

BACKGROUND

- In the U.S. lifespan autism-related expenditures range from \$1.4M to \$2.4M.
- Early intervention and treatment can significantly improve a child's function and clinical outcomes.
- State-of-the-art diagnostic tools are subjective and require highly trained clinicians, significant administration time, and substantial interpretation.
- Diagnostic tools can be used from 18 months, but their accuracy depends on a child's social and language engagement and improves with age.
- Long wait times for psychological assessments delay diagnosis, limiting access to early interventions.

Cell-El is developing an innovative blood-based diagnostic assay to aid in the early identification of ASD in children who present with early signs or elevated risk factors.

OBJECTIVES

To determine the willingness of parents to use and pay for an objective, serum-protein biomarker-based test that can differentiate between ASD and typically developing (TD) children that potentially results in earlier intervention.

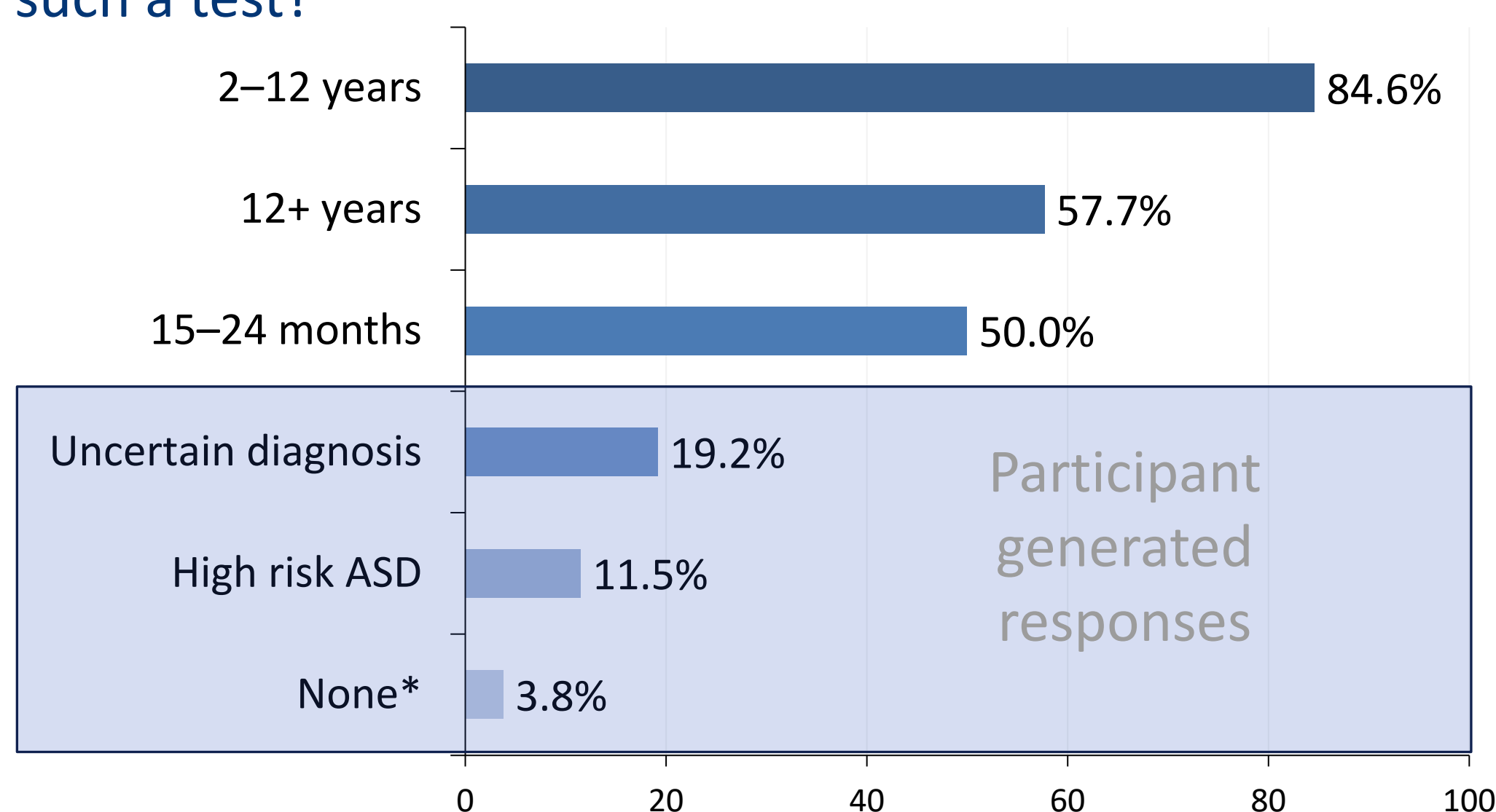
METHODS

A 12-item survey was developed by a multidisciplinary team comprised of a clinical expert, a health economist, a diagnostics specialist and a parent of an ASD child. The survey combined 6 multiple-choice questions, with multiple response options where appropriate, and 6 free-text fields for explanatory comments. A link to the online English survey was sent out via WhatsApp, Facebook, and other social media platforms to parents of children with ASD. A total of 26 respondents participated.

RESULTS

Diagnostic Test To Differentiate Between Children With ASD And TD Children

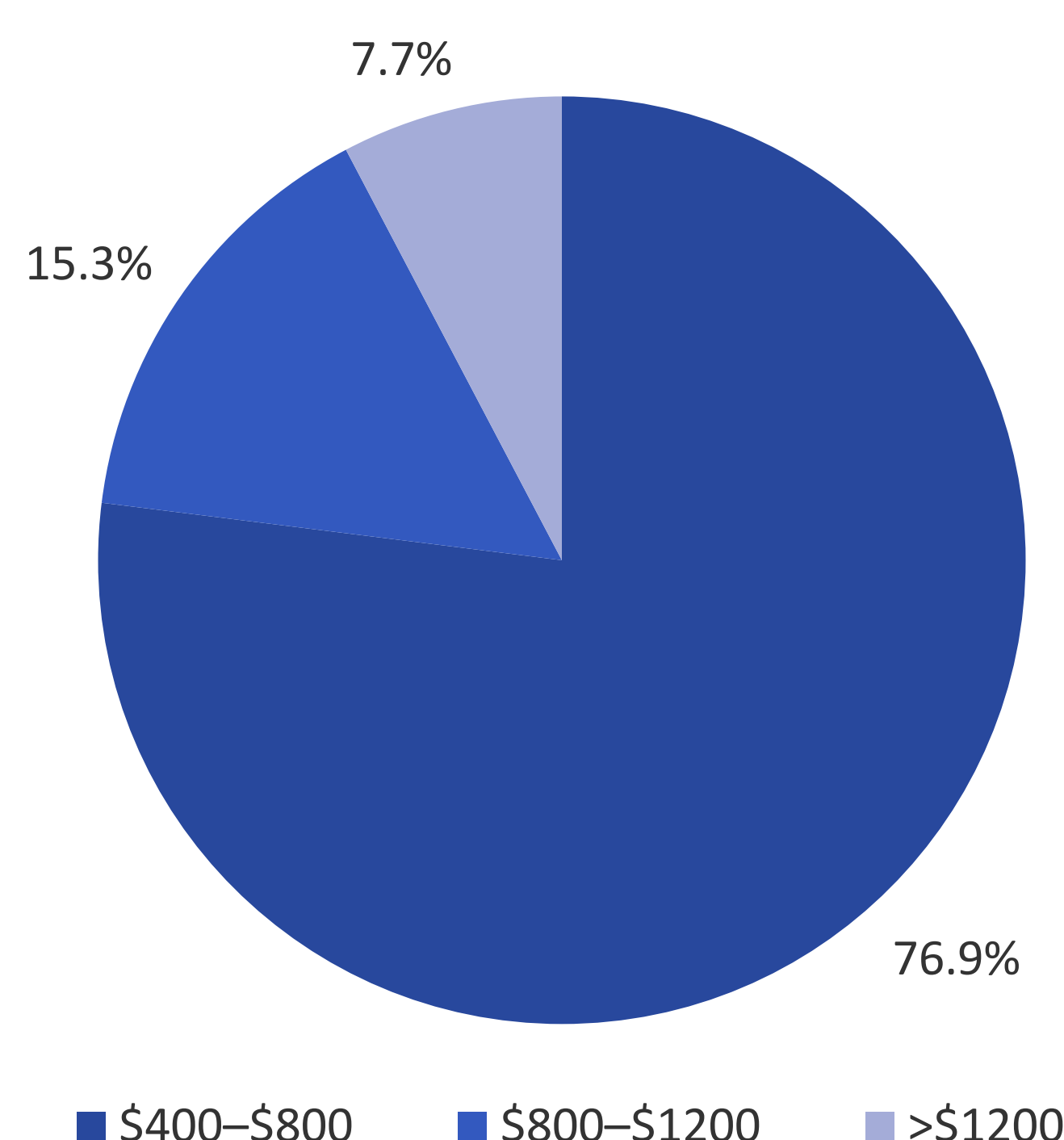
For children of which age would you as a parent use such a test?



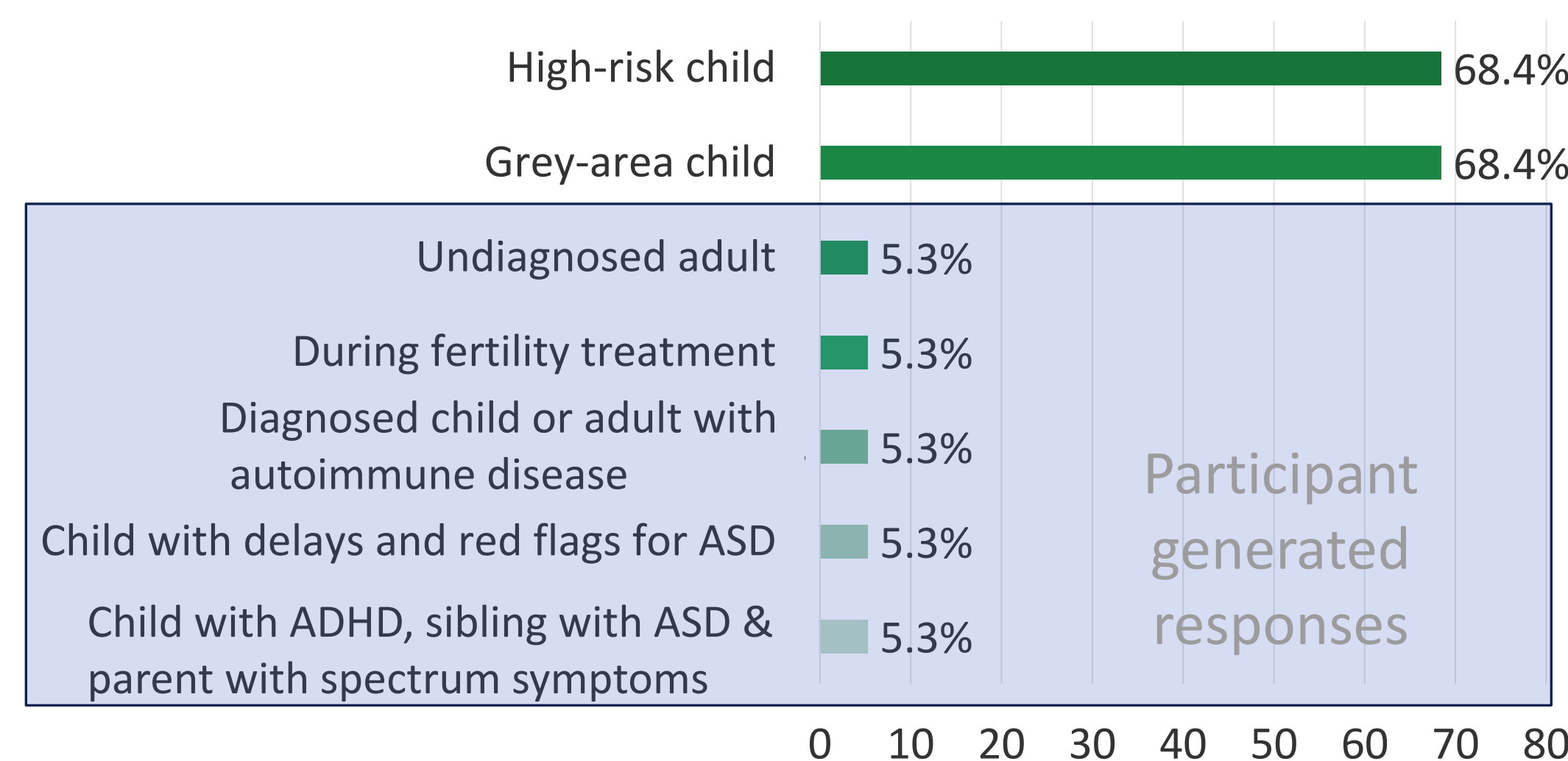
Comments provided by participants:

- Siblings are especially worrisome and often kids have an unclear diagnosis.
- Knowledge of the diagnosis can help with treatment methods.
- Early intervention. Rates of autism on the rise.
- Having a tool which provides a biological perspective would allow us to have a clearer and certain diagnostic.
- I don't think there is a point when the blood test is not recognized as a valid way to diagnose.*

How much would you pay out of pocket for such a test?



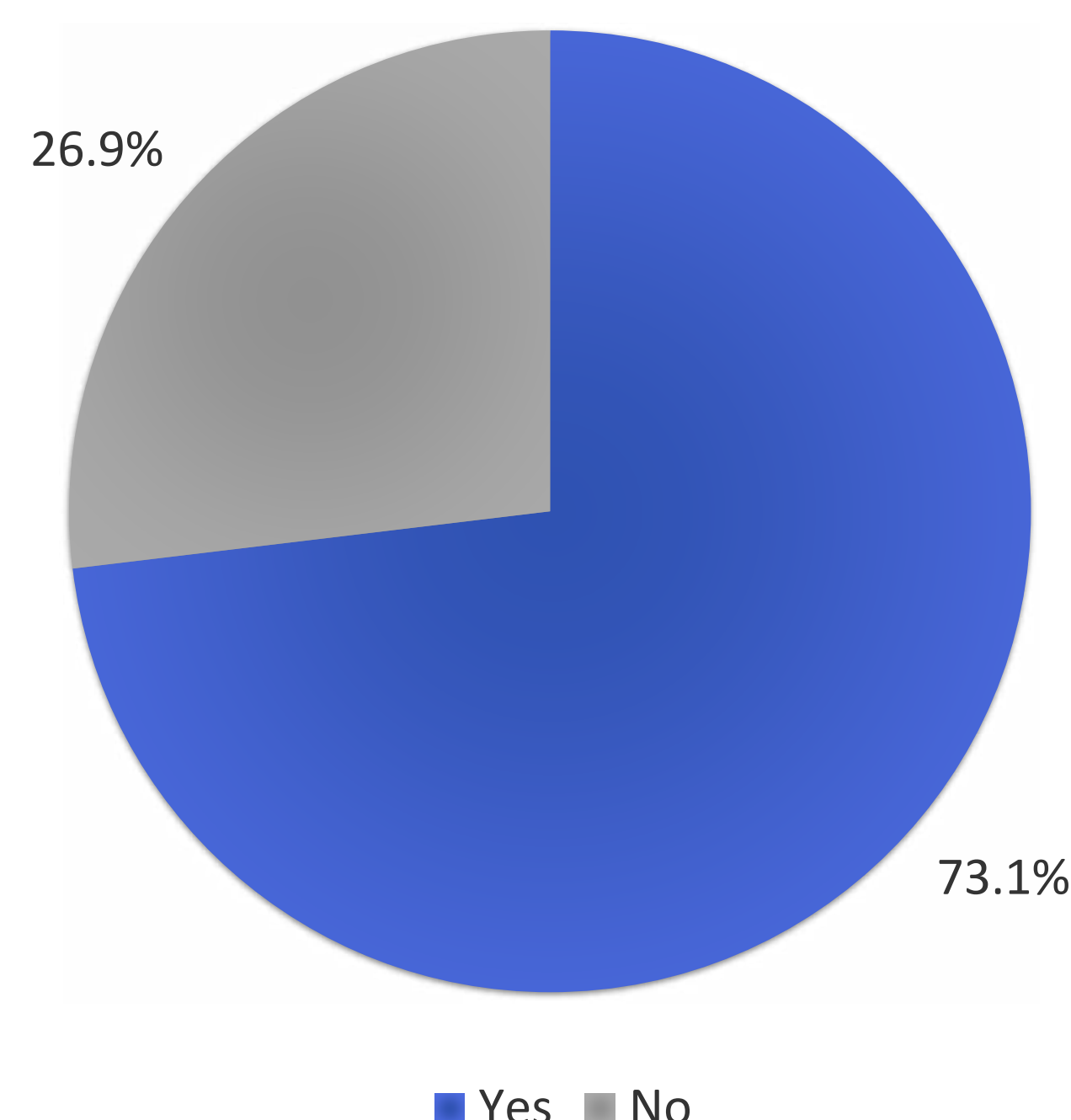
For which type of children would you as a parent use such a test?



Comments provided by participants:

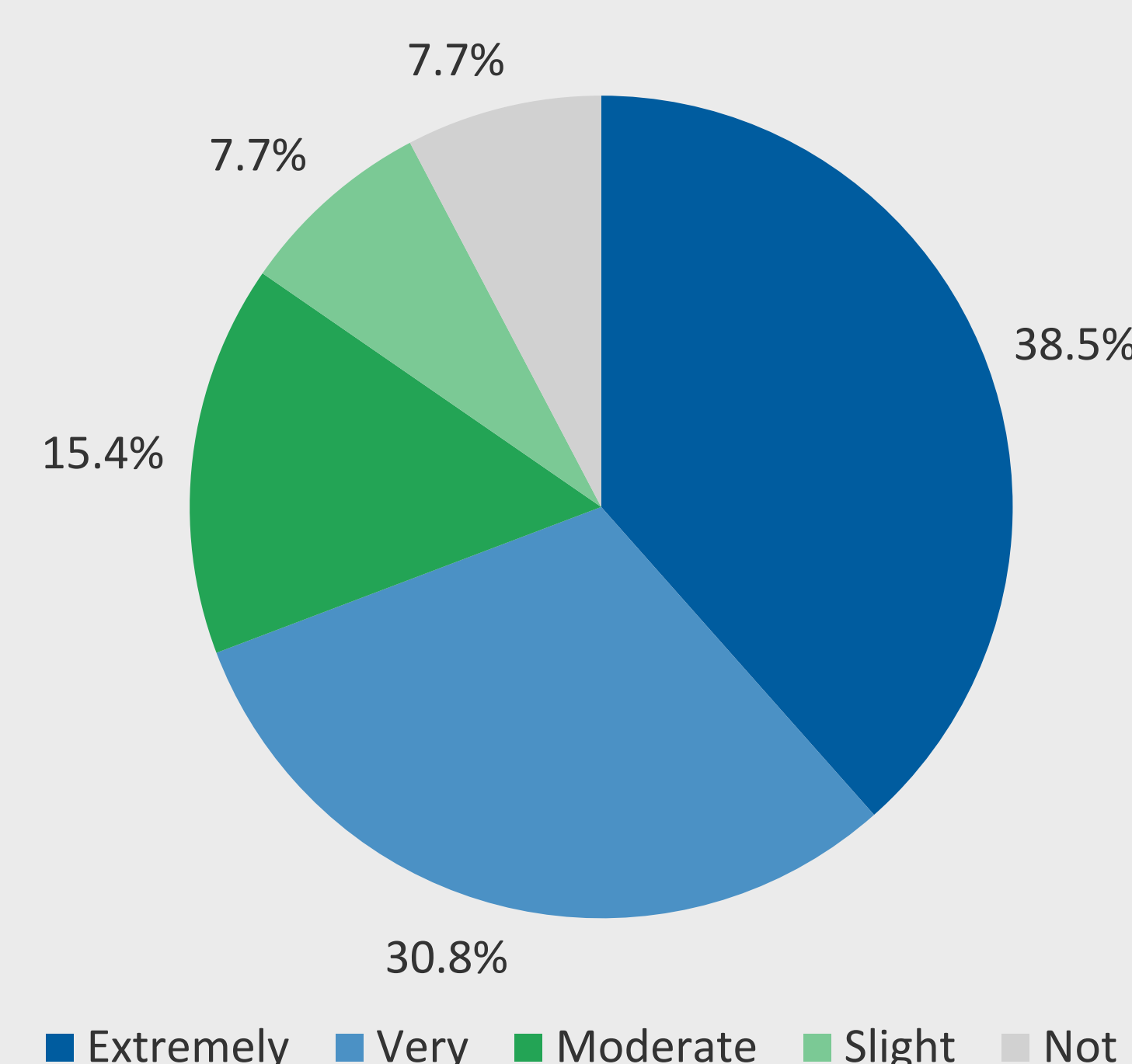
- My son had red flags after one year and three months like that. I think that test would have benefited him. When I think of it now.
- Deciding to have more children and early intervention is everything.
- Maybe for a child who I felt was autistic, but professionals disagreed.

Would you be more likely to use this test if your physician recommended it?

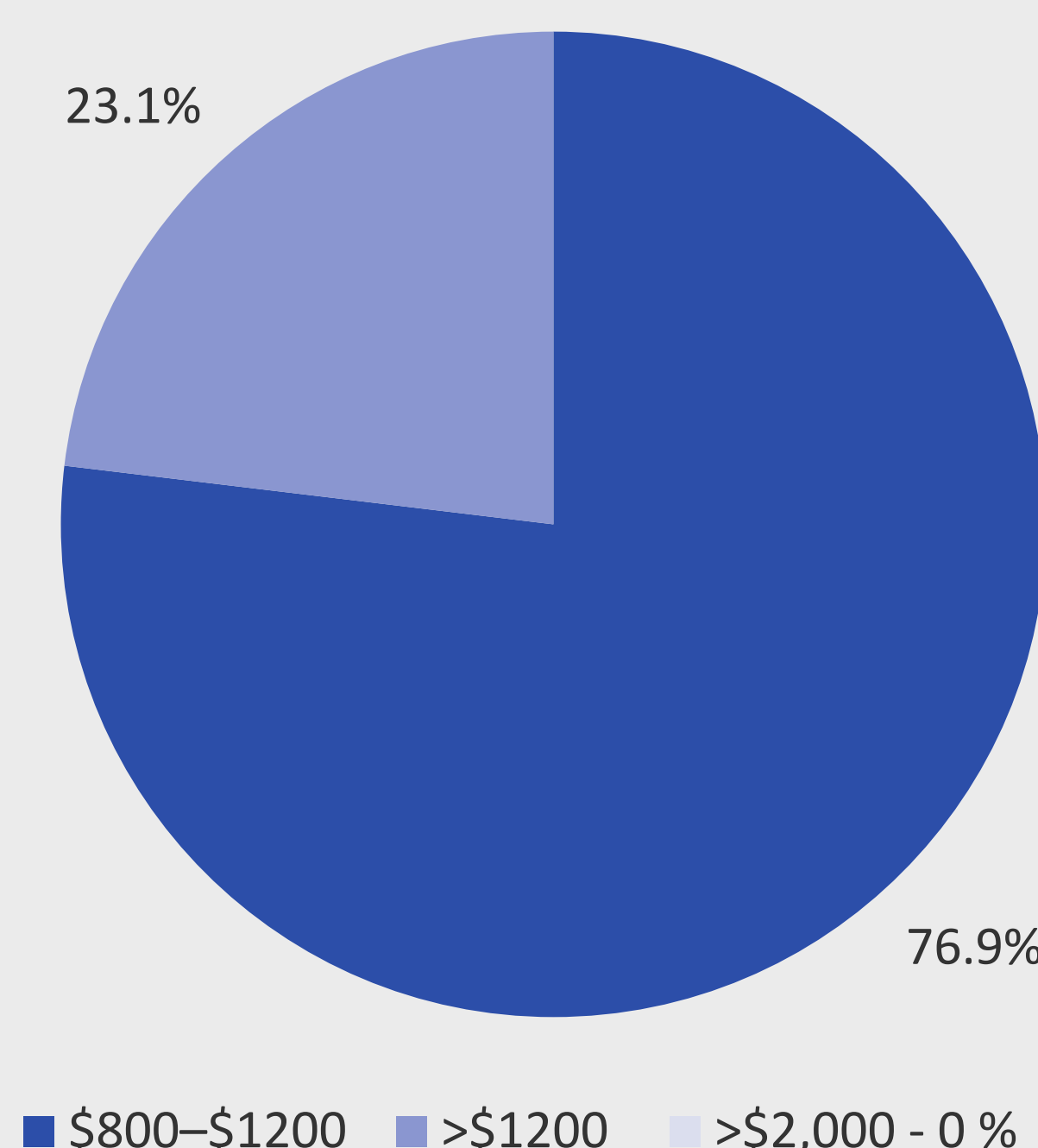


Companion Diagnostic Test: Prediction of Treatment Response

How would you, as a parent, value such a test?



How much would you pay out of pocket for such a test?



CONCLUSIONS

- ASD affects a child's and family's quality of life and is associated with a considerable economic burden.
- Parents are willing to spend significant funds for an objective test that could result in earlier intervention to improve their children's clinical outcomes.
- Most parents think that a test predicting the likelihood of a successful specific treatment, such as stem cell therapy or microbiome replacement, is very important.

NEXT STEPS

- Expanded survey with representative sample (n=200+).
- Payer perspective research for reimbursement strategy.