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Direct Measures of Medication Effects: Exploring the Scientific Utility of Behavior-Analytic Assessments

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Corresponding Author:	Blair Lloyd Vanderbilt University Nashville, TN UNITED STATES
First Author:	Blair Lloyd
Order of Authors:	Blair Lloyd
	Emily Weaver
	Jessica Torelli
	Marney Pollack
	Sunya Fareed
	Angela Maxwell-Horn
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Abstract

The purpose of the current study was to explore the scientific utility of two behavior analytic assessments (i.e., progressive ratio and demand assessments) for psychotropic medication evaluation. For a sample of 23 children with disabilities who were prescribed medication, we conducted a series of generalizability and optimization studies to identify sources of score variance and conditions in which stable estimates of behavior can be obtained. To inform construct validity, we calculated correlations between scores from each assessment and those from a standardized behavior rating scale (ABC-2). Results offer initial support for the scientific utility of progressive ratio scores. More research is needed to evaluate sensitivity to change and construct validity of scores from these and other behavior analytic assessments.

Keywords: generalizability, reliability, progressive ratio, demand assessment, psychotropic medication

Direct Measures of Medication Effects:

Exploring the Scientific Utility of Behavior Analytic Assessments

The prevalence of psychotropic medications among school-age children has increased markedly over the past 20 years (Carlson, 2019; Olfson et al., 2015), particularly among children with disabilities. As many as 50%–70% of children with autism spectrum disorders, attention deficit/hyperactivity disorder (ADHD), and other emotional/behavioral disorders take one or more psychotropic medication (Angold et al., 2000; Mandell et al., 2008; Mattison et al., 2014; Ryan et al., 2008; Spencer et al., 2013), many of which are prescribed to address behavioral concerns. Coupled with rising rates of off-label prescribing and polypharmacy (McLaren et al., 2018; Vitiello, 2017; Zito et al., 2008), these trends magnify the need to understand whether and how these medications produce therapeutic effects.

To evaluate whether medication-based treatments are effective for children with disabilities, prescribing clinicians commonly rely on informal reports by caregivers or global impressions of symptom improvement (e.g., Clinical Global Impressions [CGI] scale [Guy, 1976]; Vitiello, 2017). Researchers commonly rely on third party reports of child behavior by parents or other caregivers (Aman et al., 2004; Volpe et al., 2005; Zarcone et al., 2008). The Aberrant Behavior Checklist (ABC; Aman et al., 1985), for example, is a standardized behavior rating scale used to monitor behavioral or psychiatric problems for individuals with disabilities. The ABC is highly regarded by experts (Rush & Frances, 2000) and has been used as a primary outcome measure in numerous clinical trials, some of which led to approvals of psychotropic medications by the Food and Drug Administration for children with autism (e.g., Marcus et al., 2009; McCracken et al., 2002). Practical advantages of indirect assessments notwithstanding, these methods provide information on other people's perceptions of the extent to which

medication has impacted child behavior.

In contrast to third party reports, behavior analytic assessments are designed to identify and describe behavior-environment interactions (i.e., behavioral processes) by directly observing child behavior as environmental variables are systematically programmed. Behavior analytic researchers have hypothesized that psychotropic medication effects can be understood in terms of basic behavioral processes (e.g., Cox & Virues-Ortega, 2016; Lloyd et al., 2016; Thompson et al., 2007; Valdovinos & Kennedy, 2004). Specifically, these researchers have posited that psychotropic medications may act as motivating operations, such that they temporarily increase or decrease the value of a reinforcer, and thus the likelihood of behaviors that produced that reinforcer in the past (Laraway et al., 2003). Results of several empirical studies have offered preliminary support for this conceptualization. For example, there is evidence suggesting stimulant medication changes the value of positive reinforcers (e.g., edibles, social attention; Northup et al., 1997; Dicesare et al., 2005) and that atypical antipsychotic medication decreases the value of negative reinforcers (e.g., escape from non-preferred tasks; Crosland et al., 2003; Danov et al., 2012; Zarcone et al., 2004).

Assessments that inform behavioral processes could be useful for determining child response to intervention—including medication—as objective measures that supplement or replace third-party report (Northup & Gulley, 2001; Volpe et al., 2005; Weeden et al., 2009). But identifying relevant behavioral processes impacted by medication has further important clinical implications. For one, it might help identify behavioral indicators that predict responsiveness to medication, potentially explaining why two children with the same diagnostic profile can respond differently to the same treatment (Kollins et al., 2000). For another, identifying underlying behavioral processes by which medications produce a therapeutic effect could inform

ways to better integrate medication-based treatment with other interventions focused on skill building (Lloyd et al., 2016; Volpe et al., 2019). This implication is especially important in light of recommendations supporting psychopharmacologic intervention as an addition to—as opposed to a replacement for—behavioral or other psychosocial interventions (AACAP, 2012; Rush & Frances, 2000).

Two behavioral assessments that inform positive and negative reinforcer value, respectively, are progressive ratio and demand assessments. Progressive ratio schedules are those in which reinforcers are delivered contingent on a fixed number of responses that systematically increases within a session (Roane, 2008). Measures of responding are used to determine the amount of effort a person is willing to put forth to earn a given reinforcer. One common index of responding is known as the breakpoint: the response value of the last schedule completed in a session. Applied researchers have used progressive ratio assessments to compare positive reinforcer value among multiple stimuli for a single participant (e.g., Roane et al., 2001). This information is then used to identify the most potent positive reinforcers to incorporate in behavioral interventions. Though less common, progressive ratio schedules can also be repeated with the same stimuli to evaluate change in positive reinforcer value over time or between conditions (e.g., Chelonis et al., 2011).

Demand assessments can be used to inform the value of negative reinforcement (i.e., escaping or avoiding unpleasant conditions). Similar to escape conditions of a functional analysis (Thomason-Sassi et al., 2011), sessions involve continuous presentation of non-preferred task demands to determine how long a person will tolerate these demands without engaging in problem behavior. Latencies to problem behavior are used as an index of task aversiveness, with shorter latencies indicating lower demand tolerance (i.e., increased negative reinforcer value;

Call et al., 2009; 2016). Similar to progressive ratio assessments, demand assessments have been used to compare negative reinforcer value among multiple task demands for a single participant (Call et al., 2009; 2016), but these and similar assessments can also be repeated with the same task demand to evaluate changes in negative reinforcer value over time or between conditions (e.g., Crosland et al., 2003; Zarcone et al., 2004). Both progressive ratio and demand assessments have been recommended by behavior analytic researchers for purposes of medication evaluation and have potential to inform changes in reinforcer value between medication conditions (Carlson et al., 2012; Crosland et al., 2003; Roane, 2008; Zarcone et al., 2004). However, few studies have applied these assessments for this purpose, and to our knowledge, none have evaluated the reliability or validity of scores they produce.

To evaluate the potential for behavior analytic assessments to inform medication effects for children with disabilities, we need to begin examining the scientific utility (i.e., reliability and validity) of scores produced from these assessments (Yoder et al., 2018). Particularly outside the stimulant literature, and especially in recent years, clinical studies incorporating any direct measures of medication effects are few and far between ([redacted for review], under review). Fewer still include standardized behavioral assessments appropriate for use in group design research (e.g., clinical trials) and with potential to isolate behavioral processes ([redacted for review], in preparation; see Grondhuis et al., 2019 and Handen et al., 2013 for exceptions). Among group design studies incorporating both indirect and direct measures of medication effects for children with disabilities, indirect measures have detected changes more often than direct measures (e.g., Aman et al., 1989; Snyder et al., 2002; Waxmonsky et al., 2010). This raises the question of whether the direct measures accurately reflected non-effects or lacked sufficient reliability or validity to detect them.

The purpose of the current study was to evaluate (a) reliability (i.e., temporal stability) and (b) construct validity of scores from two behavior analytic assessments—one designed to inform the value of positive reinforcement (progressive ratio assessment) and another designed to inform the value of negative reinforcement (demand assessment). To evaluate temporal stability, we conducted a series of generalizability and optimization studies to understand sources of score variance and identify conditions in which temporally stable estimates of behavior can be obtained. To inform construct validity, we calculated correlations between scores from each behavioral assessment and those from subscales of the Aberrant Behavior Checklist-Second Edition (ABC-2; Aman et al., 1985) to determine whether scores corresponded in the expected direction. We addressed the following research questions:

1. In a sample of children with disabilities who have been prescribed medication to address behavioral concerns, what proportion of the variance in (a) progressive ratio scores and (b) demand scores is due to true score variance versus facets of the measurement system (session, observer)? (c) Based on these variance component estimates, how many sessions of each assessment are needed to meet a minimum stability criterion ($g \geq .70$)?
2. For a subset of children who completed the same assessment battery 8 weeks after starting a new medication regimen, do variance structures change across time points?
3. Within each of two time points, are there associations between scores from each behavioral assessment and parent ratings of externalizing challenging behavior (i.e., Irritability and Hyperactivity/Noncompliance subscales of the ABC-2; Aman et al., 1985)?

Method

Participants

We recruited participants from a clinic in the [blinded]. To participate, children were required to (a) be 5–17 years of age, (b) have a disability and/or diagnosed psychiatric disorder, and (c) have been prescribed a psychotropic medication to address a behavioral concern. We aimed to recruit children who were prescribed a new medication or an increased dosage of a current medication but had not begun the new regimen. The prescribing physician (last author) shared recruitment flyers with families whose child met the above criteria. She provided input on the timing between behavioral assessments (see Procedures), but was not involved in the design, implementation, or evaluation of behavioral assessments throughout recruitment or data collection. We contacted families who expressed an interest in the study by phone to share more information on study goals and procedures. If the parent indicated further interest, we sent them a link to a consent form via email.

Twenty-three children participated in the study. Most participants were boys (n = 17; 73.9%) and the majority were White (n = 14; 60.9%). Eighteen of the 23 participants had an intellectual or developmental disability; the remaining five participants' primary diagnosis was ADHD—four of whom also had a speech/language impairment and one of whom also had an anxiety disorder. Ten participants had both an intellectual or developmental disability and a comorbid psychiatric disorder (e.g., ADHD, anxiety disorder). Parents reported all participants engaged in some form of challenging behavior, and more than one topography was reported for the majority (82.6%) of participants. While all participants had recently been prescribed a new medication or a new dosage of a current medication, 19 participants were already taking at least one psychotropic medication at the time of the initial assessment visit. Twenty-two participants returned for a second assessment visit approximately 8 weeks following their initial visit. We

confirmed that 18 of these children followed through with starting a new medication regimen shortly after the initial assessment visit. Additional details on participant characteristics and medication classes are presented in Table 1.

Setting

All behavioral assessments were completed in one of two clinic rooms on a university campus. Each room contained two tables and at least two chairs. One clinic room had a one-way mirror and an adjoining observation room with recording equipment. The other room was an empty office with no adjoining observation room. With few exceptions, two adults were in the room with the child during assessment sessions. One adult served as primary therapist (i.e., assessment implementer) and a second adult was present to support implementation as needed. For sessions conducted in the empty office, a third adult was present to work the video recorder.

Materials

Progressive ratio assessment materials included a large plastic container with a 2.1 x 2.1 cm hole cut into the lid, a set of two hundred 2-cm plastic cubes, a laminated picture of a stop sign, and a set of three to five snacks (e.g., fruit snacks, pretzels, m&ms). Demand assessment materials varied by participant, but often included a set of items to clean up (e.g., toys or blocks and a bin, crumpled pieces of paper and a trash can). We used Canon VIXIA video cameras on tripods to record all sessions. We used iPhones or iPods with a timed-event data collection application (Countee; Gavran & Hernandez, 2018) to collect primary data on child behavior and paper-pencil data collection forms to collect procedural fidelity data.

Procedures

After obtaining parent consent, we scheduled a 30-min parent phone interview to collect initial information on the child (i.e., demographics, prescribed medication, description of

problem behavior). To inform selection of edibles to use for progressive ratio sessions, we shared a menu of available snacks, and asked parents to indicate which ones their child preferred. If none were highly preferred, parents identified other preferred edibles and we procured them prior to the assessment visit. We also asked parents to identify non-preferred task demands for their child, which we used to inform demand assessment procedures. Finally, we scheduled the first assessment visit, which was typically within one week of the phone interview.

Parents brought their child to the university for two 1.5- to 2-hr assessment visits, which were scheduled approximately 8 weeks apart. We wanted to keep the time between assessment visits constant across participants, thus we selected a time span that was long enough for a therapeutic effect to be present at Time 2 across all medication classes likely to be prescribed (McVoy & Findling, 2017). Though the purpose of this study was not to evaluate medication effects directly, our goal was to time the assessment visits similarly to how future medication efficacy studies might be designed. At each visit, we completed three sessions for each of two assessments: progressive ratio and demand. We also completed four trials of a concurrent operant preference assessment, the results of which are not included in this paper. We randomized the sequence of sessions within three session blocks, with 5-min breaks between each block.

Progressive Ratio Assessment

Prior to each progressive ratio session, the therapist prompted the child to choose a snack from an array of three to five options. The therapist told the child they can put blocks in the bin to earn the snack, but can stop whenever they want. She modeled the target response (i.e., placed one block in the bin), prompted the child to practice the response, and delivered an edible following the response. She told the child that sometimes they might have to put a lot of blocks

in the bin to get the snack, and other times just a few. Finally, she told the child to say "all done" or touch the stop sign if they wanted to stop, and modeled touching the stop sign. We used one of two versions of scripted instructions depending on the child's communication skills. Across all participants, we practiced the response and reward at least once before beginning the session. During the session, the therapist reinforced the target response (i.e., putting one block in the bin) according to a rapid additive progression (Fixed ratio [FR] 1, FR2, FR5, FR10, FR20, FR30, FR40; Reed et al., 2009). We set a maximum FR value (40) and session duration (5 min) to minimize the likelihood of problem behavior due to ratio strain (i.e., response requirements becoming too large) and to ensure adequate time to conduct repeated sessions of each assessment. Other researchers have taken a similar tactic in setting maximum session durations and/or breakpoints (e.g., Chelonis et al., 2011; Paule et al., 1999; Reed et al., 2009). If problem behavior occurred (9 of 135 sessions), the therapist provided a verbal reminder that the child could keep working to earn [snack] or touch the stop card if they were all done. If problem behavior continued following the verbal reminder (3 of 135 sessions), the therapist brought the stop card to touch the child's hand (to avoid hand-over-hand prompting) and terminated the session. Otherwise, the session ended when (a) the child indicated they wanted to stop, (b) 1 min elapsed with no target responses, or (c) the child completed the final response requirement (FR40). If the child had not met any of these criteria after 5 min elapsed, we ended the assessment after delivery of the next reinforcer.

Demand Assessment

The demand assessment was modeled after the escape condition of a latency-based functional analysis (Thomason-Sassi et al., 2011) as well as other demand assessments that use latency to problem behavior as an index of task aversiveness (e.g., Call et al., 2016). During each

session, the therapist presented directives to complete a non-preferred task (e.g., cleaning up toys, throwing away trash) using a three-step prompting sequence (i.e., verbal, model, physical). Contingent on compliance, therapists provided brief praise followed by a subsequent task directive. If the child did not comply within 5 s of the verbal prompt, the therapist provided a model prompt; if the child did not comply within 5 s of the model prompt, the therapist provided a physical prompt. Child requests to escape or change the activity were briefly acknowledged but not reinforced (e.g., "maybe later, right now we're cleaning up"). Contingent on the first occurrence of problem behavior, the therapist withdrew the demands (e.g., "Okay, we're all done" while setting the task materials aside), at which point the session ended. The session ended after 5 min if problem behavior did not occur. The 5-min session duration was informed by previous studies using latency-based functional analyses (e.g., Hansen et al., 2019; Lambert et al., 2017; Thomason-Sassi et al., 2011).

Measures

Parent-Completed Forms

During each assessment visit, parents completed a demographic and medication history form and the ABC-2 (Aman et al., 1985). The demographic and medication history form included items on basic child demographics and current and previous medications. The ABC-2 (Aman et al., 1985) is a 58-item behavior rating scale with five subscales (Irritability, Social Withdrawal, Stereotypic Behavior, Hyperactivity/Noncompliance, and Inappropriate Speech) that has an extensive history as an outcome measure in medication efficacy studies (Aman, 2015). When used by parents to rate the behavior of children and adolescents with developmental disabilities, each of the ABC-2 subscales has high internal consistency (Cronbach's α between .83 and .93) and high test-retest reliability over one month (Pearson's *r*

between .80 and .95; Freund & Reiss, 1991).

Direct Behavioral Assessments

From videos of progressive ratio sessions, we collected timed-event data (i.e., recorded the time at which each event occurred; Yoder et al., 2018) on frequencies of target responses and reinforcer deliveries. Though not a primary outcome measure for this assessment, we also collected data on frequencies of problem behavior (defined below). The target response was coded when the child placed a block in the bin. Reinforcer delivery was coded each time the therapist placed a small edible on a napkin or plate beside the child. For each progressive ratio session, we used the total number of responses and reinforcer deliveries to calculate the breakpoint (i.e., the response value of the last schedule completed before the child stopped responding, requested to stop, or reached the pre-defined session duration limit; Roane, 2008). We calculated target response rates by dividing the total frequency of responses by the session duration (min). We included a response rate measure to inform the temporal nature of response patterns within sessions. Unlike the breakpoint score, there was no maximum response rate.

From videos of demand sessions, we collected timed-event data on problem behavior, requests to escape the task or change activities, and child compliance with therapist task demands. Problem behavior was broadly defined to capture a range of reported topographies. We defined problem behavior to include aggression (i.e., forceful contact between the child's body and another person); disruption (i.e., forceful contact between the child's body and an object or surface; throwing or breaking objects; crying or screaming); and self-injury (i.e., forceful contact between the child's body and another part of their body or between their head and an external surface). These standard definitions applied across all participants. When parents described other forms of problem behavior that did not meet these definitions, we included additional

topographies in the problem behavior definition on an individual basis. These additional topographies included active noncompliance (i.e., overt verbal or gestural refusals to follow adult-given directives, such as yelling "No!" or pushing away materials); inappropriate language (e.g., cursing, making verbal threats of harm); and elopement (i.e., attempts to leave the assessment room by [a] placing a hand on the door knob or [b] moving at least three steps away from the therapist or session materials towards the door). We defined requests as any vocal or gestural bid to escape the activity or engage in an activity that was incompatible with completing the task demand, excluding behaviors that would meet the above definitions for problem behavior. Example requests included using a communication device to request iPad, asking to take a walk or see the parent, and pointing to materials from another assessment activity. We defined compliance as the initiation of task completion within 10 s of a therapist verbal prompt (i.e., if the child complied following the verbal or model prompt). Latencies to problem behavior were coded from the timed-event data files, as were latencies to the first instance of a request. For sessions in which a request did not occur but problem behavior did (thus ending the session), the latency to problem behavior was entered for both latency measures. Thus, the latency to request score represented the latency to request *or problem behavior*, whichever occurred first. We conceptualized this score as a broader measure of tolerance, indicating the point at which the child attempted to initiate a change in activities, either by requesting it outright or engaging in problem behavior. We calculated a percentage of compliance by dividing the number of occurrences of compliance by the total number of task demands and multiplying by 100.

Therapist and Coder Training

Graduate research assistants in a department of Special Education implemented and coded all assessment sessions. Before serving as therapist in study sessions, research assistants

completed the following training activities. First, they attended a 60-min training meeting that included didactic instruction on each assessment and role-play with feedback. Therapists then watched example videos of the assessments and practiced role-playing with another research team member. Finally, each therapist practiced implementing each assessment with the third author until they correctly implemented all procedures. Before collecting study data, research assistants attended a 45- to 60-min didactic training on data collection procedures and were required to reach 90% agreement with master codes across three consecutive sessions of each assessment for both child behavior and procedural fidelity variables.

Procedural Fidelity

Data collectors used paper-pencil forms to collect procedural fidelity data on therapist implementation across all sessions. For progressive ratio sessions, they indicated the presence or absence of four pre-session components (i.e., correct materials present, read script with model, practiced response and reward, solicited and answered questions). Then, for each schedule requirement completed in the session, they indicated whether each of the following procedures were correctly implemented (Yes, No, or Not applicable): followed prompting rules, minimized attention, delivered reward upon schedule completion, blocked attempts to put more than one block in the bin at a time, redirected problem behavior, and followed session termination procedures. For each session, we calculated a percentage of correct implementation by dividing the total number of Yes tallies by the sum of Yes and No tallies and multiplying by 100. Mean fidelity for progressive ratio sessions was 98.3% (range, 93.4%–100%) for pre-session components and 96.1% (range, 85.7%–100%) for all other within-session components.

For demand sessions, coders scored the presence or absence of one pre-session component (i.e., correct materials present) and the session termination criteria (i.e., ended session

within 2 s of the first occurrence of problem behavior or when 5 min elapsed). In addition, sessions were divided into 10-s intervals, and for each interval, coders scored whether the following three procedural components were correctly implemented: presented demand-related prompts every 5 s when the child was not complying, used the appropriate prompting sequence, and delivered brief praise following compliance. For intervals scored as containing an error, coders indicated which of these three procedural components was implemented incorrectly. Therapists had correct materials present in 100% of sessions, and correctly terminated the session in 96.3% of sessions. The mean percentage of intervals with correct implementation was 97.6% (range, 57.1%–100%). The most common error was more than 5 s elapsing between therapist demand deliveries in the absence of child compliance. Sessions with low fidelity were those that were brief, resulting in relatively few opportunities to score correct implementation.

Inter-Observer Agreement

All sessions were coded independently by two trained data collectors. For formative assessment of inter-observer agreement (IOA), we calculated total agreement percentages (i.e., [smaller/larger]*100) and monitored agreement percentages produced from the Countee software (i.e., 10-s interval-by-interval agreement). For progressive ratio sessions, mean agreement was 99.3% (range, 83.3%–100%) for target responses, 97.5% (range, 50.0%–100%) for reinforcer delivery, and 99.5% (range, 83.3%–100%) for problem behavior. For demand sessions, mean agreement was 99.7% (range, 87.5%–100%) for latency to problem behavior, 92.8% (range, 3.3%–100%) for latency to requests, and 93.3% (range, 66.7%–100%) for compliance. Low minimum agreement scores for latency to requests were identified for sessions in which observers disagreed on whether a request occurred very early in a session (producing two very different latencies). We calculated point-by-point agreement on procedural fidelity of

progressive ratio sessions as the number of agreements on each fidelity code (Yes, No, N/A) divided by the number of agreements plus disagreements, multiplied by 100. We calculated a percentage of intervals with agreement on procedural fidelity codes for demand sessions (intervals with errors had to have the same error type coded to count as an agreement). Mean agreement was 97.3% (range, 66.7%–100%) for progressive ratio sessions and 96.2% (range, 50.0%–100%) for demand sessions. Sessions with low agreement often reflected single disagreements (or single intervals with disagreement) among few opportunities to agree.

Data Analysis

To address the first research question, we conducted a series of fully crossed, 3-facet (random effects) generalizability studies using EduG software (Swiss Society for Research in Education Working Group, 2012). EduG uses Type III mean squares from analyses of variance (ANOVAs) to calculate a series of variance component estimates. Our 3-facet generalizability studies focused on variance due to Person (i.e., true score variance) and variance due to two facets of the measurement system (i.e., Session and Observer). We were particularly interested in isolating the percentages of variance accounted for by Person, which represents true score variance; Person x Session, which represents the extent to which participant score rankings vary by session; and Person x Observer, which represents the extent to which participant score rankings vary by observer.

We also calculated absolute *g* coefficients (Shavelson & Webb, 2006) for each behavior assessment score using EduG. A *g* coefficient is a type of intra-class correlation that represents the amount of variance due to Person (true score) divided by the total observed score variance (true score + measurement error; Yoder et al., 2018). Essentially, these *g* coefficients indicated whether the number of sessions (3) and observers (2) used for this study were sufficient to

produce adequately stable scores ($g > .70$; Berk, 1979; Bloch & Norman, 2012; Mitchell, 1979) given the observed variance. Formulas for calculating variance component estimates and *g* coefficients are accessible via the following link: [redacted]. We then used EduG to conduct optimization studies, which use the variance component estimates from the generalizability studies to estimate projected *g* coefficients for different measurement structures (e.g., varying the number of sessions or observers from what was used for the existing data set; Yoder et al., 2018). Our primary goal in conducting optimization studies was to determine the minimum number of sessions required to produce adequately stable scores for future studies.

To address Research Questions 1–2, we conducted separate generalizability and optimization studies using (a) all data from the initial assessment visit (23 Persons x 3 Sessions x 2 Observers) and (b) data from 18 participants who started a new medication regimen before returning 8 weeks later to complete the same assessment battery (18 Persons x 3 Sessions x 2 Observers). To address the third research question, we calculated Pearson Product-Moment correlations between each behavior assessment score (using averages across the three sessions) and subscale scores from the ABC-2 within each time point. We predicted negative associations between each behavior assessment score and each of two subscales related to externalizing challenging behavior (i.e., Irritability and Hyperactivity/Noncompliance). That is, we expected the children who were motivated to engage in an adult-defined target response to earn positive reinforcers (evidenced by high breakpoints or response rates during progressive ratio sessions) would be rated by parents as exhibiting lower levels of irritability, hyperactivity, and/or noncompliance outside the assessment context. Similarly, we expected the children who were able to tolerate and comply with non-preferred task demands (evidenced by long latencies to problem behavior or requests, and high percentages of compliance during demand sessions)

would be rated by parents as exhibiting lower levels of irritability, hyperactivity, and/or noncompliance outside the assessment context. Because separate sets of correlations were calculated and tested at each time point and were not intended to inform changes following new medication regimens, we included data from all completed assessments at each time point in the correlational analysis. We used SPSS version 26 (IBM SPSS Statistics for Macintosh) to test the statistical significance of these correlations (two-tailed significance tests against alpha values of .05 and .01).

Results

Table 2 presents descriptive statistics for behavioral assessment scores for all participants who completed the initial assessment visit, all participants who completed a second assessment visit, and the subset of participants within each time point for whom one or more medication change was made. Frequency distributions of behavioral assessment scores by time point are presented in Figure 1. Means, standard deviations, and frequency distributions suggest adequate among-participant variance for progressive ratio scores but a ceiling effect for demand scores, particularly latency to problem behavior. During initial assessment visits, 16 of 23 participants did not engage in problem behavior across demand sessions (i.e., produced a maximum latency score of 300 s). To explore the potential for systematic differences in behavioral assessment scores by medication class, we identified scores representing the most common medication class across time points (i.e., stimulants; see closed triangles in Figure 1). We saw no evidence of systematic differences.

Results of generalizability studies on scores from all participants at the initial assessment visit are shown in Table 3. For progressive ratio scores, the percentage of variance accounted for by Person (true score variance) exceeded 60% for breakpoint and 80% for response rate. The

Person x Session interaction accounted for more than 30% of variance in breakpoint scores, whereas this interaction accounted for roughly 15% of variance in response rate scores. The Person x Observer interaction accounted for 0% of variance across scores. These patterns suggest that participants would be ranked differently depending on which session was selected, particularly for break point scores. This indicates a need to average scores across more than one session to obtain adequately stable estimates. Using data from all three sessions and two observers, the absolute *g* coefficient for both progressive ratio scores exceeded .80.

Percentages of variance accounted for by Person (true score variance) varied among demand assessment scores at Time 1 (34.9%–55.7%), and were lower than estimates for progressive ratio scores. Again, the Person x Session interaction accounted for substantial variance in demand scores relative to the Person x Observer interaction, suggesting a need to average scores across multiple sessions to achieve adequate stability. Using data from all three sessions and two observers, absolute *g* coefficients ranged from .62 (percentage compliance) to .80 (latency to problem behavior). Across all behavioral assessment scores, main effects of Session and Observer as well as the Session x Observer interaction contributed trivial variance. Random error (i.e., Person x Session x Observer) also contributed trivial variance with one exception (i.e., Latency to request at Time 2 [15.0%]).

Results of optimization studies are shown in Figure 2, which depicts projected *g* coefficients across varying numbers of sessions for progressive ratio scores (top graph) and demand scores (bottom graph). These data reflect scores from single observers, given the near-zero variance component estimates associated with the observer facet. Results suggested reliable estimates of response rate can be obtained from a single progressive ratio session, whereas reliable estimates of breakpoint require at least two. A minimum of two demand sessions are

needed to obtain stable estimates of latency to problem behavior, whereas four or five sessions are needed to obtain stable estimates of latency to request and percentage of compliance.

Results of generalizability studies on scores from the set of participants who started a new medication regimen are presented in Table 4. Across scores, percentages of variance accounted for by Person (true score variance) increased from Time 1 to Time 2, and percentages of variance accounted for by the Person x Session interaction decreased. These changes in variance component estimates resulted in higher *g* coefficients at Time 2 relative to Time 1. With one exception (latency to request at Time 2), variance accounted for by the Person x Observer interaction remained zero or trivial. Based on the increased stability of scores at Time 2, we did not conduct follow up optimization studies, as the number of sessions required to achieve stability would have been equal to or fewer than the number identified for the initial data set.

Pearson product-moment correlations between each behavioral assessment score and ABC subscale score are shown in Table 5. Three behavioral assessment scores were significantly and negatively associated with parent ratings of Irritability: breakpoint (Time 1 only), response rate (Time 1 only), and percentage compliance. Four behavioral assessment scores were significantly associated with parent ratings of Hyperactivity/Noncompliance: breakpoint, response rate, latency to problem behavior (Time 1 only), and percentage of compliance. Though not predicted, two behavioral assessment scores were also significantly and negatively associated with parent ratings of Stereotypy (response rate [Time 1 only], percentage compliance), and one score (breakpoint, Time 2 only) was significantly and negatively associated with parent ratings of Inappropriate Speech. None of the behavioral assessment scores were significantly associated with Social Withdrawal subscale scores.

Discussion

The goal of this study was to explore the potential for each of two behavior analytic assessments to inform whether and how psychotropic medication impacts behavioral processes (i.e., positive and negative reinforcement). In this initial evaluation, we focused on temporal stability and construct validity of scores produced from each assessment. Results highlighted three main findings that inform future research applying these assessments for purposes of medication evaluation. First, a ceiling effect was observed for demand assessment scores, and was particularly pronounced for latency to problem behavior. Though the 5-min session maximum was informed by previous research on functional analysis (e.g., Hansen et al., 2019; Thomason-Sassi et al., 2011; Wallace & Iwata, 1999), our demand sessions did not occur in the context of a functional analysis, but were interspersed with other assessment types. In addition, though we selected task demands based on what parents reported would be likely to evoke problem behavior, we did not collect any preliminary data to confirm this pattern. In future studies, we recommend increasing the maximum duration of demand sessions from 5 to 10 min. Increasing the maximum session duration is expected to improve the degree to which scores would be sensitive to change after beginning a new medication regimen.

Second, with only one exception, scores from single sessions did not have the temporal stability needed to reliably differentiate among participants. However, the variance estimates obtained from the current data set suggest that averaging across as few as two sessions would be sufficient to obtain adequately stable estimates ($g > .70$) of progressive ratio scores without compromising their content validity (e.g., reinforcers losing value as a result of conducting too many sessions). Response rates showed more stability relative to breakpoints, which we attribute to the increased range of possible values relative to the number of possible breakpoint scores. Results also suggest averaging across as few as two sessions could be sufficient to obtain

adequately stable estimates of demand scores if latency to problem behavior is the primary outcome measure, whereas several more sessions would be needed to obtain reliable estimates of latencies to requests and percentages of compliance. We suspect extending session durations from 5 to 10 min would increase the stability of demand scores such that fewer sessions would be needed to reach reliability thresholds. Variance estimates for the observer facet were zero or near-zero across almost all scores. The single exception was the latency to request score, for which percentages of agreement at the session level were also lower relative to other scores. These results suggest that averaging scores from multiple observers is not necessary as long as formative point-by-point interobserver agreement estimates are within acceptable ranges.

Third, significant negative correlations between scores from behavior analytic assessments and ABC-2 subscale scores related to externalizing challenging behavior offer initial evidence of construct validity. In particular, breakpoint, response rate, and percentage of compliance were all significantly and negatively correlated with Irritability and Hyperactivity/Noncompliance subscale scores at one or both time points. We should point out, however, that continued evaluation of construct validity for these behavioral assessments is critical. We selected the ABC-2 based on its widespread use as a behavioral outcome measure in medication evaluations for children with disabilities. Other types of indirect assessments, such as caregiver ratings of problem behavior function, might be expected to align more closely with direct measures of positive and negative reinforcer value and provide stronger evidence of construct validity. It is also possible that associations between direct assessment scores and ABC-2 subscale scores vary by behavior function. Including multiple and varied assessment measures in future studies would offer further opportunities to evaluate construct validity of scores from each behavioral assessment.

Taken together, our results support the scientific utility of progressive ratio scores, as evidenced by the among-participant variance observed (Figure 1), their high temporal stability (Tables 3–4), and significant negative correlations with parent ratings of challenging behavior (Table 5). On the other hand, the ceiling effect observed for demand scores, as well as the low temporal stability of percentage of compliance, raises questions about whether the observed negative linear relations between demand scores and parent ratings of challenging behavior are replicable. Future studies are needed to evaluate temporal stability and construct validity for demand sessions with longer maximum durations. In addition to extending session duration, researchers might also consider the use of aggregate variables for demand assessments (i.e., combining multiple component scores by averaging or summing them). Particularly in the context of group design research, aggregating scores from one assessment has potential to improve both temporal stability and construct validity (Yoder et al., 2018).

Our findings should be interpreted with the following limitations in mind. First, participants in this study represent a heterogeneous sample, with respect to both diagnoses and medications prescribed. We do not know if results would replicate for more homogenous samples (e.g., children with autism as only diagnosis) or those prescribed medications that were minimally represented in this sample (e.g., atypical antipsychotics). Second, due to the variety of medication changes made after the first assessment visit, our analyses focused on temporal stability and construct validity within time point, rather than evaluating changes in behavior (or behavior ratings) between time points. Additional studies are needed that focus on a single class of medication to address sensitivity to change associated with each behavioral assessment. Third, we selected progressive ratio and demand assessments as potential indicators of positive and negative reinforcer value, respectively, but we did not experimentally evaluate whether edibles

used in the progressive ratio sessions indeed functioned as positive reinforcers; nor did we experimentally confirm that participants' problem behavior was maintained by negative reinforcement. In the future, brief control conditions might be added to the assessment battery to better isolate each behavioral process. For example, response rates from progressive ratio sessions might be compared to those observed when no edible rewards are delivered contingent on the target response. Or, latencies to problem behavior from demand sessions might be compared to those observed in free play sessions in which no demands are presented. Finally, we did not control for the potential influence of side effects on behavioral assessment scores. For example, decreased appetite is a common side effect of stimulant medication that could influence the value of edible reinforcers used during progressive ratio sessions. We did not find evidence of progressive ratio scores being systematically lower in the stimulant subgroup relative to other participants (see Figure 1). But in future research, especially studies focused on a single medication class, procedural adaptations to behavioral assessments may be warranted to clearly distinguish therapeutic effects of medication from common side effects.

The existing literature on behavior analytic outcome measures for medication effects is limited with respect to both quantity and quality ([redacted for review], in preparation; Courtemanche et al., 2011; Napolitano et al., 1999). The current study represents the first evaluation of measurement properties of two behavior analytic assessments with potential to inform how medication might impact positive and negative reinforcement processes for children with disabilities and behavioral concerns. Results of this initial investigation inform conditions in which scores from each assessment are likely to produce temporally stable estimates of behavior and offer preliminary evidence of construct validity. Taken together, our results suggest break point and response rate scores from progressive ratio assessments may be scientifically useful in

evaluating change in positive reinforcer value following medication. More research is needed to evaluate sensitivity to change in scores from these and other behavior analytic assessments for particular classes of medication. In addition, similar evaluations of temporal stability and construct validity are needed for behavior analytic assessments designed to inform other behavioral processes (e.g., stimulus control, sensitivity to parameters of reinforcement, impulsivity), for which the current study might serve as a model.

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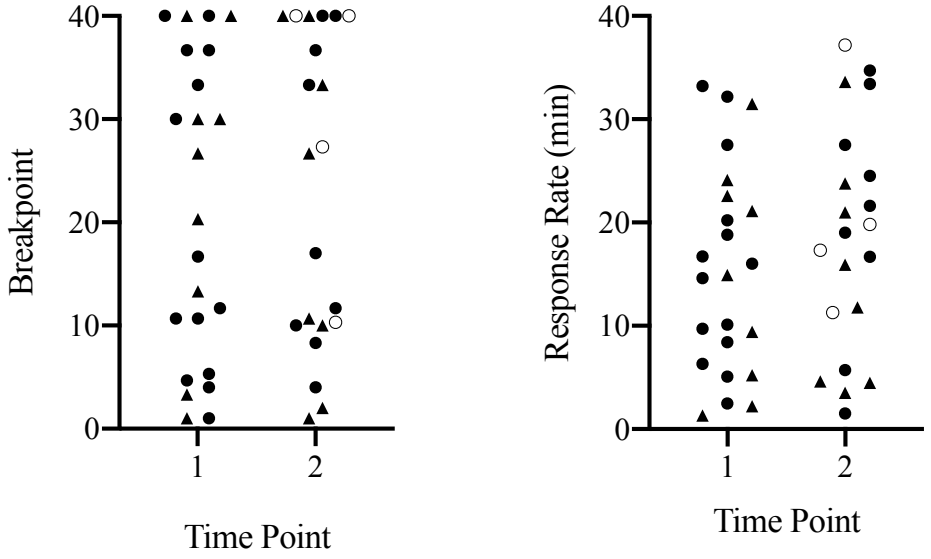
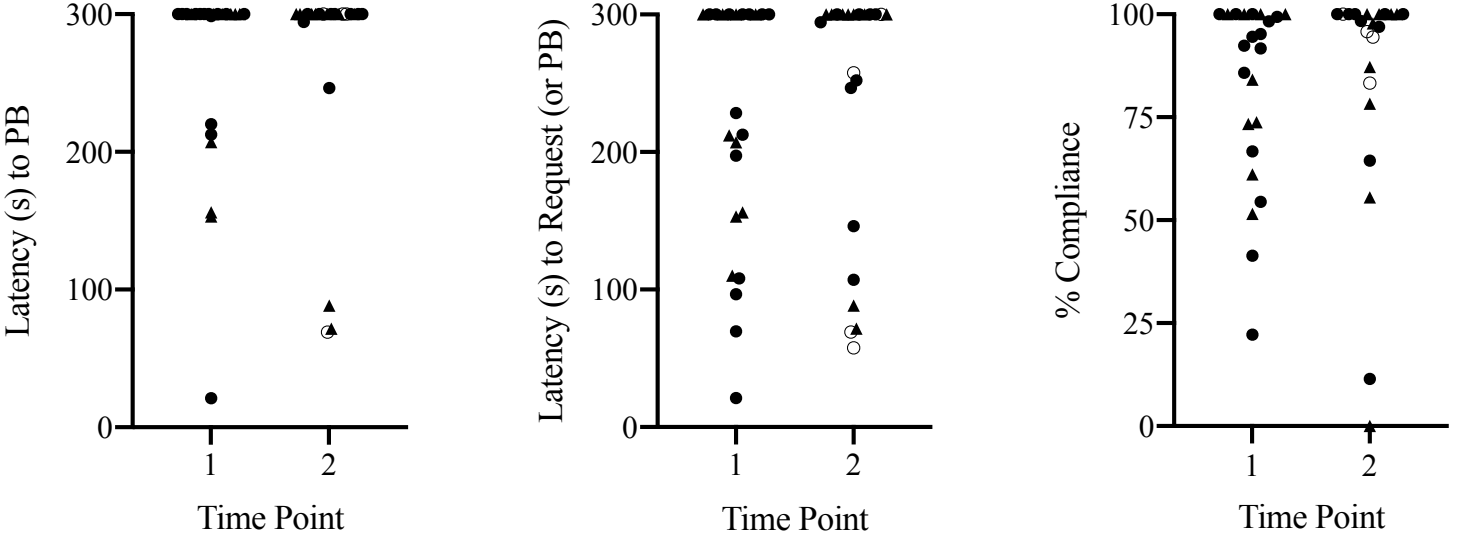
Figure 1

Frequency Distributions of Behavioral Assessment Scores by Time Point

Progressive Ratio Assessment



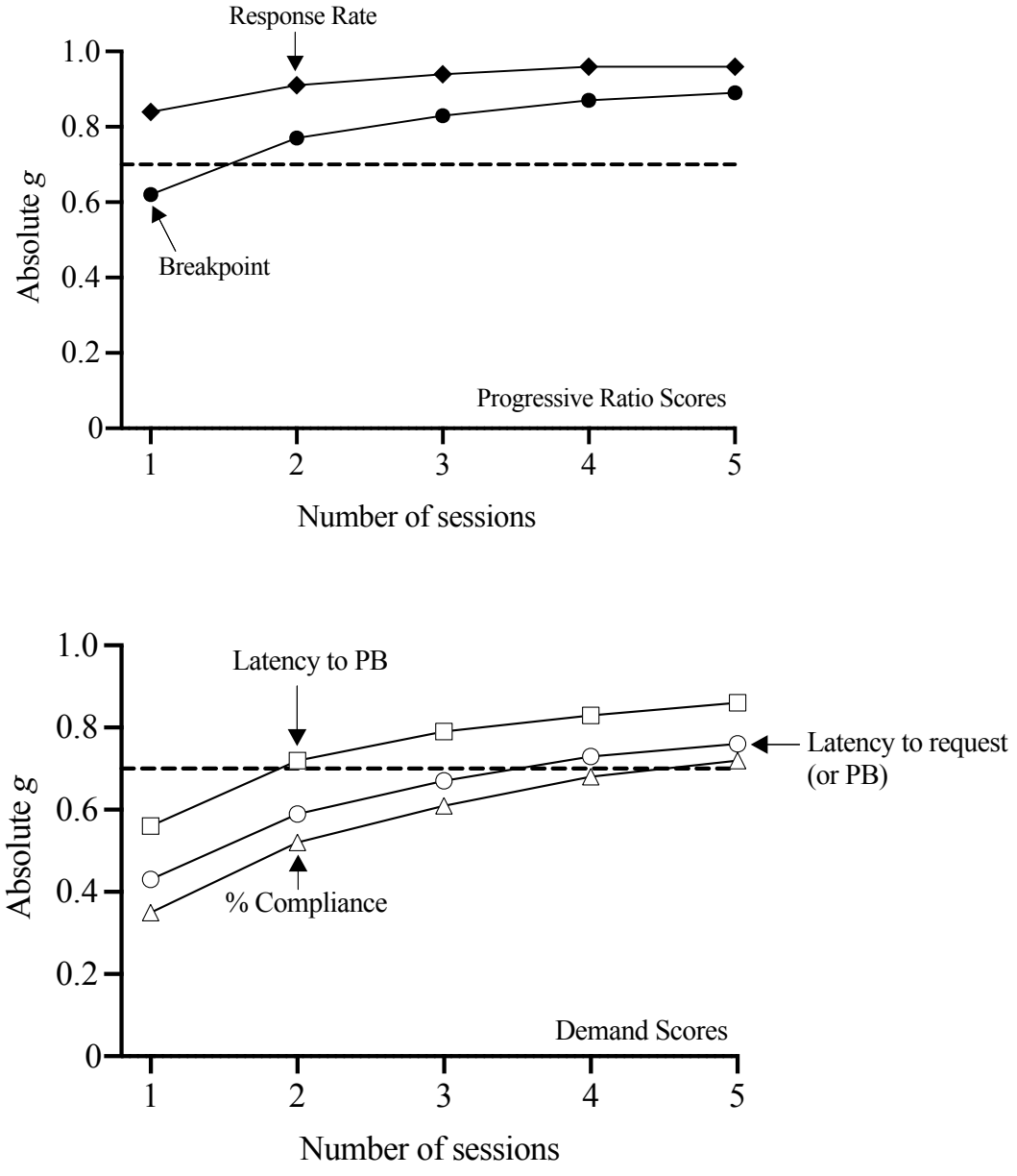
Demand Assessment



Note. PB = Problem behavior. Closed triangles represent the stimulant subgroup. Open shapes represent participants without a medication change at Time 2 (excluded from Time 2 generalizability and optimization studies).

Figure 2

Projected g Coefficients Across Varying Numbers of Sessions for Progressive Ratio (Top) and Demand (Bottom) Scores



Note. Dashed line represents criterion *g* (.70). PB = Problem behavior.

Table 1

Participant Characteristics

	n	%
Gender		
Male	17	73.9
Female	6	26.1
Ethnicity		
White	14	60.9
Black	6	26.1
Hispanic/Latino	3	13.0
Diagnoses		
Autism	15	65.2
Attention deficit/hyperactivity disorder	13	56.5
Anxiety disorder	5	21.7
Down syndrome	3	13.0
Other genetic disorders	2	8.7
Oppositional defiance disorder	1	4.3
Mood disorder	1	4.3
Parent-Reported Topographies of Problem Behavior		
Disruption	16	69.6
Active noncompliance	15	65.2
Aggression	10	43.5
Self-injury	4	17.4
Inappropriate language	4	17.4
Elopement	3	13.0
Medication Classes (Time 1; n = 23)		
None	4	17.4
Stimulant	9	39.1
α_2-adrenergic agonists	6	26.1
Selective serotonin reuptake inhibitor	6	26.1
Serotonin-norepinephrine reuptake inhibitor	1	4.3
Atypical antipsychotic	1	4.3
Medication Classes (Time 2; n = 18)		
α_2-adrenergic agonists	11	61.1
Stimulant	9	50.0
Selective serotonin reuptake inhibitor	8	44.4
Serotonin-norepinephrine reuptake inhibitor	1	5.6
Selective norepinephrine reuptake inhibitor	1	5.6
Atypical antipsychotic	1	5.6

Table 2

Descriptive Statistics for Behavioral Assessment Scores

Behavioral Assessment Score	*N*	Mean	*SD*	Min	Max
All participants at Time 1					
Progressive Ratio					
Breakpoint	23	21.13	14.54	1	40
Response Rate	23	15.38	9.95	1.30	33.20
Demand					
Latency to PB	23	263.84	71.60	21	300
Latency to Request (or PB)	23	220.51	90.93	21	300
Percentage Compliance	23	82.00	22.47	22.22	100
Medication change participants at Time 1					
Progressive Ratio					
Breakpoint	18	21.33	14.83	1	40
Response Rate	18	14.83	9.97	1.30	32.17
Demand					
Latency to PB	18	253.80	78.38	21	300
Latency to Request (or PB)	18	213.87	93.89	21	300
Percentage Compliance	18	79.71	24.48	22.22	100
All participants at Time 2					
Progressive Ratio					
Breakpoint	21	22.97	14.97	1	40
Response Rate	21	18.52	10.96	1.53	37.17
Demand					
Latency to PB	22	266.80	78.37	69.00	300
Latency to Request (or PB)	22	235.92	94.27	57.67	300
Percentage Compliance	22	84.72	28.38	0	100
Medication change participants at Time 2					
Progressive Ratio					
Breakpoint	17	21.45	15.18	1	40
Response Rate	17	17.85	11.15	1.53	34.73
Demand					
Latency to PB	18	272.26	71.13	71.67	300
Latency to Request (or PB)	18	250.33	83.55	71.67	300
Percentage Compliance	18	82.79	31.05	0	100

Note. PB = problem behavior.

Table 3

Results of Generalizability Studies for Total Sample at Time 1 (23 Participants x 3 Sessions x 2 Observers)

Score	Source	df	MS	% Variance
Progressive Ratio				
Breakpoint	P	22	1273.44	62.3
(*g* = .83)	S	2	60.03	0.0
	O	1	0.72	0.0
	P x S	44	212.15	36.9
	P x O	22	2.24	0.0
	S x O	2	0.72	0.0
	P x S x O	44	2.24	0.8
Response Rate	P	22	595.08	84.3
(*g* = .94)	S	2	13.81	0.0
	O	1	0.38	0.0
	P x S	44	34.73	15.6
	P x O	22	0.07	0.0
	S x O	2	0.11	0.0
	P x S x O	44	0.08	0.1
Demand				
Latency to PB	P	22	667644.77	55.7
(*g* = .80)	S	2	30071.48	2.7
	O	1	256.12	0.0
	P x S	44	256419.19	37.9
	P x O	22	5897.55	0.0
	S x O	2	529.80	0.0
	P x S x O	44	11767.54	3.6
Latency to Request (or PB)	P	22	42628.11	42.5
(*g* = .70)	S	2	16431.80	0.5
	O	1	647.83	0.0
	P x S	44	11947.11	47.3
	P x O	22	1532.18	2.0
	S x O	2	2434.44	0.6
	P x S x O	44	831.88	7.1
% Compliance	P	22	2970.94	34.9
(*g* = .62)	S	2	3490.89	5.9
	O	1	103.76	0.1
	P x S	44	1040.79	54.7
	P x O	22	45.57	0.3
	S x O	2	11.25	0.0
	P x S x O	44	36.93	4.0

Note. P = Person; S = Session; O = Observer; PB = problem behavior.

Table 4

Results of Generalizability Studies at Time 1 vs Time 2 for Participants with Medication Change (17/18 Participants x 3 Sessions x 2 Observers)

Score	Source	df	% Variance Accounted For	
			Time 1	Time 2
Progressive Ratio				
Breakpoint	P	16	60.9	77.2
	S	2	0.0	1.5
	O	1	0.0	0.0
	P x S	32	38.7	20.9
	P x O	16	0.0	0.0
	S x O	2	0.0	0.0
	P x S x O	32	0.3	0.4
Absolute *g*			.82	.91
Response Rate	P	16	83.0	87.5
	S	2	0.0	0.0
	O	1	0.0	0.0
	P x S	32	16.9	12.5
	P x O	16	0.0	0.0
	S x O	2	0.0	0.0
	P x S x O	32	0.1	0.0
Absolute *g*			.94	.95
Demand				
Latency to PB	P	17	56.9	82.7
	S	2	5.5	0.0
	O	1	0.0	0.0
	P x S	34	37.6	17.3
	P x O	17	0.0	0.0
	S x O	2	0.0	0.0
	P x S x O	34	0.0	0.0
Absolute *g*			.80	.94
Latency to Request (or PB)	P	17	46.6	53.8
	S	2	4.6	0.0
	O	1	0.0	2.2
	P x S	34	40.6	12.8
	P x O	17	2.0	16.2
	S x O	2	0.5	0.0
	P x S x O	34	5.6	15.0
Absolute *g*			.73	.77
% Compliance	P	17	34.4	90.6
	S	2	10.2	0.0
	O	1	0.0	0.0
	P x S	34	52.5	6.9

	P x O	17	0.1	0.0
	S x O	2	0.0	0.1
	P x S x O	34	2.7	2.4
Absolute *g*			.62	.97

Note. P = Person; S = Session; O = Observer; PB = problem behavior.

Table 5

Pearson Product-Moment Correlations Between Behavioral Assessment Scores and ABC-2 Subscale Scores at Time 1 (n = 23) and Time 2 (n = 21 [Progressive Ratio]; n = 22 [Demand])

	ABC-2 Subscales				
	Irritability	Hyperactivity/ Noncompliance	Stereotypy	Inappropriate Speech	Social Withdrawal
Breakpoint					
Time 1	-.447*	-.564**	-.385	-.218	.060
Time 2	-.112	-.458*	-.197	-.485*	.046
Response Rate					
Time 1	-.442*	-.693**	-.467*	-.165	.165
Time 2	-.123	-.656**	-.317	-.280	.220
Latency to PB					
Time 1	-.390	-.511**	-.408	.089	.079
Time 2	-.020	-.305	-.406	-.166	.027
Latency to request (or PB)					
Time 1	-.236	-.233	-.099	.052	.196
Time 2	.150	-.142	-.134	-.380	.035
Percentage compliance					
Time 1	-.605**	-.705**	-.669**	.028	-.166
Time 2	-.477*	-.610**	-.674**	-.371	-.112

Note. PB = Problem behavior. Asterisks denote statistical significance; $p < .05$ (*) and $p < .01$ (**).

November 16, 2020

Dear Dr. Zarcone:

Thank you for reviewing our revised manuscript titled "Direct Measures of Medication Effects: Exploring the Scientific Utility of Behavior Analytic Assessments," considered for publication in the *American Journal on Intellectual and Developmental Disabilities*. We appreciate the additional feedback and your invitation to submit a revised manuscript. We have carefully read and responded to each requested revision (listed on the following pages, organized by AE and reviewer). A clean copy of the revised manuscript is attached for your review.

We hope these revisions have adequately addressed all comments offered. We look forward to receiving your decision and any additional feedback on the manuscript.

Reviewer Recommendations (italics) and Author Responses

AE Requests

1. *Please confirm the number of participants at Time point 2 - was it 21 or 18? The Method and the graphs do not agree.*

Of the 23 participants who completed a Time 1 assessment visit, 22 participants returned 8 weeks later for a Time 2 visit. However, only 18 of these participants were confirmed to have followed through with a planned medication change between Time 1 and Time 2. We included these 18 participants in the Time 2 generalizability and optimization studies to inform whether a change in medication might impact the temporal stability of assessment scores (see Research Question 2). We included all participants for whom we had assessment data (23 at Time 1; 22 at Time 2 for Demand Assessment scores; 21 at Time 2 for Progressive Ratio scores) for the correlational analysis, as this analysis focused on associations between behavior assessment scores and ABC subscale scores within each timepoint (see Research Question 3). We clarified Time 2 participant numbers in the Participants section (pp. 7–8), the Data Analysis section (p. 18), Table 2, and Table 5. To improve transparency in Figure 1, we changed data points representing participant scores that were not included in the Time 2 generalizability and optimization studies (due to no medication change) from closed symbols to open symbols and added a brief explanation of this in the Figure note. Finally, we added an additional set of rows in Table 2 depicting descriptive statistics for "All participants at Time 2".

2. *Finally, I struggle with the rationale for correlating the outcome of the behavioral assessments with the ABC scores. I do not understand why you would expect there to be generalization from the brief assessment parent ratings on the ABC as stated on page 17. Or are you saying that the medications would affect both the child's behavior in the assessment and the parent ratings on the ABC in the same way? Please clarify the purpose of that analysis or consider deleting it from the paper*.

We acknowledge that the direct behavioral assessments used in this study were not intended to represent the very same constructs measured via the ABC-2. In fact, part of our rationale for exploring direct behavioral assessments for purposes of medication evaluation is that they can inform behavior-environment interactions (behavioral processes) in a way indirect assessments cannot. However, because the ABC has been used extensively and successfully as a behavioral outcome measure in medication trials, we wanted to see whether the among-participant variance in scores from each behavioral assessment correlated with these parent ratings—in particular, ratings related to externalizing challenging behavior. While we did not anticipate strong correlations between assessment scores, we did hypothesize a negative direction of association that, if exceeding a threshold of significance, might offer initial evidence that the behavioral assessments were tapping into some aspect of challenging behavior, or the motivating conditions related to challenging behavior. Though we believe these correlations should be interpreted with caution, we hope these findings may give other research groups confidence in the potential validity of these assessments to encourage future work in this area. For these reasons, we hope to retain these data in the manuscript.

We modified language on pages 17–18 to further clarify our hypotheses for negative associations. On pages 22–23 of the Discussion, we describe results of the correlational analysis as offering "*initial* evidence of construct validity" and highlight the importance of continued research to further inform the validity of scores from these assessments. We identified including alternative indirect assessments (e.g., parent ratings of behavior function) that might be expected to align more closely with direct measures of positive and negative reinforcer value as one potential next step. We also acknowledged the possibility that correlations between behavior assessment scores and ABC-2 subscale scores vary by behavior function—a response to feedback from Reviewer 3 (see Item 7 below).

Reviewer 1 Requests

3. *As the purpose of the study is presented, could the authors specify which PR scores are being evaluated (i.e., break point, response rate).*

When introducing the progressive ratio assessment, we incorporated information on measures of responding and identified and defined breakpoint as a commonly used outcome measure (p. 4). We think this change improves consistency with the subsequent description of demand assessments, and signals to readers what scores were evaluated for each assessment.

4. *The authors state that the goal is not to assess medication effects but to design methods; however, it would seem that an effect of medication has to be demonstrated to ensure the methods are sensitive to detect the change. This may be an issue of semantics but some clarity would be helpful*.

Due to the variety of medications prescribed in our study sample, we were not able to assess medication effects directly. But yes, the next important step in demonstrating the scientific utility of these direct measures would be to determine their sensitivity to change. We mention this critical next step at several points in the discussion (pp. 23–25).

5. *Interestingly, there were 4 children who were not on medication prior to starting a medication at time two (we also see an increase in the alpha adrenergic medications) - was there anything that could be gleaned from these children and changes in their performance that could be used as an illustration of the type of change in performance once might be able to capture using these measures?*

There were four children who were not on medication at Time 1. Three of these children started medication shortly after Time 1 and returned for a Time 2 assessment visit 8 weeks later. Assessment scores from these three participants are reported below. Average response rates during progressive ratio sessions increased for all three participants, yet the direction of change in breakpoint scores varied by participant (one increased, one decreased, one stayed the same). For demand scores, two of the three participants were at ceiling levels at Time 1; for the third participant, latency to problem behavior and percentage of compliance both increased from Time 1 to Time 2.

We are reluctant to highlight these data in the manuscript for the same reason we aren't focusing on pre-post differences among the larger study sample: variability in the direction and amount of change in behavior assessment scores is likely related to variation in types of medication changes made within the sample. In other words, because we are unable to confirm medication effects directly within our sample, we are reluctant to highlight pre-post differences that would suggest to readers that the change in behavioral assessments were *due to* changes in medication.

			Progressive Ratio			
	Medications		Breakpoint		Response Rate	
Participant	Time 1	Time 2	Time 1	Time 2	Time 1	Time 2
13K	None	SSRI, A2A	10.7	8.3	16.7	27.5
15M	None	SNRI	40	40	14.6	19
25M	None	Stimulant, A2A	11.7	10.7	10.1	15.9

			Demand Assessment					
	Medications		Latency to PB		Latency to Mand (or PB)		% Compliance	
Participant	Time 1	Time 2	Time 1	Time 2	Time 1	Time 2	Time 1	Time 2
13K	None	SSRI, A2A	300	300	197.3	146	100	100
15M	None	SNRI	300	300	300	300	100	100
25M	None	Stimulant, A2A	212.7	300	212.7	300	66.7	97.7

Reviewer 3 Requests

6. *In regards to the outcome measures of the behavioral assessment, I found myself wondering if a composite score of some sort that accounts for the different behavioral measurements may be better (and potentially more stable across sessions) compared to looking at several different outcomes. I know that this is difficult as there is not a precedent in the literature for developing this type of composite score, but it seems for the purpose of this paper, it may be helpful to consider. This especially seems true for the demand latency assessment when there are several related, but slightly different outcome measures. I think this is worth considering as I feel one of the strengths of this type of analysis is determining if behavioral assessments can be used in research that is done in a more group-design (i.e., large N) format, such as is often used in clinical trial research. In this type of subsequent study, it is likely that requiring analysis of multiple outcomes from the same assessment may create more complexities in data-analysis and in controlling for type 1 error compared to having a single outcome from the assessment. I understand that this type of analysis might be outside of the scope of this paper, and if this is the case, then I recommend that the authors dedicate some time in the discussion to explore this as a future research option.*

We agree that composite or aggregate variables (variables with metrics that result from combining multiple component variable scores by averaging or summing them) should be explored in future research incorporating behavioral assessments in large N studies. We also agree that exploring aggregate scores is likely more fitting for the demand assessment relative to the progressive ratio assessment. However, we hesitate to create composite variables from this study's data set, as a critical part of the rationale for aggregating variables is that each component variable be content-valid (Yoder et al., 2018). We are short of demonstrating validity

for demand assessment scores—at least with respect to medication evaluation. But we agree that aggregate variables have potential to improve both temporal stability and construct validity of demand assessment scores. We added this direction for future research in the discussion on page 23.

7. *My other concern on this point is the assumption that a higher break point (or a higher RPM) would be related to higher scores on the ABC. I am glad that the data support the authors' assumption on this relationship, but it also seems to me the opposite relationship may exist if problem behavior is maintained by access to the reinforcer tested in the progressive ratio assessment. For example, if the child engages in problem behavior maintained by access to edible items, I would expect for higher break-points in the progressive ratio assessment to be associated with higher (worse scores) on the ABC as you would expect more problem behavior maintained by that functional reinforcer. I think this is worth mentioning in the discussion section as an important area for future study as it ties in nicely to the discussion of precision medicine (tailoring medications to the individual child based on their behavioral presentation) that is already in the paper.*

We predicted that as a group, higher progressive ratio scores would be associated with *lower* (not higher) ABC subscale scores. But the question of whether this relationship might vary based on function of problem behavior (in particular, whether the function of problem behavior aligns with the reinforcer used in the progressive ratio assessment) is a fair question, and an empirical one. We acknowledged this possibility and highlighted it as a potential component of future research in the discussion (p. 22), where we highlight the importance of continued evaluation of construct validity.

Note: The example offered by the reviewer presents one possibility: if a child's problem behavior is maintained by access to edibles, that child might be more motivated to engage in a different (arbitrary) response to access that reinforcer. Another possibility is that the presence and restriction of edibles (unless the child engages in the arbitrary response) is enough to evoke problem behavior, either at the start of the session or as the schedule requirement increases to a point of ratio strain. If these conditions evoked problem behavior, the assessment would end prematurely and progressive ratio scores would be lower. In short, behavior function might influence scores on progressive ratio assessments, but the direction of impact could still vary by individual.

8. *Last, it may be worth more clearly describing the utility of standardizing assessments such as these that might be used as outcome measures in large-N treatment studies. For example, if these assessments were being used in single-subject study, I would recommend that the experimenters run each assessment until stability, select the assessment strategically based on the function of the behavior as identified in an experimental functional analysis, conduct detailed preference assessments, and make modifications to assessments as you go to reduce variability in the data. However, this type of individualization is often not feasible when conducting clinical trials with a large number of participants when assessment time may be limited and it is important to ensure assessments are the same across all participants. I think a paragraph in the introduction more explicitly explaining this could be beneficial for some readers if their background is more*

exclusively in single-subject design work (where most of the past research on these assessments has been focused).

We appreciate this suggestion, and incorporated this point on page 5 of the introduction.

9. *In the abstract, it would be helpful to present a very brief overview of the findings of the study in addition to just stating the number of outcomes discussed.*

We added a summary of findings to the abstract.

10. *Is there an updated reference that can be found for the mention of rising rates of off-label prescriptions? It seems a more recent citation is needed to really support an increasing trend across time and I believe there are more recent studies on this topic.*

We added two more recent citations (i.e., McLaren et al., 2018; Vitiello, 2017) on page 2 of the introduction.

11. *When listing the research questions, the authors state that they expect a negative association between the behavioral assessments and the ABC indirect measure. Given that the reader will not know what type of "score" was derived from the behavioral assessments this may be misleading at this point in the paper. For example, I found myself thinking a negative association would mean more problem behavior in the behavioral assessment being related to lower scores on the ABC (so the opposite of what would be expected). I recommend sticking to talking about an "association" without listing the negative vs. positive direction at this early stage in the paper.*

We made this suggested change in the statement of research questions on page 6.

12. *The manuscript states: "Eighteen participants started a new medication regimen shortly after the initial assessment visit and their second visit was scheduled 8 weeks following the medication change." At this point in the paper, I was anticipating that this phrase meant that the rest of the participants started medication at a different point, thus had a second visit at another time. It may be good to specifically state that the study for the rest of the participants ended after the first time point.*

We changed our phrasing on pages 7–8 to clarify these procedures. Twenty-two of the 23 participants returned approximately 8 weeks following the initial assessment visit; but a medication change was confirmed for only 18 of these children. These 18 participants were included in the Time 2 generalizability and optimization studies (see Research Question 2). Please see our response to Item 1 for additional information.

13. *In Figure 1, it looks like there are 21 data-points at time point 2, which does not coincide with the 18 participants described in the above bullet. The authors may want to check this or explain if there are supposed to be 21 as opposed to 18 participants at time point 2.*

Please see response to Item 1 (AE request).

14. *Did the authors screen for any food selectivity or conduct any caregiver interviews to ensure that edible items were likely to serve as a reinforcer for these kids? If not, I would list this as a limitation more explicitly (in addition to the general limitation that a reinforcer assessment was not conducted prior to the PR assessment)*

During the initial parent interview, we asked parents for permission to use edible reinforcers for the progressive ratio assessment. (Had parents not given permission, we would have used a tangible reinforcer instead, though all parents gave permission.) To inform selection of edibles to use for progressive ratio sessions, we shared a list of snacks we had available (e.g., m&ms, fruit snacks, crackers, chips, pretzels) and asked parents to indicate which ones were most preferred. If none were highly preferred, parents identified other more preferred edibles and we procured them prior to the scheduled assessment visit to make sure they were included in the options we presented to the child prior to each progressive ratio session. We clarified these procedures on page 9.

15. *The data-collection section on fidelity states that the item was scored as correct if the therapist delivered a demand every 5 s when the child was not complying. However, under the definition for compliance it states "initiation of task completion within 10 s of a therapist verbal prompt". Can you clarify if the instruction was given every 5 vs. every 10 s?*

Therapists delivered demand-related prompts every 5 s in the absence of compliance, using the following 3-step prompting sequence: verbal, model, physical. Compliance was scored if the child complied following the verbal prompt or model prompt, thus, within 10 s of the initial task demand. We made these clarifications in our description of demand assessment procedures (p. 11), data collection procedures (p. 13), and procedural fidelity data collection (p. 15).

16. *For interobserver agreement for the demand session, it is probably most appropriate to calculate the latency scores based on comparing the two latencies recorded between observers (smaller latency divided by larger latency scored and converted to a percentage). The way it is written, it seems as if a frequency-based method of IOA was still used for the primarily latency outcomes.*

The agreement percentages reported for latency to problem behavior did reflect the smaller/larger (*100) agreement method; we clarified that these percentages represented agreement on *latency* to problem behavior on page 15. We re-calculated percentages of agreement for latency to request, as the original agreement estimates for this score did indeed reflect the Countee method (interval by interval agreement). While the updated mean percentage of agreement across sessions for latency to request was within an acceptable range (92.8%), it was lower relative to mean agreement for other scores, and the range of agreement at the session level was much wider (3.3%–100%). Low minimum agreement scores for latency to requests were identified for sessions in which observers disagreed on whether a request occurred very early in the session (producing two very different latencies). For example, the session with 3.3% agreement was one in which the primary observer coded a request at 10 s, but the second observer did not code the request (producing latencies of 10 vs. 300). We added these updated agreement estimates for the latency to request score, and included a brief explanation for the

wide range of agreement by session (p. 15). After revisiting results of the generalizability studies, we think these updated agreement data help explain why latency to request was the only score for which variance estimates related to observer were non-trivial. We pointed this out on page 22 of the discussion when summarizing and interpreting results of generalizability studies.

Note: We considered whether re-coding latency to request was warranted given the low minimum agreement percentage (3.3%), but ultimately decided it wasn't for a few reasons. First, the mean percentage of agreement is still within an acceptable range (92.8%), indicating that sessions with high agreement far out-numbered those with low agreement (percentages of agreement exceeded 80% for 90% of sessions). Second, our estimates of agreement on the occurrence of requests (interval-by-interval agreement) were also within an acceptable range (*M* = 98.9%; range, 83.3%–100%), suggesting reliable coding of requests overall. Third, while we do think higher percentages of agreement on latency to request would have increased the percentage of variance accounted for by Person (true score variance), we also consider it useful to point out how a lower mean percentage of agreement impacts the variance due to the observer facets (p. 22).

17. *I believe the word "Formulae" should be "formulas"*

We made this change on page 17 (and in the Appendix, which is now accessible via external link).

18. *Based on the way a demand latency assessment is usually conducted, I assume there would be some missing data for the latency to request outcome. Specifically, if the child engaged in problem behavior before a request was made. Was this the case in the current data-set? If so, this should be included in the results section if the outcome is operating off of a smaller sample size than other outcomes.*

For sessions in which both a request and problem behavior occurred (in that order), separate latencies were recorded (one for request, one for problem behavior). For sessions in which neither request nor problem behavior occurred, latencies were entered as 300 (s) for both latency scores. For sessions in which a request did not occur but problem behavior did, the session ended with problem behavior, and this latency (to problem behavior / end of session) was entered for both latency scores. Thus, the latency to request score was the latency to request *or problem behavior* (for sessions in which requests did not occur prior to problem behavior). We clarified this aspect of the scoring rules on page 13.

We added this variable as a secondary indicator of tolerance in case ceiling effects were observed for latencies to problem behavior. That is, we anticipated that for some children, 5 min of task presentation may not be enough to evoke problem behavior, but that requests to escape or change activities might be a potential precursor to problem behavior, or at least a sign of waning tolerance for the current task demand. Thus, we considered this variable (latency to request or problem behavior) as a broader measure of tolerance than the primary latency to problem behavior measure. This broader measure of tolerance represented the point at which the child attempted to initiate a change in activities, either by requesting it outright or engaging in problem behavior. We clarified this conceptualization on page 13.

19. *I understand the importance of validating these assessments for the purpose of intervention trials focused on medications, but they may also be used for outcomes from behavioral interventions or other psychosocial strategies. I suggest the authors mention this so the potential broader impact is not lost.*

We appreciate this suggestion and incorporated this point on page 3 of the introduction.

20. *I would recommend including the information in the appendix in published material or incorporating into paper elsewhere as I do not anticipate that most readers will be familiar with the analyses.*

We appreciate this suggestion and have since been notified by the editors that AJIDD does not publish appendices or supplemental material. Rather than embed this content in the manuscript, we opted to include an accessible link in text (p. 17) that will lead readers to this document. We redacted the actual link for blinding purposes, as the appendix is housed on our research team's university-supported website.