Experiences with Recruitment and Implementation of the CASCADE Study by Meta-LARC Practice-Based Research Networks

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Background

- Atopic dermatitis (AD) affects approximately 13% of children under the age of 18[1] and can present significant challenges to the children effected and their families[2-5]
- AD represents a large burden in the primary care practice setting in the US [5]
- The Community-based Assessment of Skin Care, Allergies and Eczema (CASCADE) Study aimed to test whether daily application of an emollient from birth can prevent or delay onset of AD (NCT03409367)
- Four practice-based research networks (PBRNs) that were part of Meta-LARC participated
- We describe recruitment methods used and adjustments by PBRNs to ensure adequate enrollment

Overall Objective

To compare the efficacy of the daily use of emollients versus usual care (no routine emollient use) to prevent AD from early infancy to 24 months

Setting and Participants

Each PBRN recruited primary care clinics within their state:

- Oregon Rural Practice-based Research Networks (ORPRN); Oregon (10 clinics)
- Duke Primary Care Research Consortium (PCRC); North Carolina (5 clinics)
- State Network of Colorado Ambulatory Practices & Partners (SNOCAP); Colorado (5 clinics)
- Wisconsin Research and Education Network (WREN); Wisconsin (5 clinics)
- Clinic staff invited parent-child dyads to participate (Goal of 50 dyads per clinic over 2 years)
- The recruitment window overlapped with the COVID-19 pandemic (2018-07-03 to 2023-09-29)

Methods

- **Design:** Randomized, multisite, single-blind, pragmatic trial[6]
- **Interventions:** Eligible dyads were randomized to daily use of lipid-rich emollient group or to control (no emollient) group and were to be followed for 24 months
- Both groups received email and text message reminders to follow protocol instructions based on the group allocation until the infant reached 24 months old
- **Primary outcome:** Eczema by 2 years of age recorded in health record (cumulative incidence of physician-diagnosed AD)
- **Inclusion/exclusion criteria:** Defined elsewhere,[6] but included the ability of parents to speak, read, and write in English or Spanish, have a valid email address or phone that could receive text messages, and reliable internet access

References

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Acknowledgment: Supported by the National Institute of Arthritis and Musculoskeletal and Skin Diseases

Clinic Support and Recruitment Strategies

- Clinic staff introduced the study to parents and invited them to self-enroll
  - Screening and enrollment were completed by parents online using an iPad in the clinic or a home computer
  - English and Spanish enrollment and recruitment materials were available
- PBRNs worked with clinic staff using practice facilitation to develop workflows for patient identification and enrollment using multiple strategies, such as:
  - Placing posters in clinic
  - Handing out study cards during routine wellness visits
  - Mailing study cards
  - Mailing pre-visit letters to potential participants
- Some recruitment methods were integrated with their clinical care/ visit and by the providers/clinical staff, while the other approaches were done asynchronously by study staff
- Workflows were adjusted when enrollment goals were not met

Results

Participants

- Twenty-five participating clinics were located in rural, suburban, and urban areas
- Clinics screened 1,873 potential participants from July 2018 to February 2021
  - 1,250 participants were enrolled (67% randomization rate)

Impact of COVID-19

- Well-child visits and online screening/self-enrollment continued despite the pandemic
- In-person research coordinator visits were halted due to clinic policies and local restrictions
- Study recruitment materials could no longer be placed in clinic waiting rooms

Recruitment Challenges

- Clinic staff turnover/shortages
- Changes in electronic medical record systems
- Shifting resources during the COVID-19 pandemic
- Lack of internet access (both at clinic and in parent-child dyad homes)

Conclusions

- Working with clinics to identify barriers to recruitment and tailoring solutions to each clinic was key to ensuring successful enrollment
- Limiting clinic involvement to identifying patients and inviting patients to self-enroll helped minimize impact on clinic workflows
- Inviting patients to self-enroll online was a strategy continued during the COVID-19 pandemic
- Regular study meetings facilitated sharing of best practices and solutions to recruitment barriers

Key Points

- **Engagement with participating practices and flexibility helped develop strategies to fit varied work flows, thereby ensuring recruitment targets were met**
- **Collaboration among multiple PBRNs facilitated enrollment of 1,250 participants**

Examples of Recruitment Workflows

Patient portal recruitment (Large health system)

Strategy	Participant Identification	Enrollment	Challenges
Electronic health records scanned for eligibility (eg, every 2 weeks)	**Automated MyChart messages** sent to families identified as eligible based on recruitment criteria	Parents could navigate to the screening REDCap from the link in the MyChart message Parents could click "Interested" and research coordinators would call to follow up	• Could only send a message if the family had enabled MyChart for their baby • This method excluded Spanish speakers as English was the only language available at the time of the study

In-person recruitment (Urban health system)

Strategy	Participant Identification	Enrollment	Challenges
Clinic-based	**Clinician** hands out postcards to patients in clinic for newborn visits Large posters are hung in exam rooms Study rack cards are at the front desk that patients can take after their visit	If patients are interested, they are handed a postcard in the room to review and then given an iPad to complete the initial screening while sitting in the exam room or waiting area One clinician found this is the best way to get patients enrolled	• Some patients were ineligible as they did not have internet access at home • In some cultures, decisions about babies are made with both parents. Thus if both parents are not present at the clinic, patients are not as willing to sign up for the study

In-person recruitment (Rural health system)

Strategy	Participant Identification	Enrollment	Challenges
Clinic-based Enrollment on Ob/Gyn floor of hospital	The **first-floor receptionist** hands out postcards to patients there for newborn visits Posters are in the exam rooms After a birth and during the check-out process, the **Ob nurse** hands the new mother a CASCADE postcard and introduces the study	Parents can enroll at their clinic or Go home and enroll on their personal computer (ie, using QR code)	• Staff not remembering to introduce the study to parents and forgetting to hand out the CASCADE postcard • Some delays if clinics ran out of postcards • Staffing issues (turnover, being short-staffed, lack of continuity)

MA reminders (Rural clinic)

Strategy	Participant Identification	Enrollment	Challenges
Reception reviews upcoming newborn visits "CASCADE" is added to the MA checklist for 2-week newborn visits	Reception will give patients with the reason for visit "CASCADE" a laminated poster to remind the **MA to give the patient the iPad** with the study video playing while the patient waits for the clinician The MA will also give patients the CASCADE card to give to the clinician reminding them to discuss the study During the visit, the clinician will see the postcard and remember to discuss the study	Parents can enroll at their clinic or Go home and enroll on their personal computer (ie, using QR code)	• Difficult for reception to have time to put "CASCADE" in the 2-week visit reason • This rural clinic had challenges with internet access and iPad usage in the clinic