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Issues in Implementing a Comprehensive Intervention for Public School Children With Autism Spectrum Disorders

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Issues in Implementing a Comprehensive Intervention for Public School Children With Autism Spectrum Disorders

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Many students with autism spectrum disorders (ASD) are educated separately from their typically developing peers, while others are placed in inclusive classes but without supports that would help them benefit from less restrictive placements. The needs of students with ASD who are in inclusive settings are often not planned for or met appropriately, resulting in continuing problems and movement to increasingly restrictive environments or private placements. There is a critical need for school models to fill the gap in appropriate services for this population of children with ASD. These models should include those that are inclusive and academically challenging, that can be implemented by many school districts, and that are responsive to the unique combination of strengths and deficits in these students. In the current article, the authors describe the development and core components of the model, and implementation of the ASD Nest program in public schools in New York City.

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INTRODUCTION

The U.S. Department of Education's Office of Special Education Programs (OSEP) defines autism in the context of federal education law as a "developmental disability affecting verbal and non verbal communication and social interaction that adversely affects a child's educational performance" (U.S. Department of Education, 2006, p. 35). Based on recent surveys, the Centers for Disease Control and Prevention revised the autism spectrum disorders (ASD) prevalence estimates to 1 in 150 children in 2007; which was again revised in 2009 to approximately 1%—1 in 110 children (Centers for Disease Control and Prevention, 2009). The number of children ages 3 to 21 who have been identified as having autism and are receiving special education services has increased dramatically. In a 10-year period from 1993 to 2003, the number of children in this category jumped from 19,000 to over 186,000; which will continue to increase in tandem with the rising prevalence estimates (U.S. Department of Education, 2007).

Children with disabilities can be provided educational programming through a variety of models, but with a mandate to be in the least restrictive environment. "Despite relatively slow progress, students with autism are increasingly being educated in inclusive classrooms. Many of those same learners, however, are being excluded from rich and meaningful experiences in those classrooms, perhaps because teachers are unsure of how to include them..." (Kluth, 2003, p. 31). How then are interventions developed and implemented that foster successful, meaningful inclusion for children with ASD? The National Research Council's report (2001), *Educating Children with Autism*, articulated the belief that "education, both directly of children, and of parents and teachers, is currently the primary form of treatment of autism" (p. 12); with the school environment having the potential to be a major vehicle for therapeutic change. Thus, educational interventions should be developed and implemented with this goal in mind.

Focused interventions that are evidenced based may be used by teachers and related service personnel to teach specific skills for children with ASD (Odom, Collet-Klingenberg, Rogers, & Hatton, 2010). There is a critical need to examine effective models that use evidenced based interventions, and to assess if they are being implemented effectively for children with ASD (Barton, Lawrence, & Deurloo, 2011). This article describes the development and implementation of the ASD Nest program, an inclusive comprehensive intervention within the New York City public schools.

BACKGROUND

Often evidence-based strategies are used with specific outcome measurements for individuals or groups of students, but without examination of the implementation process and how this may affect the outcomes of intervention programs (Durlak & DuPre, 2008; O'Donnell, 2008; Stith et al., 2006). According to Durlak and DuPre “many innovations encounter implementation problems that diminish a program’s impact” (pp. 327–328), yet often the literature focuses on the innovative strategy without viewing issues related to implementation. Moreover, “accurate interpretation of outcomes depends on knowing what aspects of the intervention were delivered and how well they were conducted” (Durlak & DuPre, 2008, p. 328).

The National Autism Center’s report (2009) recommended systematic change as the most effective way to implement interventions on a larger scale. Children with high functioning autism (HFA) may have the requisite academic skills to succeed in inclusive settings (Griswold, Barnhill, Smith Myles, Hagiwara, & Simpson, 2002), but atypical responses to overwhelming sensory environments, deficits in social engagement, and poor self-regulation of behavior may have a more critical impact on their success both in inclusive settings, as well as in relation to their long term outcomes. These children are often educated in inclusive classrooms with individualized supports, but without systematic change that allows for more effective implementation integrity and sustainability of established interventions. Training, professional development, and administrative support is essential to implementation accuracy (Durlak & DuPre, 2008; Elias, Zins, Graczyk, & Weissberg, 2003; Fixsen, Naoom, Blase, Friedman, & Wallace, 2005; National Autism Center, 2009).

The systems perspective highlights the need to go beyond the individual classroom to school-wide changes (Barton et al., 2011; Fixsen et al., 2005; Odom et al., 2010). When viewing implementation of the ASD Nest program it is necessary to look at the systematic change that was necessary, in order for the community to implement a new program and alter the organizational climate. There are a myriad of issues related to implementation, but this paper will focus on three key factors identified in the implementation literature, including (1) community readiness, (2) existence of adequate resources, including administrative support, and (3) training and technical assistance (Fixsen et al., 2005; Stith et al., 2006).

Community Readiness

Prior to the establishment of the ASD Nest program described in this article, the New York City public school system had no program for higher functioning students with ASD who had the cognitive potential to do grade-level academic work. According to a 2002 report by Community School District 15,

a sub-district of the New York City public school system, many families of higher functioning children with ASD—especially those who had made great strides from extensive early intervention and inclusive preschool services—said that the special education District 75 program was not an appropriate educational environment for their children. Earlier, in 2001, a group of six such families approached the District 15 superintendent and asked her to create a class within their neighborhood elementary school for their five- and six-year-old children. They wanted their children educated close to home in as inclusive an environment as possible. The ASD Nest program was created to address these needs.

Importantly, we would expect community readiness or capacity to be related to successful implementation of the ASD Nest program (Durlak & DuPre, 2008). Adelman and Taylor (2003) identified the importance of mobilizing interest and support among key stakeholders in the early stages of adopting innovations. In this case, parents and a small group of administrators were committed to the innovation. Effective leadership and having at least one “program champion” who is often highly placed in an organization is also strongly related to successful implementation (Durlak & DuPre, 2008; Fixsen et al., 2005). The ASD Nest program had its champion in Carmen Farina, the superintendent of Community School District 15 who pressed for programs in community schools so that these children could be included in their own neighborhoods. However, the schools resisted as they had neither the resources nor the training to meet their needs. Thus, the parents of New York City’s higher functioning children with autism were ready to support a well thought out, academically focused educational program that also fostered therapeutic change, but resources and support for training were necessary.

Resources and Administrative Support

Resources sufficient to launch the project were provided by District 15, foundation grants, and the team that developed and implemented the pilot program. After the first year of implementing the pilot program (2003–04), the New York City Department of Education (NYCDOE) provided a funding structure as well as autism-specific training and support so the ASD Nest program could be replicated across New York City. Obtaining these resources was vital. Insufficient administrative support and funding for these changes can undermine program implementation (Fixsen et al., 2005; Reddy, Newman, De Thomas, & Chun, 2009), and unless structural changes were incorporated into the classrooms, it would be unlikely that the program could be effectively implemented and sustained.

Thus, the ASD Nest program originators met with individual school principals, who were tasked with implementing the model in their schools, as well as with Department of Education administrators, to strategize how to mesh the program with city and state education structures and regulations.

Strong support from special education advocacy groups, the local teachers union, and central administration, were critical to making successful structural changes (which are described in the Methods section), in order to implement the ASD Nest Program.

Training and Technical Assistance

Administrative support for training and professional development is critical for successful program implementation and sustainability (Denton, Vaughn, & Fletcher, 2003). Innovative interventions must also have a delivery system, which involves initial training and ongoing technical assistance (Durlak & DuPre, 2008). Staff training is a core component of the ASD Nest program. The preservice training for teachers and therapists consists of two graduate courses of three credits each at Hunter College. These modified courses, derived from the master's degree program in early childhood special education, focus more heavily on the types of children being served in the ASD Nest program. One course provides a broad foundation on autism spectrum disorders and intervention strategies, and the other course focuses on behavior theory and its application to young children with ASD. A one-credit course on social development intervention is also provided, utilizing ideas from relationship development intervention (Gutstein & Sheely, 2002), social thinking (Winner, 2007), and other social cognitive approaches. Teachers take all three courses, with related service personnel (e.g., speech therapists, occupational therapists, social workers/guidance counselors) taking at least two of the three courses, with all related service personnel taking the broad foundations course and all speech therapists taking the course on social development intervention. Over the past five years since training has been formalized, approximately 75–95 personnel have been trained every year.

Technical assistance and coaching are provided by Department of Education specialists and consultants hired by New York University (NYU)'s Steinhardt School, under contract to the Department of Education. For its first two years of operation, each new school program is assigned at least two technical support specialists, with different but complementary skill sets. These ASD Nest support staff include specialists in autism, inclusion, co-teaching, positive behavior supports, and communication and social development. Finally, in order to sustain high quality implementation there needs to be a commitment to ongoing professional development (Fixsen et al., 2005). New York University provides a full array of professional development trainings for all staff working in the Nest program. Related service providers (e.g., speech therapists, occupational/physical therapists, and social workers/guidance counselors) meet at least four times per year with their peers from the other Nest schools. Classroom teachers attend workshops with their grade-level peers from the other Nest schools. These workshops serve as opportunities for collective participation, a component

of high quality professional development programs (Garet, Porter, Desimone, Birman, & Yoon, 2001) that allows for groups from the same profession, the same grade level and the same school to have adequate time to meet and problem-solve.

Challenges to Implementation

As Elias and colleagues (2003) highlight, urban districts pose “particular challenges” for implementation and sustainability of innovation. We encountered challenges identified by Elias et al. (2003) that were particularly relevant in the implementation of the ASD Nest Program, namely reorganization, budgetary changes, and reform initiatives. First, during the period of model development and implementation, the NYC school system underwent several major changes. Major reorganization occurred every other year and included regular “reform” of special education involving massive personnel and structural changes. The system implemented a continually evolving accountability system built around standardized test scores, which altered the schools’ focus on all aspects of instruction and support. The city imposed a hiring freeze on the schools, complicating the selection and training of Nest staff. System-wide budget cuts reduced funding to the schools and resulted in some schools losing trained Nest staff who were subsequently replaced by teachers who did not choose to work in the Nest program. Overcrowded schools in some areas lacked sufficient space for the Nest program.

Second, Reddy and Newman (2009) identify dimensions that conceptualize barriers to program implementation that are salient in working with the specific disability group of children with high functioning autism. They detail Informational or Skill Based barriers whereby school personnel may be lacking the requisite information to address the broad range of difficulties that are often present when educating a specific disability group. In the case of the ASD Nest program, it took up to four years to enlist the support of some classroom teachers and other school staff whose attitudes, knowledge and practices had to change to a more respectful and non-judgmental approach, with a better understanding of behavioral issues and instructional strategies. Students with ASD often had non-special education cluster teachers for special subjects like music, dance, art, physical education and science, and some of these educators were resistant to making accommodations and instructional modifications for students on the spectrum in an inclusive setting.

Third, a very significant implementation barrier that remains to this day is the identification of appropriate students for the program. There are changes every year in the structure of the special education identification and evaluation systems and the assignment of clinical personnel. The ASD Nest program collaborates with the Department of Education to develop assessment protocols and to train Department of Education clinical staff on how to evaluate children for the program, which include children who

can, with support, work in groups, rather than needing one-to-one support for most of the day, and who can meet grade-level academic expectations.

Implementation Supports

In addition to these challenges, factors that facilitated initial implementation of the ASD Nest program included steadfast support at all levels of the system: dedicated, open-minded, and compassionate principals who embraced the program and the children; targeted curriculum and training designed by experts in the field of teaching children with autism spectrum disorders; and hard-working and passionate teachers and therapists inspired by the collaborative team approach and the opportunity to positively affect children's lives. These structural and support elements were critical to the early adoption and program installation of the ASD Nest program. Without these structural and support elements, implementation would not be possible. Once adopted, it was necessary to assess how well the program was being implemented, as measured by initial indicators of fidelity of the intervention.

METHODS

Participants

Piloted in the fall of 2003, and replicated from 2005–2010 in 18 additional elementary schools, the ASD Nest program is an inclusive education model that serves children diagnosed with autism spectrum disorders who are higher functioning in respect to language and cognition, but who may have substantial difficulty with self-regulation, behavioral modulation, coping with change, understanding expected social behavior, and developing social skills, social communication, and social relationships. As of September 2010 there were 97 inclusive ASD Nest classrooms in 19 elementary schools across New York City. These classrooms serve over 400 higher functioning students with ASD and 1,065 typically developing students. Observations and teacher interviews with one representative K–5 school in a middle income neighborhood that was in its fifth year of implementing the Nest program were used to assess implementation of the core components in the ASD Nest classroom. This school had 10 Nest classrooms ($n = 40$ children with ASD and approximately 160 typically developing students).

Program

IMPORTANT ELEMENTS OF THE ASD NEST PROGRAM

There are 12 important elements to the program; eight of these elements pertain to the organization and structure of the classroom, three involve

evidence-based teaching practices, and the final element is the social development intervention developed specifically for the ASD Nest Program. The focus of the assessment of implementation in this article is on the evidence-based teaching practices, but the other elements are briefly outlined here.

Organizational elements

1. Monthly meetings for each principal with the NYU project director and a Department of Education program Nest program coordinator.
2. Advanced training for at least one teacher-coach in each school who mentors new staff and offers technical assistance.
3. Reduced class size: Kindergarten classes consist of four students with ASD and eight typically developing students. In first grade through third grade the class roster has 16 students, 4 with ASD and 12 typically developing students, with the number of the typical peers increasing starting in fourth grade.
4. Co-teaching model: Two highly trained educators teach all children in the class. There are no paraprofessionals, “shadows,” or school aides. A trained professional (i.e., teacher or therapist) is with the students throughout the day, including lunch, recess and “specials” (gym, library, art, music).
5. Curricula: The ASD Nest program is built around the standard academic curriculum of the school district; it supplements that curriculum by infusing a focus on social learning, social communication, and self-regulation into classroom learning experiences.
6. Weekly team meetings: Weekly 90-minute after-school team meetings are required for all teachers and therapists in the Nest program, and feature case conferencing on individual children.
7. A formal “home–school connection”: This includes a home visit by Nest staff prior to the start of the program; a classroom visit by the child and parents prior to the first day of school; monthly parent support group meetings at the school; and parent access to their child’s therapists and teachers through a home–school communication notebook.
8. Parent workshops: The program provides five or more workshops a year on positive behavior supports, sensory issues and interventions, social development, understanding academics, and other topics parents request, at about half of the school sites.

Evidence-based teaching elements. In addition to the organizational elements that need to be in place, active treatment ingredients, or those components that are known or believed to be responsible for influencing changes in participants, must be specified in order to monitor program

implementation (Embry, 2004; Reddy & Newman, 2009). The ASD Nest program design utilizes the following three evidence-based teaching practices, which are considered its core classroom components and the focus of the initial fidelity of implementation discussed in this article:

1. *Organization of the Classroom Environment*: It is often the inability to regulate one's own behavior in response to environmental demands, many of which have a sensory or social basis that contributes to behavioral challenges for individuals with ASD. The ASD Nest Classroom is organized to minimize distractions, to organize and to predict activities and routines, and to understand expectations (Barton et al., 2011; Odom et al., 2010).
2. *Basic Instructional Strategies and Visual Aids*: The use of visual aids may enable children with ASD who are better at visual processing than auditory processing to function more productively in the classroom. Visual supports provide students with increased predictability, help structure their environment, plan their day, and clarify expectations (Barton et al., 2011; Dettmer, Simpson, Myles, & Ganz, 2000; Mesibov & Shea, 2008; National Autism Center, 2009; Odom et al., 2010;).
3. *Individualized Learning and Behavior Supports*: Reduction of behavioral difficulties, often referred to as "impeding behaviors," is one of the major tasks of school programs for children with autism spectrum disorders. Positive behavior supports (Carr, 2007; Crimmins, Farrell, Smith, & Bailey, 2007; Durand & Hieneman, 2008) are an integral component of the ASD Nest program. Systematic reviews have demonstrated the value of a Positive Behavior Support approach to working with students who have ASD (Bambara, 2005; Horner, Carr, Strain, Todd, & Reed, 2002; Howlin, Magiati, & Charman, 2009). Individualized supports serve to **prevent** impeding behavior, **replace** impeding behavior with more appropriate behavior that meets the same function, and **respond** to continued impeding behavior. The most successful strategies are proactive, and are designed to make problem behavior ineffective, inefficient, and irrelevant.

Social development intervention (SDI). The final key ingredient is Social Development Intervention (SDI) described in Koenig, Bleiweiss, Brennan, Cohen, and Siegel (2009). McConnell (2002) recommended interventions that include integration with socially competent children and extending treatment throughout the day in other activities. The ASD Nest program implements these recommendations through its inclusion structure, the social development focus of the SDI curriculum, and incorporation of social interaction interventions throughout the school day. The assessment of fidelity of the SDI intervention is outside the scope of this article, and the implementation of the Evidence-based teaching elements was the focus of the implementation assessment.

MEASUREMENT OF IMPLEMENTATION

Initial efforts, including (a) classroom observation and (b) teacher interviews, were used to measure implementation of the ASD Nest program. Observations on the presence or absence of these elements were done by assessing classroom adherence to the *Guideposts for Staff of the ASD Nest Program* (Cohen & Bleiweiss, 2007) which incorporates strategies and supports that define key aspects of high fidelity implementation of the core classroom components. From this preliminary manual, a 30-item *Guideposts Checklist* was developed to measure adherence to the core components. The *Guideposts Checklist* identifies: (a) six items related to “Organization of the Classroom” including items such as “there is a set-off quiet area with a beanbag chair and items for self-calming in it. This area is not used as a play area or for reinforcement”; (b) 10 items that are considered “Basic instructional strategies and visual aids” including the provision of many opportunities for child choice, peer support, and role play for social learning and problem solving; and (c) 13 “Individualized Learning and Behavior Supports” items including: (1) *Prevention Strategies* (eight items) including priming, social stories, task modifications, and individual schedules; (2) *Replacement Strategies* (three items) that are designed to teach the child more effective and appropriate means of communicating their wants, needs, dislikes, and preferences; and directly address the impeding/problematic behavior, which includes functional communication training, relaxation training, and a “Break” program. and (3) *Response Strategies* (two items) that involve modifying the ways in which teachers and other professionals respond to children’s problematic behaviors (e.g., decreasing the likelihood that they will be displayed) and to their positive/replacement behaviors, namely, using positive reinforcement (i.e., reward) systems, and planned ignoring in conjunction with the concept of “catch(ing) them being good.” After the classroom observations were completed, follow-up interviews were needed to provide an additional source of information as to what elements were easiest and most difficult for teachers to implement, and to obtain data on the presence or absence of strategy use for challenging behavior that were not readily observable if the challenging behavior did not occur during the observation period.

Procedure

To assess implementation fidelity, 10 classrooms in the target school were observed for between 30 and 45 minutes, two to three times each and rated for consistency with the *Guideposts Checklist* format. These observations and interviews were completed by one of the co-authors, who was trained in structured observations utilizing the *Guideposts Checklist* format. The observer recorded the presence or absence of the core components, which

was recorded on each visit as present or absent and data was combined for each class across multiple visits to assess the presence or absence of that element and determine a percentage for the class and then an overall percentage of use of core element in the observed schools.

The interviews with teachers and administrators were completed by two other co-authors and included questions in order to determine the presence of core components that were not directly observable on the *Guideposts Checklist*.

RESULTS

All six items related to effective “Organization of the Classroom Environment” were present in 100% of the observed classrooms, and if present would be seen in all visits, as they are also easily observable items (e.g., shelves with distracting play items covered, presence of a set-off quiet area, classroom not cluttered) and an expectation for how the environment should look. Organizational elements and classroom set-up are taught during the summer training, implemented, and monitored prior to the beginning of school as the teacher gets her classroom ready.

The 10 items under “Basic instructional strategies and visual aids” were used with varying fidelity. Teachers’ use of peers to provide support for the student with ASD was the only element in this category that was used in 100% of the observed classrooms.

The *Incredible 5 Point Scale*, which is a specific visual aide used for voice modulation, was displayed in 70% of classrooms, although it was not directly referenced by the teacher for use (e.g., “children remember to use your 3 voice”) during the observations of most of these classrooms. Visual aids to supplement verbal directions was observed in only 40% of the classrooms, where those teachers used visual cues and objects to supplement the provided directives (e.g., visual schedule on the board). Two items under “Basic instructional strategies and visual aids,” including teachers using “self-talk” for problem solving and role playing for social interactions during difficult situations, were not readily observable during the classroom visits (0%), which may be the result of lack of understanding of that strategy or not observing the strategy on routine visit.

The 13 items under “Individualized Learning and Behavior Supports” either could be observed directly, or were asked about in an interview to see if there was evidence of use. The concept of “Catch them being good” and telling the children what to do, rather than not to do was observed in 100% of all classrooms as well; with teachers all providing behavior-specific praise for positive behaviors displayed by students. Providing concrete examples with directions for class work was also consistently observed in 100% of the classrooms. Daily activity schedules were present in 80% of

the observed classrooms. Of these eight classrooms, the schedule was referenced and used during the limited observation time period in five of the classrooms, indicating high probability that it is referred to frequently throughout the day. Choice-making opportunities were provided by 75% of the teachers; however, it was apparent throughout the observations that there were many more opportunities where choices could have been incorporated into the lesson or activity.

Prevention strategies such as priming, mini-schedules, use of timers, environmental/activity modification and social stories, which are antecedent interventions used prior to the target behavior occurring, were observed and reported as used in 100% of the classrooms, or there was evidence of their use. For example, there was a basket of social stories in the break corner as artifacts, but they were not observed as being used in the classroom during the observation period, but were reported as frequently used by the teacher during a follow-up interview. High probability requests, a prevention strategy was a strategy that 90% of teachers did not use, as underscored by the fact that most of the teachers interviewed needed an explanation of what the strategy meant. This strategy involved the teacher delivering a series of prompts for a skill the child has mastered, the teacher reinforces the child, and then asks the child to follow up with a new skill or one the child is less likely to perform;. Replacement strategies including functional communication training, utilizing a “Break” program and relaxation training were used in 100% of the K–2 classrooms observed but were not used in grades 3–5, which may indicate these elements are not necessary in the older grade classrooms, or implementation becomes more inconsistent.

DISCUSSION

There is a critical need to develop school models that fill the gaps in appropriate education for high functioning children with ASD, which include models that are inclusive and academically challenging, that can be implemented by many school districts, and that are responsive to the rather unique combination of strengths and deficits in these students. The ASD Nest program was developed to serve children with autism spectrum disorders in or near their neighborhood schools whenever possible, utilizing an inclusion model in conjunction with the standard curriculum, but with additional training and supports for staff that emphasized ASD-specific knowledge, strategies, and supports. The extent to which implementation adheres to an intended model is impacted by community level factors, provider characteristics, innovation characteristics and the prevention delivery system, and specifically organizational capacity and training and technical assistance (Durlak & DuPre, 2008).

As is often the case in the early phases of an intervention, contextual factors that have been shown to be essential to implementation success (Durlak & DuPre, 2008; Elias et al., 2003) were the primary focus of the ASD Nest team, including training and technical assistance, the development of materials to support implementation, and the logistics of intervention delivery and system wide support. The focus on establishing the service delivery system, changing the classroom structure, garnering administrative support, and training teachers and related service professionals in autism-specific evidence-based practices has been critical to the expansion of the ASD Nest program. The ASD Nest program has been adopted by the largest urban school district in the country. In order to ensure sustainability, measuring implementation outcomes and intervention outcomes with multiple data sources will be necessary.

Initial attempts were made to assess fidelity of implementation utilizing the *Guideposts Checklist*, which indicated good implementation of organizational elements of the classroom, and use of autism specific strategies (i.e., visual aids for voice modulation, social stories) but variable fidelity with other elements (high probability requests). Researchers stress the need to promote competence through natural contexts and relationships (Barton et al., 2011; Elias et al., 2003; Odom et al., 2010). On one hand, teachers appear to use interventions at a high level, when the services are a part of the natural context of the inclusive classroom and of the teacher–student relationship, and which benefit all students (i.e., behavior specific praise, using stories to model social behavior, classroom organization). On the other hand, teachers may learn, but have more difficulty incorporating autism-specific strategies that are focused on modifying individual behavior (e.g., high probability requests).

This initial examination of implementation has highlighted the need for a full-scale implementation study that assesses the fidelity of core components across multiple schools, investigates the impact of dosage or the amount of professional development on quality implementation, and examines the adaptations that teachers make in the classroom. Additional data from multiple sources (e.g., surveys, document analyses, interviews, and observations) should be utilized in order to determine which program aspects are core components that can be altered to fit within the inclusive classroom (Durlak & DuPre, 2008). There is also a critical need for continued development of systematic manualized interventions. Continued analysis of key features of the current curricula and professional development and training with stakeholder feedback are ongoing, with revisions of the *Guideposts Checklist* to reflect observable key elements. These will yield data for use in modifying existing program guidelines, future training materials, and efficacy studies that can compare core features to a control condition.

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