

# ESETT Post-Enrollment Survey

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# Rationale

- Understanding the experiences and views of patients and surrogates in EFIC trials is important
- Prior studies have limitations
  - Small sample sizes
  - Selection bias
  - Recall bias (long delay from enrollment to interview)
  - Often involve only adults
- Integrating a simple survey into ESETT addresses many of these limitations

# Methods

- Integrated survey in ESETT
- Administered in paper and pencil form to all ESETT enrollees or surrogate after enrollment.
- 10-item survey adapted from PEER, PEER-ProTECT, and ProTECT CC studies
- Primarily descriptive analysis

# Participants

Demographics		Total
Sample size		317*
Patient age, n (%)	Surrogates for minors	151 (48)
	Adult patients	48 (15)
	Surrogates for adults	118 (37)
Patient gender, n (%)	Female	135 (43)
Patient race, n (%)	White	135 (43)
	Black	133 (40)
	Other	21 (7)
	Unknown/Missing	28 (9)

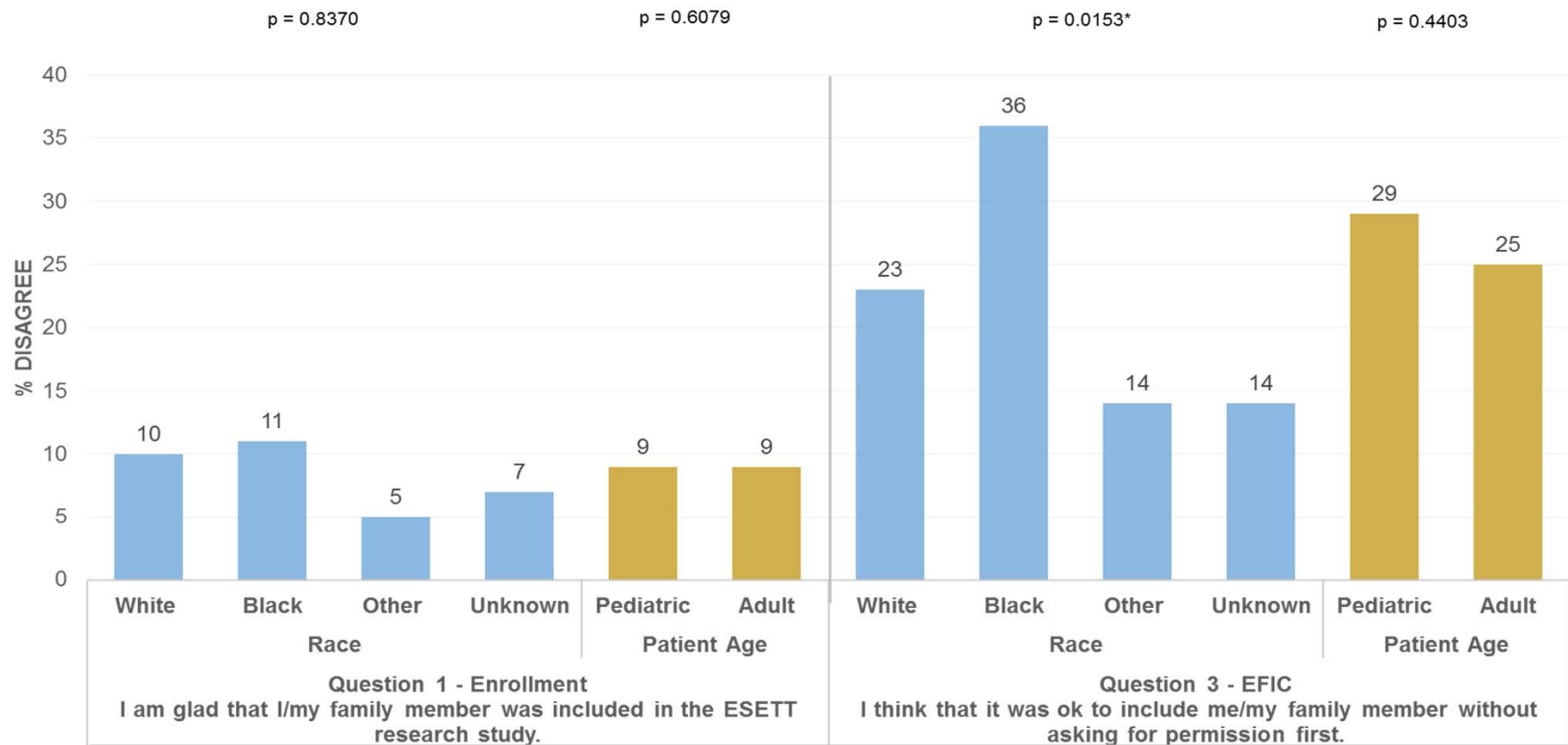
\* Response Rate 72% (317/440)

# Attitudes Toward Enrollment (n=317)

Acceptance of Enrollment	Agree n (%)	Neutral n (%)	Disagree n (%)
1 - I am glad that I/my family member was included in the ESETT research study.*	241 (76)	45 (14)	30 (10)
2 - I think that it was ok for researchers to include me/my family member in the ESETT research study when I/he/she was having the seizure.	245 (77)	31 (10)	41 (13)
3 - I think that it was ok to include me/my family member without asking for permission first.**	173 (55)	56 (18)	86 (27)
4 - I was told about the ESETT study at the appropriate time.**	231 (73)	40 (13)	44 (14)
5 - The research team treated me (and my family member) respectfully by asking for my permission to keep me/him/her in the ESETT study.	281 (89)	10 (3)	26 (8)

\* 1 missing response      \*\* 2 missing responses

# Impact of Race and Pediatric Status



# Views on Community Consultation

Public Disclosure and Community Consultation	n (%)
Had you heard of the ESETT study before you/your family member was enrolled?	14 (4)
In the ESETT study that you/your family member was included in, which groups of people do you think researchers should have talked to in order to get their thoughts about the study before the study started? (Choose all that apply)	
Patients who have had seizures	255 (80)
Family members of patients who have had seizures	205 (65)
Patients who may be likely to experience seizures (such as patients who have had a stroke or head injury)	160 (51)
Members of the general public	83 (26)
Religious leaders	31 (10)
Other specific groups***	26 (8)
Politicians	21 (7)
Other community leaders***	15 (5)

# Key Findings

- Acceptance rates of enrollment similar to prior work
  - Less disagreement with enrollment in general (10%) than when prompted specifically about enrollment under EFIC (27%)
  - Research on post-enrollment communication may be valuable
- Similar responses among pediatric and adult surrogates, but increased sensitivity to consent specifically among African-Americans
- Low enthusiasm for consultation focusing on general public, emphasis on individuals with connections to the condition/study
  - Unclear value of "population-based" efforts



# Limitations

- Single study
- Relatively low morbidity and mortality
- Still some potential for selection bias

# Acknowledgments

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