Using Community Engagement Studios to Enhance Pharmacogenetic Study Design for Maximizing Enrollment of Diverse Children and Pregnant People

Elizabeth Jasper, PhD, Leslie Boone, MPH, & Tiffany Israel, MSSW
Background

Children, pregnant individuals, and people of color are underrepresented in current pharmacogenetic (PGx) research.

Testing and validation of gene-drug associations in these populations is necessary to provide appropriate recommendations and guidance to prescribers.
Background: Community Engagement Studio

- Built on the scaffolding of the Translational Research Studios at VUMC
- Piloted as the Community Review Board in 2009-2010
- Offered as service to the Vanderbilt community in 2010
- Recognizes and amplifies the lived experiences of lay stakeholders, e.g. patients and community members


## What’s the Difference?
Community Engagement Studios and Focus Groups

<table>
<thead>
<tr>
<th></th>
<th>Community Engagement Studios</th>
<th>Focus Groups</th>
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</thead>
<tbody>
<tr>
<td><strong>Purpose</strong></td>
<td>Obtain feedback/guidance to inform research at any stage</td>
<td>Qualitative research</td>
</tr>
<tr>
<td><strong>Approach</strong></td>
<td>A dialogue; bi-directional discussion</td>
<td>Uni-directional</td>
</tr>
<tr>
<td><strong>Participants</strong></td>
<td>Serve as consultants; experts based on “lived experience”</td>
<td>Research participants</td>
</tr>
<tr>
<td><strong>How participants determined</strong></td>
<td>In consultation with community engaged research core CE Studio team</td>
<td>Research team</td>
</tr>
<tr>
<td><strong>Facilitator</strong></td>
<td>A trained community member; balances power</td>
<td>Usually research team</td>
</tr>
<tr>
<td><strong>Pre-meeting activities</strong></td>
<td>Consultation with CE Studio team; coaching for research team; orientation for community experts</td>
<td>Usually none</td>
</tr>
<tr>
<td><strong>Compensation</strong></td>
<td>Consultant fee equivalent to local volunteer compensation rate</td>
<td>Incentives determined by health research team</td>
</tr>
<tr>
<td><strong>Other distinctions</strong></td>
<td>Written and oral comments; may request additional information; may question research approach; may peruse unanticipated topics; may contact after CE studio; paperwork as advisor</td>
<td>IRB approved questions/script; Informed consent obtained; qualitative analysis of transcripts; no contact after focus group; themes identified and connected with participants</td>
</tr>
</tbody>
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## Meeting Formats: Community Engagement Studio Model

<table>
<thead>
<tr>
<th>In-Person Model</th>
<th>Virtual Model</th>
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</thead>
<tbody>
<tr>
<td>Community meeting space</td>
<td>Use of Zoom to connect</td>
</tr>
<tr>
<td>Meal provided</td>
<td>Recorded session for note taking</td>
</tr>
<tr>
<td>Use of wall space to reiterate key points provided by the experts</td>
<td>Experts may use chat function to capture additional thoughts</td>
</tr>
<tr>
<td>Compensation provided to experts</td>
<td>Compensation provided to experts</td>
</tr>
<tr>
<td>Summary provided to researchers</td>
<td>Summary provided to researchers</td>
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Community Engagement Studio (CES)

## Optimizing tools and design through Engagement Studios

**17 priority populations identified to test**

### Community Engagement Studios:
- Website and enrollment modules
- Informed consent
- Return of Value

### Completed:
- Met w/ over 600 individuals (community experts)
- Conducted over 70 community engagement studios in 6 months

### Priority Populations

<table>
<thead>
<tr>
<th>General Population</th>
<th>Parent/Child Dyads</th>
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<tbody>
<tr>
<td>Older Adults (65+)</td>
<td>Those living in rural areas</td>
</tr>
<tr>
<td>Sexual &amp; Gender Minorities</td>
<td>Asian Americans</td>
</tr>
<tr>
<td>Native Americans</td>
<td>Latinos</td>
</tr>
<tr>
<td>African Americans</td>
<td>Individuals with limited English proficiency</td>
</tr>
<tr>
<td>Individuals with limited educational attainment/literacy</td>
<td>Individuals with 3 or more chronic health conditions</td>
</tr>
<tr>
<td>Individuals with no ability to access the internet</td>
<td>Individuals who are blind or limited vision</td>
</tr>
<tr>
<td>Individuals who are deaf or hard of hearing</td>
<td>Individuals with limited technical proficiency</td>
</tr>
<tr>
<td>Individuals with limited use of upper extremities</td>
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</tbody>
</table>
Model of Dissemination
Project 1 Aim 1

- Knowledge and Attitudes Regarding Pharmacogenomics Testing Among Children with Chronic Disease and Pregnant Persons
Recruit 250 pregnant people 250 children

Baseline survey PGx testing

PGx results via MHAV portal

Educational video Follow-up survey
CES Process

Planning Meeting  Recruitment  Implementation  Summary and Recommendations
Planning Meeting

• 1-hour meeting with research team
  • Narrow to 2-3 key topics
  • Define community expert characteristics
  • Discuss ground rules
  • Presentation Review
Recruitment

Two Community Engagement Studios

- Pregnant/Parents Studio
- Parents of Children with Chronic Diseases Studio

Recruitment Strategies

- Past CES Experts
- Social Media
- Internal clinical space

<table>
<thead>
<tr>
<th>What</th>
<th>1-time online meeting to give input on a project aiming to understand parents’ opinions on genetic testing. You will not be recruited for research.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Who</td>
<td>Pregnant women and parents of children (0-3 years) Parents of children of any age with chronic health conditions.</td>
</tr>
<tr>
<td>When</td>
<td>Early to mid-November 2021</td>
</tr>
</tbody>
</table>

FOR MORE INFORMATION:
Please fill out our interest survey here:
https://redcap.link/vumcparents

Questions?
Email: cestudios@vumc.org

Are you pregnant or a parent of a child under the age of 3?
Do you care for a child of any age with a chronic condition?
Do you see a Vanderbilt pediatrician?

$75 Gift Card
Implementation

• Individual screenings and orientations
• Scheduling confirmations
• Reminders
• Studio Facilitation
**Summary & Recommendations**

<table>
<thead>
<tr>
<th>Project Name:</th>
<th>VICE-MPRINT: Maternal and Pediatric Pharmacogenetics Survey</th>
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</thead>
<tbody>
<tr>
<td>Facilitator:</td>
<td>Tiffany Israel, MSSW</td>
</tr>
<tr>
<td>Notes Prepared By:</td>
<td>CES Team</td>
</tr>
<tr>
<td>Location:</td>
<td>Virtual</td>
</tr>
<tr>
<td>Researcher/PI:</td>
<td>Sara Van Priest, MD, PhD</td>
</tr>
<tr>
<td></td>
<td>Digna Velez Edwards, PhD, MS</td>
</tr>
<tr>
<td></td>
<td>Elizabeth Jasper, PhD</td>
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1. **Research**

Inform project focused on pharmacogenetic testing for those who are pregnant or children with certain chronic conditions.

3. **Recommendations**

**Recruitment:**
1. Utilize established trust between patients and their providers by collaborating with OB/GYN/Peds to recruit women and their children for genetics studies.
2. Conduct study outreach by posting study info in a variety of locations i.e., provider offices, wait rooms, pharmacy.
3. Develop study info inserts that can be attached to prescriptions for the specific types of medications involved in the testing.
4. Highlight study on MyHealth accounts of participants.

**Survey:**
1. Include options for parents to add additional information for context (i.e., if the child is biological).
2. Add a description to the personal questions section in the REDCap survey to help participants understand the relevance of questions.
3. Add context setting sentences to the REDCap survey, to highlight that answers provided should be based on individual experience and insight.
4. Utilize hover-over definitions to define complex terms used in the survey such as
CES Results

• Pregnant/Parents Studio
  • 4 females
  • All identified as African American/Black
  • One under 30 years old and 3 between 30 and 55 years old
  • Education: H.S. to post-graduate

• Parents of Children with Chronic Diseases Studio
  • 6 female parents
  • 2 identified as African American/Black and 4 as White
  • 5 between 30 and 55 years old
  • Education: some college to post-graduate
Pharmacogenetic Testing

• Interested but apprehensive

• Particularly helpful in certain situations

• Helpful to know choices and potential problems with medications

• Would alleviate stress and worry, especially for parents of children with chronic conditions

• Fears of being experimented on
Concerns, Challenge, and Barriers

• Lack of information communicated by physicians and researchers contributes to skepticism

• Parents of children with chronic conditions were knowledgeable about testing and their questions tended to be more technical

• Communication and education: convey information to the patient in understandable terms and being able to relate to the patient
Recruitment

• Participants with less of a rapport with their physicians said common and communal areas would be best
  • *Flyers*– every peds clinic and OBGYN clinic...
  • *Using the pharmacy or like a flyer. And it could say something like “frustrated with the trial and error of medications?”*
  • *In one of the social media groups...*
  • *Through My Health portal...*

• Those with a better patient-physician relationship preferred recruitment by their physician
Study Materials

• Both groups expressed concern over several baseline questions

• Several participants were not comfortable with all providers having access to [PGx] information

• Terminology: they preferred the use of “DNA” over “genetic” when referring to testing and “medication” over “medicine”

• Educational video
  • Preferred the use of a woman’s voice
  • Definitions for ultra-rapid and slow metabolizer status
# Recommendations

## Recruitment
- Utilize established trust between patients and their providers
- Conduct study outreach by posting in variety of locations
- MyHealthatVanderbilt

## Materials
- Add description to personal questions to help participants understand relevance
- Provide info on medications that are part of the test and address possible need for future testing

## Other
- Clarify how results will be provided and who will have access to them
Tutorial: Using Community Engagement Studios to Enhance Pharmacogenetic Study Design for Maximizing Enrollment of Diverse Children and Pregnant People

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Most pharmacogenetic research is conducted in adult, non-pregnant populations of European ancestry. Study of more diverse and special populations is necessary to validate findings and improve health equity. However, there are significant barriers to recruitment of diverse populations for genetic studies, such as mistrust of researchers due to a history of unethical research and ongoing social inequities. Engaging communities and understanding community members’ perspectives may help to overcome these barriers and improve research quality. Here, we highlight one method for engaging communities, the Community Engagement Studio (CES), a consultative session that allows researchers to obtain guidance and feedback based on community members’ lived experiences. We also provide an example of its use in pharmacogenetic studies. In designing a survey study of knowledge and attitudes around pharmacogenetic testing among children with chronic conditions and pregnant individuals, we sought input from diverse community stakeholders through CESs at Vanderbilt University Medical Center. We participated in two CESs with community stakeholders representing study target populations. Our goals were to learn specific concerns about pharmacogenetic testing and preferred recruitment strategies for these communities. Concerns were expressed about how genetic information would be used beyond the immediate study. Participants emphasized the importance of clarity and transparency in communication to overcome participation hesitancy and mistrust of the study team. Recruitment strategy recommendations ranged from informal notices posted in healthcare settings to provider referrals. The CES enabled us to modify our recruitment methods and research materials to better communicate with populations currently under-represented in pharmacogenetics research.
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- Jasmine Bell
- Leah Dunkel
- Devan Ray
- Community Experts
Comments or questions?