

Medical Chart Audits for Research Endpoints in Primary Care Clinics Across Four PBRNs



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Information on Atopic Dermatitis (Eczema)

- Atopic dermatitis (AD) is a common, chronic, inflammatory skin disorder affecting approximately 13% of children in the United States.
- The majority of cases begin within 2 years of life.
- Skin barrier dysfunction is a central event in the development of AD.
- Hypothesis: Daily emollient therapy will prevent AD by constantly healing the skin barrier



Setting: Practice-based Research Networks



10 clinics



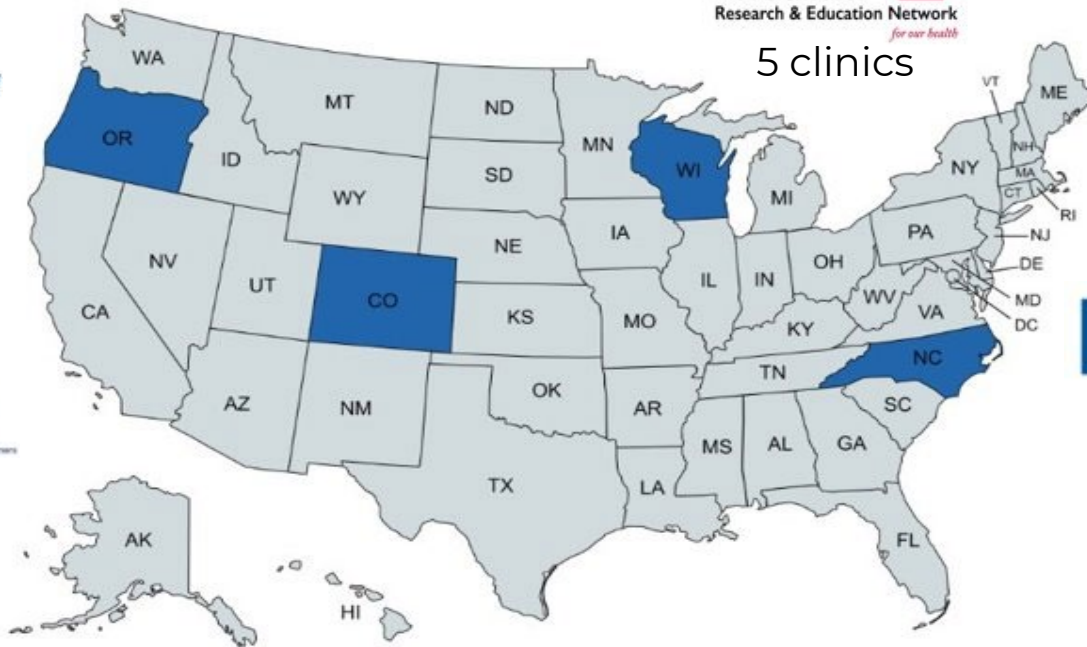
5 clinics



5 clinics



5 clinics



CASCADE Study Design



Primary outcome:

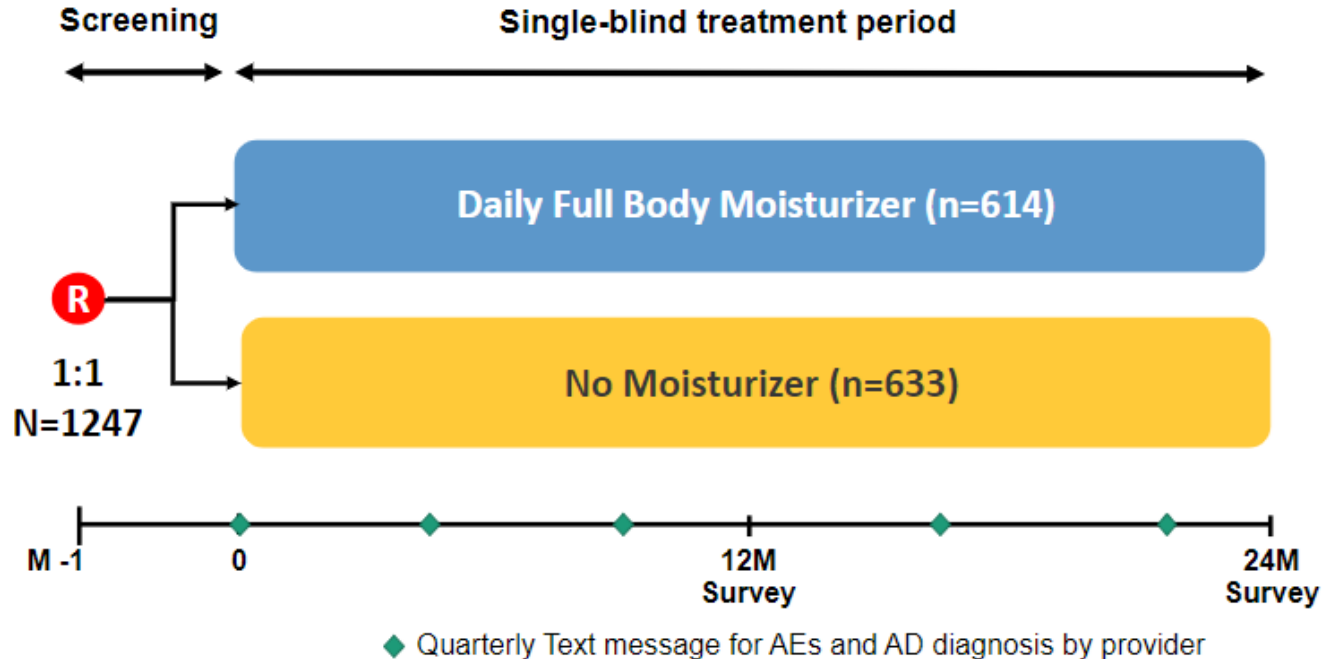
Eczema by 2 years of age recorded in health record

Eligibility criteria:

- Aged 0-8 weeks of age
- No immunosuppression
- No current rash

Inviting all families:

- Care at primary care clinics
- Simple enrollment (study iPad or personal device)
- Bilingual research professional (English / Spanish)
- Contacted families every 3 months



Methods: Manual Chart Audits For Finding Primary Outcomes

Optimizing for **ACCESSING** Protected Health Information

- Protected Health Information- BAAs, ROIs
- Electronic Medical Records/Charts
- Paper Medical Records/ Charts

Manual Chart Auditing: **The Process**

- Staff training + Orienting to record/ chart system
- Tools + Tactics



Access: A Trifecta for Success

1) Patient:

- Informed Consent Form
- Release of Information

2) Clinic & PBRN:

- BAA from clinic to PBRN's University

3) Clinic:

- IT/Medical Records Contact
- EMR Access

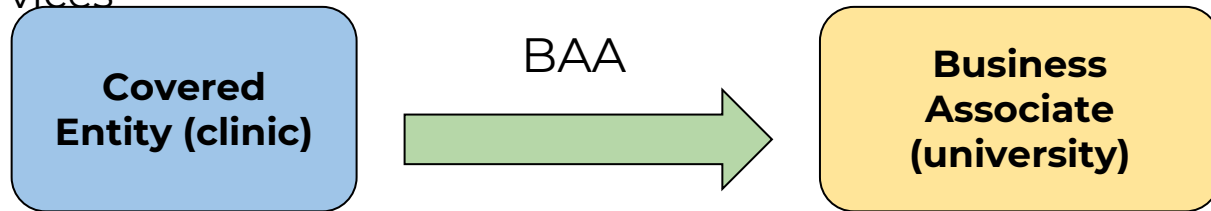


**Chart
Access**



Accessing PHI: Business Associate Agreements

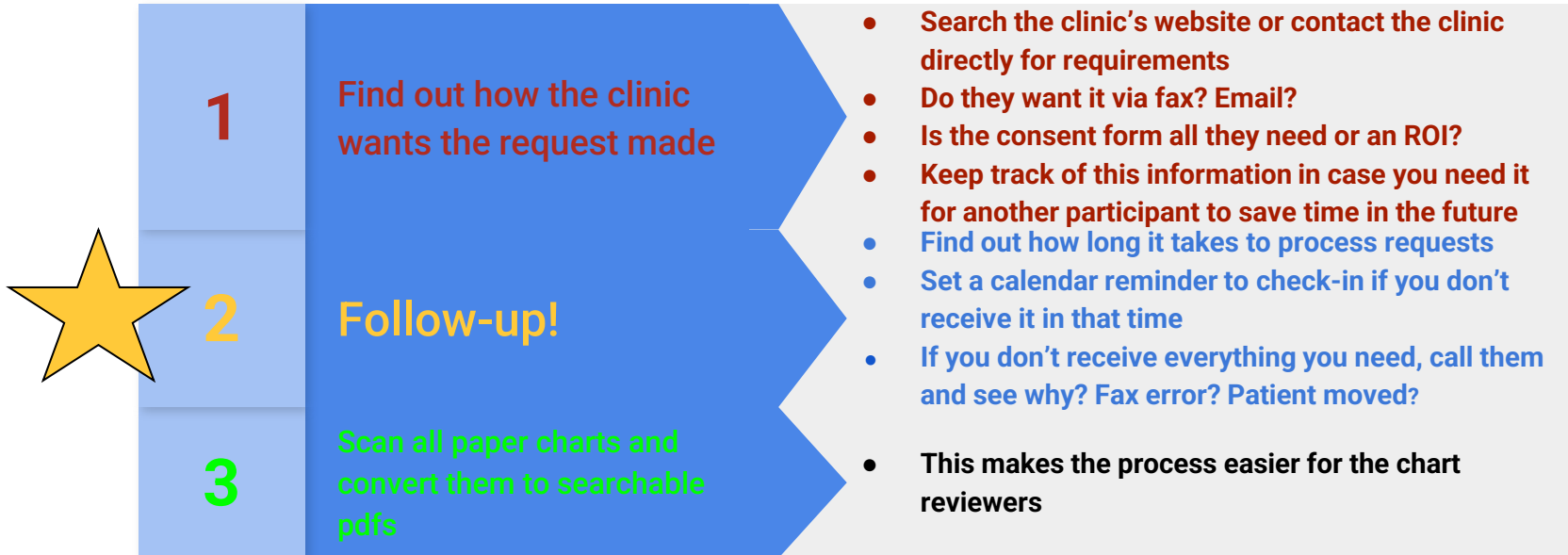
- A BAA is an agreement between two HIPAA-covered entities to ensure complete protection of PHI while they are working on a project together
- Technically optional; lawyer recommended
- NOT required if clinic is part of the university health system
- Recommended Timeline: Start this process 1 year before you expect to be auditing charts
- Guidance available through U.S. Department of Health and Human Services



Obtaining Access to Paper Charts



- EMR access is not always available
- Patient transfers to other clinics that had not heard of CASCADE



Challenges to Access

- Third party management of EHR/PHI
- EHR access not always possible, charts shared via fax or mail
- Recipient unresponsive to record requests
- Participants change clinics
- Hold times when contacting clinics
 - Sometimes 45+ minutes
- ROI requirements
 - Even if there's an alternate expiration date or expiration date of over 1 year, some clinics/clinic systems require ROI signature within 90 days of request



Process: Considerations for Auditing

Training + Quality Assurance

- Verifying auditor competencies
- Goal setting + pace
- Tracking questions, FAQ

Auditing multiple in EMR systems

- Physical Access (web links, paper files, pdfs)
- Password, required password changes
- EMR experts + resources

Tools + Tactics

- Word search
- Problem Lists
- Medications

Modality specific to setting

- Electronic data capture
- Paper data capture

Tracking Progress

- Forecasts: numbers aging into window
- Number complete
- Number to return to/answer questions



Tools + Tactics for audit success

Case Report Form Design Hacks

Pre-populate with standard information (pt name, DOB)

Align flow with EMR flows

Document auditor: who audited?

Add timers/timestamps to understand how long it takes

Assess chart auditor blindness

Clues to Root Out Information

Word searches (make a pdf searchable first)

EMR Problem Lists

Medications/Rx dates

After Visit Summaries

PERSISTENCE + DOCUMENTATION



Takeaways

- **Manual chart audits are time and labor-intensive! YOU CAN DO THIS!**
- **There are tactics to make them easier**
- **PBRN participation lead to improved diversity in study sample and greater generalizability of results**



Thank You!

To learn more email:

CASCADE@ohsu.edu



Abstract

Background

Atopic dermatitis (AD) is a prevalent and chronic skin disorder affecting approximately 13% of children in the United States, usually starting in infancy. The Community-based Assessment of Skin Care, Allergies and Eczema (CASCADE) study measures the effectiveness of emollient therapy applied to newborns in preventing AD in a pragmatic, randomized trial in primary care settings. The primary outcome is an AD diagnosis by the infant's primary healthcare provider by 27 months of age (cumulative incidence) as recorded in the health record. We describe the manual chart audit methodology across PBRNs, including coordinator training, accessing charts, data capture, and key takeaways for efficiency in the chart auditing process.

Settings & Participants

The study followed parent-child dyads via surveys and medical record audits from birth to 27 months of age. Dyads were recruited from 25 primary care practices through four practice-based research networks (PBRNs) in Oregon (10 clinics), Wisconsin (5), Colorado (5), and North Carolina (5). Clinics had diverse charting methods.

Methods

PBRN coordinators executed business associate agreements (BAAs) with participating clinics to obtain EMR access and ensure HIPAA compliance. For clinics with EMRs, coordinators obtained remote access to or audited charts in-person. For clinics with paper charts, clinics faxed or mailed patient charts to the central study site. Trained auditors systematically reviewed patient records to identify relevant data points, including incidence of clinician-diagnosed AD.

PBRN coordinator alerts central study team that charts are being requested



PBRN coordinator emails designated clinic staff member asking for charts and includes central study team member



Central study team member faxes consent documents for needed participants to clinic



Charts ready to be audited



Central study team uploads faxed charts to SharePoint and notifies research coordinator



Clinic staff member faxes charts to central study team

