



**Health Evidence Review
Commission's
Evidence-based Guideline
Subcommittee**

**November 7, 2013
2:00 PM**

**Meridian Park Hospital
Community Health Education Center, Room 117B & C
19300 SW 65th Avenue, Tualatin, OR 97062**

Section 1.0

Call to Order

AGENDA

EVIDENCE-BASED GUIDELINES SUBCOMMITTEE (EbGS)

November 7, 2013

2:00pm - 5:00pm

Meridian Park Hospital

Community Health Education Center Room 117B&C

19300 SW 65th Avenue, Tualatin, OR 97062

(All agenda items are subject to change and times listed are approximate)

#	Time	Item	Presenter
1	2:00 PM	Call to Order	Wiley Chan
2	2:05 PM	Review of August minutes	Wiley Chan
3	2:10 PM	Staff Report <ul style="list-style-type: none">Report on VBBS/HERC action on Coverage Guidances	Cat Livingston
4	2:15 PM	Evidence Evaluation of Applied Behavior Analysis (ABA)	
4.1	2:15 PM	Remarks by Ad Hoc Experts <ul style="list-style-type: none">Eric Larsson, PhD, LP, BCBA-DKatharine Zuckerman, MD, MPH, FAAPEric Fombonne, MD (written)	Ad Hoc Experts
4.2	2:35 PM	Discussion of Questions on ABA Identified by Subcommittee	Wiley Chan
4.3	3:45 PM	Public Testimony	
4.4	4:00 PM	Discussion on Evidence Evaluation of ABA for Release for 30-Day Written Comment Period	Wiley Chan
5	4:50 PM	Other business <ul style="list-style-type: none">Confirmation of next meetingNext meeting topics	Cat Livingston
6	5:00 PM	Adjournment	Wiley Chan

MINUTES

Evidence-based Guidelines Subcommittee

Meridian Park Hospital
Community Health Education Center, Room 117 B&C
19300 SW 65th Avenue, Tualatin, OR 97062
September 12, 2013
2:00pm - 5:00pm

Members Present: Wiley Chan, MD, Chair; Steve Marks, MD, Vice-Chair; Vern Saboe, DC (by phone); Beth Westbrook, PsyD; John Sattenspiel, MD; Leda Garside, RN; Som Saha, MD, MPH; Bob Joondeph, JD; Eric Stecker, MD.

Members Absent: None

Staff Present: Darren Coffman; Paige Hatcher, MD, MPH; Jason Gingerich.

Also Attending: Rachel Seltzer (OHSU), Heather Dorsey (Legacy), Tom Jenkins (Legacy), Karen Kovak (OHSU), Alison Little, MD, Shannon Vandegriff and Aasta Thielke (CeBP), Chris Gray (Lund Report), Brenna Legaard (Advocate), Denise Taray (DMAP), Jenny Fischer (ORABA), Eric Fombonne (OHSU), Duncan Neilson (Legacy), Shane Jackson (Autism Society of Oregon), Geri Auerbach (Kaiser Permanente), Katie Zuckerman (OHSU), Eric Larsson (Lovaas Institute for Early Intervention),

➤ **Roll Call/Minutes Approval/Staff Report**

The meeting was called to order at 2:00 pm and Chan called the roll. Minutes from the June 6, 2013 EbGS meeting were reviewed and approved.

Action: HERC staff will post the approved minutes on the website as soon as possible.

Coffman reported that the VbBS approved changes to the Prioritized List based on the ADHD coverage guidance recently referred by EbGS; this will now go to HERC. In addition, the HERC approved the following coverage guidances and some related Prioritized List changes: Neuroimaging in Headache, Induction of Labor, Coronary Artery Calcium Scoring, Coronary Computed Tomography Angiography, Cervical Cancer Screening and Recurrent Acute Otitis Media.

Topic: Coverage Guidance on Prenatal Genetic Testing

Discussion: Hatcher drew the subcommittee's attention to three basic questions related to changes she is recommending based on public comments. The revised draft includes more explicit mention of genetic counseling. In addition there are two additional questions: 1) if a woman is not reassured by noninvasive testing, should additional invasive testing be covered? 2) Should cell-free DNA testing be covered based on the additional evidence submitted in public comment?

Alison Little reviewed the public comment disposition from the meeting materials. In reviewing comment #1, the subcommittee discussed whether to cover genetic counseling and invasive aneuploidy testing for women over the age of 34 without additional risk factors who have had negative noninvasive screening tests. The current recommendation would cover these services. Little said that there is a higher pretest probability of abnormality but it is a judgment call how to balance the risks of an abnormal pregnancy with the risk of ending the pregnancy as a side effect of testing. Saha said that the commenter is trying to consider the value proposition of the test rather than the more traditional age cutoff. Marks would prefer to stick with the traditional age cutoff if there is no compelling evidence to change it. Hatcher pointed out that under the current language invasive testing and genetic counseling would be covered for any woman over the age of 34. Sattenspiel advocated for requiring a certain level of risk based on a calculator which includes the risk reduction from noninvasive testing rather than setting a simple age cutoff.

Joondeph said that the implication of this conversation is to incentivize or make possible the elimination of Down's Syndrome in the population. He said that many in the disabilities community do not see Down's Syndrome as a condition that should be eliminated in this way. Marks said that this is not about eliminating this condition, it's about preparing and counseling a patient about choices they face and issues that might come up.

After brief additional discussion there was a motion to leave the guidance language around invasive aneuploidy testing as it was. The motion carried 7-0 with Stecker and Joondeph abstaining. Further changes regarding genetic counseling were made to this part of the coverage guidance later in the discussion.

Little then reviewed the comments on cell-free fetal DNA testing. The subcommittee discussed the evidence submitted. Chan asked whether the evidence included normal risk women. Little said that there was one study which included average risk women and showed high sensitivity and specificity and had adequate size but which had a high risk of bias due to design. Overall the studies for normal and high risk women included thousands of pregnancies. Due to the risk of bias, and recommendations from clinicians, the subcommittee decided to cover the test for high risk women only. Chan requested public comment on this issue. There was none.

Westbrook asked whether there were special consideration for multiple gestations. Little said no one is recommending it as it has not been validated in that population.

Sattenspiel asked who would be eligible for this test. Hatcher said it would be an additional noninvasive testing modality. He asked why there is a follow-up with invasive testing. Hatcher said a positive result still requires follow-up with an invasive test to confirm the diagnosis as there is a small false negative and false positive rate. Hatcher said that one of the studies submitted in public comment shows a small net cost reduction from using cell free fetal DNA testing due to an overall decrease in invasive tests.

Saha asked about how the evidence was submitted and reviewed. Little has reviewed the evidence and staff feels comfortable with the level of evidence, and that the evidence is from one of our trusted sources.

After discussion the subcommittee added a strong recommendation in favor of coverage for cell-free fetal DNA testing for high risk women based on evidence submitted as public comment. They request that staff add the evidence to the evidence summary and update the HERC Coverage Guidance Development framework accordingly. This change was approved by a vote of 8-0 with Stecker abstaining.

Little reviewed comment #18, requesting to add a first-trimester screening protocol as an additional option for noninvasive screening. Little said she believed that there were sufficient options for first trimester screening in the coverage guidance. Little said that the methodologies have been looked at in numerous ways and she took the recommendation from the guidelines. She does not know why the high quality guidelines excluded the human chorionic gonadotropin (HCG) test.

Chan asked whether there was public comment. Tom Jenkins from Legacy Health Systems testified that the currently listed options were designed to have full interpretive capabilities to come out after 16 weeks of pregnancy. Some have some results that come out in the first trimester, but in order to limit false positives they use a different cutoff. Models show that a significant portion of abnormalities would be identified after the first trimester. Combined first trimester screening, which is recommended by NICE for a 35 year old women, would pick up 88-92 percent of all women in the first trimester, compared to 60 percent using the alternative. The options available for testing are limited by the availability of chorionic vitrus sampling (CVS) which is not available in all parts of the state or nation. For areas which have mature programs for first-trimester testing, this would be preferred as it would use a test with a higher detection rate earlier in the pregnancy. He also suggested that the cost of the combined test may result in fewer office visits, reducing costs compared to other programs.

Chan asked whether this strategy was included in the trusted sources. Little said this strategy is recommended by NICE. Jenkins pointed out that other strategies might be preferable where CVS is unavailable, but it is available in large areas of Oregon.

After brief additional discussion the subcommittee voted to add the combined first trimester screening strategy for aneuploidy 8-0 with Stecker abstaining.

Little reviewed comment #20 on carrier screening. The group discussed expanding carrier screening to all ethnicities. Heather Dorsey from Legacy Health System said her group, which provided the comment, would want some flexibility in implementing this. After some discussion, the subcommittee decided to make no changes to the guidance in this area.

Little reviewed comment #21, which addressed indications for genetic counseling. Staff has recommended changes to address the concerns for women with a family history of a genetic abnormality or disorder and women with a carrier status who desire further explanation and partner testing, but not the other concerns raised. The subcommittee agreed that this is reasonable but made some changes to clarify that maternal age over 34 is not by itself an indication for genetic counseling.

Actions: By a vote of 8-0 with Stecker abstaining, the subcommittee voted to refer the draft coverage guidance with these changes to VbBS and HERC.

HERC COVERAGE GUIDANCE

The following are recommended for coverage (*weak recommendation*):

- Genetic counseling for high risk women who have family history of inheritable disorder or carrier state, ultrasound abnormality, previous pregnancy with aneuploidy, or elevated risk of neural tube defect
- Genetic counseling prior to CVS, amniocentesis, microarray testing, Fragile X, and spinal muscular atrophy screening
- Validated questionnaire to assess genetic risk in all pregnant women
- Screening high risk ethnic groups for hemoglobinopathies
- Screening for aneuploidy with any of five screening strategies [first trimester (nuchal translucency, beta-HCG and PAPP-A), integrated, serum integrated, stepwise sequential, and contingency]
- Ultrasound for structural anomalies between 18 and 20 weeks gestation
- CVS or amniocentesis for a positive aneuploidy screen, maternal age >34, fetal structural anomalies, family history of inheritable chromosomal disorder or elevated risk of neural tube defect.
- Array CGH when major fetal congenital anomalies apparent on imaging, and karyotype is normal
- FISH testing only if karyotyping is not possible due a need for rapid turnaround for reasons of reproductive decision-making (i.e. at 22w4d gestation or beyond)

- Screening for Tay-Sachs carrier status in high risk populations. First step is hex A, and then additional DNA analysis in individuals with ambiguous Hex A test results, suspected variant form of TSD or suspected pseudodeficiency of Hex A
- Screening for cystic fibrosis carrier status once in a lifetime
- Screening for fragile X status in patients with a personal or family history of
 - fragile X tremor/ataxia syndrome
 - premature ovarian failure
 - unexplained early onset intellectual disability
 - fragile X intellectual disability
 - unexplained autism through the pregnant woman's maternal line
- Screening for spinal muscular atrophy once in a lifetime
- Screening those with Ashkenazi Jewish heritage for Canavan disease, familial dysautonomia, Tay-Sachs carrier status and cystic fibrosis carrier status.
- Expanded carrier screening only for those genetic conditions identified above

The following are recommended for coverage (*strong recommendation*):

- Cell free fetal DNA testing for evaluation of aneuploidy in women who have an elevated risk of a fetus with aneuploidy (maternal age >34, family history or elevated risk based on screening)

The following are not recommended for coverage (*weak recommendation*):

- Serum triple screen
- Screening for thrombophilia in general population or for recurrent pregnancy loss
- Expanded carrier screening which includes results for conditions not explicitly recommended for coverage

➤ **Topic: Applied Behavior Analysis (ABA) for Autism Spectrum Disorders**

Discussion: Coffman provided background information on this topic. The Oregon Legislature asked the HERC to review the topic as a part of a SB 365, which mandates coverage of this service for PEBB/OEBB and various private health insurance plans regulated by the state. The HERC has assigned the topic to the EbGS with the understanding that it will use the Coverage Guidance process but it will not be a coverage guidance since it will only inform potential coverage under the Oregon Health Plan. He then introduced Katharine Zuckerman, MD, MPH, FAAP, Eric Larsson, PhD, LP, BCBA-D and Eric Fombonne, MD, FRCP who have been appointed as ad hoc experts for the subcommittee on this topic.

Hatcher provided some background information on the topic. Autism will be considered a single disorder without regard to subdiagnoses such as Asperger's Syndrome, as per the DSM-V manual. Also, ABA comprises a broad range of therapies, with various levels of intensity. Some are manualized and others are

less so. They can be provided in clinics, educational settings or homes. In some cases parent training is required.

Little reviewed the evidence summary as presented in the meeting materials.

Sattenspiel asked about the study durations. Little said they varied but some were as long as two years of intervention and follow-up. Marks noted that most of the studies were in children aged 2-12. However he noted that the legislation requires coverage up to the age of 18 and asked whether there are studies on children 12-18. Little said there is one case series on children of that age group.

Chan said he reads the evidence as being stronger for more intensive interventions for children ages 2-12, and less strong for older groups or less intensive therapy.

Westbrook asked about the level of training for practitioners. Little said it is variable, sometimes delivered in educational settings by therapists at an early age in countries with universal preschool.

Sattenspiel said one issue is how many hours per week a plan should cover. It can be hard to know what level of service is appropriate for a patient. He asked Little whether there is evidence which might help with that question. Little said the answer is generally no. The Warren study looked at treatment duration and intensity but found insufficient evidence to draw conclusions. Hatcher said some of the manualized interventions being used for over 20 hours a week have evidence. Others have 13-17 hours per week of therapy. Sattenspiel asked whether the therapy is provided on an individual basis or in group settings. Little said it varies depending on the model.

Joondeph asked why the evidence was rated weak in Table 1. Little said that none of these are randomized studies and all are small. In addition, some of the studies in the Warren report (but not shown in Table 1) didn't show an effect. Chan said the outcomes being measured are very different, making it hard to pool the studies.

Stecker asked about the values and preferences column—whose values and preferences are we looking at? Hatcher said in this case it is those of the parents, as many of these therapies are for young children. She believes the variability in desire for treatment might be similar to that for ADHD.

Saha asked about harms associated with this treatment. Little said that she didn't recall any mention of harms in the AHRQ report. Larsson said AHRQ looked at harms from drug treatment but did not find harms associated with early interventions treatment.

Invited testimony was provided by Gina Green, PhD BCBA-D, Brian Reichow, PhD, BCBA-D, Louis Hagopian, PhD and Brenna Legaard. Their testimony is summarized in the presentations they provided, which are posted at [http://www.oregon.gov/oha/herc/EvidenceEvaluation/Invited Comments-9-12-13 EbGS Meeting.pdf](http://www.oregon.gov/oha/herc/EvidenceEvaluation/Invited%20Comments-9-12-13%20EbGS%20Meeting.pdf). No other members of the audience wished to provide testimony.

After Reichow's testimony Stecker asked why single subject experimental design studies are necessary. Green said that single subject studies are necessary because behavior occurs at the level of the individual. In a group design study such as described by Stecker, you would wash out the differences by using group averages. Understanding how behavior works with the environment, it requires a set of methods to study those processes at the level of the individual. Some of the treatment target interventions (e.g. personal safety skills, toileting, reductions in problem behaviors) would not be detected by the typical standardized IQ or adaptive behavior test.

Chan said that the issue is generalizability. If the intervention and outcomes are different for each individual, how can we generalize about the technique? The subcommittee needs to decide whether to apply a specific intervention in a large population based on general effectiveness. Green said that you wouldn't extrapolate from the results of a true single study to a population but we have demonstrated external validity empirically. To evaluate procedures for increasing language comprehension in children with autism, one might replicate it with multiple individuals, but they would be published separately. The meta-analyses and other systematic reviews of this literature show that the procedures work with many patients with autism. Reichow said that these analyses would only look at one intervention for patients with like characteristics and a similar outcome.

Stecker that this contradicts one of the arguments that the outcomes are variable, so that you can't define a trial. He said that publication bias is a significant concern with large studies, and even more so with case reports. It's hard to get a negative study published. Saha said risk of publication bias is larger in smaller studies. Reichow said that there is not a way of addressing publication bias in small studies. He noted however that even with large studies, Cochrane doesn't recommend doing such an analysis unless there are 10 or more studies, and even at 10 studies they feel the method is not very robust.

Saha said he sees the value of these single case studies. He said the standard way of doing systematic reviews is to define the population, the intervention, the comparator and the outcome. Inherently for ABA, the population is heterogeneous, the intervention is then necessarily applied differentially and the outcomes will be different based on the initial needs of the study participant. The typical randomized controlled trial is homogeneous on all these factors. However he echoed Stecker's contention that you can aggregate with effect sizes. This is

inherently difficult in a single randomized controlled trial. Therefore a meta-analysis of single case studies is as close as we can get.

Green said that while you could design a norm-referenced study which combined group and single case studies, most of the studies of ABA techniques are focused with a small number of procedures and a small number of targets.

Actions: Staff to gather questions from the subcommittee members to frame the discussion with the experts at the next meeting.

➤ **Next meeting**

November 7, 2013, 2 p.m. at the Meridian Park Community Health Education Center

➤ **New topics**

The subcommittee discussed possible new topics for coverage guidances. After discussion the subcommittee approved three additional topics:

- percutaneous interventions for cervical pain,
- screening for ovarian cancer, and
- indications for vitamin D testing

Staff will select one of these topics if it is not possible to do a report on the previously selected topic of diagnostics (cystoscopy, imaging of upper urinary tract, and urinary flow rate measurement) for men with uncomplicated lower urinary tract syndrome (LUTS) as the expected NICE report has been delayed.

Section 2.0

Previously Discussed Items

EVALUATION OF EVIDENCE: APPLIED BEHAVIOR ANALYSIS FOR AUTISM SPECTRUM DISORDERS

What are we trying to do? Oregon Senate Bill 365 was passed in 2013. This bill directs the Health Evidence Review Commission (HERC) to evaluate the evidence related to applied behavior analysis (ABA) for the treatment of autism spectrum disorder (ASD) in children that receive services as determined by the Prioritized List of Health Services under the Oregon Health Plan (OHP).

The history of coverage of treatment for ASD by OHP

- 1) This issue was last examined in 2008 by the Oregon Health Resources Commission. Currently treatment for behavioral symptoms have only limited coverage by OHP. Long-term behavioral therapy has generally not been covered. Children may be receiving services in a school-based setting outside of OHP.
- 2) ASD often exists with other conditions, and these conditions have their own considerations for treatment, most of which are covered. Short-term rehabilitation and certain medicines are also covered.

What has been done so far?

- 1) HERC met August 8, 2012, discussed the process for completion of this evaluation of evidence, and referred the issue to the Evidence-Based Guidelines Subcommittee (EBGS) for further discussion. On September 12, 2013, the EbGS reviewed the initial draft evaluation of evidence, heard public testimony and requested additional research by staff. The subcommittee will continue its discussion November 7, 2013.
- 2) Three ad hoc experts have been appointed to assist the subcommittee with its review of the evidence.
 - a. Eric Fombonne, MD (Professor, OHSU Dept. of Psychiatry)
 - b. Eric Larsson, PhD, LP, BCBA-D (Lovaas Institute for Early Intervention, Midwest Headquarters)
 - c. Katharine Elizabeth Zuckerman, MD, MPH, FAAP (Assistant Professor, OHSU Division of General Pediatrics and Child and Adolescent Health Measurement Initiative)

What are the initial conclusions based on the evidence?

- 1) The evaluation will not be final for many months, but in the initial review of the evidence, staff determined that new evidence indicates there may be some benefit for certain types of ABA in children between the ages of 2-12.

- 2) The subcommittee may accept the staff recommendation, request additional research, or choose to draw a different conclusion.

What happens now?

- 1) EbGS members will continue discussion of the evidence and testimony. They may choose to accept the staff conclusions as written or make changes to them. This may happen at the November 25 meeting or a later meeting.
- 2) This version of the evidence evaluation and conclusions will then be posted on the HERC website at www.oregon.gov/OHA/OHPR/Pages/HERC for a 30-day written public comment period.
- 3) Once finalized after considering the written public comment, the EbGS evaluation and conclusions will then go to the Value-Based Benefits Subcommittee (VbBS). VbBS will use the EbGS conclusions to determine what changes may be needed to the Prioritized List of Health Services and if there are any issues that would be involved in implementing these changes in OHP.
- 4) The evidence evaluation and any changes to the Prioritized List will eventually need final approval by the full HERC, which has members from many areas of health care (doctors, nurses, chiropractic, patients, health plan administrators, and more).
- 5) Any changes to the Prioritized List affecting OHP coverage of ABA would go into effect sometime between October 1, 2014 and April 1, 2015.

How can you participate?

- 1) You can subscribe to the HERC website at www.oregon.gov/OHA/OHPR/Pages/HERC/ to receive notifications of future meetings, look at materials being discussed or find out when the 30-day written public comment period begins and ends.
- 2) You can submit written comment of 1000 words or less (not including citations or journal articles) to HERC.Info@state.or.us once EbGS releases the evidence evaluation for the 30-day public comment period.
- 3) You can attend the meetings, which are open to the public, and provide verbal testimony during time set aside for public comment.

HEALTH EVIDENCE REVIEW COMMISSION (HERC)

EVALUATION OF EVIDENCE: APPLIED BEHAVIOR ANALYSIS FOR AUTISM SPECTRUM DISORDERS

DRAFT for 11/7/2013 EbGS Meeting Materials

BACKGROUND

Oregon Senate Bill 365 was passed by the Oregon legislature in the 2013 regular session. That bill directs the Health Evidence Review Commission to evaluate applied behavior analysis (ABA) as a treatment for autism spectrum disorder (ASD) for the purposes of updating the prioritized list of health services. The bill also directs insurers to cover ABA therapy up to a maximum of 25 hours per week for children who initially seek care before age nine, and allows continued coverage until age 18. Health plans that provide coverage to OEGB and PEGB are required to begin coverage in 2015, and all other health plans are required to begin coverage in 2016.

At their August 8, 2013 meeting, HERC assigned the evaluation of ABA to the Evidence-based Guidelines Subcommittee (EbGS). HERC further directed EbGS to conduct this evaluation using the process designed for the development of coverage guidances; but as Senate Bill 365 mandates coverage for OEGB/PEGB and commercial carriers, this process is only expected to result in a document used to inform potential changes to the Prioritized List.

This document reflects a review of the existing evidence of the effectiveness of ABA by the Center for Evidence-based Policy and an initial set of staff recommendations based on this evidence for EbGS discussion. EbGS will meet September 12, 2013 to consider these recommendations and hear public comment from patients, doctors, families, and any other interested members of the public. EbGS members will discuss the evidence and the testimony they hear. They may choose to accept the staff conclusions as written or make changes to them. This may happen at the September meeting or a meeting later in the year. The resulting version of the evidence evaluation and conclusions will then be posted on the HERC website at www.oregon.gov/OHA/OHPR/Pages/HERC for a 30-day written public comment period.

EbGS will then meet to discuss the public input and any additional sources of evidence submitted that warrant consideration, resulting in a finalized version of this document to be forwarded to the Value-Based Benefits Subcommittee (VbBS). VbBS will use the EbGS conclusions to determine what changes may be needed to the Prioritized List of Health Services and if there are any issues that would be involved in implementing these changes in OHP. The evidence evaluation and any changes to the Prioritized List will eventually need final approval by the full HERC. Any changes to the Prioritized List

affecting OHP coverage of ABA would go into effect sometime between October 1, 2014 and April 1, 2015.

EVIDENCE SOURCES

Warren, Z., Veenstra-VanderWeele, J., Stone, W., Bruzek, J.L., Nahmias, A.S., Foss-Feig, J.H., et al. (2011). *Therapies for children with autism spectrum disorders. Comparative effectiveness review no. 26.* (Prepared by the Vanderbilt Evidence-based Practice Center under Contract No. 290-2007-10065-I). AHRQ Publication No. 11-EHC029-EF. Rockville, MD: Agency for Healthcare Research and Quality. April 2011. Retrieved from <http://effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productid=651>

Lounds Taylor, J., Dove, D., Veenstra-VanderWeele, J., Sathe, N.A., McPheeters, M.L., Jerome, R.N., et al. (2012). *Interventions for adolescents and young adults with Autism Spectrum Disorders. Comparative Effectiveness Review No. 65.* (Prepared by the Vanderbilt Evidence-based Practice Center under Contract No. 290-2007-10065-I.) AHRQ Publication No. 12-EHC063-EF. Rockville, MD: Agency for Healthcare Research and Quality. Retrieved from <http://effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?productid=1197&pageaction=displayproduct>

Maglione, M., Motala, A., Shanman, R., Newberry, S., Schneider Chafen, J., & Shekelle, P. (2012). *AHRQ Comparative Effectiveness Review Surveillance Program: Therapies for Children with Autism Spectrum Disorders, 2nd Assessment.* Rockville, MD: Agency for Healthcare Research and Quality. Retrieved from <http://effectivehealthcare.ahrq.gov/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productID=1536>

Oono, I.P., Honey, E.J., & McConachie, H. (2013). Parent-mediated early intervention for young children with autism spectrum disorders (ASD). *Cochrane Database of Systematic Reviews*, Issue 4. Retrieved from <http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD009774.pub2/abstract>

Glossary Sources

Agency for Healthcare Research and Quality (AHRQ) Effective Health Care Program. (n.d.). Glossary of terms. Retrieved from <http://effectivehealthcare.ahrq.gov/index.cfm/glossary-of-terms/>

National Cancer Institute (NCI) at the National Institutes of Health (NIH). (n.d.). NCI dictionary of cancer terms. Retrieved from <http://www.cancer.gov/dictionary>

The summary of evidence in this document is derived directly from these evidence sources, and portions are extracted verbatim. Studies identified in the Maglione 2012

surveillance document are presented in additional detail, and conclusions regarding how those more recent studies impact the overall evidence base are made by HERC members.

SUMMARY OF EVIDENCE

Clinical Background

The following clinical background summary is extracted from Warren (2011).

“Autism Spectrum Disorder (ASD) is a group of pervasive developmental disorders (PDD) that includes Autistic Disorder, Asperger Syndrome, and Pervasive Developmental Disorder, Not Otherwise Specified (PDD-NOS)¹; it is estimated to affect 1 out of every 110 children. Autism spectrum disorder is characterized by impairments in communication, behavior, and social interaction and by repetitive behaviors coupled with obsessive interests, and is often accompanied by comorbid conditions, such as epilepsy and mental retardation.

A range of interventions are available for the treatment of ASD and the symptoms commonly associated with ASD (e.g., anxiety, sensory difficulties). Treatments for ASD focus on improving core deficits in social communication, as well as addressing challenging behaviors to improve functional engagement in developmentally appropriate activities. Common behavioral strategies used in the treatment of ASD are based on learning theory and make use of procedures such as reinforcement, prompting, and shaping techniques to increase the rate of positive behaviors and reduce the frequency of unwanted behaviors. Positive reinforcement and other principles to build communication, play, social, academic, self-care, work, and community living skills and to reduce problem behaviors in individuals with ASD have been used by behavioral therapists.

Applied behavior analysis (ABA) is a general intervention approach for the treatment of ASD. It is a systemic application, at any time during a child’s day, of behavioral principles to modify behavior. Some ABA techniques involve instruction that is directed by adults in a highly structured fashion, while others make use of the learner’s natural interests and follow his or her initiations. Other techniques teach skills in the context of ongoing activities. All skills are broken down into small steps or components, and learners are provided many repeated opportunities to learn and practice skills in a variety of settings, with abundant positive reinforcement. Different applications of ABA include Positive Behavioral Interventions and Support (PBS), Pivotal Response Training (PRT), Incidental

¹ The definition of autism spectrum disorder has been revised in the DSM-5 manual published in May 2013. The diagnostic terms listed here were in effect at the date of this publication in 2011, as detailed in DSM-IV-TR.

Teaching, Milieu Therapy, Verbal Behavior, and Discrete Trial Training (also known as Discrete Trial Learning), among others.

Early intensive behavioral intervention (EIBI) ... is a much more prescriptive, manualized program that integrates components of ABA. Children in an EIBI program have therapy approximately 40 hours per week over the course of up to two years. Proponents of EIBI recommend starting therapy as early as possible and preferably before the age of three. Two manualized EIBI programs are the University of California, Los Angeles (UCLA)/Lovaas model and the Early Start Denver Model (ESDM). Both programs involve high intensity instruction using ABA techniques but have several differences. The UCLA/Lovaas method uses one-on-one therapy sessions and discrete trial teaching. The ESDM uses ABA principles with developmental and relationship-based approaches for young children. Other treatment approaches exist that emphasize parent training for treatment (e.g., Pivotal Response Training, Hanen More than Words) and/or use joint attention interventions, symbolic play, and play-based interventions (e.g., Stepping Stones Triple P Program, Relationship Development Intervention (RDI), Mifne model). These therapies have not been manualized but are based on ABA principles.”

[\[Evidence Source\]](#)

Evidence Review

Children Ages Two to Twelve

EIBI and Other ABA Interventions

The Warren (2011) AHRQ review included all study designs as long as there were at least 10 participants. A total of 30 discrete studies were included, with the largest study population being 78 participants. Authors reach the following conclusions:

“The evidence suggests that early intensive behavioral and developmental intervention (EIBDI) may improve core areas of deficit for individuals with ASDs; however, randomized controlled trials (RCTs) are few and include small numbers of participants. In addition, there are no direct comparison trials. Within this category, studies of UCLA/Lovaas-based interventions report greater improvements in cognitive performance, language skills, and adaptive behavior skills than other broadly defined treatments. However, strength of evidence is currently low. In addition, the consistency of benefit is lacking, in that not all children demonstrate rapid gains, and many children continue to display substantial impairment. Although positive results are reported for the effects of intensive interventions that use a developmental framework, such as ESDM,

evidence for this type of intervention is currently insufficient because few studies have been published to date.

Less intensive interventions focusing on providing parent training for bolstering social communication skills and managing challenging behaviors have also been studied. Some interventions have shown short-term gains in social communication and language use, but the current evidence base for such treatment remains insufficient. Strength of evidence is also considered insufficient for play- and interaction-based approaches.

Only one study was identified that directly addressed whether there are any modifiers of outcomes for different ABA-based behavioral approaches. It examined the impact of which provider (parent vs. professional) delivered the UCLA/Lovaas protocol-based interventions. There was no significant difference in outcomes for children receiving the intervention in a clinical setting vs. at home from highly trained parents.

Other potential correlates that warrant further study because of conflicting data include pretreatment IQ and language skills, and age of initiation of treatment (with earlier age potentially associated with better outcomes). Social responsiveness and imitation skills have been suggested as skills that may correlate with improved treatment response in UCLA/Lovaas treatment, whereas “aloof” subtypes of ASDs may be associated with less robust changes in IQ. Other studies have seen specific improvement in children with PDD-NOS vs. Autistic Disorder diagnoses, which may be indicative of baseline symptom differences. However, many other studies have failed to find a relationship between autism symptoms and treatment response.

Research on very young children is preliminary, with four studies identified. One good-quality RCT suggested benefit from the use of ESDM in young children, with improvements in adaptive behavior, language, and cognitive outcomes. Diagnostic shifts within the autism spectrum were reported in close to 30 percent of children but were not associated with clinically significant improvements in Autism Diagnostic Observation Schedule severity scores or other measures.”

There was no evidence identified in the Warren review that addressed treatment effectiveness in specific subgroups such as race, ethnicity, gender or socioeconomic status, other than age.

[\[Evidence Source\]](#)

Surveillance of the literature pertaining to the Warren report was conducted by AHRQ in January 2012 and October 2012 (Maglione, 2012). Conclusions pertaining to ABA therapies that address the currency of the 2011 report are presented below:

- “Original conclusions regarding low strength of evidence for Early Intensive Behavioral Interventions (EIBI) are possibly out of date due to new RCTs and long-term follow-up of previously included studies.
- Original conclusion regarding insufficient evidence for parent training is possibly out of date due to several new RCTs.
- For Key Question 2 [what are the modifiers of outcome for different treatments or approaches (frequency, duration or intensity of treatment, characteristics of child or family, training of therapy provider)], conclusions are still valid, with the exception of impact of provider type, which may possibly be out of date.”

A total of 15 new studies identified in Maglione (2012) pertain to ABA and contributed to the conclusions above. The results of these studies are summarized below based on type of intervention. Conclusions regarding the impact of these new findings on the strength of evidence determinations of the Warren 2011 review are made by HERC members.

Seven studies evaluated EIBI (Maglione, 2012). Five of those were controlled trials, and the largest number of subjects was 142.

Table 1. Early Intensive Behavioral Interventions

Author	Study design	N	Intensity/Duration	Outcomes
Eikeseth 2012	Controlled clinical trial ² (CCT). Setting was mainstream school. EIBI delivered by therapist without a degree supervised by psychologist with experience in ABA. Control group received one-on-one eclectic interventions provided by special education teacher 3-5 hrs/wk and had a teachers' aide assigned to work one-on-one 50-100% of time.	59	Mean 23 hrs/wk (range 15-37 hrs/wk) for treatment group; not specified for control. Duration: 1 year	EIBI group showed significant improvements in adaptive behaviors, maladaptive behaviors, and autism symptoms after one year of treatment and the gains continued into the 2 nd year
Eldevik 2012	CCT Setting, intervention and control similar to above 2 yr follow-up	43	Mean 13 hrs/wk for a mean 25 mos	Children receiving EIBI had significantly higher IQ scores, adaptive behavior composite scores, communication and socialization
Flanagan 2012	CCT (treatment center vs. waitlist) chronological selection	142	Mean 26 hrs/wk for treatment, <10 hrs/wk waitlist with some speech and occupational therapy; mean duration 28 mos treatment, 17 mos waitlist	Children in the treatment group showed improved outcomes including lower severity of autism, higher adaptive functioning and cognitive skills (cognition not measured at onset of trial). Longer time in treatment controlled for in analysis.
Klintwall 2012	Case series ³ (mainstream kindergarten with EIBI by therapist at school)	21	20 hrs/wk for 1 year	Children who had a larger repertoire of socially mediated and reinforced behaviors benefited more from treatment than children who demonstrated more stereotypical (or automatically reinforced) behaviors
Kovshoff 2011	CCT [clinic vs. parent-mediated (parents direct treatment/employ	41	Clinic: 17 hrs/wk parent-mediated: 24 hrs/wk	No differences in any outcome between EIBI vs TAU. Sub-group analysis found significantly better

² A type of clinical trial comparing the effectiveness of one medication or treatment with the effectiveness of another medication or treatment. In many controlled trials, the other treatment is a placebo (inactive substance) and is considered the "control" (AHRQ, n.d.).

³ A group or series of case reports involving patients who were given similar treatment. Reports of case series usually contain detailed information about the individual patients (NCI NIH, n.d.).

Author	Study design	N	Intensity/Duration	Outcomes
	therapists) vs. treatment as usual (TAU)] – 2 yr follow up		Duration: 2 years	IQ and social behavior in parent-mediated group compared to clinic group or TAU. However, parent-mediated group had significantly less severe autism at baseline and received more hours of treatment.
Magiati 2011	Case series – 7 yr follow up	36	Mean 30 hours/wk for a mean of 58 mos	Increase in language skills, but at a lower rate than non-autistic peers
Strauss 2012	CCT [clinic with parental involvement vs. in-home (no parental involvement)]; self-selected	44	Mean 25 hrs/wk in a clinic setting 1 wk/mo and 19 hrs/wk provided by parents in the home 3 wks/mo after 3 wks of parent training for treatment group, mean 12 hrs/wk in-home treatment (eclectic) for control; Duration: 6 mos	Children receiving EIBI showed improvements in autism severity, developmental and language skills over 6 months. Control group that received eclectic treatment had improvements in some language and adaptive scores over that time period. While scores were generally higher in the treatment group, groups were not compared to each other statistically.

Overall, four of the five controlled trials found improved outcomes in children treated with EIBI, but one of these did not compare the intervention and control groups directly (Strauss, 2012). Intensity ranged from a mean of 13 to 26 hours/week. However, none of the trials were randomized and most were small, resulting in substantial susceptibility to bias. The overall strength of the evidence about the effectiveness of EIBI is likely unchanged.

Eight studies evaluated less intensive interventions that included parent training (Maglione, 2012).

Table 2. Less Intensive Behavioral Interventions including Parent Training

Author	Study design	N	Intensity/Duration	Outcomes
Goods 2012	RCT ⁴ [ABA + joint attention symbolic play engagement and regulation (JASPER) vs. ABA alone]	15	30 hrs/wk ABA both groups X 12 weeks. Intervention group substituted 30 min JASPER 2x/wk throughout program	Intervention group had greater play diversity, initiated more gestures and spent less time unengaged
Ingersoll 2010	RCT [reciprocal imitation training (RIT) delivered by therapists in clinic setting vs. TAU]	22	3 hr/wk RIT X 10 wks	RIT group made significantly more gains in elicited imitation and spontaneous imitation than the control group
Ingersoll 2011	Case series (parent training – Project ImPACT)	24	6 group and 6 individual coaching sessions over 4 mos	Children used a significantly higher rate of language during free play and home-based routine. Social impairment did not decrease significantly on parent report, but did on teacher report. Parents reported significantly less stress.
Kaale 2012	RCT (joint attention at preschool vs. preschool alone)	61	Two 20 min sessions (delivered by preschool teacher) 5 days/wk X 8 wks (mean 3.3 hrs/wk)	Intervention group showed significantly more joint attention with preschool teachers and longer duration of joint engagement with mothers
Kasari 2010	RCT (joint engagement instruction to parent vs. wait list) 1 yr follow up	38	24 sessions (~40 minutes) of parent instruction X 8 weeks (mean 2.0 hr/wk)	Greater improvements in 4 of 7 joint attention outcomes, maintained to 1 year
Landa 2011	RCT [Assessment, Evaluation and Programming System (AEPS) a type of EIBI curriculum vs. AEPS + Interpersonal Synchrony (IS)]	50	Classroom 2.5 hrs/day X 4 days/wk X 6 mos Home-based parent training 1.5 hrs/mo X 6 mos 38 hrs parent education follow up at 6 mos	No significant difference between groups in initiation of joint attention or shared positive affect, but the IS had significantly more socially engaged imitation than control
Minjarez 2011	Case series (pivotal response training taught to parents)	17	90 minute group session/wk for 10 wks + single 50 minute individual session	Primary outcome - child functional verbal utterances - increased significantly from baseline to week 10
Oosterling 2010	RCT [Focus parent training program (therapists as parent trainers, parents act as therapist to child) vs. usual care]	75	2 hrs/wk X 4 weeks followed by 3 hr home visit, repeated every 6 wks X 1 year (mean 1.8 hrs/week), same schedule but fewer home visits in second yr	No significant effects of intervention on any outcome

⁴ A controlled clinical trial that randomly (by chance) assigns participants to two or more groups. There are various methods to randomize study participants to their groups (AHRQ, n.d.).

Of the six identified RCTs, two evaluated specific training programs within the setting of other ABA treatment (JASPER, IS) (Maglione, 2012). Of the remaining four trials, three found positive outcomes, although the interventions differed. One involved parent training to increase joint attention, one evaluated a joint attention intervention delivered by the teacher and the third evaluated RIT delivered by a therapist. The trial that did not show an effect on any outcome evaluated the Focus parent training program. Given the small sample sizes in most trials and the diversity in interventions, it seems likely that the overall strength of the evidence remains insufficient to accurately draw conclusions about the effectiveness of parent training programs.

Only one new study was identified that addresses Key Question 2 (Maglione, 2012). As noted above, Kovshoff (2011) compared clinic delivered and parent-mediated EIBI compared to treatment as usual. While subgroup analysis found significantly better IQ and social behavior in the parent-mediated group compared to the clinic delivered group or treatment as usual, the parent-mediated group had significantly less severe autism at baseline and received more hours of treatment. This suggests that the overall prior conclusions that there is insufficient strength of evidence to evaluate the impact of provider type on efficacy of the intervention remain valid.

[\[Evidence Source\]](#)

Parent-mediated Early Intervention

A more recent review of parent-mediated early intervention in children less than seven was completed by the Cochrane collaboration in April 2013 (Oono, 2013). It included 17 RCTs (one of which was identified in the AHRQ surveillance report, and eight of which were included in the original Warren report) and drew the following conclusions:

“Overall, we did not find statistical evidence of gains from parent-mediated approaches in most of the primary outcomes assessed (most aspects of language and communication - whether directly assessed or reported; frequency of child initiations in observed parent-child interaction; child adaptive behaviour; parents’ stress), with findings largely inconclusive and inconsistent across studies. However, the evidence for positive change in patterns of parent-child interaction was strong and statistically significant (shared attention: standardized mean difference (SMD) 0.41; 95% confidence interval (CI) 0.14 to 0.68, P value < 0.05; parent synchrony: SMD 0.90; 95% CI 0.56 to 1.23, P value < 0.05). Furthermore, there is some evidence suggestive of improvement in child language comprehension, reported by parents (vocabulary comprehension: mean difference (MD) 36.26; 95% CI 1.31 to 71.20, P value < 0.05). In addition, there was evidence suggesting a reduction in the severity of children’s autism characteristics (SMD -0.30, 95% CI -0.52 to -0.08, P value < 0.05). However, this

evidence of change in children’s skills and difficulties as a consequence of parent-mediated intervention is uncertain, with small effect sizes and wide CIs, and the conclusions are likely to change with future publication of high-quality RCTs.”

[\[Evidence Source\]](#)

Adolescents and Young Adults (Ages 13 to 30)

Only one poor quality case series evaluated ABA-based intensive behavioral therapy, precluding conclusions regarding efficacy in this age group (Lounds, 2012).

[\[Evidence Source\]](#)

Evidence Summary

There is low strength of evidence that EIBI improves the core symptoms of autism, although improvements are inconsistent. Parent-mediated early intervention likely results in improved shared attention and parent synchrony. Impact on core autism symptoms is less clear, but it may improve language comprehension, and possibly lessen autism severity. The evidence is insufficient to evaluate the effects of other types of ABA-based behavioral interventions, including ESDM, parent training and play- and interaction-based approaches, as well as the effect of ABA on children older than twelve. The evidence is insufficient to determine whether there are any factors that modify the effectiveness of ABA therapy.

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GRADE-INFORMED FRAMEWORK

The HERC develops recommendations by using the concepts of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system. GRADE is a transparent and structured process for developing and presenting evidence and for carrying out the steps involved in developing recommendations. There are four elements that determine the strength of a recommendation, as listed in the table below. The HERC reviews the evidence and makes an assessment of each element, which in turn is used to develop the recommendations. Balance between desirable and undesirable effects, and quality of evidence, are derived from the evidence presented in this document, while estimated relative costs, values and preferences are assessments of the HERC members.

Indication	Balance between desirable and undesirable effects	Quality of evidence*	Resource allocation	Values and preferences
EIBI for children aged 2 to 12	There is general evidence of benefit on communication, adaptive behavior, and overall autism severity	Low	High	Moderate variability
Other less intensive ABA-based treatments for children aged 2 to 12	Parent delivered interventions under the direction of a trained therapist likely results in increased joint attention and parent synchrony, and possibly lessened overall severity of autism despite no clear benefit on language/communication, child adaptive behavior, or parent stress	Low	Moderate	Moderate variability
ABA for adolescents and young adults	Unknown	Insufficient	Moderate	Moderate variability

*The Quality of Evidence rating was assigned by the primary evidence source. The HERC has made its own assessment of the quality of the evidence after review of the studies contained within the AHRQ surveillance report.

Note: GRADE framework elements are described in Appendix A

SUMMARY CONCLUSIONS

Applied behavior analysis (ABA), including early intensive behavioral intervention (EIBI), is recommended for coverage⁵ for treatment of autism spectrum disorder⁶ in children ages 2-12 (*weak recommendation*). This recommendation is based on a review of available evidence. While there is sufficient evidence that ABA is effective in certain settings, the evidence is low quality and does not warrant a strong recommendation. This is further balanced by other values and considerations, such as those in the GRADE table above. ABA may be delivered in clinical or educational settings, and in many cases involves parent training and/or parent participation in therapy.

ABA is not recommended for coverage for treatment of autism spectrum disorder in persons over the age of 12 (*weak recommendation*). The evidence suggests that ABA is most effective when administered at younger ages, and there is insufficient evidence to support ABA treatment at older ages.

Note: The evidence for the treatment of conditions comorbid with autism spectrum disorder is beyond the scope of this evidence summary.

⁵ These conclusions apply to the Oregon Health Plan as governed by the Prioritized List of Health Services and to no other health plan.

⁶ Autism spectrum disorder should be diagnosed by a qualified health care professional according to DSM-5 criteria.

POLICY LANDSCAPE

No quality measures were identified when searching the [National Quality Measures Clearinghouse](#) pertaining to autism and Applied Behavior Analysis.

COMMITTEE DELIBERATIONS – EVIDENCE-BASED GUIDELINES SUBCOMMITTEE

COMMITTEE DELIBERATIONS – VALUE-BASED BENEFITS SUBCOMMITTEE

This report is prepared by the Health Evidence Review Commission (HERC), HERC staff, and subcommittee members. The evidence summary is prepared by the Center for Evidence-based Policy at Oregon Health & Science University (the Center). This document is intended to guide HERC in making informed decisions about the prioritization of health care services for the Oregon Health Plan.

The Center is not engaged in rendering any clinical, legal, business or other professional advice. The statements in this document do not represent official policy positions of the Center. Researchers involved in preparing this document have no affiliations or financial involvement that conflict with material presented in this document.

Appendix A. GRADE Element Descriptions

Element	Description
Balance between desirable and undesirable effects	The larger the difference between the desirable and undesirable effects, the higher the likelihood that a strong recommendation is warranted. The narrower the gradient, the higher the likelihood that a weak recommendation is warranted
Quality of evidence	The higher the quality of evidence, the higher the likelihood that a strong recommendation is warranted
Resource allocation	The higher the costs of an intervention—that is, the greater the resources consumed—the lower the likelihood that a strong recommendation is warranted
Values and preferences	The more values and preferences vary, or the greater the uncertainty in values and preferences, the higher the likelihood that a weak recommendation is warranted

Strong recommendation

In Favor: The subcommittee is confident that the desirable effects of adherence to a recommendation outweigh the undesirable effects, considering the quality of evidence, cost and resource allocation, and values and preferences.

Against: The subcommittee is confident that the undesirable effects of adherence to a recommendation outweigh the desirable effects, considering the quality of evidence, cost and resource allocation, and values and preferences.

Weak recommendation

In Favor: the subcommittee concludes that the desirable effects of adherence to a recommendation probably outweigh the undesirable effects, considering the quality of evidence, cost and resource allocation, and values and preferences, but is not confident.

Against: the subcommittee concludes that the undesirable effects of adherence to a recommendation probably outweigh the desirable effects, considering the quality of evidence, cost and resource allocation, and values and preferences, but is not confident.

Quality of evidence across studies for the treatment/outcome

High = Further research is very unlikely to change our confidence in the estimate of effect.

Moderate = Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low = Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low = Any estimate of effect is very uncertain.

Appendix B. Potentially Applicable Codes

CODES	DESCRIPTION
ICD-10 Diagnosis Codes	
F84.0	Autistic disorder
F84.2	Rett's syndrome
F84.3	Other childhood disintegrative disorder
F84.5	Asperger's syndrome
F84.8	Other pervasive developmental disorders
ICD-9 Volume 3 (Procedure Codes)	
None	
Procedure Codes	
<i>No specific procedure codes exist for Applied Behavior Analysis. The list below provides examples of how various state Medicaid agencies covering ABA instruct providers to bill.</i>	
H0002	Behavioral health screening to determine eligibility for admission to treatment program
H0004	Behavioral health counseling and therapy, per 15 minutes
H0031	Mental health assessment by non-physician
H0032	Mental health service plan development by non-physician
H2000	Comprehensive multidisciplinary evaluation
H2010	Comprehensive medication services, per 15 minutes
H2019	Therapeutic behavioral service, per 15 minutes
H2020	Therapeutic behavioral service, per diem
H2027	Psychoeducational service, per 15 min
T1023	Screening to determine the appropriateness of consideration of an individual for participation in a specified program, project or treatment protocol, per encounter
T1024	Evaluation and treatment by an integrated, specialty team contracted to provide coordinated care to multiple or severely handicapped children, per encounter
T1027	Family training and counseling for child development, per 15 min
T2013	Habilitation, educational, waiver, per hour
T2026	Specialized childcare, waiver, per diem

Note: Inclusion on this list does not guarantee coverage

Appendix C. HERC Guidance Development Framework

EIBI for Children Aged 2 to 12; Other Less Intensive ABA-based Treatments for Children Aged 2 to 12

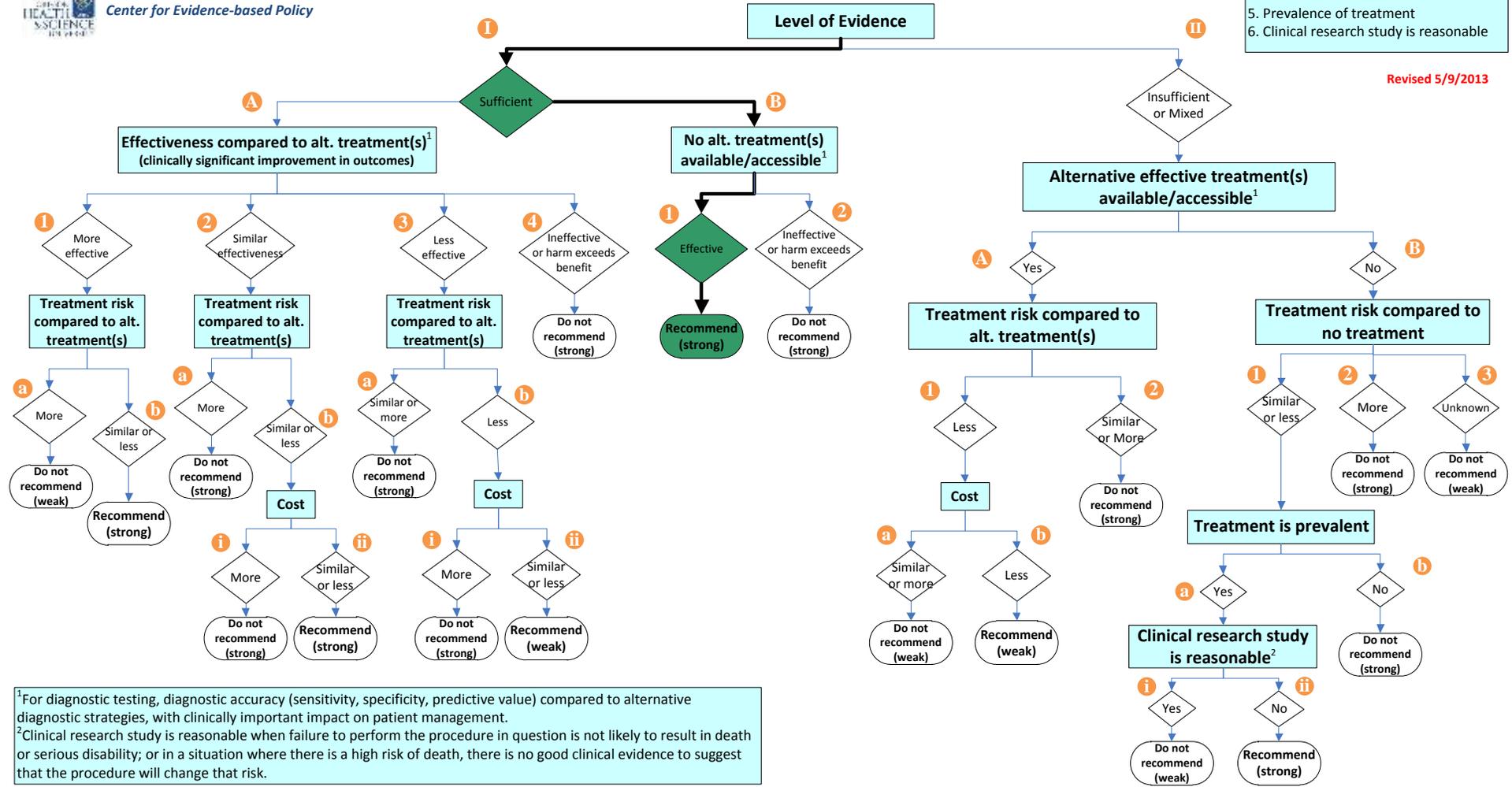


HERC Guidance Development Framework

Refer to *HERC Guidance Development Framework Principles* for additional considerations

- Decision Point Priorities**
1. Level of evidence
 2. Effectiveness & alternative treatments
 3. Harms and risk
 4. Cost
 5. Prevalence of treatment
 6. Clinical research study is reasonable

Revised 5/9/2013



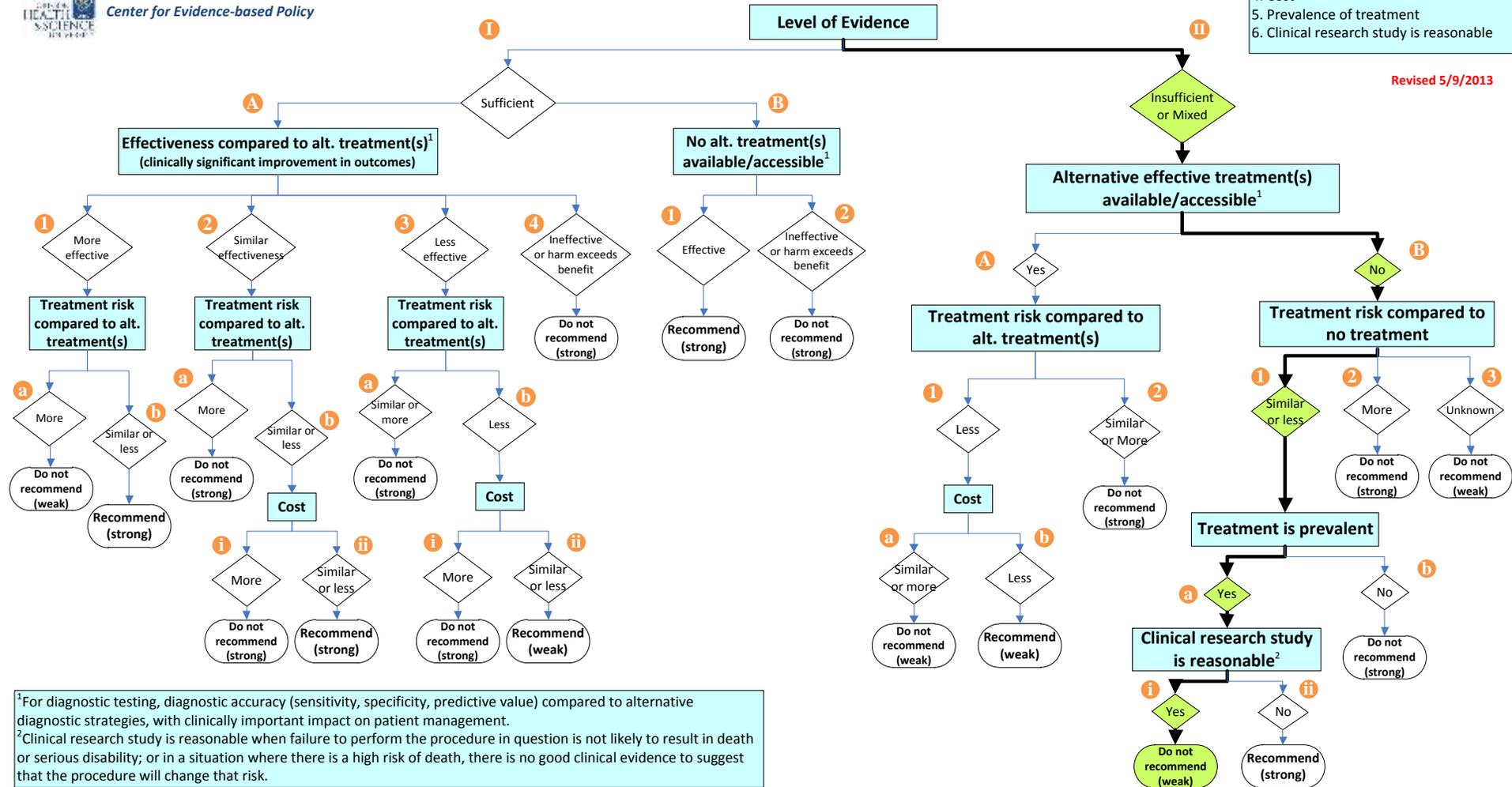
HERC Guidance Development Framework

Refer to *HERC Guidance Development Framework Principles* for additional considerations

Decision Point Priorities

1. Level of evidence
2. Effectiveness & alternative treatments
3. Harms and risk
4. Cost
5. Prevalence of treatment
6. Clinical research study is reasonable

Revised 5/9/2013



¹For diagnostic testing, diagnostic accuracy (sensitivity, specificity, predictive value) compared to alternative diagnostic strategies, with clinically important impact on patient management.
²Clinical research study is reasonable when failure to perform the procedure in question is not likely to result in death or serious disability; or in a situation where there is a high risk of death, there is no good clinical evidence to suggest that the procedure will change that risk.

Questions Pertaining to ABA for the treatment of Autism Spectrum Disorders Submitted by EbGS Committee Members

General Questions about this Review Process

1. What are the health / governmental policy considerations of our decision?

Legislation (Oregon Senate Bill 365) directs the Health Evidence Review Commission to evaluate the evidence related to applied behavior analysis (ABA) for the treatment of autism spectrum disorder (ASD) in children that receive services as determined by the Prioritized List of Health Services under the Oregon Health Plan (OHP). It is recognized that this process may result in different coverage of ABA in OHP than what is mandated for other public and commercial plans.

Questions Pertaining to the Population Addressed in this Review

2. At what functional level of impairment should ABA be made available? Are there certain levels of impairment that do or do not respond to ABA?

The question in the Warren report that addresses subgroups, including severity, found one study where children with low initial object exploration benefitted more from Response Education and Prelinguistic Milieu Teaching (RPMT), while children who were relatively high in initial object exploration demonstrated more benefit from Picture Exchange Communication System (PECS).

3. Are there specific difficult behaviors in ASD that either respond particularly well or poorly to ABA?

The specific outcomes assessed in the included studies can be identified, and those for which significant improvements were found can be specified. However, it should be noted that over 100 different outcomes measures were included in the Warren report, including multiple different scales and checklists comprised of many different unique measurements [e.g., Autism Diagnostic Observation Schedule (ADOS), Vineland Adaptive Behavior Scales (VABS), Stanford-Binet Intelligence Scale (SBIS)]. So it may be possible to generalize and say, for example, treatment had some effect on language but not on cognition. The degree to which different scales measure the same outcomes is not entirely clear.

- 4. Is a trial of ABA therapy in an individual to test effectiveness reasonable? Are there patients who don't respond to ABA therapy? If so, what is the percentage? How is failure to respond defined (after what period of time)?**

The Warren report states that not all individuals improve, and many remain substantially impaired. The literature does not identify the percentage of those who do not respond and does not define failure. May be best directed to experts.

Questions Pertaining to the Interventions Addressed in this Review

- 5. What is the difference between ABA and behavior modification? Does this distinction matter?**

Not answered by the literature; may be best directed to experts.

- 6. Can ABA be carried out by the parent/guardian?**

A study included in the Warren report examined the impact of which provider (parent vs. professional) delivered the UCLA/Lovaas protocol-based interventions. There was no significant difference in outcomes for children receiving the intervention in a clinical setting vs. at home from highly trained parents. One additional study was included in the AHRQ update, which showed better outcomes in some areas for parent-mediated group, however study design brings into question any conclusions (parent-mediated group had significantly less severe autism at baseline and received more hours of treatment).

- 7. Is group therapy effective?**

Parent training has been studied in groups. It is uncertain whether there are any studies of group therapy when treating the individual; additional review of the literature may be able to answer this question.

- 8. What limits are appropriate, with regard to frequency, duration, repetition, if ABA is recommended for coverage?**

One study in the Warren review attempted to assess the role of intensity of service. Reed 2007 compared high intensity (average 30 hours/week) home-based Lovaas programs offering primarily one-on-one teaching with low-intensity ones (average 13 hours/week). There were no significant differences between groups in autism severity, cognitive function or adaptive behavior, although the high intensity group had better educational functioning after 9-10 months of treatment. No other studies have attempted to address intensity of service.

9. Are ABA services readily available across the state?

Not answered by the literature; may be best directed to experts.

Questions Pertaining to the Outcomes Addressed in this Review

10. What are the most important health outcomes to consider in ASD (avoidance of institutionalization, reduction in self-harm or non-harmful repetitive behaviors, increase in social interaction, educational function, cognitive function)? Parent/ family outcomes should be included.

This would seem to be best addressed by the experts, or to be the judgement of the committee members. What outcomes are felt to be most important is not addressed in the literature. Common outcomes addressed in the literature reviewed thus far are IQ, language, adaptive functioning, educational functioning, social functioning and autism severity. Parent/family outcomes are addressed in many studies, specifically, parent stress.

11. Does ABA constitute treatment of an underlying disease (modifying the natural course of the condition)? Or does it modify specific behaviors in the short term only? Does this distinction matter?

Not answered by the literature; may be best directed to experts.

12. What are the appropriate values and preferences of patients/parents for the GRADE table?

Research on this question has not been searched for or reviewed. While clearly some parents have strong preferences for ABA, there may be variability in parental commitment to the intensive nature of these treatment programs.

Overarching Questions about the Evidence Base in this Review

13. Is a randomized trial of ABA reasonable, and if not, why not? Is ABA the standard of care (how is this defined?), preventing conduct of an RCT?

An RCT appears to be reasonable, since it has been done. Smith 2000 was a RCT included in the Warren report that compared the Lovaas intervention (average 25 hours/week) with 3-9 months of parent training from the Lovaas manual. This study found a modest increase in IQ in the intervention group compared to control, but no difference in adaptive behavior or challenging behavior. Seven cohort studies were included that used the following control groups: intensive parent managed model, eclectic (includes higher student/teacher ratio, DIDR-Floortime model, TEACCH),

local or community services and home-based direct teaching sessions. There are numerous RCTs of less intensive behavioral interventions, including 5 in the AHRQ update report and 17 in the Cochrane review (Oono 2013). If they can be completed for less intensive interventions, it would seem reasonable that they could be completed for more intensive ones, or that less intensive interventions could be compared to more intensive ones.

14. What are the potential problems of using single subject N-of-1 studies of ABA for making policy?

Not addressed by the current evidence; may be best directed to experts and/or methodologist.

Background Material on Single Subject (N-of-1) Study Designs

General Background on N-of-1 Studies

First described in the 1960s, single-subject research became a key research design in the field of special education and has grown in its use throughout other education and psychology disciplines (Horner, 2005). It was introduced to increase the experimental rigor of the traditional case study and the validity of results regarding interventions for an individual learner or a group of individual learners, particularly where the intervention must be tailored to the individual. This design was introduced into clinical research in the late 1980s as the “N-of-1” study design. It serves the same purpose among those types of studies – to document a cause and effect relationship between an intervention and outcome for a single individual (Guyatt, 1986). In single-subject or N-of-1 studies, the individual serves as his or her own control. If possible, the individual is randomly assigned to an experimental (intervention) or control condition and the outcome (dependent variable) is measured. The individual is then crossed over to the other condition and again the outcome is measured. Ideally, this cycle is repeated at least three times, and the outcomes are assessed by an evaluator blind to the experimental and control conditions (Guyatt, 1990; Horner, 2005; Yelland, 2009). Recently, clinical researchers have called for greater use of N-of-1 studies to assist with treatment decisions for chronic conditions where the therapy is expensive, therapeutic effectiveness is difficult to determine, and/or when there is potential for harms as well as benefits from the therapy (Larson, 2010; Scuffman, 2010; Kravitz, 2009).

For many study designs used in clinical research, there are broadly accepted criteria for assessing the internal validity (or quality) of results from these studies and for systematically incorporating this evidence into the guideline process (Guyatt, Drummond, 2008; Guyatt, Oxman 2008; NICE, 2009; SIGN, 2008). This has not been the case, for single-subject research. Horner (2005) and others have outlined indicators of high quality single-subject research. If done well, these studies can provide the highest standards for establishing the benefits and harms of an intervention for a particular individual (Guyatt, 1986; Schuffham, 2010). One caveat is that neither the experimental nor the control condition should influence the effect of the next condition on the outcome. For example, if a child is randomly assigned to the experimental condition first and communicative abilities increase to a new and permanent level; this may mask any changes that would have occurred during the control condition making the intervention look better than it actually is. In addition, it is difficult with this study

design to control for inherent developmental growth (maturation effect), an important reason to have at least three cycles of the intervention and control conditions.

From the JAMA User's Guide to the Medical Literature:

The main issue for single-subject or N-of-1 trials is the external validity or generalizability of the results beyond the individual(s) in the study. In other words, how do we know the outcome was due to the intervention and not the unique characteristics of the individual or the specific individual-intervention interaction? Can the *result* be replicated in other individuals who are reasonably similar to the subject? Horner and colleagues (2005) proposed standards to enhance our confidence that the results of single-subject studies can be generalized beyond the subjects in the studies. These standards involve replication of the study across different participants, settings, and materials. The replication should include at least five studies involving 20 or more subjects, and these studies should be carried out by at least three different researchers in three different locations. Moreover, techniques have been developed to quantitatively combine the results of rigorous single-subject and N-of-1 trials to estimate intervention effectiveness for a target population (Zucker, 1997). Unfortunately, these standards and methods that lend support to the external validity or generalizability of results from single-subject research have not been widely applied. In the meantime, one approach that has been used to incorporate information from single-subject research into an evidence review is to treat these studies as observational evidence that is graded as low quality due to the risks of bias that occur even in well done observational studies (Parr, 2009).

Warren Report Discussion of Methodologic Issues, Including Single-Subject Study Designs

“A high proportion of studies in this review (36 percent) fail to use a comparison group, and while substantial strides have been made in the analysis of single-subject designs, these are not ideal for assessing effectiveness at a population level, nor are they appropriate for comparative effectiveness research. They are, however, used frequently in the behavioral literature, and so we address our decisions regarding them here. Because there is no separate comparison group in these studies they would be considered case reports (if only one child included) or case series (multiple children) under the rubric of the EPC study designs. Case reports and case series can have rigorous evaluation of pre- and post- measures, as well as strong characterization of the study participants.

Studies using this design that included at least 10 children were included in the review. Studies of this type can be helpful in assessing response to treatment in very short time

frames and under very tightly controlled circumstances, but they typically do not provide information on longer term or functional outcomes. They are useful in serving as demonstration projects, yielding initial evidence that an intervention merits further study, and, in the clinical environment, they can be useful in identifying whether a particular approach to treatment is likely to be helpful for a specific child. Our goal was to identify and review the best evidence for assessing the efficacy and effectiveness of therapies for children with ASD, with an eye toward their utility in the clinical setting, and for the larger population of children with ASD. By definition, “populations” in single-subject design studies are likely to be idiosyncratic and therefore not to provide information that is generalizable.”

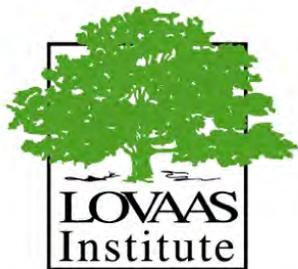
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Questions Pertaining to ABA for the treatment of Autism
Spectrum Disorders Submitted by EbGS Committee Members
October 31, 2013 – Eric V. Larsson, PhD, LP, BCBA-D

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1. What are the health / governmental policy considerations of our decision?

Given the experience of other states in implementing autism coverage mandates, it is easy to infer that the delivery of ABA services in Oregon will be much more cost effective, and result in much less strife for the citizens if uniform standards are enacted across all Plans in the state.

As examples of the risks of uncoordinated implementation, see the steps that California, New York, and New Jersey had to take this year to repair the implementation problems with their existing autism laws.

In California, the Department of Insurance was forced to declare emergency regulations, saying that they were necessary because of "widespread confusion" among insurers and policyholders regarding California's 2011 autism insurance reform law.

In New York, the Department of Financial Services was forced to issue corrected regulations to enable providers to practice according to its 2011 autism insurance reform law.

In New Jersey, the State Assembly Financial Services and Insurance Committee had to hold hearings on the lack of compliance with its 2010 autism insurance law and ordered stakeholder meetings to resolve the issues.

See Appendix I.

2. At what functional level of impairment should ABA be made available? Are there certain levels of impairment that do or do not respond to ABA?

ABA is composed of an individualized array of treatment services that is suited for the heterogeneous nature of autism. In particular, ABA is an evaluation and decision-making methodology that is used to make objective prescriptions of the kind and intensity of treatments that are best suited to the individual child.

At Intake, a Prescriptive Assessment of Individual Children's needs is conducted to determine the optimal form of treatment, intensity, and service delivery for each individual child at intake – to prescribe this optimal treatment based upon individual measures of prognosis, such as functional developmental status, parental involvement, age, and complicating conditions.

Then, at regular Re-evaluation Intervals, a Prescriptive Assessment of Individual Children's Responsiveness to Treatment is conducted in which care-determination is based upon each individual child's responsiveness to treatment.

Each child should be periodically re-assessed and referred to the optimal treatment as they show individualized patterns of response to treatment, just as every other form of medicine does. Each child will not respond the same way, and present technology does not accurately predict treatment outcomes three years hence. In our ongoing research we have found that a dynamic assessment of a child's response to treatment over time is a much better predictor than is a single static assessment at a single point in time. Therefore, in the case of early intensive home-based intervention, we have found that every six months is a cost-effective time frame for re-evaluating responsiveness to treatment and making differential referrals based upon these assessments.

How would this work to improve cost effectiveness?

To use an example, in one of the original long-term outcome studies, 16 children had been placed into state hospitals, with no hope of recovery from their symptoms, and no hope of acquiring basic language and play skills. To everyone's amazement, the children did make clinically significant progress. But what is less well known is that the study was the first of its kind to identify prognostic indicators of response to treatment. Essentially, the researchers were able to identify a matrix of response to treatment. The study compared older and younger children, in interaction with children who had high parental involvement and low parental involvement. The children who responded best were the younger children, who also had high parental involvement. Such children were then the best candidates for home-based treatment with the plain intention of training the parents to be the children's own therapists.

The other children who did not benefit from parent training were not to be "thrown away," as they had already been by society, but instead they were to be referred to other valuable treatment modalities such as center-based treatment, with other services such as medical management, respite, and social groups.

A further matrix took into account that each child could not be predicted to respond based only on the intake measures. Instead, the child's responsiveness to treatment after each six months formed the basis for further service decisions as they progressed. Some children completed treatment in 18 months, and others in three years. Some were referred to center-based care and others to normal school classrooms.

Subsequent research proved the value of that approach, and found more accurate measures of responsiveness to treatment. When replications of the approach were published in 2005, 2006, and 2007, it became clear that we could maximize the value of our limited health care dollars by focusing on real outcome measures and determining the best services for each child.

Today, the present cost-containment system would incorporate these concepts to determine the best treatment options for each child, and make the best possible referrals, based upon their prognostic indicators. Each child will receive their optimal treatment, and society's resources will be best conserved, if each child can benefit from the earliest possible care determinations. But it is much more than a single

decision. What we have learned in this dynamic, 35-year process of treatment development is that there is an ongoing process of behavior assessment, analysis, and clinical decision making that results in the best use of scarce resources.

See Appendix II for examples of such individualization.

3. Are there specific difficult behaviors in ASD that either respond particularly well or poorly to ABA?

The essential answer from ABA is that the evaluation and decision-making methodology is intended to determine the individual child's medical necessity. The child's response to treatment cannot cost-effectively be evaluated with a one-point-in-time intake assessment, but instead is evaluated through ongoing measures. And because each child's manifestation of behavioral challenges and contextual social variables is different, the assessment of response to treatment is typically customized to the individual child.

Still, it is possible to arrive at a consensus among providers of essential response-to-treatment measures that can be used to evaluate each child's treatment. For example, two basic assessments could be fashioned into an authorization tool that would be able to gain consensus amongst a large group of ABA providers and autism consumers. I would still put these assessments into a larger context of a multi-modal assessment of service usage, norm-referenced assessments, and treatment compliance, but I think that we'd be well served to focus in on these criterion-referenced behavioral assessments. The first is a set of standard best outcome objectives for Comprehensive ABA for young children. The second is to be used for Focused ABA for any age.

Standard discharge objectives for Comprehensive ABA.

We use these to give families a sense of the overarching goals of three-years of treatment, but then task analyze these goals into six-month benchmarks. I think this takes the mystery out of interpreting assessments. The discharge objectives are face valid. Similarly, without a high amount of training, a nurse can be trained to recognize whether the provider is faithfully task analyzing the discharge objectives into meaningful six-month benchmark objectives. The goal of a certification agency would be to look behind these benchmarks and evaluate whether the provider reliably measures the progress of the child using the benchmarks they put on paper. This would require a sampling of actual observations. Again, because these are face valid, it is easy to observe the child and determine the validity of the data that the provider submits.

Standard behavior assessment for Focused ABA.

We use this to help determine whether a treatment plan is valid for a school-age child. With this assessment, you see age-norms and shaded criteria, which are used to determine whether a given level of a challenging behavior is something that would require valuable treatment. If the child doesn't have these critical behavioral challenges, then they don't merit medical/behavioral treatment. If they cross the line from needing treatment to not needing treatment, then you are able to evaluate the success of the treatment. I also think that the face validity of this measure could gain a consensus amongst ABA providers and autism consumers, and also be easy to understand by a nurse.

A focus on these functional behavioral objectives will help move the field from a focus on treating an intellectual disability to a focus on medical/behavioral needs.

See examples of such an assessment in Appendix III.

4. Is a trial of ABA therapy in an individual to test effectiveness reasonable? Are there patients who don't respond to ABA therapy? If so, what is the percentage? How is failure to respond defined (after what period of time)?

Yes, the trial of ABA therapy is the most valid method for testing effectiveness. In our experience, comprehensive ABA is best evaluated on a scale of every six months, and most focused ABA treatments are best evaluated either on a scale of every three or every six months. If one is using the kinds of discharge assessments that are described above, the level of effectiveness would be expected to approximate 80% - that 80% of the children would be expected to achieve at least one socially significant discharge objective, given appropriate resources for ABA.

The issue then becomes how to assist the provider in making the appropriate determinations.

The use of regulatory resources is most cost-effective when incorporating measures of outcomes, which incorporate quality and quantity. Applied Behavior Analysis for autism offers the kind of objective data needed to make efficient care determinations.

This focus mirrors concepts proposed by Health Care Reform and value-based initiatives. These initiatives combine measures of cost with measures of quality to control health care delivery based upon value.

Where independent case reviewers can not hope to provide the level of oversight needed to make cost-saving determinations for each individual, a system of managing provider organizations can be much more efficient and effective.

Medical necessity should be based upon the evidence and the community standard of care. However, to date, most policy makers have only relied upon one level of evidence-based care determination. But actually, there are five important levels of value-based decision-making that result in the most helpful allocation of resources to all children.

Today, the present cost-containments system would incorporate these concepts to determine the absolutely best treatment options for each child, and make the best possible referrals, based upon their prognostic indicators. Each child will receive their optimal treatment, and society's resources will be best conserved, if each child can benefit from the earliest possible care determinations. But it is much more than a single decision.

1) Scientific Actuarial Research on Average Costs and Outcomes

The first level is the obvious one that most policy makers are aware of: the research on evidence-based treatment – children should receive the kind and level of treatment that has been proven to be most effective in meeting clinical needs. This evaluation must be ongoing, as new research indicates innovative approaches.

2) Process Research on Service-Delivery Effectiveness and Accessibility

But, the second level is to determine the best service-delivery method for each treatment. Some methods of delivery will be much more effective than will others. Some will be much less costly than others. Some will entail much less risk than others. And some will be much more accessible than other. At this level the important principle of "payment reform," is investigated. Some models of payment create disincentives for cost-effectiveness. For example, if payment is only made for the direct hours of one-to-one behavior therapy, and not for the behavior assessment, behavior analysis, and clinical supervision, then there is a disincentive to phase out intensity as the child responds, because a certain intensity of direct hours is required in order to cover the overhead costs. There is also a disincentive to provide low-intensity parent training to less affected children. The reimbursement model may also not accommodate long-distance services in rural areas. Or it may not allow for high-risk services for the dangerous children who become the highest cost children in the future.

3) Value-Based Assessment and Certification of Individual Provider Agencies

However, the third level of care determination is based upon a frank realization that some provider agencies are better suited to success with certain forms of treatment than others. And some have frankly abused the system. Therefore this level of care determination is to identify the most cost-effective provider organizations that are delivering each type of treatment.

5. What is the difference between ABA and behavior modification? Does this distinction matter?

The term "behavior modification" has been used to refer to many of the procedures that fall under the array of ABA treatment services. However, it has also become synonymous in lay usage to various non-ABA procedures, such as brain surgery. So it is no longer regularly used within the field of ABA.

6. Can ABA be carried out by the parent/guardian?

There are two different kinds of answers to this question.

The first is that consistent participation by all relevant caregivers is normally essential to effective ABA treatment. For example, one of the several goals of Early Intensive Behavioral Intervention (EIBI), which many parents expressly seek, is to recover the child from the symptoms of autism (Maurice, 2001). One proven model of recovery-oriented treatment requires extensive parent involvement in a complex and dynamically changing treatment plan over a period of time that ranges from 18 months to five years for most cases (Lovaas & Smith, 2003). When providers do not share such goals, it is reasonable for them to gain the parents' consent for eclectic or lesser intensity services. But parents should be well informed that it also clearly proven in research that services which do not demand of the parents that they engage in effective therapeutic skills 24 hours a day, seven days a week, are unlikely to result in the kind of recovery that they should expect for the expense of intensive treatment (Leaf, Taubman, & McEachin, 2008).

The most central focus of comprehensive ABA is the family therapy. In each family's case, extensive support and parent training is required, not just to train the parents to rationally use therapy skills, but also to support them in emotionally adopting new parenting behavior (which is in direct conflict with their history of parenting and long-term family history). Helping a parent to effectively follow through with therapy at the checkout counter, in the car, at the doctor's office, at mealtime, during a play date, at bedtime, at the grandparents' party, etc. is extremely challenging. In effective EIBI, the parents are not just responding effectively to a tantrum or other dangerous behavior, but they are also teaching social language skills at the same time, in embarrassing public situations. Further, the mother and father are not typically working together consistently when therapy begins, and their own conflicts must be addressed. Most typical families muddle through such difficult times and their children develop typically, because they are not afflicted by autism. However, if the goal of treatment is to change the very autistic symptoms that stand in the child's way of typical functioning, then families cannot succeed without extensive emotional support and skill-training expertise.

Parents do not change their emotional behavior easily. They require frequent direct supervision by sophisticated staff, during every aspect of therapy, in order to effect change. In addition, they require frequent parent-training co-therapy with a senior behavior therapist who is narrating and instructing them while they observe the model of a behavior therapist working effectively with their child. In many cases, they also require separate direct counseling by the supervisors while a behavior therapist is managing their child, simply to be able to focus on the issues at hand without constant distractions.

As part of this extensive and necessary comprehensive family skills training, the provider would also conduct a weekly review with the parents and all staff involved. This clinical review "meeting" is essential to the continuity of care of the treatment plan, by providing simultaneous direction to the parents as well as the staff, and much specific family skills training is done in this "meeting" every week. Finally, this meeting serves as an ITP review meeting on a weekly basis to ensure that the family is fully and genuinely informed of the latest treatment recommendations, goals, and procedures. Their successful training in the meeting is part of their weekly consent to the treatment.

The second answer has to do with whether parents are able to be relied upon to be effective therapists for their children (as opposed to using professional services). In 2005, Sallows and Graupner published a paper in which they found that parents who conducted a "parent-directed" form of EIBI were equally effective to a group of other families who were treated by a "clinic-directed" form of EIBI. The confusion that this caused was the implication that any parent could be equally as effective as those in the parent-directed group. However, it must be pointed out that the families in this study self-determined their participation. Only highly organized and skilled parents were included in the parent-directed group. In our experience perhaps 15 percent of families have the financial wherewithal to devote full time to managing their own child's treatment, have the organizational skills and social skills necessary to successfully supervise their own child's treatment, and also not be assailed by the kinds of stresses that would impede such a feat. This option does provide one of many individualization options which will reduce the costs of autism to society, but it cannot be relied upon to do so.

7. Is group therapy effective?

Similarly to the answer to question 7 above, some children have benefitted from group treatment to socially significant extents. In particular, some children are better treated in group settings due to the stresses that their families are experiencing. However a full array of treatment options will include both home-based and center-based treatment options. This is true whether comprehensive or focused ABA is chosen for the child. For example, one independent panel put it thusly:

“Both of these treatment approaches were rated as highly trainable, tested among youths of various ethnic backgrounds, in various format types (e.g., individual and group) and settings (e.g., school, clinic, home, and community), as well as by different therapist types (e.g., prebachelor’s-level therapists, master’s-level therapists, and doctors). The duration of both Level 1 treatments was at least a year. Another promising characteristic of these two approaches is that they were both tested on boys as young as one and two years old.”

Chorpita, B.F. et al. (2011). Evidence-based treatments for children and adolescents: An updated review of indicators of efficacy and effectiveness. *Clinical Psychology Science and Practice*. 18, 154-172.

8. What limits are appropriate, with regard to frequency, duration, repetition, if ABA is recommended for coverage?

The goal of ABA and EIBI is to deliver the most cost effective and medically necessary treatment possible. To do so, it should be flexibly individualized based upon periodic reassessment of child outcomes. The final array of services should be designed to be timely and accessible to families. To do so, the intensities and patterns of treatment services to be authorized can be informed by the evidence from ABA and EIBI research.

Further, the specification of hours should adhere to the principles of health care reform, in which payment systems are developed that motivate providers to deliver the most cost-effective, time-limited services, and eliminate disincentives for performance. The cost effective formula for hours is more complex than a simple average, as is shown below.

Many systems rely upon management of the number of hours of treatment authorized per week. The restrictions on which staff can deliver which services, and upon patterns of staffing should be based on the evidence in ABA and EIBI. The research suggests ways to increase cost effectiveness and accessibility, and conforms with the trend in health care reform, which is to manage payment principles to motivate performance based upon outcomes.

It is commonly accepted that both ABA and EIBI are effective treatments for the symptoms of autism, and that the intensity of intervention is a major determinant of effectiveness.

“Among the many methods available for treatment and education of people with autism, applied behavior analysis (ABA) has become widely accepted as an effective treatment... The basic research done by Ivar Lovaas and his colleagues at the University of California, Los Angeles, calling for an intensive, one-on-one child-teacher interaction for 40 hours a week, laid a foundation for other educators and researchers in the search for further effective early interventions to help those with ASD attain their potential.”

National Institute of Mental Health (2008). Autism Spectrum Disorders: Pervasive Developmental Disorders. NIH Publication no. 08-5511.

In the studies that are most often cited as the best evidence for comprehensive interventions, and also are the largest studies, in terms of number of participants and length of time studied (Chorpita et al. 2011; Myers & Johnson, 2007; New York State Department of Health, 1999; Rogers & Vismara, 2008; Warren, et al. 2011), the following independent variables (experimental conditions) were compared with less intensive treatments.

See Table 1 below:

Table 1: Evidence-Based Levels of Behavior Analysis and Behavior Therapy in Outcome Studies of Comprehensive ABA

Study	Reported Hours of One-to-One Behavior Therapy	Reported Additional Levels of Behavior Analysis, Assessment, and Direction	Reported Additional Levels of Parent Training	Clinical Reviews
Lovaas 1987	An average of 40 hours, with frequent co-therapy, range: 10 to 60 hours per week	Daily to weekly direct supervision by direct supervisor, clinical supervisor, and psychologist	The parents also received extensive instruction and supervision on appropriate treatment techniques for 5-8 hours per week	Weekly team clinical review meeting
Cohen et al. 2006	35 to 40 hours	Clinic Supervisors provided ongoing performance feedback	Weekly parent training	Weekly team clinical review meeting & six-month clinical review
Sallows & Graupner 2005	An average of 37 to 39 hours	6 to 10 hours of weekly co-therapy by the senior therapist and weekly supervision by the clinic supervisor	Parents attended weekly team meetings and extended treatment throughout the day	2 weekly 1-hr team clinical and progress review meetings
Howard et al. 2005	35 to 40 hours	Direct observational data reviewed by program supervisors several times per week	Weekly to monthly parent training	
Eikeseth et al. 2002, 2007	28 hours of school-based and additional home-based parent therapy	10 hours per week of apprentice observation and supervision by supervisors, weekly supervision by project directors	4 hours per week of parent training	2 hour meeting weekly
Hayward, et al. 2009	42 hours of scheduled, home- and school-based treatment	5 hours per week of programme consultant supervision. 11 hours per week of senior tutor supervision. 2 hours per month by programme director	2 to 5 hours per week of parent training	2 hour meeting weekly

How many hours should be authorized?

The intensity of treatment of each individual child should be individualized to their own needs, and for varying durations. Some children benefit from a few hours a week for less than six months, and others require many hours a week for several years. When children use a few hours during the week, those hours should be delivered by senior clinicians, and when children are treated more intensively, a higher proportion of junior clinicians can be used, while under frequent direct clinical supervision.

Each child's optimum intensity should be authorized based upon their responsiveness to treatment. This is measured by an ABA system of directly measured short-term objectives every six months. The common ratio of the hours of different direct services is as follows:

Table 2: Average Hours of Intensity of Evidence Based Treatment in Comprehensive ABA, Focused ABA, and Parent and Caregiver ABA Training

	Comprehensive EIBI Treatment		Focused ABA Treatment	Parent and Caregiver ABA Training
	Intensive Phase	Transition Phase		
Average Hours of Direct Behavior Analyst Services per Six Months				
Periodic Case Review	38	38	26	26
Average Hours of Direct Behavior Analyst Services per Week				
Behavior Assessment, Analysis, and ITP Development	4	4	1	1
Clinical Direction	3	1	1	0
Parent and Caregiver Training	6	6	6	6
Clinical Consultation and Case Management	2	2	1	2
Average Hours of Direct Behavior Technician Services per Week				
Child Intervention	40	10	10	0

The common ranges of hours delivered, after individualization, are as follows:

Table 3: Common Ranges of Intensity of Evidence Based Treatment Across the Varying Treatment Models

Treatment Model	Behavior Analyst			Behavior Technician		
	Range of Hours per Week Low	High	Average per Week	Range of Hours per Week Low	High	Average per Week
All Models	1.5	25	7	2	60	20
Comprehensive Intensive	1.5	25	18	6	60	30
Comprehensive Transition	2	24	8	-	-	-
Focused	2	10	6	2	16	10
Parent Training	1.5	8	2	-	-	-

9. Are ABA services readily available across the state?

I don't have data available on this question.

10. What are the most important health outcomes to consider in ASD (avoidance of institutionalization, reduction in self-harm or non-harmful repetitive behaviors, increase in social interaction, educational function, cognitive function)? Parent/ family outcomes should be included.

The question as stated provides a good starting point for the answer. At its most basic, the fundamental diagnostic features of autism form the central treatment goals. All of these features have proven amenable to ABA treatment, at least in some cases. In their essence, each of these outcomes can be measured by the extent to which the child or the family's independence is still limited due to the lack of realization of the outcome. In the most extreme disabling condition, the child and their family becomes isolated from the community, due to the stress of managing the child's needs in the community, and both the child and parent's health deteriorates due to the isolation. In another form, the child is placed into institutional care due to the extremely disabling behavior, and this care is either extremely costly to the community or continues the child's deterioration, or both.

Seen this way, the intent of treatment will be to delay or eliminate the need for the following successive tiers of treatment services. While some behavioral challenges, such as dangerous elopement or objectionable sexual acting out will obviously be targets of treatment in their own rite, the prevention of the need for restrictive care will reap financial and emotional benefits to the child, their family, and the community.

Tiers of Treatment Services (Goal: Prevent or lessen the need for these services).

The "best" prognosis: Early intervention. A variety of services are currently being provided to children and their families at different points in the life-span. Early identification and treatment is most promising for substantial remediation of the intrusive effects of the disorder. If the child with autism is identified by the age of three and intensive services are provided for the next several years, the child may be successfully integrated into a normal first-grade classroom with support services. The most successful results to date have found that half of the severely disordered children receiving intensive early intervention services were successfully placed into normal first-grade classrooms (Lovaas, 1987). It is possible that if the children who were not successfully placed had been identified earlier, they would also would have been successful. These intensive services should include a combination of in-home parent-training and integrated preschool services that result in 40 hours per week of highly structured, data-based, behavioral instruction for the child. In addition, the child will require well-structured transitional programming in order to adjust smoothly in the elementary classroom. These services are being provided at isolated sites.

A child with autism who has made the successful transition into a normal first-grade classroom might be expected to successfully maintain their placement with their natural family and public school system into adulthood. Progressive services through the school years would include structured behavioral instruction, a focus on natural language programming, social skills training and programmed integration activities with peers, programmed community-living skills activities, structured home-school communication, data-based management of the curriculum, and a clear focus on preparation for independent, competitive work and living as an adult.

The frequent prognosis: Ongoing moderately-intensive services. Most children do not receive effective early intervention services, however. In the majority of cases, intensive community-based services will be required in order to maintain the child's placement with their family and public school. The child's behavior may be so disruptive to the family and school that the school and community will need to provide a high staff-to-student ratio in an integrated setting; extended day, week, and year programming; highly structured, data-based, behavioral instruction; ongoing consultation and training for the family; and regular out-of-home respite services.

By the age of 16, the child will require a well-formulated vocational-training plan and a community-based, supported-work supervisor. Specialized services such as medical, dental, transportation, and recreation programs will also be sought. In addition, well-coordinated transitional planning for adult services will be necessary.

A common prognosis: Out-of-home crises. If the intensive services as described above are not provided, the child is likely to reach a crisis by the age of 16, in which an out-of-home placement is prematurely sought. This may be due to either the family or the school feeling unable to safely provide for the child's needs. When this crisis occurs, two arrays of services might be provided in order to maintain the child in the family home. In one array, intensive case-management will be necessary to bring together the consultation and advocacy needed to develop suitable services. The services usually will consist of out-of-home or in-home respite, one-to-one staffing in the school, occasional crisis placements, and in-home family support. A premium will be placed on the development of effective, data-based, behavior-management programming to rapidly reduce the likelihood of the critical dangerous and demanding behaviors. Once the array of crisis services is put in place, it will be difficult to reduce the child's reliance on these services. It is infrequent that the necessary intensity of these services is provided to needy children, and they are placed into long-term residential treatment programs.

Transitional residential programming. In the second array, the child may be placed into a short-term, intensive, residential-education program with a focus on returning the child to the natural home. If the child is identified for such services by the age of 12, they are likely to be successful in reuniting the family within six months to four years. Once again, this program should be characterized by highly structured, data-based, behavioral programming. The program should be carefully managed to maintain a focus on the critical dysfunctional behaviors and skill deficits which are preventing the child from adequate functioning in the home and school. In addition, the family and school will require on-going home- and community-based consultation and training in order to incorporate the essential features of the effective intervention into the future environments. The family will be most likely to reunite if monthly home-visits are made by the child. Careful clinical decision-making and transitional planning will be essential features of this service. Few agencies are successfully providing these services.

Premature placement into long-term residential treatment. As an alternative, the out-of-home crisis is very likely to result in the child's entry into long-term residential placement, at a great emotional toll to the family and a significant expense to the community. At present, the placement is likely to be in a small group home with four to eight children and daily transportation to a segregated day program. An alternative placement would be a specialized adult foster home. A high quality program will share the type of structured behavioral programming of the services described above, and will focus on preparation for semi-independent living and supported, competitive work options as ultimate treatment goals. The transition to the adult service system will not be potentiated by the early entry into residential living. There is little continuity between the two residential service systems.

Normal placement into adult services. If the child successfully remains at home until the age of 18 or 21, the family may then attempt to unrealistically maintain the adult with the family indefinitely. As an alternative, the adult may be prepared for semi-independent living with one to three peers and regular visits by a case manager. Other, more likely, placements would include small group homes or adult foster homes. In addition, the adult may be vocationally prepared for competitive work in natural settings with some supervision or case-management by a job coach. Today, it is still more likely that the adult will be employed in a sheltered setting. Indicators of quality would continue to be a focus on structured behavioral training and integration with normal peers.

See Appendix IV for a review of the types of costs that autism brings to the family or the community.

11. Does ABA constitute treatment of an underlying disease (modifying the natural course of the condition)? Or does it modify specific behaviors in the short term only? Does this distinction matter?

There are identifiable physical diagnoses for perhaps 5% of the children who are diagnosed with autism. Of the rest, time will tell if their "underlying" physical causes are ever identifiable. In the meantime, the differential diagnosis of autism appears to be becoming less reliable, rather than more reliable. This highlights a strength of ABA. Its focus is not to treat the overarching syndrome per se, but rather to specifically focus on each of the behavioral symptoms of autism and remediate them in the most pragmatically strategic fashion, and to the greatest extent for each child. As such it is best said that most children with autism can benefit from improvement in some or all of their symptoms, and some may even reach a point where there are no measurable symptoms. For 90% of those, the children will only maintain their symptom-free status if their parents and teachers are trained and supported in continuing the behavioral interventions that brought the children to that state. So an important caveat to treatment of the symptoms is to recognize that medical/behavioral treatment is only warranted if the child or family is suffering from the symptom, or if the symptom puts them at risk for further deterioration, or if the failure to prevent the symptom (and/or move the child further toward the typical developmental trajectory) will result in future suffering. For example, a child who prefers to study global warming over socializing with peers, may not be "suffering" from their "autistic" symptom. However a child who is screaming in community restaurants, will require remediation in order to avoid future isolation.

12. What are the appropriate values and preferences of patients/parents for the GRADE table?

It is clinically well established, and intuitive to the pediatrician, that the only parents who will benefit from treatment are those who are self-selecting the treatment. This principle operates at its most extreme in ABA treatments that require intensive parent training. Therefore a broad spectrum of treatment intensities and modalities will be most cost-effective for the community.

To this point, several state Medicaid programs and private insurance plan have had a formal ABA benefit for 6 or more years, and have published data on the actual cost of their autism coverage. With that kind of substantial track record, here's what we do know for a fact.

In states who have provided accessible funding and ABA services over a period of years, the actual utilization of ABA has proven to be much less than expected. Some of the reasons for the lower utilization of ABA include:

- 1) While the number of cases of autism that are diagnosed are very high, only about one third of the children have high needs for care.
- 2) The average age of diagnosis is estimated by the CDC to be 5.7 years of age (Shattuck, et. al., 2009). While the intent of ABA is to be delivered as early as possible, half of the target pool is not identified until after reaching school age. This dramatically decreases the average weekly hours of home-based services.
- 3) Not every family will be able to access ABA due to their location and other family challenges. The rural and the inner city families continue to be dramatically underserved.
- 4) Many other kinds of treatments are available, and various families will make other value-based choices than to engage in intensive services.
- 5) It continues to be a significant challenge to train the medical and social service referral sources to understand and refer to ABA.
- 6) The growth in available providers has been slower than might be expected, due to the high cost of personnel training and certification.

Therefore the average cost of ABA per child with autism is much lower than commonly estimated. Here are four state's experiences:

The state of Pennsylvania's Medicaid program has been widely available to children with autism since the mid 1990's. Abt Associates Inc (2007) reported that the Pennsylvania Medicaid program covered 13,800 children with autism in 2007, at an average annual cost of \$14,300 per child for all services (including ABA). There were 8,516 other diagnosed children with autism who did not access services. If this cost was extended to all children with autism (both covered and not covered), the average cost was \$8,843 per child. If this cost was extended to all children in Pennsylvania, the cost was \$59 per child.

The state of Wisconsin also had widely available services since the mid 1990's. In 2004, they reported that after six years of widespread availability of Medicaid funding for ABA, only 1,073 children, out of 7,867 eligible children, were accessing ABA in 2002. The average cost per child accessing ABA was \$29,545. The average cost per eligible child was \$4,030. The average cost per every child was \$27 per year.

In Minnesota, after seven years of widely accessible Medicaid funding, it was reported in 2009 that only 541 children out of a total of 3,333 eligible children, were accessing ABA. The average cost of treatment for those children was \$31,000. If that cost were averaged across all children with autism, the average cost would be \$2,910. Across all children in the state, that cost would be \$19 per child per year. At the same time Blue Cross Blue Shield of Minnesota also made coverage of EIBI widely available. Their data closely matches the incidence and cost data of the Medicaid program.

Similarly, in one of the Medicaid regions of California where ABA has been most widely available over a period of years, it was reported in 2009 that that about one third of the eligible children accessed ABA. The average cost was slightly over \$10,000 per child treated. Across all of the children with autism in the

region, the cost was \$3,361 per child, and across all children in the region, the cost was \$22 per child per year.

In these four states, the average utilization of ABA was 34% of all eligible children. The average cost per child (all children in the state or region) was \$32 per year.

Further, the recent Minnesota state legislature fiscal note for an autism mandate and Medicaid program is instructive. Minnesota had numerous plans in place, including a state employee plan, a Medicaid plan, and a high-risk pool, all of which had covered ABA for autism for over five years. The state Medicaid plan operated with the most micromanagement of authorizations in order to control costs, the high-risk pool with minimal micromanagement, and the state employee in between. However, the fiscal note reported the following costs:

The MN MMB fiscal note for 2013 autism bill (HF 181-3A):

The annual cost of a single child on MA for 2012 as reported by MN DHS was \$66,878 in the note on page 17 (the estimated rate used in the expenditure formula).

The annual cost of a single child on MCHA was given as \$50,000 on page 6.

The annual cost of a single child in SEGIP (State and Local Employees) was given as \$65,260 on page 16.

For all of the controls placed by the various plans, the average cost was inversely related.

This data suggests that a payment formula that allows for parent self-determination will be the most cost-effective method of managing costs.

13. Is a randomized trial of ABA reasonable, and if not, why not? Is ABA the standard of care (how is this defined?), preventing conduct of an RCT?

There are several problems with the RCT which are not immediately apparent, until one sets out to solicit grant funding.

- 1) Ethics: The typical RCT is a drug study. But a drug study can be completed in a matter of months, and so the ethical constraint of doing no harm is mitigated, because the effective treatment can then be delivered after that brief delay. However, if an effective EIBI treatment is withheld for three years, as would be necessary, then the child misses their chance to access the presumably effective early intervention. The AHRQ report provides a salient example of a drug study that met their standards, but lasted only 2-4 months. The few RCTs of ABA were also limited in time and scope, thus limiting the conclusions that could have been drawn.
- 2) Cost: If we used common criteria for 30 participants in a treatment group, at a cost of \$56,000 per year (30 children times 3 years times \$56,000) = \$5,040,000. Then add the cost of the control group and the research evaluation to that. The resulting cost of \$10,000,000 is not a realistic grant proposal.
- 3) Methodology: If the differential diagnosis is not currently reliable, then the baseline measures are not comparable across children. A strength of the ABA within-subject experiment is that it focuses instead on comparison of the same child's treatment with their own baseline, and then replicating the effect across numerous children.
- 4) Without reliable differential diagnosis criteria, the RCT does not yield the data being sought on which children respond and which do not, and which variables affect response. ABA designs are able to do so.
- 5) The RCT as typically discussed, would focus on evaluating recovery from the diagnosis instead of the behavioral outcomes, which misses the crucial point that ABA makes. Paradoxically, the RCT drug studies also typically do not evaluate "cure" of a diagnosis, nor do the short time frames look for a maintenance effect after the treatment. And in actuality the psychotropic drugs are only palliative.
- 6) The RCT would not be useless (if the above problems could be solved. Group studies still provide aggregate data on the value of coverage and on the effects of certification of providers.

So there is another solution, if the cost issue can be dealt with. And that is to take parent self-determination at its face, and study the effects of treatment when parents are self-selecting the parameters of their choice. These are the real world conditions of treatment in any event. It has been said that the nonparametric statistical tools apparently do allow for non-random assignment.

To determine whether ABA is already the standard of care, see attached Appendix V for a list of statements by various independent bodies.

14. What are the potential problems of using single subject N-of-1 studies of ABA for making policy?

The other solution is to take the direction of numerous sources and evaluate all of the data using independent peer review, expert panels, and meta-analyses. A model that uses a registry would allow for a real-world test of implementation, though it would still come with costs.

When the full body of such reviews is analyzed, it is reasonable to conclude that Applied Behavior Analysis (ABA) and Early Intensive Behavioral Intervention (EIBI) are possibly the best examples of evidence-based behavioral health care. Independent reviews consistently agree that ABA and EIBI treatments for autism are effective, and that the extensive body of research meets high standards of evidence.

Two such independent reviews are highlighted here.

One well-known review was conducted for Division 53 of the American Psychological Association (the Society for Clinical Child and Adolescent Psychology). The following was concluded:

"Randomized controlled trials have demonstrated positive effects in both short-term and longer term studies. The evidence suggests that early intervention programs are indeed beneficial for children with autism, often improving developmental functioning and decreasing maladaptive behaviors and symptom severity at the level of group analysis." (Page 8).

"Lovaas's treatment meet Chambless and colleague's (Chambless et al., 1998; Chambless et al., 1996) criteria for 'well-established'" (Page 8).

"Across all the studies we cited, improvements in language, communication, and IQ, and reduction in severity of autism symptoms indicate that the core symptoms of autism appear malleable in early childhood" (page 30).

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

In another review, the state of Hawaii convened a Department of Health Task Force to identify evidence-based treatments in children's mental health. The overarching goals of the task force were to broaden and update the summary of scientific information used to guide decisions about children's care. The report provides an extensive review of the major randomized, controlled research findings for psychosocial treatments for children. The "Evidence Based Services" committee grouped its findings into "treatment families" of similar treatments for given disorders and represented these in a report titled, "Effective Psychosocial Interventions for Youth with Behavioral and Emotional Needs."

Regarding the treatment of autism, the Evidence Based Services report stated:

"Two treatment families demonstrated Best Support. Intensive Behavioral Treatment was successful in three (3) studies, beating alternative treatments in two (2) of those, and beating a no-treatment control in one (1). Likewise, Intensive Communication Training was also successful in three (3) studies, beating alternative treatments in two (2) of those, and beating a no-treatment control in one (1) study." (Page 16).

"These results are quite promising in terms of effect size, although it should be noted that the outcome variables for these studies mainly involved reductions in the frequency of autistic behaviors or increases in social communication or other forms of social exchange (e.g., turn taking). None of these studies claimed that children were autism free following the intervention programs. Nevertheless, these findings represent an extraordinary improvement over the evidence base for interventions for autistic spectrum disorders in the previous Biennial Report." (Page 18).

"The shape of the profile suggests that all successful treatments for autistic spectrum disorders involve teaching communication skills and modeling of appropriate communication or other behaviors. Other strategies include training in non-verbal communication (social skills), teaching parents and teachers to praise desired behaviors, and the setting of goals paired with the intensive rehearsal and reinforcement of behaviors consistent with those goals (i.e., discrete trial training)." (Page 19).

Chorpita, B.F. & Daleiden, E.L. (2009). 2009 Biennial Report: Effective psychosocial interventions for youth with behavioral and emotional needs. Child and Adolescent Mental Health Division, Honolulu: Hawaii Department of Health.

Here are two other statements from recent objective scientific reviews of EIBI.

"Recovery in children with ASD through behavioral and educational interventions seems possible in a significant minority of cases." (page 360).

Helt, M., Kelley, E., Kinsbourne, M., Pandey, J., Boorstein, H., Herbert, M., & Fein, D. (2008). Can children with autism recover? If so, how? *Neuropsychology Review*. 18, 339-366. (The authors are psychologists and pediatricians at the University of Connecticut, Queen's University, the New School, Children's Hospital of Philadelphia, and Massachusetts General Hospital).

"The weight of currently available scientific evidence, however, indicates that ABA should be viewed as the optimal, comprehensive treatment approach in young children with ASD."

Barbaresi, W.J., Katusic, S.K., & Voigt, R.G. (2006). Autism: A review of the state of the science for pediatric primary health care clinicians. *Archives of Pediatric and Adolescent Medicine*, 160. 1167-1175. (The authors are pediatricians at the Mayo Clinic and at Harvard University).

Forty-five such independent, meta-analysis, and peer reviews are listed in a bibliography below. In none of these do the authors systematically refute the published evidence for ABA treatments of autism. The reviews are critical evaluations – in many cases, other non-ABA treatments are assigned to categories such as "insufficient evidence," "unproven," or even "potentially harmful."

Yet every review cites the obvious positive results of ABA and EIBI and accepts them as proven. The most "negative" conclusions that are offered are:

- 1) ABA does not cure all children of autism
- 2) ABA is not the only established treatment, nor is it clearly the best treatment
- 3) There are not well-established means to identify the best candidates for treatment

It should be noted that the above conclusions can be drawn about any medical treatment that already enjoys full coverage, so they should not be cause for denying coverage for ABA.

However, the lay impression persists that there are "negative" reviews in the literature. But let's look at what the "negative" reviews do say. The following is the *most skeptical* recent publication in the scientific literature. But see one of their concluding statements.

"There is little question now that early intensive behavioral intervention is highly effective for some children. However, gains are not universal, and some children make only modest progress while others show little or no change, sometimes after extremely lengthy periods in treatment." (page 36).

Howlin, P., Magiati, I., & Charman, T. (2009). Systematic review of early intensive behavioral interventions for children with autism. *American Journal on Intellectual and Developmental Disabilities*. 114. 23-41. (The authors are professors at the Institute of

Psychiatry, King's College (London, UK) and University College, London, Institute of Child Health).

Other "negative" reviews may exclude the majority of ABA research, by applying highly restrictive criteria for what qualifies as evidence.

For example, there is the Comparative Effectiveness Review published by the AHRQ in 2011. But, while this report has also been cited as "negative," see their main conclusions regarding ABA and EIBI interventions.

"Evidence supports early intensive behavioral and developmental intervention, including the University of California, Los Angeles (UCLA)/Lovaas model and Early Start Denver Model (ESDM) for improving cognitive performance, language skills, and adaptive behavior in some groups of children." (page vi).

"Evidence suggests that interventions focusing on providing parent training and cognitive behavioral therapy (CBT) for bolstering social skills and managing challenging behaviors may be useful for children with ASDs to improve social communication, language use, and potentially, symptom severity. (page vi).

The "negative" qualifiers of these conclusions are stated as:

"All of these studies need to be replicated, and specific focus is needed to characterize which children are most likely to benefit." (page vi).

"Information is lacking on modifiers of effectiveness, generalization of effects outside the treatment context, components of multicomponent therapies that drive effectiveness, and predictors of treatment success." (page vi).

In comparison to the above comments, these are the clearly negative conclusions about traditional biomedical treatments that are currently widely covered by insurance policies:

"No current medical interventions demonstrate clear benefit for social or communication symptoms in ASDs." (page vi).

"Little evidence is available to assess other behavioral interventions, allied health therapies, or complementary and alternative medicine." (page vi).

Warren, Z., Veenstra-VanderWeele, J., Stone, W., Bruzek, J.L., Nahmias, A.S., Foss-Feig, J.H., Jerome, R.N., Krishnaswami, S., Sathé, N.A., Glasser, A.M., Surawicz, T., & McPheeters, M.L. (April, 2011). Therapies for Children With Autism Spectrum Disorders. *Comparative Effectiveness Review No. 26*. (Prepared by the Vanderbilt Evidence-based Practice Center under Contract No.290-2007-10065-I.) AHRQ Publication No. 11-EHC029-EF. Rockville, MD: Agency for Healthcare Research and Quality. Available at: www.effectivehealthcare.ahrq.gov/reports/final.cfm.

The AHRQ report reached these positive conclusions about ABA and EIBI despite excluding a large number of studies, including all studies published prior to 2000. Yet the AHRQ report still found 78 studies of behavioral interventions, which included 34 studies of EIBI that met their criteria for inclusion.

Other "negative" reviews cited are typically proprietary reports published privately. For example, the Kaiser Blue Cross report did not offer positive statements (Rothenberg & Samson, 2009). However in their methodology, they limited their analysis to only 16 studies, out of the hundreds available, and concluded that more research needs to be done. Interestingly, unlike the AHRQ review, this report did not comment on the comparable lack of data for psychotropic medications, yet insurance companies readily cover such treatment.

Three other areas of research, that were not addressed by the AHRO report or the proprietary reports, are the following: cost-benefit analyses, meta-analyses of effect magnitude, and direct analyses of significant behavior improvement. Here are some sample conclusions from these fields of research.

Cost-Benefit Analyses

"Under our model parameters, expansion of IBI to all eligible children represents a cost-saving policy whereby total costs of care for autistic individuals are lower and gains in dependency-free life years are higher. (page 136).

Motiwala, S.S., Gupta, S., Lilly, M.D., Ungar, W.J., & Coyte, P.C. (2006). The cost-effectiveness of expanding intensive behavioural intervention to all autistic children in Ontario. *Healthcare Policy*, 1, 135-151.. (The authors are members of the Department of Health Policy, Management and Evaluation of the University of Toronto, ON).

Meta-Analyses of Magnitude of Effect

"Results suggested that long-term, comprehensive ABA intervention leads to (positive) medium to large effects in terms of intellectual functioning, language development, acquisition of daily living skills and social functioning in children with autism. Although favorable effects were apparent across all outcomes, language-related outcomes (IQ, receptive and expressive language, communication) were superior to non-verbal IQ, social functioning and daily living skills, with effect sizes approaching 1.5 for receptive and expressive language and communication skills. Dose-dependant effect sizes were apparent by levels of total treatment hours for language and adaptation composite scores." (page 387).

Virues-Ortega, J. (2010). Applied behavior analytic intervention for autism in early childhood: Meta-analysis, meta-regression and dose-response meta-analysis of multiple outcomes. *Clinical Psychology Review*. 30, 387-399. (The author is a professor of psychology at the University of Manitoba).

Analyses of the Direct Effect of ABA on Clinically Significant Behavior Disorders

"The available intervention technology is reasonably effective at reducing problem behaviors performed by people with developmental disabilities, including autism. Reductions of 80% or greater were reported in half to two thirds of the comparisons. Reductions of 90% or greater were reported for all classes of problem behavior, and with individuals with all diagnostic labels." (page 429).

Horner, R.H., Carr, E.G., Strain, P.S., Todd, A.W., & Reed, H.K. (2002). Problem behavior interventions for young children with autism: A research synthesis. *Journal of Autism and Developmental Disorders*. 32, 423-446. (The authors are professors at the University of Oregon, the State University of New York at Stony Brook, and the University of Colorado).

"Within the last 8 years, 66 studies with strong or acceptable methodological rigor have been conducted and published. These studies have been conducted using over 500 participants, and have evaluated interventions with different delivery agents, methods, target skills, and settings. Collectively, the results of this synthesis show there is much supporting evidence for the treatment of social deficits in autism." (page 161).

Reichow, B. & Volkmar, F.R. (2010). Social Skills Interventions for Individuals with Autism: Evaluation for Evidence-Based Practices within a Best Evidence Synthesis Framework. *Journal of Autism and Developmental Disorders*. 40, 149-166. (The authors are professors at the Yale University Child Study Center, New Haven, CT).

See Appendix VI for a recent list of all of the relevant independent reviews, as well as a list of many of the N=1 studies.

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Appendix I.

California's Challenge:

In February of 2013, the California Department of Insurance was forced to declare autism a "public health crisis" and propose emergency regulations to prevent health plans from imposing arbitrary limits, denials, or unreasonable delays on medically necessary behavioral health treatment for autism. The Department of Insurance declared that emergency regulations were necessary because of "widespread confusion" among insurers and policyholders regarding California's 2011 autism insurance reform law. The Department also cited California's 1999 Mental Health Parity Act as the basis for taking action, estimating that over 40,000 children are directly affected.

The Department estimated that insurance lapses were costing the state's taxpayers between \$138.8 million to \$197.8 million a year. Insurer denials and delays of mandated treatment were causing substantial harm to the public health and welfare and making enormous and unsustainable demands on scarce governmental finances and services, such as special education and adult habilitative treatment. California health insurers were paying for only 9-13% of autism treatment, leaving taxpayer funded school districts and Regional Centers to bear burdens that they could ill afford.

The Department of Insurance found that appropriately covered behavioral health treatment allowed children with autism to succeed in school, participate productively in family and community activities, obtain gainful employment, and avoid institutionalization as adults, thereby lessening demands on public resources and services over their lifetimes.

The department listed examples of enforcement actions and non-compliance involving the insurance industry's autism-related coverage:

- A market conduct examination of one insurer identified 1,539 instances of improper claims payment practices involving behavioral and speech therapy for autism
- Approximately 1,600 individuals transitioning from Regional Centers to insurers for behavioral health treatment for autism have encountered delays and denials
- In 2012, the cumulative delays across all complaints totaled 12,864 days, or 35.2 years, in obtaining medically necessary treatment

Specifically, in cases where behavioral health treatment was determined to meet the criteria for being medically necessary for the treatment of the defined health condition (autism),

Health Plans would inappropriately impose:

- (1) An annual visit limit; or
- (2) An annual dollar limit when the same limit is not equally applicable to all benefits under the policy.

Health Plans would inappropriately deny or unreasonably delay coverage:

- (1) Based on an asserted need for additional cognitive or intelligence quotient (IQ) testing
- (2) On the grounds that behavioral health treatment is experimental, investigational, or educational; or
- (3) On the grounds that behavioral health treatment was not being provided or supervised by a licensed provider even though the provider in question was certified by the Behavior Analyst Certification Board.

New York's Challenge:

In July of 2013, Governor Cuomo was forced to repair a regulatory error that had blocked children from gaining the insurance coverage for Applied Behavior Analysis (ABA) that had been promised under New York's 2011 autism insurance reform law. The issue involved regulations issued just as the state's autism insurance reform law took effect. The state Department of Financial Services (DFS) required that

ABA practitioners obtain a state license in order to qualify for insurance reimbursement under the new law. However, New York had no such ABA license. Instead, the 2011 law had specified that national certification by the Behavior Analyst Certification Board (BACB) would be the basis for ABA practitioners to provide services in New York. In yielding to intense advocacy pressure, the Department issued a new regulation making clear that BACB certification, as specified under the original 2011 law, would now be sufficient.

The repaired regulations included standards of professionalism, supervision and relevant experience for individuals who provide or supervise behavioral health treatment in the form of ABA. This rule also was necessary to ensure that insurers and health maintenance organizations ("HMOs") establish adequate provider networks and provider credentialing requirements that comply with this rule so that those entities may effectively provide insurance coverage for critical ABA therapy to those individuals diagnosed with ASDs, and for whom out-of-pocket costs for those services are prohibitively expensive.

New Jersey's Challenge:

On March 17, 2013, a legislative hearing was held in New Jersey to examine difficulties encountered by New Jersey families trying to access autism insurance benefits that were supposed to be provided pursuant to that state's 2009 court order and 2010 autism insurance reform statute. Gary Schaer, chairman of the Assembly Financial Services and Insurance Committee, gave insurance officials and disability advocates six months to collaborate on ways to make the law mandating autism treatment coverage more consumer-friendly. Key stakeholders were directed to work to resolve these issues for a further hearing to be scheduled for the fall of 2013. Local advocates are working to develop recommendations to resolve the myriad issues that have impeded full access to the intended benefits, including difficulties in claims procedures, authorizations, network adequacy other issues.

Samples of the testimony heard included:

"I'm a medical doctor and the issues with coding were so involved I had to hire someone to help me," Meredith Blitz-Goldstein, an oral surgeon, told the Assembly Financial Institutions and Insurance Committee.

Gina Pastino, a pharmacologist from Montclair said, "The amount of time that is required is so out of bounds and unreasonable, I've had to take vacation days to take care of some of these things. I can appeal these claims one by one, but at some point something has to change. I am going to go out of my mind."

Appendix II. Individualizing Treatment based upon Child Characteristics

Periodic and accountable behavioral assessment of treatment

The heavy investment in comprehensive therapy will be beneficial, to whatever extent the child achieves the recovery objectives. Should the child begin to show diminished results in this treatment, it is essential to be certain to detect that trend as quickly as possible, and attempt to remediate that; but also to be quick to transition the child on to traditional services if the intensive services can do no better. If treatment falls short of recovery goals, then at the very least, the parents will have been trained to effectively provide the ongoing treatment that the intensive provider will no longer provide. If treatment data shows that the child is maximally benefiting from the level of services provided, then the provider will continue to recommend the medically necessary level of services. The determination of medical necessity can be based upon the following process.

The EIBI provider develops, implements, and evaluates many specific individualized treatment objectives on a weekly basis. However, those weekly ITP objectives are not suitable for determining the ultimate prognosis or cost-benefit analysis of the child's treatment. Nor is it appropriate to expect either the family or the funder to wait 18 months to five years in order to evaluate the results. Therefore, every six months the provider would conduct a comprehensive, multi-modal assessment, which includes an analysis of the child's functional behavior patterns, typical social behavior with the parents, clinical focus of therapy, criterion-referenced progress in a standard set of skills, norm-referenced progress on developmental milestones, independently evaluated progress on standardized assessments, overall rate of acquisition on weekly objectives, timely achievement of individualized benchmarks, treatment condition suitability, diagnostic status, and achievement of standard long-term discharge objectives. Then the provider would make recommendations to the family for the most suitable treatment services for the next six-month term. As part of this comprehensive assessment, the provider would evaluate the child's timely achievement of individualized benchmarks. In the child's case, the provider reports the results of such a multi-modal assessment and the subsequent determination of medical necessity for the next six months, with requests for prior authorization of coverage for treatment.

The Behavior Analyst Clinical Supervisors are heavily engaged in timely, direct observation, assessment, and treatment planning in order to ensure that the treatment is effective. Most of this activity is conducted at the same time as the behavior therapists work with the children. This is because the clinical supervisors must observe and intervene with staff and parent implementation on a weekly basis, in order to direct optimal treatment. The effectiveness of the clinical supervision is significantly weakened without direct observation, and active analysis of the effects of the clinical direction.

Then, every six months the clinical supervisor conducts a comprehensive, multi-modal assessment, which includes an analysis of the child's functional behavior patterns, typical social behavior with the parents, clinical focus, criterion-referenced progress in the standard set of skills, norm-referenced progress on developmental milestones, independently evaluated progress on standardized assessments, overall rate of acquisition on weekly objectives, timely achievement of individualized benchmarks, treatment condition suitability, diagnostic status, and achievement of standard ultimate discharge objectives.

Individualization

Each child presents a unique set of challenging behaviors and skills, and requires highly individualized planning on a weekly basis in order to make progress. The feature of therapy that requires the most individualization is the type and schedule of reinforcement. Reinforcers may be the common type of events that typical children find rewarding, such as hugs, tickles, and songs. But the children that come to us for therapy have very unique and difficult to analyze reinforcers. If the process were simple, parents would not need expensive and demanding therapy in order to make progress. The reinforcer for one child, reading a book, is not at all reinforcing for another child, who prefers being tossed into the air. Tickling works temporarily for a child, but only by a parent, and then only for several minutes before it starts to annoy the child. The forms of stereotypy with preoccupy the children are reinforcers, talking about butterflies, picking at lint, listening to quiet noises. Some complex interactions may be reinforcing. A commonly reinforcing social interaction is oppositional responding – doing the opposite of what is desired by the parent. These complex interactions may be difficult to discern, or the reinforcers may be

fleeting and varied. The therapist will have to be highly skilled in delivering the reinforcer in just the right manner that pleases the child.

Positive Reinforcement

Ninety percent of the effectiveness of the program depends upon using effective reinforcers on an appropriate schedule to increase the child's independence. As such, all staff are highly trained to constantly assess the momentary motivation of the child and use it to increase the rate of learning. The therapy is most effective when the therapist can make sure that no matter what they do; the child is finding success and enjoying inherent satisfaction in what he did, because he is getting the reinforcing consequences that he sought.

If the child at any moment doesn't seem to be interested in the reinforcers being used, the therapist wouldn't even initiate a program until they could locate a motivation that gains the interest and attention of the child. If a sufficient motivator couldn't be found, the staff would ideally direct the child to appropriate independent play until the therapist is able to reinforce the child effectively. Many children, however, at the start of therapy do not play appropriately, so the therapist will then allow the child to engage in stereotyped responding until the therapist is able to effectively reinforce. Therefore, early in therapy the child is receiving many "breaks" from planned interactions. Another long-term process of therapy, though, would be to gradually decrease the length of the non-natural breaks, as the length of appropriate interactions and play is increased. In this manner, stereotyped responding is gradually crowded out of the child's daily life. Even new forms of play can be developed through reinforcement and these new forms of play actually become self-reinforcing in the future through a process known as "conditioned reinforcement."

Typically the therapist would end a break by engaging in an activity with a potential reinforcer that attracts the child's attention. This indicates that the child will be motivated by the activity. The therapist may verify that the activity is a reinforcer by letting the child access the materials. When the child becomes eagerly engaged with the activity, then it can be used as a reinforcer, for as long as it maintains the child's attention. For example, the therapist sits down and spins a top. The child comes to the therapist to play with the top, so the therapist quickly instructs the child, taking advantage of that teachable moment, and reinforces the child's most successful response with some time to play with the top.

Generalization and Maintenance

Generalization is another extremely important process in therapy. Autism is a pervasive disorder, meaning that the child will be challenged by his autistic behavior patterns throughout his day. He is as likely to be distracted by asking his mom about the toy store the first thing in the morning as the last thing at night and all day in between – to the exclusion of engaging in other conversations. If we were to provide a traditional model of speech therapy to remediate this, by working for half an hour, three days a week, at the clinic, the therapist may be very effective during that half hour, but when he comes home, the parents are going to see very little generalization from that therapy to home; because at home, he's practicing these other pervasive behaviors. So we want to train the parents to follow through with the same therapy as the staff, and we want to do more hours of the therapy throughout the day, so that the responses we are teaching generalize throughout his day. Then we further plan the therapy to generalize from the teaching activities to related, nontherapy activities of the day. There are a large and individualized variety of such generalization procedures that we use with each child. We use a sufficient variety of materials in therapy, so that the child is likely to generalize to yet another material without prompting. We use a variety of statements in our language programs. We use a variety of staff and locations. We use errand, compliance, fading, momentum, delay, and modeling procedures to establish spontaneous responses in novel situations. We begin conversations in as many different forms as possible, so that he doesn't just respond to a single form of initiation. We want to use as many therapists as possible, so that he doesn't just respond to his mother and two therapists, but that he will generalize to any one who approaches him, including other young children.

These newly taught and generalized behaviors will be maintained without requiring specialized therapy, if the therapy is designed to fit into the ecology of his environment. All day long, the child is either practicing autistic behaviors or social behaviors, and he's getting consequences for both. We can pull him

out of his typical day, and practice new behaviors in isolation, and not see them maintained without our constant attention. So we must then program similar behaviors into his regular activities, in a way that results in reinforcement that naturally occurs in his regular life, so that the skills will be maintained without therapy. Training the parents is one way to accomplish this. Another is to develop skills, such as requesting reinforcers, which will effectively recruit natural reinforcement.

So again using the example of conversations, after teaching the skill, we make sure that he's getting reinforced the rest of his day when he initiates a conversation. We train all of his regular care providers to give him the same kinds of rewards for the same form of conversation as he's currently mastered in therapy. The natural reinforcement, being his real life, is more important to the long-term survival of the new skill, than is the structured therapy. As we design the conversational skills, we must design skills that fit into natural rates of reinforcement, rather than conversational skills that are too brief or too long for natural reinforcement to occur, for example.

24-hour-a-day therapy

This brings us back to the importance of parent training. Even when you talk about a 40-hour-a-week therapy program, the parents are with the child four times as much, 168 hours per week. A majority of the children with whom we work even have critical sleep disorders that require remediation in order to accomplish the best outcomes. So the best our 40-hour program can do is to provide some help to the parents as they engage in much more and more important therapeutic time. The planned therapy time is very demanding. There is a lot that needs to be taken into account: managing a child's motivation, planning out the immediate procedures, fading out prompts to avoid dependency, data collection, etc. We don't even want our professional staff to typically work more than three hours at a stretch, in order to keep their intensity up. Many parents have tried to be the primary therapist due to lack of funding and they typically burn out when doing so. Therefore we usually expect only three to five hours per week of planned therapy time by the parents, primarily for training purposes, and focus then on more relaxed follow-through the rest of the day. Still, some procedures, such as compliance training, toilet training, or sleep programs will require a great deal of diligence round the clock by the parents.

Because of the highly complex effects of reinforcement and the complex planning required to make progress with the many skills, the therapy is only going to obtain the best outcomes if it is consistently implemented in all of the child's social interactions. Therefore, the process of intensive early intervention is one of transforming the child's 24-hour day into a consistent therapeutic environment. Less than complete consistency is likely to have negative effects. The intensity of the staffing is necessary in order to train and support the parents to function as professional behavior therapists for the typical three years of therapy.

Other, more advanced procedures involve complex social contingencies such as cooperation, competition, advanced observational learning, and responsive tutoring. These procedures are used on an individualized basis to increase the fundamental social motivation and resulting development of individual children.

The child who has a prognosis for best outcomes is not a child who has simple cognitive deficits. Instead, it is a child whose challenging behavior patterns interfere with normal development. If we can identify these challenging behavior patterns and remediate them, then the child will be free to develop normally and will attain the best outcomes. Common challenges are forms of noncompliance, preoccupation with stereotyped stimulation, avoidance of stimulation, attention-getting, sleep deprivation, or withdrawal. These are challenging behavior problems that prevent normal learning, but which can often be remediated with behavior therapy.

Medical Treatment and Special Education

In some cases, the question has been raised whether the treatment should be delivered in school through special education, or whether it should be home-based therapy. Because autism is a medical disorder that is being heavily researched for its biological origins and cures, it is clearly something that should be treated medically. It is considered a mental health disorder by the American Psychiatric Association in the DSM-5, and by the World Health Organization in the ICD-9.

The deep meaning of this is that autism is not effectively treated by only providing some academic skills or special education in school. Autism requires 24-hour therapy in order to treat the pervasive behavioral deficits and skill deficits that cause the child to fail to function in regular daily life. ABA research has clearly shown that the significant stereotyped behaviors interfere with normal development, and that it takes consistent 24-hour behavior therapy to remediate them. ABA research has also clearly shown that children with autism typically suffer from significant self-care deficits in essential areas such as eating, sleeping, and toileting, and that it takes consistent 24-hour behavior therapy to remediate these symptoms. Similarly, while simple language and social skills can be taught in structured, "pull-out" sessions during the school day, the child with autism does not start pervasively using these skills in a natural way until the skills are developed and generalized in 24-hour natural treatment by the parents and all regular care-providers. This 24-hour-a-day, 7-day-a-week, 365-day-a-year, behavior therapy is essential to successfully treat autism. As a result of these needs, we have learned that we must clearly identify a clinical focus of behavior therapy in order to successfully treat the core symptoms of autism, rather than only directly teach the necessary skills for functioning.

School districts do not provide 24-hour special education programs. But they do play a role in providing the necessary adapted academic training to support this treatment, while the child is in school. And for some children, the parents' only goals are the special educational adaptations. Those adaptations are certainly worthwhile for the children.

Reviewing the Research in Applied Behavior Analysis

In the field of Applied Behavior Analysis, much is known about intensive early intervention. Here we will review some of the areas of study, which are necessary to form a complete evaluation of intensive early intervention with behavior therapy.

The fundamental body of research in Applied Behavior Analysis is comprised of the molecular single-subject studies of the immediate effects of an environmental manipulation upon the behavior of an individual (Baer, Wolf, & Risley, 1968). Only these clinical experiments can successfully analyze the specific effects of therapy upon individual behavior patterns. There are several hundred of these single-subject studies of effective interventions that are relevant to intensive early intervention. These studies have been conducted all across the world in many university research centers.

An example of such a molecular study would be a study of conversational skills, in which the behavior of six children was analyzed over a period of three months. The researchers identified the target conversational skills of the intervention and also defined the treatment procedure that was designed to improve the children's conversational skills. The researchers then collected baseline data on each of the children's patterns of conversational behavior to clearly assess each child's problems in learning conversational skills. After this data was clearly assessed, the researchers then individually applied the form of intervention best suited to each child, and tracked the results of the interventions across several variations over the three months. As a result, the researchers were able to show which techniques were most effective with the various challenging behavior patterns for each child. The researchers could then draw conclusions about how to individualize therapy for various children's conversational skills.

Behavior analysts are currently using such methods to study all kinds of human behavior. The effectiveness of interventions in business, crime, shopping, education, etc. is being studied around the world by numerous behavior analysts. Where ever persons are behaving, the effects of changes in the environment upon those behaviors can be studied.

Over the past 40 years, behavior analysts have similarly studied the treatment of all of the diagnostic features of autism, as well as the systems issues which must be addressed, in order to successfully treat autism. Taken as a whole, this research describes a package of interventions for successfully treating all of the clinical challenges of autism. For example, there are over 39 salient studies of the use of positive reinforcement to remediate stereotyped, repetitive behavior; 31 studies of the effects of structure on stereotyped, repetitive behavior; 18 studies of the development of social compliance; 42 studies of effective teaching strategies; 29 studies of generalization of treatment gains; 19 studies of the development of imitation skills; 28 studies of the development of basic language skills; 32 studies of the development of complex language skills; 31 studies of the development of social play skills; 18 studies of

the development of creativity and spontaneity; 32 studies of the development of social conversation skills; and 26 studies of the development of group and classroom skills. The diversity of the effects of these studies suggests the generality of the procedures employed, through systematic variation of treatment conditions and settings.

These molecular studies are the foundation of Applied Behavior Analysis and can not be ignored when discussing outcome evaluation. Further areas of study depend upon this foundation in order to make meaningful conclusions.

As a specific example of these molecular studies, let's look at the study of language development. The primary mechanism in human language development is imitation. Children learn to speak by imitating the language of their parents. If a child is growing up in Greece, they learn to speak Greek; in Great Britain, they learn to speak English, because that is what they hear their parents say. In addition, they learn all of the communicative nuances, gestures, and inflections, accents that their parents also model. To my northern ears, it seems strange, but cute, that a little child growing up in Alabama is using a southern accent, complete with all of the style and exuberance of their accent, but that is what is being modeled for them.

Children with autism, however, may be so absorbed in their stereotyped behavior that they don't even learn how to imitate others. Or if they do imitate, they may not imitate very accurately, the way a typical two-to-three-year-old can do extremely well.

So our primary goal in teaching language to a child, whether they come to us mute (as half the children do) or with some stereotyped speech, is to teach them to speak in the typical style of their culture, as a typical child in first grade would speak. Of course, if a child is mute, we can't wait around all day hoping that they speak a word to be reinforced; nor can we reach into their mouth to prompt a word and then reinforce it. One of the secrets of behavior therapy is that, we would first teach the child to imitate, and then use that skill of imitation to teach them first to speak, and then to use the relatively sophisticated nuances of communication.

Here's an example of a specific imitation study, conducted by Baer, Peterson, and Sherman in 1967. What those researchers found was that not only were they able to establish a procedure for teaching the children to imitate specific behaviors through discrete-trial training; but that by teaching the children to imitate a sufficient variety of behaviors, clapping, stomping, waving, that the skill of imitation then generalized to other, untaught behaviors, twisting, jumping; behaviors that were never originally prompted or reinforced. Then they found that when they ceased to reinforce the original imitations, the children stopped performing the behaviors that had never been reinforced either. And when they began to reinforce the original imitations again, the children began again to imitate all behaviors, whether reinforced or not. This showed that imitation itself was a class of behavior or a skill in its own right, and the separate behaviors were just instances of the skill of imitation.

The process where a therapist can teach a skill by prompting and reinforcing individual behaviors until the child generalizes to untaught behaviors is the very important process of generalizing through multiple exemplars. This type of generalization allows the child to develop concepts and language skills that are never directly taught. The child's skill is now not directly dependent upon the therapy, and he can learn independently.

When the child has mastered the skill of generalized motor imitation, he'll copy anything he sees the therapist do. The child will also now very likely imitate the vocal behavior of the therapist, behavior that the therapist couldn't originally prompt. Now the therapist can say, "ball," and the child will imitate. The therapist can say, "ball" in the presence of a ball and then reinforce the child's spontaneous label of the ball. And the therapist can give the child a ball when he spontaneously says, "ball," so now the child is learning to effectively request what he wants.

The next step in evaluation of the package of interventions for autism is to examine the success of training staff and parents to use the interventions. We have been able to review 41 studies of staff and parent

training procedures. In addition, 8 studies were reviewed which involved the study of the dissemination of a comprehensive intervention package to new providers and parents. An additional evaluation is the use of consumer and social validation measures of the intervention. Many of the studies include these consumer and social validation measures of the specific clinical procedures.

In addition to a thorough molecular evaluation of the treatment package, molar long-term outcome studies have also been conducted to evaluate the effects of the comprehensive treatment package. We have been able to review 13 such molar studies of intensive early intervention, although the scope of these studies varies widely. In general, in these studies, the researchers study the progress of a group of children from the beginning to the end of therapy several years later, in order to demonstrate the long-term effects of the therapy. These studies are not suited to analyzing the best form of clinical treatment for each child, but do allow consumers to judge the overall significance of the treatment package.

Because of the nature of outcome studies, single-subject methods are not sufficient to answer the relevant questions. Traditional between-group studies are necessary to compare the natural incidence of developmental progress with the outcomes produced by the intervention being studied. But, as stated above, within the field of Applied Behavior Analysis, between-group studies cannot stand alone. They can only be evaluated within the context of the breadth of research described above.

In a series of outcome studies conducted by Lovaas et. al. of the University of California at Los Angeles, the following results were found. 90 percent of children with autism spectrum disorders improved to the point that independent evaluators agreed that the result was worth the intensity of intervention. During treatment, scores of mental age, language, social, preacademic, and self-care skills typically doubled on standardized assessments, while challenging behaviors reduce to clinically insignificant levels. All children developed vocal language skills. Further, 47 percent of the children were able to be placed into a regular first-grade class, functioning normally, without the need for special educational supports and also attained a normal IQ score by the age of seven years. These children were also found to be indistinguishable from their natural peers in first grade and will maintain those gains until adulthood. In control groups, however, only four percent of the children have been found to recover without intensive intervention.

This is the best study that systematically varies the parameters of the treatment package. This study (Lovaas, 1987) compared the effectiveness of 40 hours per week of exclusive behavior therapy over an average of two years, followed by one year at an average of 10 hours per week of therapy; with a second group which received up to 10 hours per week of behavior therapy in addition to traditional therapies and school services. While striking differences were found, the control group has been criticized due to partial lack of random assignment. However, when this criticism was initially raised prior to publication, the author obtained comparison data from a completely independent source to demonstrate the natural likelihood of similar outcomes. This additional comparison group, the membership of which could not be manipulated by the author, would seem to serve the needs of the random assignment condition, as far as logical analysis is concerned.

Another criticism has been that the Lovaas (1987) study focused on children with high IQ's. Lovaas did include a cutoff of 30 or higher at the age of 30 months in order to distinguish between autism spectrum disorders and mental retardation, which often co-occur. Even so, the cutoff of 30 only requires the child to attain a single item in typical IQ tests, as 30 is often below the lowest possible IQ score on most accepted tests. 85 percent of children with developmental disabilities have IQ's above 30 at 30 months. A review of the effects of IQ upon best outcomes found a correlation of .58.

Other prognostic markers were also found to be important. All children were not using functional words, and were showing substantial amounts of stereotyped behavior and social deficits by the age of 24 months. At the age of 30 months, each child was estimated to have had a developmental index (or intelligence quotient) of between 30 and 70. If a child had few verbal skills, they initiated intensive intervention by 40 months of age. If they had language, but it was dominated by stereotyped forms, they initiated intensive intervention by 48 months of age. If a child's mental age score was no more than 10 months at 30 months of age, they were not likely to reach a developmental level such that they may be placed into a regular first-grade classroom without special services.

All children had parents who participated in therapy, mastering all therapy skills, providing an average of five hours of structured therapy per week, and generalizing the therapy throughout the child's day.

Children who attained the best outcomes were able to pass the early learning measure (learning ten new skills in each of the areas of motor and vocal imitation, receptive commands, and expressive labeling) by the end of the fifth month of therapy. They then continued to make six months of developmental progress in each of the subsequent six-month periods. Their parents continued to participate in structured therapy, and they maintained 40 hours per week of structured therapy throughout the program, until being faded into regular kindergarten classes.

The children who did not fully recover from their symptoms by first grade still made large gains; six percent recovering at a later age, and 32 percent requiring only mild special education services (percentages out of the original 100). Eleven percent of children who receive intensive therapy at an older age have been found to attain very good outcomes and 79 percent made substantial gains that were commensurate with their individual prognosis at intake. However, children who have received less intensive services have typically failed to show any greater improvement over that of control groups.

In 1993, a follow-up of the 1987 study showed that eight of the nine children who had attained the best outcomes were able to maintain these gains through elementary school, and one of the ten who had failed to attain best outcomes by first grade, had done so by sixth, with further intensive treatment (McEachin, Smith, & Lovaas, 1993). Continued follow up of these children shows maintenance of gains through early adulthood (Lovaas, 1999).

In a review of the further outcome studies, the largest results were clearly associated with the most intensive programs. For example, one study which evaluated largely center-based treatment with limited home-training, limited hours per week, and for limited calendar time (Anderson et. al., 1987), produced clearly less substantial results than the program with much more home involvement, hours per week and extended calendar time (Lovaas, 1987). This program of limited services is typical of standard services by today's traditional providers. Further, long-term program evaluations of low intensity, eclectic services, such as the TEACCH model, have consistently concluded that cognitive measures such as IQ were not affected by eclectic treatment (Freeman, Rahbar, Ritvo, Bice, Yokota, & Ritvo, 1991; Lord, & Schopler, 1989; Venter, Lord, & Schopler, 1992).

In summary, a complete behavior analysis of a comprehensive treatment package requires much more than a simple accounting of treatment hours over a long-term outcome evaluation. A complete evaluation begins with and must focus on the molecular behavior analyses of specific interventions. Then an analysis of the relative value of major components of the package, long-term follow-up of the maintenance of treatment effects, evaluation of the success of training staff and parents to use the package, evaluation of consumer and social validity of the effects of the package, and evaluation of dissemination and replication of the package must be undertaken. In addition, measures of treatment fidelity should also be reported. Finally, the cost-effectiveness of treatment intensity should be analyzed according to the long-term impact of the intensity of treatment. Each of these studies have been completed in the field of Applied Behavior Analysis in Intensive Early Intervention.

Considerations When Transitioning a Child into a Community or School Setting

As a result of the above, it is essential to carefully transition a child into a community or school setting to ensure that the treatment gains are generalized and maintained. The following considerations and procedures are individualized as necessary to greater and lesser extents for each child.

The goals of the placement. The placement will normally be an attempt to mainstream the child into a typical classroom, generalize skills learned in therapy to an outside environment, work on socialization with other children, and learn more group-oriented behaviors, all while maintaining the behavioral control over challenging behaviors that has been established in the home.

Prerequisite skills of the child. Some skills that are necessary in order for the child to benefit from a school setting would be the following:

- Expressive language necessary to complete 80% of the classroom activities.
- Behavioral control over any overly interfering behavior problems (e.g. high level of aggression or disruptive tantrums).
- Compliance with 80% of all transitional demands and individual instructions needed for the classroom.
- Sufficient independent play skills to begin succeeding with peers.

The optimal classroom.

- A classroom size of 15 or less for children who may require one-to-one supervision.
- A structure that includes transitions between activities that are clear and activities that have clear expectations.
- Cooperative teachers who are receptive to training and flexible in structure to accommodate the child's behavioral needs.
- Appropriate peer models of an appropriate age and skill level.

Optimal schedule flexibility

The child will most likely begin slowly and gradually increase the number of hours in which they attend school. An ultimate schedule will consist of the entire week and the entire school day, depending upon how much the child is benefiting from the school environment.

Sufficient case management

The clinical supervisor will need to meet with the administration and teachers of the school on a sufficient frequency to ensure that the school understands and accepts the procedures, and implements them consistently. This may involve:

- Modifying the curriculum to maintain the child's success.
- Using the least intrusive prompts and fading them appropriately.
- Avoiding inadvertent reinforcement of noncompliance or stereotyped behaviors.

General procedure for transitioning control from the therapist to the teacher.

- The therapist pre-teaches and then follows through with instructions from the teacher.
- The therapist prompts the child to attend to the teacher prior to the initial instruction so that the child can respond on the first trial.
- The therapist facilitates social interactions with other children.
- The therapist serves as a liaison between school and home so that skills needed for school can be incorporated into the home program and vice-versa.

Dynamic program management.

- The clinical supervisor designs program transition steps to ensure 80-90% success with each daily activity, and gradually increases the time in programming and the level of demands to keep the child at that level.
 - On a weekly basis, the clinical supervisor evaluates the success of the current programming and modifies the expectations in order to move the child as rapidly as possible to independence.
 - The clear goal is that the child will no longer require behavior therapist intervention by the end of the first year of transition.
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Appendix III. Samples from potential standard assessment tools for comprehensive ABA and for focused ABA.

Comprehensive ABA Discharge Assessment

ABA Treatment Outcome Discharge Objective Assessment

The following assessment of 41 ABA Discharge Objectives can be used to determine the medical necessity of treatment. Children who are eligible for ABA treatment should require the mastery of one or more of these objectives. Treatment will be concluded when the targeted objectives from this assessment is mastered. Individual objectives may be customized to address the unique needs of individual children.

The accompanying behavior assessment checklist may be used to obtain a periodic severity score for these objectives. Next to each objective place the score for severity of need (0-7 as scored on the assessment). At the bottom, give the total severity score.

Child: _____ Behavior Analyst: _____ Date: _____

_____ Total Severity Score (0 - 287).

Receptive Language, the child will understand and comply with instructions.

- _____ Generalized compliance. Throughout the day, the child will comply with at least 90 percent of novel instructions the first time given within an appropriate time limit for the response, as measured by the first four novel instructions given during two daily one-hour assessments for two consecutive weeks.
- _____ Distal compliance. When at least 25 feet away from an adult who gives an instruction to complete a familiar ten-step generalized task, the child will accurately complete the task while remaining over 25 feet away in three consecutive assessments.
- _____ Respond to novel adults. When an unfamiliar adult gives eight different instructions from the Receptive Language area, the child will comply appropriately to seven of the eight across two consecutive novel adults on separate assessments.
- _____ Comply with group instructions. When in a group of five or more natural peers and presented with an instruction given to the group, the child will comply within the time required by the natural peers on three of three opportunities during three consecutive assessments.
- _____ Learn without specialized therapy. When in a natural activity and given a single receptive instruction and prompt without the use of targeted reinforcement, the child will acquire the correct response, generalize to a novel exemplar, and maintain the generalized response across each of two consecutive days, in nine out of ten consecutive assessments.

Expressive Language, the child will use functional language with care-providers and natural peers.

- _____ Intelligible speech. When speaking to an unfamiliar adult, the child will speak audibly and intelligibly enough to be clearly understood in nine of ten consecutive sentences in three consecutive assessments.

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- _____ Generalized speech. When given a variety of comprehension questions mixed in random fashion in a natural activity, the child will answer 18 of 20 correctly on five consecutive assessments.
- _____ Colloquial speech. When speaking to natural peers in a natural activity, the child will use at least five instances of natural speech forms including contractions, slang, and common phrases and avoid all instances of excessively formal language or jargon in five 30-min assessments.
- _____ Creative story telling. When instructed, the child will tell a ten-part story creatively, but within reasonable contextual limits according to the judgment of the care-provider and using appropriate sentence structure on five of five consecutive assessments.
- _____ Attain typical developmental milestones. When assessed with the Learning Accomplishment Profile, the child will attain all of the developmental items for a child of the child's chronological age in months.

Pro-social skills, the child will interact appropriately with natural peers.

- _____ Joint attention. When in a free play activity with typical peers and a peer calls attention to a toy, item, or activity, the child will readily look at the toy, item, or activity, comment meaningfully, and respond accurately to any follow-up comment of the peer on at least three occasions in three consecutive assessments.
- _____ Generalized imitation. Throughout the day, the child will imitate at least 90 percent of novel models the first time given within an appropriate time limit for the response, as measured by the first four novel models given during two daily one-hour assessments for two consecutive weeks.
- _____ Independent observational learning. When presented with a novel ten-step play activity involving verbal and motor steps in a natural setting and told to observe, the child will accurately learn the novel activity by demonstrating appropriate generalized play in a similar situation, on three consecutive assessments.
- _____ Cooperative play with adult. While playing with the same collection of toys with an adult within three feet, the child will play cooperatively with the adult by looking at items to which the adult refers, instructing the adult, complying with the adult's instructions, congruently imitating the adult's physical play, congruently imitating the adult's play statements, reciprocating the adult's statements, making spontaneous statements to the adult, asking questions of the adult, answering the adult's questions, and demonstrating play to the adult, showing at least ten instances of these behaviors within five minutes without prompting on three consecutive assessments.
- _____ Cooperative play with a typical age-peer. While playing with the same collection of toys with a peer within three feet, the child will play cooperatively with the peer by looking at items to which the peer refers, instructing the peer, complying with the peer's instructions, congruently imitating the peer's physical play, congruently imitating the peer's play statements, reciprocating the peer's statements, making spontaneous statements to the peer, asking questions of the peer, answering the peer's questions, and demonstrating play to the peer, showing at least ten instances of these behaviors within five minutes without care-provider contact on three consecutive assessments.
- _____ Congruent social play. While playing with three to four natural peers, the child will display ten behaviors identical to those of the peers in magnitude, and no behaviors that are not identical in magnitude, on three of three consecutive ten-minute observations.
- _____ Social responsiveness. When in a novel natural play activity with peers, the child will effectively give play-organizing statements with appropriate timing and discretion, in five consecutive assessments.
- _____ Small-group attending. When in a small-group activity with at least four natural peers, and six 30-second demonstrations of a relevant activity by the peers, the child will watch five of the activities with no more than two glances away and accurately answer a comprehension question about each on each of three consecutive assessments.
- _____ Large-group attending. When in a large-group activity with at least twelve natural peers, and six 30-second demonstrations of a relevant activity by the peers, the child will watch five of the

Focused ABA Behavior Assessment

Clinical Focus Assessment of Behavior which Interferes with Natural Development

Page 2

BEHAVIORS**A. VERBAL AGGRESSION**

1. Verbal Aggression To Peers.
2. Threatens Peers.
3. Starts Fight.
4. Verbal Aggression To Adults.
5. Threatens Adult.

B. STEREOTYPED SPEECH

1. Repetitive Speech.
2. Lack of Context.
3. Echolalia.
4. Loud Talk.

C. STEREOTYPED BEHAVIOR

1. Tantrums.
2. Inappropriate Use of Materials.
3. Stereotyped Motor Behavior.
4. Misuse of Clothing.
5. Stereotyped Noises.
6. Hoarding.
7. Indiscrete with Body.
8. Stereotyped Walking.
9. Stereotyped Acting Out of Feelings.
10. Not Toilet Trained.

D. SELF-INJURIOUS BEHAVIOR

1. Rumination.
2. Pica.
3. Bruxism.
4. Dangerous Climbing.
5. Self-Injury with Objects.
6. Mouthing.
7. Emitus.
8. Body Abuse.
9. Starvation.
10. Suicidal Threats.

E. ISOLATE BEHAVIOR

1. Positioning.
2. Excessive Watching.
3. Excessive Sleeping.
4. Unresponsive.
5. Incongruent Affect.

6. Lethargy.
7. Withdrawal.

F. PHYSICAL AGGRESSION TO OTHERS

1. Hurts Peers.
2. Using Objects on Peers.
3. Upsets Peers' Objects.
4. Inappropriate Touch of Peer.
5. Rape.
6. Mouths Peers.
7. Hurts Animals.
8. Hurts Adult.
9. Using Objects Against Adult.
10. Upsets Adults' Objects.
11. Mouths Adults.
12. Inappropriate Touch (Adult).

G. PROPERTY DESTRUCTION

1. Damages Clothing.
2. Damages Possessions.
3. Damages Materials.
4. Damages Furnishings.
5. Fire-Setting.

H. NONCOMPLIANT BEHAVIOR

1. Tantrums When Touched.
2. Physically Resists Touch.
3. Verbally Resists Touch.
4. Physically Resists Physical Guidance.
5. Verbally Resists Physical Guidance.
6. Resists Food.
7. Does Not Imitate.
8. Limited Eye Contact.
9. Passive Noncompliance.
10. Delayed Response.
11. Incomplete Response.
12. Opposition.
13. Refuses.
14. Refuses to Participate.
15. Argues.
16. Aggresses to Peer.
17. Aggresses to Adult.
18. Damages Object.
19. Noncompliant Tantrum.
20. Tantrums when Refused.

21. Tantrums when Corrected.

I. DISRUPTIVE BEHAVIOR

1. Indirect Danger.
2. Indirect Disruption.
3. Steals.
4. Blocks Passage.
5. Direct Disruption.
6. Disrupts Group.

J. DEPENDENT BEHAVIOR

1. Hyperactive.
2. Not Engaged.
3. Incomplete Work.
4. Perseveration.
5. Overselectivity.
6. Limited Schedule Following.
7. Fails Errands.
8. Avoids Stairs.
9. Avoids Places.
10. Wanders.
11. Bolts.
12. Sleep Disruption.
13. Inadequate Diet.

K. DYSFUNCTIONAL SOCIAL BEHAVIOR

1. Hides Face.
2. Limited Sharing.
3. Avoids Peers.
4. Avoids Adult.
5. Acts Silly Excessively.
6. Inappropriate Style of Communication.
7. Selective Mutism.
8. Noncontextual Conversation.
9. Excessively Asks For Praise.
10. Vomits When Upset.
11. Cries Easily.
12. Negative Self-Talk.
13. Passive.
14. Denies Responsibility.
15. Submissive.
16. Rigidity.
17. Inappropriate Touch.
18. Does Not Differentiate.
19. Inappropriate Boundaries.

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Appendix IV: Costs of Autism

Effective treatment of autism saves money this year, not just over the child's lifetime.

The following studies of the financial impacts of the autism treatment mandates prove that access to effective ABA reduces medical costs this year and every year.

How could this be?

Medical treatment for children with autism is far more expensive every year than is medical treatment for typical children. For example, a child with autism may not comply with daily dental care, and also not comply with dental visits. So parents will resort to hospital-based services. The bill for a teeth-cleaning procedure that requires anesthesia can be up to \$10,000.

- o ABA can effectively prevent the need for such costly procedures, by training and desensitizing the child's compliance with normal medical procedures.
- o ABA also can develop the child's compliance with medication regimens.
- o ABA can also develop the child's compliance with basic health routines – eating, toileting, sleep, and safety.
- o ABA can also eliminate challenging behaviors that normally would be managed by medications.

The following study shows *the important immediate cost savings from enacting a mandate that gives parents access to effective ABA services.*

78% of families with a child with autism reported having health care expenditures for their child for the prior 12 months.

Among these families, 54% reported expenditures of more than \$500, with 34% spending more than 3% of their income.

However, families living in states that enacted legislation mandating coverage of autism services were 28% less likely to report spending more than \$500 for their children's health care costs.

And families living in states that enacted parity legislation mandating coverage of autism services were 29% less likely to report spending more than \$500 for their children's health care costs.

Parish, S., Thomas, K., Rose, R., Kilany, M., & McConville, R. (2012). State Insurance Parity Legislation for Autism Services and Family Financial Burden. *Intellectual and Developmental Disabilities*. 50, 190-198.

And this is all in return for not increasing the cost of care. Traditional services in Minnesota cost \$60,000 for the care of a high-utilization child. ABA services in Minnesota are estimated to cost \$65,000 per year for the same child in the State of Minnesota 2013 fiscal note. The ABA services replace the traditional services for a net increase in ABA cost of \$5,000. However, at the same time, the immediate savings from eliminating unnecessary medical care are at least \$5,813 per year, in the following studies, resulting in a net savings to the medical system this year for the 909 children currently served in Minnesota, of \$739,017.

The following national studies document the average medical costs of autism every year.

CDC, 2012:

The average annual medical costs for Medicaid-enrolled children with an ASD were \$10,709 per child, which was about six times higher than costs for children without an ASD (\$1,812). \$8,897 more.

The average annual medical cost was \$8,897 more than for a child without ASD.

Children with an ASD and none of the co-occurring conditions had average medical costs of about \$7,200.

Children with an ASD and ID had average medical costs of about \$19,200.

Children with an ASD and epilepsy had average medical costs of about \$11,900.

Children with an ASD and ADHD had average medical costs of about \$9,500.

(Among children with an ASD, about half had at least one of the three commonly co-occurring conditions: ADHD, intellectual disability, or epilepsy.)

(Researchers identified children who were enrolled in the Medicaid Multi-State Databases. A total of 1,472,781 children 2 through 17 years of age were included in the study, 8,398 of whom were diagnosed with an ASD. Children with an ASD, as well as ID, ADHD, or epilepsy, were identified using the ICD-9.)

Peacock, G., Amendah, D., Ouyang, L., & Grosse, S. (2012). Autism spectrum disorders and health care expenditures: the effects of co-occurring conditions. *Journal of Developmental and Behavioral Pediatrics*. 33, 2-8.

CDC, 2008:

Individuals with an ASD had average medical expenditures that exceeded those without an ASD by \$4,110–\$6,200 per year.

On average, medical expenditures for individuals with an ASD were 4.1–6.2 times greater than for those without an ASD.

The average cost of medical expenditures for children with ASD was \$5,155 every year. This was \$4,155 more than for those without an ASD.

Shimabukuro, T., Grosse, S., & Rice C. (2008). Medical expenditures for children with an autism spectrum disorder in a privately insured population. *Journal of Autism and Developmental Disorders*. 38, 546-552. Epub 2007 Aug 10.

University of Rochester, 2006:

Children with ASD had more outpatient visits, physician visits, and medications prescribed than children in general. They spent more time during physician visits than other children. Annual expenses for children with autism spectrum disorder (\$6,132) were more than for other children (\$860). This was \$5,272 more than for those without an ASD every year.

Liptak, G., Stuart, T., & Auinger, P. (2006). Health Care Utilization and Expenditures for Children with Autism: Data from U.S. National Samples. *Journal of Autism and Developmental Disorders*. 36, 871-879.

University of Michigan, 2006:

Autism prevalence among children aged 3 to 17 years was 53 per 10,000 equating to a national estimate of 324,000 children.

Children with autism had a significantly higher prevalence of depression anxiety problems (38.9% vs. 4.2%)

They also had more behavioral problems (58.9% vs. 5.2%) than children without autism.

Respiratory, food, and skin allergies were more often for children with autism.

Children with autism had significantly higher mean physician visits over 12 for preventive care, nonemergency care, and emergency care, and were far more likely than without autism to receive physical, occupational, therapy (76.0% vs. 6.3%),

Children with ASD were more likely to need treatment or counseling for an emotional, developmental, or behavioral problem (75.4% vs. 7.0%),

And, among those taking prescribed medication, children with ASD were more likely to be using a medication (51.4% vs. 14.5%).

(Cross-sectional analysis of the 2003 to 2004 National Survey of Children's Health.)

Gurney, J., McPheeters, M., Davis, M. (2006). Parental Report of Health Conditions and Health Care Use Among Children With and Without Autism: National Survey of Children's Health. *Archives of Pediatric and Adolescent Medicine*, 160, 825-830.

Kaiser Foundation Research Institute (2006):

Children with autism spectrum disorders had a higher annual mean number of total clinic (5.6 vs. 2.8), pediatric (2.3 vs. 1.6), and psychiatric (2.2 vs. 0.3) outpatient visits.

A higher percentage of children with autism spectrum disorders experienced inpatient (3% vs. 1%) and outpatient (5% vs. 2%) hospitalizations.

Children with autism spectrum disorders were nearly 9 times more likely to use psychotherapeutic medications and twice as likely to use gastrointestinal agents than children without autism spectrum disorders.

Mean annual member costs for hospitalizations (\$550 vs. \$208), clinic visits (\$1,373 vs. \$540), and prescription medications (\$724 vs. \$96) were more than double for children with autism spectrum disorders compared with children without autism spectrum disorders.

The mean annual age- and gender-adjusted total cost per member was more than threefold higher for children with autism spectrum disorders (\$2,757 vs. \$892). \$1,865 more.

Among the subgroup of children with other psychiatric conditions, total mean annual costs were 45% higher for children with autism spectrum disorders compared with children without autism spectrum disorders; excess costs were largely explained by the increased use of psychotherapeutic medications. Data included all children enrolled in the Kaiser Permanente Medical Care Program in northern California between July 1, 2003, and June 30, 2004.

Croen, L., Najjar, D., Ray, G., Lotspeich, L., & Bernal, P. (2006). A Comparison of Health Care Utilization and Costs of Children With and Without Autism Spectrum Disorders in a Large Group-Model Health Plan. *Pediatrics*, 118;e1203-e1211.

University of Pennsylvania, 2006:

The total average annual cost of children with ASD in Medicaid receiving mental health services was \$9,980.

The total average annual cost of other children in Medicaid receiving mental health services was \$1,102. Children with ASDs cost \$8,878 more than children without ASDs every year.

Mandell, D., Cao, J., Ittenbach, R., & Pinto-Martin, J. (2006). Medicaid Expenditures for Children with Autistic Spectrum Disorders: 1994 to 1999. *Journal of Autism and Developmental Disorders*, 36, 475-485.

University of Michigan / Blue Cross Blue Shield of Michigan, 2004:

People with autism incur about \$306,000 in incremental direct medical costs, implying that people with autism spend twice as much as the typical American over their lifetimes and spend 60% of those incremental direct medical costs after age 21 years.

The typical American spends about \$317,000 over his or her lifetime in direct medical costs, incurring 60% of those costs after age 65 years.

People with autism cost \$4,250 per year more than people without every year.

Alemayehu, B. & Warner, K. (2004). The lifetime distribution of health care costs. *Health Service Research*, 39, 627-642.

Other costs are also saved each year.

Harvard University, 2007:

Fathers of children with lower levels of disability were assumed to be unemployed 10% of the time (and working full-time during the remaining 90%) and mothers were assumed to be unemployed 55% of time (and were working half-time 25% of the time and full-time, 20%). Fathers of children with higher levels of disability were assumed to be unemployed 20% of the time and mothers were assumed to be unemployed 60% of time (and were working half-time 30% of the time and full-time, 10%).

Ganz, M.L. (2007). The lifetime distribution of the incremental societal costs of autism. *Archives of Pediatric and Adolescent Medicine*, 161, 343-349.

Bank One / Northwestern University, 2004:

Once the child's skills and living situation are more naturalized, the costs to the family are immediately reduced. For example, with untreated autism, lost productivity for parents who care for children with autism is associated not only with increased absenteeism and work limitations for an employee, but an increase in the parents' number of health risks as well. Work disruptions caused by caregiving responsibilities result in productivity losses of \$1,142 per employee per year.

Burton, W., Chen, C., Conti, D., Pransky, G., & Edgington, D. (2004). Caregiving for ill dependents and its association with employee health risks and productivity. *Journal of Occupational Environmental Medicine*, 46, 1048-1056.

Appendix V. Is Applied Behavior Analysis (ABA) and Early Intensive Behavioral Intervention (EIBI) an Effective Treatment for Autism? A Cumulative History of Impartial Independent Reviews.

Applied Behavior Analysis (ABA) and Early Intensive Behavioral Intervention (EIBI) for Autism are quite possibly the best examples of evidence-based behavioral health care. Impartial independent review panels consistently agree that ABA and EIBI treatments for autism are effective, and that the extensive body of research meets high standards of scientific evidence. These reviews also report that ABA and EIBI significantly improves the net health outcome in Autism in substantial and far-ranging ways.

What is striking about the independent reviews of EIBI and ABA for autism is that the more careful the scrutiny, the more emphatic are the conclusions. For example, the New York, the Maine, and the US AHRQ commissions embarked upon yearlong independent reviews of the scientific support of ALL possible interventions for autism. Each panel stringently applied scientific standards of proof to all interventions and found that *ABA-based therapies alone, of all possible treatments for children with autism, had been proven effective.*

As a result, the practice of ABA and EIBI have become part of the mainstream community standard of care. The conclusions from many years of independent review are quoted below.

"Lovaas's (1980, 1982) experimental design included both an intensive treatment group that received 40 hours or more of treatment per week and a less intensive treatment group that received 10 hours of treatment per week. In other respects the nature of intervention was the same for all children. As summarized in Table 4, the intensive application of this approach resulted in substantial improvement for about half the autistic children. They attained IQs, school placements, and social-emotional ratings not different from normal peers. Children receiving a less intensive version of this approach did not, in any of 19 cases, achieve such gains."
Simeonsson, R.J., Olley, J.G., & Rosenthal, S.L. (1987). Early intervention for children with autism. In M.J. Guralnick & F.C. Bennett (Eds.) *The effectiveness of early intervention for at-risk and handicapped children.* (pp. 275-296). Orlando FL: Academic Press.

"During the past 10 years, behavioral interventions have become the predominant treatment approach for promoting the social, adaptive, and behavioral functioning of children and adults with autism. The sophistication of these strategies has increased substantially, reflecting advancements in technique and refinements in behavioral assessment."
Bregman, J.D. & Gerdtz, J. (1997). Behavioral Interventions. In D.J. Cohen & F.R. Volkmar, (Eds.), *Handbook of Autism and Pervasive Developmental Disorders* (pp. 606-630). New York: Wiley.

An editorial in the Autism Research Review International concerning such results stated:

"we are beginning to hear increasingly about recovery. The matter deserves our close attention. Reports of recovery, partial recovery, or near-recovery, come from several sources."
Rimland, B. (1994). Recovery from autism is possible. *Autism Research Review International*, 8, 3.

The Autism Society of America, in their informational paper on ABA approaches, stated:

"Properly designed and executed ABA programs contain many if not all of the components of effective treatment approaches found to be most successful in treating children with autism... Research and anecdotal evidence indicate that ABA programs produce comprehensive and lasting improvements in many important skill areas."
Autism Society of America (1998) Intensive Behavioral Intervention. Informational handout downloaded from www.autism-society.org

In 1998, Division 53 of the American Psychological Association (the Society for Clinical Child and Adolescent Psychology) conducted a Task Force on Empirically Supported Child Psychotherapy. For autism, they found:

"The literature on effective focal treatments in autism is plentiful and published in a variety of journals, in the fields of developmental disabilities, applied behavior analysis, and discipline-specific journals. These studies generally consist of single-subject multiple-baseline designs or small sample treatment designs. Behavioral treatment approaches are particularly well represented in this body of literature and have been amply demonstrated to be effective in reducing symptom frequency and severity as well as in increasing the development of adaptive skills." (p. 168).

Rogers, S.J. (1998) Empirically supported comprehensive treatments for young children with autism. *Journal of Clinical Child Psychology*, 27, 168-179.

In 1999, the US Surgeon General issued a lengthy report on the Mental Health in America. In the section on autism, he concluded:

"Thirty years of research demonstrated the efficacy of applied behavioral methods in reducing inappropriate behavior and in increasing communication, learning, and appropriate social behavior."

"A well-designed study of a psychosocial intervention was carried out by Lovaas and colleagues. Nineteen children with autism were treated intensively with behavior therapy for 2 years and compared with two control groups. Followup of the experimental group in first grade, in late childhood, and in adolescence found that nearly half the experimental group but almost none of the children in the matched control group were able to participate in regular schooling. Up to this point, a number of other research groups have provided at least a partial replication of the Lovaas model" (p. 164).

Satcher, D. (1999). *Mental health: A report of the surgeon general*. U.S. Public Health Service. Bethesda, MD.

In 1999, the New York State Department of Health convened a panel of nationally regarded experts and consumers who were charged with evaluating the scientific evidence in support of all available treatments for autism. This panel produced a large monograph that exhaustively reviewed the evidence in support of each treatment. The New York State Department of Health then published a three-volume report based upon its extensive analysis of the available treatments. It also found that only ABA-based treatments had sufficient scientific support to merit endorsement. The three volumes include "The Technical Report," which contains the most complete information, including all the evidence tables from the articles reviewed, a full report of the research process, and the full text of all the recommendations. "The Report of the Recommendations" gives the background information, the full text of all the recommendations and a summary of the supporting evidence. "The Quick Reference Guide" gives a summary of background information and a summary of the major recommendations, and is also written in a less technical manner. Sample statements from the Quick Reference Guide follow. While this panel found little support for most available treatments, their conclusion for ABA, after regarding the evidence of efficacy is:

"It is recommended that principles of applied behavior analysis (ABA) and behavior intervention strategies be included as important elements in any intervention program for young children with autism."

In contrast, their conclusions about a common treatment for autism, sensory integration therapy, is characteristic of their conclusions about all other treatments, to wit:

"No adequate evidence has been found that supports the effectiveness of sensory integration therapy for treating autism. Therefore, sensory integration therapy is not recommended as a primary intervention for young children with autism."

The New York Department of Health also concluded:

"[Based upon strong scientific evidence] it is recommended that principles of applied behavior analysis and behavior intervention strategies be included as an important element of any intervention program for young children with autism... [Based upon strong scientific evidence] it is recommended that intensive behavioral programs include as a minimum approximately 20

hours per week of individualized behavioral intervention using applied behavioral analysis techniques (not including time spent by parents)... It is recommended that all professional and paraprofessionals who function as therapists...receive regular supervision from a qualified professional with specific expertise in applied behavioral approaches... [Based upon strong scientific evidence] it is important to include parents as active participants in the intervention team to the extent of their interests, resources, and abilities... [Based upon strong scientific evidence] it is recommended that training of parents in behavioral methods for interacting with their child be extensive and ongoing and include regular consultation with a qualified professional..." (pp. 138-140).

New York State Department of Health Early Intervention Program. (1999). *Clinical Practice Guideline Report of the Recommendations for Autism/Pervasive Developmental Disorders*. New York State Department of Health, Albany, NY.

Also in 1999, a Practice Parameters Consensus Panel of the following Professional Organizations and Agencies was convened.

(American Academy of Neurology
 American Academy of Family Physicians
 American Academy of Pediatrics
 American Occupational Therapy Association
 American Psychological Association
 American Speech-Language Hearing Association
 Society for Developmental and Behavioral Pediatrics
 Autism Society of America
 National Alliance for Autism Research
 National Institute of Child Health & Human Development
 National Institute of Mental Health):

The practice parameters consensus panel on the diagnosis of autism stated that it was formed because:

"The press for early identification comes from evidence gathered over the past 10 years that intensive early intervention in optimal educational settings results in improved outcomes in most young children with autism, including speech in 75% or more and significant increases in rates of developmental progress and intellectual performance."

While the focus of this report was on diagnosis, the panel made a number of significant statements about the need for early and intensive treatment. For example:

"However, these kinds of outcomes have been documented only for children who receive 2 years or more of intensive intervention services during the preschool years. (page 440)"

"Autism must be recognized as a medical disorder, and managed care policy must cease to deny appropriate medical or other therapeutic care under the rubric of "developmental delay" or "mental health condition. (page 472)"

"Existing governmental agencies that provide services to individuals with developmental disabilities must also change their eligibility criteria to include all individuals on the autistic spectrum, whether or not the relatively narrow criteria for Autistic Disorder are met, who nonetheless must also receive the same adequate assessments, appropriate diagnoses, and treatment options as do those with the formal diagnosis of Autistic Disorder. (page 472)"

Filipek, P.A. et al. (1999). The screening and diagnosis of autistic spectrum disorders. *Journal of Autism and Developmental Disorders*. 29, 439-484.

A practice parameters panel of the American Academy of Child and Adolescent Psychiatry found:

"At the present time the best available evidence suggests the importance of appropriate and intensive educational interventions to foster acquisition of basic social, communicative, and cognitive skills related to ultimate outcome... Early and sustained intervention appears to be particularly important, regardless of the philosophy of the program, so long as a high degree of structure is provided. Such programs have typically incorporated behavior modification procedures and applied behavior analysis... These methods build upon a large body of research on the application of learning principles to the education of children with autism and related

conditions... It is clear that behavioral interventions can significantly facilitate acquisition of language, social, and other skills and that behavioral improvement is helpful in reducing levels of parental stress." (p. 476).

"Considerable time (and money) is required for implementation of such programs, and older and more intellectually handicapped individuals are apparently less likely to respond." (p. 515)

Volkmar, F., Cook, E.H., Pomeroy, J., Realmuto, G. & Tanguay, P. (1999). Practice parameters for the assessment and treatment of children, adolescents, and adults with autism and other pervasive developmental disorders. *Journal of the American Academy of Child and Adolescent Psychiatry*, 38 (Supplement), 32s-54s.

In another yearlong, exhaustive review, the Maine Administrators of Services for Children with Disabilities found:

"Early interventionists should leverage early autism diagnosis with the proven efficacy of intensive ABA for optimal outcome and long-term cost benefit... (p. 29).

"The importance of early, intensive intervention for children with autism cannot be overstated... Furthermore, early, intensive, effective intervention offers the hope of significant cost/benefit." (p. 6).

"Over 30 years of rigorous research and peer review of applied behavior analysis' effectiveness for individuals with autism demonstrate ABA has been objectively substantiated as effective based upon the scope and quality of science." (p. 29).

Maine Administrators of Services for Children with Disabilities (2000). *Report of the MADSEC Autism Task Force*. MADSEC, Manchester, ME.

In an extensive report on the facts of litigation by parents who were seeking health-care funding in British Columbia, the Supreme Court made the following conclusions. In a subsequent ruling, the Court found that it was more appropriate for the executive to set policy than to have it imposed upon them by the courts, but its conclusions on the facts remain:

"What children experience in their early years will shape the rest of their lives. We now know from research in a variety of sectors, that children's early brain development has a profound effect on their ability to learn and on their behaviour, coping skills and health later in life."

"Research also indicates that intensive early behavioural intervention with children with autism can make a significant difference in their ability to learn and keep pace with their peers. With the intervention many children with autism will make considerable gains by grade one."

"[1] These words embody the philosophy underlying the Ontario Government's "Intensive Early Intervention Program For Children With Autism" commenced in 1999, and numerous programmes undertaken in other provinces, the United States and several countries."

"[156] The Crown discriminates against the petitioners contrary to s. 15(1) by failing to accommodate their disadvantaged position by providing effective treatment for autism. It is beyond debate that the appropriate treatment is ABA or early intensive behavioural intervention." *Auton et al. v. AGBC*. (2000). British Columbia Supreme Court 1142.

Policy Statement of the American Academy Of Pediatrics - The Pediatrician's Role in the Diagnosis and Management of Autistic Spectrum Disorder in Children. The AAP regularly issues policy statements to guide and define the child health care system. The more recent AAP Clinical Report is also cited here, but this one from 2001 is included to help illustrate that the general professional consensus on the evidence for intensive early intervention had begun to turn by this earlier date. This policy statement is accompanied by a lengthy technical report. In both papers, the AAP clearly defines accepted treatments as behavioral interventions, and draws heavily on the ABA literature to support their findings. For example, in the introduction to the treatment section, the AAP makes two central statements, as follows:

"There is a growing body of evidence that intensive early intervention services for children in whom autism is diagnosed before 5 years of age may lead to better overall outcomes... Behavioral training, including teaching appropriate communication behaviors, has been shown to be effective in decreasing behavior problems and improving adaptation." (pp. 8-10).

"Currently accepted strategies are to improve the overall functional status of the child by enrolling the child in an appropriate and intensive early intervention program that promotes development

of communication, social, adaptive, behavioral, and academic skills; decrease maladaptive and repetitive behaviors through use of behavioral and sometimes pharmacologic strategies... Early diagnosis resulting in early, appropriate, and consistent intervention has also been shown to be associated with improved long-term outcomes... Behavioral training, including communication development, has been shown to be effective in reducing problem behaviors and improving adaptation." (p.1223).

American Academy of Pediatrics (2001). Policy Statement: The Pediatrician's Role in the Diagnosis and Management of Autistic Spectrum Disorder in Children (RE060018) *Pediatrics*, 107, 1221-1226.

In the more detailed technical report, the AAP states:

"There is a growing body of evidence that intensive early intervention services for children in whom autism is diagnosed before 5 years of age may lead to better overall outcomes. (page 8)"

The most heavily emphasized treatment strategy in the technical report is "behavioral management," about which the AAP states:

"One of the mainstays of the management of ASD in children at any age is the implementation of behavioral training and management protocols at home and at school. Behavioral management must go hand-in-hand with structured teaching of skills to prevent undesirable behavior from developing. Behavioral training, including teaching appropriate communication behaviors, has been shown to be effective in decreasing behavior problems and improving adaptation. (page 10)" Committee on Children With Disabilities (2001). Technical Report: The Pediatrician's Role in the Diagnosis and Management of Autistic Spectrum Disorder in Children. *Pediatrics*, 107, e85.

The National Research Council convened a panel of perhaps the most well recognized national experts in the treatment of autism. The United States Department of Education commissioned the National Research Council to provide input into the controversy circling around the press for school funding for behavior therapy and early intervention. In turn the National Research Council engaged the services of a large number of respected researchers in the field of autism. This panel was also charged with integrating the scientific literature and creating a framework for evaluating the scientific evidence concerning the effects and distinguishing features of the various treatments for autism. The resulting report clearly focused on ABA-based interventions. For example, the chapter on "comprehensive programs" identifies ten "well-known model approaches," all of which are ABA-based. A sample of the many statements, upon which it can be fairly said that the primary focus of the book is on ABA-based treatment, are offered here:

"There is general agreement across comprehensive intervention programs about a number of features of effective programs... The consensus across programs is generally strong concerning the need for: early entry into an intervention program... Overall, effective programs are more similar than different in terms of levels of organization, staffing, ongoing monitoring, and the use of certain techniques, such as discrete trials, incidental learning, and structured teaching periods... there is substantial research supporting the effectiveness of many specific therapeutic techniques and of comprehensive programs in contrast to less intense, nonspecific interventions."

"There is now a large body of empirical support for more contemporary behavioral approaches using naturalistic teaching methods that demonstrate efficacy for teaching not only speech and language, but also communication... Some advantages of the behavioral research on teaching social skills have been the measurement of generalization and maintenance, attention to antecedents and consequences, and use of systematic strategies to teach complex skills by breaking them down into smaller, teachable parts." (p. 53).

"Outcomes of discrete trial approaches have included improvements in IQ scores, which are correlated with language skills, and improvements in communication domains of broader measures... Behavioral interventions use the powerful tools of operant learning to treat symptoms of autism spectrum disorders. (p. 53).

"Early research on the benefits of applied behavior analysis by Lovaas and his colleagues (1973) showed that children with autism who returned to a home prepared to support their learning maintained their treatment gains better than children who went to institutional settings that failed to carry over the treatment methods. (page 35)"

"There is now a large body of empirical support for more contemporary behavioral approaches using naturalistic teaching methods that demonstrate efficacy for teaching not only speech and language, but also communication. (page 53)"

"Behavioral interventions use the powerful tools of operant learning to treat symptoms of autism spectrum disorders. (page 68)"

"Some advantages of the behavioral research on teaching social skills have been the measurement of generalization and maintenance, attention to antecedents and consequences, and use of systematic strategies to teach complex skills by breaking them down into smaller, teachable parts. Some drawbacks of traditional behavioral approaches are the complex data systems that often accompany them and that may impede their use in more typical settings, as well as the lack of training in their use that most staff members on early childhood teams receive. (page 72)"

The conclusions and recommendations of the report revolve around how to set up easily accessible funding and training for more teachers. While the report clearly endorses school department funding for intensive early intervention with behavior therapy, it also suggests that health-care based funding, such as the U.S. Medicaid program would also be appropriate:

"A state fund for intensive intervention, or more systematic use of Medicaid waivers or other patterns of funding currently in place in some states, should be considered. (page 224)"

National Research Council (2001). *Educating Children with Autism, Committee on Educational Interventions for Children with Autism*, Division of Behavioral and Social Sciences and Education, Washington, D.C.: National Academy Press.

A review by Mayo Clinic and Harvard pediatricians found:

"The weight of currently available scientific evidence, however, indicates that ABA should be viewed as the optimal, comprehensive treatment approach in young children with ASD."

Barbarese, W.J., Katusic, S.K., & Voigt, R.G. (2006). Autism: A review of the state of the science for pediatric primary health care clinicians. *Archives of Pediatric and Adolescent Medicine*, 160. 1167-1175.

The Department of Health Policy, Management and Evaluation of the University of Toronto, ON found:

"Under our model parameters, expansion of IBI to all eligible children represents a cost-saving policy whereby total costs of care for autistic individuals are lower and gains in dependency-free life years are higher." (page 136).

Motiwala, S.S., Gupta, S., Lilly, M.D., Ungar, W.J., & Coyte, P.C. (2006). The cost-effectiveness of expanding intensive behavioural intervention to all autistic children in Ontario. *Healthcare Policy*, 1, 135-151.

The Hawaii Department of Health Empirical Basis to Services Task Force found:

"These results are quite promising in terms of effect size, although it should be noted that the outcome variables for these studies mainly involved reductions in the frequency of autistic behaviors or increases in social communication or other forms of social exchange (e.g., turn taking). None of these studies claimed that children were autism free following the intervention programs. Nevertheless, these findings represent an extraordinary improvement over the evidence base for interventions for autistic spectrum disorders in the previous Biennial Report."

"Two treatment families demonstrated Best Support. Intensive Behavioral Treatment was successful in three (3) studies, beating alternative treatments in two (2) of those, and beating a no-treatment control in one (1). Likewise, Intensive Communication Training was also successful in three (3) studies, beating alternative treatments in two (2) of those, and beating a no-treatment control in one (1) study. ...The shape of the profile suggests that all successful treatments for autistic spectrum disorders involve teaching communication skills and modeling of appropriate communication or other behaviors. Other strategies include training in non-verbal communication (social skills), teaching parents and teachers to praise desired behaviors, and the setting of goals paired with the intensive rehearsal and reinforcement of behaviors consistent with those goals (i.e., discrete trial training)." (pp. 16-19).

Chorpita, B.F. & Daleiden, E.L. (2007). 2007 Biennial report: Effective psychosocial interventions for youth with behavioral and emotional needs. Child and Adolescent Mental Health Division, Honolulu: Hawaii Department of Health.

The California Blue Ribbon Commission on Autism found:

“Early identification and intervention for ASD is critical for children to reach their full potential and reduce their level of disability and dependence. Although the outcomes of interventions and treatment for ASD vary with each child, there is widespread agreement in the field based on a large body of research that it is important for children with ASD to receive intensive interventions during early childhood. (page 26)”

“Children with ASD who have improved functioning as a result of early intervention services may have less intensive and costly service needs for the rest of their lives, thereby reducing hardships on families and costs for systems of care to serve these individuals during adulthood. For this reason, investments in early identification and intervention services are considered an important, cost-effective approach for society. (page 27)”

“Health plans may deny services for ASD for reasons related to medical necessity that are at odds with medical science. For example, some plans have denied ASD interventions on the basis that ASD is a disorder of brain development that is present from birth and therefore not amenable to medical treatments or interventions. This ruling by some health plans seems to contradict the numerous and mounting scientific evidence that ASD may be associated with multiple factors, usually become evident in the second or third year of life, are frequently associated with demonstrable changes in brain function, and appear to be caused by the interactions of genetic and environmental factors. (page 33)”

“Another reason for denial of services by some health plans is that ASD is a chronic disorder and therefore not amenable to acute treatments or cure. Such reasoning seems at odds with the coverage that health plans routinely provide for numerous other chronic illnesses (such as diabetes and congestive heart failure) that are also frequently incurable. Thus, the frequent denial of these services for ASD by some health plans may be inconsistent both with current scientific evidence as well as with the standards and approaches applied to other illnesses and medical conditions. (page 34)”

The report specifically addresses the value of ABA:

“Behavioral interventions that include pivotal response therapy, applied behavioral analysis, and directed response interventions have also proven therapeutic value in the treatment of ASD. (page 34)”

“There is also compelling evidence that many children with ASD can respond to and improve with intensive behavior modification therapy. Although the exact mechanism of action is the subject of ongoing research, there is evidence of improved brain plasticity in children with autism as the result of early interventional therapy. (page 39)”

“Often this therapy is provided in the home environment and may require multiple professionals working simultaneously with the child and the family for up to 40 or more hours per week. The duration of these services varies widely, but most children with ASD will require early intensive behavior intervention for a minimum of several years as well as ongoing interventions and supports throughout their lifetimes. In addition, parent education is recommended so that intervention may be ongoing throughout the child’s waking hours. (pages 39-40)”

The California Legislative Blue Ribbon Commission on Autism (2007). *Report: An Opportunity to Achieve Real Change for Californians with Autism Spectrum Disorders*. Sacramento, CA: The Legislative Office Building ([HTTP://senweb03.sen.ca.gov/autism](http://senweb03.sen.ca.gov/autism)).

In a second Clinical Report of the American Academy Of Pediatrics Council on Children With Disabilities: Management of children with autism spectrum disorders, the overall impact is inescapable: Children with autism are best treated by continuous, integrated behavior therapy throughout their daily lives, and can make great gains when treated so. The definitive research cited is for the ABA research. By contrast this report also clearly cites the nonbehavioral interventions that have insufficient evidence to support them, or may even be harmful. The report also clearly reviews the critical variables of effective intensive early intervention. For example, the AAP makes the following central statement about Applied Behavior Analysis (ABA):

“The effectiveness of ABA-based intervention in ASDs has been well documented through 5 decades of research by using single-subject methodology and in controlled studies of

comprehensive early intensive behavioral intervention programs in university and community settings. Children who receive early intensive behavioral treatment have been shown to make substantial, sustained gains in IQ, language, academic performance, and adaptive behavior as well as some measures of social behavior, and their outcomes have been significantly better than those of children in control groups. (pg. 1164)"

Then, regarding specific behavioral interventions, the AAP makes the following statements:

"DTT methods are useful in establishing learning readiness by teaching foundation skills such as attention, compliance, imitation, and discrimination learning, as well as a variety of other skills. (pg. 1164)"

"Naturalistic behavioral interventions, such as incidental teaching and natural language paradigm/pivotal response training, may enhance generalization of skills. (pg. 1164)"

"Functional assessment is a rigorous, empirically based method of gathering information that can be used to maximize the effectiveness and efficiency of behavioral support interventions. (pg. 1164)"

"A variety of approaches have been reported to be effective in producing gains in communication skills in children with ASDs. Didactic and naturalistic behavioral methodologies (e.g., DTT, verbal behavior, natural language paradigm, pivotal response training, milieu teaching) have been studied most thoroughly. (pg. 1165)"

"Traditional, low-intensity pull-out service delivery models often are ineffective, and speech-language pathologists are likely to be most effective when they train and work in close collaboration with teachers, support personnel, families, and the child's peers to promote functional communication in natural settings throughout the day. (pg. 1165)"

"There is some objective evidence to support traditional and newer naturalistic behavioral strategies and other approaches to teaching social skills. (pg. 1165)"

"Proponents of behavior analytic approaches have been the most active in using scientific methods to evaluate their work, and most studies of comprehensive treatment programs that meet minimal scientific standards involve treatment of preschoolers using behavioral approaches. (pg. 1166)"

"Three studies that compared intensive ABA programs (25–40 hours/week) to equally intensive eclectic approaches have suggested that ABA programs were significantly more effective. (pg. 1166)"

"It is now recognized that parents play a key role in effective treatment. Physicians and other health care professionals can provide support to parents by educating them about ASDs; providing anticipatory guidance; training and involving them as cotherapists; (pg 1174)"

Myers, S.M., Johnson, C.P. & the American Academy of Pediatrics Council on Children With Disabilities, (2007). Management of children with autism spectrum disorders. *Pediatrics*. 120, 1162–1182. Available online at <http://aappolicy.aappublications.org/cgi/reprint/pediatrics;120/5/1162.pdf>. Accessed November 27, 2007.

In a second review, the Division 53 of the American Psychological Association Task Force on Empirically Supported Child Psychotherapy again found:

"Randomized controlled trials have demonstrated positive effects in both short-term and longer term studies. The evidence suggests that early intervention programs are indeed beneficial for children with autism, often improving developmental functioning and decreasing maladaptive behaviors and symptom severity at the level of group analysis... Lovaas's treatment meet Chambless and colleague's criteria for 'well-established'" (p. 8).

"Across all the studies we cited, improvements in language, communication, and IQ, and reduction in severity of autism symptoms indicate that the core symptoms of autism appear malleable in early childhood." (p. 30).

Report for Division 53 of the American Psychological Association (the Society for Clinical Child and Adolescent Psychology): Rogers, S.J., & Vismara, L.A. (2008). Evidence-based comprehensive treatments for early autism. *Journal of Clinical Child and Adolescent Psychology*. 37, 8-38.

While the common finding is that one third to one half of the children dramatically outperform controls, there is also evidence that a subset even reach typical levels of functioning. These results are important to

note, because the results of these studies are not that the children are scoring barely higher than the controls. Instead, the results are clinically significant in that a substantial number of the children are reaching socially important levels of functioning. For example in a review of children referred to a number of leading comprehensive medical evaluation clinics throughout the Northeastern US, a review by pediatricians and psychologists compared a group of such "optimal outcome" (OO) children with a group of typical children, and with a group of "high functioning autism" (HFA) children, at least three years after treatment had concluded. They found:

"The pattern of test results was consistent across all measures: On all measures, the typically-developing children had the highest average scores, followed by the optimal-outcome group, and the HFA group showed the lowest level of functioning on all tasks. Additionally, the optimal outcome group, as a whole, scored within the normal range on all tasks and only the high-functioning ASD group scored in the impaired range on some of the standardized tests. The OO group also scored lower than the typically developing group (but well within the average range) on parent ratings of attention problems, atypical behavior, and depression. On the numerous other tasks that we used to assess these groups, the children in the optimal-outcome group were statistically indistinguishable from their typically developing peers. In sum, we appear to have found a group that, with the possible exception of some very subtle pragmatic deficits, is currently functioning at the same level as their typically developing peers, and we are continuing to follow this group."

Helt, M., Kelley, E., Kinsbourne, M., Pandey, J., Boorstein, H., Herbert, M., & Fein, D. (2008). Can children with autism recover? If so, how? *Neuropsychology Review*. 18, 339-366.

The NIMH (National Institute of Mental Health) states:

"Among the many methods available for treatment and education of people with autism, applied behavior analysis (ABA) has become widely accepted as an effective treatment. ...The basic research done by Ivar Lovaas and his colleagues at the University of California, Los Angeles, calling for an intensive, one-on-one child-teacher interaction for 40 hours a week, laid a foundation for other educators and researchers in the search for further effective early interventions to help those with ASD attain their potential."

National Institute of Mental Health (2008). *Autism Spectrum Disorders: Pervasive Developmental Disorders*. NIH Publication no. 08-5511.

A review by US and British pediatricians in the *Lancet* found:

"The most well researched treatment programmes are based on principles of applied behaviour analysis. Treatments based on such principles represent a wide range of early intervention strategies for children with autism—from highly structured programmes run in one-on-one settings to behaviourally based inclusion programmes that include children with typical development. The first types of behavioural treatment programmes developed and examined were very structured, intensive, one-on-one programmes called discrete trial training, which were highly effective for up to half of children enrolled in four randomised clinical trials and six studies with closely matched comparison groups done in the past 20 years."

"These intensive programmes are expensive, and children have difficulty generalising the information from a very structured session to group and community settings. Less structured, more naturalistic behavioural programmes have been developed, such as pivotal response training and incidental teaching. In individual and nonrandomised group studies, researchers noted that about half of children have good outcomes in these types of programmes. Presently, even structured sessions typically include naturalistic methods for increasing generalisation and maintenance. A combination of these behavioural methods is more effective than is usual care for improvement of outcomes for children with autism. Parent-mediated interventions have been shown in controlled studies to be an important aspect of intervention. Investigators identified that generalisation and maintenance of behaviour changes were improved when parents were trained in highly structured behavioural methods. As behavioural programming for children with autism evolved from teaching one behaviour at a time to a broadened focus of increasing general motivation and responsiveness, parent education also began to change. Parents were taught naturalistic strategies that were easier to use in the home, needed fewer hours of training, increased both leisure and teaching time, and improved parent satisfaction and enjoyment of the treatment."

Levy, S.E., Mandell, D.S., & Schultz, R.T. (2009). Autism. *Lancet*. 374, 1627-1638.

A subsequent review by the Hawaii Department of Health Empirical Basis to Services Task Force again found:

"The best support favored Intensive Behavioral Treatment and Intensive Communication Training, although the effect sizes were relatively small. Both of these treatment approaches were rated as highly trainable, tested among youths of various ethnic backgrounds, in various format types (e.g., individual and group) and settings (e.g., school, clinic, home, and community), as well as by different therapist types (e.g., prebachelor's-level therapists, master's-level therapists, and doctors). The duration of both Level 1 treatments was at least a year. Another promising characteristic of these two approaches is that they were both tested on boys as young as one and two years old."

Chorpita, B.F. et al. (2011). Evidence-based treatments for children and adolescents: An updated review of indicators of efficacy and effectiveness. *Clinical Psychology Science and Practice*. 18, 154-172.

A review by the US Agency for Health Care Research and Quality found that ABA and EIBI had sufficient evidence to support a recommendation for practice:

"Evidence supports early intensive behavioral and developmental intervention, including the University of California, Los Angeles (UCLA)/Lovaas model and Early Start Denver Model (ESDM) for improving cognitive performance, language skills, and adaptive behavior in some groups of children. ...Evidence suggests that interventions focusing on providing parent training and cognitive behavioral therapy (CBT) for bolstering social skills and managing challenging behaviors may be useful for children with ASDs to improve social communication, language use, and potentially, symptom severity."

But further, by comparison, the AHRQ also reviewed all alternative available treatments. They reached clearly negative conclusions about all other treatments that are currently widely covered by insurance policies:

"No current medical interventions demonstrate clear benefit for social or communication symptoms in ASDs. ...Little evidence is available to assess other behavioral interventions, allied health therapies, or complementary and alternative medicine. ...repetitive behavior showed improvement with both risperidone and aripiprazole. Both medications also cause significant side effects, however, including marked weight gain, sedation, and risk of extrapyramidal symptoms (side effects, including muscle stiffness or tremor, that occur in individuals taking antipsychotic medications). These side effects limit use of these drugs to patients with severe impairment or risk of injury."

Warren, Z., Veenstra-VanderWeele, J., Stone, W., Bruzek, J.L., Nahmias, A.S., Foss-Feig, J.H., Jerome, R.N., Krishnaswami, S., Sathe, N.A., Glasser, A.M., Surawicz, T., & McPheeters, M.L. (April, 2011). Therapies for Children With Autism Spectrum Disorders. Comparative Effectiveness Review No. 26. (Prepared by the Vanderbilt Evidence-based Practice Center under Contract No.290-2007-10065-I.) AHRQ Publication No. 11-EHC029-EF. Rockville, MD: Agency for Healthcare Research and Quality. Available at: www.effectivehealthcare.ahrq.gov/reports/final.cfm.

Autism Speaks states:

"Behavior analysis is a scientifically validated approach to understanding behavior and how it is affected by the environment. In this context, "behavior" refers to actions and skills.

"Environment" includes any influence – physical or social – that might change or be changed by one's behavior. On a practical level, the principles and methods of behavior analysis have helped many different kinds of learners acquire many different skills – from healthier lifestyles to the mastery of a new language. Since the 1960s, therapists have been applying behavior analysis to help children with autism and related developmental disorders. ...Today, ABA is widely recognized as a safe and effective treatment for autism. It has been endorsed by a number of state and federal agencies, including the U.S. Surgeon General and the New York State Department of Health. Over the last decade, the nation has seen a particularly dramatic increase in the use of ABA to help persons with autism live happy and productive lives. In particular, ABA principles

and techniques can foster basic skills such as looking, listening and imitating, as well as complex skills such as reading, conversing and understanding another person's perspective." Autism Speaks (2012) Applied Behavior Analysis (ABA). Downloaded from <http://www.autismspeaks.org/what-autism/treatment/applied-behavior-analysis-aba> on November 2, 2012.

The US CDC (Centers for Disease Control) states:

"A notable treatment approach for people with an ASD is called applied behavior analysis (ABA). ABA has become widely accepted among health care professionals and used in many schools and treatment clinics. ABA encourages positive behaviors and discourages negative behaviors in order to improve a variety of skills. The child's progress is tracked and measured." Centers for Disease Control (2012) Autism Spectrum Disorders. Downloaded from <http://www.cdc.gov/ncbddd/autism/treatment.html> on November 2, 2012.

Conclusion

These results aren't occasional findings. As has been repeatedly stated in many peer-reviewed research reports and in many medical editorials and medical review panel recommendations, Applied Behavior Analysis, Behavior Therapy, and Early Intensive Behavioral Intervention treatments are the only substantiated treatment for children with autism. It is the widely held conclusion of ABA researchers, expert independent review committees, and the central consumer advocacy agencies in the field of autism that Applied Behavior Analysis consists of a large body of valid scientific evidence demonstrating that the technology improves the net health outcome as much as or more than established alternatives, and that these results have been readily attained outside the investigational settings.

Appendix VI: Bibliography of Reviews of the Evidence for Applied Behavior Analysis and Early Intensive Behavioral Intervention

Bibliography of Reviews of the Evidence for Applied Behavior Analysis and Early Intensive Behavioral Intervention

By Independent Panels; by Meta-Analysis, and by Peer Review;

Bibliography of Long-Term and Group Outcome Studies of ABA, and Comparison Data;

Bibliography of Peer Reviews of N=1 Clinical Experimental Studies;

Bibliography of Cost-Effectiveness Analyses; and

Bibliography of ABA (Within-Subject Experimental Research) Studies.

(Organized by Most Recent Publication)

Independent Panels and Reviews

Warren, Z., McPheeters, M.L., Sathe, N., Foss-Feig, J.H., Glasser, A., & Veenstra-VanderWeele, J. (2011). A systematic review of early intensive intervention for autism spectrum disorders. *Pediatrics*, 127, e1303-e1311. doi: 10.1542/peds.2011-0426

Warren, Z., Veenstra-VanderWeele, J., Stone, W., Bruzek, J.L., Nahmias, A.S., Foss-Feig, J.H., Jerome, R.N., Krishnaswami, S., Sathe, N.A., Glasser, A.M., Surawicz, T., McPheeters, M.L. (2011). Therapies for children with autism spectrum disorders. *Comparative Effectiveness Review*, No. 26, Rockville, MD: Agency for Healthcare Research and Quality. Available at: www.effectivehealthcare.ahrq.gov/reports/final.cfm.

Dawson, G. & Burner, K. (2011). Behavioral interventions in children and adolescents with autism spectrum disorder: A review of recent findings. *Current Opinion in Pediatrics*, 23, 616-620 doi:10.1097/MOP.0b013e32834cf082

Brosnan, J. & Healy, O. (2011). A review of behavioral interventions for the treatment of aggression in individuals with developmental disabilities. *Research in Developmental Disabilities*, 32, 437-446.

American Psychological Association Division 53: Society of Clinical Child and Adolescent Psychology. Review of Evidence-Based Mental Health Treatment for Children and Adolescents, including Autism. http://effectivechildtherapy.com/sccap/?m=sPro&fa=pro_ESToptions#sec13 Accessed November 29, 2010

Young, J., Corea, C., Kimani, J., & Mandell, D. (2010). *Autism spectrum disorders (ASDs) services: Final report on environmental scan*. Columbia, MD: IMPAQ International.

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