Collaboration with Children and Families in Pediatric Clinical Research

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KIDS CT: Kids and Families Impacting Disease through Science  
iCAN: International Children’s Advisory Network
Patient Focused Drug Development

A systematic process to engage patients and gain their input and learn insights and knowledge about the clinical context of their disease*

*2012 US FDA Prescription Drug User Fee Act Fifth Reauthorization
Patient Engagement

What does it mean?
- To Patients/Caregivers/Advocates
- To Researchers and Doctors

Perceived Contributions and Value

Need Best Practice Guidance

Meaningful Engagement

Setting research priorities
Comparative effectiveness research program governance
Framing research questions/protocols
Peer review
Monitoring trials
Dissemination of results
At What Stage Can You Engage?

- Research question
- Study design
  - Process
  - Leaflets, consent/assent, other materials
- Study implementation
  - Recruitment
  - Retention
- Ongoing improvement/monitoring trials
- Dissemination of results

Or just.... Early and Often

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What is Gained by Talking to Kids?

Insight into readability/appropriateness of study materials

Creative ideas for drawing more interest/relevance

Insight into what children and families consider meaningful endpoints

Insight into the level of risk that children and families are willing to accept for a new molecule or device
What is Gained by Talking to Kids?

Insight into what a protocol would look like to a family

Understanding what aspects are scary or off-putting to kids

How much is too much? Blood draws, clinic visits, time at clinic...

-Improved overall child focus-
65% Recruitment 
58% Retention 

95% 
85%

iCAN - Who we are

Worldwide network
- 17 chapters
- 6 countries

Youth advisory groups
- Age 8-18 years
- Learn about science, health, medicine
- Give feedback to researchers, doctors, innovators

www.icanresearch.org
To improve pediatric healthcare by providing a platform for children and their families to provide input and feedback into study designs, treatment plans, and other elements important to the care of children.
Why Children Join

“I know what it’s like to be a kid”

“I want to learn more about research in children”

“I just want to help children with medical conditions and give input on how to make their medical experience better”

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Why I Joined

• Aisling’s story
• Learning about KIDS CT
What we Do

Locally
- Teach children about science, research, health, and advocacy
- Facilitate meetings between children and health professionals

Internationally
- Attend regional and national conferences
  - Survey participants
  - Speaking/panel opportunities for children
  - Present abstracts
- Virtual meetings with researchers
- Online surveys
- Annual Research & Advocacy Summit

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KIDS CT

• Visited Headzone (center for concussion rehabilitation)
• Visited the CCMC Motion Analysis Lab
• Helped test auto-injectors
• Spent a day at Pfizer Groton
• Worked with UCONN undergraduate students
• Spoken to Doctors, member of IRB, and a nurse scientist
Some of the Activities (2013-15)

- Provided feedback to an NIH-funded online educational tool aimed at teaching children about pediatric research. The resource plays out like a video game.

- Pediatric assent survey - designed to gain information about children’s and parents’ preferences for assent documents, especially which media would be most appropriate for children. iCAN presented those results at the 2015 Eastern Societies for Pediatric Research Meeting and the 2015 Pediatric Academic Societies Meeting.

- Connecticut chapter provided guidance to Nuffield Council on Bioethics to help develop a magazine version of their study titled “Involving Children and Young People in Health Research - Getting it Right” (available here: http://nuffieldbioethics.org/project/children-research/)

- Connecticut chapter piloted smartphone app for a nutrition study & provided feedback via online survey
More Examples (2015-16)

- Online survey to give feedback on a study design for a clinical trial of a therapeutic for influenza

- Online survey to give feedback on a storyline for a study gamification app which would be used in a pediatric clinical trial to increase retention

- Online focus group to help develop an online, interactive tool funded by the NIH aimed at educating children about pediatric research

- Connecticut chapter reviewed an assent template for a major pharmaceutical company and gave feedback on how to improve the document for their pediatric patients

- Kansas City chapter met with a medical IT company to do user testing on an electronic assent program and provide feedback from pediatric patients’ and families’ perspectives.
iCAN Launch and Research Summit

- June 2015
- A week-long conference held in Washington, DC, USA
- Brought together 130 young people and families from each chapter (current and in development)
- Interacted with regulators, pharma companies, bioethics, lobbyists, advocacy organizations, and more
2016 Research & Advocacy Summit

June 27 – July 1, 2016

Barcelona, Spain

With Sant Joan de Déu Hospital

150 youth members, parents

www.icanresearch.org
2017 Summit

• July 10-14th
• Orlando, Florida
• Confirmation for hotel
• Agenda drafted
• Speakers invited
How to Elicit Feedback

1. Allow for a lot of preparation time
2. Think about what you want to ask the children
3. Think about how you should ask
   a. In-person consultation/focus group
   b. Virtual focus group
   c. Online survey
   d. Email correspondence
4. Reach out to group leadership and revise your questions together
5. Act on the information you gained

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Tips

Respect the children’s time
- Consider their many activities and those of their families
- Make your “ask” very simple—only what you need to know

Make it interesting and educational

Make it engaging

The children are consultants/advisors, NOT research participants

Close the loop- how did it go? What did you change based on feedback?
Children wrote and conducted survey of participants

N = 188

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<th>Category</th>
<th>Percentage</th>
<th>Number</th>
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<tr>
<td>Medical providers</td>
<td>67%</td>
<td>125</td>
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<tr>
<td>Researchers</td>
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<tr>
<td>Other profession</td>
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<tr>
<td>Females</td>
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<tr>
<td>Caucasians</td>
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<tr>
<td>Mean range</td>
<td>36-50 years</td>
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BACKGROUND
- Parent and patient satisfaction
- Many obstacles to research collaboration
- Patients can be positive partners in research
- Lack of clear expectations for research participation

OBJECTIVE
- To explore factors affecting meaningful research collaboration between PCPs and pediatric researchers

METHODS
- 188-patient survey designed by members of the International Childhood Advisory Network (ICAN)
- Participants recruited via ICAN members and attending PCPs at ICAN meeting in April 2015

RESULTS
- Mean age: 36-50 years
- Caucasians: 57%
- Females: 58%
- Medical providers: 67%
- Researchers: 12%
- Other: 21%

CONCLUSIONS
- Most respondents agreed that children should have representation in healthcare research
- Most respondents had a positive experience with children, but for children, a positive experience is not always achieved
- Younger patients tend to have a more positive experience than children
- Children have been identified as an important group for future research
What challenges do you think researchers have the most trouble with?
What type of feedback from children do you think is MOST useful to researchers?
What outcomes would make it worthwhile to consult a children’s advisory group?

- Recruitment
- Assent comprehension
- Overall child focus
- Retention
- Quality
- Efficiency
- None of the above

Improved
For what reasons would you choose NOT to consult an advisory group of children?
Thank you!
Resources

Principles of Community Engagement:  

Medical Research Council Guidance on Consent and Information Sheets:  http://www.hra-decisiontools.org.uk/consent/examples.html


Patients as Partners Annual Conference:  http://theconferenceforum.org/conferences/patients-as-partners/agenda/
Patient Centered Outcomes Research Institute (PCORI): www.pcori.org

Center for Information & Survey on Clinical Research Participation (CISCRP): www.ciscrp.org

International Children’s Advisory Network (iCAN): www.icanresearch.org

European Patients’ Academy (EUPATI): www.eupati.eu

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