How to Determine Withdrawal of Pediatric Assent

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- NIH/NIAID Pediatric asthma and allergy based research, focused on understanding how the environment, allergens, and genetics interact with the body's immune system to cause asthma and aggravate it's symptoms.

- Two major questions:
  - Why do some kids get asthma
  - What is the best way to treat asthma; specifically in the inner city.

- Two IND Phase II trials, birth cohort, and recruitment registry.
- Active for almost 20 years at Boston University

Active Studies

MUPPITS-2

- Phase II, double blind placebo-controlled, trial of Mepolizumab in severe asthmatics.
- Ages 6-17, with 12 months of therapy (given by injection)

CRITICAL

- Phase II, double blind, placebo-controlled trial of cockroach immunotherapy in allergic children.
- Ages 8-14, with 2-3 years of therapy. (given by injection)

URECA IV

- Birth Cohort – children now 13-14
- Annual study visits with blood draws, spirometry, and AST

RACR-2

- Recruitment registry
- One time visit with blood draw, spirometry and AST

Pediatric Clinical Research

Opportunities:

- Able to gather crucial insight to a disease process throughout early life stages.
- Pediatric studies can lead to guidelines about the best way to treat common childhood diseases.
- Provide information on the safety and efficacy of a mediation/treatment in that population

Obstacles:

- Difficult to get parents/kids to participate at times.
- Ensuring a pediatric participant fully understands what is being asked of them.
- Procedures/tests may be uncomfortable

Pediatric Clinical Research Continued

"Most drugs prescribed for children have not been tested in children. Before the Food and Drug Administration initiated a pediatric program, only about 20 percent of drugs approved by the FDA were labeled for pediatric use. By necessity, doctors have routinely given drugs to children "off label", which means the drug has not been approved for use in children based on the demonstration of safety and efficacy in adequate, well controlled clinical trials."

(https://www.fda.gov/drugs/resourcesforyou/consumers/ucm143565.htm)

Today's Discussion

Will Review:

- The role of pediatric assent in ICAC studies.
- The difference between "Medically Necessary" treatments and research
- Subtle and not so subtle signs of assent withdrawal.
- Three case studies

Will NOT Review:

- State and Federal guidelines regarding the structure and content of assent.

The Role of Assent in ICAC:

- Conversation between the researcher(s) and pediatric participant.
- Topics include:
  - The purpose of our research
  - What we will ask the participant to do
  - What risks/benefits are involved
  - Their ability to say “no” or withdrawal at anytime
- Verbal assent: Ages 6-11
- Written assent: Ages 12-17
- Assent is written at an age appropriate level with language they can easily understand.

ICAC Research vs. Clinical Practice

ICAC Research

- Tests and procedures are being conducted to answer a question or gain more insight on a process.
- NOT medically necessary
- Participants have the option to say “No” to anything we ask them to do, and can withdrawal from the study at any time.

Clinical Practice

- Tests and procedures are done to help facilitate treatment and ultimately the health of the child.
- Medically necessary
- Children are often restrained in hospitals/clinics and emergency rooms to obtain the medically necessary tests.

Let's have the "Medically Necessary" talk:

- Discussion with Caretaker:
  - We can't restrain your child to collect the samples or complete the procedures we need.
  - We will work with both you and your child to make sure all parties are comfortable with what they are being asked to do.
  - This may make our visit last a little longer than normal, and may involve taking some breaks to "talk".
  - If we aren't able to collect the samples/complete the procedures we need to, we may reschedule the visit and give you a chance to talk with your son/daughter about their continued participation.
- Depending on age of participant, this discussion may involve the caretaker and participant or just caretaker.

So….. you've consented/assented, and talked about what Research vs. Medically Necessary

Now WHAT?

We attempt collection.....

You want me to do WHAT?!

Common ICAC Tests/Procedures pediatric participants are fearful of:

- Blood Draws
- Injections
- Allergy Skin Tests
- Nasal Wash
- Nasal Brushing

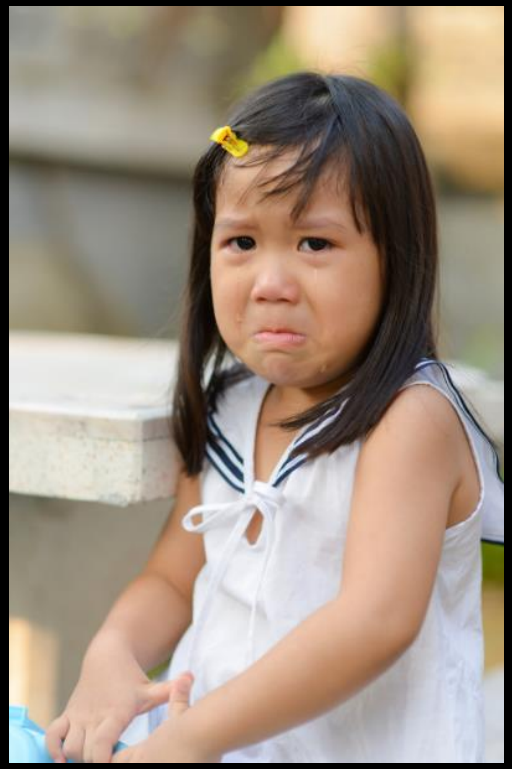
Expressing Fears to Tests/Procedures

Subtle Ways:

- I have to finish my snack first, go to the bathroom or get a drink
- I have a belly ache
- Can we do it tomorrow?
- Moving further away from the research team

Not so Subtle

- Crying
- Running away
- Hiding
- Fighting
- Fight/Flight



Is there a correlation between the child's reaction and your ability to successfully get past their fears?

No…. Not really.

The three step approach:

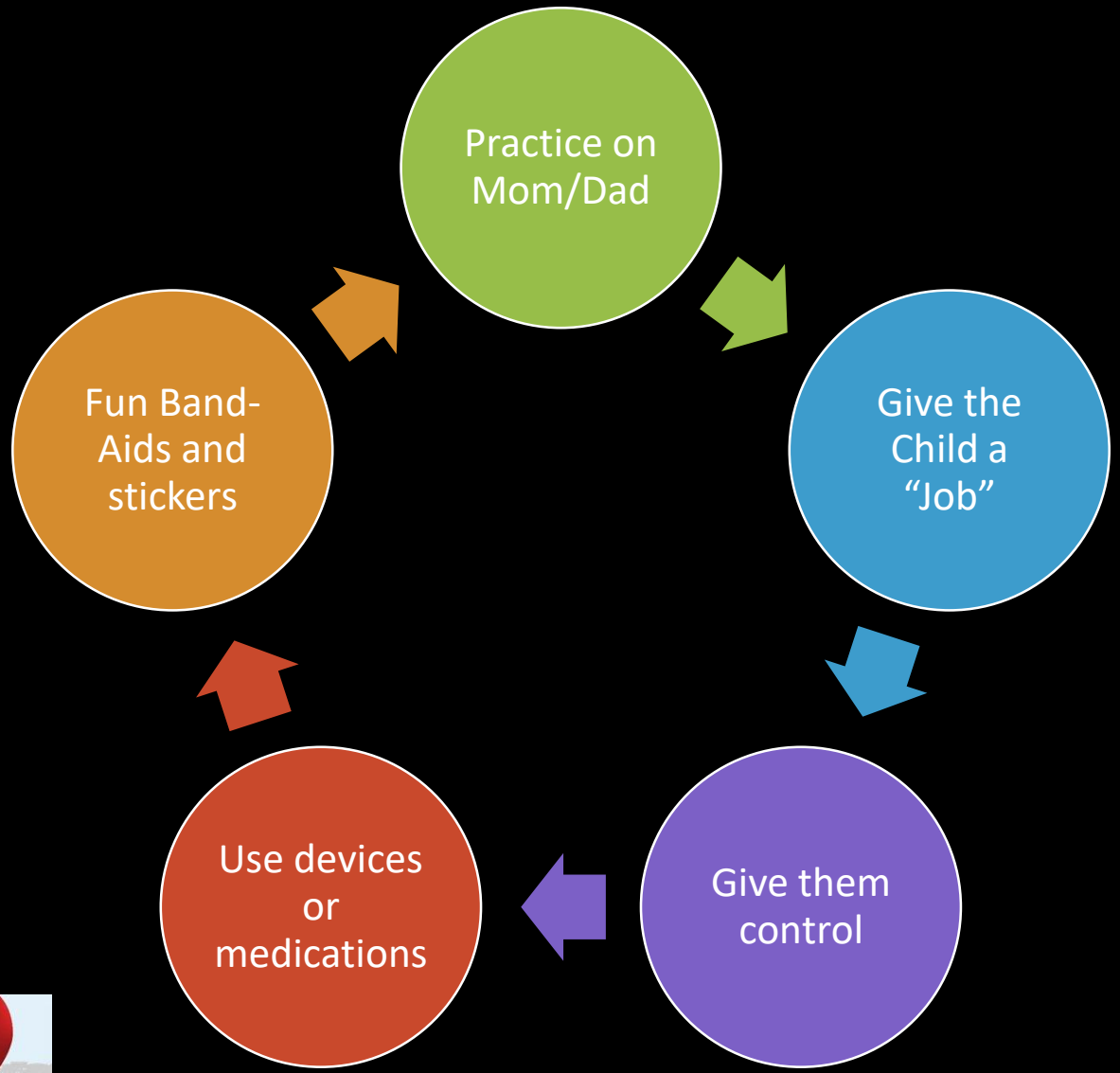
- Address Fear and Response
- Employ Methods to Ease Fears
- Reschedule as Necessary

Step #1: Address the Fear and Response

- What scares the child about the blood draw (pain, blood loss, etc?)
- How are they expressing this fear? (crocodile tears vs. flight response)

HINT: Crying is Ok.

Step 2: Easing Fears



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Step #3: Rescheduling

- Step 3 involves sending the family home with an option to return to clinic at a later date.
- We encourage the caretaker and participant to go home and talk about their fears, and whether or not they want to participate.
- The “give them time” method typically results in a 75% return rate AND we are most often successful the second time around.

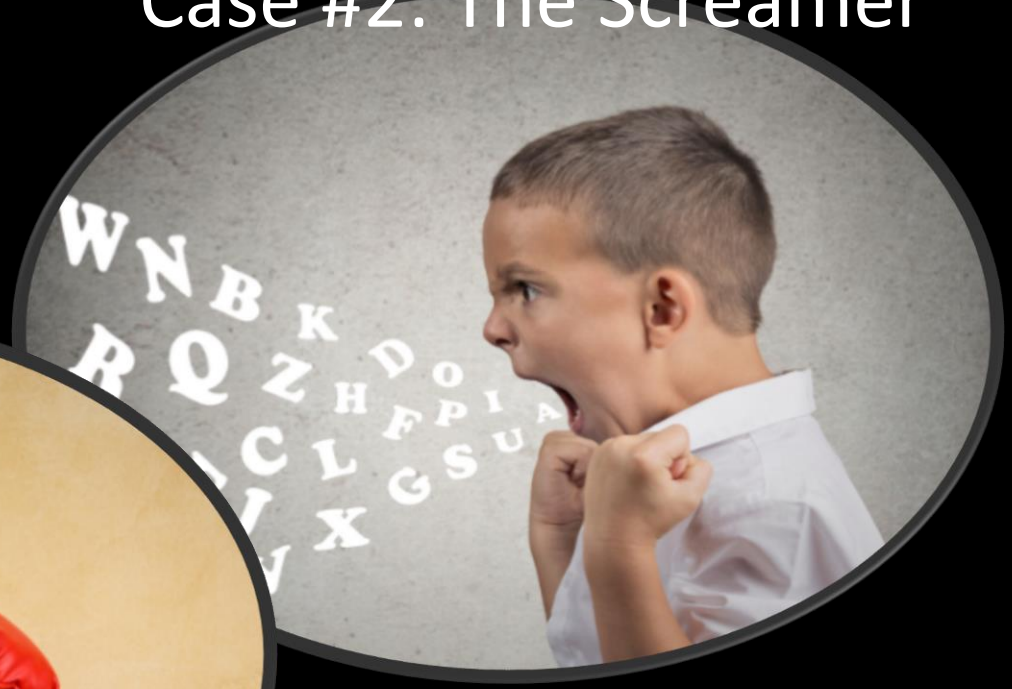
Step #3 Continued: When to no reschedule.

- If the participant seems genuinely scared of the researchers
- If the participants seems scared of the caretakers reaction to not completing the procedure.
- If the participant is unwilling to do basic tasks, such as height, weight and blood pressure.
- If the participant verbally indicates they do NOT want to come back.
- If something doesn't seem "right".

Three Case Studies:

Case #1: The Teenager

Case #2: The Screamer



Case #3: The Fighter

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Case Study #1: The Teenager

- 14 year old child
- RACR2 Study
- Consent/assent obtained and child had “no questions” and willingly signed assent.
- When study staff took participant outside the clinic room to obtain height/weight and vitals, the child said “I don’t’ want to participate” and that her “Mom was making her”. Wouldn’t take off shoes to allow us to obtain weight, and adamantly stated “I don’t want to”.

Case Study #1: Continued

- STAFF RESPONSE: After the conversation with the child about why she didn't want to participate. We stopped all research activities and met with PI/project manager to discuss best way to proceed.

- FINAL DETERMINATION: The visit was halted, and the family was sent home as we felt this was a clear withdrawal of assent. The family was still compensated for their time and effort the PI met with the mother to discuss our decision.

Case Study #2: The Screamer

- 10 year old child seen in clinic with caretaker for an injection study. Caretaker and participant consented/assented and both had good questions and demonstrated they understood what was being asked. As part of injection trial, the child was scheduled for three subcutaneous injections at each visit. Two in arm and one in thigh. Participant completed all other procedures, but was fearful of injections and cried and screamed at study staff during the initial injection visit. Mom asked study staff to restrain participant.

Case Study #2: Continued

- STAFF RESPONSE:
  - We talked with the CT about the difference between “medically necessary” and research, and our inability to restrain participants.
  - We then asked the participant to walk us through what he was scared of. He indicated that he was fearful that the injection would hurt, even with the numbing agents. We asked if he would like to try the numbing cream and BuzzyBee and made a deal that if it hurt after one that we would stop, and he could decide whether or not to continue.
  - We “practiced” what would be involved with the injection. An RA sat in a chair and pretended to be the participant, the nurse moved from arm to arm, then to leg showing each step.
  - The participant counted down from 3 each time during our practice session.

Case Study #2: Continued

- FINAL DETERMINATION:
  - The participant was able to get through all three injections with the addition of EMLA cream and BuzzyBee.
  - He counted down from 3 each time, and controlled the pace of the counting.
  - A note was made in his chart to ensure that each time hee was seen these methods were used.
  - He successfully completed 72 injections throughout the course of the study, and by the end felt confident in his ability to control his fears surrounding injections and blood draws.

Case Study #3: The Fighter

- A 7 year old child was enrolled into an injection study involving allergy skin testing, frequent blood draws, and monthly injections. Caretaker was consented and the participant was verbally assented. At the beginning of the visit, child was jovial, loved coloring with staff and playing games, and completed height/weight and vital signs easily. However, when it came time to draw blood, the child immediately started crying, screaming and fighting with Mom. Mother noted the child did this often with needles and asked if we could restrain.

Case Study #3: Continued

- STAFF RESPONSE:
  - We talked with the CT about the difference between “medically necessary” and research, and our inability to restrain participants.
  - We talked with the participant to better understand her fear of needles. Not only was she scared it would hurt, but he was also scared we would “take all her blood during the blood draw”.
  - We made a deal to use EMLA and BuzzyBee, and we practiced drawing blood on a teddy bear to show her what the process involved.
  - We also explained to her that her body had LOTS of blood and showed her the tubes we were collecting and reinforced that it was a small amount and that her body would make more.
  - We reminded him that she could say “No” at anytime.

Case Study #3 Continued

- FINAL DETERMINATION:

Despite all our best efforts we were not able to convince the child to allow us to draw blood that day. We made a decision to send the child home and tentatively reschedule the visit. The Caretaker and child and the opportunity to talk at home, and agreed to a second screening. During the second screening the child was able to get through the blood draw (with crocodile tears), and felt empowered after. The child continued to have crocodile tears with every blood draw, but has gradually improved over time, and has stated multiple times how much she loves participating in research.

In Conclusion

“Rather than avoiding pediatric research because of the challenges, experts say it's more important to build the foundation and resources needed to conduct the studies. Without them, children face significant risks.”

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Questions?