Interventions for Autism Spectrum Disorders

STATE OF THE EVIDENCE

Report of the Children’s Services Evidence-Based Practice Advisory Committee

October 2009

A Collaboration of the
Maine Department of Health and Human Services
& the Maine Department of Education
Interventions for Autism Spectrum Disorders

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THE MAINE DEPARTMENT OF HEALTH AND HUMAN SERVICES &

THE MAINE DEPARTMENT OF EDUCATION

October 2009
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ACKNOWLEDGEMENTS

This document represents a remarkable collaboration by a diverse group of stakeholders all committed to a single goal – improving the lives of children and youth with Autism Spectrum Disorders. The vision and support of the Maine Department of Education and the Maine Department of Health and Human Services enabled this work to be done, while Lindsey Tweed and Nancy Connolly provided the leadership that kept the project moving forward. We received invaluable input and guidance from a variety of viewpoints, including people with autism, parents, educators, providers, researchers, and policymakers. This was a challenging task requiring countless hours of article review and discussion over a one-year period. Although opinions differed at times, enthusiasm for the project never waned, and consensus was achieved. Throughout this involved process, the focus was always on the children and families impacted by Autism Spectrum Disorders. We are grateful to the consumers and families who shared their stories, experiences, and opinions, and who gave meaning to our work.

The members of the Committee collaboratively developed a common understanding of research and evidence-based practice, selected interventions to evaluate, and outlined a literature review and rating process. The Committee collectively endorses the findings and conclusions expressed herein. However, due to the diversity of perspectives and experiences within the Committee, the conclusions and thoughts on each position in this document do not necessarily represent the individual opinions of each member or the organization they represent.
CHILDREN'S SERVICES EVIDENCE-BASED PRACTICE ADVISORY COMMITTEE

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EXECUTIVE SUMMARY |

Introduction |

The number of children in Maine with Autism Spectrum Disorders (ASD) has increased significantly over the past decade. Since 2000, the number of children receiving Special Education services for ASD in Maine schools jumped from 594 to 2,231 in 2008 – an increase of 276%. A recent study estimated that the total cost of caring for a person with autism over his or her lifetime can reach $3.2 million, with more than $35 billion spent collectively per year (Ganz, 2007). To conserve already scarce resources and offer the best possible services to children with ASD, it is necessary to identify and understand the treatments and methods that produce positive outcomes as proven by research. Science helps to clarify some of the confusion about what “works” and enables evidence-informed treatment decisions, thus saving precious time and resources.

Autism Spectrum Disorders are a category of neurodevelopmental disorders characterized by distinct and pervasive impairment in multiple developmental areas, particularly social skills and communication (American Psychological Association, 2000). Children with ASD exhibit atypical patterns of social interaction and communication that are not consistent with their developmental age. These patterns become apparent in the first few years of life and are generally lifelong challenges (Schieve, Rice, Boyle, Visser, & Blumberg, 2006). Early, intensive identification and intervention can greatly improve outcomes for children with ASD (Eikeseth, Smith, Jahr, & Eldevik, 2007). Early and effective treatment also offers opportunity for significant cost/benefit improvement through regained productivity of individuals with ASD and their caregivers (Ganz, 2007).

Evidence-Based Practice |

Evidence-based practice is a framework for integrating what is known from research into real-world settings in a manner that responds to the individual characteristics and values of the individual being served. There are three main components to evidence-based practice (APA Presidential Task Force on Evidence-Based Practice, 2006; Burns & Hoagwood, 2002):

- **Best Research Evidence**: In order to integrate research into practice, it is critical to be aware of the scope and quality of the literature. The quality and type of research is an important factor in the evaluation of evidence. Efficacy, the extent to which the treatment had the desired effect on the outcomes, is the critical determinant of empirical evidence (Chorpita, 2003).

- **Clinical Expertise & Judgment**: Practitioners in an evidence-informed framework exercise their clinical judgment to select methods that address the client’s needs by taking into account the client’s
environment, life circumstances, strengths, and challenges (APA Presidential Task Force on Evidence-Based Practice, 2006).

- **Values:** Evidence-based practice is consistent with the child and family’s values and perspectives (APA Presidential Task Force on Evidence-Based Practice, 2006; Chambless & Hollon, 1998; Chorpita, 2003). Engaging families in the process of evaluating, identifying, and implementing evidence-based interventions is critical. Family engagement promotes collaboration between families and practitioners and better informs individual treatment planning.

This project focused on the first factor in evidence-based practice – best research evidence. The purpose of this work was twofold: Systematically review the research literature for treatment in ASD and subsequently determine the levels of empirical evidence for treatments commonly used for children with ASD. It is hoped that addressing this first element of evidence-based practice will enable providers, families, and systems to use the latest research to better inform treatment planning, decision making, policy making, and resource development.

**Process**

In response to a growing need for information on evidence-based treatments for ASD, the Maine Department of Education and the Maine Department of Health and Human Services led a partnership of stakeholders in a systematic review of the latest research on treatment for ASD. This review was designed as an update to the Maine Administrators of Services for Children with Disabilities (MADSEC) Autism Task Force Report issued in 2000, one of the first efforts in Maine to review the treatment literature for ASD. Over the course of a year, laypersons, state agency staff, providers, and researchers, reviewed more than 150 studies of 43 different treatments for children with ASD.

The Committee objectively reviewed the research using a validated rubric, the *Evaluative Method for Determining Evidence-Based Practice in Autism* (Reichow, Volkmar, & Cicchetti, 2008), and assigned each intervention a level of evidence rating. The quality of each study was carefully evaluated using a set of primary and secondary quality indicators and factored into the determination of the level of evidence using a corresponding rating scale.

**Levels of Evidence**

- **Established Evidence:** The treatment has been proven effective in multiple strong or adequately rated group experimental design studies, single-subject studies, or a combination. Results must be replicated in studies conducted by different research teams.

- **Promising Evidence:** The intervention has been shown effective in more than two strong or adequately rated group experimental design studies or at least three single-subject studies. Additional research is needed by separate teams to confirm that the intervention is effective in across settings and researchers.

- **Preliminary Evidence:** The intervention has been shown effective in at least one strong or adequately rated group or single-subject design study. More research is needed to confirm results.
- **Studied and No Evidence of Effect:** Numerous (three or more) strong or adequately rated studies have determined that the intervention has no positive effect on the desired outcomes.
- **Insufficient Evidence:** Conclusions cannot be drawn on the efficacy of the intervention due to a lack of quality research and/or mixed outcomes across several studies.
- **Evidence of Harm:** Studies or published case reports indicate that the intervention involves significant harm or risk of harm, including injury and death.

## Findings

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<th>Level of Evidence</th>
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| **Established Evidence** | Applied Behavior Analysis | - Applied Behavior Analysis for Challenging Behavior  
- Applied Behavior Analysis for Communication  
- Applied Behavior Analysis for Social Skills  
- Early Intensive Behavioral Intervention (EIBI) |
|                   | Augmentative and Alternative Communication | - Picture Exchange Communication System (PECS) |
|                   | Pharmacological Approaches | - Halperidol (Haldol) – Effective for aggression  
- Methylphenidate (Ritalin) – Effective for hyperactivity  
- Risperidone (Risperidol) – Effective for irritability, social withdrawal, hyperactivity, and stereotypy |
| **Promising Evidence** | Applied Behavior Analysis | - Applied Behavior Analysis for Adaptive Living Skills |
|                   | Augmentative and Alternative Communication | - Voice Output Communication Aid (VOCA) |
|                   | Psychotherapy | - Cognitive-Behavioral Therapy (CBT) for Anxiety |
- Applied Behavior Analysis for Vocational Skills |
|                   | Augmentative and Alternative Communication | - Sign Language |
|                   | Developmental, Social-Pragmatic Models | - Developmental, Social-Pragmatic Models - Eclectic Models |
|                   | Diet & Nutritional Approaches | - Vitamin C – Modest effect on sensorimotor symptoms only |
|                   | Pharmacological Approaches | - Atomoxetine (Strattera) – Effective for attention deficit and hyperactivity  
- Clomipramine (Anafranil) – Effective for stereotypy, ritualistic behavior, social behavior |
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Conclusions

Based on its investigation of the research literature, the Committee concludes the following:

- The research clearly indicates that there are effective treatments for some core deficits and related challenges of ASD. For instance, comprehensive behavioral treatment has some of the most compelling evidence which emphasizes the importance of early and intensive intervention for children with ASD.
- Substantial investment in quality research is needed to further define effective treatment for ASD.
- Research specific to educational and behavioral interventions for children with ASD in the context of schools is seriously lacking. This is of deep concern since children receive a great deal of services through the education system.
- Comparative research on the efficacy of various treatment models would be very valuable.
- There is a dearth of research on treatment of older youth, adolescents, and adults with ASD. This is worrisome given that the number of adults with ASD is expected to significantly increase in the coming years as children with ASD mature.
- Families should be informed consumers of treatment and ask questions of providers about the nature and quality of the research behind the treatment their child is receiving.
- Providers need to make treatment decisions in active partnership with families while integrating relevant research into their practice and treatment planning process.
- Resources are needed to build capacity throughout Maine in order to efficiently and effectively deliver evidence-based treatments to children in their schools, homes, and communities. This requires resources for training, evaluation, and workforce development. For example, ABA has some of the best evidence for treatment in ASD yet Maine has only 26 certified ABA practitioners, with most located in the southern counties.

Evidence-based practice does not seek to dictate the interventions that should be used at the expense of others. Rather, it is a framework to integrate what is known from research into real-world practice in a manner that is accessible to families, responsive to what children need, and consistent with what providers can accomplish given available skills and resources. The first step toward evidence-based practice is creating awareness of what the best available research says. It is no longer enough to use what we believe works, we must consider what we know works in order to close the gap between science and practice, utilize limited resources wisely, and best serve Maine children with ASD.
Interventions for Autism Spectrum Disorders

STATE OF THE EVIDENCE

INTRODUCTION

Recent statistics indicate that the number of children diagnosed with Autism Spectrum Disorder (ASD) has skyrocketed—the latest figures suggest that approximately 1 in 91 children in the United States are currently diagnosed with ASD (Kogen, Blumberg, Schieve, Boyle, Perrin, Ghandour, et al., 2009). In Maine, the rate is thought to be even higher with an estimated 1 in 77 children identified with ASD—the second highest rate in the nation (Thoughtful House Center for Children, 2009). In response to increasing demand for services for children with ASD in our schools and communities, the Maine Departments of Education and Health and Human Services partnered with members of the community to assess the research and determine the level of scientific evidence for interventions currently available for ASD.

This project continued the efforts of the Children’s Services Evidence-Based Practice Advisory Committee (“the Committee”) to study and disseminate information on the scientific evidence for treatments of childhood behavioral health conditions. This work also serves as a comprehensive update to the Autism Task Force Report issued in 2000 by the Maine Administrators of Services for Children with Disabilities (MAD-SEC). To the best of the Committee’s knowledge, the MADSEC report was the first multidisciplinary effort in Maine to objectively examine the research for select interventions for ASD. In the years since MADSEC issued its report, the breadth and depth of the research of ASD has evolved; in fact, more than 2,100 studies regarding autism have been published in peer-reviewed journals since 2001. Given the significant number of children with ASD being served in Maine and advances in research over the last decade, a new review of the literature is timely and appropriate.

The Committee evaluated peer-reviewed research for more than 40 interventions for children and youth with ASD, including psychosocial, behavioral, developmental, complementary, educational, and pharmaceutical treatments. A wide variety of treatment options have been developed for children with ASD and it can be difficult for parents, educators, and practitioners to know what could be most effective given each child’s unique circumstances. Science helps to clarify some of the confusion about what “works.” Well-designed studies can show that some interventions are very effective for certain symptoms or behaviors while others are not. The implications of this information are profound; understanding what works as demonstrated by research can inform choices that improve lives (Steele, Roberts, & Elkin, 2008).
How to Use This Report

This document is intended to provide an updated view of the best available research evidence for treatments for Autism Spectrum Disorders. Certain stakeholders may find this report especially useful:

- **Families, Educators, & Practitioners:** Evaluating and selecting treatments can be a daunting task. This report provides an objective evaluation of the best available research evidence for the myriad of treatment options currently available for ASD (Steele, et al., 2008).

- **Policymakers:** As Maine continues to enhance its system of care, it is hoped that policymakers will consider this information in their decision making so that all children in Maine have sufficient access to evidence-based interventions.

- **Business & Community Leaders:** ASD touches the lives of many families in the places where we live and work. The Committee hopes that sharing information on effective treatment methods inspires leadership, innovation, and support among business and community leaders to improve service delivery systems.

- **Researchers:** Describing the amount and quality of research behind available treatments draws attention to areas needing further research and investigation.

Children with ASD truly have a spectrum of challenges and abilities therefore treatments should be tailored to reflect their individuality. It is not enough to simply use any evidence-based treatment - they are not “one size fits all.” The treatments discussed in this report vary widely in their focus, intensity, duration, and methods, and thus must be carefully evaluated and matched to a child’s unique needs.

It is not the intention of this report to indicate what interventions should or should not be used; families should always decide what treatment best meets the needs of their child. Children have a right to treatment that is reflective of their individual strengths and challenges and that accommodates any change in the nature and intensity of their needs (Office of Child and Family Services, March 2008). However, families and providers should seek the most current and complete research information to factor into their decisions regarding treatment. As

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“Treatment” & “Intervention”

**Treatment** is generally understood as a service used to correct or alleviate a specific medical condition, issue, or problem. The effectiveness of treatment is usually evaluated and measured based on the individual’s outcome (Barker, 1999).

**Intervention** includes treatment, but also encompasses other services or activities practitioners use to address or prevent an individual’s problems (Barker, 1999). Intervention is a term sometimes used in social work, education, and other ecological, cross-disciplinary fields to describe services that address the problems of an individual.

The Committee reviewed “treatments” and “interventions” without regard to the field or entity that might utilize them. These terms are used interchangeably in this report.
science continues to evolve, it is expected that ASD treatment will be further refined. Therefore, periodic reassessments of the scientific literature will be needed so that families and providers have current information in order to inform their choices and decisions.

PROJECT ORGANIZATION

The Children’s Services Evidence-Based Practice Advisory Committee formed in 2007 as the child-focused Subcommittee of the DHHS Evidence-Based Practice Advisory Committee. The Committee is charged with reviewing the research base for treatments of childhood behavioral health disorders in order to better inform policy, practice, and resource development in Maine. It is not a policy-making entity, but an advisory body that informs state agency work. The Committee is led by Children’s Behavioral Health Services, a division of the Office of Child and Family Services.

A diverse group of stakeholders convened in 2007 to review and rate the research on psychosocial treatments for disruptive behavior disorders (Beaulieu, 2008). Following this successful review, the Committee turned its attention to ASD due to a growing concern about the needs of this population. The Maine Departments of Education and Health and Human Services agreed to jointly lead this project in recognition of the mutually important roles that education and behavioral health systems play in serving children with ASD. The Muskie School of Public Service provided technical assistance, research support, and data analysis to the project through a cooperative agreement with the Office of Child and Family Services.

Due to the nuances involved in ASD research and the relevance of this issue across systems, the Committee incorporated stakeholders and experts in the field of ASD, including parents, an adult with ASD, educators, providers, and advocates. The Autism Spectrum Disorders project began in August of 2008. Initial work focused on establishing common language and understanding about ASD, research methodology, and evidence-based practice. Following a review of the literature, the Committee adopted a systematic review process with a corresponding rating scale to organize the work.

ABOUT AUTISM SPECTRUM DISORDERS

Definition

Autism Spectrum Disorders, also referred to as Pervasive Developmental Disorders (PDD), are a category of neurodevelopmental disorders that include:
- Autistic Disorder (autism);
- Pervasive Developmental Disorders-Not Otherwise Specified (PDD-NOS);
- Asperger’s Syndrome;
- Rett’s Disorder; and
- Childhood Disintegrative Disorder.

Due to their lower prevalence and differing symptom profile, Childhood Disintegrative Disorder and Rett’s Disorder were not included in this review. Research of treatments for ASD generally does not include children with these two diagnoses. Studies that focused on children with Autistic Disorder, PDD-NOS, and/or Asperger’s Syndrome were reviewed.

Because functional ability and expression of symptoms can vary widely among children with these diagnoses, from profound disability to high functioning, they are said to exist on a “spectrum.” The Committee chose to use the term “Autism Spectrum Disorders” rather than Autism or PDD in recognition that no two children are impacted by these disorders in exactly the same manner or to the same degree.

According to the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV-TR), Autism Spectrum Disorders (ASD) are characterized by distinct and pervasive impairment in multiple developmental areas, primarily social skills and communication (American Psychiatric Association, 2000). These disorders are marked by the presence of stereotypical behavior such as hand flapping and body rocking, as well as by excessive preoccupation with certain objects, interests, or activities. Children with ASD exhibit patterns of social interaction and communication that are not consistent with their developmental age. These patterns become apparent in the first few years of life and are generally lifelong challenges (Schieve, Rice, Boyle, Visser, & Blumberg, 2006), although with early and effective intervention, children can often learn new skills and improve existing ones.

Prevalence

Studies have consistently documented a significant increase in the number of children identified with ASD across the United States over the last 15 years (Centers for Disease Control and Prevention, 2009; Hollenbeck, 2004; Schieve, et al., 2006). While it is not known if this increase is attributable to how ASD is identified and diagnosed, an actual increase in prevalence, or a combination of factors, the number of children identified with ASD in Maine and across the country has been growing. ASDs are now the second most common developmental disability after mental retardation (Centers for Disease Control and Prevention, 2009). A recent national survey of parents by

![Graph showing increase in autism cases from 2000 to 2008 in Maine.](image)
U.S. Department of Health & Human Services estimated that 1 in 91 children ages 3-17 years old were currently diagnosed with ASD (Kogan, et al., 2009). This is a substantial increase from earlier estimates by the Centers for Disease Control and Prevention, 2009).

Prevalence in Education

Education data echo this trend. Federal data gathered for the Individuals with Disabilities in Education Act (IDEA) indicate that the number of Maine children ages 6-22 with ASD receiving Special Education services grew by 1672% between 1992 and 2003 (Hollenbeck, 2004). This is compared to a nationwide 834% increase in children ages 6-17 with ASD between 1994 - 2006 (Centers for Disease Control and Prevention, 2009). Maine Department of Education data shows this trend is likely to continue. Since 2000, the number of children in Maine schools classified with ASD has increased by 276% (Department of Education, 2009).

Prevalence among Medicaid Recipients

Utilization data from the Medicaid program also shows an increase in the prevalence of ASD in Maine. Between 2000 and 2008, the number of people with ASD who received MaineCare services increased by 281%.

The significant growth of ASD in Maine’s systems of care underscores the need for planful resource and capacity development in order to adequately address the needs of this expanding population (Department of Health and Human Services, February 2009).

WHAT IS EVIDENCE-BASED PRACTICE?

Evidence-based practice has been a priority in the behavioral health and education fields over the past decade. The growing need for high-quality children’s behavioral health services has increased the demand for treatments that are proven to produce better outcomes (Levant, 2005; New Freedom Commission on Mental Health, 2003). The education system has also emphasized the use of evidence-based practice through legislation and policy such as No Child Left Behind (Coalition for Evidence-Based Policy, December 2003). For example, federal education policy calls for educators to address the needs of students struggling with academics and behavior with interventions supported by research (Gresham, 2007). The emphasis on inter-
ventions backed by research necessitates a common understanding of evidence-based practice.

Defining and coming to a common understanding of “evidence” is not simple (Chambless & Hollon, 1998; Chorpita, 2003). Our current understanding of evidence-based practice in behavioral healthcare is largely rooted in the work of American Psychological Association Task Forces (Task Force on Promotion and Dissemination of Psychological Procedures, 1995; Task Force on Psychological Intervention Guidelines of the American Psychological Association, 1995). These Task Forces developed some of the first guidelines on research-informed practice (Chambless, et al., 1996). The Committee has endorsed the American Psychological Association’s definition of evidence-based practice: Evidence-based practice is the integration of the best available research evidence with clinical expertise in the context of patient characteristics, culture and preference (APA Presidential Task Force on Evidence-Based Practice, 2006). This definition acknowledges that evidence-based practice does not exist in a vacuum, and that research, clinical practice, and client values influence each other.

Although the terms are often used interchangeably, the meanings of “evidence-based practice” and “evidence-based treatment” are distinct. Evidence-based treatment refers to specific treatments or intervention models that have proven effective for specific problems in certain circumstances by numerous scientific studies (Levant, 2005). Evidence-based practice bridges the science-to-practice gap by using research evidence to inform clinical practice in the context of the client’s needs and environment.

There are three core components to evidence-based practice: Best research evidence, clinical expertise and judgment, and client values and voice (APA Presidential Task Force on Evidence-Based Practice, 2006; Burns & Hoagwood, 2002).

**Best Research Evidence**

The main element in the determination of research evidence is **efficacy** (Chorpita, 2003). Efficacy refers to the strength of the causal relationship between the treatment and its intended outcomes. In other words, does the treatment have the desired effect on the target behavior or skill? Efficacy is established

---

**Control condition:** A comparison group of subjects in a research study that receive treatment as usual, or are placed on a waiting list for the treatment under study.

**Efficacy:** The strength of the causal relationship between the treatment and its intended outcomes - Does it work?

**Effectiveness:** An assessment of how well the treatment generalizes to real-world settings.

**Randomized Controlled Trial:** A type of research study in which subjects are randomly selected to receive the experimental intervention or a control condition.

**Single-Subject Design:** A type of research that measures effects of an intervention at the level of the individual under carefully controlled conditions.
through well-designed research studies in which outcomes are observed and measured and compared to a no-treatment condition.

The quality and type of a research study is an important factor in the evaluation of evidence. Research studies are conducted using different methods to varying levels of scientific integrity. Well-designed research is highly controlled, meaning that the families and children are carefully screened and selected to fit the parameters of the research, and administration of the treatment is closely monitored to ensure that it is identical to the original treatment protocol (Chorpita, 2003). If a study is well-controlled, the researcher can reasonably suggest that the outcomes of the study are due to the intervention.

However, if a study does not include good controls, the researcher cannot say with certainty that the treatment was responsible for the outcomes of the study. Poor experimental control means that any number of other factors, such as the passage of time, other treatments the subject may have received, or the environment, cannot be ruled out as an influence on the outcomes. Unfortunately, studies with lackluster methodology that nonetheless report good outcomes are sometimes published. If quality is not considered in the assessment of the study, the reader may be misled in concluding that the treatment in question is indeed effective.

Group Experimental Research Design

Different types of research studies have varying levels of rigor. Studies using between-group research design assign participants to receive the experimental treatment or a “control” condition i.e., a comparison group of subjects who receive treatment as usual or who are placed on a waiting list for the experimental treatment. There are certain advantages of between-group research design, including the ability to test interventions with large numbers of people which allows for research results to be generalized more easily back to the population (Smith, Scahill, Dawson, Guthrie, Lord, Odom, et al, 2007).

According to Sibbald & Roland (1998) randomized controlled trials (RCT) are among the most rigorous between-group research designs that can detect a cause-and-effect relationship between the treatment and the results. Large RCTs are authoritative tests of efficacy because they allow researchers to measure and analyze various factors related to responses to the interventions with a greater degree of statistical sensitivity (Smith, et al., 2007).

However, between-group research studies, including RCTs, have important limitations worth noting. Because results are aggregated from a large group of people, it can be difficult to discern individual changes (Smith, et al., 2007). Conversely, results may be also be overgeneralized if studies do not have a good degree of experimental control. Randomized group experiments are also costly and time consuming. Ethical concerns often discourage the use of experimental group studies because withholding treatment or providing a possibly inferior treatment to children in a control condition is often considered unethical (Sibbald & Roland, 1998). Such concerns have made the use of RCTs and large controlled group studies in ASD research relatively rare. A substantial portion of ASD research, especially research
on treatment efficacy, is done through the use of single-subject design studies. Single-subject research seeks evidence supporting functional relationships between the intervention and changes in behavior comes with rigorous, controlled methods, and as such can also be used to identify evidence-based practices (Horner, et al., 2005).

**Single-Subject Research Design |**

Single-subject research studies are designed to document the effect of an intervention at the individual level and can establish the generalization of treatment effects across individuals, therapists, and settings. Treatment effectiveness is established for an individual by repeatedly measuring the frequency of target behaviors before and after the treatment is implemented. The no treatment-treatment comparison is then replicated multiple times to demonstrate a functional relationship between the treatment and therapeutic behavior change. Generalization of treatment effects is established by systematically replicating the single-case research design across different patients, behaviors, therapists, and settings. Data generated through single-subject design are presented using visual graphs, making possible clear comparisons of behavior before and after the intervention possible (Fisher, Kelley, & Lomas, 2003).

Despite their utility and applicability to ASD research, there are important limitations to this type of research. For example, it can be difficult to directly compare interventions to each another in an experiment due to the small number of subjects and the inability to easily combine different methods into an intervention package (Smith, et al., 2007). Because the intervention is studied with the individual or with very small groups of individuals, inferences cannot be drawn about the applicability of the intervention to other people with ASD without multiple single-subject studies by several researchers. Long-term outcomes can also difficult to gauge since single-case studies tend to focus on immediate or short-term changes in behavior following the intervention (Smith, et al., 2007).

Most reviews of treatments in ASD generally do not include single-subject research, leading many to conclude that there are few or no evidence-based treatments in ASD (Chorpita, 2003). The Committee feels it is important to include single-subject research in this review given that much of the research relies on this methodology. To exclude these studies would distort the state of the research and possibly lead to inaccurate conclusions.

**Clinical Expertise & Judgment |**

Many interventions are developed in labs and tested under highly controlled conditions that do not resemble practice in real-world settings. In contrast to efficacy, effectiveness is defined by how well the treatment performs in real-world settings where environment and client characteristics cannot be controlled. Effectiveness may be viewed as the generalizability of an intervention across individuals, settings, practitioners, and target behaviors. This factor is equally important when evaluating evidence because treatments shown to be effective in lab conditions may not necessarily translate well to the field.
In an evidence-based practice model, providers exercise their clinical judgment to select methods that address the client’s needs by taking into account the client’s environment, life circumstances, strengths, and challenges (APA Presidential Task Force on Evidence-Based Practice, 2006). Treatment is chosen to be consistent with the client’s unique needs, the clinician’s own knowledge, skills, and abilities as well as the treatment’s effectiveness in the given context. Evidence-based practice enables providers to exercise their best clinical judgment in weighing the research evidence against what is most likely to be effective based upon the provider’s clinical skills and training, the environment, and the client’s situation.

**Values**

The final dimension of evidence-based practice relates to the unique characteristics, culture, and values of the client. Ideally, evidence-based practice is consistent with the child and family’s values and perspectives (APA Presidential Task Force on Evidence-Based Practice, 2006; Chambless & Hollon, 1998; Chorpita, 2003). Engaging families in the process of evaluating, identifying, and implementing evidence-based interventions is critical. Family engagement promotes collaboration between families and practitioners and better informs individual treatment planning. Furthermore, using research to inform treatment decisions can expand the choices of possible treatment methods.

**PROCESS & APPROACH**

**Review Process**

It is important to place levels of scientific support on a continuum in order to identify interventions with little or no evidence, those that are repeatedly substantiated by objective evidence, and those that are building an evidence base. “Levels of evidence” rating scales have been developed and implemented in numerous reviews of social services research, including autism, in order to organize these distinctions (J. A. Case-Smith, Marian, 2008; Chambless & Hollon, 1998; Levant, 2005; Rogers & Vismara, 2008). Rating systems are tools that enable systematic detection and consistent definition of relative amounts of research evidence between interventions. Without these rubrics, there is a risk of inconsistent and subjective definitions of “evidence,” as well as the subsequent identification of too many or too few evidence-based treatments (Chorpita, 2003). For example, prior large-scale reviews using more traditional level of evidence standards identified very few, if any, evidence-based treatments for ASD (Lord, et al., 2001; Rogers, 1998) - certainly a limited and discouraging conclusion.

Most rating scales categorize treatment effectiveness on two-levels: “well-established” treatments and treatments that are “promising” or “probably efficacious” (Chorpita, 2003; Higa & Chorpita, 2008; Task Force on Promotion and Dissemination of Psychological Procedures, 1995). However, these rating
Rating Method

A consistent and objective method to apply research quality to level of evidence determinations has been lacking until recently in behavioral health research. In order to deliver a comprehensive and consistent review, the Committee adopted a method developed specifically to evaluate evidence in ASD research. The *Evaluative Method for Determining Evidence-Based Practice in Autism* incorporates both experimental group research and single-subject research in the determination of levels of evidence (Reichow, Volkmar, & Cicchetti, 2008). It includes a rubric to evaluate the quality of research studies and also outlines corresponding criteria to determine level of evidence based on both the quality and outcomes of the research (Reichow, et al., 2008). This method represents a standardized, empirically validated, and structured way to discern evidence-based practices specific to ASD.

Quality Indicators

The Evaluative Method uses two sets of quality indicators: one for group experimental studies and one for single-subject studies. There are two types of quality indicators within each research category (group and single-subject): primary quality indicators and secondary quality indicators.

Primary quality indicators are aspects of a study that are important to control in order for the research to be valid. Based on careful assessment of a study, each primary indica-
tor is assigned a rating of strong, acceptable, or unacceptable, according to pre-determined guidelines.

Secondary quality indicators are elements of research that are important to ensure quality, but are not critical for the research’s validity. Secondary indicators have two levels: evidence or no evidence. The Committee made some minor adaptations to the quality indicators to better meet the objectives of its work.

Each research study that was reviewed was assigned a rating of “strong,” “adequate,” or “weak” according to the number of primary and secondary quality indicators. The Committee developed a worksheet to structure and guide reviews of studies and to help ensure inter-rater reliability.

Small groups reviewed studies for each intervention, with Committee members independently reviewing studies and completing their worksheets. The small groups met to compare ratings, resolve any disagreements or inconsistencies, and reach consensus regarding each study’s rating. At least two Committee members reviewed each study to ensure reliability and objectivity. Research staff also reviewed and rated each study for purposes of reliability, although formal inter-rater reliability measurement was beyond the resources of the Committee.

Levels of evidence

The Committee determined a level of evidence for each treatment based on an expanded version of the Evaluative Method rating scale (Reichow, et al., 2008). Several levels were added to the rating scale to meet the needs of this review: preliminary evidence, studied and no evidence of effect, insufficient evidence, and evidence of harm. Some interventions, such as secretin, have many strong studies which concluded that the treatment had no beneficial effect. Rather than simply omitting the treatment from a list of evidence-based practices, the Committee believes that it is more accurate to acknowledge that the treatment has consistently been shown not to work, describing it accordingly as studied and no evidence of effect. Furthermore, some interventions in ASD have either poor research or no research meeting the Commit-

Levels of Evidence

- **Established Evidence** – The treatment has been proven effective in multiple strong or adequately rated group experimental design studies, single-subject studies, or a combination. Results must be replicated in studies conducted by different research teams.

- **Promising Evidence** – The intervention has been shown effective in more than two strong or adequately rated group experimental design studies or at least three single-subject studies. Additional research is needed by separate teams to confirm that the intervention is effective in different settings.

- **Preliminary Evidence** – The intervention has been shown to be effective in at least one strong or adequately rated group or single-subject design study. More research is needed to confirm results.

- **Studied and No Evidence of Effect** – Numerous (two or more) strong or adequately rated studies have determined that the intervention has no positive effect on the desired outcomes.

- **Insufficient Evidence** – Conclusions cannot be drawn on the efficacy of the intervention due to a lack of quality research and/or mixed outcomes across several studies.

- **Evidence of Harm** – Studies or published case reports indicate that the intervention involves significant harm or risk of harm, including injury and death.

Without valid research, the Committee cannot draw conclusions about efficacy. In such instances, assigning a rating of insufficient evidence points to a need for high-quality research. Some treatments that have not yet been proven effective by the scientific method are highly available and heavily marketed to families. The Committee feels that parents, providers, and policymakers should have information on what does not work as well as what does work so that resources, time, opportunities, and effort are used effectively.

Review teams presented their research report strength ratings and impressions of the research in each treatment to the full Committee for review and ratification. Based on the research report strength ratings and discussion, a final level of evidence rating was determined by consensus of the Committee according to the rating scale.

Inclusion Criteria

Studies had to meet several requirements to qualify for review:

1. Studies must have been published in a peer-reviewed, scholarly journal;

2. Study samples included only children with Autism, PDD/PDD-NOS, and/or Asperger’s Syndrome. Children described with diagnoses of mental retardation, developmental disability, or other conditions without a concurrent ASD diagnosis excluded the study from review; and

3. The intervention addressed the core symptoms of ASD and/or associated issues, such as aggression or self-injurious behavior.

Literature searches were conducted using the following academic databases: Academic Search Premier, ERIC, Medline, PubMed, Cochrane Database of Systematic Reviews, CINAHL, PsychLit, PsychInfo, and SAGE Journals Online. The references in qualifying articles were also examined to identify additional studies. Main keywords included autism, Asperger’s Syndrome, PDD, and terms specific to the treatment being reviewed.

Interventions Reviewed

The review was structured based on broad categories of interventions that the Committee believes are identifiable and understandable by a cross-section of the public. Specific treatments were identified for review within the larger categories. Selections were based on a review of the literature, discussion by the Committee, and feedback solicited from parents within and outside of the Committee. Based on this information, the Committee selected 11 intervention categories. Within these categories, 41 specific interventions were identified for review. The Committee aimed to select and describe interventions in as much of a “user-friendly” manner as possible by identifying treatments that are used in the community and organizing them by type of treatment.
<table>
<thead>
<tr>
<th>Category</th>
<th>Interventions</th>
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| **Applied Behavior Analysis (ABA)**          | • Early Intensive Behavioral Intervention  
• ABA for Academics  
• ABA for Adaptive Living Skills  
• ABA for Challenging Behavior  
• ABA for Communication  
• ABA for Social Skills  
• ABA for Vocational Skills |
| **Augmentative and Alternative Communication (AAC)** | • Facilitated Communication (FC)  
• Picture Exchange Communication System (PECS)  
• Sign Language  
• Voice Output Communication Devices (VOCA) |
| **Developmental, Social-Pragmatic (DSP) Models** | • Eclectic models  
• DIR/Floortime  
• RDI  
• SCERTS  
• Solomon’s PLAY model |
| **Diet & Nutritional Approaches**            | • Vitamin B₆-Magnesium Supplements  
• Vitamin C Supplements  
• Gluten-casein free diets  
• Omega-3 Fatty Acid Supplements |
| **Pharmacological Approaches**               | • Atomoxetine HCl (Strattera)  
• Clonidine (Catapres)  
• Clomipramine  
• SSRIs - Fluoxetine (Prozac), Citalopram (Celexa)  
• Guanfacine (Tenex)  
• Haloperidol (Haldol)  
• Methylphenidate (Ritalin)  
• Naltrexone (Revia)  
• Risperidone (Risperidal)  
• Valproic Acid (Depakote)  
• DMG  
• Intravenous Chelation  
• Intravenous Immunoglobin  
• Melatonin  
• Secretin |
| **Psychotherapy**                            | • Cognitive-Behavioral Therapy for anxiety and anger management |
| **Sensory Integration Therapy**              | • Auditory Integration Training (AIT)  
• Sensory Integration Therapy (includes deep pressure, weighted vests, etc.)  
• Touch Therapy / Massage |
| **Social Skills Training**                   | • Social Skills Training  
• Social Stories™ |
| **Other approaches**                        | • Hyperbaric treatment  
• TEACCH |
FINDINGS

Applied Behavior Analysis

Applied Behavior Analysis (ABA) uses procedures derived from the principles of operant behavior to meaningfully improve socially significant behavior (Cooper, Heron, & Heward, 1987). ABA methods are designed to demonstrate through clear, objective data (e.g. visual analysis of graphs) that the procedures used were responsible for the improvement in behavior (Cooper, et al., 1987; Myers, Plauche Johnson, & Council on Children With Disabilities, 2007). ABA aims to discover and understand the underlying principles of behavior with the function of a particular behavior considered in the design of behavior change interventions. Interventions are designed for the individual, recognizing that the function of behavior varies based on complex combinations of variables.

ABA uses single case study design to record changes in behavior and document an intervention’s effectiveness across people, time, providers, and settings. Behavior analysts document the effectiveness of an intervention for an individual by measuring the target behavior repeatedly before and after the intervention is implemented in order to document any change in the behavior. This data is then usually graphed and visually analyzed.

ABA has been used extensively to address behavior in children with ASD. Specific techniques used in ABA include chaining, shaping, reinforcement, pivotal response training, incidental teaching, and discrete trial training, among many others. It is important to note that ABA is frequently perceived to be synonymous with discrete trial teaching. However, ABA is comprised of a broad scope of empirically derived behavioral principles used in interventions including the Matching Law, response class hierarchies, and motivating operations, among others.

There are various methods of ABA studied with children with ASD, including a comprehensive model for young children and skill-specific methods.

Early Intensive Behavioral Intervention | ESTABLISHED EVIDENCE

Early Intensive Behavioral Intervention (EIBI) is a comprehensive ABA program for young children based on the work of Lovaas and colleagues at the UCLA Young Autism Project, now the Lovaas Institute (Lovaas, 1987; Lovaas, et al., 1981). EIBI is intensive and highly individualized with 40 hours per week of 1:1 direct instruction recommended that can be delivered at school and in-home. The treatment begins early, preferably before age three and continues for at least two years (Eikeseth, Smith, Jahr, & Eldevik, 2002; Howlin, Magiati, & Charman, 2009). Parental involvement is a key component to the program; parents are trained alongside the therapist for four hours per week so they may use the interventions at home and in the community, thereby generalizing the treatment’s effects to the child’s typical environment. Treatment begins by using discrete trials to teach simple skills like responding to basic requests, and progresses to more complex skills such as initiating verbal behavior and engaging in imaginative play (Eikeseth, et al., 2002). The model is prescriptive and has a treatment manual that practitioners must follow. However, this rigidity has made replication with fidelity challenging and most practitioners and contemporary studies use an adapted version of the model (Howlin, et al., 2009).
Most of the studies reviewed by the Committee were of contemporary adaptations of the Lovaas approach and include ABA methods such as pivotal response training and incidental teaching (Cohen, Amerine-Dickens, & Smith, 2006; Remington, et al., 2007). EIBI has been shown effective by various research teams in multiple studies, including several RCTs (Eikeseth, et al., 2002; Eikeseth, Smith, Jahr, & Eldevik, 2007; T. Smith, Groen, & Wynn, 2000). Recent reviews and meta-analyses also concluded that EIBI is effective for young children, but stressed the need for more rigorous research to extend these findings (Howlin, et al., 2009; Reichow & Wolery, 2009; Rogers & Vismara, 2008).

Studies suggest that EIBI may be more effective for some children than others. For instance, one study found that children with higher IQ scores upon entry to treatment tended to have more significant gains in IQ scores following treatment. Based on the literature reviewed, there is established evidence for EIBI’s efficacy as a comprehensive method. However, rigorous research is needed to determine for what children EIBI is most effective. It is clear from these studies and other research that early intervention is critical in ASD, although it cannot be determined with certainty what children benefit most. In addition, studies examining EIBI in more natural settings would be beneficial as most research has taken place in university-based clinics or programs. Research comparing EIBI with other comprehensive interventions such as SCERTS and DIR/Floortime are also needed. Measurement of the degree to which EIBI is implemented with fidelity is also necessary.

**Applied Behavior Analysis for Academics | PRELIMINARY EVIDENCE, INSUFFICIENT EVIDENCE**

ABA methods have been used in academic settings in various ways and the reader is referred to a review by Dunlap, Kern, & Worcester (2001) for a general overview of ABA applications in academic instruction. Studies in this area are lacking, and those studies that are published use varying ABA techniques and focus on skill acquisition in different subject areas. Areas studied include reading, mastery of social studies, numeral recognition, and spelling. There are no studies of students with ASD specific to mathematics, science, or other curricular areas. Much of the literature is speculative and descriptive. There are more studies in this area specific to children with mental retardation, developmental disabilities, and learning disabilities.

Due to the varied focus of the interventions that were studied, the Committee decided to review and rate ABA’s efficacy for specific instructional strategies or subject matter. Conclusions could not be drawn about the area as a whole. Seven studies met the criteria for review.

**PRELIMINARY EVIDENCE:**

- **Simultaneous prompting to teach numeral recognition** (Akmanoglu, 2004)
- **Classwide peer tutoring for reading** (Kamps, Barbetta, Leonard, & Delquadri, 1994)
- **Pivotal response training for use of grammatical morphemes** (Koegel, 2003)
- **Incidental teaching for reading instruction** (McGee, Krantz, & McClannahan, 1986)
- **Speech output and orthographic feedback to teach spelling** (Schlosser, 1998)
INSUFFICIENT EVIDENCE:

- Cooperative learning groups for reading and social studies (Dugan, et al., 1995; Kamps, Leonard, Potucek, & Garrison-Harrel, 1995)

Applied Behavior Analysis for Adaptive Living Skills | PROMISING EVIDENCE

Children with ASD frequently have challenges in adaptive skills, which are those activities essential in day-to-day life such as toileting, dressing, eating, and grooming. Impairments in these skills can limit a child’s ability to function in the community; for example, frequent toileting accidents can disrupt the education of a child who has not yet mastered toileting. There is some evidence that ABA can be used to successfully teach children skills in the activities of daily living.

Eight studies met the Committee’s criteria for review. Three good quality studies addressed incontinence in young children (Cicero & Pfadt, 2002; Keen, Brannigan, & Cuskelty, 2007; Leblanc, Carr, Crossett, Bennett, & Detweiler, 2005), with two studies replicating a modified version of Azrin and Foxx’s Rapid Toilet Training program (Azrin & Foxx, 1971). Recent data indicates that more than half of parents of children with autism report incontinence problems (Whiteley, 2004) so clearly this is an issue of significance.

The use of picture guides to teach children to follow a schedule and complete multiple-step skills such as dressing was also found to be an effective method in two well-done studies that met the Committee’s criteria (MacDuff, Krantz, & McClannahan, 1993; K. L. Pierce & Screibman, 1994). Finally, video modeling was effective in teaching youth how to purchase items in a store (Alcantara, 1994).

More studies are needed to confirm the efficacy of ABA to develop adaptive skills, but the evidence thus far is encouraging.

Applied Behavior Analysis for Challenging Behavior | ESTABLISHED EVIDENCE

Behavior such as aggression, property destruction, disruptive vocalizations, stereotypic behavior (e.g. flapping), and self-injury are common in children with ASD (Lord, et al., 2001; Myers, et al., 2007). These behaviors can cause injury to the child and/or others as well as interfere with the child’s education and community life. Behaviors may be caused by a physiological condition, such as a pain (Myers, et al., 2007), or by a concurrent mental health condition. However, challenging behaviors are oftentimes triggered or exacerbated by environmental factors.

ABA has been documented in numerous studies as an effective method to diminish or eliminate problematic behaviors. The Committee reviewed several recent single-subject studies and a recent meta-analysis of single-subject research to determine the level of evidence (Campbell, 2003). The Campbell review analyzed 117 studies using 181 individuals and concluded that applied behavior analytic interventions are effective in addressing problem behaviors in children with ASD. Mean age of the participants was 10 years old, with an age range of 5 to 15 years old. Campbell’s analysis found that subjects averaged a 76% reduction in challenging behaviors. The Committee did not have the expertise or resources to review a literature that is so extensive and based solely on single-subject designs. Therefore, the Committee decided to rely on the conclusions of the Campbell review (2003) for the level of evidence rating.
Challenges in communication skills are a core manifestation of ASD. Communication challenges in children with ASD extend beyond vocal speech because “language” encompasses non-verbal communication such as gestures and facial expressions as well as eye contact and inflection. Some common communication deficits in children with ASD include difficulties engaging in social communication, echolalia (“parroting”), associating words with particular events (“idiosyncratic language”), and problems interpreting figures of speech and metaphorical language (The National Autistic Society - U.K., 2006).

Based on a review of six studies of strong and adequate research strength, the Committee concludes that ABA has established evidence for improving communication skills in children with ASD. Outcomes were defined differently across studies but all fell under the same general communication rubric. Several studies were effective in increasing spontaneous speech using methods such as incidental teaching and time delay (Charlop & Carpenter, 2000; Charlop & Trasovech, 1991; Jones, Feeley, & Takacs, 2007). Another study the Committee found intriguing used Reciprocal Imitation Training (RIT) to increase children’s imitation of descriptive gestures during communication (Ingersoll, Lewis, & Kroman, 2007).

Social skills deficits are another core deficit of ASD and remain one of the most difficult areas to treat (Weiss & Harris, 2001). Children with ASD struggle with initiating and responding to social interaction, understanding facial expressions and other non-verbal social cues, establishing joint attention, and engaging in play. Without early and continued intervention, these challenges are often profound and persist over time (Myers, et al., 2007). Due to the pervasiveness of social skills deficits in children with ASD, much attention has been given to treatment in this area (Weiss & Harris, 2001). ABA has been shown to be effective with skills from establishing eye contact to more complex skills such as responding to bids for joint attention and engaging in complex play sequences.

The Committee reviewed 11 studies, finding eight positive studies of strong or adequate research quality, which qualifies the area as “established.” Using peers to model and teach social skills is a trend emerging in the field that has shown encouraging results (Pierce & Schreibman, 1995; Pierce & Screibman, 1997). Modeling skills via video (“video modeling”) is also proving effective, with studies using the technique to teach play sequences to toddlers and social initiation skills, among other abilities (D’Ateno, Mangiapanello, & Taylor, 2003; Gena, Couloura, & Kymissis, 2005). Finally, ABA is now being extended to help children develop the ability to understand another person’s perspective (Yun Chin & Bernard-Optiz, 2000).

The ability to gain meaningful employment is important for a successful transition to adulthood. Planning for transition to adult roles such as work is part of the Individualized Education Plan (IEP) process through the schools and should begin by age 14. Vocational activities and goals are often included on IEPs for children with ASD.
The Committee located four studies of ABA methods specific to employment skills of people with ASD. Some of the studies meet aspects of the evaluation criteria, but the Committee had concerns about the ability to generalize these findings to youth in Maine due to the characteristics of the participants in the studies. Most of the research subjects were adults with severe/profound mental retardation who lived in institutional settings. The Committee could not find any employment-related research focused on youth specifically identified as having ASD. One study with adequate research report strength found that simulating work site activities plus on-the-job training ‘increased subjects’ ability to complete tasks independently (Lattimore, Parsons, & Reid, 2006). On the basis of this result, the use of ABA for vocational skills has preliminary evidence, but the Committee cautions that high-quality research is needed in this area in order to draw further conclusions.

### Augmentative and Alternative Communication

Augmentative and Alternative Communication (AAC) is a set of interventions, processes, and tools that enhance an individual’s skills to produce and comprehend communication in all of its forms in order to improve functional communication ability (American Speech-Language-Hearing Association, 1995). AAC includes aided and unaided methods of supplementing or replacing speech or writing using tools such as symbols, devices, pictures, and sign language.

### Facilitated Communication | **INSUFFICIENT EVIDENCE**

Facilitated Communication was first introduced by Rosemary Crossley during the 1970s as a technique to support individuals with physical disabilities to communicate. Proponents of Facilitated Communication suggest that motor planning difficulties might interfere with the ability of some individuals with autism to communicate either through speech or modalities requiring the use of their hands (Biklen, 1990). In Facilitated Communication, a provider gives physical, communication, and/or emotional support to an individual with ASD in order to help him or her to communicate by pointing to pictures, symbols or letters. Physical facilitation is provided by the facilitator’s support on the individual’s hands, forearm, upper arm, or shoulder (Braman, Brady, Linehan, & Williams, 1995). Facilitators offer communication support by rephrasing questions in order to clarify the message, while emotional support can take the form of praise, sitting near the individual, and working with the individual’s strengths (American Speech-Language-Hearing Association, 1995).

Facilitated Communication has been controversial, partially as a result of allegations of serious abuse disclosed through facilitated communication. This controversy caused the focus of the research to shift to the validity of authorship in Facilitated Communication; that is, whether the individual being supported to communicate truly authored the message or the facilitator consciously or subconsciously generated the message.

Of the eight studies qualifying for review by the Committee, six examined authorship (Bebko, Perry, & Bryson, 1996; Braman, et al., 1995; Cabay, 1994; Cardinal, Hanson, & Wakeham, 1996; Sheehan & Matuzzi, 1996; Weiss, Wagner, & Bauman, 1996). There is very little empirical literature focusing on the actual effectiveness of Facilitated Communication to increase the ability to communicate. Those studies that do exist were rated as methodologically weak, according to the Committee’s criteria (Cardinal,
The Committee determined there is insufficient research evidence to support the efficacy of Facilitated Communication. Any future research should focus on rigorous studies that clearly assess Facilitated Communication’s impact on increasing communication authored by individuals with ASD.

**Picture Exchange Communication System | ESTABLISHED EVIDENCE**

The Picture Exchange Communication System (PECS) is a visual communication system designed to increase a child’s use of spontaneous and functional communication in their child’s everyday environment (Ostryn, Wolfe, & Rusch, 2008). The child uses PECS to exchange pictures of items to obtain desired objects and otherwise get his or her needs met. PECS does not necessarily aim to increase vocalization, but to help children improve their ability to spontaneously communicate in a functional manner during their day-to-day lives (Ostryn, et al., 2008). PECS is delivered in six sequential phases, beginning with teaching requests, or “mands,” and progresses to more sophisticated skills such as answering questions (Bondy & Frost, 2002).

Seven studies using PECS were reviewed by the Committee; four were strong analyses with positive outcomes, including one RCT (Yoder & Stone, 2006). One interesting study compared PECS to sign language but had mixed results (Tincani, 2004), thus limiting the ability to draw direct comparisons. Although PECS has established evidence according to the Committee’s rating rubric, it is surprising there are not more published studies of the intervention given its popularity in the field. More research is needed to compare the effectiveness of PECS with other aided and unaided communication systems.

**Sign Language | PRELIMINARY EVIDENCE**

Some children with limited verbal ability are taught use sign language as an augmentative communication strategy. Sign language enables the child to communicate symbolically in order to ask for things and get his or her needs met, which can be highly frustrating tasks for a child who has limited verbal ability. Sign language is not meant to take the place of speech, but rather to augment the development of verbal skills.

Research on sign language as a communication strategy is fairly dated; most literature was published in during the 1970s and 1980s. One recent study reviewed by the Committee compared PECS and sign language in the acquisition of mands and vocalization, but showed inconclusive findings (Tincani, 2004). Two studies of adequate research report strength found that children improved their ability to request and label objects using sign language (Carr, Binkoff, Kologinsky, & Eddy, 1978; Remington & Clarke, 1983). Overall, there is preliminary evidence for the efficacy of sign language as a communication aid; however, methodologically sound research is needed to gain a clearer picture of the conditions in which sign language is most effective.

**Voice Output Communication Aids | PROMISING EVIDENCE**

Voice Output Communication Aids (VOCAs) are electronic devices that help children with no or limited verbal ability to communicate using an artificial voice. The literature examining VOCAs that met review
criteria is limited to a few single-subject studies. Most of these studies determined that children using a VOCA improved in communication at least to a small degree. There were several comparisons of the Picture Exchange Communication System (PECS) and VOCA in the literature. However, results were inconclusive as the rate of speech acquisition and the child’s preference for either method was not significantly different and varied between the individuals (Beck, Stoner, Bock, & Parton, 2008; Son, Sigafoos, O’Reilly, & Lancioni, 2005).

Developmental, Social-Pragmatic Models | PRELIMINARY EVIDENCE

Eclectic Developmental, Social-Pragmatic models

Developmental, Social-Pragmatic (DSP) models aim to develop social communication abilities using naturalistic techniques in the child’s regular setting. These models are based on the theory that communication develops through interaction with others and attempts to build on the child’s ability to communicate within the context of relationships. The treatment centers around child-directed interaction, with adults responding to and encouraging the child’s attempts to communicate in any and all forms, such as vocalization and gestures (Ingersoll, Dvortcsak, Whalen, & Sikora, 2005). Interactions take place in the child’s everyday environment with the caregiver acting as the main facilitator of the child’s language and social development (Keen, Rodger, Doussin, & Braithwaite, 2007). The child guides and sets the tone for interaction as adults engage the child in the moment based on the child’s interests and focus of attention. Caregivers provide positive feedback and encouragement and arrange the child’s environment to facilitate interactions (Ingersoll, et al., 2005). DSP models believe that this interactional pattern enables the child to feel connected with and understood by the caregiver, thereby encouraging further communications.

Several distinct approaches fall within this category, with DIR/Floortime perhaps being the best known (Greenspan & Wieder, 1997; Prizant, Wetherby, Rubin, Laurent, & Rydell, 2006). The objective of DIR/Floortime is to increase opportunities for back-and-forth communication and engagement with the child that provide learning opportunities to enhance the child’s social communication skills. Relationship Development Intervention (RDI) (Gutstein, Burgess, & Montfort, 2007) and Responsive Teaching (Mahoney & Perales, 2003) are also considered DSP models. SCERTS is sometimes placed in this category as well (Ingersoll, et al., 2005). However, the Committee reviewed the evidence for SCERTS separately as an idiosyncratic “comprehensive” model of treatment that includes additional instruction above and beyond social communication (Prizant, et al., 2006).

Nine studies of eclectic interventions based on a combination of DIR, SCERTS, PLAY, and other DSP models were reviewed. Most studies had weak research methodology. A strong RCT and a strong single-subject study of these eclectic DSP interventions were identified (Aldred, Green, & Adams, 2004; Schertz & Odom, 2007), indicating there is preliminary evidence for this general model of intervention.

DIR/Floortime | INSUFFICIENT EVIDENCE

Although studies are underway, no published controlled trials of Greenspan’s DIR/Floortime model met the Committee’s criteria for review.
Relationship Development Intervention (RDI) | INSUFFICIENT EVIDENCE

No trials published on RDI met the Committee’s review criteria; the lone study available had questionable methodology (Gutstein, et al., 2007).

SCERTS | INSUFFICIENT EVIDENCE

The Social Communication/Emotional Regulation/Transactional Support (SCERTS) model is a comprehensive, manualized educational intervention for children ages 0-10 years-old. SCERTS uses a multidisciplinary approach to build the communication, social, and emotional regulation abilities of a child in the context of daily activities, experiences, and interactions (Prizant, et al., 2006). Naturalistic learning opportunities are provided with deliberate implementation of “transactional supports” - those people, environments, and tools that build on the child’s strengths and create opportunities for growth that are responsive to ever-changing needs (Prizant, Wetherby, & Rydell, 2000).

Although the developers of SCERTS argue that the research support for SCERTS lies in the evidence for individual techniques, methods, and theory embedded within the model (Wetherby, Rubin, Laurent, Prizant, & Rydell, 2006), at present there are no studies meeting criteria for review of SCERTS as a comprehensive model. An RCT comparing SCERTS to a parent education and support group is currently underway by Wetherby and Lord. The Committee concludes there is insufficient evidence for SCERTS at this time.

Diet & Nutritional Approaches |

Dietary and nutritional therapies fall into a category of approaches commonly termed Complementary and Alternative Medicine (CAM), which are defined as medical and health-related practices and products not considered part of mainstream medical treatment (Myers, et al., 2007). These approaches are commonly used by children with ASD; one study found that 74% of surveyed families were using CAM practices for their autistic children (Hanson, et al., 2007). CAM approaches related to diet and nutrition include nutritional supplements and restriction diets. The Committee categorized interventions by the target of their use, rather than group all CAM practices in one category.

Gluten-Casein Free Diet | INSUFFICIENT EVIDENCE

Elimination of gluten and casein from diets are believed by some to prevent symptoms of ASD linked to opioid activity that is triggered by the peptides in these substances (Millward, Ferriter, Calver, & Connell-Jones, 2008). A recent high-quality clinical trial of a gluten/casein free diet did not detect any significant differences in behavior or other symptoms of ASD (Harrison, et al., 2006), while another study showed positive results but had some concerning methodological flaws (Knivsberg, Reichelt, Hoien, & Nodland, 2003). A recent Cochrane review concluded that the evidence for these diets is poor and more research is needed and the Committee echoes this finding (Millward, et al., 2008). A large clinical trial of gluten- and casein-free diets is currently underway.
Omega-3 Fatty Acid Supplements | **INSUFFICIENT EVIDENCE**

Deficiencies in Omega-3 fatty acids have been theorized to play a role in certain mental health conditions, including ASD (Politi, et al., 2008). One strong study of children receiving Omega-3 fatty acid supplements had a small, exclusively male sample (Amminger, et al., 2007). This raises concerns about whether the outcomes could generalize to females. There was no benefit of Omega-3 on behavior or other symptoms, but the researchers found a small effect on one subscale after retrospectively reanalyzing the data. This retrospective data analysis risks misinterpretation of an effect that could be due to chance. Therefore, the data is inconclusive and this area requires further investigation.

Vitamin B6-Magnesium Supplements | **INSUFFICIENT EVIDENCE**

Vitamin B6-Magnesium has been anecdotally linked to improvement in speech and language performance as well as social skills (Nye & Brice, 2005). Various researchers in the 1970s and 1980s published observations of improvement in social and behavioral functioning in patients with schizophrenia and autism, leading to wider use of the megavitamins. Three recent RCTs meeting the Committee’s criteria and a Cochrane review were evaluated (Findling, ScoteSe-Wojtila, Huang, Yamashita, & Wiznitzer, 1997; Kuriyama, et al., 2002; Tolbert, Haigler, Waits, & Dennis, 1993).

Most of the RCTs reviewed found no significant improvements in behavior following use of Vitamin B6-Magnesium supplements. However, Kuriyama and colleagues (2002) found that children who received the supplement improved in verbal IQ scores but not in functional IQ or social behavior. Due to mixed results and the limited number of published studies that met criteria for review, the Committee concludes that there is not sufficient research at this time to draw conclusions on the impact of Vitamin B6-Magnesium.

Vitamin C (Ascorbic Acid) Supplements | **PRELIMINARY EVIDENCE** *(FOR SENSORIMOTOR IMPROVEMENT)*

Researchers have theorized that nutrients such as Vitamin C may modulate certain neurotransmitters, thereby inhibiting problematic behavior associated with ASD such as stereotypy. Vitamin C is thought to modulate levels of dopamine, a neurotransmitter that plays a role in controlling voluntary movement, mood, sleep, and attention.

One positive RCT that met criteria for review found that children receiving supplemental doses of Vitamin C had a significant reduction in sensorimotor symptoms (Dolske, Spollen, McKay, Lancashire, & Tolbert, 1993). However, there was no significant improvement in any of the other subscales of autistic behavior. The clinical impact of this improvement is unknown as the scale used by the researchers, the Ritvo-Freeman Real Life Scale (RFRLS), is unfamiliar. Replication is needed to confirm the findings. The Committee finds Vitamin C has preliminary evidence for a modest effect on sensorimotor behavior only.
Pharmacological Approaches | Psycho|tropic Medication

Psycho|tropic medication is commonly used to treat disruptive behaviors, agitation, inattention, and hyperactivity in children with ASD (Myers, et al., 2007). Drugs studied in children with ASD are listed according to their class. However, only the specific medications listed have been studied relative to ASD, not the entire class of medication. Medication should be approached as an adjunctive intervention and part of a full psychosocial treatment program. All medications carry certain risks and benefits which must be weighed carefully by the family and the child’s physician when administering psychotropic medications. Studies were screened for inclusion, reviewed, and rated by two child psychiatrists.

Table 2: Psycho|tropic Medications Studied in Children and Youth with ASD

<table>
<thead>
<tr>
<th>Class</th>
<th>Medication (Brand name)</th>
<th>Level of Evidence</th>
<th>Target Symptoms</th>
<th>Significant Potential Side Effects</th>
<th>Studies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antipsychotics</td>
<td>Risperidone (Risperidal)</td>
<td>Established</td>
<td>Irritability, hyperactivity, and stereotypy</td>
<td>Weight gain, drooling, dizziness, fatigue, involuntary muscle movement</td>
<td>(Jesner, Aref-Adib, &amp; Coren, 2007; McDougle, et al., 2005; Miral, et al., 2008; RUPP, 2002)</td>
</tr>
<tr>
<td>Stimulants</td>
<td>Methylphenidate (Ritalin)</td>
<td>Established</td>
<td>Hyperactivity</td>
<td>Social withdrawal, irritability, agitation, stereotypy</td>
<td>(Handen, Johnson, &amp; Lubetsky, 2000; Quitana, et al., 1995)</td>
</tr>
<tr>
<td>Norepinephrine Reuptake Inhibitor</td>
<td>Atomoxetine HCl (Strattera)</td>
<td>Preliminary</td>
<td>Attention deficit, hyperactivity</td>
<td>None</td>
<td>(Arnold, et al., 2006)</td>
</tr>
<tr>
<td>Alpha 2 Agonist</td>
<td>Clonidine (Catapres)</td>
<td>Preliminary</td>
<td>Hyperactivity, irritability, inappropriate speech, stereotypy, oppositionality</td>
<td>Drowsiness, low blood pressure, irritability</td>
<td>(Jaselskis, Cook, Fletcher, &amp; Leventhal, 1992)</td>
</tr>
<tr>
<td></td>
<td>Guanfacine (Tenex)</td>
<td>Insufficient</td>
<td>Hyperactivity, inattention, impulsivity, aggression</td>
<td>Transient sedation</td>
<td>(Posey, Puntney, Sasher, Kem, &amp; McDougle, 2004)</td>
</tr>
<tr>
<td>Selective Serotonin Reuptake Inhibitors (SSRIs)</td>
<td>Fluoxetine (Prozac) &amp; Citalopram (Celexa)</td>
<td>Insufficient Evidence (conflicting results)</td>
<td>Repetitive behavior</td>
<td>Celexa: Hyperactivity, insomnia, inattention, impulsivity, diarrhea, dry skin</td>
<td>(Hollander, et al., 2005; King, et al., 2009)</td>
</tr>
<tr>
<td>Class</td>
<td>Medication (Brand name)</td>
<td>Level of Evidence</td>
<td>Target Symptoms</td>
<td>Significant Potential Side Effects</td>
<td>Studies</td>
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<tr>
<td>Other</td>
<td>Clomipramine (Anafranil)</td>
<td>Preliminary Evidence</td>
<td>Stereotypy, ritualistic behavior, social behavior</td>
<td>Insomnia, constipation, twitching, tremors</td>
<td>(Gordon, State, Nelson, Hamburger, &amp; Rapoport, 1993)</td>
</tr>
<tr>
<td></td>
<td>Valproic Acid (Depakote)</td>
<td>Insufficient evidence</td>
<td>N/A</td>
<td>Rash, weight gain, hair loss, fatigue</td>
<td>(Heillings, et al., 2005; Hollander, et al., 2006)</td>
</tr>
<tr>
<td></td>
<td>Naltrexone (Revia)</td>
<td>Insufficient evidence</td>
<td>N/A</td>
<td>Increased stereotypy</td>
<td>(Willemsen-Swinkels, Buitelaar, Weijnen, &amp; van Engeland, 1995)</td>
</tr>
</tbody>
</table>

**Dimethylglycine | STUDIED AND NO EVIDENCE OF EFFECT**

Dimethylglycine (DMG) is a natural substance thought to inhibit the build-up of certain amino acids in the body and enhance the immune response in children with ASD. Anecdotal reports have suggested that use of DMG results in improved social behavior, frustration tolerance, speech, and reduced aggressive behavior. However, two RCTs that qualified for the review found no significant differences in behavior after taking DMG (Bolman & Richmond, 1999; Kern, et al., 2001).

**Intravenous Chelation using Edetate Disodium | EVIDENCE OF HARM**

Chelation agents such as Edetate Disodium were developed to treat lead poisoning. However, the question of a possible connection between heavy metals and ASD has led to the use of chelation for children with ASD. Chelation agents work by encouraging the excretion of toxic metals through urination and/or the liver and gallbladder (Brown, Willis, Omalu, & Leiker, 2006). Edetate Disodium is delivered intravenously and carries a risk of lowering the amount of calcium in the bloodstream if not delivered and monitored correctly. In extreme cases, improper administration of Edetate Disodium may lead to cardiac arrest. Two deaths have been reported in children administered Edetate Disodium, one of whom was a 5-year-old boy being treated for autism. The Committee is aware of other non-invasive and less toxic methods of chelation such as mud and clay wraps, but cannot comment on their effectiveness due to lack of research.

While there are no controlled trials of intravenous chelation using Edetate Disodium, the Committee feels there is enough documented risk of harm to recommend that this procedure should be avoided. The American Academy of Pediatrics has taken the position that children should never be administered Edetate Disodium for chelation therapy (Brown, et al., 2006).

**Intravenous Immunoglobulin | INSUFFICIENT EVIDENCE**

It has been suggested that the symptoms of ASD may be partially attributable to an irregular autoimmune reaction (Plioplys, 1998). Immunoglobulin, an immune-enhancing agent, has been administered intravenously to children with ASD to boost their immune response. There are no controlled trials of immunoglobulin therapy for ASD; therefore, conclusions on its efficacy are not possible at this time pending rigorous
research. As with any intravenous treatment, this is considered an invasive procedure and carries a risk of infection due to the donor antibodies present in immunoglobulin. There is no indication in the literature that administration of intravenous immunoglobulin has harmed children with ASD.

**Melatonin | INSUFFICIENT EVIDENCE**

Sleep problems are frequently reported in children with ASD with research indicating that sleep disturbance may be more common in this population than in typical children (Garstang & Wallis, 2006; Myers, et al., 2007). The cause of the sleep disturbance is highly individual and could be due to a number of factors such as stress, medical issues, or poor sleep habits. Melatonin is an over-the-counter hormone that is commonly administered to children with ASD to help them sleep (Garstang & Wallis, 2006). Two RCTs specific to Melatonin and ASD met review criteria (Garstang & Wallis, 2006; Wasdell, et al., 2008). Both were rated with weak research report strength and had inconclusive results. More research is needed to determine Melatonin’s efficacy in children with ASD.

**Secretin | STUDIED AND NO EVIDENCE OF EFFECT**

Secretin is a gastrointestinal hormone administered intravenously and thought to work through the hypothesized gut/brain connection in ASD. Research claiming that secretin improved ASD was based on anecdotal observations of improvement in three children who received secretin during routine medical care.

The Committee reviewed several studies that met criteria for inclusion, along with a Cochrane review (Williams, Wray, & Wheeler, 2005). The Cochrane review looked at 13 RCTs of secretin for children with ASD; none found any positive effect. No evidence of harm was detected in the studies (Ratliff-Schaub, Carey, Dahl Reeves, & Rogers, 2005; Sponheim, Offedal, & Helverschon, 2002). However, similar to immunoglobulin, caution and careful consideration and consultation with a health care provider is recommended prior to using any invasive procedure such as this.

The Cochrane Collaboration is one of the most well-respected research organizations for its meta-analyses and is very conservative in its views. The authors of the Cochrane review on secretin state the following reservations about secretin: “There is no evidence that single or multiple dose intravenous secretin is effective and as such it should not currently be recommended or administered as a treatment for autism. Further experimental assessment of secretin’s effectiveness for autism can only be justified if methodological problems of existing research can be overcome” (Williams, Wray, & Wheeler, 2005, p. 21). This statement speaks to the strong evidence of the ineffectiveness of secretin.

**Psychotherapy |**

**Cognitive-Behavioral Therapy for Anxiety | PROMISING EVIDENCE**

**Cognitive-Behavioral Therapy for Anger Management | PRELIMINARY EVIDENCE**

Children with ASD often suffer from anxiety and depression (Wood, et al., 2009). Youth with Asperger’s Syndrome are at particular risk of developing a concurrent mood disorder (American Psychiatric Association, 2000). These youth have great difficulty identifying and understanding the thoughts and
feelings of themselves and others which contributes to feelings of confusion and uncertainty (Sofronoff, Attwood, Hinton, & I., 2007). As a result, they often struggle with a sense of distress, anger, and anxiety. Youth with Asperger’s Syndrome and high-functioning autism tend to react quickly and without stopping to think reflexively when feeling angry or upset (Sofronoff, et al., 2007). Cognitive-Behavioral Therapy is a proven treatment method that helps people accurately perceive the emotions and thoughts of themselves and others. It also helps people develop the ability to modulate their actions and reactions in response to stress.

The studies of CBT in youth with ASD that met criteria for this review focused on anxiety and anger management. The Committee established two ratings, one for the treatment model for each target symptom since the treatment protocols would be expected to differ in content according to the focus of treatment. Several RCTs were reviewed by the Committee, all were focused on youth with high functioning autism and Asperger’s Syndrome. Most studies used manualized interventions that included family psychoeducation and were rated with strong research report strength.

It is important to keep in mind that the approaches to CBT described in these studies were modified for youth on the autism spectrum. Thus, the standard CBT treatment given to the typical population would not necessarily be consistent with these specialized models of CBT.

**Sensory Integration Therapy |**

**Auditory Integration Training** | **INSUFFICIENT EVIDENCE**

In addition to general sensory processing difficulties, children with ASD are hypothesized to have abnormal responses to auditory stimuli due to sensitivity or insensitivity to certain frequencies of sound (Berard, 1993). Auditory Integration Training (AIT) was developed as a method of retraining a child’s auditory pathways to tolerate these frequencies. However, the exact theory of why and how AIT works is yet to be confirmed. Despite this lack of clarity, AIT is frequently marketed to families with anecdotal reports of significant improvements in behavior (Mudford, et al., 2000). Children receiving AIT typically listen to 10 hours of digitally modified music over special headphones over twice per day half-hour sessions. A device filters out the high and low peak frequencies to which the child may be oversensitive (Dawson & Watling, 2000).

Five studies of AIT qualified for review. All were group studies, most with small samples of 9-10 children, but one study had a much larger sample of 80 children (Bettison, 1996). Most of the studies had significant methodological flaws, although two were rated with adequate research report strength. However, all of the studies but one found that AIT had no impact on autistic behavior. Bettison (1996) measured long-term outcomes following AIT for 12 months and found significant improvement in verbal and performance IQ scores; however, the methodology of the study makes its results highly questionable (Sinha, Silove, Wheeler, & Williams, 2004). High-quality controlled studies are needed to determine if there is indeed any merit to AIT’s claims.
Sensory Integration Therapy | **INSUFFICIENT EVIDENCE**

Sensory Integration Therapy (SIT) aims to improve the functional behavior of children with ASD by addressing sensory integration dysfunction, which is believed to be prevalent in people with ASD (Leong & Carter, 2008). It is thought that people with ASD have underlying impairments in sensory processing i.e., they have difficulty integrating the sensory input continuously received from the environment in the form of touch, movement, sounds, and sensation. The discomfort that results from the inability to manage an over- or under-stimulating environment is believed to inhibit the child’s ability to regulate his or her level of arousal (Baranek, 2002) thereby contributing to behavioral issues such as agitation and aggression.

SIT is delivered with the goal of improving the sensory processing pathways so that learning and functional ability can grow.

Sensory processing and motor pathways of children with ASD are not well understood. Most accounts of sensorimotor difficulties are by parent report or qualitative descriptive studies rather than standardized, objective measurement (Baranek, 2002). The few studies that address prevalence of sensory processing issues in children with ASD give estimates between 30-100% of children exhibit sensory challenges (Dawson & Watling, 2000). Furthermore, 15-100% of children with ASD have been estimated to have fine and gross motor impairments (Dawson & Watling, 2000).

Traditional SIT models are delivered in clinical settings by licensed, trained professionals, usually occupational therapists, although speech-language therapists often deliver auditory integration training. SIT provides manageable sensory input through three main channels: vestibular (movement); tactile (touch); and proprioceptive (the sense of one’s relative position of body parts in space). Vestibular interventions can include activities such as spinning or the use of a balance board. Tactile interventions include brushing of the skin and other deep-pressure touch. Weighted vests and blankets, as well as manual manipulation of joints, are examples of activities aimed at the proprioceptive system. Therapists work with the child to gradually develop an adaptive response to stimuli and the ability to regulate responses to the environment (Baranek, 2002). “Sensory diets,” a structured schedule of sensory activities the child engages in throughout the day, are also implemented for children with ASD.

Seven studies of SIT met criteria for review. These studies used a mix of methods such as application of deep pressure via a “hug machine” and weighted vests, massage, swinging, and brushing. All seven studies used weak research methodology according to the Committee’s evaluation criteria, and most found no significant improvement in functioning (J. Case-Smith & Bryan, 1999; Edelson, Edelson, Kerr, & Grandin, 1999; Fazlioglu & Baran, 2008; Kane, Luiselli, Dearborn, & Young, 2004-05; Linderman & Stewart, 1999; S. A. Smith, Press, Koenig, & Kinnealey, 2005; Watling & Dietz, 2007).

Based on the studies it reviewed, the Committee concludes there is no scientific evidence at this time that SIT has long-term impact on the core symptoms of ASD. These conclusions are consistent with recently published reviews (Baranek, 2002; Dawson & Watling, 2000; Leong & Carter, 2008). However, many parents and people with ASD report that sensory interventions have an immediate effect and enable their child to achieve better self-regulation. The results of this review should not negate the use of sensory interventions as immediate coping strategies by individuals who find them helpful since there is no apparent risk of harm.
**Touch Therapy / Massage | PRELIMINARY EVIDENCE**

A controlled group study by Field and colleagues found that children who received massage, or “touch therapy,” twice per week over four weeks improved significantly in attention to tasks, joint attention, self-regulation, and social behavior, and also manifested fewer stereotypical behaviors as compared to the control group (Field, et al., 1997). The study was rated as having adequate research report strength by the evaluation criteria. On the basis of this result, the Committee finds there is preliminary evidence supporting this method related to sensory processing. However, this result should be interpreted with caution. Replicating the intervention exactly as presented in the experiment may be difficult due some ambiguity in the operational description of the procedure regarding the amount of pressure applied.

**Social Skills Training | INSUFFICIENT EVIDENCE**

As one of the core deficits of ASD, social skills are a main target of treatment. Many forms of social skills treatment (or “training”) are available, including social skills groups, peer modeling, video modeling, and Social Stories™. Social skills programs for children with ASD should address skills such as reciprocating interaction, initiating socialization, minimizing stereotypical behavior or perseveration in social situations, and choosing the appropriate social skill/response in a given situation (Myers, et al., 2007). The programs currently in use vary widely in their desired outcomes and approach.

Trials of manualized interventions or standard curriculums for social skills training are lacking. In fact, RCTs do not appear to be published for any social skills training intervention. Several group experimental and single-subject studies specific to peer-mediated and other methods of social skills training were reviewed. Of these studies, at least two were rated as methodologically strong but showed mixed effects on various aspects of social skills. Although evidence may be developing to support this method, the clear lack of skills generalization and the use of different outcome measures across studies seriously inhibit the ability to interpret findings with validity at this time.

The Committee also reviewed four recent reviews and meta-analyses on social skills training (Bellini, Peters, Benner, & Hopf, 2007; Reynhout & Carter, 2006; S. Rogers, 2000; White, Keonig, & Scahill, 2007). On the basis of these reviews as well as reviews of the individual studies, the Committee concluded that social skills training is an insufficiently studied area with promise. The research indicates that the transfer of social skills from the treatment setting to natural environments such as school and home, is challenging. In the school setting, studies indicated that social skills training was more effective in natural environments rather than pulling out the child from the classroom for separate instruction. Social skills deficits are a significant and inherent challenge in children with ASD and the need for identification of effective treatments in this area continues to be great.

**Social Stories™ | INSUFFICIENT EVIDENCE**

Social Stories™ are four to six sentence narrative and/or visual tools designed to help high-functioning individuals with autism gain an accurate understanding of social situations (Thiemann & Goldstein, 2001). Social Stories™ describe probable social situations, possible reactions of others in that social situation, and directive statements of appropriate or desired social responses. Although Social Stories™ are commonly used with children with ASD, most of the literature consists of descriptive studies and case reports.
A methodologically weak single-subject design study by Thiemann and Goldstein (2001) showed limited improvement and generalization of skills.

Other Approaches

Hyperbaric Oxygen Treatment | PRELIMINARY EVIDENCE
Hyperbaric oxygen treatment involves providing 100 percent oxygen at greater than normal atmospheric pressure which is normally delivered in a sealed chamber. This treatment is thought to increase the concentration of oxygen in the bloodstream, thus reducing problems with irritability, stereotypy, hyperactivity, speech, and sensory awareness in people with ASD. An RCT by Rossignol and colleagues found that 30% of children who received hyperbaric oxygen treatment significantly improved immediately following treatment versus 7.7% in the comparison group (Rossignol, et al., 2009). However, the only significant improvement made by children receiving hyperbaric oxygen treatment was in sensory/cognitive awareness, and the researchers did not evaluate whether the effects persisted well after the treatment. Despite these concerns, this study is certainly worthy of replication.

TEACCH | INSUFFICIENT EVIDENCE
Treatment and Education of Autistic and Communication Handicapped Children (TEACCH) is a psychoeducational “structured teaching” model (Myers, et al., 2007; Odom, Boyd, Hall, & Hume, 2009). Structured teaching arranges the child’s environment to accommodate his or her challenges in order to maximize opportunities for learning (Myers, et al., 2007). Self-contained classrooms are often used with the classroom environment organized to accommodate and address the aspects of ASD. Structure is further accomplished by following a predictable schedule of events, using pictorial schedules, and implementing visually structured activities. Parents are key partners in TEACCH, working alongside the clinician and helping to set treatment goals.

Currently, there are no published outcome studies of TEACCH meeting this Committee’s criteria. A comparative study of TEACCH and the Lifeskills and Education for Students with Autism and other Pervasive Behavioral Challenges program (LEAP), is underway at the University of North Carolina.
CONCLUDING COMMENTS

Children and youth with ASD represent a rapidly growing population. The profound and variable expression of ASD in children requires a coordinated, thoughtful, and research-informed response by the system of care.

Based on our investigation of the research literature, the Committee has concluded the following:

- There are available, effective treatments for ASD that are supported by scientific research. Research is currently underway which may reveal further evidence-based treatments in the near future. Access to current research allows families, providers, and policymakers to make informed decisions.
- Research is seriously lacking specific to outcomes in academic curriculum areas, such as science and math. This is of deep concern since children receive a great deal of instruction and services through the educational system.
- Substantial investment in quality research is needed to further define effective treatments for ASD.
- Research is needed that directly compares the efficacy of various treatment models.
- There is a dearth of research on treatment with older youth, adolescents, and adults with ASD. This is worrisome given the large increase in the number of adults with ASD that can be expected during the coming years as children with ASD mature.
- Families should be informed consumers of treatment and ask questions of providers about the nature and quality of the research behind the treatment their child is receiving.
- Providers need to make treatment decisions in active partnership with families while integrating relevant research into their practice and treatment planning process.
- Resources are needed to build capacity throughout Maine in order to efficiently and effectively deliver evidence-based treatments to children in their schools, homes, and communities. This requires resources for training, evaluation, and workforce development. For example, ABA has some of the best evidence for treatment in ASD yet Maine has only 26 certified ABA practitioners, most located in the southern counties.

Evidence-based practice does not seek to dictate the interventions that should be used at the expense of others. Rather, it is a framework to integrate what is known from research into real-world practice in a manner that is accessible to families, responsive to what children need, and consistent with what providers can accomplish given available skills and resources. The first step toward evidence-based practice is creating awareness of what the best available research says. It is no longer enough to use what we believe works, we must consider what we know works in order to close the gap between science and practice, utilize limited resources wisely, and best serve Maine’s children with ASD.
### Table 3: Group Research Primary Quality Indicators

<table>
<thead>
<tr>
<th>Quality Indicator</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary Indicator</strong></td>
<td></td>
</tr>
<tr>
<td>Participant characteristics</td>
<td>Age, gender, and specific diagnostic information provided for all participants. Standardized test/assessment scores provided as applicable. Information on the characteristics of the person providing the intervention was provided.</td>
</tr>
<tr>
<td>Independent variable (the intervention)</td>
<td>Information about the treatment was provided with replicable precision.</td>
</tr>
<tr>
<td>Comparison condition (control group)</td>
<td>The conditions for the comparison group were defined with replicable precision. This includes, at minimum, a description of any other interventions the control group received during the course of the study.</td>
</tr>
<tr>
<td>Link between research question and data analysis</td>
<td>Data analyses (statistics) were strongly linked to the research question(s) and used correct units of measurement.</td>
</tr>
<tr>
<td>Use of statistical tests</td>
<td>Proper statistical analyses were conducted for each measure with adequate power and sample size greater than 10 subjects. This is rated as ‘high’ if the study is published in a peer-reviewed journal and ‘unacceptable’ if no statistical analysis was provided.</td>
</tr>
<tr>
<td><strong>Secondary Indicator</strong></td>
<td></td>
</tr>
<tr>
<td>Random assignment</td>
<td>Participants were randomly assigned to experimental and comparison groups.</td>
</tr>
<tr>
<td>Interobserver agreement</td>
<td>Interobserver agreement measures were collected across all conditions, raters, and participants with inter-rater agreement at or above .60.</td>
</tr>
<tr>
<td>Blind raters</td>
<td>Fidelity to the procedures of the intervention was continually assessed across participants, conditions, and treatment providers.</td>
</tr>
<tr>
<td>Attrition</td>
<td>Attrition (dropout) from the study did not differ between treatment and control groups by more than 25% across conditions and less than 30% at the final outcome measure.</td>
</tr>
<tr>
<td>Generalization / Treatment maintenance</td>
<td>Outcome measures were collected after the final data collection to assess treatment generalization and/or maintenance of treatment effects.</td>
</tr>
<tr>
<td>Social validity</td>
<td>The outcomes of the study are socially important; the intervention was time and cost effective; the change brought about by the intervention was clinically significant; children/parents were satisfied with the results; people in regular contact with the child provided the treatment (e.g. school personnel), and/or the study tool place in a natural setting.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Quality Indicator</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary Indicator</strong></td>
<td></td>
</tr>
<tr>
<td>Participant characteristics</td>
<td>Age, gender, and specific diagnostic information provided for all participants. Standardized test/assessment scores provided as applicable. Information on the characteristics of the person providing the intervention was provided.</td>
</tr>
<tr>
<td>Independent variable (the intervention)</td>
<td>Information about the treatment was provided with replicable precision.</td>
</tr>
<tr>
<td>Dependent variable (the outcome)</td>
<td>Dependent measures were described with operational and replicable precision, showed a clear link to the treatment outcome, and were collected at appropriate times.</td>
</tr>
<tr>
<td>Baseline condition</td>
<td>All baselines (a) encompassed at least three measurement points, (b) appeared through visual analysis to be stable, (c) had no trend or counter therapeutic trend, and (d) were operationally defined with replicable precision.</td>
</tr>
<tr>
<td>Visual analysis</td>
<td>All relevant data for each participant was graphed. Inspection of the graphs revealed (a) all data appeared to be stable (level and/or trend), (b) contained less than 25% overlap of data points between adjacent conditions, unless behavior was at ceiling or floor levels in previous condition, and (c) showed a large shift in level or trend between adjacent conditions which coincided with implementation or removal of the independent variable.</td>
</tr>
<tr>
<td>Experimental control</td>
<td>There were (a) at least three demonstrations of experimental effect, (b) at three different points in time, and (c) changes in the dependent variables co-varied with the manipulation of the independent variable in all instances of replication.</td>
</tr>
<tr>
<td><strong>Secondary Indicator</strong></td>
<td></td>
</tr>
<tr>
<td>Interobserver agreement</td>
<td>Interobserver agreement measures were collected on at least 20% of sessions across all conditions, raters, and participants with inter-rater agreement at or above .80.</td>
</tr>
<tr>
<td>Kappa</td>
<td>Kappa statistic was collected on at least 20% of sessions across all conditions, raters and participants with a score greater or equal to .60.</td>
</tr>
<tr>
<td>Fidelity</td>
<td>Procedural fidelity was continuously assessed across participants, conditions, and interventionists with reliability of at least .80.</td>
</tr>
<tr>
<td>Blind raters</td>
<td>Raters were blind to the treatment condition of the participants.</td>
</tr>
<tr>
<td>Social validity</td>
<td>The outcomes of the study are socially important, the intervention was time and cost effective; the change brought about by the intervention was clinically significant; children/parents were satisfied with the results; people in regular contact with the child provided the treatment (e.g. school personnel); and/or the study tool place in a natural setting.</td>
</tr>
</tbody>
</table>

Table 5: Levels of Evidence

<table>
<thead>
<tr>
<th>Level</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Established Evidence</td>
<td>5 or more single-subject studies of strong research report strength that meet the following criteria: (1) conducted by at least 3 different research teams, (2) conducted in at least 3 different locations, and (3) had a total sample size of at least 15 different participants across studies.</td>
</tr>
<tr>
<td></td>
<td>10 or more single-subject studies of at least adequate research report strength that meet the following criteria: (1) conducted by at least 3 different research teams, (2) conducted in at least 3 different locations, and (3) had a total sample size of at least 30 different participants across studies.</td>
</tr>
<tr>
<td></td>
<td>2 or more group experimental design studies of strong research report strength conducted in separate settings by separate research teams.</td>
</tr>
<tr>
<td></td>
<td>4 or more group experimental design studies of adequate research report strength conducted in at least two separate settings by separate research teams.</td>
</tr>
<tr>
<td></td>
<td>1 group experimental design study of strong research report strength and 3 single-subject studies of strong research report strength.</td>
</tr>
<tr>
<td></td>
<td>2 group experimental design studies of at least adequate research report strength and 3 single-subject studies of strong research report strength.</td>
</tr>
<tr>
<td></td>
<td>1 group experimental design study of strong research report strength and 6 single-subject studies of at least adequate research report strength.</td>
</tr>
<tr>
<td></td>
<td>2 group experimental design studies of at least adequate research report strength and 6 single-subject studies of at least adequate research report strength.</td>
</tr>
<tr>
<td>Promising Evidence</td>
<td>2 or more group experimental design studies of at least adequate research report strength. Studies may be conducted by the same research team in the same or similar settings.</td>
</tr>
<tr>
<td></td>
<td>3 or more single-subject studies of at least adequate research report strength that meet the following criteria: (1) conducted by at least 2 different research teams, (2) conducted in at least 2 different locations, and (3) total sample size of at least 9 different participants across studies.</td>
</tr>
<tr>
<td>Preliminary Evidence</td>
<td>1 group experimental design or single-subject design study or strong or adequate research report strength that shows positive effect on the desired outcomes.</td>
</tr>
<tr>
<td>Studied and No Evidence of Effect</td>
<td>Numerous studies (more than three) of strong or adequate methodological rigor indicate no positive effect on the desired outcomes.</td>
</tr>
<tr>
<td>Insufficient evidence</td>
<td>An insufficient number of studies of acceptable methodological rigor exist and/or several studies of strong or adequate research report strength indicate mixed results such that a conclusion on the efficacy of the intervention cannot be determined.</td>
</tr>
<tr>
<td>Harm</td>
<td>Studies or published case reports indicate significant harm or risk of harm, including injury and death.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Category</th>
<th>Intervention</th>
<th>Studies</th>
<th>Research Report Strength Rating</th>
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</thead>
<tbody>
<tr>
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<td></td>
<td><em>Research in Developmental Disabilities, 23, 319-331.</em></td>
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<tr>
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<tr>
<td></td>
<td>Reichle, J. et al. (2005). Teaching an individual with severe intellectual delay to request assistance conditionally. Educational Psychology, 25(2-3), 275-286.</td>
<td>Weak</td>
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<tr>
<td>Category</td>
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<td>Studies</td>
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<td></td>
<td>通风s, 3(4), 194-198.</td>
<td></td>
<td>Strong</td>
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<tr>
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</table>

*Disorders, 37, 1505-1513.*


_Adequate*


_Adequate*


_Weak*


_Weak*
<table>
<thead>
<tr>
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<td></td>
<td>Intravenous</td>
<td>N/A: No controlled trials</td>
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</tr>
<tr>
<td>Category</td>
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<tr>
<td>Chelation</td>
<td>Intravenous Immunoglobin</td>
<td>N/A: No controlled trials</td>
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<tr>
<td>Category</td>
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<td>Studies</td>
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<tr>
<td></td>
<td></td>
<td><strong>Kamps, D., Royer, J., Dugan, E., Kravits, T., Gonzalez-Lopez, A., Garcia, J., et al. (2002).</strong> Peer training to facilitate social interaction for elementary students with autism and their peers.</td>
<td>Weak</td>
</tr>
<tr>
<td>Category</td>
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</table>
Maine Children’s Services Evidence-Based Practice Advisory Committee: Autism-PDD Project

**Literature Review Worksheet: Determination of Research Report Strength**

Derived from *The Evaluative Method to Determine Evidence-Based Practices in Autism* (Reichow, Volkmar, & Cicchetti, 2008) (Reprinted with Permission)

**Article citation:**

Is this study: □ Group research □ Single-subject Research

Based on the review of the study using the following criteria, is the methodology of this study: □ Strong □ Adequate □ Weak

Comments:

<table>
<thead>
<tr>
<th>Strength Rating</th>
<th>Group Research</th>
<th>Single-subject Research</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strong</td>
<td>Received high quality ratings on:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• All primary quality indicators</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Four or more secondary quality indicators</td>
<td></td>
</tr>
<tr>
<td>Adequate</td>
<td>Received high quality ratings on four or more primary quality indicators</td>
<td></td>
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<tr>
<td></td>
<td>No unacceptable quality ratings on any primary quality indicators.</td>
<td></td>
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<tr>
<td></td>
<td>Showed evidence of two or more secondary quality indicators.</td>
<td></td>
</tr>
<tr>
<td>Weak</td>
<td>Received fewer than four high quality ratings on primary quality indicators or Showed evidence of less than two secondary quality indicators.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Received fewer than four high quality ratings on primary quality indicators or showed evidence of less than two secondary quality indicators.</td>
<td></td>
</tr>
<tr>
<td>Primary Quality Indicator</td>
<td>Quality Rating</td>
<td>Comments</td>
</tr>
<tr>
<td>------------------------------------------------------------------------------------------</td>
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<td>----------</td>
</tr>
<tr>
<td><strong>1. Participant Characteristics:</strong> Age and gender were provided for all participants, specific diagnostic information was provided for all participants with autism, standardized test scores were provided as applicable, and information on the characteristics of the interventionist was provided.</td>
<td>□ High</td>
<td></td>
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<tr>
<td>□ Acceptable</td>
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</tr>
<tr>
<td>□ Unacceptable</td>
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<tr>
<td><strong>2. Independent Variable (Intervention):</strong> Information about the treatment was provided with replicable precision. <em>If a manual was used, this is always given a high quality rating.</em></td>
<td>□ High</td>
<td></td>
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<tr>
<td>□ Acceptable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Unacceptable</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>3. Comparison Condition (Control group):</strong> The conditions for the comparison group were defined with replicable precision, including, at a minimum, a description of any other interventions participants received.</td>
<td>□ High</td>
<td></td>
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<tr>
<td>□ Acceptable</td>
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<td></td>
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<tr>
<td>□ Unacceptable</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>4. Dependent Variable (Outcome):</strong> Dependent measures were described with operational and replicable precision, showed a clear link to the treatment outcome, and were collected at appropriate times.</td>
<td>□ High</td>
<td></td>
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<tr>
<td>□ Acceptable</td>
<td></td>
<td></td>
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<tr>
<td>□ Unacceptable</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>5. Link between research question &amp; data analysis:</strong> Data analyses were strongly linked to the research question(s) and the data analysis used correct units of measure on all variables.</td>
<td>□ High</td>
<td></td>
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<tr>
<td>□ Acceptable</td>
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<tr>
<td>□ Unacceptable</td>
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<tr>
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</tr>
<tr>
<td><strong>6. Use of statistical tests:</strong> Proper statistical analyses were conducted for each measure with an adequate power and a sample size of ( n \geq 10 ). Please rate as High if the study was published in a peer-reviewed journal. Please rate as Unacceptable if no statistics were provided in the article.</td>
<td>☐ High</td>
<td>☐ Unacceptable</td>
</tr>
</tbody>
</table>

**Number of Primary Quality Indicators Rated:**

- High:  
- Medium / Acceptable:  
- Low / Unacceptable:

See Page 1 of worksheet for corresponding report strength rating scale

<table>
<thead>
<tr>
<th>Secondary Quality Indicator</th>
<th>Present?</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. Random Assignment:</strong> Participants were assigned to groups using a random assignment procedure.</td>
<td>☐ Yes</td>
<td>☐ No</td>
</tr>
<tr>
<td><strong>2. Interobserver agreement:</strong> Interobserver agreement measures were collected across all conditions, raters, and participants with inter-rater agreement at or above .80, and a minimum of .60. Psychometric properties of standardized tests were reported and were ( k = &gt; .40 -.70 ).</td>
<td>☐ Yes</td>
<td>☐ No</td>
</tr>
<tr>
<td><strong>3. Blind raters:</strong> Raters were blind to the participant’s treatment condition.</td>
<td>☐ Yes</td>
<td>☐ No</td>
</tr>
<tr>
<td><strong>4. Fidelity:</strong> Procedural fidelity (treatment fidelity) was continuously assessed across participants, conditions, and implementers, and if applicable, had measurement statistics ( &gt; .80 ).</td>
<td>☐ Yes</td>
<td>☐ No</td>
</tr>
<tr>
<td><strong>5. Attrition:</strong> Attrition (dropout rate) was comparable, meaning it did not differ between groups by more than 25% across conditions and less than 30% at the final outcome</td>
<td>☐ Yes</td>
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<tr>
<td>Secondary Quality Indicator</td>
<td>Present?</td>
<td>Comments</td>
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<td>-----------------------------------------------------------------</td>
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<tr>
<td>measure.</td>
<td>□ No</td>
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<tr>
<td>6. <strong>Generalization / Treatment maintenance:</strong> Outcome measures were collected after the final data collection to assess generalization and/or maintenance.</td>
<td>□ Yes</td>
<td>□ No</td>
</tr>
<tr>
<td>7. <strong>Effect size:</strong> Effect sizes were reported for at least 75% of the outcome measures and were equal or greater than .40.</td>
<td>□ Yes</td>
<td>□ No</td>
</tr>
<tr>
<td>8. <strong>Social Validity:</strong></td>
<td>Please indicate if the study includes the following:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Four or more are needed to show evidence of social validity.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>□ The dependent variables were socially important (i.e. society would value the changes in the study’s outcomes)</td>
<td></td>
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<tr>
<td></td>
<td>□ The intervention was time and cost effective (i.e. the ends justified the means)</td>
<td></td>
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<tr>
<td></td>
<td>□ The study makes comparisons between persons with and without disabilities</td>
<td></td>
</tr>
<tr>
<td></td>
<td>□ The behavioral change brought about by the treatment (if any) was large enough for practical value (i.e. it was clinically significant)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>□ Consumers and/or parents were satisfied with the results</td>
<td></td>
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<tr>
<td></td>
<td>□ People in regular contact with the participant provided the treatment (e.g. clinic or school staff)</td>
<td></td>
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<tr>
<td></td>
<td>□ The study took place in a natural setting (e.g. community, school, outpatient clinic)</td>
<td></td>
</tr>
<tr>
<td><strong>Does the study contain at least 4 of the above?</strong></td>
<td>□ Yes</td>
<td>□ No</td>
</tr>
<tr>
<td><strong>Comments:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Number of Secondary Quality Indicators (checked ‘Yes’):</strong></td>
<td></td>
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</tr>
</tbody>
</table>
# Single-subject Research

<table>
<thead>
<tr>
<th>Primary Quality Indicator</th>
<th>Quality Rating</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. Participant Characteristics:</strong> Age and gender were provided for all participants, specific diagnostic information was provided for all participants with autism, standardized test scores were provided as applicable, and information on the characteristics of the interventionist/researcher was provided.</td>
<td>□ High&lt;br&gt; □ Acceptable&lt;br&gt; □ Unacceptable</td>
<td></td>
</tr>
<tr>
<td><strong>2. Independent Variable (Intervention):</strong> Information about the treatment was provided with replicable precision. <em>If a manual was used, this is always given a high quality rating.</em></td>
<td>□ High&lt;br&gt; □ Acceptable&lt;br&gt; □ Unacceptable</td>
<td></td>
</tr>
<tr>
<td><strong>3. Dependent Variable (Outcome):</strong> Dependent measures were described with operational and replicable precision, showed a clear link to the treatment outcome, and were collected at appropriate times.</td>
<td>□ High&lt;br&gt; □ Acceptable&lt;br&gt; □ Unacceptable</td>
<td></td>
</tr>
<tr>
<td><strong>4. Baseline Condition:</strong> All baselines (a) encompassed at least three measurement points, (b) appeared through visual analysis to be stable, (c) had no trend or a counter therapeutic trend, and (d) were operationally defined with replicable precision.</td>
<td>□ High&lt;br&gt; □ Acceptable&lt;br&gt; □ Unacceptable</td>
<td></td>
</tr>
<tr>
<td><strong>5. Visual analysis:</strong> All relevant data for each participant was graphed. Inspection of the graphs revealed (a) all data appeared to be stable (level and/or trend), (b) contained less than 25% overlap of data points between adjacent conditions, unless behavior was at</td>
<td>□ High&lt;br&gt; □ Acceptable&lt;br&gt; □ Unacceptable</td>
<td></td>
</tr>
</tbody>
</table>
Primary Quality Indicator | Quality Rating | Comments
--- | --- | ---
ceiling or floor levels in previous condition, and (c) showed a large shift in level or trend between adjacent conditions which coincided with implementation or removal of the independent variable*.

6. **Experimental control:** There were (a) at least three demonstrations of the experimental effect, (b) at three different points in time, and (c) changes in the dependent variables covaried with the manipulation of the independent variable in all instances of replication*.

Number of Primary Quality Indicators Rated:

<table>
<thead>
<tr>
<th>High:</th>
<th>Medium / Acceptable:</th>
<th>Low / Unacceptable:</th>
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* Note: If there was a delay in change at the manipulation of the independent variable, the delay was similar across different conditions or participants (±50% of delay).

Secondary Quality Indicator: | Present? | Comments
--- | --- | ---
1. **Interobserver agreement:** Interobserver agreement was collected on at least 20% of sessions across all conditions, raters, and participants with inter-rater agreement at or above .80.

2. **Kappa:** Kappa was collected on at least 20% of sessions across all conditions, raters, and participants with a score ≥ .60 (good reliability).

3. **Fidelity:** Procedural fidelity and/or treatment fidelity was continuously assessed across participants.

* See Page 1 of worksheet for corresponding report strength rating scale
pants, conditions, and implementers with reliability > .80

<table>
<thead>
<tr>
<th>4. <strong>Blind raters:</strong> Raters were blind to the treatment condition of the participants.</th>
<th>□ Yes □ No</th>
</tr>
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<tbody>
<tr>
<td>5. <strong>Generalization / Treatment maintenance:</strong> Outcome measures were collected after the conclusion of the intervention to assess generalization and/or maintenance.</td>
<td>□ Yes □ No</td>
</tr>
</tbody>
</table>
| 6. **Social Validity:** | **Please indicate if the study includes the following in your estimation:**

*Four or more are needed to show evidence of social validity*

- □ The dependent variables were socially important (i.e. society would value the changes in the study’s outcomes)
- □ The intervention was time and cost effective (i.e. the ends justified the means)
- □ The study makes comparisons between persons with and without disabilities
- □ The behavioral change brought about by the treatment (if any) was large enough for practical value (i.e. it was clinically significant)
- □ Consumers and/or parents were satisfied with the results
- □ People in regular contact with the participant manipulated the independent variables
- □ The study took place in a natural setting (e.g. community, school, outpatient clinic)

**Does this study contain at least 4 of the above?** □ Yes □ No

**Comments:**
REFERENCES


---


ii A complete list of search terms is available upon request to the author.