Eye-conic Approaches to Eye Health

July 13-14, 2022

A Virtual Interactive Event
Equitable Practices for Children’s Vision Research

Barbara E. Bierer MD
MRCT Center
Harvard Medical School
The Multi-Regional Clinical Trials Center (MRCT Center)

Our Vision

Improve the integrity, safety, and rigor of global clinical trials.

Our Mission

Engage diverse stakeholders to define emerging issues in global clinical trials and to create and implement ethical, actionable, and practical solutions.
Importance of diversity and inclusion in clinical research

• Analyses of group differences in outcome among diverse populations can promote identification of underlying biological and socially relevant factors that affect health, but only if data exist.

• Diversity in enrollment seeks fairness in the distribution of direct and long-term benefits of research.

• Diverse representation in clinical trials is not simply a matter of biology, but a matter of health equity and fairness.

• Participation helps build public trust in research and healthcare.
Diversity is multi-dimensional

- Race
- Ethnicity
- Sex
- Gender
- Children
- Elderly
- Disabled
- LGBTQIA+ ...

- Each dimension must be considered
- And each person, in their own unique individuality, needs to be considered
Children with vision disorders in clinical research

205 Studies found for: Vision Disorders | United States | Child

115 Studies in last 10 years
71 Studies in last 5 years
16 Studies with key word “Blindness”
Studies of children with vision disorders in clinical research

ClinicalTrials.gov
115 Studies in last 10 years

20 June 2022
Underappreciated: COVID-19 and pediatrics

United States: Number of COVID-19 Cases Added in Past Week for Children and Adults*

- Adult cases
- Child cases

- 2.6% child cases
- 25.1% child cases
- 13.8% child cases

[Link to report]

Underappreciated: COVID-19 and pediatrics

Case Data Available on 6/9/22

<table>
<thead>
<tr>
<th>Child population, 2019</th>
<th>Cumulative total cases (all ages)</th>
<th>Cumulative child cases</th>
<th>Cumulative percent children of total cases</th>
<th>Cases per 100,000 children</th>
</tr>
</thead>
<tbody>
<tr>
<td>75,266,842</td>
<td>71,733,195</td>
<td>13,541,153</td>
<td>18.9%</td>
<td>17990.9</td>
</tr>
</tbody>
</table>

Children deserve to be included in research.

Access to clinical trials, and to accessible clinical trials

Achieving Diversity, Inclusion, Equity In Clinical Research

https://mrctcenter.org/diversity-in-clinical-trials/
Barriers to inclusion at all levels

- Sponsors/Institutions/Sites/Regulators
- Investigators/Referring Physicians/Staff
- Patients/Advocates/Communities
- Data Collection/Data Analysis

It can be done
Patient and community engagement support diverse participation

- **Form Relationships**
  - Patient/community: leaders, advisors, and consultants.

- **Provide Training and Support**
  - Research priorities and questions

- **Identify Shared Goals**
  - Tailor study design and conduct

Study Question -> Study Design -> Data Collection -> Analysis Interpretation -> Dissemination

Trust and trustworthiness

Focus on Eye Health Summit: Eye-conic Approaches to Eye Health | July 13–14, 2022
Participation in any trial is a journey

- Trial access and knowledge
- End of study and communications
- Eligibility for the trial
- Trial costs and accommodation
- Trial accessibility
- Trial burden and operations

- Child
- Parent(s) or Guardian
- Caregiver
- Siblings and family
- Legally authorized representative
The challenge of participation

Benefit Risk

Benefit Risk

Privacy
Childcare
Travel
Trust
Lost work
Uncertainty
Discomfort
$$$

Focus on Eye Health Summit: Eye-conic Approaches to Eye Health | July 13–14, 2022
Clear communication is a shared responsibility

• The listener does not have “poor literacy,” and is not responsible for making sense of the information.
• The communicator is responsible for sharing information that is understandable to the listener.
• The listener should be comfortable communicating any lack of understanding.
• And it is a greater problem for individuals whose preferred language is other than English.

https://mrctcenter.org/health-literacy/
A Broad View of Health Literacy Components

• Plain language
• Numeracy
• Visualization
• Clear design
• Cultural considerations
• Interactive techniques
• Usability testing
Plain Language Across the Clinical Trial Life Cycle

DISCOVERY
- Awareness
- Outreach
- Engagement
- Education

RECRUITMENT
- Flyers
- Recruitment
- Adverts

CONSENT
- Consent
- Instructions
- Calendars

ON STUDY
- Medications
- Adverse Events
- Satisfaction

END OF STUDY
- Study results
- Transition to care
- Access
- Follow-up
Health literacy beyond the ICF

How to give yourself the study medicine
Panel A (Days 1-5) and Panel B (Days 6-10)

Study medicine
Each bottle holds 1 ml of active drug or placebo.

The study staff will tell you how much medicine to use each time (this is called your dose). Only give yourself the dose the study staff told you. Do not use all the medicine in the bottle.

The study staff will tell you how much to inject from each bottle.

Important safety information
- Refrigerate the kit box – Do not freeze.
- Only use each bottle 1 time.
- Use a new syringe and needle each time.
- Only uncap the bottles when you use them.

Steps to give yourself the study medicine
Get ready

1. Gather your supplies:
   - 2 syringes
   - 2 bottles of medicine
   - 2 alcohol swabs

2. Take out 2 bottles from the kit box and put the kit box back in the refrigerator.
   - Let the bottles sit on the counter for at least 15 minutes to get to room temperature.
   - Turn the bottles upside down and then right side up at least 3 times.

3. Wash your hands with soap and water.

https://mrctcenter.org/health-literacy/

Focus on Eye Health Summit: Eye-conic Approaches to Eye Health

Merck & Co., Inc. example with input from Health Literacy Media
In 20% (or 1 in 5) of patients, tumors got at least 30% smaller.
In 20% (or 1 in 5) of patients, tumors got at least 30% smaller.

In 80% (or 4 in 5) of patients, tumors did not get at least 30% smaller.
Use and Share Plain Language Information

- The MRCT Center Clinical Research Glossary provides plain language research information developed by and for participants.
- Now being expanded.

https://mrctcenter.org/clinical-research-glossary/
Promoting Clinical Research in Children

- The problem: Protection from research, not through research
- Shift in perspective: Protection by inclusion
- Global differences, such as:
  - Laws
  - Health care available
- Cultural differences
- Process differences
Promoting Clinical Research in Children

- Listening to children (and their parents)
  - How can we do that well?
  - How do you know if you have spoken to enough children?
  - Can one child speak for another?
  - Can anyone speak for “everyone”?
  - Consider a 7 year old versus a 17 year old.
Prioritize participant engagement

• Gap in accessible general information about clinical research for children
  • All materials were developed by young people and reviewed by young people’s advisory groups and international stakeholders.

https://mrctcenter.org/blog/resources/pediatric-research-informational-materials/
Resources for children

https://mrctcenter.org/blog/resources/covid-19-clinical-research-flyers/

Focus on Eye Health Summit: Eye-conic Approaches to Eye Health | July 13–14, 2022
Resources for children

https://www.youtube.com/watch?v=m8e0z-96QTU&t=6s

https://catalyst.harvard.edu/publications-documents/sophies-science-project-what-is-medical-research/?ref=true
We are all accountable

Current state

Inclusion

Equity

ACCOUNTABILITY

Journal Editors
Sponsors
IRBs/Ethics Committees
Funders
Regulatory Agencies
CROs
Participants, Advocates, Communities
Research Institutions & Sites
Healthcare Professionals
Investigators, Study Teams

Focus on Eye Health Summit: Eye-conic Approaches to Eye Health | July 13–14, 2022
We need your help

• How do we do this work and do it well?
• What is representativeness?
• What are successful strategies?
• How can we work together?
Thank you

Barbara E. Bierer, MD

bbierer@bwh.harvard.edu

http://MRCTcenter.org/