

PCORI (PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE)
AND PATIENT-ENGAGED RESEARCH WITH DECISIONALLY
IMPAIRED PEOPLE

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#7 2023 IRB Member Retreat

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Vision: Patients and the public have information they can use to make decisions that reflect their desired health outcomes

Mission: PCORI helps people make informed healthcare decisions, and improves healthcare delivery and outcomes, by producing and promoting high-integrity, evidence-based information that comes from research *guided by patients, caregivers, and the broader healthcare community*

New priority: PCORI's 2019 reauthorizing legislation specifies **intellectual and developmental disabilities (IDD)** as a research priority



Priority populations:

Underrepresented racial and ethnic groups

Low-income groups

Women

Children (ages 0 to 17 years)

Older adults (ages 65 years and older)

Residents of rural areas

Individuals with special healthcare needs or disabilities

Individuals with multiple chronic diseases

Individuals with rare diseases

Individuals whose genetic makeup affects their medical outcomes

Patients with low health literacy or numeracy or limited English

Gender and sexual minorities

Veterans and members of the US Armed Forces and their families

Do you think we should engage and recruit
possibly decisionally impaired people?

Honoring the Diversity of People Living in Oregon

To advance health equity, the Oregon Health Authority (OHA) established a strategic goal to eliminate health inequities by 2030. A critical component to meeting this goal is ensuring meaningful access to services for everyone in Oregon, regardless of:

- Their race, ethnicity, language or disability (REALD); or
- Their sexual orientation or gender identity (SOGI).

REALD and SOGI both help to reveal the diversity of the people living in Oregon. This helps us:

- Identify and address health disparities, and
- Support data justice in communities most affected by health disparities.



At AcademyHealth in June,
Marjorie McGee said, 'Data is a catalyst for social justice'

THESE ARE THE PEOPLE I'VE WORKED WITH

Adults with

- Autism
- IDD
- Psychiatric crisis care users
- ASL users
- Disabilities of all types

Children with

- Autism
- Mental health conditions
- IDD

THERE WAS ONE EVENT EXAMINED FOR ADVERSE CONSEQUENCES



Have you experienced adverse events
or positive feedback
from your projects that recruit
possibly decisionally impaired people?

NEXT UP: THREE ISSUES FROM OUR CURRENT WORK

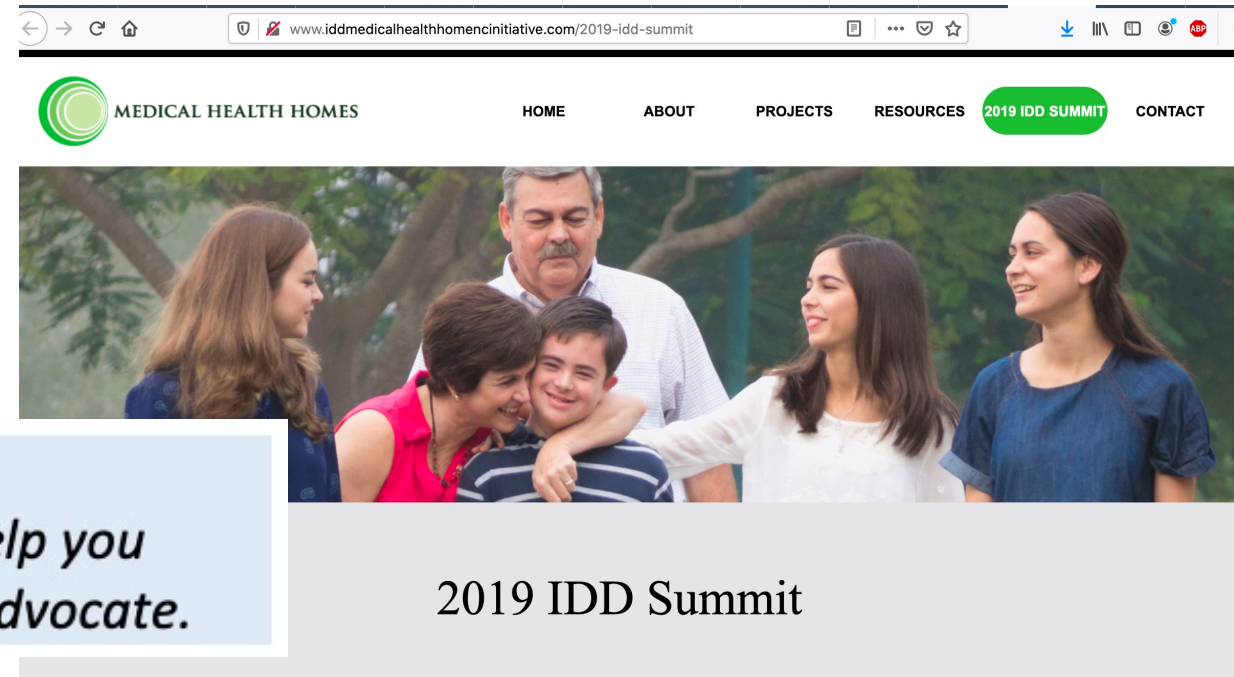
1. PCORI's mission to fund better research
2. Inherent challenges to pushing the envelope
3. Strategies to address those challenges

INFORMED CONSENT/ASSENT IN POSSIBLY DECISIONALLY IMPAIRED PEOPLE

Mission: PCORI is particularly interested in including previously understudied and hard-to-reach populations for whom effectiveness information is especially needed

Parent: He is still [in his 20's] aggressive sometimes...but, for the most part, he's very remorseful very quickly...it's just a very difficult path with a special needs child.

Parent: You need guidance to some degree...somebody that could maybe help you start to think about when you start to advocate.



INFORMED CONSENT/ASSENT IN POSSIBLY DECISIONALLY IMPAIRED PEOPLE

Challenges:

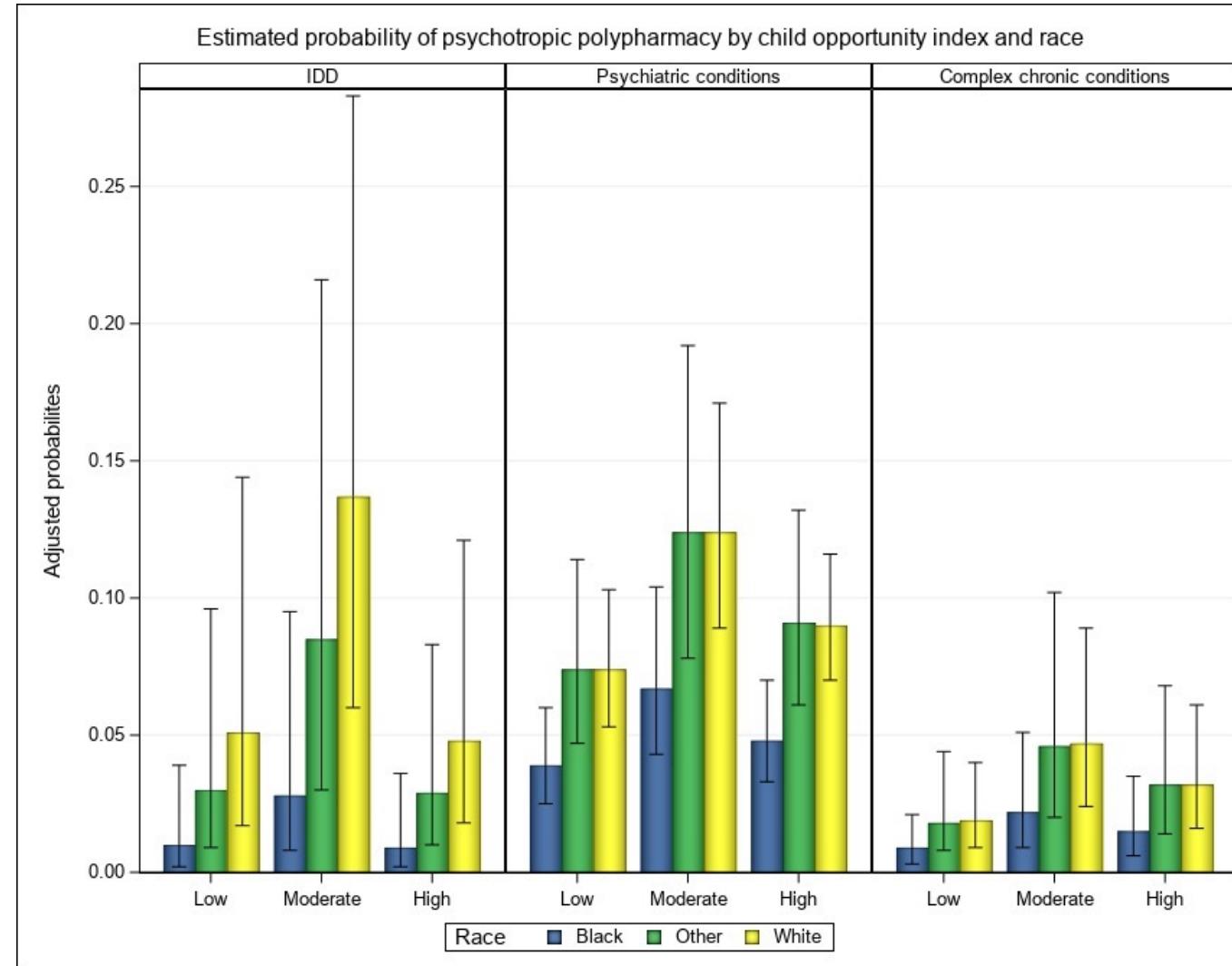
- Youth may have limited language
- Youth may be highly literate with limited conceptual capacity

Strategies to address them:

- Obtain informed consent/assent from youth with the capacity to give it
- Get parent reports on youth functioning, 'triangulate' measurement
- Involve youth in nonverbal/visual activities

REPRESENTATIVE RECRUITMENT IN POSSIBLY DECISIONALLY IMPAIRED PEOPLE

Mission: Comparisons should examine the impact of the strategies in various subpopulations, with attention to the possibility that the strategy's effects might differ across subpopulations



REPRESENTATIVE RECRUITMENT IN POSSIBLY DECISIONALLY IMPAIRED PEOPLE

Challenges:

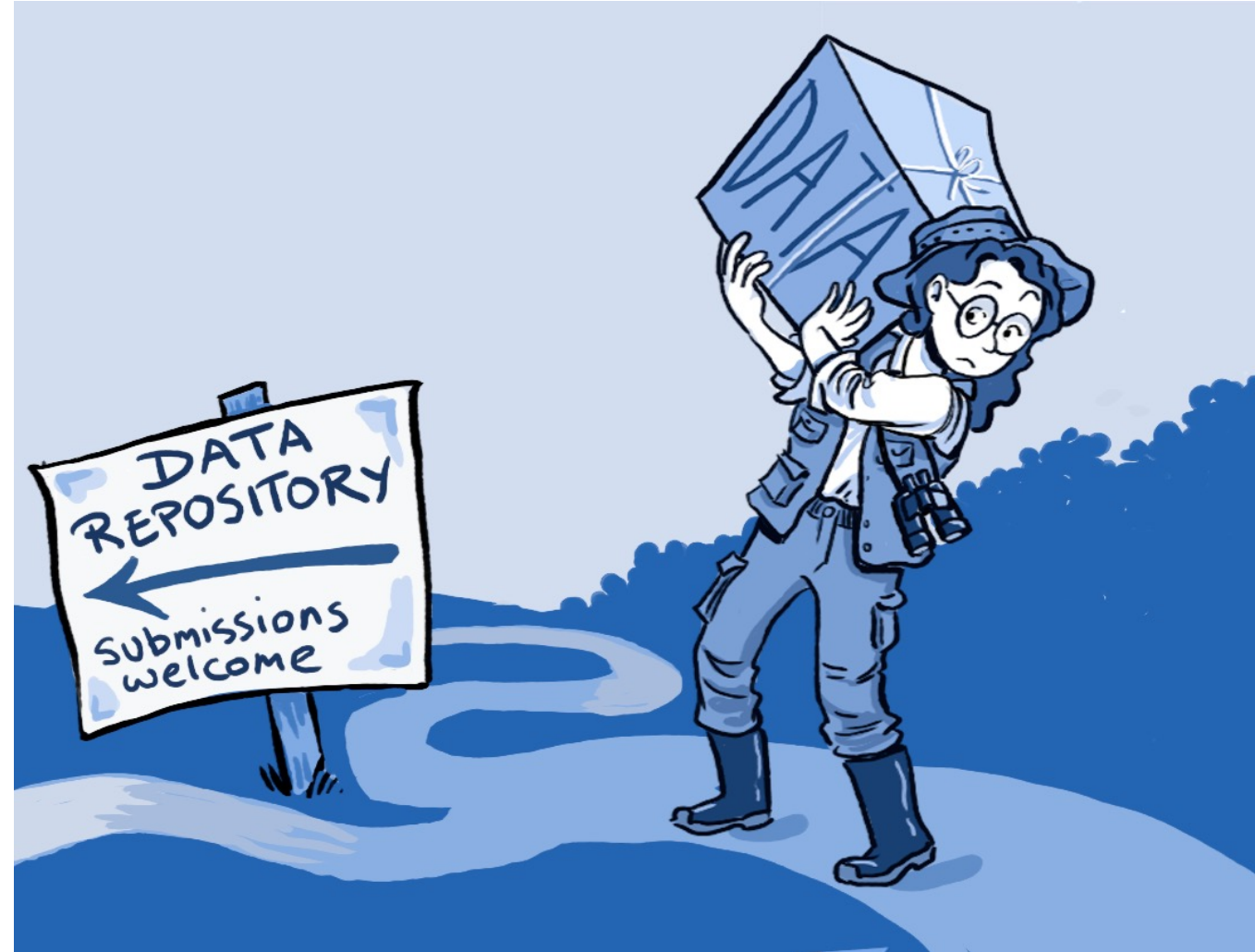
- It's hard to recruit youth with IDD and their busy families
- When youth have severe impairment, families don't have time to sit around and talk
- Some families mistrust doctors, research, us
- It's hard to recruit youth with IDD and their busy families

Strategies to address them:

- Make learning about the project convenient
- Explain why family advisors believe this might be helpful
- Compare clinic and recruited populations

DATA SHARING IN POSSIBLY DECISIONALLY IMPAIRED PEOPLE

Mission: PCORI is committed to publishing and disseminating all information and materials developed using PCORI funding, in accordance with its authorizing legislation. All recipients of PCORI contracts must agree to these principles and take steps to facilitate data availability.



Roche DG et al., 2014

DATA SHARING IN POSSIBLY DECISIONALLY IMPAIRED PEOPLE

Challenges:

- Emerging science on how to preserve confidentiality
- Emerging science on how to assess success in deidentifying a dataset
- Unknown how to do this in small, unusual datasets

Strategies to address them:

- Remove variables or observations
- Impute 'slightly off' values

Are these strategies adequate?

WHERE IS THE BALANCE BETWEEN RISK AND BENEFIT?

OHRE considers
psychological,
social, economic,
legal and
physical risk



PCORI funds
comparative
effectiveness
research to
address a
question
important to
stakeholders

WE NEED A COMMON LANGUAGE TO DISCUSS RISK AND BENEFIT

Where is the common ground?

- Sneaky awful drug trials vs stakeholder-engaged research on peer group interventions

What is a common language we can use?

- Risk of harm vs What does participation entail?



This is what parents said about working together

- 1. We have learned that parent voices can be heard and can help professionals improve access to others*
- 2. They asked outstanding questions and listened intently to our answers*
- 3. Very good listening, and incorporating ideas and suggestions*

Padres efectivos: a short film

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possibly decisionally impaired people?



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