

Findings: Perspectives from Community Providers

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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

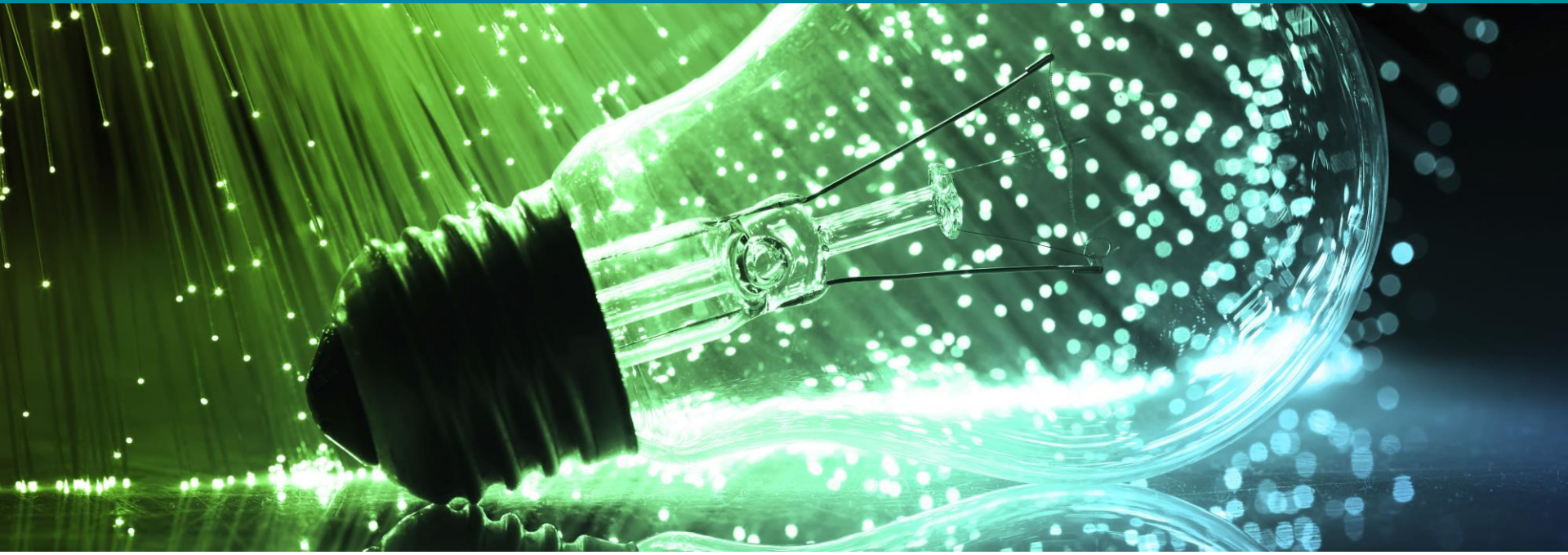
Responses:

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

Ethical and Regulatory

Preparing required regulatory documents	8.9	17.9	30.9	38.2	0.8	3.3
Addressing IRB questions and concerns	12.9	32.3	29.8	21.0	0.8	3.2
Obtaining parental consent	24.4	34.1	23.6	15.4	0.8	1.6
Obtaining child assent	23.6	42.3	20.3	8.9	2.4	2.4

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

Parental Concerns	Not a barrier	Somewhat	Moderate	Major	N/A	Not sure
Concerns about side effects of the drug	3.9	15.0	36.2	41.7	0	3.1
Concerns about the number of invasive procedures	3.9	17.3	36.2	39.4	0	3.1
Concerns about child taking a drug not previously tested in children	7.1	18.9	32.3	39.4	0	2.4
Concerns about the number of blood draws	5.5	21.3	43.3	25.2	0	4.7
Perception that the child will be at increased risk for physical harm	8.7	18.3	38.9	31.0	0	3.2
Perception of insufficient study benefits for child	8.7	31.5	31.5	25.2	0	3.1
Concerns about consent length and complexity	9.5	31.7	38.1	17.5	0	3.2
Concerns about being randomized to placebo	11.0	32.3	30.7	24.4	0	1.6
Concerns about blinding/not knowing what drug their child is taking	11.8	23.6	38.6	23.6	0	2.4
Parent and Child Logistics						
Parents' work schedules	2.4	21.8	39.5	33.1	0	3.2
Children's school schedules	6.4	26.4	39.2	26.4	0	1.6
Transportation difficulties for parents/children	7.9	30.2	37.3	23.0	0	1.6
Insufficient compensation for time and transportation costs	8.7	24.6	38.1	27.0	0	1.6
Childcare concerns	7.3	29.3	37.4	22.0	0	4.1
Length of study visits	14.5	25.0	41.9	15.3	0.8	2.4

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

Parent & Child Logistics

▶ All seven factors considered barriers (*major, moderate, somewhat*) by the majority

▶ Top five *major* barriers:

33%
Parents' work
schedules

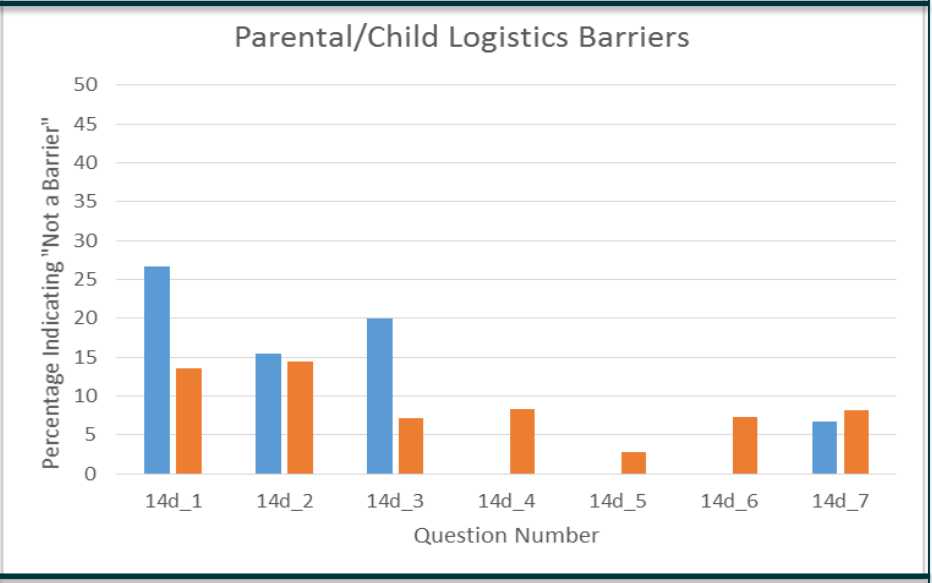
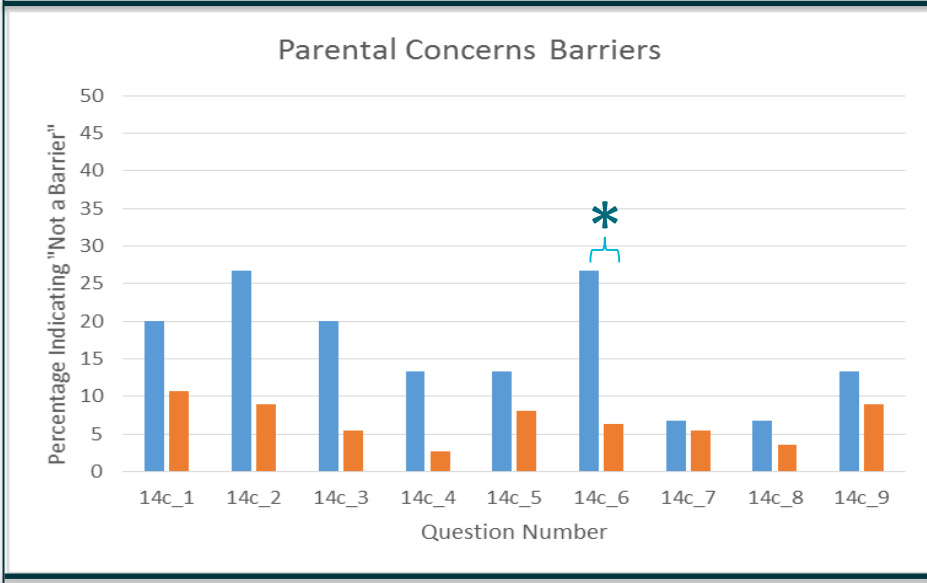
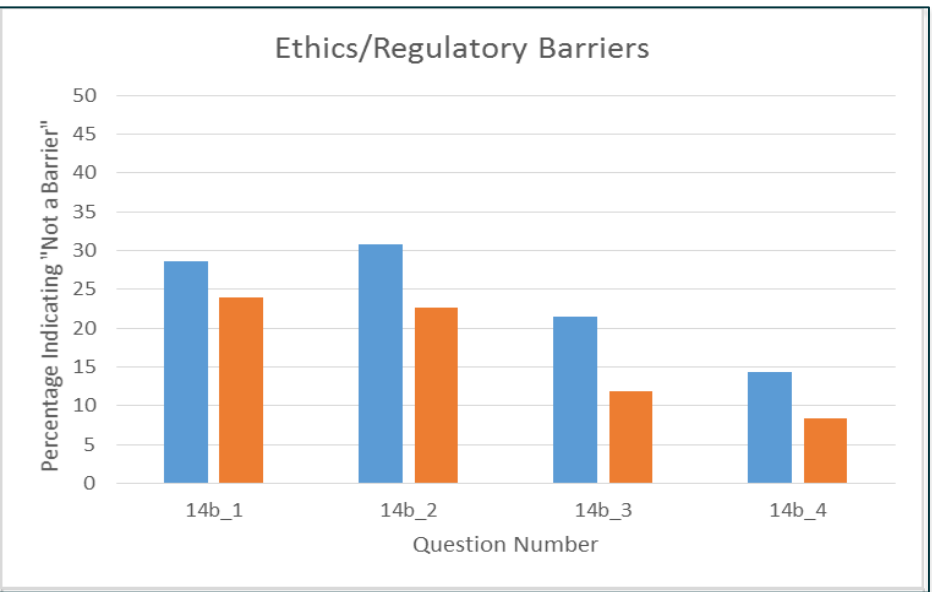
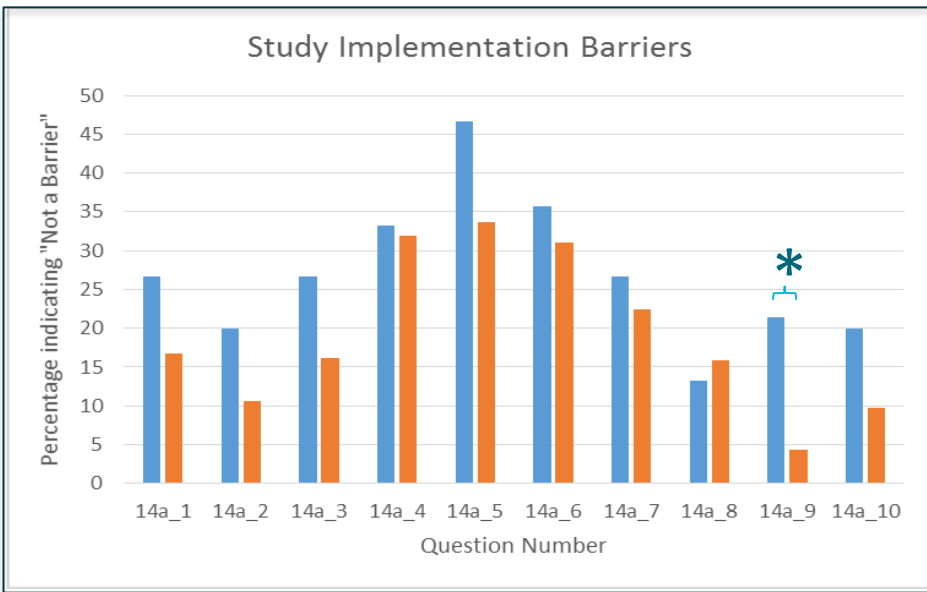
27%
Insufficient
compensation for
time and
transportation costs

26%
Children's school
schedules

23%
Transportation
difficulties for
parents/children

22%
Childcare concerns

Effect of investigator experience on perceived barriers



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

Discussion (1)

- ▶ 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

Discussion (3)

- 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.



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