Findings: Perspectives from Community Providers
Rachel G. Greenberg, MD (Duke University)

April 5, 2016
Keep the following disclaimer slide unless you meet the following:

- You are exclusively presenting official CTTI Projects/Recs
- If multiple presenters, please include appropriate disclaimers for everyone.

*If you do not use the CTTI PowerPoint template, please continue to use our disclaimer.
Overview

- Issue
- Purpose
- Methods and Survey Topics
- Results
Issue

Despite legislation to stimulate pediatric drug development through clinical trials, children still remain relative therapeutic orphans.

# of registered clinical trials for adults exceeds the number for children by a factor of 10.

Community providers are essential to recruitment of pediatric patients.

Little is known regarding the specific barriers that prevent community pediatric providers from participating in and referring their patients to clinical trials.
Purpose

To describe factors influencing community providers’ awareness and willingness to refer their patients for pediatric clinical trials and the perceived barriers to serving as a site for pediatric clinical trials.
Methods

Instrument: Online survey administered through Qualtrics

Sampling: Convenience sample

Study Population:
- Community-based medical providers who provide care and treatment to children
  - Those with/without previous experience as investigators
  - Those with/without Peds ID/Peds Hospitalist training

Recruitment
- Professional network
- Recruitment firm
- AAP Sections

Data Collection Dates
- August and September, 2015
Survey Topics

Barriers to implementing pediatric AB drug trials

- Study implementation
- Ethics and Regulatory
- Parental concerns
- Parental and child logistics

Responses:
- Major barrier
- Moderate barrier
- Somewhat of a barrier
- Not a barrier
RESULTS
Community Providers (N=136)

- **Specialty**
  - Family Medicine (40%)
  - General Pediatrics (33%)
  - Peds Hospitalist (15%)
  - Peds ID (11%)

- **Experience:**
  - 83% in practice for >10 years
  - 12% had been an investigator for a pediatric drug trial
  - 38% had previously referred pediatric pts to a drug trial

- **Location:**
  - 17% in an academic medical center
  - 52% near an academic medical center (<30 min)
Patient Referral

38% had referred a pediatric patient to a clinical trial
- Of these, 52% referred to an AB trial

Of those who have not previously referred:
- 92% not aware of any drug trials to refer
- 77% interested in learning more about referring patients

Considerations when deciding to refer:
- Risks to patients, very important (93%)
- Benefits to patients, very important (88%)
- Distance to study site, very important (21%); somewhat important (65%)
- Time needed to discuss with parents, very important (36%); somewhat important (53%)
Barriers to Implementing AB trials:

**ALL** factors were considered barriers by the majority of providers

*Major, moderate, somewhat*
# Community provider perceptions of barriers to pediatric clinical trials

## Study Implementation

<table>
<thead>
<tr>
<th>Study Implementation</th>
<th>Not a barrier</th>
<th>Somewhat</th>
<th>Moderate</th>
<th>Major</th>
<th>N/A</th>
<th>Not sure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Obtaining funding for research costs</td>
<td>6.3</td>
<td>18.1</td>
<td>26.8</td>
<td>41.7</td>
<td>1.6</td>
<td>5.5</td>
</tr>
<tr>
<td>Initially training site staff in research</td>
<td>11.7</td>
<td>25.8</td>
<td>27.3</td>
<td>32.0</td>
<td>0.8</td>
<td>2.3</td>
</tr>
<tr>
<td>Reaching the required number of study patients</td>
<td>11.0</td>
<td>29.1</td>
<td>30.7</td>
<td>23.6</td>
<td>1.6</td>
<td>3.9</td>
</tr>
<tr>
<td>Having site staff for patient enrollment</td>
<td>17.3</td>
<td>22.8</td>
<td>26.0</td>
<td>31.5</td>
<td>0.8</td>
<td>1.6</td>
</tr>
<tr>
<td>Recruiting study patients from your practice</td>
<td>18.0</td>
<td>26.6</td>
<td>34.4</td>
<td>18.8</td>
<td>0.8</td>
<td>1.6</td>
</tr>
<tr>
<td>Impact on non-research clinical work flow</td>
<td>15.6</td>
<td>26.6</td>
<td>31.3</td>
<td>21.1</td>
<td>1.6</td>
<td>3.9</td>
</tr>
<tr>
<td>Length of patient study visits</td>
<td>23.0</td>
<td>27.8</td>
<td>34.9</td>
<td>9.5</td>
<td>2.4</td>
<td>2.4</td>
</tr>
<tr>
<td>Finding office space for administration</td>
<td>32.0</td>
<td>25.8</td>
<td>19.5</td>
<td>20.3</td>
<td>1.6</td>
<td>0.8</td>
</tr>
<tr>
<td>Frequency of patient study visits</td>
<td>31.5</td>
<td>26.0</td>
<td>26.0</td>
<td>12.6</td>
<td>2.4</td>
<td>1.6</td>
</tr>
<tr>
<td>Finding clinic space for patient study visits</td>
<td>35.2</td>
<td>25.0</td>
<td>20.3</td>
<td>15.6</td>
<td>2.4</td>
<td>1.6</td>
</tr>
</tbody>
</table>

## Ethical and Regulatory

<table>
<thead>
<tr>
<th>Ethical and Regulatory</th>
<th>Not a barrier</th>
<th>Somewhat</th>
<th>Moderate</th>
<th>Major</th>
<th>N/A</th>
<th>Not sure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preparing required regulatory documents</td>
<td>8.9</td>
<td>17.9</td>
<td>30.9</td>
<td>38.2</td>
<td>0.8</td>
<td>3.3</td>
</tr>
<tr>
<td>Addressing IRB questions and concerns</td>
<td>12.9</td>
<td>32.3</td>
<td>29.8</td>
<td>21.0</td>
<td>0.8</td>
<td>3.2</td>
</tr>
<tr>
<td>Obtaining parental consent</td>
<td>24.4</td>
<td>34.1</td>
<td>23.6</td>
<td>15.4</td>
<td>0.8</td>
<td>1.6</td>
</tr>
<tr>
<td>Obtaining child assent</td>
<td>23.6</td>
<td>42.3</td>
<td>20.3</td>
<td>8.9</td>
<td>2.4</td>
<td>2.4</td>
</tr>
</tbody>
</table>
Study Implementation

- Reflected on 10 factors; all considered barriers (major, moderate, somewhat) by majority

- Top five anticipated major barriers:
  - 42% Obtaining adequate funding to cover research costs
  - 32% Initially training site staff in research
  - 32% Having site staff available to assist with enrolling
  - 24% Reaching the required number of study patients
  - 21% Impact on non-research clinical work flow
# Community provider perceptions of barriers to pediatric clinical trials

<table>
<thead>
<tr>
<th>Parental Concerns</th>
<th>Not a barrier</th>
<th>Somewhat</th>
<th>Moderate</th>
<th>Major</th>
<th>N/A</th>
<th>Not sure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concerns about side effects of the drug</td>
<td>3.9</td>
<td>15.0</td>
<td>36.2</td>
<td>41.7</td>
<td>0</td>
<td>3.1</td>
</tr>
<tr>
<td>Concerns about the number of invasive procedures</td>
<td>3.9</td>
<td>17.3</td>
<td>36.2</td>
<td>39.4</td>
<td>0</td>
<td>3.1</td>
</tr>
<tr>
<td>Concerns about child taking a drug not previously tested in children</td>
<td>7.1</td>
<td>18.9</td>
<td>32.3</td>
<td>39.4</td>
<td>0</td>
<td>2.4</td>
</tr>
<tr>
<td>Concerns about the number of blood draws</td>
<td>5.5</td>
<td>21.3</td>
<td>43.3</td>
<td>25.2</td>
<td>0</td>
<td>4.7</td>
</tr>
<tr>
<td>Perception that the child will be at increased risk for physical harm</td>
<td>8.7</td>
<td>18.3</td>
<td>38.9</td>
<td>31.0</td>
<td>0</td>
<td>3.2</td>
</tr>
<tr>
<td>Perception of insufficient study benefits for child</td>
<td>8.7</td>
<td>31.5</td>
<td>31.5</td>
<td>25.2</td>
<td>0</td>
<td>3.1</td>
</tr>
<tr>
<td>Concerns about consent length and complexity</td>
<td>9.5</td>
<td>31.7</td>
<td>38.1</td>
<td>17.5</td>
<td>0</td>
<td>3.2</td>
</tr>
<tr>
<td>Concerns about being randomized to placebo</td>
<td>11.0</td>
<td>32.3</td>
<td>30.7</td>
<td>24.4</td>
<td>0</td>
<td>1.6</td>
</tr>
<tr>
<td>Concerns about blinding/not knowing what drug their child is taking</td>
<td>11.8</td>
<td>23.6</td>
<td>38.6</td>
<td>23.6</td>
<td>0</td>
<td>2.4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Parent and Child Logistics</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Parents’ work schedules</td>
<td>2.4</td>
<td>21.8</td>
<td>39.5</td>
<td>33.1</td>
<td>0</td>
<td>3.2</td>
</tr>
<tr>
<td>Children’s school schedules</td>
<td>6.4</td>
<td>26.4</td>
<td>39.2</td>
<td>26.4</td>
<td>0</td>
<td>1.6</td>
</tr>
<tr>
<td>Transportation difficulties for parents/children</td>
<td>7.9</td>
<td>30.2</td>
<td>37.3</td>
<td>23.0</td>
<td>0</td>
<td>1.6</td>
</tr>
<tr>
<td>Insufficient compensation for time and transportation costs</td>
<td>8.7</td>
<td>24.6</td>
<td>38.1</td>
<td>27.0</td>
<td>0</td>
<td>1.6</td>
</tr>
<tr>
<td>Childcare concerns</td>
<td>7.3</td>
<td>29.3</td>
<td>37.4</td>
<td>22.0</td>
<td>0</td>
<td>4.1</td>
</tr>
<tr>
<td>Length of study visits</td>
<td>14.5</td>
<td>25.0</td>
<td>41.9</td>
<td>15.3</td>
<td>0.8</td>
<td>2.4</td>
</tr>
</tbody>
</table>
Parental Concerns

- All nine factors considered barriers (major, moderate, somewhat) by the majority – a high percentage
- Top five major barriers:
  - 42% Concerns about the side effects of the drug
  - 39% Concerns about child taking a drug not previously tested in children
  - 39% Concerns about the number of invasive procedures
  - 31% Perception the child will be at an increased risk for physical harm
  - 25% Concern about the number of blood draws
All seven factors considered barriers (major, moderate, somewhat) by the majority

Top five *major* barriers:

- **33%** Parents’ work schedules
- **27%** Insufficient compensation for time and transportation costs
- **26%** Children’s school schedules
- **23%** Transportation difficulties for parents/children
- **22%** Childcare concerns
Effect of investigator experience on perceived barriers

- Study Implementation Barriers
- Ethics/Regulatory Barriers
- Parental Concerns Barriers
- Parental/Child Logistics Barriers
Effect of subspecialty on perception of potential barriers

No significant difference among any of the barriers between Peds ID/Peds Hospitalist vs. Gen Peds/Family Medicine
Experience as an investigator was associated with higher likelihood of classification of several potential issues as “not a barrier,” including:

- Obtaining adequate funding to cover research costs
  - Investigators: 3/14 (21%); non-investigators: 5/113 (4%); P=0.04)

- Perception of insufficient study benefits for the child
  - Investigators: 4/15 (27%); non-investigators: 7/112 (6%); P=0.02)
Discussion (2)

Referral by community providers to clinical trial centers is vital to ensuring clinical trial recruitment.

Targeting community sites has been shown to increase trial recruitment rates, particularly in minority/underserved populations.

Imperative to establish a trusting relationship between the principal investigator and community providers.
Reducing barriers likely requires a multifaceted approach, including:

- Improvements in compensation of sites so logistical challenges can be overcome
- Compensation for providers and the participants’ families widely variable
- Education: Most providers unaware of potential pediatric drug trials in progress
- Strategies to improve feasibility: mobile/web-based technology, master protocols
Thank you.

Rachel G. Greenberg, MD
Department of Pediatrics, Duke University
Duke Clinical Research Institute
rachel.greenberg@duke.edu