Improving Atopic Dermatitis Patient Outcomes Through the Electronic Medical Record

Grant ID: 36661607

Lindsay C. Strowd, MD
Rita O. Pichardo-Geisinger, MD

Abstract

Our study aims to fill the gaps in standardized clinical assessment of atopic dermatitis (AD), adherence, and the quality of care AD patients receive. Our study proposes implementation of an atopic dermatitis assessment tool within the electronic medical record system (EMR) that can be utilized by dermatologists and non-dermatology health care providers to quickly document the severity of the patient's AD and its impact. The template would guide the provider to create an individualized eczema treatment plan, providing a patient and/or their caregiver with written information structured to maximize adherence. The EMR patient portal would also be utilized as a way to communicate with patients shortly after their clinic visit to assess the effectiveness of their AD treatment regimen, providing the accountability that encourages patients to fill their prescriptions and start on treatment and an advance over interventions that provide only education[1]. Our information technology team has the skills to implement these approaches via our EMR. A randomized controlled trial is proposed to generate evidence to support the value of the intervention. Intervention and control groups would be compared to assess adherence to AD treatment guidelines and for objective clinical disease improvement. Physicians and subjects in the intervention group would be surveyed to receive feedback on the EMR assessment tool. Demonstration of the feasibility of this approach will provide us a foundation for further studies to optimize this intervention and the care of patients of AD.

Table of Contents:

Reviewer Comments:

While all review panel members were interested by your program and look forward to reading your full proposal, there is a request for more information on the EMR implementation and overall project detail.

The proposal principal investigator met personally with the Epic outpatient template developer to determine the feasibility of the proposed updates to the EMR system. The concept is feasible and will be completed with support from our Information Technology (IT) department. IT creates applications specific to department needs on a regular basis and is willing and able to add the required questionnaires for Dermatology. The additional information on the EMR implementation is included within the overall proposal.

Overall Goal and Objectives:

Goal 1: Standardize the assessment of atopic dermatitis (AD) patients

Objective 1: Develop a "clinician-friendly" eczema patient assessment tool using a combination of EASI and quality of life measures that can be utilized in real time during patient visits to assess disease severity and impact on quality of life

Objective 2: Incorporate the patient assessment tool into the electronic health record (EMR) via template construction

Objective 3: Receive feedback from participating physicians regarding ease of use of the assessment tool and further refine the tool based on their feedback

Goal 2: Assess if utilizing this assessment tool and EMR patient portal will improve clinical outcomes in atopic dermatitis patients

Objective 1: Create an EMR-compatible Eczema Action Plan (EAP) which can be inserted into the clinical documentation and available to print out for the patient as well as available through the patient EMR portal

Objective 2: Participants in the intervention group will report clinical response to treatment 1 week following clinic appointment by completing the Dermatology Life Quality Index on their EMR patient portal site

Objective 3: Assess differences in clinical improvement between intervention and control groups

Assessment of Need:

Atopic dermatitis (AD) is the most common pediatric inflammatory disease in the United States, with an estimated annual cost of greater than one billion dollars.[2] The prevalence of atopic dermatitis in developed countries such as the United States is increasing and the Global Burden of Diseases Study demonstrated skin disease was the fourth leading cause of nonfatal disease burden.[3] Once classically thought to be a pediatric disease, there is an increasing number of adult patients suffering from atopic dermatitis.[4] AD is a chronic relapsing and remitting skin disease characterized by classic skin changes along with significant pruritus and sleep disturbance. AD is commonly associated with high levels of stigmatization, social withdrawal, anxiety, and depression among patients and may affect their careers.[5] Current management methods of AD often involve a combination of non-pharmacologic modalities to maximize overall skin barrier integrity and prescription medications to address chronic, active disease and flares. Though they can be effective when employed, there are significant barriers to treatment for patients. Poor adherence to treatment is a widespread problem and may explain poor AD

treatment outcomes.[6] Studies demonstrate patients do not even fill 1/3 of atopic dermatitis prescriptions, and even when patients do get their medications they use them poorly.[7-9]

An agreed-upon definition of AD is of particular value in clinical trials in order to properly define study populations; however, it is also beneficial for clinical practice, especially for the non-dermatologist. There has been great effort to develop diagnostic criteria over the last several decades. At least 28 disease severity scales have been developed to measure disease severity in AD. These scales vary widely in the clinical signs assessed, extent of subjective symptom inclusion, and defining clinically significant improvement. At least 22 quality of life instruments have been used to measure outcomes in AD, which are similarly highly variable.[10, 11] Outcome assessment measurements are needed to guide individual treatment in routine clinical practice. The existing severity and quality of life scales were not designed for this purpose, and are too cumbersome to be used in an office visit setting. Efforts at addressing this show promise but need further validation. Ultimately, current evidence does not support the routine clinical use of the available disease severity and quality of life scales. Furthermore, patients often do not receive adequate education regarding their disease and the best methods for managing atopic dermatitis in both short-term and long-term scenarios.[12]

Target Audience:

Participants included in this study would be children and adults with a new or established diagnosis of atopic dermatitis who are seeking care at Wake Forest University dermatology clinic. Patients can be included regardless of current treatment regimen. Patients agreeing to participate who are randomized to the control group will receive their regular AD treatment and visits as determined by their treating physician. Participants in the intervention group will receive an Eczema Action Plan in print form and in electronic form on their patient portal, their treating physician will assess their disease severity using the developed clinical assessment tool, and the participants will also be asked to report their progress 1 week after each clinic visit by completing the Dermatology Life Quality Index and a patient global assessment of disease severity (ptPGA) via the EMR patient portal. All participants regardless of their group assignment will continue to receive medications and clinic visits according to the standard of care as determined by their physician.

This study has the potential to eliminate several gaps in the care of AD sufferers of all ages and ethnicities with a wide range of disease severity. These gaps include treatment alignment with guidelines, standardized monitoring of disease severity, patient education, and timing of follow up with patients. Given the high prevalence of AD in the United States, this assessment and treatment tool could impact thousands of patients. If this tool is successful, it has potential to be utilized by both dermatologists and non-dermatology providers who treat atopic dermatitis, such as family medicine practitioners, pediatricians, and advanced practice providers. For providers looking to participate in the Centers for Medicare and Medicaid (CMS) Merit-based Incentive Payment System (MIPS) use of this assessment tool would qualify both as an Improvement Activity and as part of the Advancing Care Information (ACI) which helps providers earn bonus payments from CMS and increase their overall practice quality metric.

Project and Evaluation Design and Methods

Forty patients will be recruited to participate in the study during their visits to the Wake Forest University Department of Dermatology outpatient clinic. Patients will be randomized by provider, with 2 providers in the intervention group and 2 in the control group. Inclusion criteria include patients with a new or existing diagnosis of atopic dermatitis. Exclusion criteria include patients who do not have a diagnosis of atopic dermatitis. Patients will be included regardless of age, gender, ethnicity, or AD disease severity. The structure of this study is intended to provide pilot data for the feasibility of this EMR instrument and to be used for future larger multicenter studies of this intervention.

In the intervention group, every time a participant returns to clinic, the provider will utilize the assessment tool in the EMR encounter that day and fill out the EAP, adjusting treatment medications as deemed necessary. After each clinic appointment, the provider will ask the patient (or patient's guardian if patient is a minor) to provide a one week clinical update using the EPIC EMR patient portal and filling out the DLQI tool and ptPGA. Patients in both study arms will be followed prospectively for 6 months, and all AD clinic appointments made during that year will be included in the study results (Figure 1). Other recorded data will include number of visits made during the twelve month study period and number of changes to the treatment plan.

This tool has the potential, if deemed successful, to be disseminated to other institutions who utilize Epic EMR. Based on recent estimates, Epic accounts for 47% of all EHR systems and its share of the EMR market is growing.[8] Successful novel Epic templates are poised to make a large impact on our health care systems given the number of providers utilizing this EMR.

Project Design and Methods and Evaluations Relevant to Goal 1:

Objective 1: Develop a "clinician-friendly" eczema patient assessment tool using a combination of EASI (Figure 2a) and quality of life measures that can be utilized in real time during patient visits to assess disease severity and impact on quality of life.

The clinical assessment tool will utilize the Eczema Area and Severity Index grading system during the physical exam to assess the degree of atopic dermatitis present, and will also utilize the Dermatology Life Quality Index (Figure 2b) to gain the patient's perspective of their disease impact. The EASI will be constructed within an atopic dermatitis clinic visit template, where the physician will have to enter a score for each part of the EASI from drop down boxes, and the computer will calculate the score from the entered data. The DLQI will be administered by the clinic nurse who is rooming the patient in a paper format, completed by the patient while waiting for the physician and then the score will be entered into the templated clinic visit. The template will provide "best practices" information for clinicians to consider when developing the treatment plan for their patient (Figure 3).

Objective 2: Incorporate the patient assessment tool into the electronic health record (EMR) via template construction.

The study team will collaborate with the medical center IT department and the Clinical and Translational Science Institute (CTSI) to create a functional assessment tool which incorporates directly into the clinic visit EMR document. Wake Forest's version of Epic (WakeOne) already allows physicians to send patient surveys via the portal, and allows for patients to respond to them electronically and submit back to their physician. WakeOne is configured to insert assessment tools directly into the clinic note using Smart Phrases, Smart Templates, and drop-down menus, making the incorporation of the tool into the EMR fairly straightforward. By entering a single smart phrase such as "ADassessment" an entire clinic note can be pre-populated with the visit information listed in Objective 1, including patient education. Previous tools have been developed at Wake Forest for use in other specialties such as oncology. WakeOne is also configured to allow easy dissemination and sharing of created templates and questionnaires among providers (Figure 4).

Objective 3: Receive feedback from participating physicians regarding ease of use of the assessment tool and further refine the tool based on their feedback.

Participating physicians assigned to the intervention group will be queried regarding their overall impression of the tool, ease of use, effect of the tool on patient-physician interactions during the clinic visit, and effectiveness of the patient portal questionnaire on patient adherence and communication. Based on this information, the tool may be modified prior to future use or potential dissemination. We anticipate that the standard measure used for severity assessment, the EASI, will be considered overly burdensome by providers (particularly those who are not familiar with the EASI and DLQI); we already have a simpler disease assessment tool under development (not yet validated) that a future study could assess.

<u>Project Design and Methods and Evaluation Relevant to Goal 2:</u>

Objective 1: Create an EMR-compatible Eczema Action Plan (EAP) which can be inserted into the clinical documentation and available to print out for the patient as well as available through the patient EMR portal.

The EAP will provide guidance for physicians regarding best practices for treatment of atopic dermatitis based on the degree of severity, and will provide opportunities for physicians to outline treatments for AD flares and basic daily skin care routines (Figure 5). The best practices information will serve as a reminder to the dermatologist of the American Academy of Dermatology's published guidelines on atopic dermatitis treatment recommendations. For future use by non-dermatologists, these guidelines would provide important evidence-based information to help providers make informed decisions regarding treatment. This EAP would also be visible through the patient EMR portal and a hard copy would be provided, addressing a key gap in post-visit patient knowledge of their disease and its treatment. Incorporation of the

EAP into the patient information portion of the clinic visit is fairly easy and straightforward and would be accomplished by a simple Smart Phrase.

Objective 2: Participants in the intervention group will report clinical response to treatment 1 week following clinic appointment by completing the Dermatology Life Quality Index and ptPGA on their EMR patient portal site.

Study participants in the intervention group will be told that they will be sent a message within their patient portal 1 week after each clinic visit to update the physician on their AD disease activity and improvement using the DLQI and overall impression of their disease status. This survey can be easily sent to the patients at the time of the visit, using the Epic patient portal (Figure 4) Percentage of patients who complete this task will be monitored and recorded.

Patients in the intervention group will be assessed for their response to the EAP, including their overall impression of the EAP, ease of understanding the EAP, and whether the EAP influenced the way they treat their AD or the way they use their medications. Similarly, the patients will be assessed on their impression of the patient portal tool. This data will be used for future optimization of the EAP.

Objective 3: Assess differences in clinical improvement between intervention and control groups.

At the end of the study, the two study groups will be assessed for overall differences in AD disease severity and clinical improvement over the length of the study period. These differences will be assessed using the serial EASI scores by providers, and by differences in DLQI scores and ptPGA. Statistical differences between intervention and control subjects will be determined using paired T-test and other statistical methods as deemed appropriate by our statistician. Differences in clinicians documenting disease severity and impact on quality of life between the two groups will also be assessed.

Figures

Figure 1: Outline of Study Design

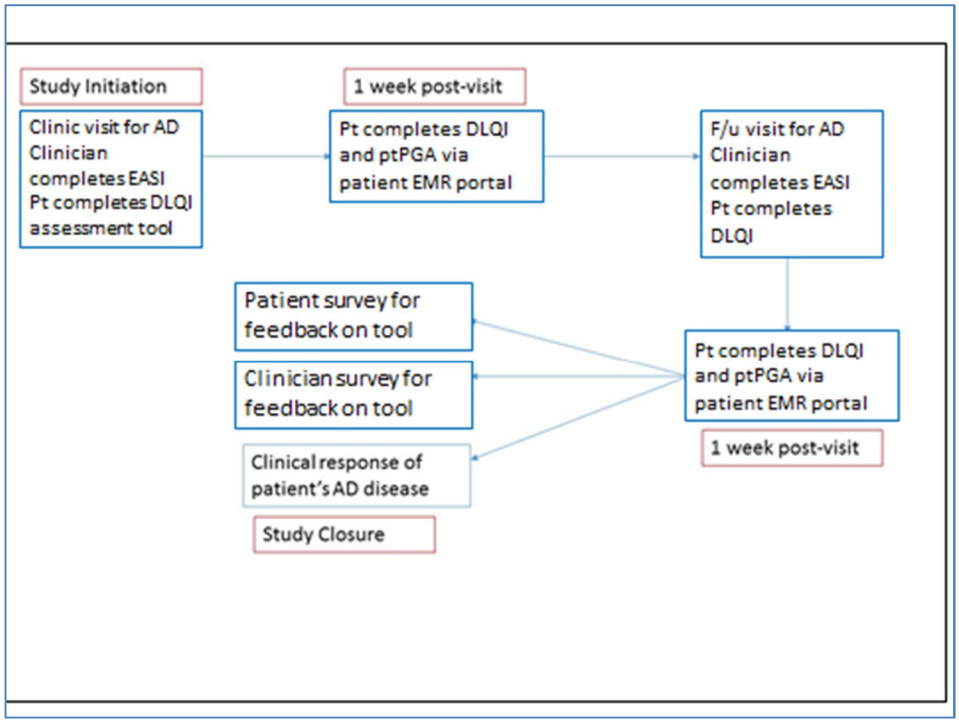
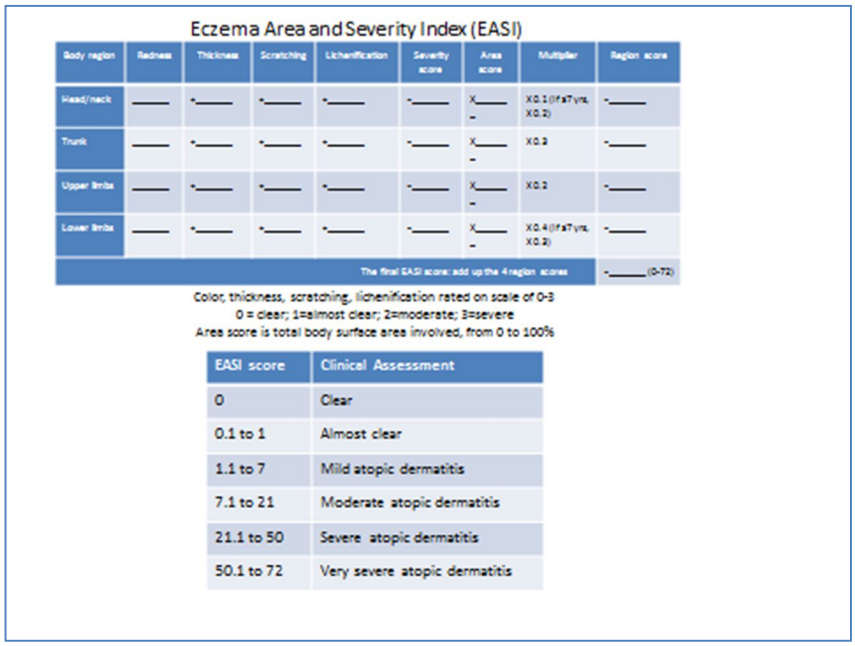


Figure 2a: Clinic Visit Patient Assessment Tool
The scoring in each category can be made into a drop-down box which allows the provider to quickly and easily document in this tool.



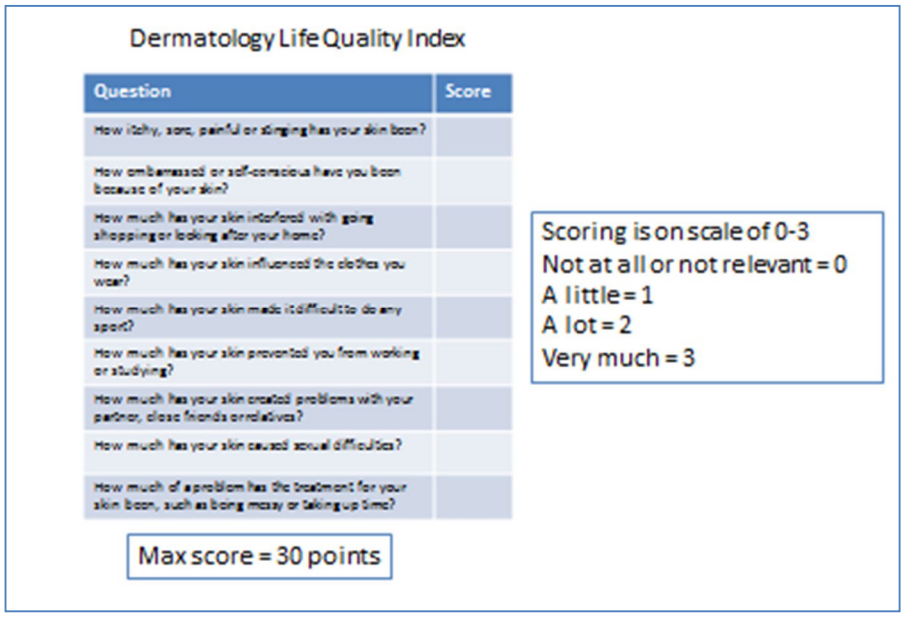
Eczema Area and Severity Index (EASI)

Body region	Redness	Thickness	Scratching	Lichenification	Severity score	Area score	Multiplier	Region score
Head/neck	_____	+_____	+_____	+_____	=_____	X_____	X0.1 (if ≥7 yrs, X0.2)	=_____
Trunk	_____	+_____	+_____	+_____	=_____	X_____	X0.3	=_____
Upper limbs	_____	+_____	+_____	+_____	=_____	X_____	X0.2	=_____
Lower limbs	_____	+_____	+_____	+_____	=_____	X_____	X0.4 (if ≥7 yrs, X0.3)	=_____
						The final EASI score: add up the 4 region scores		=_____ (0-72)

Color, thickness, scratching, lichenification rated on scale of 0-3
0 = clear; 1=almost clear; 2=moderate; 3=severe
Area score is total body surface area involved, from 0 to 100%

EASI score	Clinical Assessment
0	Clear
0.1 to 1	Almost clear
1.1 to 7	Mild atopic dermatitis
7.1 to 21	Moderate atopic dermatitis
21.1 to 50	Severe atopic dermatitis
50.1 to 72	Very severe atopic dermatitis

Figure 2b: Clinic Visit Patient Perspective Tool: Dermatology Life Quality Index
To be completed by the patient while waiting for the physician at the clinic visit. Score will be entered into the clinic note.



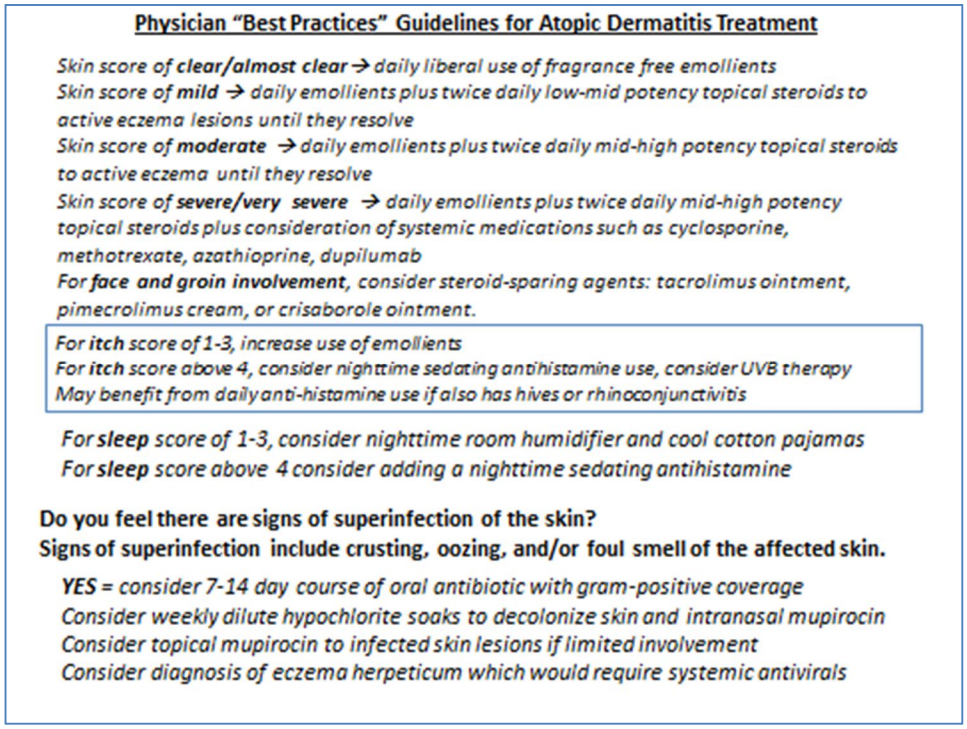
Dermatology Life Quality Index

Question	Score
How itchy, sore, painful or stinging has your skin been?	
How embarrassed or self-conscious have you been because of your skin?	
How much has your skin interfered with going shopping or looking after your home?	
How much has your skin influenced the clothes you wear?	
How much has your skin made it difficult to do any sport?	
How much has your skin prevented you from working or studying?	
How much has your skin created problems with your partner, close friends or relatives?	
How much has your skin caused sexual difficulties?	
How much of a problem has the treatment for your skin been, such as being messy or taking up time?	

Scoring is on scale of 0-3
Not at all or not relevant = 0
A little = 1
A lot = 2
Very much = 3

Max score = 30 points

Figure 3: Guidance for physicians regarding treatment strategies for AD patients based on EASI score



Physician "Best Practices" Guidelines for Atopic Dermatitis Treatment

*Skin score of **clear/almost clear** → daily liberal use of fragrance free emollients*
*Skin score of **mild** → daily emollients plus twice daily low-mid potency topical steroids to active eczema lesions until they resolve*
*Skin score of **moderate** → daily emollients plus twice daily mid-high potency topical steroids to active eczema until they resolve*
*Skin score of **severe/very severe** → daily emollients plus twice daily mid-high potency topical steroids plus consideration of systemic medications such as cyclosporine, methotrexate, azathioprine, dupilumab*
*For **face and groin involvement**, consider steroid-sparing agents: tacrolimus ointment, pimecrolimus cream, or crisaborole ointment.*

*For **itch** score of 1-3, increase use of emollients*
*For **itch** score above 4, consider nighttime sedating antihistamine use, consider UVB therapy*
May benefit from daily anti-histamine use if also has hives or rhinoconjunctivitis

*For **sleep** score of 1-3, consider nighttime room humidifier and cool cotton pajamas*
*For **sleep** score above 4 consider adding a nighttime sedating antihistamine*

Do you feel there are signs of superinfection of the skin?
Signs of superinfection include crusting, oozing, and/or foul smell of the affected skin.

***YES** = consider 7-14 day course of oral antibiotic with gram-positive coverage*
Consider weekly dilute hypochlorite soaks to decolonize skin and intranasal mupirocin
Consider topical mupirocin to infected skin lesions if limited involvement
Consider diagnosis of eczema herpeticum which would require systemic antivirals

Figure 4: Patient survey through patient portal

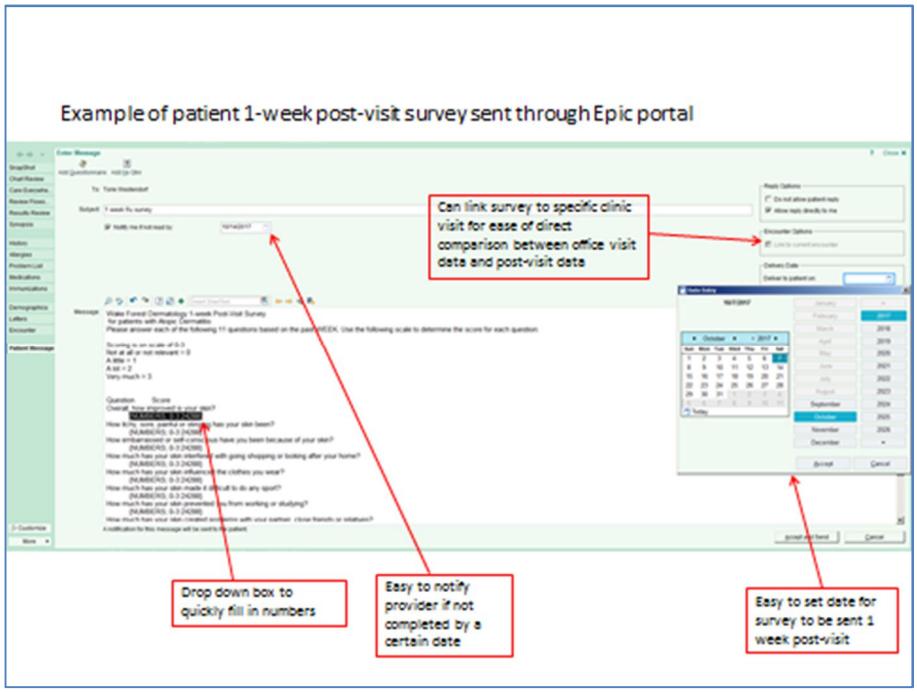
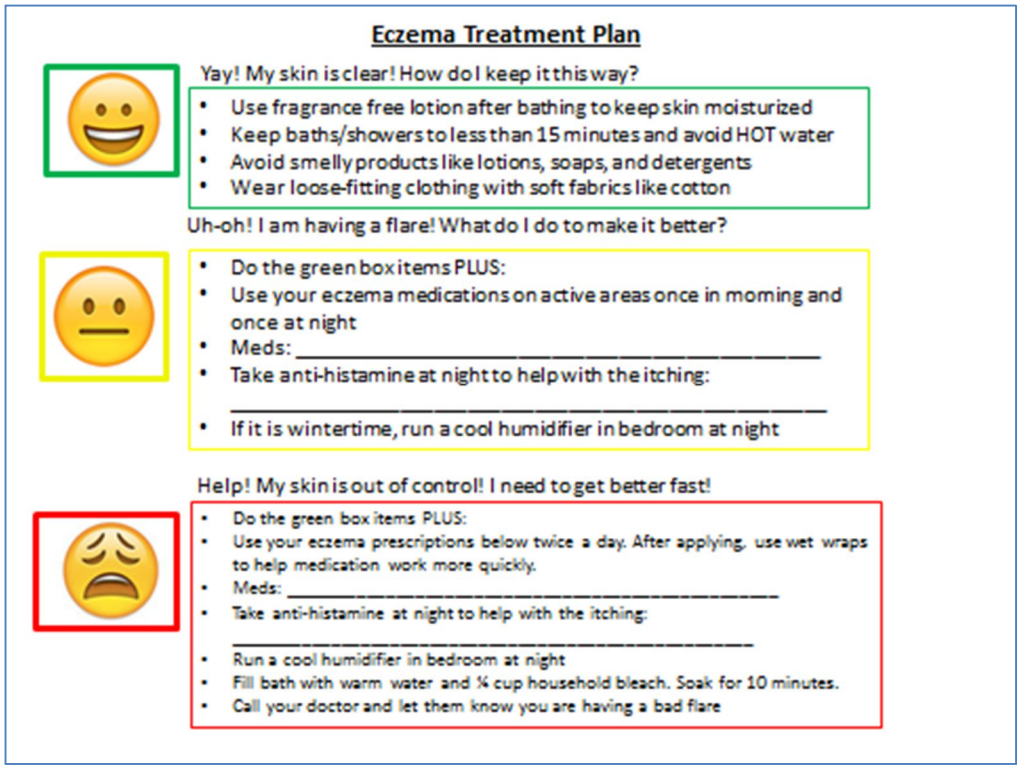


Figure 5: Example of an Eczema Action Plan (EAP)



Detailed Workplan and Deliverables Schedule

Anticipated Project Timeline:

Task	*Month 1*	*Month 2*	*Month 3*	*Month 4*	*Month 5*	*Month 6*	*Month 7*	*Month 8*	*Month 9*	*Month 10*	*Month 11*	*Month 12*	*Month 13*	*Month 14*	*Month 15*	*Month 16*	*Month 17*	*Month 18*
Institutional application and IRB approval process	■	■																
Create a "clinician-friendly" eczema patient assessment tool		■																
IT development and testing protocol related tools for EMR		■	■	■														
Provider Feedback on new EMR protocol tools				■														
IT refinement of tools in EMR					■													
Recruit and enroll 40 participants					■	■	■											
Controlled testing of the tools by providers and participants						■	■	■	■	■	■	■	■					
Data entry and data analysis												■	■	■				
Writing, publication, and dissemination of the findings															■	■	■	■

The project timeline will anticipate an 18-month timeline to complete the project. The first task upon notification of funding is the institutional application and approval process which can take as little as 4 weeks up to 6 weeks. The study team will work on creating the EMR-compatible Eczema Action Plan (EAP) which can be inserted into the clinical documentation and available to print out for the patient as well as available through the patient EMR portal. The IT department will support the development and implementation of the study-related forms; this process could take up to three months to complete, taking into consideration other projects that may be already in their queue. The EPIC outpatient template developer has agreed the forms creation and replication is totally feasible, but would be the work of IT. Upon development, it will be tested by the end-user, the provider. With feedback from the provider, the pages will be refined. Once finalized and institutional approved, the study team will spend the next 3 months recruiting the 40 subjects to participate in the 6 months of follow-up. Data entry will begin as the first enrollees are nearing completion and continue until submission of data for analyses. The study team will move directly into writing, obtaining manuscript approval from the sponsor to move forward with publication submission and dissemination of the findings.

References

1. Oussedik E, Foy CG, Masicampo EJ, Kammrath LK, Anderson RE, Feldman SR. Accountability: a missing construct in models of adherence behavior and in clinical practice. Patient Prefer Adherence. 2017 Jul 25;11:1285-1294.
2. Mancini AJ, Kaulback K, Chamlin SL. The socioeconomic impact of atopic dermatitis in the United States: a systematic review. Pediatric Dermatology 2008;25:1-6.
3. Hay RJ, Johns NE, Williams HC, Bollinger, IW, Dellavalle, RP, Margolis DJ, Marks R, Naldi L, Weinstock MA, Wulf SK, Michaud C, Murray CJ, Maghavi M. The global burden of skin disease in 2010: an analysis of the prevalence and impact of skin conditions. Journal of Investigative Dermatology Symposium Proceedings 2014;134:1527-1534.
4. Silverberg JL. Public Health Burden and Epidemiology of Atopic Dermatitis. Dermatol Clin. 2017 Jul;35(3):283-289. doi: 10.1016/j.det.2017.02.002. Epub 2017 Apr 22.
5. Salek MS, Jung S, Brincat-Ruffini LA, MacFarlane L, Lewis-Jones MS, Basra MK, Finlay AY. Clinical experience and psychometric properties of the Children's Dermatology Life Quality Index (CDLQI), 1995–2012. British Journal of Dermatology 2013;169:734-759.
6. Patel NU, D'Ambra V, Feldman SR. Increasing Adherence with Topical Agents for Atopic Dermatitis. Am J Clin Dermatol. 2017 Jun;18(3):323-332. doi: 10.1007/s40257-017-0261-5.
7. Storm A, Andersen SE, Benfeldt E, Serup J. One in 3 prescriptions are neverredeemed: primary nonadherence in an outpatient clinic. J Am Acad Dermatol. 2008 Jul;59(1):27-33.
8. Brown KL, Krejci-Manwaring J, Tusa MG, Camacho F, Fleischer AB Jr, Balkrishnan R, Feldman SR. Poor compliance with topical corticosteroids for atopic dermatitis despite severe disease. Dermatol Online J. 2008 Sep 15;14(9):13. PubMed PMID:19061595.
9. Krejci-Manwaring J, Tusa MG, Carroll C, Camacho F, Kaur M, Carr D, Fleischer AB Jr, Balkrishnan R, Feldman SR. Stealth monitoring of adherence to topical medication: adherence is very poor in children with atopic dermatitis. J Am Acad Dermatol. 2007 Feb;56(2):211-6. Epub 2006 Nov 13. PubMed PMID: 17224366.
10. Eichenfield LF, Tom WL, Chamlin SL, Feldman SR, Hanifin JM, Simpson EL et al. Guidelines of care for the management of atopic dermatitis: section 1. Diagnosis and assessment of atopic dermatitis. J Am Acad Dermatol 2014;70:338-51
11. Rehal B , Armstrong AW. Health outcome measures in atopic dermatitis: a systematic review of trends in disease severity and quality-of-life instruments 1985-2010. PloS one 2011;6:e17520.
12. Johnson III RJ. A Comprehensive Review of an Electronic Health Record System Soon to Assume Market Ascendancy: EPIC®. J Healthc Commun. 2016, 1:4. DOI: 10.4172/2472-1654.100036
13. Storm A, Benfeldt E, Andersen SE, Andersen J. Basic drug information given by physicians is deficient, and patients' knowledge low. J Dermatolog Treat. 2009;20(4):190-3.