>
<td>3.3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>596 (V09) (596) Lexington, KY</td>
<td>Southeast</td>
<td>1b</td>
<td>9298</td>
<td>1.1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>621 (V09) (621) Mountain Home, TN</td>
<td>Southeast</td>
<td>1c</td>
<td>8001</td>
<td>6.6</td>
<td></td>
</tr>
<tr>
<td></td>
<td>578 (V12) (578) Hines, IL</td>
<td>Midwest</td>
<td>1a</td>
<td>14762</td>
<td>2.4</td>
<td></td>
</tr>
<tr>
<td></td>
<td>570 (V21) (570) Fresno, CA</td>
<td>Pacific</td>
<td>2</td>
<td>5139</td>
<td>6.1</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>565 (V06) (565) Fayetteville, NC</td>
<td>North Atlantic</td>
<td>2</td>
<td>4480</td>
<td>2.5</td>
<td></td>
</tr>
<tr>
<td></td>
<td>659 (V06) (659) Salisbury, NC</td>
<td>North Atlantic</td>
<td>1c</td>
<td>13245</td>
<td>3.3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>516 (V08) (516) Bay Pines, FL</td>
<td>Southeast</td>
<td>1a</td>
<td>24412</td>
<td>3.9</td>
<td></td>
</tr>
<tr>
<td></td>
<td>589 (V15) (589) Wichita, KS</td>
<td>Midwest</td>
<td>1c</td>
<td>21176</td>
<td>2.6</td>
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<tr>
<td></td>
<td>660 (V19) (660) Salt Lake City, UT</td>
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<td>7911</td>
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</tr>
<tr>
<td></td>
<td>678 (V18) (678) Southern Arizona HCS, AZ</td>
<td>Pacific</td>
<td>1a</td>
<td>13192</td>
<td>7.9</td>
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</tr>
</tbody>
</table>
F. Balance in the means of continuous variables after constrained randomization

<table>
<thead>
<tr>
<th>Sequence</th>
<th>Number of visits</th>
<th>Percent teledermatology encounters</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>14,995</td>
<td>3.3</td>
</tr>
<tr>
<td>2</td>
<td>15,629</td>
<td>3.7</td>
</tr>
<tr>
<td>3</td>
<td>14,111</td>
<td>3.5</td>
</tr>
<tr>
<td>4</td>
<td>14,111</td>
<td>3.5</td>
</tr>
<tr>
<td>5</td>
<td>11,743</td>
<td>3.5</td>
</tr>
<tr>
<td>6</td>
<td>14,069</td>
<td>3.5</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>14,110</strong></td>
<td><strong>3.5</strong></td>
</tr>
</tbody>
</table>
G. Balance in geographic location distribution of facilities after constrained randomization

<table>
<thead>
<tr>
<th>Region Name</th>
<th>Trial Sequence</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Continental</td>
<td>1</td>
</tr>
<tr>
<td>Midwest</td>
<td>1</td>
</tr>
<tr>
<td>North Atlantic</td>
<td>2</td>
</tr>
<tr>
<td>Pacific</td>
<td>1</td>
</tr>
<tr>
<td>Southeast</td>
<td>1</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>6</strong></td>
</tr>
<tr>
<td><strong>World Health Organization data set</strong></td>
<td></td>
</tr>
<tr>
<td>----------------------------------------</td>
<td></td>
</tr>
<tr>
<td><strong>Primary registry and trial identifying number</strong></td>
<td>ClinicalTrials.gov NCT03241589</td>
</tr>
<tr>
<td><strong>Date of registration in primary registry</strong></td>
<td>4 August, 2017</td>
</tr>
<tr>
<td><strong>Secondary identifying numbers</strong></td>
<td>SDR 16-192, PEC 15-467</td>
</tr>
<tr>
<td><strong>Source(s) of monetary or material support</strong></td>
<td>US Department of Veterans Affairs Health Services Research and Development</td>
</tr>
<tr>
<td></td>
<td>US Department of Veterans Affairs Quality Enhancement Research Initiative</td>
</tr>
<tr>
<td><strong>Primary sponsor</strong></td>
<td>US Department of Veterans Affairs Health Services Research and Development</td>
</tr>
<tr>
<td><strong>Secondary sponsor(s)</strong></td>
<td>US Department of Veterans Affairs Office of Connected Care</td>
</tr>
<tr>
<td><strong>Contact for public queries</strong></td>
<td>DHO</td>
</tr>
<tr>
<td><strong>Contact for scientific queries</strong></td>
<td>JCP</td>
</tr>
<tr>
<td><strong>Public title</strong></td>
<td>VA Telederm Teledermatology App</td>
</tr>
<tr>
<td><strong>Scientific title</strong></td>
<td>Teledermatology Mobile Apps: Implementation and Impact on Veterans’ Access to Dermatology</td>
</tr>
<tr>
<td><strong>Countries of recruitment</strong></td>
<td>USA</td>
</tr>
<tr>
<td><strong>Health condition(s) or problem(s) studied</strong></td>
<td>Dermatological conditions</td>
</tr>
<tr>
<td><strong>Intervention(s)</strong></td>
<td>Active comparator: Web-based mobile teledermatology application and clinical process</td>
</tr>
<tr>
<td></td>
<td>Placebo comparator: workstation-based teledermatology and in-person dermatology practice</td>
</tr>
<tr>
<td><strong>Key inclusion and exclusion criteria</strong></td>
<td>Individual inclusion criteria: Ages eligible for study: ≥18 years; Sexes eligible for study: both; Accepts healthy volunteers: No</td>
</tr>
<tr>
<td></td>
<td>Cluster inclusion criteria: VHA facility located within the continental United States; &gt;0.0 provider full-time equivalents practicing dermatology; &gt;0.1% and ≤8.8% of total FY2016 dermatology encounters at the facility were for teledermatology readings</td>
</tr>
<tr>
<td></td>
<td>Cluster exclusion criteria: Facilities participating in pre-trial mixed-methods formative evaluation</td>
</tr>
<tr>
<td><strong>Study type</strong></td>
<td>Interventional</td>
</tr>
<tr>
<td><strong>Allocation</strong></td>
<td>randomized</td>
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<tr>
<td><strong>Intervention model</strong></td>
<td>stepped-wedge</td>
</tr>
<tr>
<td><strong>Masking</strong></td>
<td>non-blinded</td>
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<tr>
<td><strong>Primary purpose</strong></td>
<td>increasing access to care</td>
</tr>
<tr>
<td><strong>Phase</strong></td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Date of first enrollment</strong></td>
<td>January 2019 (expected)</td>
</tr>
<tr>
<td><strong>Target sample size</strong></td>
<td>36 clusters, 16,000 individuals</td>
</tr>
<tr>
<td><strong>Recruitment status</strong></td>
<td>Not yet recruiting</td>
</tr>
<tr>
<td><strong>Primary outcomes</strong></td>
<td>Consult completion time for teledermatology consults;</td>
</tr>
<tr>
<td></td>
<td>Appointment completion time for new dermatology consults;</td>
</tr>
<tr>
<td></td>
<td>Travel distance for dermatology services;</td>
</tr>
<tr>
<td><strong>Key secondary outcomes</strong></td>
<td>Volume of total dermatology encounters (instances of care)</td>
</tr>
<tr>
<td></td>
<td>Volume and relative proportion of teledermatology consults among all dermatology encounters at the health care facility level</td>
</tr>
<tr>
<td>Section/item</td>
<td>Item No</td>
</tr>
<tr>
<td>---------------------------</td>
<td>---------</td>
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<td>Administrative information</td>
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<tr>
<td></td>
<td>2b</td>
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<tr>
<td>Protocol version</td>
<td>3</td>
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<td>Funding</td>
<td>4</td>
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<td>Roles and responsibilities</td>
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<tr>
<td></td>
<td>5b</td>
</tr>
<tr>
<td></td>
<td>5c</td>
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<td>5d</td>
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<tr>
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<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Introduction

Background and rationale 6a Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention

6b Explanation for choice of comparators

Objectives 7 Specific objectives or hypotheses

Trial design 8 Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)

Methods: Participants, interventions, and outcomes

Study setting 9 Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained

Eligibility criteria 10 Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)

Interventions 11a Interventions for each group with sufficient detail to allow replication, including how and when they will be administered

11b Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)

11c Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)

11d Relevant concomitant care and interventions that are permitted or prohibited during the trial

Outcomes 12 Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended

Participant timeline 13 Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)
<table>
<thead>
<tr>
<th>Sample size</th>
<th>14</th>
<th>Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recruitment</td>
<td>15</td>
<td>Strategies for achieving adequate participant enrolment to reach target sample size</td>
</tr>
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</table>

**Methods: Assignment of interventions (for controlled trials)**

**Allocation:**

<table>
<thead>
<tr>
<th>Sequence generation</th>
<th>16a</th>
<th>Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allocation concealment mechanism</td>
<td>16b</td>
<td>Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned</td>
</tr>
<tr>
<td>Implementation</td>
<td>16c</td>
<td>Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions</td>
</tr>
</tbody>
</table>

**Blinding (masking):**

<table>
<thead>
<tr>
<th>Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how</th>
<th>17a</th>
<th>Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how</th>
</tr>
</thead>
<tbody>
<tr>
<td>If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant’s allocated intervention during the trial</td>
<td>17b</td>
<td>If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant’s allocated intervention during the trial</td>
</tr>
</tbody>
</table>

**Methods: Data collection, management, and analysis**

<table>
<thead>
<tr>
<th>Data collection methods</th>
<th>18a</th>
<th>Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol</th>
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<td>18b</td>
<td>Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols</td>
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N/A: Not applicable
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<tr>
<td>Data management</td>
<td>19</td>
<td>Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol</td>
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<tr>
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<td>20a</td>
<td>Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol</td>
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<td>20b</td>
<td>Methods for any additional analyses (eg, subgroup and adjusted analyses)</td>
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<td>20c</td>
<td>Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)</td>
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<tr>
<td>Methods: Monitoring</td>
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<td>21a</td>
<td>Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed</td>
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<td></td>
<td>21b</td>
<td>Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial</td>
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<td>Harms</td>
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<td>Ethics and dissemination</td>
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<td>Plans for seeking research ethics committee/institutional review board (REC/IRB) approval</td>
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<td>Item</td>
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<td>26a</td>
<td>Consent or assent: Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)</td>
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<td>26b</td>
<td>Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable</td>
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<td>27</td>
<td>Confidentiality: How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial</td>
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<td>28</td>
<td>Declaration of interests: Financial and other competing interests for principal investigators for the overall trial and each study site</td>
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<td>29</td>
<td>Access to data: Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators</td>
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<td>30</td>
<td>Ancillary and post-trial care: Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation</td>
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<td>31a</td>
<td>Dissemination policy: Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (e.g., via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions</td>
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<td>31b</td>
<td>Authorship eligibility guidelines and any intended use of professional writers</td>
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<td>31c</td>
<td>Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code</td>
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<tr>
<td>32</td>
<td>Appendixes: Informed consent materials: Model consent form and other related documentation given to participants and authorised surrogates</td>
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<tr>
<td>33</td>
<td>Biological specimens: Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable</td>
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*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.*
The VA Telederm Study: Protocol for a Stepped-Wedge Cluster Randomized Trial to Compare Access to Care for a Mobile App versus a Workstation-Based Store-and-Forward Teledermatology Process

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<td>10-Nov-2018</td>
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| Keywords: | Telemedicine < BIOTECHNOLOGY & BIOINFORMATICS, DERMATOLOGY, Organisation of health services < HEALTH SERVICES ADMINISTRATION & MANAGEMENT |
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Manuscripts
The VA Telederm Study: Protocol for a Stepped-Wedge Cluster Randomized Trial to Compare Access to Care for a Mobile App versus a Workstation-Based Store-and-Forward Teledermatology Process

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Authors’ Contributions:
DHO, MW and JCP initiated the study design and specified the trial access outcomes.

DHO and MW are leading the implementation of the intervention

ND provided statistical expertise in clinical trial design and analysis, conducted power calculations, and designed and performed the constrained randomization

GLJ and HAK conceptualized the formative evaluation and the trial implementation framework

JDW, SBP, and ARE provided expertise with implementation and study design

DHO, MW, and JCP are grant holders

All authors contributed to the refinement of the study protocol and approved the final manuscript

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Competing Interests
Abstract

Introduction. Teledermatology has emerged as an important strategy to enhance access to high-quality skin care. VA Telederm is a provider-facing, web-based mobile app designed to integrate into the existing teledermatology workflow in the United States Veterans Health Administration (VHA). In this study, we will conduct a systematic evaluation of VA Telederm on access outcomes in VHA facilities using a pragmatic trial guided by clinical and operational leaders.

Methods and analysis. The study is a prospective, stepped-wedge cluster randomized trial (SW-CRT) with cross-sectional exposure and outcome measurement via retrospective database analysis of administrative records. Each cluster is a VHA facility deemed eligible for the trial. We assign the intervention using a cluster-level balanced randomization scheme based on facility size, baseline teledermatology uptake, and geographic location. The trial will test whether patients receiving dermatological care at participating facilities will have better access compared with patients receiving care through the current standard process. The primary outcomes proxy for patient-level access to dermatology services, including (1) consult completion time for teledermatology consults; (2) appointment completion time for new dermatology consults; and (3) travel distance for dermatology services. As secondary outcomes, we will assess facility-level adoption outcomes, i.e. the number of dermatology encounters and the proportion of teledermatology consults out of all dermatology encounters. To account for secular trends in outcomes and for correlation across individuals within clusters, we will assess the impact of the intervention using generalized linear mixed regression models.

Discussion: Streamlining the current practice for store-and-forward teledermatology in the VHA can improve access to expert dermatological care for US Veterans. The lessons learned in this trial could validate the use of mobile technology for consultative store-and-forward dermatology in a large health care organization. The results may also be of interest to other medical specialties assessing the merits of implementing mobile telehealth.

Article Summary

Strengths and Limitations of This Study

- The stepped-wedge cluster-randomized design allows for strong causal inference.
- The national coverage ensures diversity of geographic settings and organizational cultures within a public integrated health care delivery system.
- The close partnership with clinical and operational leaders maximizes the opportunity for rigorous implementation.
- The findings of the study may not be fully generalizable to other populations and health care delivery systems.
- The complex implementation process requiring buy-in from multiple stakeholders may produce variations across sites.
Introduction

Background and Rationale

With the dermatology workforce facing a persistent shortage\(^1\) and misdistribution of providers and services across the country,\(^2\) access to dermatology services in the United States is severely lacking. Teledermatology has emerged as an important strategy to enhance access to dermatologic care. Asynchronous or store-and-forward telehealth (SFT) teledermatology transmits still digital photographs and textual information to dermatologists who need not be present at the same time and place, while live-interactive teledermatology uses real-time video interactions to exchange medical data and skin exams. SFT teledermatology has been shown to improve access to care in diverse populations and settings, enhancing patients’ ability to receive care\(^4,5\) and increasing service timeliness.\(^6\) Besides making care more accessible, SFT teledermatology may increase efficiency, thus allowing dermatologists time to provide more in-person visits to patients with more severe conditions.\(^5,7\) Teledermatology may also improve access for underserved populations, particularly by allowing providers in safety-net settings to prioritize patients with the most urgent and severe conditions.\(^8\) The few studies which have been conducted on the impact of mobile devices in provider-to-provider SFT teledermatology show significant decreases in wait times.\(^9,10\) However, these studies are limited by small sample sizes recruited from single, urban clinic locations.

Access to health services is a key priority for the Veterans Health Administration (VHA), both in terms of geographic proximity and timeliness of care.\(^11,12\) Veterans disproportionately live in rural areas, thus accentuating the problem of geographic access to specialty care,\(^13\) particularly for patients seeking care from specialty providers such as dermatologists who tend to cluster in urban metropolitan areas.\(^2\) SFT teledermatology has grown rapidly in the VHA\(^14\) resulting in enhanced access of both rural and non-rural Veterans to skin care and more timely skin disease treatment.\(^15–17\)

Despite recent improvements in overall wait times, access to dermatology remains challenging, in part due to inconsistent implementation of teledermatology in the VHA. Data from fiscal year (FY) 2016 shows wide variation in the uptake of SF teledermatology consult use, from zero to about 50 percent of all consults in a given facility. One important impediment to the adoption of teledermatology by primary care clinics may be the inefficiency of the current workstation-based process, which involves several steps performed by VHA-trained imagers before the image can be reviewed by a dermatologist.

The convenience and capability of smart mobile devices (e.g., tablet computers) to combine data acquisition (i.e., photographs) with efficient communication strategies creates significant opportunities for the VHA to streamline teledermatology practice and expand it more widely. Capitalizing on these opportunities, the VHA Office of Connected Care (OCC) developed a mobile app, VA Telederm, as a more facile option to increase SF teledermatology use among providers. VA Telederm is designed to integrate into the existing teledermatology workflow and is interchangeable with the conventional workstation-based process. Its target users are primary care providers (PCPs) and imagers, and it recapitulates the same steps that are performed by these users on workstations, but using a streamlined graphical user interface, and permits dictation of patient histories. Importantly, imagers are able to obtain or automatically transfer patient histories as well as capture skin images, and seamlessly upload images to the electronic health record using the app, instead of using a separate camera. Since no images reside on the mobile device, there is no need for imagers to perform the extra step of deleting camera images.

In this study, we will conduct a systematic evaluation of VA Telederm impact on dermatology access outcomes in VHA facilities using a clinically-driven, pragmatic trial with a stepped-wedge cluster-
randomized design (SW-CRT). To our knowledge, this is the first systematic study of teledermatology roll-out nationally, encompassing rural and urban facilities across the United States. The SW-CRT design allows for rigorous assessment of the causal impact of the VA Telederm app implementation on providers’ adoption of SF teledermatology and the associated change in patients’ access to care in a large, integrated health care delivery system. This trial will help expand the evidence base for the effectiveness of provider-facing mobile apps in improving adoption and access to care by introducing subtle to moderate gains in user-friendliness and process efficiency. The comparator in our study is the current standard of care in the VHA facilities selected for the trial, which includes regular in-person dermatology visits and workstation-based SFT teledermatology.

The rationale for the study design evolved from the combination of several scientific and pragmatic considerations. Scientifically, the requirement for randomization stems from the VHA leadership desire to produce the most rigorous evidence on which to base system policy. Thus, the pilot tests proposed initially were redesigned as a fully randomized trial. Pragmatically however, the OCC’s operational need to begin disseminating and testing the app as quickly as possible to sites that were ready for implementation brought the stepped-wedge design to the forefront as a more feasible way of rolling out the highly anticipated apps to providers. It became apparent that this design would allow evaluation of the app while gradually releasing it in the field, thus using the system’s limited capacity to solve the inevitable implementation challenges in a small number of facilities at any given time.

This paper provides the trial protocol following the SPIRIT statement, which provides recommendations for a minimum set of scientific, ethical, and administrative elements that should be addressed in a trial protocol. The WHO dataset as required by the SPIRIT statement is included in the Supplementary File. Given the absence of specific items in the SPIRIT statement for SW-CRTs, we also include more detailed items proposed in recent methodological papers on SW-CRT design, analysis, and reporting.

Primary Objective
Our primary objective is to assess the impact of the VA Telederm mobile app on teledermatology consult completion times, dermatology appointment completion times, and travel distance in Veterans seen in outpatient dermatology practice.

Secondary Objectives
Our secondary objective is to determine if the VA Telederm App affects the number of dermatology encounters (instances of care) and adoption rates of teledermatology consults in outpatient dermatology practice in the VHA.

Specific Hypotheses
The study will test two specific hypotheses:

1) The VA Telederm mobile app improves access to dermatology services among VHA patients, as measured by reduced teledermatology consult completion time, appointment completion times for new dermatology consults, and travel distance for dermatology services. In addition, we measure exposure to dermatologic care by the total dermatology encounters (instances of care).

2) The VA Telederm mobile app increases the adoption of teledermatology consults in VHA dermatology clinics.
Trial Design and Study Organization
This study is a prospective, stepped-wedge cluster randomized superiority trial. VHA facilities are randomized to receive the intervention according to a constrained randomization scheme that also ensures balance in key facility-level characteristics across the study sequences. Patients’ exposure to the intervention will be cross-sectional (i.e., patients are exposed when they visit a VHA facility for dermatology care) and outcome measurement will be done via retrospective database analysis of administrative records. The trial involves a partnership between VHA telehealth clinical operations, research, and implementation scientists in the VHA.

Methods and Analysis
Participants and setting
Each cluster participating in the trial is a VHA facility deemed eligible for participation, defined as having patients with at least one in-person outpatient visit for dermatology or teledermatology encounter in the VA during the course of the study. Each facility represents a VHA Medical Center providing care for a variable number of associated medical centers or clinics. The individuals receiving dermatological care at the eligible facilities, i.e. patients with at least one in-person outpatient dermatology or teledermatology encounter in the VHA during the course of the study, will be automatically included in the study and have their outcomes evaluated by retrospective, automated statistical analysis.

Eligibility Criteria
We selected 36 eligible facilities using the inclusion and exclusion criteria presented in Table 1, with the rationale for each criterion. Specifically, we included facilities located within the continental United States which had a dermatology clinic on-site (thus able to implement the intervention) and which only had a moderate penetration of SFT teledermatology. We excluded three facilities participating in a mixed-methods formative evaluation of the implementation to avoid contamination of the intervention.

The Current Standard of Care
Teledermatology services are currently provided in VHA facilities using a workstation-based SFT process. This process is consultative and consists of several stages, depicted schematically in Figure 1. When a patient or the provider has a skin concern, a referring provider (typically a PCP) initiates the consult request for skin imaging in the electronic medical record, known as the Computerized Patient Record System (CPRS), which also prompts the PCP for pertinent medical history. Upon receipt of the imaging consult request, an imager trained in the VHA protocol schedules the patient for imaging and transmits information from the PCP’s consult request or, and if necessary, obtains further medical history from the patient according to a scripted set of questions that are recorded in a templated CPRS note. Usually imaging appointments are made for the same day when the imaging consult is placed, though in some situations the patient or the clinic may delay the appointment to a different day. The imager captures images of the patient’s skin using a standard digital camera and must then manually upload the photos and link them with the patient’s CPRS record. Finally, the imager then generates a new consult request to a teledermatology reader, typically a board-certified dermatologist. This imager must then manually delete the images to ensure that the patient’s privacy is protected. The reader reviews the history and images and writes a CPRS note that includes an impression and recommendations for the PCP, who is then responsible for enacting them. A face-to-face visit may also be recommended as follow-up.
The Intervention

The intervention studied in this trial consists of three elements, deployed under the umbrella of the Replicating Effective Programs (REP) framework.25–27

(1) **The VA Telederm app** is the key technology at the core of the intervention. The app has been developed by a Federal contractor to be in strict compliance with VHA standards and regulations and is anticipated to be ready for national release by January 2019 by the OCC. Clinics within the participating facilities will be provided with mobile devices (i.e., tablets) which can be used to download the app and perform the new imaging process. The app will not be available for download or use on any personal mobile devices, either of the physician or the patient, as the app is intended to be used only on secure government-issued devices. Teledermatology leads at each facility will provide guidance on how to test it prior to use, and each provider will first have to enroll their device with the VHA Mobile Health Services. The app will be implemented at the facility level (up to five tablets will be made available at no cost to each facility, though facilities may have additional tablets due to prior inventory or purchase) and will be available to referring providers in a participating facility after adoption during the corresponding trial step. However, use of the app will be at the discretion of providers and imagers, and thus not all patients may have the opportunity to receive care using the new app. Screenshots of the app’s interface are included in Appendix A.

The VA Telederm app is intended to improve the existing teledermatology workflow by seamlessly integrating image capture and upload into the VHA electronic records system. The app’s target users are both referring providers and imagers. The app will allow referring providers to submit consults using touch screen entries and will permit dictation of patient histories. Imagers will be able to process those consults without transcribing or copying/pasting histories and to capture and upload images to the CPRS using the app, instead of using a separate camera. Thus, while it recapitulates the various steps that are performed by these users on workstations, the app will have a streamlined graphical user interface integrating these steps for an improved workflow. Since no images reside on the mobile device, there is no need for imagers to perform the extra step of deleting camera images.

(2) **Education programs and resources** specifically targeted to providers involved in the teledermatology process (PCPs, imagers, and dermatologists) have been streamlined by the study team in collaboration with OCC. OCC will conduct training sessions for Telehealth Leads in each VHA Veterans Integrated Service Network (VISN) and the Facility Telehealth Coordinators (FTCs) at each facility, who will then be responsible for training teledermatology providers. These sessions will be conducted using the existing process in the VHA by which new processes of care and guidelines are introduced. The core materials used for training are included in Appendix B.

(3) **Continuing support** will be made available to the participating facilities to assist them with the adoption of the new process. Technical support will be provided via a 24/7 telephone hotline to assist with any app- or device-related problems encountered by the providers. Implementation support will be provided by the VISN leads during monthly calls and via email by designated OCC staff. During these calls, providers will be able to share their experiences with the new app and will receive help to address any issues they have with the new care process.
Technical Field Testing
Before national release, the app will be field-tested at the pilot VHA facilities in San Francisco, CA, Providence, RI, and Denver, CO. During this process, the VA Telederm app will be used by providers with the goal of identifying any technical issues with the mobile app or the new clinical process it requires. Any issues identified at this stage, such as software bugs, incompatibilities with the existing systems, or security vulnerabilities will inform any modifications necessary for the national rollout of the intervention.

Formative Evaluation
To complement and inform the randomized trial, we will also conduct a mixed-methods formative evaluation in the same facilities involved in the technical pilot field-testing (i.e. San Francisco, Providence, and Denver). The evaluation will be guided by the Organizational Theory of Implementation Effectiveness, which is based on the work of Klein and Sorra as modified by Weiner and colleagues. The goal of this evaluation will be to understand the factors that may impact the organizational readiness for change (ORC) and process of implementation, how these factors change over time, and how they are associated with successful implementation and sustainability of the app. The findings of the formative evaluation will inform the process of implementing the teledermatology apps during the randomized implementation nationally as well as the implementation of future mobile clinical applications.

In addition to their initial roles in field-testing, the three pilot sites—San Francisco, Denver and Providence—are appropriate for evaluation since the teledermatology leadership are located at San Francisco and Providence VHA Medical Centers and Dermatology Field Advisory Council is located in Denver. These sites may have specific qualities that impact implementation. However, since they vary in terms of both organization and location, lessons learned will likely translate to the mix of other VHA facilities with dermatology programs. Differences among the three sites include: 1) San Francisco and Denver have Dermatology Services, whereas Providence has Dermatology as a section of the Medicine service; 2) San Francisco and Denver do not use dermoscopy, whereas Providence does; and 3) each facility is in a different VHA information technology (IT) administrative region.

We will first identify baseline characteristics of each organization and implementation teams that may impact implementation process and success. This will be followed by a qualitative and quantitative assessment of readiness to implement teledermatology; monitoring of the implementation process and progress through bi-monthly site reports; as well as qualitative interviews approximately 6-8 months following initial implementation of the teledermatology app; and qualitative and quantitative evaluation of program sustainability 1 year after the first use of the teledermatology application.

Baseline Assessment. The three sites will be asked to identify individuals directly involved in planning and execution of app implementation, whose work or clinical decision-making may change as a result of app implementation. These sites will be asked to submit information on these core implementation team members and processes and size and composition of the medical centers and impacted clinical services. For each separate facility, individuals representing the core implementation team will participate in a group conference call with the goal of providing detail on the planned process of implementing the app. Written bi-monthly (every other month) updates of the process will be provided by the sites.

Organization Readiness for Change (ORC). Core implementation team members and clinical staff from impacted services will be surveyed using the validated Organization Readiness for Implementing Change instrument, a computer-based survey developed specifically to measure aspects of the Weiner Theory of
This instrument examines perceptions of organizational-level change efficacy and commitment to newly implemented interventions. In addition, we will conduct semi-structured qualitative telephone interviews of the core implementation team and clinical staff at each site to assess ORC and factors that are hypothesized to predict ORC.

**Stages of Implementation Completion.** We will also measure the advancement of the implementation process through monthly reports from the three sites. Implementation progress will be assessed utilizing the Stages of Implementation Completion (SIC). SIC enumerates key pre-implementation, implementation and sustainability milestones. Dates by which specific implementation milestones are reached will be identified. This information will also enable us to examine if the degree of ORC is associated with the rapidity with which sites go through implementation steps. Bi-monthly (every other month) reports will also include assessment of barriers and facilitators identified through the ORC measurement process. Bi-monthly information will be fed back to project and OCC leadership so that program adjustments can be made.

**Program Sustainability.** At 6-8 months following the start of the implementation process at the 3 early adopter sites, we will conduct semi-structured qualitative telephone interviews, ideally with the same individuals interviewed at baseline. The goal is to understand changes in the process of utilizing the teledermatology app and the degree of implementation over time. At approximately one year, we will assess the sustainability of use of the mobile apps, using the Mancini & Marek Model of Community-based Program Sustainability as a conceptual guide. Specifically, we will measure the six elements essential for sustainability (leadership competence, effective collaboration, demonstrating program results, strategic funding, staff involvement and integration, and program responsivity) using a modification of the validated Program Sustainability Index (PSI). At this stage, we will again conduct qualitative interviews with the individuals involved in planning and implementation.

To inform the national rollout, we will continually analyze results and provide feedback to stakeholders. Rapid analysis approaches will generate preliminary findings to share among the research team, followed by in-depth content analysis.

**Intervention Timeline**

Figure 2 illustrates the main features of our stepped-wedge design for the national rollout, using the terminology proposed by Copas et al. For national rollout, the app is targeted to sites that are clinically appropriate and best positioned to benefit from the app. The evaluation of the app will be structured as a prospective, stepped-wedge cluster randomized trial, a form of randomized design which delivers the intervention to all participants in a staggered fashion over time. This design has a long history in statistical research but has only more recently been used for program evaluation. In brief, as detailed below, 36 participating facilities (or clusters of patients) will be randomly assigned to receive the intervention successively in sequences of 6 facilities each at the beginning of each trial step. Starting January 2019, one sequence will be exposed to the app, and at subsequent 3-month intervals an additional sequence will join the intervention until all groups are exposed starting April 2020. Therefore, the trial will consist of 6 steps, each one quarter apart. Unexposed cohorts in the sequences that have not yet crossed over at any given time will serve as controls. Measurements of outcomes will be performed every quarter after the start of the trial, with the exception of the quarters reserved for implementation in each sequence commencing rollout of the intervention. Additional measurements will be performed for two baseline quarters and two post-rollout quarters.
Outcomes
The primary study outcomes serve as proxies for access to dermatology services at the patient level, and will be used to test specific hypothesis 1) above. Table 2 specifies the outcome measures, the sources of data, and other important variables used in the study. Specifically, using statistical techniques (presented in the Statistical methods section below) we will assess changes in:

1. Consult completion time (continuous) – the interval between the time when a teledermatology consult is requested by a PCP until and when the dermatologist completes a note in the health record with his or her medical assessment.
2. Appointment completion time for new dermatology consults (continuous) – the interval between the time when a dermatology appointment (either in-person or teledermatology imaging) is requested and when it is completed.
3. Travel distance for dermatology services (continuous) – the distance between the centroid of the patient’s ZIP code of residence and the VHA facility to which he/she is receiving care.

We will also examine measures of teledermatology adoption at the facility level over time, such as the number and relative proportion of teledermatology consults among all dermatology encounters. These measures will be used to test specific hypothesis 2) above.

Outcomes will be extracted from the VHA’s Corporate Data Warehouse (CDW), which is regularly updated with information from individual electronic patient records at each clinic. Data on clinical full-time equivalents (FTEs) employed in dermatology will also be extracted from the VHA’s Office of Productivity, Efficiency and Staffing (OPES) in order to monitor changes in the supply of dermatologists at the study facilities. We hypothesize the teledermatology apps will have a larger impact on Veterans who live in rural areas. Consequently, models will also be secondarily stratified on urban/rural/highly rural status based on the Rural Urban Codes assigned to the ZIP code of residence for each patient.

Sample Size and Power Analyses
Our intended sample size is 16,000 individuals receiving care at the study facilities. We conducted power analyses separately for binary and continuous outcome measures under the parameters characterizing trial design. We conducted all power analyses in Stata using the user-written package steppedwedge41 following the authors’ guidance. We implemented the power analyses by using an incomplete design matrix with a three-month transition period with no outcome measurement, consistent with our proposed rollout. We verified our power analyses with analytical calculations performed using an alternative package written for the R statistical software42 and found the two methods to be highly consistent with each other. However, because the Stata package allowed for a user-specified design matrix with a 3-month transition period, which more closely reflects our intended rollout approach, we chose it as our preferred power analysis method. We provide the full code for the power analysis in Appendix C.

We used a level of precision $\alpha = 0.05$ (probability of a Type I error) and a minimum power level of 0.80, corresponding to probability of a Type II error $\beta = 0.20$. We also assumed a total number of clusters $I = 36$ as per the study design and the number of baseline measurements $B=2$ (since we will measure two pre-rollout quarters). Table 3 shows other key parameters used for selected power calculations and the corresponding statistical power level calculated with the steppedwedge commands. Because of the number of values the parameters can take leads to quite a large number of combinations, in multi-way sensitivity analyses we allowed the parameters to vary within certain ranges we consider reasonable. For brevity we show calculations that are at or near the predetermined limit of desired power (i.e., 0.80) illustrate potential cut-off values for our parameters.
The average cluster size per measurement occasion $K$ (this represents the number of relevant
encounters in a measured period of time, i.e. quarterly) was varied depending on the outcome, with the
base value estimated using encounter data extracted from the VHA CDW. Specifically, for continuous
outcomes the values are shown in the first three panels of Table 3. We estimated reasonable baseline
values via preliminary exploration of data from eligible sites for FY2016. We estimated an intraclass
correlation coefficient (ICC) $\rho = 0.268$ (CI = [0.071-0.427]) for continuous outcomes in the eligible sites by
performing a post-estimation procedure after estimating a mixed model with cluster-level random
effects on baseline data on consult completion times (we used full year data with $l=36$ and total number
of observations $N = 589,901$). We used $\rho \cong 0.25$ as the base ICC value for our power calculations and
varied it from 0.10 to 0.30 in our sensitivity analyses. The effect size $\Delta \mu$ was varied between -0.03% and
-0.15% for the continuous outcomes (representing the percent change in the baseline mean).

For the binary outcomes we assumed an average cluster size $K = 500$ and found upper and lower values
of between 150 and 1,700 depending on other key parameter values (fourth panel). Using FY2016 data,
we estimated an average proportion of teledermatology encounters of $p_0 = 0.03$ (varied up to 0.20 to
allow for the possibility of increasing teledermatology before the intervention begins rollout). We
estimated an ICC of $\rho = 0.136$ (CI = [0.091-0.190]) for the binary outcome, and we used a baseline value $\rho
\cong 0.10$ and varied it between 0.05 and 0.20 in the sensitivity analyses. The effect size was expressed as
an odds ratio for the binary outcome and was varied between 1.10 and 1.30, which was considered
clinically meaningful but also conservative for the analysis.

Recruitment
The eligible facilities were contacted by the operations partner (i.e., OCC) in November 2017 to confirm
their participation in the trial and to identify staff, including the Clinical Applications Coordinators (CACs)
and providers, who will need training in order to implement the intervention. Moreover, each facility’s
FTC and the associated overseeing VISN telehealth lead will be notified by email of the mobile app’s
implementation 1-3 months prior to the implementation date assigned to their specific site. These have
been and will continue to be supplemented by announcements of the app and trial during weekly
national VISN lead and FTC conference calls with OCC, and monthly conference calls by OCC’s
teledermatology leads with the field. The FTC, supported by the VISN leads, will be responsible for
disseminating information about the app to all clinical and allied support staff and recruiting their
support, including informatics and information technology staff. One month prior to implementation, a
conference call will be held with the FTC and VISN telehealth leads to review the app and its
implementation.

Assignment of Intervention
We used a constrained randomization procedure to assign the order in which the facilities will receive
the intervention. Given the small number of clusters included in the trial, this procedure avoids the
potential imbalance in critical facility characteristics across the trial sequences simply due to chance. In
these situations, constrained randomization has been shown to perform better in achieving baseline
balance on several potential confounders than simple randomization, matching, or stratification.\textsuperscript{43,44} This
procedure is described briefly below and more detail is provided in Appendix D.

We followed a two-stage procedure in a similar vein to the approach proposed by Bertsimas et al.,\textsuperscript{43}
which entails first an allocation of study units (facilities) to sequences such that the difference between
the sequences is minimized (the optimization stage) followed by random assignment of the order in
which the sequences will receive the intervention (the randomization stage). Bertsimas et al. developed
their procedure in the context of a parallel randomized controlled trial with multiple treatments and a
small number of units in each treatment arm. To our knowledge, this is the first time this procedure is adapted to a SW-CRT. Besides balancing sequence characteristics, we also randomize sequence to the order in which they receive (the same) treatment, as opposed to different treatments. Either way, the goal of systematically decreasing the differences between sequences while preserving the random component is achieved.

Site characteristics used for the optimization stage consisted of two continuous variables and one categorical variable. Specifically, the two continuous variables were the size of dermatology practice (measured by the number of dermatology encounters in the baseline year) and the level of teledermatology activity (measured by the percentage of teledermatology consults of all dermatology appointments in the baseline year). The categorical variable was the geographic location (determined by one of the five VHA administrative regions encompassing each facility). These characteristics were chosen as they are likely to affect the implementation of the intervention and its impact on outcomes. For example, larger facilities may have more resources for implementation and stronger incentives to increase efficiency. Similarly, facilities that are already extensively providing teledermatology may be more effective in implementing it compared to facilities with lower uptake. Finally, facilities in different geographic areas differ in their practice patterns and constraints and may have systematic differences in pre-intervention outcome trends.

The sequences of facilities in order of implementation are shown in Appendix E. Balance across sequences in the number of visits and the percentage of teledermatology encounters is shown in Appendix F, while balance in geographic location is shown in Appendix G. We also considered balancing on facility complexity level, a VHA-specific measure that indicates the relative size and complexity of clinical services and administrative structures of a given VHA treatment facility. However, because this measure is highly correlated with the number of dermatology practices at each facility, we did not end up using this measure for balancing. Nevertheless, this procedure achieved reasonable balance on this measure by virtue of balancing on dermatology practice size (data not shown).

Blinding
The health care professionals (PCPs and imagers) involved in the study will not be blinded to the intervention, as it is impossible to conceal the use of the app on a mobile device compared to the current workstation workflow. The Veteran patient experiences a different imaging device depending on whether the VA Telederm app is used versus a traditional workstation and auxiliary camera, so they are also not blinded to the process. However, other than the imaging technique the consult generation process is relatively transparent to the Veteran. Furthermore, data collection will be performed passively from patient records.

Data Collection and Management
Outcomes data will be collected by the research team via automated extraction from the CDW. Data will be stored on the Department of Veterans Affairs Informatics and Computing Infrastructure (VINCI) and only accessible by the research team. VINCI is a VA Health Services Research & Development (HSR&D) resource center that provides a secure, central analytic platform for performing research and supporting clinical operations activities. The platform includes a cluster of services for securely hosting suites of databases integrated from national data sources (such as the VHA CDW). VINCI servers for data, applications and virtual sessions are physically located at the VA Austin Information Technology Center (AITC) located in Austin, Texas. AITC hosts a secure enclave of high-performance servers and high-speed storage and has multiple layers of security and disaster recovery to prevent data loss.
VINCI maintains compliance with the guidelines established by the VHA policies and regulations. VA-credentialsd research staff will be granted access to the study data along with tools for analysis and reporting in the secure virtual working environment through a certified VHA network computer. This computing environment will enable uniform security standards for access, a common point of entry for all investigators who use the data, and consistent control of data quality.

Study data will be kept in accordance with the Department of Veterans Affairs Record Control Schedule 10-1. Storage and transfer of any Personally Identifiable Information (PII) or Protected Health Information (PHI) will be performed in accordance with applicable VA policies and directives, state and federal regulations, and applicable statutes including the Health Insurance Portability and Accountability Act (HIPAA). Standard data quality checks such as examination of outliers or significant changes over time will be conducted to identify potential problems with the data extracted from CDW. Analytical files will be built in the VINCI secure environment and will be analyzed on the VINCI servers. Upon completion of the research project, the study principal investigators and the VA Information Security Officer will insure that data containing sensitive, confidential information will be returned to the VA and removed from all servers, desktops, removable storage devices, etc.

Statistical Methods
We will employ data analysis strategies that account for the causal structure implied by our trial design and mitigate its potential shortcomings. Two related issues which may confound the treatment effect are the within-cluster correlation and potentially significant secular trends in the outcomes of interest given the long duration of the trial (2.5 years). In fact, the exposure of each cluster to both the control and intervention allows us to partially exploit the within-cluster variance towards estimation, which renders this type of trial less sensitive to the intra-cluster correlation coefficient. To ensure that these confounding factors are properly handled, we will analyze the data using several model specifications. This will also allow us to explicitly test some of the assumptions underlying our empirical model.

Our first analysis relies on an intent-to-treat approach, in which we will directly assess the impact of being randomized to implement the VA Telederm app on the following specialty care access outcomes: consult completion time, appointment completion time, and travel distance for VHA care. This model yields an estimate of the average effect of being randomized to receive the VA Telederm app (average treatment effect). From a policy perspective, this effect can be interpreted as the efficacy of deploying an app in real-world outpatient clinics, where overall uptake to clinical practice is likely less than 100%.

Specifically, we will estimate generalized linear mixed models of the form:

\[ Y_{iqt} = F(\mu + \alpha_q + \beta_t + \theta V_{qt} + X_{iqt}) + e_{iqt} \]

where

- \( Y_{iqt} \) is the outcome for patient \( i \) in cluster \( q \) treated in quarter \( t \);
- \( \mu \) is the outcome in the first observation;
- \( \alpha_q \sim N(0, \phi^2) \) is the random effect for clusters (VHA facilities);
- \( \beta_t \) is a fixed effect adjusting for being in quarter \( t \);
- \( V_{qt} \) is a fixed effect for whether or not facility \( q \) was randomized to the intervention in quarter \( t \);
θ, the coefficient of interest, is the effect of the being randomized to receive the intervention on the outcome;

\( X_{iq} \) are fixed effects adjusting for demographic characteristics of patient \( i \) in cluster \( q \), i.e. age, gender, ethnicity, and rurality; and

\( e_{iqt} \sim N(0, \sigma^2) \) is the error term for each dermatology encounter.

Depending on the distribution of the outcome variable, the function \( F(.) \) is either the identity function (for continuous, normally distributed outcomes like travel distance) or inverse gamma distribution (for highly skewed and always positive outcomes like completion times for appointments and consults and time to follow-up).

This type of model, proposed for the analysis of SW-CRTs by Hussey and Hughes,\(^{40}\) clearly involves several important underlying assumptions, such as a common underlying piece-wise secular trend across all clusters, a constant change in this common trend as a result of the intervention, and an identical correlation between two observations in a cluster irrespective of treatment and time duration between the observations.\(^{24}\) In secondary analyses, we will relax these assumptions in order to assess whether they impact the results. For example, we will allow the secular trends to vary by strata of clusters, such as VHA administrative regions or VHA Integrated Service Networks (VISNs) (using a fixed-effect interaction between time and stratum), or even by clusters (by adding a random interaction between time and cluster, and thus allowing intracluster correlation to vary by time period). Similarly, we will test models allowing for treatment effect heterogeneity across strata of clusters or across time (using either fixed or random effects), with the important caveat that some of these models will be estimable only on data collected in time periods in which there are both treated and control clusters.\(^{24}\)

In addition to the intent-to-treat analysis, we will also assess the impact of the intervention using an instrumental variable (IV)-based two-stage residual inclusion (2SRI) procedure. In this approach, we will estimate two parameters of interest. First, we are concerned with the effect of the randomization on uptake of the apps, as a factor leading to teledermatology adoption in the sites receiving the intervention. This effect can be obtained by estimating the following first-stage model:

\[
(1) \quad A_{p_{iqt}} = \text{Logit}^{-1}(\mu + a_q + \beta_t + \theta V_{qt} + X_{iq}) + e_{iqt}
\]

Second, we are interested in the average effect of the treatment among compliers (patients who only receive the treatment as a direct result of their exposure to the intervention), referred to as the Local Average Treatment Effect (LATE). This effect better reflects the efficacy of teledermatology compared to regular practice and can be estimated using the following second-stage model:

\[
(2) \quad Y_{iqt} = F(\nu + a_q + \delta_t + A_{p_{iqt}} + X_{iq} + \hat{e}_{iqt}) + \epsilon_{iqt}
\]

where \( \hat{e}_{iqt} \) is the predicted residual from estimating equation (1). Estimating this effect would allow future work to investigate why the intervention works and why uptake of the intervention varies across facilities. Pointing out that, for example, access can be improved significantly provided that the leadership of a health care system can ensure uptake of the app, would be important for future policy decisions.

**Continuous monitoring of implementation**

Implementation will also be assessed at all participating sites by monitoring intermediate milestones and quantitative indicators of implementation that are available in CDW as well as from OCC’s own
telehealth database and WMS mobile device procurement program. Randomized sites, in addition to
the three sites in the formative evaluation, will be asked to complete a bi-monthly implementation site
report monitoring key milestones, collected electronically via the VHA intranet. Sites will be sent email
reminders two weeks and one week prior to, and one week after the due date, with follow up via phone
call, if necessary. Collection of these data will be descriptively summarized every quarter (3 months) to
understand how rapidly sites meet key milestones as a result of the OCC implementation process,
correlate the milestones to the number of patients serviced via the apps (i.e., reach), and allow for
stratified analyses of main quantitative study results by degree of implementation based on reaching
milestones to determine if the apps are more effective among sites that have reached more
implementation milestones. The study will not have a separate data monitoring committee, due to the
low risk of the intervention and its minimal interference with patient care. Since we do not anticipate
any adverse effects to be reported, a data monitoring committee is not necessary.

Patient and Public Involvement
The VA Telederm mobile app is designed to be used by primary health care providers and by imaging
staff respectively to order and to process teledermatology consults prior to being read by a dermatology
reader. The app interchangeably substitutes for these steps in VHA’s existing teledermatology process
using its electronic health record. While the app is intended to make teledermatology services available
to more patients, patients are not the actual users of the app. For all of these reasons, it is anticipated
that the patient experience itself will not be affected by the use of the VA Telederm app, and no
patients or patient advocacy groups were consulted in the design of the app or this trial. The
development of the research questions and outcome measures was informed by prior scientific
literature (including work published by the authors) on the impact of teledermatology on access and on
patient wait time measures for primary and specialty care services. For similar reasons, there are no
plans to disseminate the results of this trial directly to patients or patient groups, and the burden of the
intervention was not assessed by patients.

Ethics and Dissemination

Research Ethics Approval
The research has been approved by the Institutional Review Board (IRB) at VHA Boston (IRB Project
#3069), which has designated the study as exempt since it involves collection and analysis of data in a
way that subjects cannot be identified, either directly or through identifiers linked to the subjects.45
Specifically, since the app will be implemented within the process of care in the VHA, the data in the
cluster-randomized trial will be deidentified and collected retrospectively in the administrative
database. The research team will query the relevant database tables and extract the data necessary for
the proposed analyses and will conduct the research in a secure environment following all required
procedures for protection of privacy and confidentiality. For the purposes of the Ottawa statement, the
research participants in this study are the patients receiving dermatology care at the eligible facilities,
since they will be affected by the change in the health care delivery process.46 However, the study
interventions and data collection procedures pose no more than minimal risk.

The research components of the formative evaluation have been approved by the IRBs at the VHA
Durham, San Francisco, and Providence facilities, respectively. In this study component, the research
participants are the VHA employees involved in the implementation, from whom consent will be
obtained before being interviewed or surveyed.
Protocol Amendments
Any modifications to the protocol which may impact on the conduct of the study, including study objectives, design, patient population, sample sizes, study procedures, or significant administrative aspects will require a formal amendment to the protocol. All such amendments will be agreed upon by the study investigators and approved by the institutional review board prior to implementation and notified to the VHA OCC and HSR&D. Administrative changes of the protocol, such as minor corrections that have no effect on the way the study is conducted, will be agreed upon by the study investigators and documented in a memorandum. The IRB may be notified of these administrative changes at the discretion of the study investigators.

Dissemination Policy
The project team is comprised of specialist clinicians, academic researchers, and experts in implementation science. This provides the project with access to a wide range of channels for results dissemination to policy makers, researchers, and system stakeholders. The results of the study will be published in academic peer-reviewed journals and presented at professional conferences. Additionally, VHA leadership will be briefed on the preliminary as well as final study findings in order to inform future VHA policy regarding teledermatology. Communications with VHA leadership will be facilitated by two members of the research team who also serve as the clinical leads for teledermatology in OCC (DHO and MAW). No use of professional writers will be made. Only investigators involved in the study planning, design, or analysis will be eligible for authorship of study communications.

Participant level data will not be made available to the public due to privacy and confidentiality concerns, but statistical code may be shared by request from the study authors. Study investigators and approved study personnel will be the only individuals who can access the final trial dataset.

Patient and Public Involvement
Patients were not involved in the development of the research question or the outcome measures.

Discussion
Study Impact and Importance
At the end of the study period, the trial will document the effectiveness of mobile store-and-forward teledermatology in enhancing Veterans’ access to dermatology services. Moreover, it will produce a comprehensive understanding of the factors that lead to successful mobile telehealth implementation and adoption. The results will be of significance to the VHA as it develops and implements other mobile telehealth programs, and more generally to other healthcare organizations planning for large-scale telehealth interventions.

In particular, the study will allow us to assess whether web-based mobile teledermatology apps improve access to expert dermatology services by decreasing consult times, reducing appointment completion times for new patients, increasing instances of dermatologic care, and reducing the distance traveled by patients to receive dermatology services.

Strengths
This study has several important strengths. First, the stepped-wedge design of the trial will allow us to assess with increased confidence the causal impact of the new teledermatology intervention, by assigning the order of the intervention in a randomized fashion. Stepped-wedge designs allow clusters to be compared to other sites and to also serve partially as their own control, thus permitting us to
account for outcome time-trends for each participating facility. Second, the constrained randomization scheme will ensure that imbalance in measured facility characteristics due to sheer chance will not bias the findings. This bias is an important concern in trials in which randomization is performed for a small number of clusters. Third, in contrast with previous studies which were mainly conducted on small and relatively homogeneous samples, our study includes individuals accessing care in facilities throughout the US. This includes rural and urban facilities serving patients characterized by geographic and socioeconomic diversity.

Fourth, the close partnership with clinical and operations leaders will ensure that all eligible sites receive the intervention and that clinician buy-in, which is crucial for the success of the intervention, is maximized.

Finally, the pilot testing and formative evaluation will ensure that implementation issues are addressed early by learning from the early test sites. In this way, any early issues with on-the-ground implementation can be mitigated.

Limitations
The study also has several limitations. First, implementation will likely vary by facility depending on the local culture, resources, efficacy and engagement of local leadership. Although we will conduct a formative evaluation in three facilities in order to inform the national roll-out of the intervention, it is likely that we cannot ensure uniform implementation across facilities. For example, some of the participating sites will use dermatoscopes that attach to imaging devices in order to collect high-quality photos. Since the cost of dermatoscopes is not covered by OCC or the VHA Mobile Health Services office, there will likely be some variation in the quality of the images across sites.

Second, the impact of the app will depend on the effectiveness of the education and support provided to providers and to the extent to which the providers find the new process more intuitive and easy to use. Although we have adapted previously used training materials developed by OCC, there is still potential for inconsistent dissemination and support for the app.

Finally, the implementation requires the cooperation of multiple stakeholders at the national, regional, and local level in order to ensure proper training, education, and support for providers in their adoption process. It is inevitable that some confusion or improper deployment will occur at least initially, which may affect the implementation process. Moreover, although we have allowed for three months for implementation in each facility, the possibility for longer delays still exists.

Generalizability
The study findings may not be generalizable outside the VHA, which has a different institutional structure from most other practices in the United States. The findings may also not be generalizable to health care systems outside the United States or other teledermatology mobile apps.

Acknowledgments
The authors would like to acknowledge superb administrative support from Rebecca Lamkin at VHA Boston, MA, Andrea Grenga at VHA Providence, RI, and Jennifer Chapman at VHA Durham, NC. The authors would also like to acknowledge Junius Lewis for excellent facilitation of contact with the VHA Facility Telehealth Coordinators and VISN leads.
References


Figure legends

*Figure 1.* Current workstation-based teledermatology process in the VHA.

*Figure 2.* Timeline and design features for the VA Telederm SW-CRT.
Table 1. Inclusion and exclusion criteria used for selecting the participating facilities and rationale for each

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Located within the continental United States</td>
<td>VHA facilities outside the continental US do not reliably report electronic medical record data to the CDW and/or do not have dermatology clinics</td>
</tr>
<tr>
<td>2. Greater than zero provider full-time equivalents practicing dermatology</td>
<td>Have a dermatology clinic on-site</td>
</tr>
<tr>
<td>Inclusion</td>
<td></td>
</tr>
<tr>
<td>3. Higher than 0.1% and at most 8.8% of total FY2016 dermatology encounters at the facility were for teledermatology readings</td>
<td>Already performing some teledermatology consults at baseline using the existing store-and-forward technology, but their total teledermatology encounter rates were below the median; based on prior experience, these sites were judged to be good candidates for implementing the new mobile app</td>
</tr>
<tr>
<td>Exclusion</td>
<td></td>
</tr>
<tr>
<td>Participating in pre-trial mixed-methods formative evaluation</td>
<td>Three facilities will participate in the formative evaluation, which will be conducted to inform the implementation of the mobile app; these facilities are located in Providence, RI, San Francisco, CA, and Denver, CO.</td>
</tr>
<tr>
<td>Measure/Variable</td>
<td>Data Sources</td>
</tr>
<tr>
<td>------------------------------------------------------</td>
<td>--------------</td>
</tr>
<tr>
<td>Consult completion time</td>
<td>VHA CDW</td>
</tr>
<tr>
<td>Appointment completion time for new patients</td>
<td>VHA CDW</td>
</tr>
<tr>
<td>Travel distance for VA care</td>
<td>VHA CDW</td>
</tr>
<tr>
<td>Number of dermatologic encounters by type (in-person vs. teledermatology)</td>
<td>VHA CDW</td>
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<tr>
<td>Percentage of dermatology encounters by type (in-person vs. teledermatology)</td>
<td>VHA CDW</td>
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Table 3. Key results of power calculations under base assumptions

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Average cluster size (per measurement occasion)</th>
<th>Treatment effect (Δμ or OR)</th>
<th>Parameter in control group (SD)</th>
<th>Parameter in treatment group (SD)</th>
<th>ICC</th>
<th>Power</th>
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<tr>
<td>Consult completion time</td>
<td>120</td>
<td>Δμ=-0.10</td>
<td>μ₀=27.8 (44.3)</td>
<td>μ₁=25.0 (44.3)</td>
<td>0.25</td>
<td>0.800</td>
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<tr>
<td></td>
<td>120</td>
<td>Δμ=-0.10</td>
<td>μ₀=27.8 (44.3)</td>
<td>μ₁=25.0 (44.3)</td>
<td>0.30</td>
<td>0.800</td>
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<td>Appointment completion time</td>
<td>60</td>
<td>Δμ=-0.15</td>
<td>μ₀=27.8 (44.3)</td>
<td>μ₁=23.6 (44.3)</td>
<td>0.25</td>
<td>0.845</td>
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<td></td>
<td>50</td>
<td>Δμ=-0.15</td>
<td>μ₀=27.8 (44.3)</td>
<td>μ₁=23.6 (44.3)</td>
<td>0.25</td>
<td>0.775</td>
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<tr>
<td></td>
<td>60</td>
<td>Δμ=-0.15</td>
<td>μ₀=27.8 (44.3)</td>
<td>μ₁=23.6 (50.0)</td>
<td>0.25</td>
<td>0.798</td>
</tr>
<tr>
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<td>70</td>
<td>Δμ=-0.15</td>
<td>μ₀=27.8 (50.0)</td>
<td>μ₁=23.6 (50.0)</td>
<td>0.30</td>
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</tr>
<tr>
<td>Travel distance (miles)</td>
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<td>μ₁=57.0 (50.0)</td>
<td>0.20</td>
<td>0.930</td>
</tr>
<tr>
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<td>Δμ=-0.05</td>
<td>μ₀=60.0 (50.0)</td>
<td>μ₁=57.0 (50.0)</td>
<td>0.20</td>
<td>0.820</td>
</tr>
<tr>
<td></td>
<td>300</td>
<td>Δμ=-0.05</td>
<td>μ₀=60.0 (75.0)</td>
<td>μ₁=57.0 (75.0)</td>
<td>0.20</td>
<td>0.800</td>
</tr>
<tr>
<td></td>
<td>110</td>
<td>Δμ=-0.05</td>
<td>μ₀=60.0 (50.0)</td>
<td>μ₁=57.0 (40.0)</td>
<td>0.10</td>
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</tr>
<tr>
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<td>μ₀=50.0 (50.0)</td>
<td>μ₁=47.5 (60.0)</td>
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<td></td>
<td>500</td>
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<td>1,000</td>
<td>Δμ=-0.03</td>
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Notes: μ₀ = is the mean of the outcome variable in the control group; μ₁ is the mean of the outcome variable in the treatment group; p₁ is the proportion of interest in the control group; p₂ is the proportion of interest in the treatment group; Δμ is the difference in means between the treatment and control arms, i.e. the expected treatment effect to be detected for continuous outcomes; OR = the odds ratio between the treatment and control arms, i.e. the expected treatment effect to be detected for the binary outcome; ICC = intracluster correlation coefficient; SD = standard deviation
Figure 1. Current workstation-based teledermatology process in the VHA.

254x190mm (300 x 300 DPI)
Figure 2. Timeline and design features for the VA Telederm SW-CRT.

338x190mm (300 x 300 DPI)
A. Sample Screen Shots of the VA Telederm App

1. Initial Login: Imager may also get an introduction and overview of the app by touching the “Tour the App” button.

2. Pending consults list: Imager selects patient of interest and touches “Complete Consult” button to process consult request.

3. Imaging consent: Imager documents patients consent to be imaged.

4. Reader consult request order: Imager orders request for teledermatology reader. History from PCP is automatically inserted.

5. Photography prompt: Imager is guided to obtain skin images.

6. Image review: Imager reviews photos, signs and submits consult request.
B. Training materials for VA providers and telehealth leads

The below description, once approved, will be posted to the Beta App Store: mobile.va.gov/app/beta/va-telederm

The Department of Veterans Affairs VA TeleDerm mobile application (app) allows VA care teams to capture and store digital images and associated clinical data to provide safe, appropriate and cost-effective teledermatology services to Veterans. The app seamlessly integrates with current Veterans Affairs consultative store-and-forward teledermatology workflow practices by packaging all the necessary teledermatology tasks for referring clinicians and imagers into a single workflow app. The app enables users to conveniently and wirelessly upload clinical history and captured images to Veterans Health Information Systems and Technology Architecture (VistA), ensuring that all members of the health care team have access to the most up-to-date records and that images will be correctly associated with the appropriate patients.

Features:

- Create and complete Computerized Patient Record System (CPRS) consults for teledermatology
- Capture and upload images to VistA Imaging. No images are stored on the mobile device.
- Verify image upload and assess image quality
- View images that have been uploaded to patients’ files
- Automatically transfer information from imaging consult request to reader consult request
- Use native mobile device dictation capabilities
Overview
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Prerequisites
To use the VA TeleDerm App, you must be a VA health care professional with credentials for the Veterans Health Information Systems and Technology Architecture (VistA). To use VA Telederm on a mobile device, you must use a government-furnished mobile device and have PIV-exemption. The intended users of the app are clinicians who refer patients for teledermatology consultation, and imagers.

Getting Oriented
Using the “Menu” and “Patient Search” functions
When you log into the VA TeleDerm App, the “Select a Patient” screen will appear, displaying a Patient Search box above a list of the names of patients you recently searched for and a list of all patients in your facility’s Computerized Patient Record System (CPRS). There are also two icons in the upper left of your screen to help you navigate the app:

- Menu (three-line icon in upper left corner)
- Search for or Select a Patient (magnifying glass icon in upper left corner) – Quickly find patients to see their consults and dermatology information.

Menu functions

- Consults: The Consults option will only appear if you are currently viewing a specific patient’s details screen. It will return you to the “Select a Patient” screen
• Notifications: The Notifications option alerts you to notifications on your patients, e.g., completed consults that you have submitted. You can make sure you are viewing the most current list of notifications by tapping Refresh in the upper right corner. If any new notifications have come in, they will then appear in the list. **NOTE:** To follow up on any of the notifications, you will have to search for and select the patient in the patient search function.

• Tour the App: You can view app features and screenshots in more detail

• About: A brief summary of the app

• Logout: Exits the app. All unsaved work and images will be lost.
Getting Started

FOR REFERRING CLINICIANS/PRIMARY CARE PROVIDERS – CREATING A
TELEDERMATOLOGY IMAGING REQUEST

1. Select your patient
   a) In the “Select a Patient” screen, enter your patient name into the Patient Search field
      and tap Search. A list of patients matching your search criteria will appear below.
   b) Tap the name of the patient you would like to view. A pop-up box with the patient’s
      identifying information will appear.
   c) Tap Confirm Patient to go to the “Dermatology Consults” screen.

You can also search for a different patient anywhere in the app by tapping Search for or Select
a Patient (magnifying glass icon).

2. Create an imaging consult request
   a) In the “Dermatology Consults” screen, tap New Imager Consult + at the upper right.
   b) The Provider & Location for Current Activities screen appears. Select Clinic
      Appointments or New Visit radio buttons as appropriate. If you select New Visit, scroll
      through and tap the appropriate clinic location.
   c) Tap Create New Visit at the bottom of the screen to go to the “Create New Consult”
      screen.
   d) The “Create New Consult” screen is generally self-explanatory and is similar to VA’s
      standardized CPRS teledermatology templates.
      o General History: The Imaging Instructions and Chief Complaint fields, and any
         asterisked (*) questions must be answered to submit a consult. Use Imaging
         Instructions to specify all anatomic sites you wish to be photographed.
      o Problem A: The Locations and How Long Ago Did This Problem Begin? must be
         answered to submit a consult.
      o + Add Problem: Allows you to specify additional distinct skin problems. If you add a
         problem in error, you can tap Remove Problem at the bottom of each problem’s
         history questions.
      o When entering information into a free text field, you may use your mobile device’s
         microphone to dictate if you want to convey a lot of history or details. The app is not
         specifically trained to recognize medical jargon.
   a) Once all history is entered, tap Create Consult at the bottom of the screen. You may
      need to scroll down to see it.
   b) In the “Sign Order” screen, review the history. If you need to revise the history, you can
      use the mobile device’s “Back” button to return to the “Create New Consult” screen, but
      you will need to re-enter all information. If the history is acceptable, enter your
      signature code, and tap Sign.
   c) You will return to the “Dermatology Consults” screen where you can view the pending
      imaging consult request you just created.
VA Telederm App

Quick Start Guide

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FOR IMAGERS – PROCESSING A TELEDERMATOLOGY IMAGING REQUEST

1. Identify and select pending imaging consults
   a) Select the patient you wish to image
   b) In the “Dermatology Consults” screen, tap the consult that you wish to process. It will expand, and you can scroll through the consult request in the grey box. When ready, tap Complete Consult button on the right side to go to the “Provider & Location for Current Activities” screen
   c) The Provider & Location for Current Activities screen appears. Select Clinic Appointments or New Visit radio buttons as appropriate. If you select New Visit, scroll through and tap the appropriate clinic location. Tap the date and either 1) type in the date in the form MM/DD/YYYY or 2) tap the date from the pop-up calendar that appears.
   d) Tap Create New Visit at the bottom of the screen to go to the “Consult Note Properties” screen.

2. Complete the imaging consult
   a) Enter a Level of understanding – selecting Poor will not allow the consult to be submitted.
   b) Answer the “Patient understands and consents…” question. Selecting Yes will expand the template. Answer the additional questions that are part of VA’s standardized teledermatology template.
c) Review the history in the Consult Reason for Request box. If any fields are blank or if you have additional information to add, you may edit the history.
d) Tap Finish at the bottom of the form. You may need to scroll down to see it.
e) In the “Sign Note” screen, review the history. If you need to revise the history, you can use the mobile device’s “Back” button to return to the “Create New Consult” screen, but you will need to re-enter all information. If the history is acceptable, enter your signature code, and tap Sign. This will generate an imager note in CPRS and complete the imaging consult.
f) You will return to the “Dermatology Consults” screen where you can view the completed imaging consult request.

3. Create the Reader Consult
   a) In the “Dermatology Consults” screen, tap the consult that you just completed. It will expand to show the consult details. Tap the Create Reader Consult button. The “Create New Reader Consult” screen appears.
   b) In the “Create New Reader Consult” screen, enter information as requested
   c) Tap the Create Consult button at the bottom.
   d) In the “Sign Order” screen, you can review the history. Enter your signature code, and tap Sign.
   e) The “Reader Consults” screen appears showing the pending Reader consult request that you just created. The pending Reader consult request should also show in CPRS.

4. Capture photos of the skin
   a) In the “Reader Consults” screen, tap the pending consult request that you just created. It will expand.
b) Tap **Select** on the right hand side of the expanded consult request. The “Capture Images” screen appears.

c) To take photos, tap the green **Take Picture** button and select Take Photo. The camera view will appear.

d) Orient the mobile device and take a photo by pressing the shutter button on the mobile device. The photo is displayed. If it is acceptable, tap **Use Photo** at the bottom right. If it is unacceptable, tap Retake at the bottom left.

e) Once you return to the “Capture Images” screen you can continue to tap **Take Picture** and repeat steps (d) and (e) as often as required.

f) In “Capture Images” screen, you can review the images as follows
   o Tap <**Previous** or >**Next** to move through the images. You can also swipe the images forward or backward.
   o Tap **Zoom In** or **Zoom Out** to adjust the size of the photo or look at an area in detail.
   o Type notes into the comment box. If you have typed in more than one comment, you can tap **←Move Forwards** or **→Move Backwards** to move through the entered comments.
   o Tap **Remove** to delete the image and comments that are currently selected.
g) Tap **Capture Image**, and a pop-up Images Uploaded box will appear, verifying that the number of images you have selected have been stored in VistA Imaging. The pending Reader consult request should now also appear in VistA Imaging TeleReader.

![Image of Lист Patient Studies]

h) To view the thumbnails you have just uploaded, tap **View Patient Studies**.
Help and Additional Information

Additional Training Materials for the VA TeleDerm App
More resources, such as a User Manual, FAQ and Slideshow, are available at mobile.va.gov/appstore, and search for the app to access the resources.

Help Desk Information
If you need help with the VA TeleDerm App, dial 1-844-482-6624 to speak with a VA representative. The Help Desk is open weekdays from 7 a.m. to 7 p.m. CT. For TTY assistance, dial 711.

Emergencies
If you feel your information may have been compromised, contact your local VA facility to obtain the contact information for your Privacy Officer. To locate your local VA facility, visit VA’s Facility Locator: http://www.va.gov/directory/guide/home.asp?isflash=1. Note that you should never use this app in an emergency. If you encounter an emergency, call your local medical center or dial 911.
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Overview

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Features:
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- Capture and upload images to VistA Imaging. No images are stored on the mobile device.
- Verify image upload and assess image quality
- View images that have been uploaded to patients’ files
- Automatically transfer information from imaging consult request to reader consult request
- Use native mobile device dictation capabilities

VA TeleDerm is available for iOS, Android and Windows operating systems, and is supported by these Internet browsers:
1. Internet Explorer 10 and higher
2. Safari 7 and higher
3. Firefox 24 and higher
4. Google Chrome 30 and higher

The app is optimized for an Apple iPad, though it will run on a variety of mobile devices.

This user manual provides an in-depth, step-by-step guide for using the VA TeleDerm App.

The Basics

**How VA TeleDerm integrates with teledermatology:** VA TeleDerm is an app designed to allow mobile devices to function within the framework of VA’s existing consultative multi-step store-and-forward teledermatology process that involves referring clinicians, teledermatology imagers and teledermatology readers.
1. **Initiation of teledermatology consultation:** Referring clinician identifies a patient who needs dermatologic consultation, and orders a teledermatology imaging consult request in CPRS that directs the imager what areas of skin to photograph, and that provides relevant clinical history.

2. **Completion of teledermatology imaging consult.** Imager receives the teledermatology imaging consult request, and completes the consult by responding to some imager-specific questions, and also recording the clinical history from the referring clinician. This is recorded as an imaging note in CPRS.

3. **Creation of reader consult request:** Imager orders in CPRS a teledermatology reader consult request that automatically extracts relative information from the imaging note.

4. **Image capture:** Imager photographs skin according to instructions in the referring clinician’s original imaging consult request. Images are then uploaded into VistA using VistAImaging Capture to be associated with the reader consult request; this enables the reader consult to appear on the “Read” list of VistAImaging TeleReader, visible to the reading teledermatologist. Once the imager confirms successful upload, the images must be deleted from the camera.

5. **Scheduling appointments:** Appointments for teledermatology imaging and for teledermatology reading must be separately entered in order to correctly record encounters. These are done by various staff, often imagers.

6. **Reading: The Teledermatology Reader** views the reader consult through VistAImaging TeleReader, including clinical history and images, and writes a consult note in CPRS including impression and recommendations to the referring clinician, completing the teledermatology reader consult.

7. **Patient care:** The original referring clinician receives a view alert when the reader consult is completed, views the reader’s note in CPRS, and executes any recommendations as appropriate.

**VA Telederm limitations**

- **VA Telederm** is an app that, in its current version, is intended only to be used by referring clinicians and imagers. Therefore, **VA Telederm** enables steps 1-4 above to be performed on a mobile device. Step 5 must likely still be done on CPRS separately. The device may also assist with 6, but this has not been validated. Future versions may allow for scheduling, and for dermatologists to view consults and images as well as respond and complete reader consults.

- The use of **VA Telederm** currently necessitates separately logging in to a different program/app than CPRS. As the use of mobile devices becomes more prevalent in VA’s clinical care, separate login may not be as significant an issue.

**VA Telederm advantages**
• **VA Telederm** is also interchangeable with CPRS for steps 1-4, and possibly step 6. That is, a referring clinician may use **VA Telederm** to create an imaging consult, and an imager may use CPRS to process that imaging consult. Conversely, a referring clinician may use CPRS to create an imaging consult request, and an imager may use **VA Telederm** to process that request, including capturing images. Finally, both clinicians and imagers may use **VA Telederm** to participate in the teledermatology process for a patient.

• When entering information in free text fields of **VA Telederm**, the mobile device’s built-in microphone can be used to dictate text. This can improve the efficiency of entering data, particularly for referring clinicians, when entering in detailed symptoms and other clinical history. The app is not specially designed to understand medical terminology.

• **VA Telederm** uses the mobile device’s built-in camera to capture images and allows the imager to complete all imaging steps with a single device. Because the app wirelessly communicates with the facility’s VistA Imaging server, there is no need for the imager to physically connect a separate camera or a camera’s storage card to a workstation to upload images.

• **VA Telederm** does not store images on the mobile device. All images are automatically deleted from memory when exiting the app. Thus, imagers do not need to delete images following an imaging session to ensure privacy and security of imaging data.

**Prerequisites:** To use the **VA TeleDerm** App, you must be a VA health care professional with credentials for the Veterans Health Information Systems and Technology Architecture (VistA). To use **VA Telederm** on a mobile device, you must use a government-furnished mobile device and have PIV-exemption. The intended users of the app are: 1) Clinicians who refer patients for teledermatology consultation, and 2) imagers.

**Touring the app** Get to know the app before you log in by taking a tour, which provides a bulleted overview of the app’s features as well as screenshots. On the bottom left of your screen, tap **Tour the App**. You will go to the first screen of the tour. To move through the tour, tap the circles at the bottom of the screen. To close the tour, tap the X in the upper right corner of your screen. **NOTE:** The app tour will still be available after you log into the app. To get to the tour after you have logged in, tap **menu** (three-line icon in the upper left corner) > A drop-down menu will appear > Tap **Tour the App**.
Designer Change all names under Recent Results, Results, Patient Orders and “Awarb, George” in the white box and on the top blue bar to “MobileAppVeteran, One” “MobileAppVeteran, Two” ect.

Change the SSN to either five leading zero’s or five leading six’s (000-00-1234 or 666-66-1234)

Change the DOB year to “1900”

Logging in 
Enter your VistA Username > Enter your VistA Password > Begin typing in a VA Hospital Location > A list of matching facilities will appear in a drop-down menu > Tap your VA facility > Tap Sign In > You will proceed into the app.
Getting to know the screen

When you log into the VA TeleDerm App, you will see a Patient Search feature as well as a list of patients whose records you have recently viewed. There are two icons in the upper left of your screen to help you navigate the app:

- Menu (three-line icon in upper left corner) – Access Consults, Notifications, Tour the App, About and Logout. **NOTE:** The consults option will only appear if you are currently viewing a specific patient’s details screen.
- Search for or Select a Patient (magnifying glass icon in upper left corner) – Quickly find patients to see their consults and dermatology information.
Learning about the app Tap menu (three-line icon in upper left corner) > A drop-down menu will appear > Tap About > You will go to an About screen that provides you with a brief overview of the app, its main features and the version number.

Logging out Tap menu (three-link icon in upper left corner) > A drop-down menu will appear > Tap Logout > You will be logged out of the app.

Notifications Review notifications related to your patients’ teledermatology consults.
Viewing your notifications  Notifications are triggered when a consult is created for your patient. Tap menu (three-line icon in upper left corner) > A drop-down menu will appear > Tap Notifications > You will see a list of notifications you have received related to your patients’ teledermatology consults. The notifications show you:

- Patient Name – Patients’ last and first name and the last initial and last 4 SSN digits.
- Location
- Urgency – This will default to routine. To change, tap the bar under the heading > A drop-down menu will appear > Tap the level or deadline you would like to select.
- Alert Date/Time – Date and time the alert was created.
- Message – Notes on the status of the consult.
- Forwarded By/When – Name of provider/reader/imager, if the message was forwarded.

You can make sure you are viewing the most current list of notifications by tapping Refresh in the upper right corner. If any new notifications have come in, they will then appear in the list.

NOTE: To follow up on any of the notifications, you will have to search for and select the patient in the patient search function.

Search for or Select Patients
Quickly find and select patients to view their dermatology information.
Searching for and selecting patients When you log into the VA TeleDerm App, you will arrive at the Select a Patient screen. You can also get to the search and select feature at any time by tapping Search for or Select a Patient (magnifying glass icon). NOTE: If you are already viewing a patient’s records, you can select a new patient at any time by tapping the magnifying glass icon > You will see a Patient Search box, and underneath you will see the names of patients you recently searched for and a list of all patients in CPRS at your facility. If you immediately see the name of the patient whose records you will like to view, you can tap the name of the patient. If you need to search for the patient you would like to view, type in the patient’s first and/or last name in the bar underneath the Patient Search heading > Tap Search > A list of patients matching your search criteria will appear below > Tap the name of the patient you would like to view > A pop-up box with the patient’s identifying information will appear > Tap Confirm Patient to go to the patient’s Dermatology Consults screen.

Understanding a patient’s screen After you search for a patient, you will first arrive at the patient’s Dermatology Consults list screen. In the upper left corner, you will see the patient’s identifying information including patient name, date of birth (DOB), age, gender and social security number (SSN).
The screen is divided into two panes. On the left pane, you will see the total number of consults in parenthesis next to Results, a Refreshed button and a list of filters to help you narrow down or expand your search. On the right pane, you will see a list of dermatology consults. To change the type of list you would like to view, tap the **List** heading > A drop-down menu will appear > Tap one of the following lists:

- **Dermatology Consults** – View a list of complete or in-progress teledermatology consults for providers and imagers, complete a consult, create a new imager consult or create a reader consult.
- **Reader Consults** – View a list of reader consults, and capture and upload images.
- **Patient Orders** – View a list of patient orders, and edit or sign orders that have not yet been released.
- **Patient Studies** – View images that have been uploaded to VistA Imaging.

**Dermatology Consults**

See or complete a patient’s dermatology consults and create a new imager or reader consult.

**Accessing and filtering a patient’s dermatology consults** First search for and select a patient. If not already selected, tap the **List** heading > A drop-down menu will appear > Tap **Dermatology Consults**. The Dermatology Consults screen will be divided into two panes: status filter options on the left and the list of consults on the right. To use the status filters, tap the checkbox(es) next to any or all of the following statuses:
• Active
• Cancelled
• Complete
• Discontinued
• No status
• Other
• Partial results
• Pending
• Scheduled

Tap Refreshed (circle with two arrows), and the list of consults in the right pane will adjust based upon the criteria you selected. The list provides you with an overview of the consult information:

• Date – Date consult was created.
• Description – Type of consult.
• Status – Current status of the dermatology consult.
• IEN – Internal entry number assigned to the consult request.

Creating a new imager consult This is the first step in the teledermatology process. Referring clinicians/primary care providers can create new consults and send them to imagers. First search for and select a patient. On a patient’s Dermatology Consults screen, tap New Imager Consult+ > Enter the following information:

• Encountered Provider Results – The name will default to the provider who requested the consult. To change the name, tap the bar under the heading > A drop-down menu will appear > Tap the name of the provider you would like to select.
• Select Location Type - Tap the circle next to the location type:
  o Clinic Appointments – Under Select a Clinic Appointment, tap on the specific clinic appointment you would like to complete > The selected hospital admission will have a checkmark next to it and the background will be light blue > Tap Select Clinic Appointment.
  o Hospital Admissions – A list of hospital admissions will appear > Tap the specific hospital admission you would like to complete > The selected hospital admission will have a checkmark next to it and the background will be light blue > Tap Select Hospital Admission.
  o New Visit – Under Visit Location, tap the specific type of appointment you would like to complete > Under Date of Visit, tap the date, and either 1) type in the date in the form MM/DD/YYYY or 2) tap the date from the pop-up calendar that appears > Tap Create New Visit.
You will go to the Create New Consult screen where you will see logistical information, general history and problems. Fill out the following information:

- **Consult to Service/Specialty** – The service/specialty will default to the title chosen when the clinician created the original consult. To change it, tap the bar under the heading > A drop-down menu will appear > Tap the service/specialty you would like to select.

- **Patient Will Be Seen** – Tap the circle next to either Outpatient or Inpatient.

- **Attention Results** – Tap the bar under the heading > A drop-down menu will appear > Tap the name of the person who should be alerted as to the results of the consult.

- **Clinically Indicated Date** – The date will default to the current date. To change it, tap the date and type in the form MM/DD/YYYY.

- **Urgency** – This will default to routine. To change, tap the bar under the heading > A drop-down menu will appear > Tap the level or deadline you would like to select.

- **Place of Consultation** – This will default to the location that was chosen when the consult was created. To change it, tap the bar under the heading > A drop-down menu will appear > Tap either **Consultant’s Choice** or **Emergency Room**.

For General History, you are required to fill out the first section of the patient’s health history. Enter information by:

- Typing in your comment. You may also dictate by tapping on the microphone symbol on the keyboard.

- Tapping a circle or checkbox next to the information that corresponds to your patient.

- Tapping the image of a family member on a family tree.

For Problems, you are required to enter at least one problem and its location on your patient’s body. Enter information by:

- Typing in your comments or by dictating if the mobile device has a built-in microphone.

- Tapping a circle or checkbox next to the information that corresponds to your patient.

- To add another problem, tap **+Add Problem**, and a new field will appear where you can enter the additional information.

- To edit problem information, tap the problem you want to edit (e.g., **Problem A**, **Problem B**, etc.) > The problem will appear below, and edit as you would normally.

- To remove a problem, tap the problem you want to delete (e.g., **Problem A**, **Problem B**, etc.) > The problem will appear below > Tap **Remove Problem**.

Tap **Create Consult** > Review the order information > Under the Electronic Signature Code, type in your name > Tap **Sign**.
Completing a teledermatology imaging consult

Teledermatology imaging consult requests from clinicians are processed by imagers who have been trained according to protocols established by Office of Connected Care / Office of Health Informatics. The section is intended to be used during an appointment with a patient.

First search for and select a patient. From the Dermatology Consults screen, tap a pending consult in the Dermatology Consult list > Full details about the consult will expand below > Tap **Complete Consult** > You will go to a Provider & Location for Current Activities screen > You will see a list of clinic appointments > Enter xxx

- **Encounter Provider** – Type in the first or last name of a provider > Tap **Search**
- **Encountered Provider Results** – The name will default to the provider who requested the consult. To change the name, tap the bar under the heading > A drop-down menu will appear with a list of names > Tap the name of the provider you would like to select.
- **Select Location Type** - Tap the circle next to the location type:
  - **Clinic Appointments** – Under Select a Clinic Appointment, tap on the specific clinic appointment you would like to complete > The selected clinic appointment will have a checkmark next to it and the background will be light blue > Tap **Select Clinic Appointment**.
  - **Hospital Admissions** – A list of hospital admissions will appear > Tap the specific hospital admission you would like to complete > The selected hospital admission will have a checkmark next to it and the background will be light blue > Tap **Select Hospital Admission**.
  - **New Visit** – Under Visit Location, tap the specific type of appointment you would like to complete > Under Date of Visit, tap the date, and either 1) type in the date in the form MM/DD/YYYY or 2) tap the date from the pop-up calendar that appears > Tap **Create New Visit**.
You will go to a Consult Note Properties screen > Fill out the form to create the appointment:

- Progress Note Title – The note title will default to the one chosen when the consult was created. To change it, tap the bar under the heading > A drop-down menu will appear > Tap the title you would like to select.

- Date of Note – The date will default to the current date. To change it, tap the date, and type the date in the form MM/DD/YYYY.

- Author – Type in the first or last name of a provider > Tap Search > XXX

- Author Results – The name will default to the provider who requested the consult. However, you can change the name by tapping the bar under the heading > A drop-down menu will appear with a list of names > Tap the name of the provider you would like to select.

Read the education section to your patient to inform him or her about the background and process of teledermatology care > Record your patient’s understanding by:

- Level of understanding – Tap the bar under the heading > A drop-down menu will appear > Tap the applicable description.

- Comment – If desired, type in any information about your interaction with the patient.

- Patient consent – Tap the circle next to either Yes or No. If you selected yes, a drop-down survey will appear > Ask your patient the questions, and record the answers by either tapping a checkbox or circle or typing in comments.

Tap Finish > Review the note > Under the Electronic Signature Code, type in your name > Tap Sign.
Creating a reader consult

Imagers can create a consult to send to readers. First search for and select a patient. From the Dermatology Consults screen, tap a completed consult in the Dermatology Consult list > Full details about the consult will expand below > Tap Create Reader Consult > You will go to a Create New Reader Consult screen > Fill out the form to create the appointment:

- **Consult to Service/Specialty** – The service/specialty will default to the title chosen when the clinician created the original consult. To change it, tap the bar under the heading > A drop-down menu will appear > Tap the service/specialty you would like to select.
- **Patient Will Be Seen** – Tap the circle next to either Outpatient or Inpatient.
- **Attention Results** – Tap the bar under the heading > A drop-down menu will appear > Tap the name of the person who should be alerted as to the results of the consult.
- **Clinically Indicated Date** – The date will default to the current date. To change it, tap the date, and type in the form MM/DD/YYYY.
- **Urgency** – This will default to routine. To change it, tap the bar under the heading > A drop-down menu will appear > Tap the level or deadline you would like to select.
- **Place of Consultation** – This will default to the location that was chosen when the consult was created. To change it, tap the bar under the heading > A drop-down menu will appear > Tap either Consultant’s Choice or Emergency Room.
- **Provisional Diagnosis** – Tap Lexicon

Tap Create Consult > Review the order information > Under the Electronic Signature Code, type in your name > Tap Sign > You will go to a Reader Consults screen where you can view the consults sent to readers and capture and upload images. (For detailed instructions, visit the Reader Consults section.)

Reader Consults

Imagers can create consults for readers, and take and upload photos.
Accessing and completing reader consults

First search for and select a patient. From the Dermatology Consults screen, tap the List heading > A drop-down menu will appear > Tap Reader Consults > You will go to a Reader Consults screen where you will see a list of the consults > The list provides you with an overview of the consult information:

- Date – Date consult was created.
- Service
- Procedure
- Sending Provider – Provider who created the original consult request.
- Status – Current status of the dermatology consult.
- IEN – Internal entry number assigned to the consult request.

Tap on the consult you would like to view > The details for the consult will expand below > Tap Select > You will go to a Capture Images screen > Details about the image will automate based on the information clinicians and imagers entered about the requested image, but you can change these by typing in information, tapping options from drop-down menus or tapping to check/uncheck boxes:

- Document/Image Date
- Origin
- Document/Image Type
- Specialty
- Proc/Event
- Image Description
- Controlled Image

Tap Take Picture > Depending on the device you are using, choose and upload an image file saved on the device you are using to access the VA TeleDerm App > The selected image will appear in a preview within the Capture Image screen > If desired, you can:
  - Tap Take Picture again to upload more photos > If you have uploaded more than one image, you can tap <Previous or >Next to move through the uploaded images.
  - Tap Zoom In or Zoom Out to adjust the size of the photo or look at an area in detail.
  - Type notes into the comment box. If you have typed in more than one comment, you can tap ⇐Move Forwards or ⇒Move Backwards to move through the entered comments.
  - Tap Remove to delete the image and comments that are currently selected.

Tap Capture Image > A pop-up Images Uploaded box will appear, verifying that the number of images you have selected have been stored in VistA. To close the pop-up box and remain on the Capture Images screen, tap Close. To view the thumbnails you uploaded, tap View Patient Studies.
Patient Orders

Review, sign and edit patient orders.
Viewing patient orders First search for and select a patient. From the Dermatology Consults screen, tap the List heading > A drop-down menu will appear > Tap Patient Orders > You will see a list of orders with the following information:

- Order Date – Date the order was created.
- Order – Description of the order.
- Provider – Name of the provider who created the order.
- Status – Current status of the dermatology consult.
- Location – Area of medicine.

Tap on the consult you would like to view > The details for the order will expand below.

Signing patient orders First search for and select a patient. From the Dermatology Consults screen, tap the List heading > A drop-down menu will appear > Tap Patient Orders > You will see a list of orders > Tap the order you would like to sign, and the details for the order will expand below > Tap Sign Order > Review the order information > Under the Electronic Signature Code, type in your name > Tap Sign or tap Cancel to return to the Patient Orders screen.

Editing patient orders First search for and select a patient. From the Dermatology Consults screen, tap the List heading > A drop-down menu will appear > Tap Patient Orders > You will see a list of orders > Tap the order you would like to edit, and the details for the order will
expand below > Tap **Edit Order** > You will go to a Provider & Location for Current Activities screen > Edit the following information as needed:

- **Encounter Provider** – Type in the first or last name of a provider > Tap **Search**
- **Encountered Provider Results** – The name will default to the provider who requested the consult. To change the name, tap the bar under the heading > A drop-down menu will appear with a list of names > Tap the name of the provider you would like to select.
- **Select Location Type** - Tap the circle next to the location type:
  - **Clinic Appointments** – Under Select a Clinic Appointment, tap on the specific clinic appointment you would like to complete > The selected hospital admission will have a checkmark next to it and the background will be light blue > Tap **Select Clinic Appointment**.
  - **Hospital Admissions** – A list of hospital admissions will appear > Tap the specific hospital admission you would like to complete > The selected hospital admission will have a checkmark next to it and the background will be light blue > Tap **Select Hospital Admission**.
  - **New Visit** – Under Visit Location, tap the specific type of appointment you would like to complete > Under Date of Visit, tap the date, and either 1) type in the date in the form DD/MM/YYYY or 2) tap the date from the pop-up calendar that appears > Tap **Create New Visit**.

You will go to an **Edit Order** screen > Type in any additional notes into the order box > Tap one of the following

- **Cancel** - Return to the Patient Orders screen.
- **Save Changes** - A pop-up Order Updated box will appear > Tap **Close** to return to the Patient Orders screen, or tap **Sign** to continue and sign the order.
- **Sign Order** - Complete the order. Under the Electronic Signature Code, type in your name > Tap **Sign**, or tap **Cancel** to return to the Patient Orders screen without signing.

**Patient Studies**

See images that have been uploaded to patients’ files.
Viewing patient studies Currently, the target users for VA Telederm are referring clinicians/primary care providers and certified imagers in VA. While dermatologists can also use the app to view which consults are pending or completed, the app does not permit a review of the submitted images, and VA Telederm should not be used to complete teledermatology reader consult requests. Reading and completion of teledermatology reader consult requests should continue to be done using VistA Imaging TeleReader until further notice.

Help and Additional Information

Additional Training Materials for the VA TeleDerm App More resources, such as a Quick Start Guide, Slideshow and FAQs, are available at mobile.va.gov/appstore, and search for the app to access the resources.

Help Desk Information If you need help with the VA TeleDerm App, dial 1-844-482-6624 to speak with a VA representative. The Help Desk is open weekdays from 7 a.m. to 7 p.m. CT. For TTY assistance, dial 711.

Emergencies If you feel your information may have been compromised, contact your local VA facility to obtain the contact information for your Privacy Officer. To locate your local VA facility, visit VA’s Facility Locator: http://www.va.gov/directory/guide/home.asp?isflash=1. Note that you should never use this app in an emergency. If you encounter an emergency, call your local medical center or dial 911.
Appendices

Appendix #1: Project References
This app was developed according to an approved concept paper. The app was tested in a demo environment to ensure optimal functionality.

Appendix #2: Glossary
App – An application, or software program, that can be accessed through a website or mobile device and is designed to fulfill a particular purpose

CPRS – Computerized Patient Record System

DoD – Department of Defense

DS Logon (Department of Defense Self-Service Logon) – A secure logon ID, created by the Department of Defense (DoD), that verifies the identities of individuals affiliated with DoD or the Department of Veterans Affairs (VA) and allows them to access secure websites and digital resources across DoD and VA using a single username and password.

   DS Logon Level 1 (Basic) Account: Provides limited access to website features

   DS Logon Level 2 (Premium) Account: Offers the highest level of access to website features. (NOTE: You must have a DS Logon Level 2 (Premium) Account to use VA’s Mobile Apps.)

IEN – Internal entry number

VA – Department of Veterans Affairs

VA Mobile Health – An initiative that aims to improve Veterans’ health by providing technologies to expand care beyond the traditional office visit and that includes the creation of secure mobile apps to leverage the popularity of wireless technologies to support Veterans, Caregivers and VA care teams [More at: mobilehealth.va.gov]

VHA – Veteran Health Administration

VistA – Veterans Health Information Systems and Technology Architecture) - VA’s computerized patient record system.
C. Stata code for the power analyses

*First need to create a design-pattern matrix in a replicable way

```stata
clear all
set obs 36 //this is the number of clusters
gen base1 = 0
gen base2 = 0

gen step1 = 0
replace step1 = . in 1/6

gen step2 = 0
replace step2 = 1 in 1/6
replace step2 = . in 7/12

gen step3 = 0
replace step3 = 1 in 1/12
replace step3 = . in 13/18

gen step4 = 0
replace step4 = 1 in 1/18
replace step4 = . in 19/24

gen step5 = 0
replace step5 = 1 in 1/24
replace step5 = . in 25/30

gen step6 = 0
replace step6 = 1 in 1/30
replace step6 = . in 31/36

gen step7 = 1
gen step8 = 1

cd "Y:\CAPER\Nicolae\Telederm\Analyses\Power calculations"
save design_va_telederm, replace

*CALCULATE POWER USING THE DESIGN MATRIX

clear all

cd "Y:\CAPER\Nicolae\Telederm\Analyses\Power calculations"
use design_va_telederm, clear

**Consult completion time

steppedwedge, power alpha(0.05) beta(0.8) incomplete(1) vartotal(0) m(120) mu1(27.8) mu2(25.0) sd1(44.3) sd2(44.3) rho(0.25)
steppedwedge, power alpha(0.05) beta(0.8) incomplete(1) vartotal(0) m(120) mu1(27.8) mu2(25.0) sd1(44.3) sd2(44.3) rho(0.30)
steppedwedge, power alpha(0.05) beta(0.8) incomplete(1) vartotal(0) m(120) mu1(27.8) mu2(25.0) sd1(44.3) sd2(44.3) rho(0.25)
steppedwedge, power alpha(0.05) beta(0.8) incomplete(1) vartotal(0) m(120) mu1(27.8) mu2(25.0) sd1(44.3) sd2(44.3) rho(0.25)
steppedwedge, power alpha(0.05) beta(0.8) incomplete(1) vartotal(0) m(50) mu1(27.8) mu2(23.6) sd1(44.3) sd2(50.0) rho(0.25)
steppedwedge, power alpha(0.05) beta(0.8) incomplete(1) vartotal(0) m(50) mu1(27.8) mu2(23.6) sd1(44.3) sd2(50.0) rho(0.25)
steppedwedge, power alpha(0.05) beta(0.8) incomplete(1) vartotal(0) m(70) mu1(27.8) mu2(23.6) sd1(50.0) sd2(50.0) rho(0.25)
```

**Appointment completion time**

steppedwedge, power alpha(0.05) beta(0.8) incomplete(1) vartotal(0) m(200) mu(60.0) mu2(57) sd(50.0) sd2(50.0) rho(0.2)

steppedwedge, power alpha(0.05) beta(0.8) incomplete(1) vartotal(0) m(140) mu(60.0) mu2(57) sd(50.0) sd2(50.0) rho(0.2)

steppedwedge, power alpha(0.05) beta(0.8) incomplete(1) vartotal(0) m(300) mu(60.0) mu2(57) sd(75) sd2(75) rho(0.2)

steppedwedge, power alpha(0.05) beta(0.8) incomplete(1) vartotal(0) m(110) mu(60.0) mu2(57) sd(50.0) sd2(40.0) rho(0.1)

steppedwedge, power alpha(0.05) beta(0.8) incomplete(1) vartotal(0) m(240) mu(50.0) mu2(47.5) sd(50.0) sd2(60.0) rho(0.1)

steppedwedge, power alpha(0.05) beta(0.8) incomplete(1) vartotal(0) m(400) mu(60.0) mu2(58.2) sd(50.0) sd2(50.0) rho(0.3)

**Travel distance**

steppedwedge, power alpha(0.05) beta(0.8) incomplete(1) vartotal(0) m(550) mu(13.0) mu2(12.61) sd(13) sd2(13) rho(0.2)

steppedwedge, power alpha(0.05) beta(0.8) incomplete(1) vartotal(0) m(300) mu(13.0) mu2(12.48) sd(13) sd2(13) rho(0.2)

steppedwedge, power alpha(0.05) beta(0.8) incomplete(1) vartotal(0) m(300) mu(13.0) mu2(12.48) sd(13) sd2(13) rho(0.1)

steppedwedge, power alpha(0.05) beta(0.8) incomplete(1) vartotal(0) m(500) mu(13.0) mu2(12.48) sd(13) sd2(20) rho(0.2)

steppedwedge, power alpha(0.05) beta(0.8) incomplete(1) vartotal(0) m(1000) mu(10.0) mu2(9.7) sd(12) sd2(15) rho(0.1)

**Proportion of telederm encounters**

steppedwedge, power binomial alpha(0.05) beta(0.8) incomplete(1) vartotal(0) m(1700) p(0.03) p2(0.0329) rho(0.05)

steppedwedge, power binomial alpha(0.05) beta(0.8) incomplete(1) vartotal(0) m(450) p(0.03) p2(0.035785) rho(0.05)

steppedwedge, power binomial alpha(0.05) beta(0.8) incomplete(1) vartotal(0) m(200) p(0.03) p2(0.038652) rho(0.1)

steppedwedge, power binomial alpha(0.05) beta(0.8) incomplete(1) vartotal(0) m(150) p(0.1) p2(0.117647) rho(0.1)

steppedwedge, power binomial alpha(0.05) beta(0.8) incomplete(1) vartotal(0) m(350) p(0.2) p2(0.215686) rho(0.05)

steppedwedge, power binomial alpha(0.05) beta(0.8) incomplete(1) vartotal(0) m(600) p(0.10) p2(0.108911) rho(0.25)
D. Full Constrained Randomization Algorithm

1. The first stage of the procedure involved an optimization method that evaluated the potential combinations in sequence assignments and ranked these combinations according to balance in site characteristics. Since evaluating the full set of combinations is prohibitive in terms of time and computing power (the total number of combinations is \( N = \binom{36}{6} \binom{30}{6} \binom{24}{6} \binom{18}{6} \binom{12}{6} \approx 2.67 \times 10^{24} \)), we performed a simplified step-wise procedure instead, relying on the assumption that if at each iteration a group of 6 facilities is chosen that is similar to the ones that are left, then the procedure will produce 6 groups of facilities that are similar to each other. We implemented this procedure in the SAS statistical software.

Thus, starting with the full set of \( K = 36 \) sites, we selected an allocation of 6 facilities at a time, compared their characteristics with the rest of the unselected facilities, chose the most balanced combination, and then repeated these steps an additional 4 iterations on a progressively restricted subset of the facilities obtained by excluding the facilities already selected in the previous iteration. In the last iteration, 6 sites were chosen out of the 12 remaining sites and the most balanced combination of site allocations was chosen. This method produced 6 groups of sites that were balanced in baseline characteristics. In more detail:

1.1. We first created a 0/1 matrix of all the possible combinations of 6 facilities to be chosen in the first group (group A). The total number of rows in this matrix was equal to the total number of ways of choosing exactly 6 elements out of a group of 36 when the order of the elements does not matter, meaning \( \binom{36}{6} = \frac{36!}{30!6!} = 1,947,792 \). The number of columns of this matrix was 6.

1.2. A continuous score was created for each possible combination of 6 facilities by standardizing the quantitative variables being balanced, calculating the means of each variable in each combination, and then squaring the means and summing the squared means.

1.3. Since our only categorical variable to balance is the region, a regional score was also calculated for each combination of 6 elements as the sum of two subscores. The first subscore was calculated as the maximum number of facilities selected from any given region minus the minimum number of facilities selected from any given region. To illustrate, if a combination selected 6 facilities from region A but zero facilities from region B, it was assigned a regional subscore of 6. This subscore was higher than a combination that chose 3 facilities from region A and 3 facilities from region B, which received a regional subscore of 3-3=0. The same subscore was then calculated for the left-over facilities after subtracting the selected combination to ensure that the set of combinations was not restricted too much for the following iteration.

1.4. In the next step, the overall regional score was first minimized, and the sequence with the lowest continuous score was chosen out of all the combinations with the lowest regional score.

1.5. The sequence of facilities selected with the lowest continuous score and lowest regional score was selected and excluded from the set, thus leaving \( K-6 \) facilities.

1.6. Steps 1.1 through 1.4 were then repeated for the \( K-6 \) facilities another 4 times, until a sequence of 6 facilities was left. Ultimately, the first stage resulted in 6 sequences of 6 facilities each, balanced on geographic composition, size, and percentage of teledermatology consults.
2. The second stage involved obtaining a computer-generated list of random allocation numbers using the Stata program version 14.1 (StataCorp, LLC). These numbers were assigned to the sequences of facilities allocated in stage (1). Since this involved randomly assigning an order to 6 sequences of facilities, we randomly chose one order out of a total of \(6! = 720\) potential orderings.

The full SAS and Stata code for conducting the constrained randomization procedure is provided below.

**SAS Code for Selecting a Balanced Combination of Groups**

```sas
libname dt "Y:\Nicolae\Telederm\Analyses\Work";
proc import
datafile="Y:\Nicolae\Telederm\Analyses\Work\sites_vaderm_for_sas_fy16.csv" dbms=csv out=dt.vaderm replace; run;
proc contents data=dt.vaderm; run;
proc freq data=dt.vaderm; tables districtnumberfy17; run;

*RESTRICT THE TELEDERM DATA TO THE VARIABLES AND OBSERVATIONS NEEDED;
data dt.vaderm_rest(keep=id sta3n totvis pctd695_6 districtnumberfy17);
set dt.vaderm;
  id=_N_; run;
data dt.vaderm_rest; set dt.vaderm_rest; run;
*STANDARDIZE THE CONTINUOUS VARIABLE DATA;
proc standard data=dt.vaderm_rest mean=0 std=1 out=dt.vaderm_st print;
var pctd695_6 totvis; run;

####################################################################
*MACRO THAT SELECTS A NUMBER Nsel of observations out of a total of Nfac;
*trial provides which study we are conducting the analysis for and can be either "va" or "my"
*group provides the group that we are selecting (=A, B, C, D, or E since F is selected at the same time as E by elimination);
*Nblk is a number equal to the number of combinations for the step, equal to (Nfac choose Nsel);
%macro procstep(trial,group,Nblk,Nfac,Nsel);
  *CREATE A DATASET THAT CONTAINS ALLOCATIONS WITH ID OF UNITS CHOSEN;
  proc plan seed=123;
    factors block=&Nblk ordered station=&Nsel of &Nfac comb;
    ods output plan=dt.&trial.derm_comb_&group;
run;
  *CREATE A DATASET THAT CONTAINS ALL THE ALLOCATIONS AS 0/1 MATRIX;
  data dt.&trial.derm_comb2_&group (drop=station:);
    set dt.&trial.derm_comb_&group;
    array c (*) c1-c&Nfac;
    array stations (*) station1-station&Nfac;
```

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml
do i=1 to &Nfac;
    do j=1 to &Nsel;
        if stations(j)=i then c(i)=1;
    end;
    if c(i)=. then c(i)=0;
end;
drop i j;
run;

*COPY THE FACILITY DATA C TIMES AND MERGE WITH THE ALLOCATION MATRIX;
*if there are n facilities total and C total allocations there will be nXC total records;
data dt.&trial.derm_z_&group;
    set dt.&trial.derm_st_&group;
    do block = 1 to &Nblk;
        output;
    end;
run;
proc sort data=dt.&trial.derm_z_&group; by block id;
run;

*MERGE FACILITY DATA WITH ALL POSSIBLE ALLOCATIONS;
data dt.&trial.derm_z2_&group;
    merge dt.&trial.derm_comb2_&group
dt.&trial.derm_z_&group;
    by block;
run;

*ASSIGN EACH FACILITY TO EITHER CONTROL OR INTERVENTION ACCORDING TO THE POSSIBLE COMBINATIONS;
data dt.&trial.derm_z3_&group;
    set dt.&trial.derm_z2_&group;
    array c(*) c1-c&Nfac;
    do i=1 to dim(c);
        group=(c(i) ^= c(id));
    end;
run;

*SAVE A MATRIX WITH WHAT THE BLOCKS LOOK LIKE - SO I CAN MERGE LATER WITH THE SCORES AND KEEP TRACK OF WHAT FACILITIES GET PICKED;
data dt.&trial.derm_blocks1_&group (keep=block c:);
    set dt.&trial.derm_z3_&group;
    by block;
    if first.block then output;
run;

*CREATE VARIABLES WITH THE SCORES FOR EACH DISTRICT;
data dt.&trial.derm_z4reg_&group;
    set dt.&trial.derm_z3_&group;
    dis1=0; dis2=0; dis3=0; dis4=0; dis5=0;
    array d(*) dis1-dis5;
    do i = 1 to 5;
        d(i) = (districtnumberfy17=i);
    end;
run;
*ADD UP REGION SCORES BY BLOCK AND GROUP;
proc means data=dt.&trial.derm_z4reg_&group sum;
  class block group;
  var dis1--dis5;
  ods output summary=dt.&trial.derm_z5reg_&group;
run;

data dt.&trial.derm_regscores_&group;
  set dt.&trial.derm_z5reg_&group;
  reg_score =
    (max(dis1_Sum,dis2_Sum,dis3_Sum,dis4_Sum,dis5_Sum) -
    min(dis1_Sum,dis2_Sum,dis3_Sum,dis4_Sum,dis5_Sum));
run;

proc means data=dt.&trial.derm_regscores_&group mean;
  class block;
  var reg_score;
  ods output summary=dt.&trial.derm_regscores2_&group;
run;

*GET A SORTED DATASET WITH REGION SCORE FOR EACH BLOCK;
proc sort data=dt.&trial.derm_regscores2_&group; by reg_score_Mean; run;

*****AT THIS POINT THE DATASET HAS THE REGION SCORES FOR EACH BLOCK

*CREATE THE MEAN VALUES BY GROUP OF ALL POSSIBLE COMBINATIONS OF FACILITIES;
proc means data=dt.&trial.derm_z3_&group mean;
  class block group;
  var totvis pctd695_6;
  ods output summary=dt.&trial.derm_s1_&group;
run;

*CALCULATE SUM OF SQUARED DIFFS BETWEEN CONTROL AND INTERVENTION GROUPS OF FACILITIES;
proc sort data=dt.&trial.derm_s1_&group; by block group; run;
data dt.&trial.derm_s2_&group(keep= block totalssq);
  set dt.&trial.derm_s1_&group;
  by block;
  retain fvis fpct;
  array f(*) fvis fpct;
  array z(*) totvis_Mean pctd695_6_Mean;
  array sqdiff(*) dvis dpct;
  if first.block then do i=1 to dim(f);
    f(i)=z(i);
  end;
  else if last.block then do;
    do i=1 to dim(f);
      sqdiff(i)=(f(i)-z(i))**2;
    end;
  else do;
    do i=1 to dim(f);
      sqdiff(i)=(f(i)-z(i))**2;
    end;

totalssq=sum(dvis, dpct);
output;
end;
run;
proc sort data=dt.&trial.derm_s2_&group; by totalssq;
run;  
****AT THIS POINT THE DATASET CONTAINS THE CONTINUOUS
SCORES AND IS SORTED IN ASCENDING ORDER;
proc sort data=dt.&trial.derm_s2_&group; by block;
run;
proc sort data=dt.&trial.derm_regscores2_&group; by block; run;
data dt.&trial.derm_step_&group;
merge dt.&trial.derm_blocks1_&group
dt.&trial.derm_s2_&group dt.&trial.derm_regscores2_&group;
by block;
run;
proc sort data=dt.&trial.derm_step_&group; by reg_score_Mean totalssq; run;
*GET TOP PERCENT OF BLOCKS;
proc univariate data=dt.&trial.derm_s2_&group;
var totalssq;
id block;
ods output quantiles=dt.&trial.derm_q_&group
(drop=varname);
run;
*SET INITIAL DATA ONE MORE TIME TO IDENTIFY SELECTED
OBSERVATIONS;
data dt.&trial.derm_st_&group; set dt.&trial.derm_s2_&group; run;
%mend prostep;

*--------------------------------------------------------------------;
*RUNNING PROCEDURE MACRO FOR THE VA TELEDERM TRIAL;
*--------------------------------------------------------------------;

*RUN THE MACRO 5 TIMES WITH THE APPROPRIATE SUBSETTING AFTER EACH RUN
TO ELIMINATE THE FACILITIES THAT WERE JUST SELECTED;
data vaderm_st_A; set dt.vaderm_st; run;
%prostep(va,A,1947792,36,6)

data vaderm_st_Bt(drop=id); set dt.vaderm_st; if id
NOTIN(1,6,7,10,35,36) then output; run;
data vaderm_st_B; set vaderm_st_Bt; id=_N_; run;
%prostep(va,B,593775,30,6)

data vaderm_st_Ct(drop=id); set dt.vaderm_st_B; if id
NOTIN(4,6,13,15,21,25) then output; run;
data dt.vaderm_st_C; set vaderm_st_Ct; id=_N_; run;
%procstep(va,C,134596,24,6)

data vaderm_st_Dt(drop=id); set dt.vaderm_st_C; if id NOTIN(1,5,8,18,19,22) then output; run;
data dt.vaderm_st_D; set vaderm_st_Dt; id=_N_; run;
%procstep(va,D,18564,18,6)

data vaderm_st_Et(drop=id); set dt.vaderm_st_D; if id NOTIN(2,4,5,6,10,12) then output; run;
data dt.vaderm_st_E; set vaderm_st_Et; id=_N_; run;
%procstep(va,E,924,12,6)

Stata Code for Selecting a Random Ordering

*****VA TELEDERM
cd "Y:\Nicolae\Telederm\Analyses\Work"
use sites_vaderm_group_fy16, replace

*PERFORM RANDOMIZATION OF ORDER IN WHICH GROUPS RECEIVE INTERVENTION
preserve
    set seed 123
    sort vatd_group
    by vatd_group: gen _keep=(_n==1)
    keep if _keep==1
    keep vatd_group
    list, clean noobs
    generate u = runiform()
    sort u
    gen vatd_step = _n
    list, clean noobs
cd "Y:\Nicolae\Telederm\Analyses\Work"
save vatd_order, replace
restore

*MERGE GROUPS WITH THE ORDER IN WHICH THEY WILL RECEIVE INTERVENTION
cd "Y:\Nicolae\Telederm\Analyses\Work"
use sites_vaderm_group_fy16, clear
merge m:1 vatd_group using vatd_order_fy16
drop _merge

label var vatd_step "VA Telederm Step"
cd "Y:\Nicolae\Telederm\Analyses\Work"
save sites_vaderm_randomized_fy16, replace
### E. Facilities in order of implementation sequence and relevant facility characteristics

<table>
<thead>
<tr>
<th>Sequence</th>
<th>Facility</th>
<th>Facility Name</th>
<th>District</th>
<th>Complexity</th>
<th>Visits</th>
<th>Percent Telederm</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 V01</td>
<td>(523) VA Boston, MA</td>
<td>North Atlantic</td>
<td>1a</td>
<td>15057</td>
<td>2.7</td>
<td></td>
</tr>
<tr>
<td>2 V05</td>
<td>(688) Washington, DC</td>
<td>North Atlantic</td>
<td>1a</td>
<td>14110</td>
<td>1.4</td>
<td></td>
</tr>
<tr>
<td>3 V08</td>
<td>(548) West Palm Beach, FL</td>
<td>Southeast</td>
<td>1c</td>
<td>17945</td>
<td>7.1</td>
<td></td>
</tr>
<tr>
<td>4 V23</td>
<td>(636) Iowa City, IA</td>
<td>Midwest</td>
<td>1b</td>
<td>22938</td>
<td>0.3</td>
<td></td>
</tr>
<tr>
<td>5 V16</td>
<td>(598) Little Rock, AR</td>
<td>Continental</td>
<td>1a</td>
<td>15846</td>
<td>0.2</td>
<td></td>
</tr>
<tr>
<td>6 V21</td>
<td>(654) Reno, NV</td>
<td>Pacific</td>
<td>1c</td>
<td>4076</td>
<td>8.1</td>
<td></td>
</tr>
</tbody>
</table>
F. Balance in the means of continuous variables after constrained randomization

<table>
<thead>
<tr>
<th>Sequence</th>
<th>Number of visits</th>
<th>Percent teledermatology encounters</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>14,995</td>
<td>3.3</td>
</tr>
<tr>
<td>2</td>
<td>15,629</td>
<td>3.7</td>
</tr>
<tr>
<td>3</td>
<td>14,111</td>
<td>3.5</td>
</tr>
<tr>
<td>4</td>
<td>14,111</td>
<td>3.5</td>
</tr>
<tr>
<td>5</td>
<td>11,743</td>
<td>3.5</td>
</tr>
<tr>
<td>6</td>
<td>14,069</td>
<td>3.5</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>14,110</strong></td>
<td><strong>3.5</strong></td>
</tr>
</tbody>
</table>
G. Balance in geographic location distribution of facilities after constrained randomization

<table>
<thead>
<tr>
<th>Region Name</th>
<th>Trial Sequence</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Continental</td>
<td>1</td>
</tr>
<tr>
<td>Midwest</td>
<td>1</td>
</tr>
<tr>
<td>North Atlantic</td>
<td>2</td>
</tr>
<tr>
<td>Pacific</td>
<td>1</td>
</tr>
<tr>
<td>Southeast</td>
<td>1</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>6</strong></td>
</tr>
</tbody>
</table>
## World Health Organization data set

<table>
<thead>
<tr>
<th>Primary registry and trial identifying number</th>
<th>ClinicalTrials.gov NCT03241589</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Date of registration in primary registry</strong></td>
<td>4 August, 2017</td>
</tr>
<tr>
<td><strong>Secondary identifying numbers</strong></td>
<td>SDR 16-192, PEC 15-467</td>
</tr>
<tr>
<td><strong>Source(s) of monetary or material support</strong></td>
<td>US Department of Veterans Affairs Health Services Research and Development</td>
</tr>
<tr>
<td></td>
<td>US Department of Veterans Affairs Quality Enhancement Research Initiative</td>
</tr>
<tr>
<td><strong>Primary sponsor</strong></td>
<td>US Department of Veterans Affairs Health Services Research and Development</td>
</tr>
<tr>
<td><strong>Secondary sponsor(s)</strong></td>
<td>US Department of Veterans Affairs Office of Connected Care</td>
</tr>
<tr>
<td><strong>Contact for public queries</strong></td>
<td>DHO</td>
</tr>
<tr>
<td><strong>Contact for scientific queries</strong></td>
<td>JCP</td>
</tr>
<tr>
<td><strong>Public title</strong></td>
<td>VA Telederm Teledermatology App</td>
</tr>
<tr>
<td><strong>Scientific title</strong></td>
<td>Teledermatology Mobile Apps: Implementation and Impact on Veterans' Access to Dermatology</td>
</tr>
<tr>
<td><strong>Countries of recruitment</strong></td>
<td>USA</td>
</tr>
<tr>
<td><strong>Health condition(s) or problem(s) studied</strong></td>
<td>Dermatological conditions</td>
</tr>
<tr>
<td><strong>Intervention(s)</strong></td>
<td>Active comparator: Web-based mobile teledermatology application and clinical process</td>
</tr>
<tr>
<td></td>
<td>Placebo comparator: workstation-based teledermatology and in-person dermatology practice</td>
</tr>
<tr>
<td><strong>Key inclusion and exclusion criteria</strong></td>
<td>Individual inclusion criteria: Ages eligible for study: ≥18 years; Sexes eligible for study: both; Accepts healthy volunteers: No</td>
</tr>
<tr>
<td></td>
<td>Cluster inclusion criteria: VHA facility located within the continental United States; &gt;0.0 provider full-time equivalents practicing dermatology; &gt;0.1% and ≤8.8% of total FY2016 dermatology encounters at the facility were for teledermatology readings</td>
</tr>
<tr>
<td></td>
<td>Cluster exclusion criteria: Facilities participating in pre-trial mixed-methods formative evaluation</td>
</tr>
<tr>
<td><strong>Study type</strong></td>
<td>Intervenational</td>
</tr>
<tr>
<td><strong>Allocation</strong></td>
<td>randomized; Intervention model: stepped-wedge; masking: non-blinded</td>
</tr>
<tr>
<td><strong>Primary purpose</strong></td>
<td>increasing access to care</td>
</tr>
<tr>
<td><strong>Phase</strong></td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Date of first enrollment</strong></td>
<td>January 2019 (expected)</td>
</tr>
<tr>
<td><strong>Target sample size</strong></td>
<td>36 clusters, 16,000 individuals</td>
</tr>
<tr>
<td><strong>Recruitment status</strong></td>
<td>Not yet recruiting</td>
</tr>
<tr>
<td><strong>Primary outcomes</strong></td>
<td>Consult completion time for teledermatology consults; Appointment completion time for new dermatology consults; Travel distance for dermatology services;</td>
</tr>
<tr>
<td><strong>Key secondary outcomes</strong></td>
<td>Volume of total dermatology encounters (instances of care) Volume and relative proportion of teledermatology consults among all dermatology encounters at the health care facility level</td>
</tr>
<tr>
<td>Section/item</td>
<td>Item No</td>
</tr>
<tr>
<td>---------------------------</td>
<td>---------</td>
</tr>
<tr>
<td>Administrative information</td>
<td></td>
</tr>
<tr>
<td>Title</td>
<td>1</td>
</tr>
<tr>
<td>Trial registration</td>
<td>2a</td>
</tr>
<tr>
<td></td>
<td>2b</td>
</tr>
<tr>
<td>Protocol version</td>
<td>3</td>
</tr>
<tr>
<td>Funding</td>
<td>4</td>
</tr>
<tr>
<td>Roles and responsibilities</td>
<td>5a</td>
</tr>
<tr>
<td></td>
<td>5b</td>
</tr>
<tr>
<td></td>
<td>5c</td>
</tr>
<tr>
<td></td>
<td>5d</td>
</tr>
</tbody>
</table>
Introduction

Background and rationale 6a Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention

6b Explanation for choice of comparators

Objectives 7 Specific objectives or hypotheses

Trial design 8 Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)

Methods: Participants, interventions, and outcomes

Study setting 9 Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained

Eligibility criteria 10 Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)

Interventions 11a Interventions for each group with sufficient detail to allow replication, including how and when they will be administered

11b Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)

11c Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)

11d Relevant concomitant care and interventions that are permitted or prohibited during the trial

Outcomes 12 Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended

Participant timeline 13 Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)
<table>
<thead>
<tr>
<th>Sample size</th>
<th>14</th>
<th>Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recruitment</td>
<td>15</td>
<td>Strategies for achieving adequate participant enrolment to reach target sample size</td>
</tr>
</tbody>
</table>

**Methods: Assignment of interventions (for controlled trials)**

**Allocation:**

<table>
<thead>
<tr>
<th>Sequence generation</th>
<th>16a</th>
<th>Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allocation concealment mechanism</td>
<td>16b</td>
<td>Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned</td>
</tr>
</tbody>
</table>

**Implementation**

| Implementation | 16c | Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions |

**Blinding (masking)**

<table>
<thead>
<tr>
<th>Blinding (masking)</th>
<th>17a</th>
<th>Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>17b</td>
<td>If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant’s allocated intervention during the trial</td>
</tr>
</tbody>
</table>

**Methods: Data collection, management, and analysis**

<table>
<thead>
<tr>
<th>Data collection methods</th>
<th>18a</th>
<th>Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>18b</td>
<td>Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols</td>
</tr>
</tbody>
</table>

N/A: Information not applicable or not applicable.
<table>
<thead>
<tr>
<th>Section</th>
<th>Page No.</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data management</td>
<td>19</td>
<td>Plans for data entry, coding, security, and storage, including any related processes to promote data quality. Reference to where details of data management procedures can be found, if not in the protocol.</td>
</tr>
<tr>
<td>Statistical methods</td>
<td>20a</td>
<td>Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol.</td>
</tr>
<tr>
<td></td>
<td>20b</td>
<td>Methods for any additional analyses (e.g., subgroup and adjusted analyses).</td>
</tr>
<tr>
<td></td>
<td>20c</td>
<td>Definition of analysis population relating to protocol non-adherence (e.g., as randomised analysis), and any statistical methods to handle missing data (e.g., multiple imputation).</td>
</tr>
</tbody>
</table>

**Methods: Monitoring**

| Data monitoring               | 21a      | Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed. |
|                               | 21b      | Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial. |
| Harms                         | 22       | Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct. |
| Auditing                      | 23       | Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor. |

**Ethics and dissemination**

<p>| Research ethics approval      | 24       | Plans for seeking research ethics committee/institutional review board (REC/IRB) approval. |
| Protocol amendments          | 25       | Plans for communicating important protocol modifications (e.g., changes to eligibility criteria, outcomes, analyses) to relevant parties (e.g., investigators, REC/IRBs, trial participants, trial registries, journals, regulators). |</p>
<table>
<thead>
<tr>
<th>Consent or assent</th>
<th>26a</th>
<th>Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>26b</td>
<td>Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable</td>
</tr>
<tr>
<td>Confidentiality</td>
<td>27</td>
<td>How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial</td>
</tr>
<tr>
<td>Declaration of interests</td>
<td>28</td>
<td>Financial and other competing interests for principal investigators for the overall trial and each study site</td>
</tr>
<tr>
<td>Access to data</td>
<td>29</td>
<td>Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators</td>
</tr>
<tr>
<td>Ancillary and post-trial care</td>
<td>30</td>
<td>Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation</td>
</tr>
<tr>
<td>Dissemination policy</td>
<td>31a</td>
<td>Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (e.g., via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions</td>
</tr>
<tr>
<td></td>
<td>31b</td>
<td>Authorship eligibility guidelines and any intended use of professional writers</td>
</tr>
<tr>
<td></td>
<td>31c</td>
<td>Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code</td>
</tr>
</tbody>
</table>

**Appendices**

**Informed consent materials**

| 32  | Model consent form and other related documentation given to participants and authorised surrogates |

**Biological specimens**

| 33  | Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable |

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.*