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Interest in Research Participation Among Caregivers of Children with Neurodevelopmental Disorders

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Abstract

The goal of this study was to examine caregiver agreement to hear about local research opportunities by joining a clinical research registry. Data from this cross-sectional study were gathered, between 2014 and 2017, across two outpatient clinics: (1) a multidisciplinary Autism Spectrum Disorder (ASD) clinic (N = 5228) and (2) a general psychology clinic serving youth with, or at risk for, a neurodevelopmental disorder (NDD; N = 5040). Overall, more than 8 in 10 caregivers agreed to join the registry. Several child clinical characteristics, as well as racial and sociodemographic factors, were predictive of parental agreement. Findings suggest caregivers of youth with ASD and NDD are amenable to joining the local research enterprise, however further work is needed to understand why some caregivers decline.

Keywords

Consent; Neurodevelopmental disorders; Registry; Autism; ADHD

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Author Contributions LK was responsible for conducting the analyses. LK, LJ, GA, DM, VS, and AZ assisted with data acquisition. LK and AP were responsible for developing the initial study questions. All authors contributed to the study design, writing, and interpretation.

Conflict of interest No conflicts exists. Author D has provided consultation to Takeda Pharmaceuticals, however those services had no bearing, influence, or relevance to the current study.

Ethical Approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed Consent For this type of study, a retrospective chart review, formal consent is not required. As such, the authors received a waiver of consent from the governing IRB.

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Neurodevelopmental disorders (NDDs) are a group of heterogeneous disorders of the central nervous system. These conditions, which emerge in early childhood, manifest through impairment in physical, cognitive, language, social-emotional, motor and behavioral functioning (Mahone et al. 2018). Prevalence of NDDs has risen dramatically over recent decades, especially among Autism Spectrum Disorder (ASD) and attention-deficit/hyperactivity disorder (ADHD; Bajo et al. 2018). Today, NDDs affect at least one in six children in the US (Boyle et al. 2011).

Individuals with NDD tend to experience numerous health disparities, including lower quality of life and earlier age of mortality compared to their neurotypical peers (Danckaerts et al. 2010; Fairthorne et al. 2014). Unfortunately, there has been a historical lag in the development, dissemination, and implementation of evidenced-based treatments that can reduce these disparities (Mash and Barkley 2006). The delay in developing evidenced-based practices for those with NDD may be due, in part, to the challenges involved in study recruitment specific to this population (Bonevski et al. 2014; Lennox et al. 2005; Oliver-Africano et al. 2010).

Research recruitment has been identified as one of the most significant challenges to successful study completion (Baquet et al. 2006). Recruiting and retaining subjects is a problem that stretches across all populations, disciplines, and study designs. Difficulties with study recruitment can result in biased and self-selected populations, which have direct implications for the quality of inference that can be attributed to a finding, whether it is an epidemiologic estimate (e.g., survey non-response) or an effect size from a clinical trial (e.g., generalizability).

For the NDD population, there are unique recruitment barriers when compared to those without disabilities (Adams et al. 2017; Cleaver et al. 2010; Lennox et al. 2005; Catherine Lord et al. 2005). Cognitive and language delays create specific challenges for the consent designee, when obtaining assent, in determining whether the child can fully understand the protocol. For the parent, the added burden of engaging in a study protocol may be difficult when the family experiences many demands related to caring for a child with substantial educational and healthcare-related needs. Medical mistrust and barriers to health literacy create further disparities among this group, particularly for minority populations (Dang et al. 2014; Dash et al. 2014; Rollins et al. 2018).

An important precursor to successful research recruitment in any study protocol is the participants' interest in engaging in the research enterprise itself. Willingness to entertain the possibility of enrolling in a study is a necessary, but not sufficient, condition to consenting to a study protocol. Understanding differences between those who are or are not interested in participating in research is critical to understanding the degree and direction of bias in an individual study or a body of research. This information can also be leveraged to create targeted efforts at recruiting these hard-to-reach populations (Baquet et al. 2008). If non-response remains a concern, information on those who do and do not respond to research announcements or recruitment efforts can be used to address potential sources of bias through advanced statistical techniques (e.g., weighting, post-stratification; Little and Vartivarian 2003).

Research registries have become a popular solution to address the challenges of research recruitment. Registries come in many forms, from national or international disorder-specific registries (e.g., the Interactive Autism Network; Kalb et al. 2012, b) to institution-specific clinical research registries, such as the registries discussed in the current study. Institution-specific clinical research registries provide patients with the opportunity to be contacted about local research opportunities for which they might be eligible. In order to join such a registry, patients are often required to complete a brief form, that is approved by the institutional review board (IRB), consenting to be contacted about research opportunities.

Clinical research registries are attractive to researchers since they are inexpensive, have the potential to tap into rare populations, and may be able to draw upon valuable data from patients' clinical encounters. They also provide investigators with a more proactive approach to study recruitment. For the patients, joining a registry offers an opportunity to hear about a wide variety of opportunities, which can be targeted to their own specific characteristics, rather than relying on chance encounters (e.g., study flyers).

To our knowledge, no prior study has examined consent rates, or predictors of parent/caregiver willingness to consent, to any type of NDD clinical research registry. This gap in the literature is likely due to the lack of information on non-responders. On the other hand, numerous studies have examined factors related to consent to medical research among the typically-developing population, particularly adults. There is evidence to suggest that older age (Baquet et al. 2006; Damery et al. 2011), greater number and severity of medical conditions (Buckley et al. 2007; Dunn et al. 2004), and non-minority status (Giuliano et al. 2000) increases the likelihood of consent (Adams et al. 2017). While these findings provide insight into factors which might relate to study participation, the current study is specifically attempting to identify factors which influence parental motivation to participate in NDD research. The benefits and risks, study purpose and protocol, and many other factors play a critical role in whether a patient or parent provides consent to a particular protocol (Tait et al. 2003; Treschan et al. 2003). Research registries are quite different, however, as they are far less risky and simply open the door to future opportunities. Nevertheless, parents may be less inclined to join general registries because they could perceive less value in participating in a project that does not address a specific need related to their child at that moment in time.

The primary purpose of this study was to answer the question: are caregivers interested in joining a research registry to hear about prospective research opportunities for their child with NDD? To address this question, trends in caregiver consent, and predictors of such, were examined across two different geographic settings that serve disparate populations with/at-risk of NDD. Incorporating multiple settings improves the generalizability of the findings, while identifying particular populations who are more or less likely to consent. More specifically, the first objective was to evaluate the proportion of caregivers of youth with NDDs who agreed to join an institution-specific clinical research registry during their child's specialty clinic visit. The second objective was to examine the demographic (e.g., child age, gender, race, insurance type, clinic type, and distance to clinic) and clinical factors (e.g., child medical, developmental, and mental health problems) which may predict caregiver consent to the registry. The third objective was to examine differences in consent trends over time and across clinics, with particular attention paid to race and insurance status

(the fourth objective). Since there was little literature to guide theories about consent rates or predictors of consent, coupled with the fact this study was descriptive in nature, we do not posit any hypotheses.

Methods

Sample

Data from this cross-sectional study were gathered between 2014 and 2017 across two outpatient clinics located in the Mid-Atlantic region of the United States. Both clinics are part of a larger medical institution focused on the care of individuals with NDD. The first (N = 5228 observations) is a general psychology clinic where youth were referred for evaluation for a wide range of cognitive, academic, developmental, and mental health concerns. The most common diagnoses in this setting include attention-deficit/hyperactivity disorder (42%), anxiety disorders (8%), adjustment disorders (5%), oncologic diseases (3%), epilepsy (2%), and unspecified encephalopathy (3%). This clinic, which provides mostly one-time evaluations, is situated in a dense urban setting and directly adjacent to a large academic medical center.

The second clinic (N = 5040 observations) solely focuses on the evaluation and treatment of youth with ASD or suspected ASD. This clinic is highly multidisciplinary and located on the outskirts of the city, away from the main medical center site. Demographic and clinical information about each site is provided in Table 1. These sites were chosen based on their long-standing (since 2014) research registries, availability of structured psychometric data and background information, affiliation under the same medical institution and IRB, and collaboration between investigators across sites.

There were three inclusion criteria for this study. First, families had to attend their appointment since the psychology clinic offered the research registry consent form on paper at the initial visit. Although the ASD clinic offered the research registry consent form as part of the electronic pre-visit questionnaire, families were only included if they attended the appointment as well. This was required to avoid selection bias between clinics, since there tend to be known demographic differences between those who do and do not attend their appointments (Kalb et al. 2012b). Second, patients were required to be between 0 and 17 years of age, otherwise the patient would be required to provide their own consent. Due to local IRB restrictions, patients in foster care were excluded.

Dependent Variable

The dependent variable was caregiver agreement (yes/no) to be contacted for future research, as measured by the research registry consent form. In the ASD clinic, parents were provided with the registry consent form when completing their intake forms, accomplished via a secure online survey prior to their appointment. For families who did not respond or have the opportunity to fill out this pre-appointment form, another opportunity was provided right before their appointment via their pre-appointment medical forms. Introducing the consent form a second time, right before the appointment via the medical form, was rare (N

= 109) because this change in procedure took effect late 2017. This change also had little effect on consent rates.

On average, this questionnaire was completed 7 months prior to the appointment in the ASD clinic. In the psychology clinic, caregivers filled out the registry consent form via paper and pen upon checking in on the morning of their child's appointment. Difference in time between when the consent form was received and date of appointment was adjusted for in the multivariate analyses.

In the ASD clinic, the consent form was completed by 90% of families. Since there was some inconsistency in the delivery of the paper consent form by psychology staff, we aren't able to know the true non-response rate. However, we estimate the response rate was likely equal to or greater than that observed in the ASD clinic since the consent form was always bundled with the consent for treatment form and parents almost always filled out and returned that form. When the form was collected, across both clinics, almost no (< 1%) missing data were present.

While the consent forms remained the same within clinics over the study period, the consent forms across the clinics were not identical. The registry consent form for the general psychology form was slightly less than a page, while the consent form was a single paragraph (nested in a larger 1-page form) for the ASD clinic. Both forms required < 5 min to complete. No data were available regarding the relationship to the child of the caregiver who provided consent in the psychology clinic. As such, appointment guarantor, or the caregiver who scheduled the child for the appointment, was used as a proxy for this variable in both clinics. The registry consent forms and the use of the data included in the present study were approved by the local IRB.

Independent Variables

Demographics and Parent-Reported Clinical Information About the Child

Much of the relevant demographic data were retrieved from the hospital scheduling information system. These data, including child age, gender, race/ethnicity, insurance status, distance to clinic (measured as the zip code centroid distance, in miles, between the patient's home and the clinic), and guarantor, were rarely missing (< 2%).

Caregiver educational level and clinical information about the child were available via clinic-specific medical history questionnaires provided to parents before their clinical visit. On this form, we gathered information about history of ASD/ADHD diagnosis, sleep problems, and seizures, all of which were measured dichotomously. These data points were available for a smaller proportion of patients due to form non-response, item non-response, and site-specific changes in form implementation. For the latter, the psychology clinic launched the medical history questionnaire in late 2016, resulting in missing information before that date (2014–October 2016). As a result, data on ASD/ADHD diagnosis, sleep problems, seizures, and caregiver education were available on 16–20% of the psychology sample and 60–83% of the ASD sample (see Table 1 for details).

Parent-Reported Child Mental Health—Internalizing and externalizing symptoms were measured via norm-referenced standardized scores from the child behavior checklist (in the ASD clinic; 65% available; Achenbach and Edelbrock 1983) or the Behavior Assessment System for Children (2nd or 3rd edition; Reynolds and Kamphaus 2004) (in the psychology clinic; 25% available). T-scores from the internalizing (e.g., anxiety, depression) and externalizing (e.g., behavior problems) scales were combined, across measures, and used in the analyses. A score of 66–70 is considered at-risk of clinical problems, while > 70 represents the clinical range.

Standardized Clinician-Administered Measures

There was variation between clinics in the availability of standardized assessments since measures were administered at clinician discretion based on presenting concerns and appointment type.

Intelligence Quotient (IQ)—IQ was measured by the language-based reasoning component of a standardized intellectual assessment. The most commonly measures included the Verbal Comprehension Indices from the Wechsler Intelligence Scales for Children (WISC) Fourth and Fifth Editions (Wechsler 2014, p. 78%), Differential Ability Scales-Second Edition (DAS-2; Elliott 2007 early years; 10%), and the Wechsler Preschool and Primary Scale of Intelligence-Fourth Edition (WPPSI-4; Wechsler 2012; 5%). The verbal measure of intelligence, opposed to full scale, was employed since these data had greater availability. IQ was available on 40% of the psychology clinic sample; it was not available in the ASD clinic.

Autism Symptom Severity—For the ASD clinic, ASD symptomatology was measured via the ADOS (Autism Diagnostic Observation Schedule, Version 2; (Lord et al. 2012) calibrated symptom severity (CSS) score (available on 56% of the ASD clinic sample; Gotham et al. 2009). The ADOS-2 is a semi-structured, play-based assessment of ASD. It is a gold standard measure of ASD. The CSS score, which ranges from 1 to 10, reflects the level of autism severity. CSS ratings of ≥ 6 reflect ASD. The ADOS was not administered in the psychology clinic.

Analysis

Addressing the first study question, descriptive statistics were used to examine the proportion of caregivers who consented to the clinical research registry. The second objective was addressed by employing bivariate analyses (Wilcoxon and Chi square tests) to examine demographic and clinical factors related to providing authorization to be contacted about prospective research opportunities. A logistic regression model was then built to examine changes in the odds of parents providing consent to the research registry over time, while adjusting for all significant factors identified in the bivariate analyses. More specifically, this model assesses changes in the odds of consent, among new referrals, for every single year increase in time (2014–2017). In this model, a clinic-by-year interaction term was included to determine whether there were differences in time trends across clinics, addressing the third objective.

Finally, four separate, fully-adjusted models tested whether there were differences, within each clinic, in consent rates over time between private versus medical assistance insurance types and African American versus all other races. All models adjusted for potential clustering via robust variance. In the fully adjusted model, missing data indicators (or dummy variables) were included for items without complete data. This approach was taken for the purposes of retaining the full sample, which is preferred compared to complete case analysis (Groenwold et al. 2012). All analyses were conducted in STATA 15.0 (College Station, TX).

Results

Differences Between Clinics

Overall, the clinics differed in patient demographic and clinical characteristics. Patients seen at the ASD clinic were younger and more likely to be male than those seen in the psychology clinic (Table 1). In addition, the racial composition of the ASD clinic's patients differed from that of the psychology clinic and caregiver education tended to be lower in the former. Patients of the ASD clinic also were more likely to be covered under private insurance, live further from the clinic, and have a father as the appointment guarantor. Clinically, youth in the ASD clinic had greater parent-reported internalizing and externalizing problems, history of ASD and a decreased likelihood regarding a history of seizures or ADHD (all differences $p < .05$, statistics shown in Table 1).

Consent Rates

The overall consent rate was 81%. Across clinics, the proportion that consented was slightly lower in the ASD (80%) compared to psychology (82%) clinic $\chi^2(1, 10,268) = 8.7, p < .01$.

Predictors of Consent to a Research Registry

The unadjusted bivariate analyses examining factors related to registry consent are shown in Table 2. Within the ASD clinic, year, age, race, distance to clinic, externalizing, and internalizing, problems, days until the child's appointment, parent-reported child ADHD and sleep problems were significantly related to consent. In the psychology clinic, race, insurance type, guarantor, distance to clinic, and internalizing, and externalizing problems were related to consent.

Overall, or when combining data from both clinics, those who consented tended to have slightly younger children, be non-White, have private insurance, have a father or 'Other' guarantor, live further from the clinic and have children with elevated parent-reported levels of internalizing, and externalizing problems. More recent year of consent, and history of parent-reported ADHD symptoms, and sleep problems, also were significantly positively associated with consent. Child gender, caregiver education, child IQ, and parent-reported ASD diagnosis or ASD symptom severity, measured via the ADOS, were not significantly related to consent (all $p > .05$). See Appendix Table 3 for bivariate test-statistics.

In the fully adjusted analyses, which included data from both clinics, caregivers were more likely to consent in later years (OR = 1.09, 95% CI 1.03, 1.14, $p < .001$), when there were fewer days until the appointment (OR = .99, 95% CI .98, .99, $p = .01$), if the child was 11–13 years of age (OR = 1.21, 95% CI 1.03, 1.42, $p = .02$), and when the child had elevated externalizing (OR = 1.34, 95% CI 1.12, 1.61, $p = .002$) and sleep (OR = 1.25, 95% CI 1.08, 1.50, $p = .004$) problems. On the other hand, African American caregivers were less likely to consent (OR = .66, 95% CI .59, .75, $p < .001$) than caregivers who were Caucasian. Insurance type, guarantor, distance to clinic, parent-reported ADHD symptoms, or internalizing problems were no longer significant and were therefore removed from subsequent models.

Consent Rates Over Time Across Clinics

As shown in Fig. 1, the consent rate did not change significantly over time in the psychology clinic (OR = 1.04, 95% CI .96, 1.14, $p = .33$), but did show an increase in the ASD clinic (OR = 1.13, 95% CI 1.05, 1.21, $p < .001$). When the time-by-clinic interaction term was included, there was a decrease in the probability of consent in the psychology versus ASD clinic over time, although this difference did not reach statistical significance (OR = .92, 95% CI .83, 1.02, $p = .13$).

Consent Rates Over Time Across Insurance Types and Race

Shown in Fig. 2, there was a significantly larger increase in the probability of consent among parents of youth with medical assistance (public) compared to private insurance over time in the ASD clinic (OR = 1.25, 95% CI 1.08, 1.45, $p = .003$). No time-by-insurance type interaction was found in the psychology clinic (OR = .95, 95% CI .83, 1.11, $p = .57$).

Shown in Fig. 3, there was no difference in consent rates over time in the ASD clinic, among those who were African American compared to all other races (OR = 1.04, 95% CI .90, 1.21, $p = .58$). However, there was a decrease in the probability of consent among African American parents, compared to all other races, in the psychology clinic over time (OR = .84, 95% CI .73, .97, $p = .02$).

Discussion

The primary goal of this study was to examine the willingness of caregivers raising a child with an NDD to join an institution-specific clinical research registry. While this question was addressed across two very different settings, one serving the long-term needs of youth with ASD and the other a general psychology evaluation clinic, across both settings the answer was quite clear: a large majority of caregivers, who were actively seeking clinical care for their child, were willing to join a clinical research registry. This can be seen in the data from 2017, where more than 8 in 10 caregivers joined their respective clinic registry. This finding is critical as it speaks to caregivers' willingness to participate in the research enterprise as a whole. It should also alleviate concerns among clinicians who are tentative about speaking with patients' caregivers in regard to prospective, low-risk protocols such as joining a research registry.

In the ASD clinic, the consent rate rose across the 4 year observation period. This trend was not evident in the psychology clinic serving youth with, or at risk for, NDD. The discrepancy between clinics could be due to unique aspects of the ASD community, including numerous national autism registry efforts (e.g., the SPARK initiative, SPARK: Simons Foundation Powering Autism Research for Knowledge 2018), which may be uniquely increasing awareness of the importance of research registries in the ASD community. There is also growing coverage of ASD-related research in the media, several well-resourced parent-based ASD organizations that heavily invest in science, and numerous federally funded ASD research initiatives, including the Combating Autism Act. Perhaps all of these efforts have created a growing culture of acceptance of research specific to the ASD community. This is difficult to assess, however, since no additional information about caregivers' perceptions of research were available.

A key feature of the rise in consent rates within the ASD clinic was the closing of the insurance-related consent gaps. More specifically, there was a precipitous rise over time in the consent rate among those receiving medical assistance, compared to those receiving private insurance, in the ASD clinic; a trend that was not evident in the psychology clinic. The consent gap also closed between African Americans and all other races over time, in the ASD clinic, although the difference in slopes did not reach statistical significance after adjusting for numerous child, clinical, and sociodemo-graphic factors. In the psychology clinic, this racial gap actually expanded over time, leaving a large disparity in consent rates between African Americans and all other races in 2017.

What has led to the disparate consent rates across clinic sociodemographic lines is unknown. One potential explanation for the race finding is that the psychology clinic is located next to a major medical institution, in a dense urban setting. As a result, the perceived stigma of research involving minorities at that large medical institution, combined with a different referral group, may have resulted in a qualitatively different sample than that of the ASD clinic. Another explanation for both the insurance and race-related findings is the possibility of a cohort effect. More specifically, there may be differential changes in the referral population, in later versus earlier years, across clinics. While the analyses were adjusted for numerous socio-demographic variables that help to address this concern, available background information was not fully complete. Understanding the role of race and income regarding caregivers' underlying interests in and concerns about joining research in general is an important next step for future research in NDD, one that is particularly well suited to qualitative methods.

Beyond race and insurance type, numerous other demographic and clinic factors were related to consent. In the unadjusted analyses, greater distance to clinic was associated with increased probability of consent. This finding may reflect fewer opportunities for research in other, notably rural, regions; although it washed out in the multivariate analyses. Greater parent-reported child mental health issues, especially increased behavioral problems, were a robust predictor of consent throughout the analyses. Presence of parent-reported sleep problems also followed the same pattern. This was counter to intuition, which suggests that families who may experience greater stress due to their child's difficulties would be less inclined to commit to additional responsibilities. Perhaps this finding suggests that families

perceive research as a means of identifying solutions to their child's difficulties, and those of other similar children. Further work is needed to confirm this hypothesis. Interestingly, increasing developmental problems, including greater ASD severity and lower IQ, were not related to consent. This implies that comorbid factors, rather than core developmental limitations, may drive decisions about research engagement, a finding consistent with other research showing comorbid factors can be more stressful for these caregivers than developmental delay itself (Herring et al. 2006; Theule et al. 2010).

As always, the findings should be interpreted in light of the study's strengths and limitations. Strengths of this study included recruitment from two large samples from neuro-diverse settings. There was also a breadth of information available about the socio-demographic characteristics of the family and clinical information, from both standardized assessment and parent-reported information, about the child. The novelty of this information and ability to examine trends over time are also viewed as strengths. In terms of limitations, complete data were not available for the sample for a variety of reasons including caregiver non-response, caregiver-reported questionnaires being instituted at various times across clinics, and clinician discretion in administering standardized assessments. Additional critical information, particularly surrounding caregivers' perceptions of research, if they actually participated in any of the studies that recruited from the registry, and if the nature of appointment (evaluation vs. treatment) influenced their decision to consent, was also not available. The findings are also not necessarily generalizable to the larger ASD and NDD communities, since we utilized a referred clinical sample. Lastly, the consent forms were gathered at different time points in time (relative to the appointment) using different methods (online vs. paper) and forms (a single vs. multiple paragraphs) across clinics. Since these factors overlapped, it was not possible to disentangle their relative contribution to consent rates.

In sum, caregivers were overwhelmingly interested in hearing about research opportunities by joining a clinical research registry. In the ASD clinic, the proportion of interested caregivers rose between 2014 and 2017, particularly among families receiving medical assistance. In the psychology clinic, there was a decrease in consent rates among African Americans and no trend related to insurance. Caregivers of youth 11–13 years of age, with elevated levels of parent-reported externalizing and/or sleep problems were more likely to consent. These findings suggest that clinical research registries are an accessible way to engage families raising a child with a NDD in the research enterprise. It also points to the ability to reach families at different times (both before and at the time of appointment) and through different methods (including electronic and paper consent). However, there are specific trends across populations that increase or decrease the likelihood of participation. Further research, particularly utilizing qualitative approaches, is needed to better understand these trends.

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Appendix

Table 3

Statistics from bivariate analyses

	Test (df, N, test statistic) = p-value		
	Autism Spectrum Disorder clinic	Psychology clinic	Overall
Year	$\chi^2(3, N = 5040, 17.65) = p < .001$	NS	$\chi^2(1, N = 10,268) = 17.50, p < .001$
Child age	$\chi^2(3, N = 5040) = 18.35, p < .001$	NS	$\chi^2(1, N = 10,098) = 82.51, p < .001$
Child gender	NS	NS	NS
Race	$\chi^2(3, N = 4956) = 28.31, p < .001$	$\chi^2(3, N = 5142) = 61.92, p < .001$	$\chi^2(1, N = 10,098) = 82.51, p < .001$
Insurance	NS	$\chi^2(1, N = 5228) = 12.04, p = .01$	$\chi^2(1, N = 10,268) = 10.94, p < .001$
Guarantor	NS	$\chi^2(1, N = 5228) = 9.38, p = .01$	$\chi^2(1, N = 10,268) = 6.03, p < .05$
Distance to clinic	$Z(N = 10,190) = -3.13, p = .002$	$Z(N = 5119) = -7.34, p < .001$	$Z(N = 10,190) = -7.07, p < .001$
Days until Appt.	$Z(N = 4593) = 2.66, p = .01$	-	-
Education	NS	NS	NS
Internalizing	$\chi^2(1, N = 3253) = 13.34, p < .001$	$\chi^2(1, N = 1331) = 8.95, p < .001$	$\chi^2(1, N = 4584) = 15.41, p < .001$
Externalizing	$\chi^2(1, N = 3253) = 16.51, p < .001$	$\chi^2(1, N = 1331) = 12.31, p < .001$	$\chi^2(1, N = 4585) = 25.28, p < .001$
ASD	NS	NS	NS
ADHD	$\chi^2(1, N = 3449) = 8.12, p = .01$	NS	$\chi^2(1, N = 4526) = 10.81, p < .001$
Sleep problems	$\chi^2(1, N = 4593) = 19.40, p < .001$	NS	$\chi^2(1, N = 5383) = 17.98, p < .001$
Seizures	NS	NS	NS
IQ	-	NS	-
ADOS autism symptoms	NS	-	-

NS = $p > .05$, non significant; χ^2 = Chi square test; Z = Wilcoxon test

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Fig. 1.
The proportion of caregivers consenting to be contacted about future research efforts across clinics

Fig. 2. Differences in consent rates across clinics and insurance-type. *MA* medical assistance insurance. *Private* private insurance

Fig. 3.
Differences in consent rates across clinics and child race

Table 1

Sample demographics

	Autism Spectrum Disorder (ASD) clinic	Psychology clinic	Overall	Test statistic, df, p value
Year, N (%)				
2014	1221 (24)	1294 (25)	2515 (24)	$\chi^2 = 6.29, 3, p = .10$
2015	1363 (27)	1501 (29)	2864 (28)	
2016	1399 (28)	1354 (26)	2753 (27)	
2017	1057 (21)	1079 (21)	2136 (21)	
Child age, N (%)				
0–6 years	2938 (58)	1078 (21)	4016 (39)	$\chi^2 = 1500, 3, p < .001$
7–10 years	1213 (24)	2363 (45)	3576 (35)	
11–13 years	562 (11)	1004 (21)	1666 (16)	
14–17 years	327 (6)	683 (13)	1010 (10)	
Child gender				
Female	1032 (20)	2008 (38)	3040 (30)	$\chi^2 = 395.6, 1, p < .001$
Male	4008 (80)	3220 (62)	7228 (70)	
Race, N (%)				
White	2513 (51)	2512 (49)	5025 (50)	$\chi^2 = 135.56, 1, p < .001$
Black	1334 (27)	1840 (36)	3174 (31)	
Other	860 (17)	577 (11)	1437 (14)	
Hispanic	249 (5)	212 (4)	461 (5)	
Insurance, N (%)				
Private insurance	3030 (60)	2820 (54)	5850 (57)	$\chi^2 = 365.71, 1, p < .001$
Medical assistance	1563 (31)	2307 (44)	3870 (38)	
Other	447 (9)	101 (2)	548 (5)	
Guardian, N (%)				
Mother	2610 (52)	3080 (59)	5690 (55)	$\chi^2 = 333.98, 1, p < .001$
Father	2337 (47)	1729 (33)	4066 (40)	
Other	93 (2)	419 (8)	512 (5)	
Education				
HS or less	828 (27)	79 (10)	907 (23)	$\chi^2 = 141.44, 3, p < .001$

	Autism Spectrum Disorder (ASD) clinic	Psychology clinic	Overall	Test statistic, df, p value
Trade/associates	585 (19)	265 (33)	850 (22)	
Bachelors	846 (27)	209 (26)	1055 (27)	
Graduate	841 (27)	256 (32)	1097 (28)	
Miles from clinic, (median, SD)	45.0 (176.0)	32.5 (151.0)	38.2 (163.9)	Z = 13.51, 10,188, p < .001
Internalizing, N (%)				
No	1458 (45)	911 (68)	2369 (52)	$\chi^2 = 211.0$, 1, p < .001
Yes	1795 (55)	420 (32)	2215 (48)	
Externalizing, N (%)				
No	1921 (59)	896 (67)	2817 (61)	$\chi^2 = 26.9$, 1, p < .001
Yes	1332 (41)	436 (33)	1768 (38)	
ASD, N (%)				
No	2839 (60)	1049 (97)	3888 (67)	$\chi^2 = 562.6$, 1, p < .001
Yes	1912 (40)	27 (2)	1939 (33)	
ADHD, N (%)				
No	2605 (76)	775 (72)	3380 (75)	$\chi^2 = 5.53$, 1, p < .001
Yes	844 (25)	302 (28)	1146 (25)	
Sleep problems, N (%)				
No	3042 (66)	530 (67)	3572 (66)	$\chi^2 = .22$, 1, p = .6
Yes	1551 (34)	260 (33)	1811 (34)	
Seizures problems, N (%)				
No	4368 (97)	710 (88)	5078 (96)	$\chi^2 = 114.90$, p < .001
Yes	147 (3)	95 (12)	242 (6)	
Verbal IQ (mean, SD)	-	90.80 (23.4)	-	-
ADOS autism symptoms (mean, SD)	5.42 (2.9)	-	5.42 (2.9)	-

Table 2

Characteristics of children and families who consented to a clinical research registry

	Autism clinic		Psychology clinic		Overall	
	N	Y	N	Y	N	Y
Year, N (%) ^{a,c}						
2014	291 (24)	930 (76)	254 (20)	1040 (80)	545 (22)	1970 (78)
2015	269 (20)	1094 (80)	271 (18)	1229 (82)	541 (19)	2323 (81)
2016	279 (20)	1120 (80)	219 (16)	1135 (84)	498 (18)	2255 (82)
2017	178 (17)	879 (83)	190 (18)	889 (82)	368 (17)	1768 (83)
Child age, N (%) ^{a,c}						
0–6 years	651 (22)	2287 (78)	188 (17)	890 (83)	839 (21)	3177 (79)
7–10 years	212 (17)	1001 (83)	426 (18)	1937 (82)	638 (18)	2938 (82)
11–13 years	91 (16)	471 (84)	187 (17)	916 (83)	278 (17)	1387 (83)
14–17 years	63 (19)	264 (81)	133 (19)	550 (80)	196 (19)	814 (81)
Child gender						
Female	219 (21)	813 (79)	355 (18)	1653 (82)	574 (19)	2466 (81)
Male	789 (20)	3210 (80)	579 (18)	2640 (82)	1377 (19)	5850 (81)
Race, N (%) ^{a,b,c}						
White	451 (18)	2062 (82)	358 (14)	2153 (86)	810 (16)	4215 (84)
Black	333 (25)	1001 (75)	430 (23)	1410 (77)	763 (24)	2411 (76)
Other	165 (19)	695 (81)	97 (17)	481 (83)	262 (18)	1176 (82)
Hispanic	44 (18)	205 (82)	31 (15)	181 (86)	75 (16)	386 (84)
Insurance ^{b,c}						
Private insurance	592 (20)	2438 (81)	457 (16)	2363 (84)	1048 (18)	4801 (82)
Medical assistance	338 (22)	1225 (78)	460 (20)	1847 (80)	798 (21)	3072 (79)
Other	87 (20)	360 (80)	18 (18)	83 (82)	105 (19)	443 (81)
Guardian ^{b,c}						
Mother	535 (20)	2075 (80)	591 (19)	2489 (81)	1126 (20)	4564 (80)
Father	471 (20)	1866 (80)	270 (16)	1458 (84)	742 (18)	3324 (82)
Other	11 (12)	82 (88)	73 (17)	346 (82)	84 (16)	428 (84)

	Autism clinic		Psychology clinic		Overall	
	N	Y	N	Y	N	Y
Distance to clinic ^{a,b,c} (in miles; median, SD)	42.3 (247.6)	45.2 (152.8)	24.0 (83.9)	34.4 (161.9)	32.4 (188.1)	38.7 (157.6)
Education						
HS or less	164 (20)	664 (80)	17 (22)	62 (78)	181 (20)	726 (80)
Trade/associates	114 (19)	471 (81)	35 (13)	230 (87)	149 (18)	701 (82)
Bachelors	155 (18)	691 (82)	32 (15)	177 (85)	187 (18)	868 (83)
Graduate	153 (18)	688 (82)	36 (14)	220 (86)	189 (17)	908 (83)
Internalizing, N (%) ^{a,b,c}						
No	311 (21)	1147 (79)	155 (17)	766 (83)	466 (20)	1903 (80)
Yes	293 (16)	1502 (84)	45 (11)	377 (89)	338 (15)	1877 (85)
Externalizing, N (%) ^{a,b,c}						
No	401 (21)	1520 (79)	156 (17)	740 (83)	557 (20)	2260 (80)
Yes	203 (15)	1129 (85)	44 (10)	392 (90)	247 (14)	1521 (86)
ASD						
No	605 (21)	2234 (79)	177 (17)	872 (83)	782 (20)	3105 (80)
Yes	367 (19)	1545 (81)	3 (12)	24 (89)	370 (19)	1569 (81)
ADHD ^{a,c}						
No	516 (20)	2089 (80)	138 (18)	637 (82)	654 (19)	2726 (81)
Yes	130 (15)	714 (85)	42 (14)	260 (86)	172 (15)	974 (85)
Sleep problems ^{a,c}						
No	627 (22)	2370 (78)	83 (16)	447 (84)	755 (21)	2817 (79)
Yes	257 (17)	1294 (84)	38 (15)	222 (85)	295 (16)	1514 (84)
Seizures						
No	885 (20)	3453 (80)	106 (15)	589 (85)	991 (20)	4076 (80)
Yes	20 (18)	119 (82)	15 (16)	80 (84)	35 (17)	199 (83)
IQ (M, SD)	N/A	N/A	91.4 (23.3)	90.5 (23.6)	-	-
ADOS autism symptoms (mean, SD)	5.6 (2.8)	5.4 (2.9)	N/A	N/A	-	-
Time until appointment (mean, SD) ^a	305.0 (268.2)	272.6 (231.4)	-	-	-	-

ADOS Autism Diagnostic Observation Scale, Version 2; ID intellectual disability, as determined by cognitive assessment; ASD Autism Spectrum Disorder; ADHD Attention Deficit-Hyperactivity Disorder

overall
 $d_c > .10$
 $d_q > .10$ for psychology clinic;
 $d_g > .10$ for autism clinic;

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