

**Title of Project:**

Patient-Centered Online Care Model for Follow-Up Management of Atopic Dermatitis

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## 1. Structured Abstract

**Purpose:** To compare effectiveness of a direct-access, online model for follow-up dermatologic care in pediatric and adult patients with atopic dermatitis with that of in-person office visits.

**Scope:** New models of healthcare delivery for dermatological care have the potential to increase access and improve patient-centered outcomes.

**Methods:** We performed a one-year, randomized controlled equivalency clinical trial in medically underserved areas, outpatient clinics, and the general community. The participants included children and adults with atopic dermatitis with access to the internet, computer, and digital camera. After an initial in-person visit, patients were randomized 1:1 to direct-access online or usual in-person care for follow-up management of atopic dermatitis. In the direct-access online group, patients capture and transmit clinical images and history asynchronously to dermatologists online; dermatologists evaluate the clinical information, provide recommendations and education, and prescribe medications online asynchronously. In the in-person group, patients visit dermatologists in their offices for follow-up care.

**Results:** A total of 156 children and adults were randomized to either direct-access online or in-person care for follow-up management of atopic dermatitis. Between baseline and 12 months, the within-group difference in POEM score in patients in the direct-access online group was -5.1 (SD±5.48, 95% CI -6.32 to -3.88); in the in-person group, the within-group difference was -4.86 (SD±4.87, 95% CI -6.27, -3.46). The difference in the change in POEM scores between the two groups was 0.24 (SD±6.59) with 90% CI of -1.70 to 1.23, which was contained within the pre-determined 2.5 equivalence margin. The percentage of patients achieving clear or almost clear (IGA score of 0 or 1) was 38.4% (95% CI 27.7%-49.3%) in the direct-access online group and 43.6% (95% CI 32.6%-54.6%) in the in-person group. The difference in the percent of patients achieving clear or almost clear between the two groups was 5.1% with 90% CI of 1.7%-8.6%, which was contained within the pre-determined 10% equivalence margin. The direct-access online model results in *equivalent* improvements in atopic dermatitis clinical outcomes as in-person care. Direct-access online care may represent an innovative model of delivering dermatological services to patients with chronic skin diseases.

**Key Words:** Healthcare delivery, telemedicine, teledermatology, patient-centered online care, management of chronic skin diseases, atopic dermatitis.

## 2. Purpose

The objective of this study is to compare effectiveness of a direct-access, online model with that of in-person model for follow-up management of pediatric and adult patients with atopic dermatitis. In this one-year, randomized controlled equivalency trial, we test the hypothesis that patients with atopic dermatitis managed through the direct-access online model have equivalent improvement in their disease severity as those managed in-person, as measured by the Patient-Oriented Eczema Measure (POEM) and Investigator Global Assessment (IGA).

## 3. Scope

In the U.S., there is an inadequate supply of dermatologists to meet the demand for dermatologic services.<sup>1-4</sup> Lack of access to dermatologists is especially pronounced in rural and underserved communities.<sup>5-7</sup> As a result, patients with chronic skin diseases, such as atopic dermatitis, who lack access to regular dermatologic care experience poor clinical outcomes and significant impairment in quality of life.<sup>8</sup>

Studies suggest that tele dermatology presents an opportunity to improve access to dermatological specialist care.<sup>9,10</sup> Store-and-forward (S&F) tele dermatology is defined as the practice of dermatology through digital capturing and transmission of clinical images and patient history followed by asynchronous evaluation of the clinical information by a dermatologist. The diagnostic accuracy and reliability of store-and-forward tele dermatology have been studied and found to be relatively comparable to those of face-to-face care.<sup>11,12</sup> However, few studies have examined clinical outcomes associated with store-and-forward tele dermatology.<sup>13-16</sup>

While S&F telemedicine is increasingly utilized to provide underserved communities with access to dermatologic consultations, several limitations exist with traditional consultative tele dermatology. In the consultative S&F model, in order to engage in tele dermatology, patients need to identify primary care providers (PCPs) with telemedicine capabilities in their community and travel to their office in order to be connected to a tele dermatologist. All recommendations from the dermatologists are relayed to the patients through PCPs. That is, dermatologists serve as *consultants* in this practice model and have no direct patient contact. Thus, the traditional consultative model makes it difficult for patients to ask follow-up questions or dialogue with their dermatologists. Studies have shown that patients are most concerned with the lack of direct contact with dermatologists in the traditional S&F consultative model.<sup>19</sup>

Not all PCPs are enthusiastic about consultative S&F tele dermatology due to the increased workload related to implementing dermatologists' recommendations without explicit accounting for these efforts. Furthermore, when patients have follow-up questions, not all PCPs receive timely and robust support from specialists in order to adequately address patient questions.

New models of specialty-care delivery are necessary to provide distance-independent and time-independent care to patients. One innovative healthcare-delivery model in dermatology involves direct-access online care, where patients can communicate directly with dermatologists and receive timely recommendations to manage their skin diseases.<sup>20-22</sup> This model may be especially suitable for managing chronic skin diseases such as atopic dermatitis, where regular follow-up care is necessary to control disease flares and maintain disease control.

## **4. Methods**

### ***Study Design***

In this randomized controlled *equivalency* trial, we compared the effectiveness of a direct-access, asynchronous, online model for delivering follow-up dermatologic care in patients with atopic dermatitis with that of in-person office visits. We compared clinical outcomes between the two groups, where the participants are followed for one year. The study was approved by the University of California Davis Institutional Review Board (243201).

We recruited five dermatologists from the UC Davis Department of Dermatology to participate in this study: four dermatologists providing clinical care to the study (either face-to-face or online depending on the subject randomization), and one dermatologist blinded to the randomization who performed Investigator Global Assessment (IGA) based on the digital photographs. The four dermatologists providing care to patients in person were also trained on how to provide care to patients online via the RelayHealth online telemedicine site. Relay Health is a website that provides asynchronous clinical connectivity between patients and physicians.

Due to the nature of the intervention, the study staff, dermatologists and participants could not be blinded to the group assignment during the course of the study. However, the rater responsible for performing the IGA assessment based on digital images was blinded to the randomization of the participants.

### ***Patient Selection***

We recruited pediatric and adult patients with atopic dermatitis from medically underserved clinics, general outpatient clinics, and the general community in the greater Sacramento area. Specifically, we recruited patients from federally qualified health centers (FQHCs), free clinics serving indigent patient populations, primary care network clinics affiliated with University of California Davis (UC Davis), dermatology clinic at UC Davis, and the general community.

Regardless of race and gender, all children and adults were considered for the study if they met the following inclusion criteria: (1) Met Hanifin criteria for diagnosis of atopic dermatitis,<sup>23</sup> (2) age 4 years and older, (3) had internet connection, computer, and digital camera (4) Were able to have their skin imaged by themselves or by family members. The exclusion criteria included (1) patients who do not speak English or Spanish, (2) patients requiring systemic treatments (e.g., cyclosporine, phototherapy), and (3) patients requiring regular laboratory monitoring.

### ***Study Interventions***

#### Initial visit for all participants:

All participants had an initial in-office visit, where they provided informed consent and were examined by dermatologists to confirm the diagnosis of atopic dermatitis and eligibility criteria. The study staff took baseline clinical photographs of the subject's skin lesions. All participants also underwent baseline assessments of disease severity and quality of life using validated instruments. They were then randomized in 1:1 into one of the two arms of the study—direct-access online group and in-person group.

Participants in *both* the online and the in-office comparison groups underwent a standardized training session consisting of instruction on specific image capturing techniques to ensure that high-quality images would be taken with the correct lighting and focus. During this training session, the participants and their family members were taught how to take standardized global and representative, close-up lesional photos. The global images were used to assess the *body surface area* of involvement of atopic dermatitis, whereas the close-up lesional images were used for morphologic examination (e.g., erythema, induration, lichenification, impetiginization). For most participants, the “global” images were taken by the family members. However, for the participants wishing to take their own global images, they were taught how to take full-body images with the auto-timer function on digital cameras. In addition, the participants in the direct-access online group were trained on how to access the direct-access online website for their dermatologic care. These patients had to demonstrate competence navigating the telemedicine site prior to conclusion of their first visit. All instructions on navigating the telemedicine site and how to capture skin images were provided both electronically and in hardcopies to patients.

#### In-Person Group (Control Arm):

The participants randomized to the office visits had six in-person visits with a dermatologist at two-months intervals. Within 24 hours of each in-office visit with their dermatologists, these participants were asked to take their skin images at home and submit the images to the study team via the same website. This was to ensure that the blinded rater was not able to distinguish the randomization assignment based on the photography technique or the image quality. A study staff reviewed these clinical images to ensure adequate image quality for outcome assessment. If images were not adequate, the subject would be asked to re-take and re-submit the images within 24 hours.

During the in-person visits, the participants received usual care from the study dermatologists, including evaluation of atopic dermatitis and discussion of treatment plan. At each of these in-person follow-up visits, the participants also completed the standardized assessments for disease severity and quality of life.

### Direct-Access Online Group (Intervention Arm):

The participants randomized to the direct-access online group had six online visits with a dermatologist at two-months intervals. During the online visits, the participant went to the secure online healthcare-delivery platform to submit all the necessary information for online visits and communicate with dermatologists asynchronously. For example, they completed a standardized questionnaire, where they reported their progress as well as any adverse events. Throughout the study, all participants had access to instructions on how to take pictures of their skin lesions, upload and transmit images and history, and other steps necessary to complete an online visit and view dermatologist recommendations.

After the patients completed the online visits, a research staff reviewed the submitted visit information for completeness and ensured that the images were of high quality prior to forwarding them to the dermatologist. The dermatologists caring for the online participants evaluated the transmitted clinical information and digital photographs, made treatment recommendations or modifications, and prescribed medications electronically. The dermatologist had three business days to complete the online visit. If the patient has follow-up questions, he or she could communicate with dermatologists online asynchronously through the same telehealth platform (Figure 1).

### **Outcome Instruments**

Baseline Patient-Oriented Eczema Measurement (POEM) and Investigator's Global Assessment (IGA) scores were recorded at the initial office visit as well as all follow-up visits. At each of the six subsequent online or in-person visits, all participants responded to the POEM questionnaire, a sensitive and validated patient-oriented disease severity measurement.<sup>27</sup> POEM comprises seven questions that assess the symptom morbidity of patients with atopic dermatitis during the week leading up to the questionnaire. The response to each question indicates the number of days the subject experienced a particular sign or symptom (No Days, 1-2 Days, 3-4 Days, 5-6 Days, Every Day) with a maximum score of 28 points.<sup>27</sup> Higher scores denote greater symptom morbidity.

All participants also received baseline digital photographs taken at the initial visit. For each of the subsequent study visits, participants in both comparison groups took digital photographs of their skin lesions. A dermatologist blinded to the randomization rated each subject's atopic dermatitis severity using the Investigator Global Assessment (IGA) scale based on the photographs. The IGA scale is a validated disease outcome measurement for atopic dermatitis that is widely used in clinical trials.<sup>28-31</sup> The IGA comprises a 6-point ordinal scale that ranges from 0 to 5 (clear, almost clear, mild disease, moderate disease, severe disease, very severe disease).

### **Statistical Analysis**

The power analysis and sample size calculation for this study were calculated based on the primary outcome measure--patient-oriented eczema measure (POEM). This is an *equivalency trial* comparing the effectiveness of two models of delivering follow-up dermatological care for atopic dermatitis. We aimed to establish  $\delta_L < \delta < \delta_U$ , where  $\delta_L$  and  $\delta_U$  are *a priori* specified values used to define equivalence. The null hypothesis  $H_0: |\delta| \geq \delta_U$  is tested against the two-sided alternative hypothesis  $H_a: |\delta| < \delta_U$ , at significance level  $\alpha = 0.05$ . With 156 participants that accounted for dropout rates up to 15%, this study has 80% power to test  $\delta_U = 2.5$  as the *a priori* determined equivalence limit for POEM score.

The analysis was based on the intention-to-treat population, which includes all randomized patients. In this longitudinal study, we measured POEM and IGA at baseline and the subsequent 6 follow-up visits. We examined the differences in the change in POEM scores from

baseline to 12-months between the direct-access online group and the in-person group and compared them against the equivalence margin. We also compared differences in the proportion of patients achieving clear or almost clear on IGA at 12 months between the two comparison arms. We tested these proportions against pre-determined equivalence margin of 10%. Sensitivity analyses were performed using repeated measures ANOVA approach for POEM and generalized estimating equations (GEE) approach for IGA scores between the two comparison groups.<sup>32</sup> All statistical analyses were performed using STATA 13.

## 5. Results

A total of 156 children and adults with atopic dermatitis were randomized to receive follow-up care via either direct-access online model or in-person visits over a 12-month period. Demographic information of the study population is depicted in Table 1. Patients submitted on average 8.7 photos and 8.2 photos per visit in the direct-access group and in-person group respectively. The staff requested re-imaging in 6.3% and 6.6% of the online and in-person visits respectively. No significant differences existed in the number of submitted photos or requests for re-imaging between the two arms.

Patients in both the direct-access online and in-person groups showed significant improvement in atopic dermatitis disease severity as measured with POEM over the 12-month study period (Figure 2A). Specifically, in the direct-access online group, patients' POEM score improved from baseline of 13.04 (SD  $\pm$ 5.32) to 7.94 (SD  $\pm$ 4.55) at 12 months. This represented a within-group difference of -5.1 (SD $\pm$ 5.48, 95% CI -6.32 to -3.88) for the direct-access online arm. In the in-person group, the patients' POEM score improved from baseline of 12.71 (SD  $\pm$ 5.58) to 7.85 (SD  $\pm$ 4.44) at 12 months. This represented a within-group difference of -4.86 (SD $\pm$ 4.87, 95% CI -6.27, -3.46) for the in-person arm.

To compare the differences in the change of POEM scores between the direct-access online group and the in-person group, we applied the pre-determined equivalence margin of  $\delta=2.5$  and 90% confidence intervals typically used for equivalency trials. The difference in the change in POEM scores between the two groups was 0.24 (SD $\pm$ 6.59) with 90% CI of -1.70 to 1.23. Because the confidence interval of -1.70 to 1.23 is contained entirely within the equivalence margin from -2.5 to 2.5, the direct-access online model is equivalent to in-person model for follow-up care of atopic dermatitis (Figure 2B).

Patients in both the direct-access online and in-person groups showed significant improvement in atopic dermatitis disease activity as measured with IGA over the 12-month study period (Figure 3A). In particular, in the direct-access online group, patients' IGA score improved from a baseline median of 3 (interquartile range 2, 3) to a median IGA score of 2 (interquartile range 1, 2) at 12 months. The percentage of patients achieving clear or almost clear (IGA score of 0 or 1) was 38.4% (95% CI 27.7%-49.3%) in the direct-access online group. In the in-person group, patients' IGA score also improved from a baseline median of 3 (interquartile range 2, 3) to a median IGA score of 2 (interquartile range 1, 2) at 12 months. The percentage of patients achieving clear or almost clear (IGA score of 0 or 1) was 43.6% (95% CI 32.6%-54.6%) in the in-person group (Figure 4).

To compare differences in the percentage of patients achieving an IGA score of clear or almost clear between the direct-access online group and the in-person group, we applied the pre-determined equivalence margin of 10%. That is, if the differences in the percentage of patients achieving IGA clear or almost clear at 12 months is 10% or less, we deem the two interventions to be equivalent. The difference in the percent of patients achieving clear or almost clear between the two groups is 5.1% with 90% CI of 1.7%-8.6%. Because the confidence interval of

1.7%-8.6% is contained entirely within the equivalence margin from -10% to 10%, the direct-access online model is equivalent to in-person model for follow-up care of atopic dermatitis (Figure 3B). Sensitivity analyses were performed using repeated measures ANOVA approach for POEM and generalized estimating equations (GEE) approach for IGA scores.

We evaluated a patient-centered, direct-access online model for delivering following-up care for patients with atopic dermatitis. In this randomized controlled equivalency trial, we found that patients managed through the direct-access online model achieved *equivalent* improvements in atopic dermatitis disease severity compared to those managed through the usual, in-person visits. The study finding of equivalence in managing atopic dermatitis is primarily limited to a population with relatively moderate disease based on POEM and IGA assessments.

Skin diseases account for 30% of all physician office visits.<sup>33,34</sup> Chronic skin diseases are associated with markedly decreased quality of life and financial consequences.<sup>35</sup> Many patients with chronic skin diseases such as atopic dermatitis or psoriasis desire expedient and convenient access to dermatologists for long-term management of their skin diseases.

While evidence supports diagnostic accuracy and reliability of asynchronous teledermatology,<sup>11,12</sup> teledermatology has not been as widely adopted as previously expected.<sup>9,10</sup> Real-world challenges of implementing and disseminating traditional consultative asynchronous teledermatology include a lack of direct communication between patients and dermatologists and inconsistent support from primary care providers for the existing consultative teledermatology models. To be responsive to patient needs and to address challenges associated with consultative asynchronous teledermatology, it is valuable to evaluate novel technology-enabled specialty-care delivery models. Few studies to date have examined the effect of direct-access online models on clinical outcomes in dermatology.<sup>20-22</sup>

The strengths of this study include its equivalency testing, randomized controlled design, and consistent follow-up with low dropout rate throughout the study. The equivalency study designs enable investigators to test for and declare whether equivalence truly exists when comparing various interventions. Furthermore, a significant proportion of the patients were recruited from underserved communities, which enabled us to evaluate the direct-access online model among populations with relatively greater healthcare needs and fewer technological resources.

The direct-access online model affords direct, versatile, and expedient clinical interactions for both patients and dermatologists. In this online model for follow-up care, patients no longer need to travel to a primary care facility with telemedicine capabilities in order to engage dermatologists. Instead, they are able to upload clinical images and history online and obtain asynchronous evaluation and recommendations from dermatologists directly. However, it is also important to understand potential limitations with direct-access online models. Appropriate patient selection, disease selection, and availability of in-person safe guards are important considerations.

This patient-centered direct-access online specialty-care delivery model can be applied to other chronic conditions where regular access to specialists is critical to patient outcomes, such as in psoriasis and wound management. For example, psoriasis patients require long-term, regular care to maintain disease control, and this model has the potential to improve access and outcomes for this patient population.<sup>20</sup> Patients with chronic wounds such as diabetic foot ulcers and venous leg ulcers cannot travel easily. This online model can encourage wound patients to increase engagement in their wound management with online specialist support.

The findings need to be interpreted in the context of the study design. This study population comprises children and adults with mean age in the late twenties. While this generally reflects the demographic of the atopic dermatitis population, computer fluency of this study population

may differ from that of patients with other chronic skin diseases. Furthermore, studies beyond one-year duration are necessary to determine the persistence of the effects of these healthcare delivery models.

Health services delivery in dermatology is an exciting and evolving field. With the changing healthcare environment and a growing demand for dermatologic services, technology-enabled healthcare delivery models have the potential to increase access and improve outcomes. Critical examination of existing telemedicine models and determination of barriers to dissemination serve as the foundation for designing novel healthcare delivery models. The direct-access online model provides a patient-centered approach to addressing dermatological care, and it may afford dermatologists flexible work models. As with any novel health services delivery models, comparative effectiveness studies investigating health outcomes are critical to evaluate these new models in an evidence-based approach.

## 6. List of Publications and Products

Below is a list of publications that were generated during the Principal Investigator's K08 award period:

- 2014 Armstrong AW, Johnson MA, Lin S, Maverakis E, Fazel N, Liu FT. Patient-Centered, Direct-Access Online Care for Management of Atopic Dermatitis: A Randomized Clinical Trial. *JAMA Dermatol*. 2014 Oct 22. doi: 10.1001/jamadermatol.2014.2299. PubMed PMID: 25338198.
- 2014 Brezinski EA, Harskamp CT, Ledo L, Armstrong AW. Public Perception of Dermatologists and Comparison with Other Medical Specialties: Results From a National Survey. *J Am Acad Dermatol*. 2014 Aug 27. PubMed PMID: 25175709.
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- 2014 Brezinski EA, Armstrong AW. Strategies to Maximize Treatment Success in Moderate to Severe Psoriasis: Establishing Treatment Goals and Tailoring of Biologic Therapies. *Semin Cutan Med Surg*. 2014 June. PubMed PMID: 25085668.
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- 2014 Gottlieb AB, Armstrong AW, Christensen R, Garg A, Duffin KC, Boehncke WH, Merola JF, Gladman DD, Mease PJ, Swerlick RA, Rosen CF, Abernethy A. The International Dermatology Outcome Measures Initiative as Applied to Psoriatic Disease Outcomes: A Report from the GRAPPA 2013 Meeting. *J Rheumatol*. 2014 June. PubMed PMID: 24882858
- 2014 Hsu L, Armstrong AW. JAK Inhibitors: Treatment Efficacy and Safety Profile in Patients with Psoriasis. *J Immunol Res*. 2014 May 5. [Epub ahead of print] PubMed PMID: 24883332.
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- 2014 Foolad N, Armstrong AW. Prebiotics and probiotics: the prevention and reduction in severity of atopic dermatitis in children. *Beneficial Microbes*. 2014 Jan 24:1-10. PubMed PMID: 24463205.
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- 2013 Harskamp CT, Armstrong AW. Immunology of atopic dermatitis: novel insights into mechanisms and immunomodulatory therapies. *Seminars in Cutaneous Medicine and Surgery*. 2013 Sep;32(3):132-9.
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