

## Treatment Intervention Advisory Committee Review and Determination

**Date:** July 31, 2015

**To:** DHS/DLTC

**From:** Wisconsin Department of Health Services, Treatment Intervention Advisory Committee: Lana Collet-Klingenberg, Ph.D. (chairperson) LCK

**RE:** Determination of Early Start Denver Model (ESDM) as a proven and effective treatment for individuals with autism spectrum disorder and/or other developmental disabilities

This is an initial review

This is a re-review. The initial review was February 8, 2013

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### Section One: Overview and Determination

Please find below a statement of our determination as to whether or not the committee views Early Start Denver Model (ESDM) as a proven and effective treatment for children with autism spectrum disorder and/or other developmental disabilities. In subsequent sections you will find documentation of our review process including a description of the proposed treatment, a synopsis of review findings, the treatment review evidence checklist, and a listing of the literature considered. In reviewing treatments presented to us by DHS/DLTC, we implement a review process that carefully and fully considers all available information regarding a proposed treatment. Our determination is limited to a statement regarding how established a practice is in regard to quality research. We do not make funding decisions.

#### Description of proposed treatment

The Early Start Denver Model is a comprehensive early intervention program for toddlers and pre-school-aged children, ages 12-48 months, with Autism Spectrum Disorder (ASD). ESDM was developed in 2003, by Sally Rogers and Geri Dawson, as an early-age extension of the Denver Model. ESDM utilizes developmental, relationship-based, and behavioral approaches (i.e., applied behavior analysis) during play-based interactions to increase communication, imitation, sharing, joint attention, and play. The key characteristics of ESDM include the following:

- Naturalistic applied behavioral analytic strategies
- Sensitive to normal developmental sequence
- Deep parental involvement
- Focus on interpersonal exchange and positive affect
- Shared engagement with joint activities
- Language and communication taught inside a positive, affect-based relationship

ESDM is usually provided in various natural settings such as the home or the daycare/preschool by an ESDM therapist. An ESDM therapist is trained and certified in ESDM and may be a qualified health professional such as a psychologist, behavior analyst, occupational therapist, speech and language pathologist, early intervention specialist or developmental pediatrician.

### Synopsis of review

In the case of ESDM , please refer to the attached reference listing that details the reviewed research. The committee's conclusions regarding ESDM include that there have not been any, peer-reviewed, experimental studies from authors other than those who created ESDM.

A literature search was conducted for years 2013 through 2015 in order to find updates on empirical evidence on the ESDM published since the last review. There have been two, peer-reviewed, experimental studies since the last review of the ESDM.

The previous review found the efficacy of ESDM was studied in a NIH-funded, randomized controlled trial (Dawson, 2010) showing that children who received ESDM therapy for 20 hours a week (15 hours by trained therapists, 5 hours by parents) over two years demonstrated improvement in cognitive skills, language skills, and adaptive behavior along with fewer autism symptoms than children referred for interventions not involving ESDM.

There have been two peer-reviewed studies since the last review of ESDM. One study (Vivanti et al, 2014) examined whether delivering ESDM in a group day care setting would be feasible and effective. In Australia, 27 preschoolers with ASD received from 15 to 25 hours of ESDM per week for a year in a group setting. Their results were compared with a similar group of children with ASD who received a combined educational and therapy program at another day care center. At the end of a year, improvement in adaptive, cognitive, and social skills were seen in both groups. Greater gains in receptive language and developmental rate were made by children in the ESDM group (Vivanti et al, 2014).

Another study (Vivanti, 2013) investigated learning profiles associated with response to the Early Start Denver Model delivered in a group setting. Preliminary results from 21 preschool children with ASD aged 2 to 5 years suggest that the children with more advanced skills in functional use of objects, goal understanding and imitation made the best developmental gains after 1 year of treatment. Cognitive abilities, social attention, intensity of the treatment and chronological age were not associated with treatment gains (Vivanti, 2013).

In sum, it is the decision of the committee that the Early Start Denver Model, based on a lack of research conducted by those other than the model's creators to examine the efficacy of ESDM for children with ASD, remain at a rating of Level 2 - Established or Moderate Evidence.

## Section Two: Rationale for Focus on Research Specific to Comprehensive Treatment Packages (CTP) or Models

In the professional literature, there are two classifications of interventions for individuals with Autism Spectrum Disorder (National Research Council, 2001; Odom et al., 2003; Rogers & Vismara, 2008):

- (a) **Focused intervention techniques** are individual practices or strategies (such as positive reinforcement) designed to produce a specific behavioral or developmental outcome, and
- (b) **Comprehensive treatment models** are “packages” or programs that consist of a set of practices or multiple techniques designed to achieve a broader learning or developmental impact.

To determine whether a treatment package is proven and effective, the Treatment Intervention Advisory Committee (TIAC) will adopt the following perspective as recommended by Odom et al. (2010):

The individual, focused intervention techniques that make up a comprehensive treatment model may be evidence-based. The research supporting the effectiveness of separate, individual components, however, does *not* constitute an evaluation of the comprehensive treatment model or “package.” The TIAC will consider and review only research that has evaluated the efficacy of implementing the comprehensive treatment *as a package*. Such packages are most often identifiable in the literature by a consistently used name or label.

National Research Council. (2001). *Educating children with autism*. Washington, DC: National Academy Press.

Odom, S. L., Brown, W. H., Frey, T., Karusu, N., Smith-Carter, L., & Strain, P. (2003) Evidence-based practices for young children with autism: Evidence from single-subject research design. *Focus on Autism and Other Developmental Disabilities, 18*, 176-181.

Odom, S. L., Boyd, B. A., Hall, L. J., & Hume, K. (2010). Evaluation of comprehensive treatment models for individuals with Autism Spectrum Disorders. *Journal of Autism and Developmental Disorders, 40*, 425-436.

Rogers, S., & Vismara, L. (2008). Evidence-based comprehensive treatments for early autism. *Journal of Clinical Child and Adolescent Psychology, 37*, 8-38.

### Section Three: DLTC-TIAC Treatment Review Evidence Checklist

Name of Treatment: Early Start Denver Model

#### Level 1- Well Established or Strong Evidence (DHS 107 - Proven & Effective Treatment)

- Other authoritative bodies that have conducted extensive literature reviews of related treatments (e.g., National Standards Project, National Professional Development Center) have approved of or rated the treatment package as having a strong evidence base; authorities are in agreement about the level of evidence.
- There exist ample high quality studies that demonstrate experimental control and favorable outcomes of treatment package.
  - Minimum of two group studies or five single subject studies or a combination of the two.
  - Studies were conducted across at least two independent research groups.
  - Studies were published in peer reviewed journals.
- There is a published procedures manual for the treatment, or treatment implementation is clearly defined (i.e., replicable) within the studies.
- Participants (i.e., N) are clearly identified as individuals with autism spectrum disorders or developmental disabilities.

*Notes:* At this level, include ages of participants and disabilities identified in body of research

#### Level 2 – Established or Moderate Evidence (DHS 107 - Proven & Effective Treatment)

- Other authoritative bodies that have conducted extensive literature reviews of related treatments (e.g., National Standards Project, NPDC) have approved of or rated the treatment package as having at least a minimal evidence base; authorities may not be in agreement about the level of evidence.
- There exist at least two high quality studies that demonstrate experimental control and favorable outcomes of treatment package.
  - Minimum of one group study or two single subject studies or a combination of the two.
  - Studies were conducted by someone other than the creator/provider of the treatment.
  - Studies were published in peer reviewed journals.
- Participants (i.e., N) are clearly identified as individuals with autism spectrum disorders or developmental disabilities.

*Notes:* Participants ranged in age from 10 months to 65 months (18-60 months for recent literature review) with diagnoses on the ASD spectrum

Level 3 – Emerging Evidence (DHS 107 – Promising as a Proven & Effective Treatment)

- Other authoritative bodies that have conducted extensive literature reviews of related treatments (e.g., National Standards Project, NPDC) have recognized the treatment package as having an emerging evidence base; authorities may not be in agreement about the level of evidence.
- There exists at least one high quality study that demonstrates experimental control and favorable outcomes of treatment package.
  - May be one group study or single subject study.
  - Study was conducted by someone other than the creator/provider of the treatment.
  - Study was published in peer reviewed journal.
- Participants (i.e., N) are clearly identified as individuals with autism spectrum disorders or developmental disabilities.

*Notes:*

Level 4 – Insufficient Evidence (Experimental Treatment)

- Other authoritative bodies that have conducted extensive literature reviews of related treatments (e.g., National Standards Project, NPDC) have not recognized the treatment package as having an emerging evidence base; authorities are in agreement about the level of evidence.
- There is not at least one high quality study that demonstrates experimental control and favorable outcomes of treatment package.
  - Study was conducted by the creator/provider of the treatment.
  - Study was not published in a peer reviewed journal.
- Participants (i.e., N) are not clearly identified as individuals with autism spectrum disorders or developmental disabilities.

*Notes:*

Level 5 – Untested (Experimental Treatment) &/or Potentially Harmful

- Other authoritative bodies that have conducted extensive literature reviews of related treatments (e.g., National Standards Project, NPDC) have not recognized the treatment package as having an emerging evidence base; authorities are in agreement about the level of evidence.
- There are no published studies supporting the proposed treatment package.
- There exists evidence that the treatment package is potentially harmful.**
  - Authoritative bodies have expressed concern regarding safety/outcomes.
  - Professional bodies (i.e., organizations or certifying bodies) have created statements regarding safety/outcomes.

*Notes:* At this level, please specify if the treatment is reported to be potentially harmful, providing documentation

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Date: July 31, 2015

Committee Members Completing Initial Review of Research Base: Brooke Winchell, Lana Collet-Klingenberg

Committee Decision on Level of Evidence to Suggest the Proposed Treatment is Proven and Effective: Level 2- Established or Moderate Evidence.

**References Supporting Identification of Evidence Levels:**

- Chambless, D.L., Hollon, S.D. (1998). Defining empirically supported therapies. *Journal of Consulting and Clinical Psychology*, 66(1) 7-18.
- Chorpita, B.F. (2003). The frontier of evidence---based practice. In A.E. Kazdin & J.R. Weisz (Eds.). *Evidence-based psychotherapies for children and adolescents* (pp. 42---59). New York: The Guilford Press.
- Odom, S. L., Collet-Klingenberg, L., Rogers, S. J., & Hatton, D. (2010). Evidence-based practices in interventions for children and youth with autism spectrum disorders. *Preventing School Failure*, 54(4), 275-282.

#### **Section Four: Literature Review**

Dawson, G., Rogers, S.J., Munson, J., Smith, M., Winter, J., Greenson, J., Donaldson, A., & Varley, J. (2010). Randomized, controlled trial of an intervention for toddlers with autism: The Early Start Denver Model. *Pediatrics*, *125*, e17-e23

Vismara, L.A., Young, G.S., & Rogers, S.J. (2011). Community dissemination of the Early Start Denver Model: Implications for science and practice. *Topics in Early Childhood Special Education*. doi: 10.1177/02711214114092

Vivanti G, Dissanayake C, Zierhut C, Rogers SJ, Victorian ASELCC Team.(2013). Brief report: predictors of outcomes in the Early Start Denver Model delivered in a group setting. *Journal of Autism and Developmental Disorders*, *43*(7):1717–24.

Vivanti, G., Paynter, J., Duncan, E., Fothergill, H., Dissanayake, C., Roger, S.J, & the Victorian ASELCC Team.(2014). Effectiveness and Feasibility of the Early Start Denver Model Implemented in a Group-Based Community Childcare Setting. *Journal of Autism and Developmental Disorders*. DOI: 10.1007/s10803-014-2168-9