Testimony on the Study of Autism Spectrum Disorder
Human Services Interim Committee
July 31, 2012

Chairman Wieland and committee members, for the record I am Rod St. Aubyn, representing Blue Cross Blue Shield of North Dakota (BCBSND). Thank you for the opportunity to appear before your committee for this important study. I wanted to explain to your committee several issues that come into play with your study of autism.

During a previous meeting, I noted that the Autism Task Force had as one of their recommendations an Autism Insurance Mandate. Though it was one of the lower priorities in the list of recommendations, I felt that it was important to inform your committee of provisions in both State and Federal law that will come into play with any health insurance mandate. According to NDCC 54-35-02.4 any health insurance mandate must be heard by the Employee Benefits Programs Committee before a standing legislative committee can take action on the bill. In addition, according to NDCC 54-03-28 an actuarial analysis must be completed prior to a decision by a standing committee. The reason for that is that all health insurance mandates must be applied to NDPERS for one biennium to ascertain the actual cost/benefit. The process is as follows:

- A standing legislative committee during a regular session must determine if the particular bill is a health insurance mandate according to the definitions in the Century Code.
- The Committee must then refer the bill to an actuarial firm contracted by the Insurance Department to determine the estimated actuarial cost/benefit.
- If the bill has not already been heard by the Employee Benefits Programs Committee for their recommendation, the bill must then be re-referred to that committee.
- Taking the information from the Employee Benefits Programs Committee and the cost/benefit analysis supplied by the contracted actuarial firm into consideration, the Standing Committee must make a final recommendation after amending the bill to apply to only NDPERS for the next biennium.
- If the mandate bill passes, NDPERS is responsible for tracking the actual cost/benefit of the mandate and then prepare a bill for consideration during the following legislative session to have the mandate apply to all insurers.
- The rationale for this process is to ensure that true cost/benefits are considered before applying any mandate to all health insurers.

Now with the passage of the Affordable Care Act (ACA), another important factor comes into play. Health and Human Services (HHS) is responsible for determining the "Essential Health Benefits" (EHB) that must be in every health plan beginning on January 1, 2014. The ACA defines 10 basic broad categories, but does not specify the particular benefits that must be included within each category. For 2014 and 2015, HHS has delegated that responsibility to each state. Each state is supposed to select a "benchmark plan" among several options by September 30, 2012. If a state elects to NOT select a

"benchmark plan", then the Federal default is the plan with the largest enrollment in the small group market as of the end of the first quarter of 2012. The benefits within the selected plan will then become the "Essential Health Benefits" and according to the ACA there can be NO annual or lifetime limits on EHB's. This is the process that HHS has elected to use for 2014 and 2015. In effect, there could actually be 50 different EHB's. Beginning on January 1, 2016, HHS will finally determine the "Essential Health Benefits" that must be included in all plans throughout the United States.

According to the ACA, states are permitted to establish health insurance mandates that go beyond the "Essential Health Benefits". However, the state must pay for the additional costs of the mandate for those individuals securing insurance through the exchange.

I bring this to your attention because this potentially could apply to our state should the Legislature approve a health insurance mandate that goes beyond the "Essential Health Benefits" within the "Benchmark Plan".

Because no specific health insurance mandate bill was submitted by the Autism Task Force, it is impossible for me to speculate what problems may occur with the proposed bill. However, we have seen several bills in other states that mandate Applied Behavioral Analysis (ABA) coverage. Without going into a lot detail, I wanted to inform your committee that our insurance reimbursement policies are "evidence-based". Evidence-based medicine is commonly defined as the "conscientious, explicit, and judicious use of current evidence in making decisions about the care of individual patients. The practice of evidence based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research." (Sackett DI., Straus S., Richardson S., Rosenberg W., Haynes RB. Evidence-based Medicine: how to practice and teach EBM, ed. 2. London: Churchill Livingston, 2000). Medical Necessity determinations for coverage must be consistent with the Technology Evaluation Center Criteria of the Blue Cross Blue Shield Association. The TEC criteria are a primary resource for the development of medical policy for BCBSND. TEC was re-awarded a contract from the Agency for Healthcare Research and Quality (AHRQ) as one of 13 Evidence-based Practice Centers in the United States. BCBSND reviews its medical policies for medical necessity consistent with evidence-based practices on an annual basis.

I have provided the executive summary from a TEC report on the therapy commonly called ABA for your information. I highlighted the key points within their analysis.

Even though ABA is not a covered benefit, BCBSND specifically pays for diagnostic evaluations, speech therapy, occupation therapy, physical therapy, psychiatric care, prescription drugs, and other medically necessary services for patients with autism spectrum disorders. In fact, BCBSND's total allowed costs for members with autism totaled the following:

- 2008 - $5,085,608
- 2009 - $5,916,810
- 2010 - $5,624,733
- 2011 - $6,882,483

I cannot speak for other insurers, but I can assure you that members of BCBSND are afforded medically necessary benefits for the specified services for members with autism.

Mr. Chairman and committee members, I hope that I have been able to provide you with additional important information for your study. Thank you again for being able to testify before your committee. I would be willing to answer any questions the committee may have.

Special Report: Early Intensive Behavioral Intervention Based on Applied Behavior Analysis among Children with Autism Spectrum Disorders

Assessment Program
Volume 25, No. 9
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Executive Summary

Background

In recent years, public attention has focused on the number of children diagnosed with autism spectrum disorders or ASDs, which include autism, Asperger's disorder, and "pervasive developmental disorder—not otherwise specified" or PDD-NOS. The estimated prevalence in the U.S. is about 1 in 151 children 8 years of age. In December 2007, Congress authorized $162 million for fiscal year 2008 for autism spectrum disorders to fund the Combating Autism Act. Traditionally, behavioral and educational interventions for children with ASDs have fallen within the domain of public education systems.

Early Intensive Behavioral Intervention based on Applied Behavior Analysis or ABA (hereafter referred to as "EIBI") is among the most commonly cited and best-researched intervention for these children. EIBI was championed by researchers led by Lovaas at the University of California Los Angeles (UCLA) in the 1970s and 1980s. This Special Report is a systematic review on the effectiveness of EIBI; the intent is to inform the public discussion. Other uses of ABA are not addressed in this Report.

Children with autism spectrum disorders face many difficulties; this condition is a challenge for them and for their families. This Report systematically reviews the evidence on EIBI because it is important to know which interventions are most effective, especially for conditions like ASDs that have such a profound impact on peoples' lives. If we are not sure what works in treating any disorder and do not push forward with learning what does work, the people who are affected may potentially be deprived of benefit.

Objective

To conduct a systematic review of the research literature on the use of EIBI among young children with autism, pervasive developmental disorder, or Asperger's disorder. A systematic review "aims to identify all relevant primary research, undertake standardized appraisal of study quality, and synthesize the studies of acceptable quality" (Hunink et al. 2001). Three questions are addressed in this Special Report:

Question 1. How effective is EIBI in improving the functioning of children with autism spectrum disorders, and how does it compare to other early intervention approaches?
Question 2. Can patient characteristics be identified that predict better outcomes from EIBI?
Question 3. Does the effect of EIBI vary with the intensity of treatment?

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Search Strategy

A literature search was conducted of articles in peer-reviewed journals published between 1966 (MEDLINE®) or 1970 (PsychLit®) and July 2008. The search terms were related to autism, pervasive developmental disorders, (applied) behavior therapy, and other behavior modification (for the specific list, see text). A more narrowly defined update was performed in January 2009 using MEDLINE®.

Selection Criteria

Selection criteria for this systematic review were that the study:

1. reported on the use of EIBI compared to another treatment strategy;
2. attempted to identify features of EIBI that had the most impact on its effectiveness; or
3. sought to identify children most likely to benefit from EIBI.

Exclusion criteria were:

1. the sample size was less than 10, including single-subject studies;
2. the interventions were very poorly described;
3. the interventions were not comprehensive, addressing a number of domains affected by ASD, but rather were narrowly focused, e.g., only on speech or play;
4. the intervention within a treatment group was heterogeneous, combining a variety of methods;
5. the experimental intervention was not intensive (i.e., less than 20 hours per week);
6. the study did not directly measure outcomes through a direct assessment of the child's achievement but relied, for example, on follow-up through telephone surveys with parents; and
7. the study was published before 1987, when the seminal article on EIBI by Lovaas was released.

Single-subject studies were excluded for two reasons. First, they aim to evaluate the effect of an intervention on a specific individual, rather than on a group of diverse individuals with the condition. We are interested in the latter objective: how effective is EIBI among children with ASDs in the U.S.? Group designs, ideally randomized, controlled trials, but also nonrandomized comparative studies, are the only type that can address this question. Second, in a report in 2001 on small clinical trials, the Institute of Medicine identified a set of criteria to consider in deciding whether or not to perform single-subject studies, which they call "n-of-1," trials. Several aspects of researching EIBI among children with ASDs make it more difficult to derive valid results from the single-subject design, including the inability to use blinding, the variability of the condition over time, and the carryover effect. In single-subject designs, the goal is for the researcher to repeat a task or approach several times, alternated with other tasks, and measure the impact of each. But if the effect of the first task is long lasting, as one would want it to be in children with ASDs, it makes it impossible to separate the impact of that first task from all subsequent tasks and, thereby, undermines the utility of this approach. As a result, the selection criteria for this Report are limited to group designs.

Results

Sixteen studies were abstracted, including 2 randomized, controlled trials; 9 nonrandomized, comparative studies; and 5 single-arm studies. No studies were found that included children with Asperger's disorder; 4 studies explicitly included children with PDD or PDD-NOS. The 5 single-arm studies addressed Questions 2 and 3; this study design could not provide information on Question 1.

Overall, the quality and consistency of results of this body of evidence are weak. Consequently, no conclusions can be drawn from this literature on how well EIBI works. Weaknesses in research design and analysis, as well as inconsistent results across studies, undermine confidence in the reported results. It is important to distinguish between certainty about ineffectiveness and uncertainty about effectiveness. Based on the weakness of the available evidence, we are uncertain about the effectiveness of EIBI for ASDs.

Conclusions and recommendations for future studies are as follows:

- **Randomized, Controlled Trials.** Autism and PPD-NOS are highly variable conditions, with substantial differences both in each child's symptoms and progression over time. Since it is difficult to measure those differences and to predict reliably who will do better in the short and long term, the best way to evaluate the impact of EIBI is to conduct randomized, controlled trials with enough children that any differences are likely to be evenly distributed across treatment groups. If children in one treatment group demonstrate more progress than children in comparison treatment groups, then we can be fairly confident in the results. Unfortunately, only two randomized, controlled trials have been conducted, and they compared different interventions, had small sample sizes, and came to different conclusions.

- **Larger Sample Sizes.** Only two studies included more than 50 children, and 10 had fewer than 30, including the 2 randomized, controlled trials. Given the variation in the presentation and progression of autism spectrum disorders, larger sample sizes are necessary to detect small to moderate differences between treatments. They are also required for the analyses needed to deal with potential analytical difficulties when children are not randomly assigned to a treatment.

- **Greater Consistency.** The types of treatment vary greatly, both within and across the available studies, especially for the control groups. Adding to the complexity is the use of different approaches to measure symptoms and progress over time. These factors make it difficult to interpret the results and to aggregate evidence across studies.

- **Longer Follow-up.** As the American Academy of Pediatrics has pointed out, autism spectrum disorders are generally chronic conditions. Children may progress at differing rates. While results of treatment after a year or two are relevant, only longer follow-up can demonstrate whether durable outcomes—with academic achievement and the ability to function at school and work—are attained. About half of the studies followed children for approximately 2 years or less, and some for only 1 year. This is not sufficient follow-up time to assess the potential impact of an intervention over a lifetime.

- **Incremental Research Strategy.** For ethical reasons, randomized, controlled trials cannot be performed comparing EIBI to no treatment. However, they can be done comparing various aspects of treatment (e.g., length and intensity, behavioral versus other approaches, different combinations of behavioral strategies, type of person providing the intervention, extent of parental involvement, and setting). The results of such studies can be used to build an understanding of which strategies are most effective for which types of children with ASD, so that the benefit of the intervention can be optimized for each child, and time and effort will not be wasted on less-effective strategies.

The results for each question are summarized below.

Question 1. How effective is EIBI in improving the functioning of children with autism spectrum disorders, and how does it compare to other early intervention approaches?

The strongest evidence is provided by two randomized, controlled trials (Smith et al. 2000; Sallows and Graupner 2005). However, weaknesses in research design, differences in the treatments and outcomes compared, and inconsistent results mean that the impact of EIBI versus other treatments on outcomes for children with autism cannot be determined. For example, Sallows and Graupner (2005) found that children in the experimental and control groups improved significantly over time, but there was no statistically significant difference in the rate of improvement between groups. Smith et al. (2000), in contrast, found that the experimental group had significantly better cognitive and communication skills than the control group at follow-up, but there was no difference between the groups' adaptive skills.

The EIBI treatments used in the two studies also varied: For example, Sallows and Graupner (2005) compared groups receiving clinic-directed therapy for 39 hours per week in year 1 versus a parent-directed therapy averaging 32 hours per week. So both groups had fairly intensive, ABA-based therapy and differed on the precise hours of treatment and the intensity of supervision by more experienced staff. Smith et al. (2000), in contrast, compared a clinic-run program for about 25 hours per week versus special education classes for 10–15 hours per week combined with a parent training program. **The evidence is insufficient to determine whether or not EIBI is more effective than alternative approaches for children with ASDs.**

Question 2: Can patient characteristics be identified that predict better outcomes from EIBI?

Given the lack of a definitive answer to Question 1 on the relative effectiveness of EIBI, Question 2 on whether there are characteristics of children that predict a greater likelihood of success cannot be answered either. However, researchers have attempted to measure the relationship between specific characteristics and outcomes. The ideal method of identifying characteristics likely to predict treatment outcomes is to examine treatment by covariate (i.e., child characteristics) interaction terms in the context of a randomized, controlled trial. Such analyses can be performed for nonrandomized studies, but the evidence is weaker due to the uncertain influence of initial differences between the treatment groups. Single-arm studies can suggest candidate characteristics that could be investigated in future randomized, controlled trials. Therefore, the reported results should be interpreted with caution. Age and cognitive functioning at intake (usually measured by IQ) were the most commonly studied characteristics in the studies included in this review. Three of the 4 studies examining the impact of pretreatment cognitive functioning found that it significantly predicted outcomes, while one (a randomized, controlled trial) did not. **The findings on age were more variable, with some studies suggesting that younger age at the start of therapy is a predictor of better outcomes (e.g., Howard et al. 2005), while others found no difference based on initial age (e.g., Magiati et al. 2007).**

Question 3: Does the effect of EIBI vary with the intensity of treatment?

The findings on whether more intense treatment leads to better outcomes were inconsistent, and no conclusions can be drawn. In a nonrandomized study, Lovaas and colleagues (Lovaas 1987; McEachin et al. 1993) reported that outcomes were better in the more-intensive group (more than 40 hours per week versus 10 or fewer hours per week). This study has a number of limitations, however, including lack of randomization; use of multiple instruments to measure the same outcome; and focus on IQ and school placement, while overlooking other important outcomes such as socialization and communication. Sallows and Graupner (2005) randomized children into groups receiving about 39 versus 32 hours per week and detected no difference in outcomes across groups. **However, the variation in intensity was not as great in this study, and there were other differences in the programs as well (e.g., clinic- versus parent-directed therapy programs).**

Author's Comments and Conclusions

The variability of presentation and progression among children with autism spectrum disorders, as well as potential differences in delivery of behavioral interventions, make this topic challenging to study. Nevertheless, given the importance of caring for children with ASD, additional research is needed to identify those characteristics of treatment—content, technique, intensity, starting and ending age, etc.—that maximize its effectiveness. Because of the challenges in launching a very large randomized trial and the ethical necessity to provide some treatment to the control group, this body of research needs to be built piece by piece, with a series of studies that investigate different components of the larger research question. **For this to be effective, however, the overall quality of studies needs to be improved, including a greater emphasis on randomized, controlled trials, where at all possible; substantially larger sample sizes; uniformity of outcomes evaluated and instruments used to measure them; and consistent treatments that do not vary widely within treatment groups (i.e., experimental or control group).**

The cost of continuing the current course of assuming that EIBI works may not be obvious. EIBI is costly financially for society and requires a large time commitment from children, their families, and their teachers or therapists. However, these programs may not appear to pose any harm for the children themselves. Nevertheless, the opportunity costs could be high, indeed, of providing suboptimal care to these children, simply because we as a society do not know what works best. The children may be treated with an intervention that is not as effective as the alternatives. And if we accept an intervention because it seems to work, without solid evidence, research on the alternatives or on how it can be improved is likely to be stifled.

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