Assessing atopic eczema using online tools – a protocol for secondary analysis of EczemaNet study data

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Short title: Analysis of EczemaNet data

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SYNOPSIS

Title	**Assessing atopic eczema using online tools – a protocol for secondary analysis of EczemaNet study data**
Short title	Secondary Analysis of EczemaNet data
Chief Investigator	Professor Kim Thomas
Objectives	Aim: to inform development of an AI tool to assess eczema severity from digital images Objectives • To explore different approaches to calculating a 'per person' severity score based on data available using the EczemaNet machine learning platform (combining extent scores with severity scores from multiple images) and comparing it with in-person Eczema Area and Severity Index (EASI), EASI banded severity ratings and validated Investigators Global Assessment (vIGA) based severity ratings <u>Available data:</u> • Demographic data • In-person Eczema Area and Severity Index (EASI) score • Extent of eczema– number of areas selected on the online manikin (0-45 areas). • Estimated percentage area affected for each of the EASI four body regions. • Extent based on EASI area scores – extent categorised as per EASI scoring (0-6) per body region. • In person Validated Investigators Global Assessment (vIGA) score • Image scores: ○ Each image uploaded by the recruiter will be given a score in seven different signs: cracking, oedema, dryness, lichenification, erythema, excoriation, crusting. Each sign will have a score from 0-3, with a total maximum score of 21. The EczemaNet score creation will focus on the four

	EASI signs – erythema, excoriation, lichenification and oedema. ○ There will be 1 or more image from each area whereby there is eczema on each of the four EASI body regions (head and neck, trunk, upper limbs, lower limbs)
Study Configuration	Secondary analysis of a prospective observational study
Setting	Paediatric secondary care
Sample size estimate	We hypothesise that the EczemaNet score will provide a similar approximation of eczema severity when compared with existing methods such as EASI or the IGA. We will use data from the first 50 participants from the ongoing EczemaNet study to explore different approaches to combining the data to identify the best approximation to EASI and vIGA scores. We will then test the validity and reliability of the approach(es) with at least another 100 participants.
Number of participants	50 for exploratory analysis 100 for validation
Eligibility criteria	Children or adolescents with UK Working Party Criteria defined Atopic Eczema
Methods of analysis	Baseline descriptive characteristics will be presented. Several methods of arriving at a per-person score will be evaluated using correlations, weighted kappa and Bland-Altman plots to assess levels of agreement with EASI and IGA. The first 50 participants will be an exploratory analysis allowing selection of the best fitted model for further testing in the validation dataset. At least another 100 participants will then be used to validate the models.

ABBREVIATIONS

Add to / amend accordingly (please ensure ALL abbreviations used in the protocol are listed here)

CI Chief Investigator overall

CRF Case Report Form

EASI Eczema Area and Severity Index

GCP Good Clinical Practice

HOME Harmonising Outcome Measures for Eczema

NHS National Health Service

P/GIS Parent / Guardian Information Sheet

PI Principal Investigator at a local centre

PIS Participant Information Sheet

REC Research Ethics Committee

R&D Research and Development department

UoN University of Nottingham

vIGA Validated Investigator's Global Assessment

STUDY BACKGROUND INFORMATION AND RATIONALE

Atopic dermatitis (AD) (synonym with eczema and atopic eczema) is the most common chronic inflammatory skin disease globally (1). Given it's chronicity and prevalence, the disease exerts a significant burden on a individuals and healthcare resources (2). In addition, severity assessments of AD can be complex and variable. It has been shown that objective assessments of AD severity have also been shown to be prone to inter- and intra-observer variation alongside variable reliability (9,10). This variability may disproportionately affect people with skin of colour, whose eczema has been reported to be more likely be undertreated(12), as studies have shown that eczema severity is often underestimated in darker skin people(13). This may be in part because training of healthcare professionals is often based on white skin (12) and further compounded by the fact that erythema, a frequent marker of eczema acuity, is masked due to background pigmentation (13). As such, there is a definite need for solutions that could mitigate this complexity and variability, whilst simultaneously reducing healthcare resources.

As such, there has been an increasing interest in incorporating teledermatology tools, which supported by the NHS Getting It Right First Time (GIRFT) document(11). Indeed, a remote assessment tool could potentially empower patient self-management, facilitate remote monitoring of treatment response, and allow remote clinical trial follow-up, thereby reducing burden on clinicians, researchers and hospital resources. Additionally, it could also reduce health inequalities by making clinical care and research more accessible whilst also standardising AD severity assessments. Indeed, several groups have shown that photographic, remote assessments of AD correlate and agree with in-person assessments (14,15). However, this still requires usage of a clinician/ researcher's time and it has been shown that inter-rater reliability suffers when patient supplied images are used(14). An automated remote assessment tool using digital images would be desirable to further standardise remote assessments of AD severity, reduce healthcare utilisation and mitigate variability(16).

Alongside this, there has been a surge in clinical trials investigating novel AD systemic treatments. To standardise outcomes and to allow comparisons, the international Harmonising Outcome Measures for Eczema (7) initiative has recommended the Eczema Area and Severity Index (EASI) as an objective assessment of clinical signs. Similarly, the Food and Drug Administration utilises the validated Investigator's Global Assessment (vIGA)(8) to make decisions on approving treatments for use. Both of these outcome

measures require a face-to-face examination of the patient's skin, which is time and resource intensive for both patient and researcher. An automated remote assessment tool using digital images would similarly be sought after to help make research more accessible, more efficient and reduce research costs.

This is currently being explored by the EczemaNet tool (16–18), among others. The tool is able to reliable grade eczema severity from individual photographs (16,18). However, it remains unclear the best way to combine severity of signs from multiple photographs with the extent of eczema to produce a whole person severity score. Such a score would need to align with EASI and vIGA for it to be useful in clinical practice and research settings.

The aim of our study is to utilise available data from the EczemaNet IRAS 325468 study to establish the best way of combining severity of signs and extent of eczema from multiple photographs on an online platform that could facilitate self-assessment of eczema.

STUDY OBJECTIVES AND PURPOSE

PURPOSE

Aim: to inform development of an AI tool to assess eczema severity from digital images by establishing the best way of combining severity of signs and extent of eczema from multiple images that could facilitate self-assessment of eczema.

To create a tool that would allow remote assessment of eczema severity that maps to existing validated eczema severity scores recommended by the HOME initiative such as EASI (7) and the vIGA (8).

OBJECTIVES

Primary objective

- To explore different approaches to calculating a 'per person' severity score using the EczemaNet machine learning platform (combining extent scores with severity scores from multiple images) and comparing it with in-person Eczema Area and Severity Index (EASI), EASI banded severity ratings and validated Investigators Global Assessment (vIGA) based severity ratings

STUDY DESIGN

This will be a secondary data analysis project using data collected as part of an existing project – the EczemaNet IRAS 325468 study (see appendix 1).

The EczemaNet IRAS 325468 study is a project which aims to train a machine learning algorithm to assess eczema severity objectively from digital images of children and young people with a range of skin tones and determine its prediction accuracy. Children and adolescents under the age of 18 with confirmed eczema based on the UK Working Part Diagnostic Criteria, have been recruited during clinic visits to Imperial College Healthcare NHS Trust, Chelsea and Westminister NHS Trust, and Nottingham University Hospitals NHS Trust, UK. These secondary care study sites treat an ethnically diverse population with eczema of varying severity. Written informed consent has been obtained from the parents/ guardians of the participants involved. Trained research staff captured images of participants' eczema-affected skin in four body regions (head & neck, body, arms and legs – excluding sensitive areas), with a minimum of one photo per affected area of eczema, with up to four angles. The images are then graded 0-3 for seven different clinical sign domains (cracking, dryness, erythema, excoriation, exudation, lichenification, oedema) by the researchers to train the model.

Alongside clinical images, research teams collected EASI data that includes an assessment of area affected by eczema in four body regions (head & neck, body, arms and legs.) Research teams also collected vIGA data which is a global assessment of the patient's eczema severity. The manikin extent data were entered by assessors using an online manikin by clicking on affected areas (figure 2).

Data available

- Demographic information
- Estimated percentage area affected for each of the EASI four body regions.
- In-person Eczema Area and Severity Index (EASI) score
    - Extent based on EASI area scores – extent categorised as per EASI scoring (0-6) per body region.
- Extent on an online manikin – number of areas selected on the online manikin (0-45 areas).
- In-person Validated Investigators Global Assessment (vIGA) score
- Image based clinical sign scores:

- Each image uploaded by the recruiter will be assigned a score in seven different signs: cracking, oedema, dryness, lichenification, erythema, excoriation, crusting. Each sign will have a score from 0-3, with a total maximum score of 21.
- There will be 1 or more image from each area whereby there is eczema on each of the four EASI body regions (head and neck, trunk, upper limbs, lower limbs)

Demographic information

Demographic information includes: gender, age, skin tone, Fitzpatrick scale, and ethnicity.

The estimated percentage area of each body region affected

Assessors will estimate the area of each of the four body regions (head and neck, trunk, arms and legs) affected by eczema and assign a percentage to it, ranging from 0-100%. This percentage will be used in the EASI area score below.

Eczema Area and Severity Index (EASI)

The EASI is a composite score that utilises a combination of extent of eczema (area score) and the severity of clinical signs(5,19).

For the EASI area score, the percentage involved of the four main body regions (head and neck, upper limbs, trunk and lower limbs) must be estimated and assigned an area score: 1 (1%–9%), 2 (10%–29%), 3 (30%–49%), 4 (50%–69%), 5 (70%–89%), and 6 (90%–100%). The feet and buttocks are part of the lower limbs while the axilla, and groin are part of the trunk.

Next, the eczema in each region is asssesed for four clinical signs: erythema, oedema/papulation, excoriation, and lichenification. Each clinical domain is given a score from 0 to 3, whereby 0 = absent and 3 = severe.

The score of each region is then calculated by the following formula: sum of severity score x area score x region-specific multiplier. The region-specific multiplier is determined by the contribution of that region to the total body surface area. The region-specific multiplier is different for those <8 and >= 8 years of age.

The final EASI score is then calculated by summing the four region scores. Figure 1 illustrates a guide on how EASI is calculated and severity strata for EASI.

Severity Score
Grade each sign on a scale: 0=clear/none 1=mild 2=moderate 3=severe

Area Score							
% Involvement	0	1-9%	10-29%	30-49%	50-69%	70-89%	90-100%
Area Score	0	1	2	3	4	5	6

EASI Calculator (Adults)

Body Region	Erythema (0-3)	Edema/ Papulation (0-3)	Excoriation (0-3)	Lichenification (0-3)	Area Score (0-6)	Multiplier	Score
Head/Neck	(+	+	+	)	x	x 0.1	
Trunk	(+	+	+	)	x	x 0.3	
Upper Extremities	(+	+	+	)	x	x 0.2	
Lower Extremities	(+	+	+	)	x	x 0.4	
The final EASI score is the sum of the 4 region scores (0-72):							_____

EASI Calculator (Pediatrics < 8 years old)

Body Region	Erythema (0-3)	Edema/ Papulation (0-3)	Excoriation (0-3)	Lichenification (0-3)	Area Score (0-6)	Multiplier	Score
Head/Neck	(+	+	+	)	x	x 0.2	
Trunk	(+	+	+	)	x	x 0.3	
Upper Extremities	(+	+	+	)	x	x 0.2	
Lower Extremities	(+	+	+	)	x	x 0.3	
The final EASI score is the sum of the 4 region scores (0-72):							_____

EASI Score Interpretation

Clear	Almost Clear	Mild	Moderate	Severe	Very Severe
0	0.1-1.0	1.1-7.0	7.1-21.0	21.1-50.0	50.1-72.0

Figure 1 EASI score assessment and calculation taken from Hanifin et al (5,19,20)

Online manikin

The areas affected by eczema are inputted into EczemaNet by selecting areas of an online manikin (Figure 2). There are 45 areas in total. The online manikin is based on the Nottingham Eczema Severity Scale (21).

This scale has been shown to have a strong correlation between extent as assessed by the scale and clinician-examined percentage extent of disease using the 'rule of nines'(21).

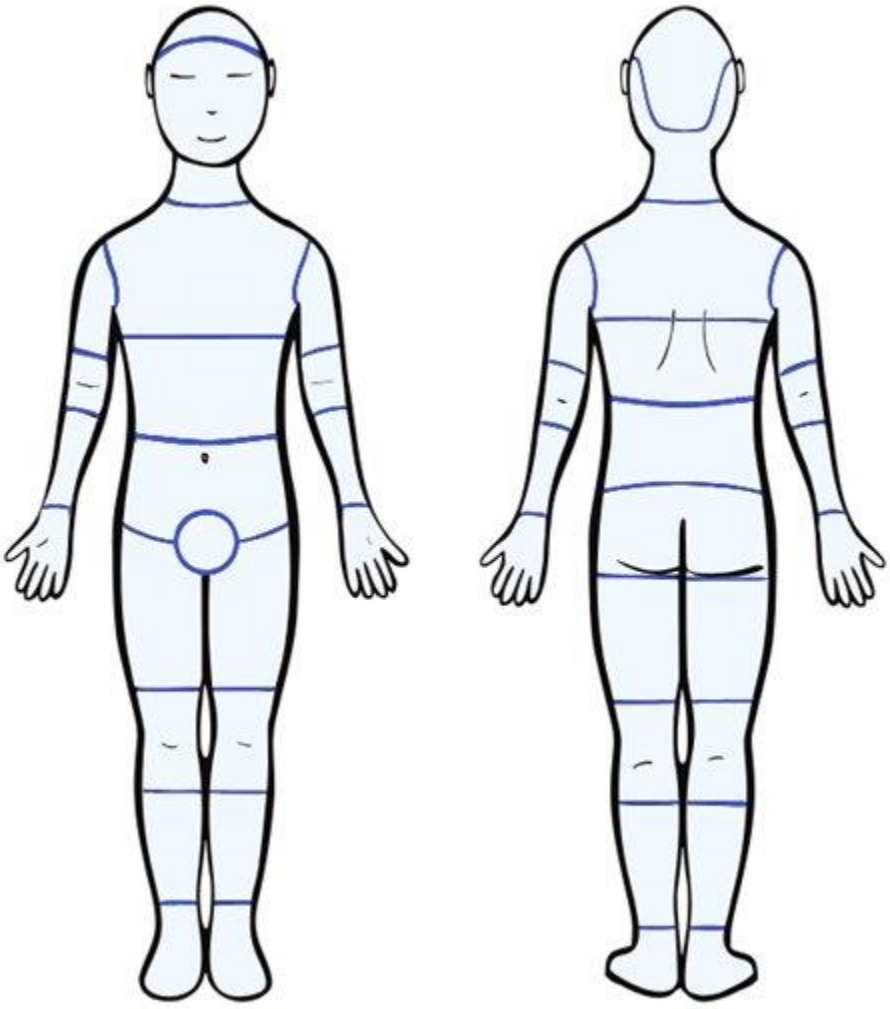

Figure 2. Mannikin adapted from Emerson et al (21)

In-person Validated Investigators Global Assessment (vIGA) score

The validated Investigator's Global Assessment (IGA) of eczema is a global assessment of a patient's overall disease severity at a given time point. It is recommended by the the US Food and Drug Administration (FDA) and other health agencies as an endpoint for trials supporting new drug applications in eczema. The researcher will assess the overall severity of eczema and assign an IGA score and categorise as described in the table below.

Score	Category	Description
0	Clear	No inflammatory signs of atopic dermatitis (no erythema, no induration/papulation, no lichenification, no oozing/crusting). Post-inflammatory hyperpigmentation and/or hypopigmentation may be present.
1	Almost Clear	Barely perceptible erythema, barely perceptible induration/papulation, and/or minimal lichenification. No oozing or crusting.
2	Mild	Slight but definite erythema (pink), slight but definite induration/papulation, and/or slight but definite lichenification. No oozing or crusting.
3	Moderate	Clearly perceptible erythema (dull red), clearly perceptible induration/papulation, and/or clearly perceptible lichenification. Oozing and crusting may be present
4	Severe	Marked erythema (deep or bright red), marked induration/papulation, and/or marked lichenification. Disease is widespread in extent. Oozing or crusting may be present.

Table 1: Categories of the validated Investigator's Global Assessment(8)

Image based scores:

As illustrated in the methods, trained research staff captured images of participants' eczema-affected skin in four body regions (head & neck, body, arms and legs – excluding sensitive areas), with a minimum of one image per affected area of eczema, with up to four angles. The images are then graded by researchers between 0-3 for seven different clinical sign domains (cracking, dryness, erythema, excoriation, exudation, lichenification, oedema). For this study there will be particular focus on the four EASI signs (erythema, lichenification, oedema, excoriation).

Of the multiple images per person, the recruiting clinician will select an image which most represents the patient's eczema (Representative image).

Although not directly collected by clinical assessors, the image with the highest total severity score for each body region based on the four EASI signs (erythema, lichenification, oedema,

excoriation) will be deemed the worst image for that body region. The image with the highest total score across all body regions will be classed as the worst area of the body.

Sample size and justification

We will use data from the first 50 participants from the ongoing EczemaNet IRAS 325468 study (appendix 1) for the initial exploratory analysis and mapping of number of areas selected on the online manikin for each body area against the body area's EASI region scores. We will then use at least an additional 100 participants to validate the approaches.

Analysis:

The first 50 participants will be used for an initial exploratory analysis and to create models that have the highest fit with vIGA and EASI.

The completeness and useability of image upload data will be assessed descriptively. Only participants with complete extent and severity data will be used in the analyses.

Baseline descriptive characteristics for the participants will be presented. Continuous data will be presented with mean + standard deviation or median + interquartile range. Categorical data will be presented with number and percentage. The measurements of extent will also be presented descriptively.

Sample tables:

Baseline Characteristics	
Age	Mean, SD
Gender	Male – N, % Female – N, % Other
Skin tone	Fair – N, % Light – N, % Medium – N, % Dark – N, %
Ethnicity	
Fitzpatrick Scale	I – N, % II – N, % III – N, % IV – N, %

	V – N, % VI – N, %
EASI	Mean, SD
vIGA	Mean, SD

Phase 1

Step 1 - Extent

Body region: Head and Neck							
EASI Area Score categories	0	1	2	3	4	5	6
N, %							
Extent measured in percentage Mean, SD							
Areas selected on manikin Mean (SD) Median (IQR)							

Body region: Upper Limbs							
EASI Area Score categories	0	1	2	3	4	5	6
N, %							
Extent measured in percentage Mean, SD							
Areas selected on manikin Mean (SD) Median (IQR)							

Body region: Trunk							
EASI Area Score categories	0	1	2	3	4	5	6
N, %							
Extent measured in percentage Mean, SD							
Areas selected on manikin Mean (SD) Median (IQR)							

Body region: Lower limbs							
EASI Area score categories	0	1	2	3	4	5	6
N, %							
Extent measured in percentage Mean, SD							

Areas selected on manikin Mean (SD) Median (IQR)							

- Correlation
    - Spearman's correlation for the number of areas selected for each of the 4 body areas against the body area's EASI region score.
    - Spearman's correlation for the number of areas selected for each of the 4 body areas against the body area's BSA expressed as %.
    - Spearman's correlation for the number of areas selected for the whole body against the body's total BSA expressed as %.
    - Correlations of greater than or equal to 0.3 is sufficient to warrant mapping to the EASI categories.
- Weighted kappa, and adjustments
    - If correlation is sufficient, different ranges of the number of areas selected will be mapped to the 0 to 6 EASI region score categories.
    - Weighted kappas will then be performed against the EASI region scores.
    - The range which has the highest kappa coefficient will be selected as the range to be representative of the EASI region scores.

Step 2: A 'per person' severity

Initial creation

Different approaches to calculating a 'per person' severity score based on data available will be explored. This includes:

- **EczemaNet-EASI**: Per region extent x severity score for each of the four EASI body regions (based on mean of score for each region) x multiplier – this mirrors EASI most closely
- **EczemaNet-EASI Max** : Per region extent x severity score for each of the four EASI body regions (based on MAX of score for each region) x multiplier – this is close to EASI
- **Representative image x Extent:** Whole body extent x severity score for representative patch
- **Worst Area x Extent:** Whole body extent x severity score for worst patch
- **Sum of Means Approach:** Mean upper limb score + Mean lower limb score + Mean Trunk score + Mean Head and Neck score

- **Sum of Max Approach:** Total Max severity score Max upper limb score + Max lower limb score + Max Trunk score + Max Head and Neck score

Correlate and compare

- EASI
  - Spearman's correlation for the score generated by the approaches against the total clinic assessed EASI score
  - Correlations of greater than or equal to 0.3 is sufficient to warrant checking of agreement between the score and the clinic assessed EASI score
  - A bland-altman plot will then be used to display agreement between the two EczemaNet EASI scores and the clinic assessed EASI score
- EASI bandings
  - The value generated from the approaches of the EczemaNet score will be mapped to the clinic assessed EASI severity strata
  - Weighted kappas will then be performed
  - The approach which has the highest kappa coefficient will be selected as the approach for further refinement.
  - Further cycles of tweaking of the range of values until the highest kappa coefficient is achieved that can be representative of the EASI severity strata.
- vIGA
  - The value generated from the approaches of the EczemaNet score will be mapped to the vIGA categories (clear, almost clear, mild, moderate, severe)
  - Weighted kappas will then be performed
  - The approach which has the highest kappa coefficient will be selected as the approach for further refinement.
  - Further cycles of tweaking of the range of values until the highest kappa coefficient is achieved that can be representative of the vIGA categories.

Phase 2: Validation

For validation dataset we will aim for at least 100 participants. Only participants with complete data will be analysed.

Demographic data will be reported descriptively.

The best models from the exploratory dataset for the different approaches will be validated in the validation dataset of at least 100 participants, similarly assessing for agreement and correlation as described above.

Data analysis will be performed by Dr Fong with assistance of Dr Lucy Bradshaw and from the wider study team, the EczemaNet IRAS 325468 study team and colleagues from the Center of Evidence Based Dermatology.

STUDY MANAGEMENT

The study is a project nested within the EczemaNet IRAS 325468 study. Dr Fong will be leading the study with support from the wider EczemaNet IRAS 325468 study team, colleagues at the Center of Evidence Based Dermatology, and his clinical and academic supervisors.

The Chief Investigator has overall responsibility for the study and shall oversee all study management.

The data custodian will be the Chief Investigator.

SELECTION AND WITHDRAWAL OF PARTICIPANTS

Recruitment

No recruitment is planned in this secondary analysis study. Participants will be recruited in the main study (appendix 1) .

Eligibility criteria as per EczemaNet IRAS 325468 study

Children and adolescents with clinician-diagnosed eczema based on UK Working Party Diagnostic Criteria.

Inclusion criteria as per EczemaNet IRAS 325468 study

1. Children and young people age under 18 years with diverse skin tones
2. Confirmed eczema diagnosis based on UK Working Party Diagnostic Criteria
3. Visible eczema at the time of recruitment
4. Written, informed consent of parent/legal guardian and patient consent/assent

Exclusion criteria as per EczemaNet IRAS 325468 study

1. Eczema diagnosis not confirmed.
2. Severe underlying medical conditions that may present with eczematous lesions

Informed consent

This secondary data analysis does not involve any consent. However, in the main study (Appendix 1), written informed consent has been obtained by parents/ guardians of the participants involved.

ETHICAL AND REGULATORY ASPECTS

ETHICS COMMITTEE AND REGULATORY APPROVALS

This secondary analysis project does not need ethical approval as there will be no direct patient involvement. The main study (the EczemaNet IRAS 325468 study) already has ethical approval : West of Scotland REC 5REC23/WS/0098.

DATA PROTECTION

All study staff and investigators will endeavour to protect the rights of the study's participants to privacy and informed consent, and will adhere to the Data Protection Act, 2018. No personal identifiable information will be utilised in this study.

All source data of the main study (appendix 1) will be held in secure servers at Imperial College London. An analysis file of only the relevant data without any personal identifiable information, and will extracted and transferred to to the University of Nottingham, Center of Evidence Based Dermatology for this secondary analysis.

We will establish a data-sharing agreement between the University of Nottingham and Imperial College London. No personal data, raw data, or any other results generated will be made available to any third party, except for governance or audit by a regulatory authority.

STATEMENT OF CONFIDENTIALITY

No personal identifiable information will be utilised in this study.

Data generated as a result of this study will be available for inspection on request by the participating physicians, the University of Nottingham representatives, the REC, local R&D Departments, and the regulatory authorities.

PUBLICATION AND DISSEMINATION POLICY

Study results will be presented at local journal club meetings and may be presented at national and international meetings. The final report will be published in a peer-reviewed academic journal. Study data will only be available in the public doman with agreement by the whole team to protect trade secrets of the EczemaNet artificial intelligence.

USER AND PUBLIC INVOLVEMENT

Patient and publication involvement (PPI) was obtained as part of the EczemaNet IRAS 325468 study (appendix 1). This includes working with a PPI panel to discuss output styles, app development and useability of the tool. The PPI panel also provided input as to which of the whole-person score calculation approaches they think would be most appropriate and most reflective of their experiences. A workshop with researchers and clinicians was also undertaken to determine what validated severity score would they want to be reflected in the EczemaNet score.

STUDY FINANCES

Funding source

The main study is funded by funded by an independent, peer-reviewed grant from the National Institute for Health and Care Research (NIHR204505). Dr Fong is funded through his appointment in a NIHR ACF programme (August 2023 – August 2026).

Appendix 1: EczemaNet IRAS 325468 study

Title **EczemaNet Study: Feasibility of machine learning algorithm to assess eczema severity across a range of skin tones using digital photographs**

Research Question: Can eczema severity be reliably measured from digital images in people across a range of skin tones?

Aim: To train a machine learning algorithm to assess eczema severity objectively from digital images for children and young people with a range of skin tones and determine its prediction accuracy.

Objectives and Methods:

1. Create a dataset of sufficient quality and representativeness of diverse skin types for the training of a machine learning algorithm (based on EczemaNet) by collecting over 5,000 eczema images from ~500 paediatric patients with diverse skin tones who have clinician-diagnosed eczema. Collected images will be annotated with eczema severity scores assessed in-person by trained research nurses and research professionals.
2. Obtain qualitative feedback on the usability of a web platform to collect data (acceptability, feasibility, accessibility and ability to correctly enter data) from ~50 patients/carers and ~10 HCPs via structured interviews.
3. Train the machine learning algorithm (previously applied mainly to white skin) so that it is able to assess eczema severity on darker skin tones and evaluate how accurately it predicts eczema severity from digital images.

Sample size: At least 500 children and young people with eczema and with diverse skin tones under age 18 years old

Study design: Basic science study involving procedures with human participants

- data collection and analysis only
- machine learning separate from data collection and clinical setting
- not diagnostic, no interaction with clinical decision making or interventions in patient care

Patient population:	Children and adolescents with clinician-diagnosed eczema
Inclusion Criteria:	Children and young people age under 18 years with diverse skin tones Confirmed eczema diagnosis based on UK Working Party Diagnostic Criteria Visible eczema at the time of recruitment Written, informed consent of parent/legal guardian and patient consent/assent
Exclusion criteria:	Eczema diagnosis not confirmed. Severe underlying medical conditions that may present with ezematous lesions (not common in allergy clinics).
Test articles:	Machine learning algorithm (based on EczemaNet)
Procedure:	Eczema severity scoring by research team, digital photographs of eczematous skin taken and uploaded to the server through a web interface. Optional participation in user evaluation pilot identifying if the web-interface if fit for purpose for correct data entry.
Recruiting centers:	Imperial College Healthcare NHS Trust, Nottingham University Hospitals NHS Foundation Trust
Duration:	30 months (from date of full approvals)

OUTCOME MEASURES AND ASSESSMENTS

Primary outcome:

Prediction accuracy of severity scoring by machine learning algorithm across a range of skin tones

Secondary outcomes:

- User feedback on acceptability, functionality (patients / parents or guardians)
- User feedback on acceptability, functionality (healthcare professionals)

Analysis:

The main study will involve training a machine learning algorithm (based on EczemaNet) and evaluating the difference between machine learning based and in-person assessment-based severity scores for each disease sign. The analysis is separated from the clinical and data collection setting, i.e. will **not** give scores or information at the point of clinical care for participants.

Data protection:

The study is registered under the Data Protection Act and the Data Protection Officer at Imperial College London has reviewed and approved eczemanet.org.

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