Generally accepted standards of care re: ABA intervention intensity

- CASP: independent nonprofit trade association
- Guidelines developed by many subject matter experts over a decade
- Intensity based on *medical necessity* and *scope of treatment*.
- Comprehensive intervention (*multiple target behaviors in multiple domains*): 30 - 40 hrs/wk for extended duration
- Focused intervention (small number of target behaviors): 10 – 25 hrs/wk. More may be needed if behaviors jeopardize health, safety, or progress.

"Patients should receive treatment at the intensity that is most effective to achieve treatment goals. Decisions to adjust treatment intensity should be individualized and based on the patient's response to treatment."

Best available evidence

- Preponderance of evidence from multiple scientific studies.
- Criteria for evidence-based interventions, National Clearinghouse on Autism Evidence and Practice:
  - At least 2 high-quality group-design studies conducted by at least 2 different researchers or groups OR
  - At least 5 high-quality single-case design studies conducted by at least 3 different researchers or research groups with a total of at least 20 participants across studies OR
  - A combination of at least 1 high-quality group-design study and at least 3 high-quality single-case design studies conducted by at least 2 different research groups

A non-exemplar

- Sandbank, M. et al. (2024) Determining associations between intervention amount and outcomes for young autistic children: A meta-analysis. *JAMA Pediatrics, 178(8),* 763 – 773.

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  - In "behavioral" category, authors lumped together studies that varied across several dimensions:
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    - ABA and non-ABA interventions
    - Child and caregiver participants
    - Child participant characteristics (e.g., age, autism severity, cognitive and other skills)
    - Direct and indirect outcome measures
- Calls into question authors' conclusions that intervention intensity has no bearing on child outcomes, and any conclusions re: ABA interventions.

Low Intensity Studies Selectively Sample from Participants with Higher IQ

	Low	Medium	High	F	p	η2
Hours Per Day	77.75 (18.94) [a]	70.98 (20.87) [b]	58.94 (9.94) [ab]	11.58	<.001	.23
Number of Days	73.62 (17.60) [a]	66.10 (15.16)	63.07 (14.28) [a]	5.25	<.01	.08
Cumulative Hours	74.43 (20.01) [a]	69.72 (18.71)	60.90 (13.07) [a]	5.23	<.01	.11

The size of selective sampling was meaningful!

Creates a big problem because IQ is a strong predictor of outcome

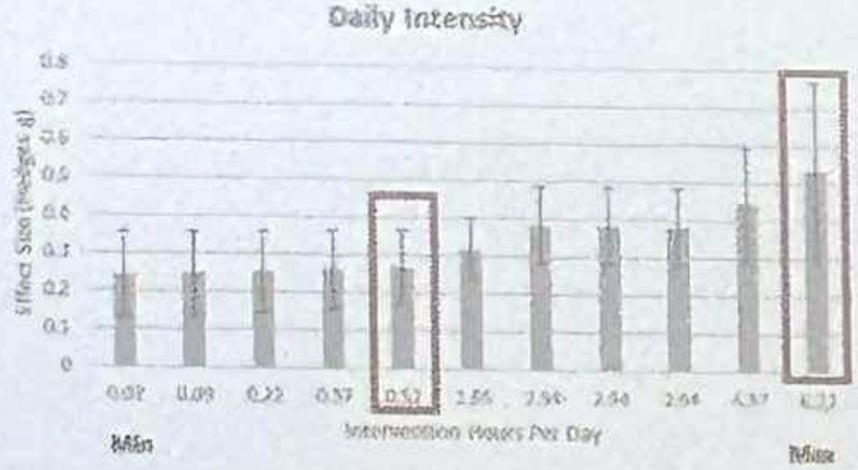
Intensity Matters!

Re-ran same models

Added IQ as a covariate

Effect is Big!

- For example, low daily intensity half hour per day (2.5 hours per week) yields only 50% of the effect of 6 hours per day



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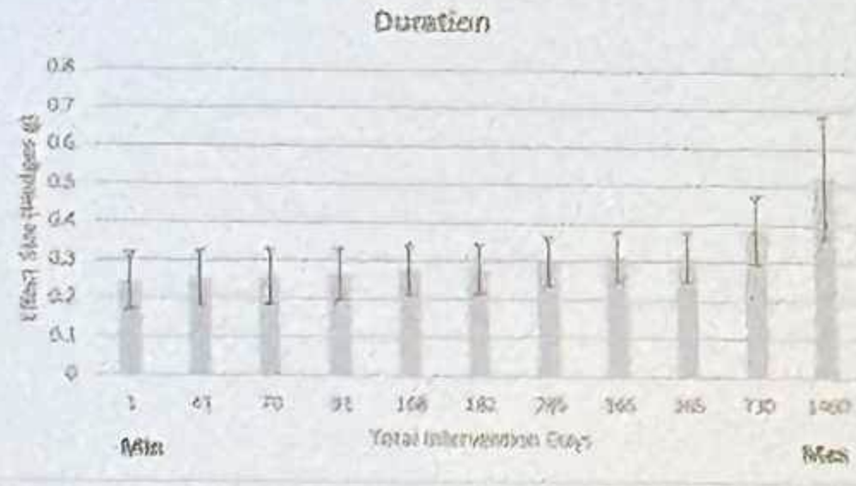

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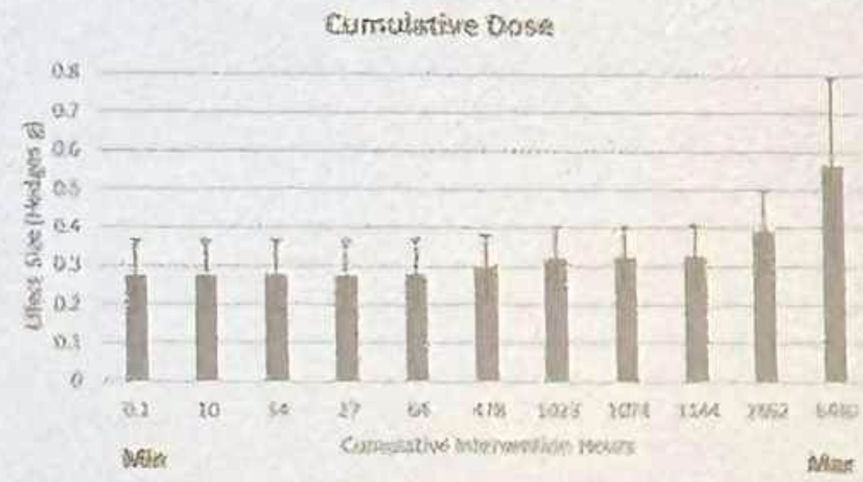


p=.0323

Effects Remain After Adjustment for Methodology

Predictor Categories Only						Adjustment for Method and Reporting Quality		Adjustment for Method and Reporting Quality and Study Design	
	b	SE	z	p	95% CI	b	95% CI	b	95% CI
Adaptive Function	.233	.039	6.04	<.001	.158 to .310	.255	.139 to .372	.229	.051 to .407
Age	.004	.042	0.10	.920	-.078 to .087	.027	-.095 to .148	.001	-.180 to .182
Autism Symptoms	.209	.039	5.36	<.001	.133 to .285	.231	.115 to .347	.210	.030 to .390
Cognitive/Language	.279	.037	7.60	<.001	.207 to .351	.297	.184 to .410	.274	.099 to .449
Foundational Social Skills	.320	.050	6.44	<.001	.222 to .417	.335	.207 to .463	.316	.131 to .501
Intensity	.175	.054	3.25	.001	.069 to .281	.192	.059 to .325	.152	-.042 to .345
Motor	.091	.057	1.60	.110	-.021 to .203	.111	-.031 to .252	.083	-.109 to .276
Parent Characteristics	.208	.059	3.51	<.001	.092 to .324	.240	.091 to .388	.217	.011 to .423
Socioeconomic Status	.065	.080	0.81	.420	-.092 to .222	.089	-.086 to .264	.087	-.129 to .303
Sex	.084	.055	1.52	.123	-.025 to .191	.104	-.033 to .242	.087	-.103 to .277
Other	.384	.173	2.22	.026	.046 to .722	.382	.031 to .733	.376	.015 to .737

Variation Between EIBI and NDBI Studies

Predictor Category	EIBI Studies (k = 11)		NDBI Studies (k = 28)	
	b	95% CI	b	95% CI
Adaptive Function	.43	.31 to .54	.10	.01 to .19
Age	.04	-.08 to .16	.05	-.05 to .15
Autism Symptoms	.27	.15 to .39	.20	.11 to .27
Cognitive/Language	.51	.40 to .62	.14	.06 to .22
Foundational Social Skills	.49	.34 to .63	.25	.13 to .36
Intensity	.07	-.10 to .25	.21	.10 to .33
Motor	.41	.23 to .58	-.08	-.21 to .05
Parent Characteristics	.39	.10 to .69	.15	.03 to .27
Socioeconomic Status	-.01	-.30 to .29	.06	-.11 to .23
Sex (Male)	-.18	-.51 to .15	.01	-.10 to .12

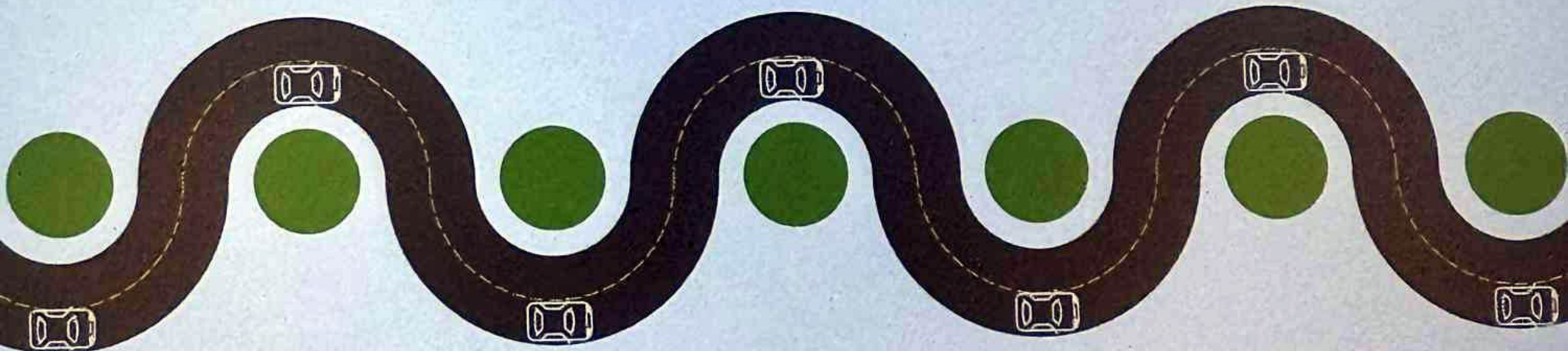
Lower predictive strength in EIBI studies is almost certainly due to restricted range of intensity at

Road to Value-Based Care

Collect Multi-Modal Client Characteristics to Inform Initial and Ongoing Intervention
(e.g., age, cognitive level, etc.)

Collect Session and Epoch-Based Quality Indicators
(# sessions attended, caregiver participation, etc.)

Develop and Refine Individual and Aggregate Indicators of Value Relative to Cost



Scalable Data Captures Across Patients

Collect Intervention Program Target Behavior Data
(ex. accuracy, prompt)

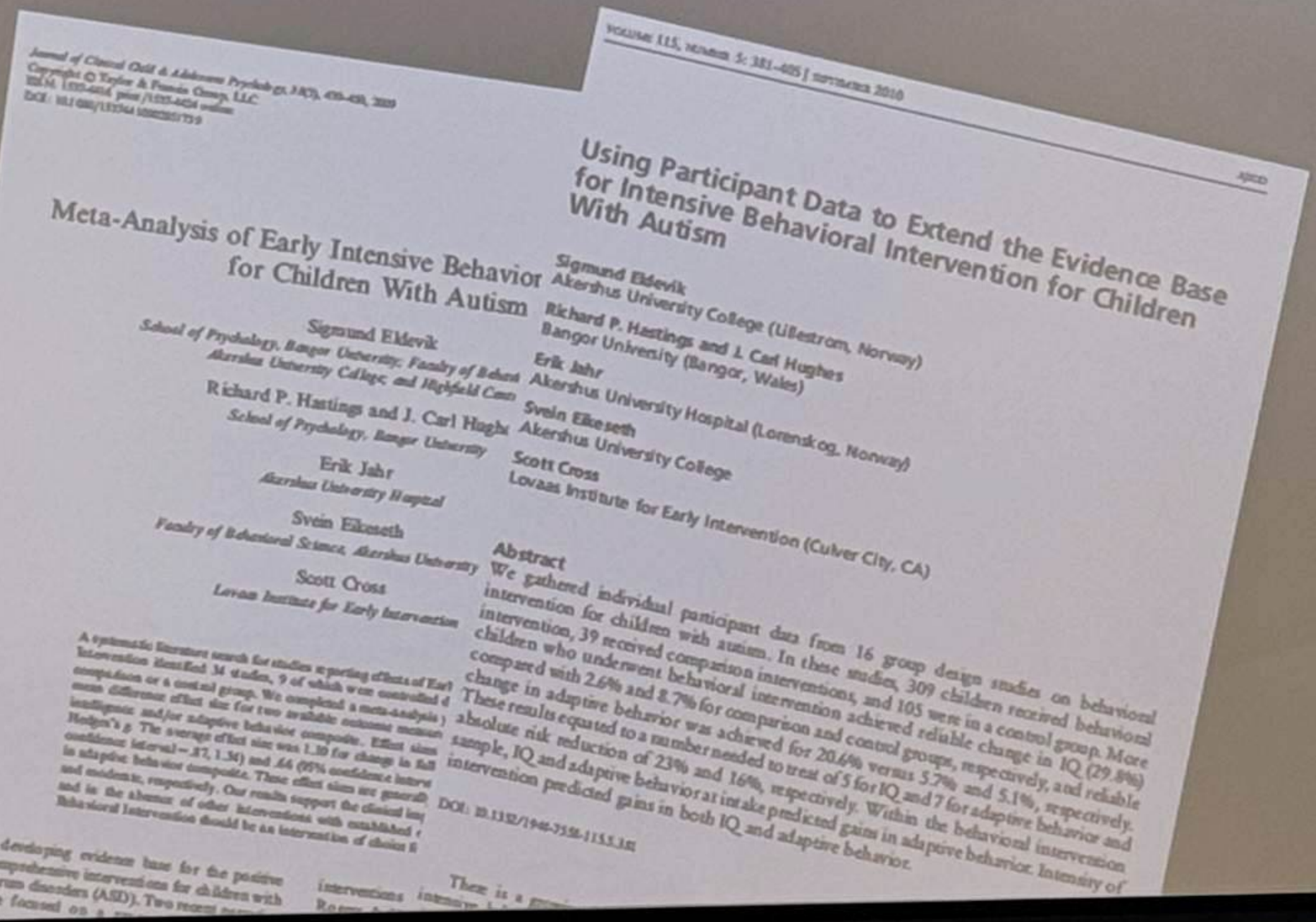
Store in a Common Data Platform for Ongoing Analysis

Tie Value to Financial Incentives

A SYSTEMATIC REVIEW OF EARLY INTENSIVE BEHAVIOURAL INTERVENTION FOR CHILDREN WITH AUTISM USING INDIVIDUAL PARTICIPANT DATA

Sigmund Eldevik, Kristine Berg Titlestad, Svein Eikeseth, Børge Strømgren, Anya Fields and Christina Melanie Saez

Updated IPD Meta-analysis of EIBI



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DOI: 10.1080/15374416.2010.486315

Meta-Analysis of Early Intensive Behavioral Intervention for Children With Autism

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Richard P. Hastings and J. Carl Hughes
School of Psychology, Bangor University

Erik Jahr
Akershus University Hospital

Svein Eikeseth
Faculty of Behavioral Sciences, Akershus University

Scott Cross
Lovaas Institute for Early Intervention

A systematic literature search for studies reporting effects of Early Intensive Behavioral Intervention identified 34 studies, 9 of which were controlled designs (comparison or a control group). We completed a meta-analysis of these studies to obtain different effect size (for two available outcome measures: intelligence and/or adaptive behavior composite). Effect sizes were Hedges's g. The average effect size was 1.20 for change in full confidence interval = .87, 1.54) and .44 (95% confidence interval = in adaptive behavior composite. These effect sizes are generally and moderate, respectively. Our results support the clinical impact and in the absence of other interventions with established effectiveness Behavioral Intervention should be an intervention of choice fo

There is a developing evidence base for the positive effects of comprehensive interventions for children with autism spectrum disorders (ASD). Two recent systematic reviews have focused on a

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AJMR

Using Participant Data to Extend the Evidence Base for Intensive Behavioral Intervention for Children With Autism

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Akershus University College (Lillestrom, Norway)
Richard P. Hastings and J. Carl Hughes
Bangor University (Bangor, Wales)
Erik Jahr
Akershus University Hospital (Lorenskog, Norway)
Svein Eikeseth
Akershus University College
Scott Cross
Lovaas Institute for Early Intervention (Culver City, CA)

Abstract

We gathered individual participant data from 16 group design studies on behavioral intervention for children with autism. In these studies, 309 children received behavioral intervention, 39 received comparison interventions, and 105 were in a control group. More children who underwent behavioral intervention achieved reliable change in IQ (29.8%) compared with 2.6% and 8.7% for comparison and control groups, respectively, and reliable change in adaptive behavior was achieved for 20.6% versus 5.7% and 5.1%, respectively. These results equated to a number needed to treat of 5 for IQ and 7 for adaptive behavior and absolute risk reduction of 23% and 16%, respectively. Within the behavioral intervention sample, IQ and adaptive behavior at intake predicted gains in adaptive behavior. Intensity of intervention predicted gains in both IQ and adaptive behavior.

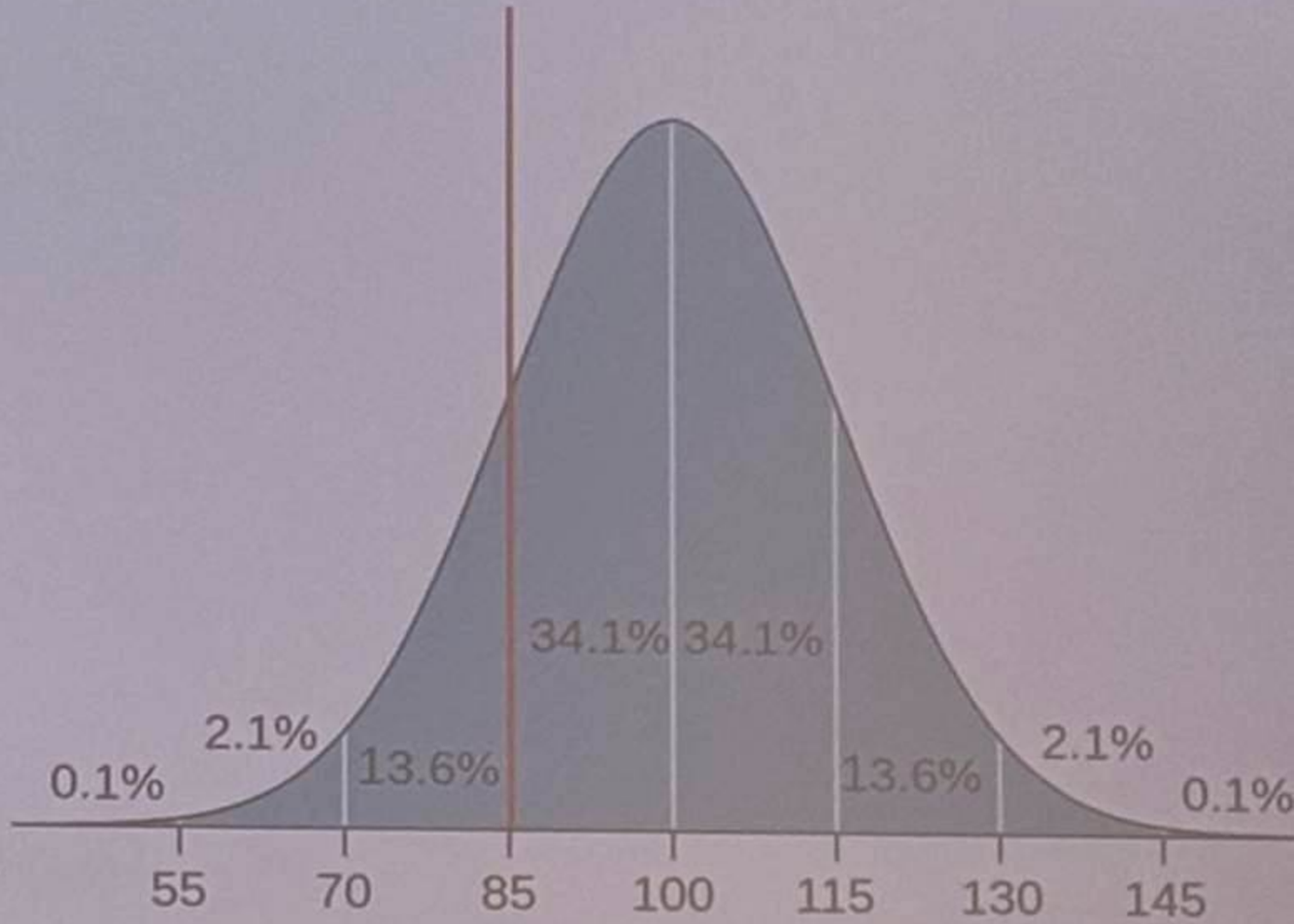
DOI: 10.1352/1948-3558-115.5.381

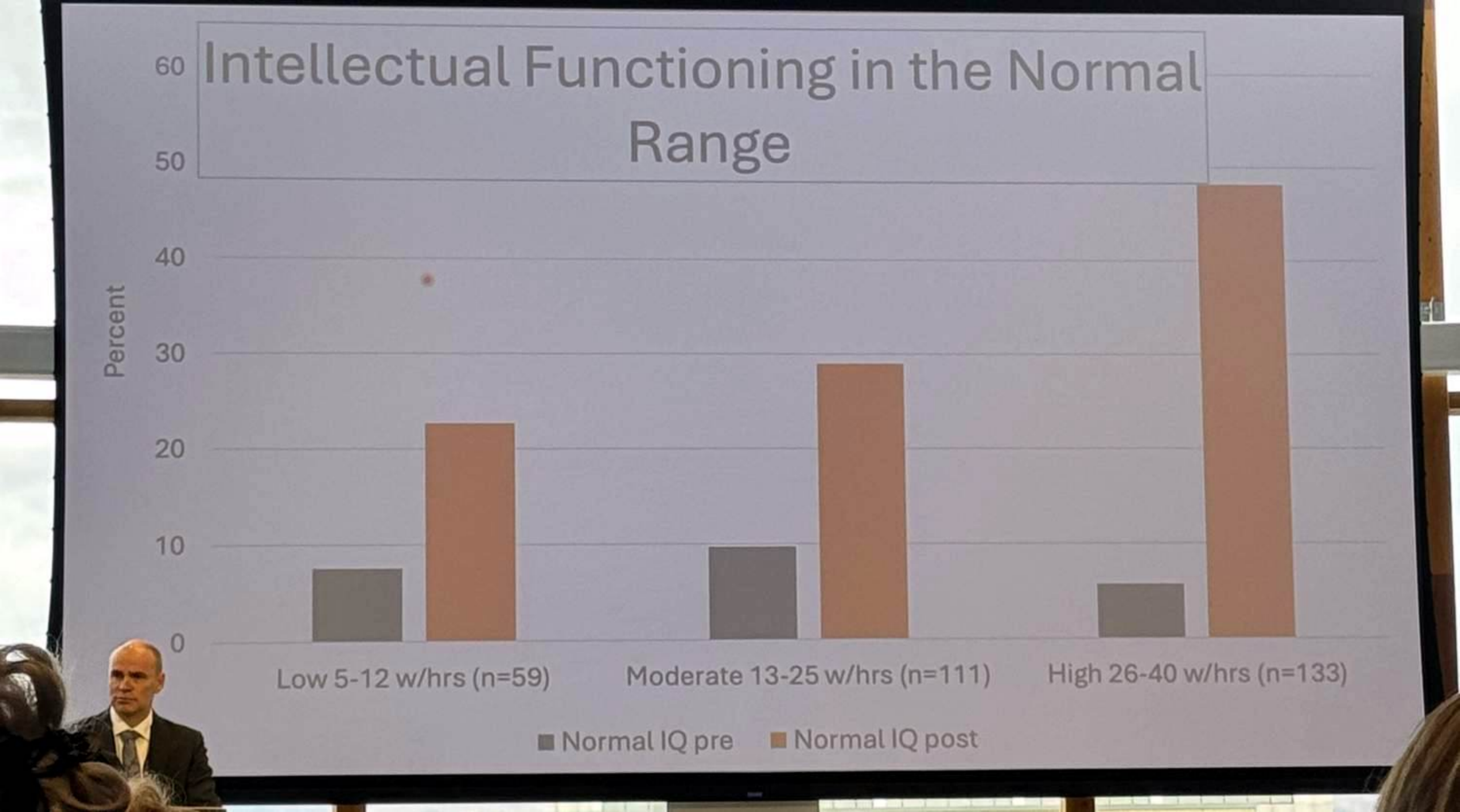
There is a
interventions

	EIBI (n=341)		Comparison (n=280)	
	Mean	SD	Mean	SD
Age (months)	43.1	11.9	45.0	12.9
Adaptive (ABC)	63.3	10.8	65.2	11.9
Autism Severity	40.6	7.4	39.9	7.5
Intellectual (IQ)	56.5	18.5	58.7	18.2
Weekly hours	24.2	11.1	13.1	9.8

Clinical Significance

- Scores moving to within one standard deviation of the population mean can be considered clinically significant (Jacobson & Truax, 1991)
- 85 or higher for intellectual and adaptive functioning

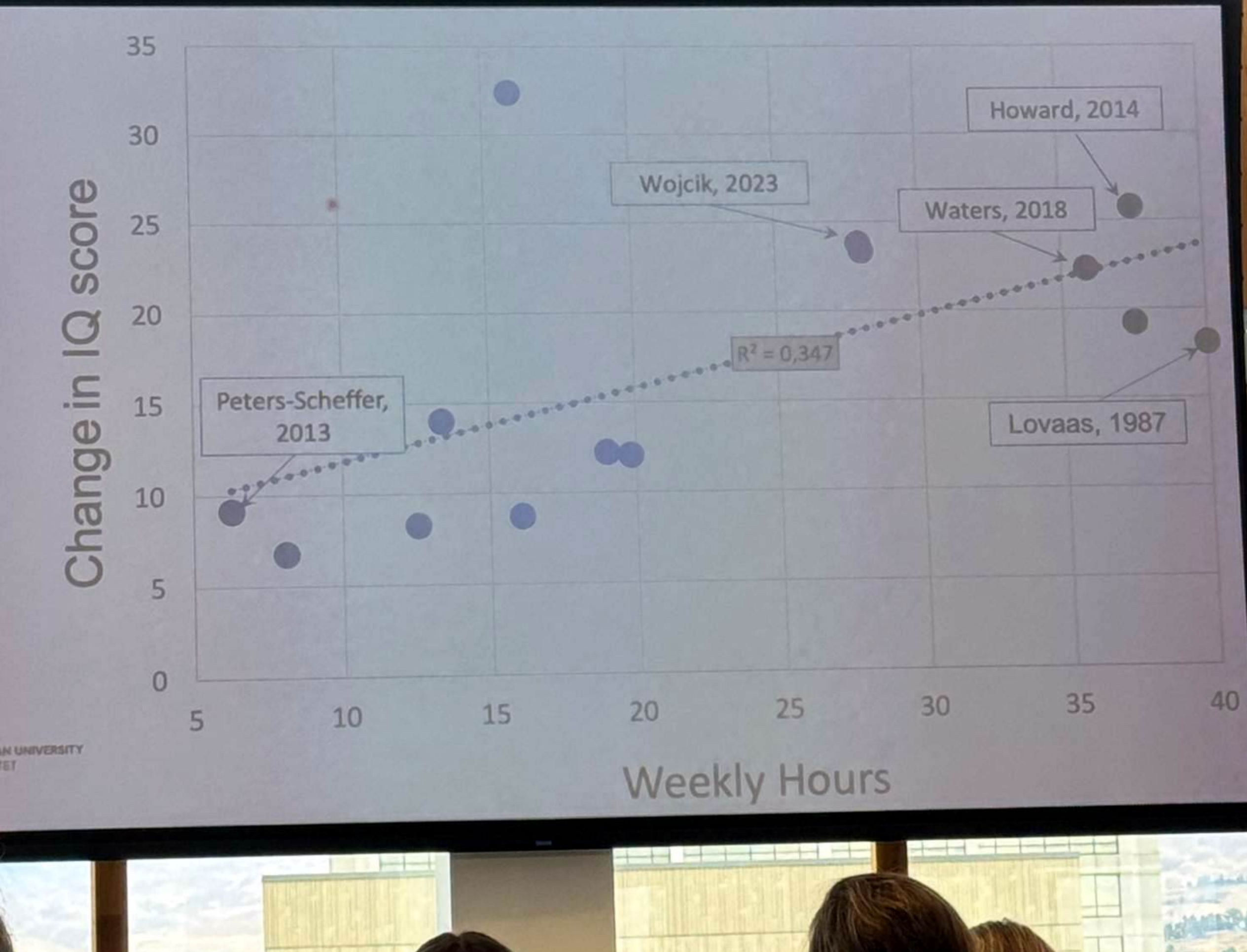


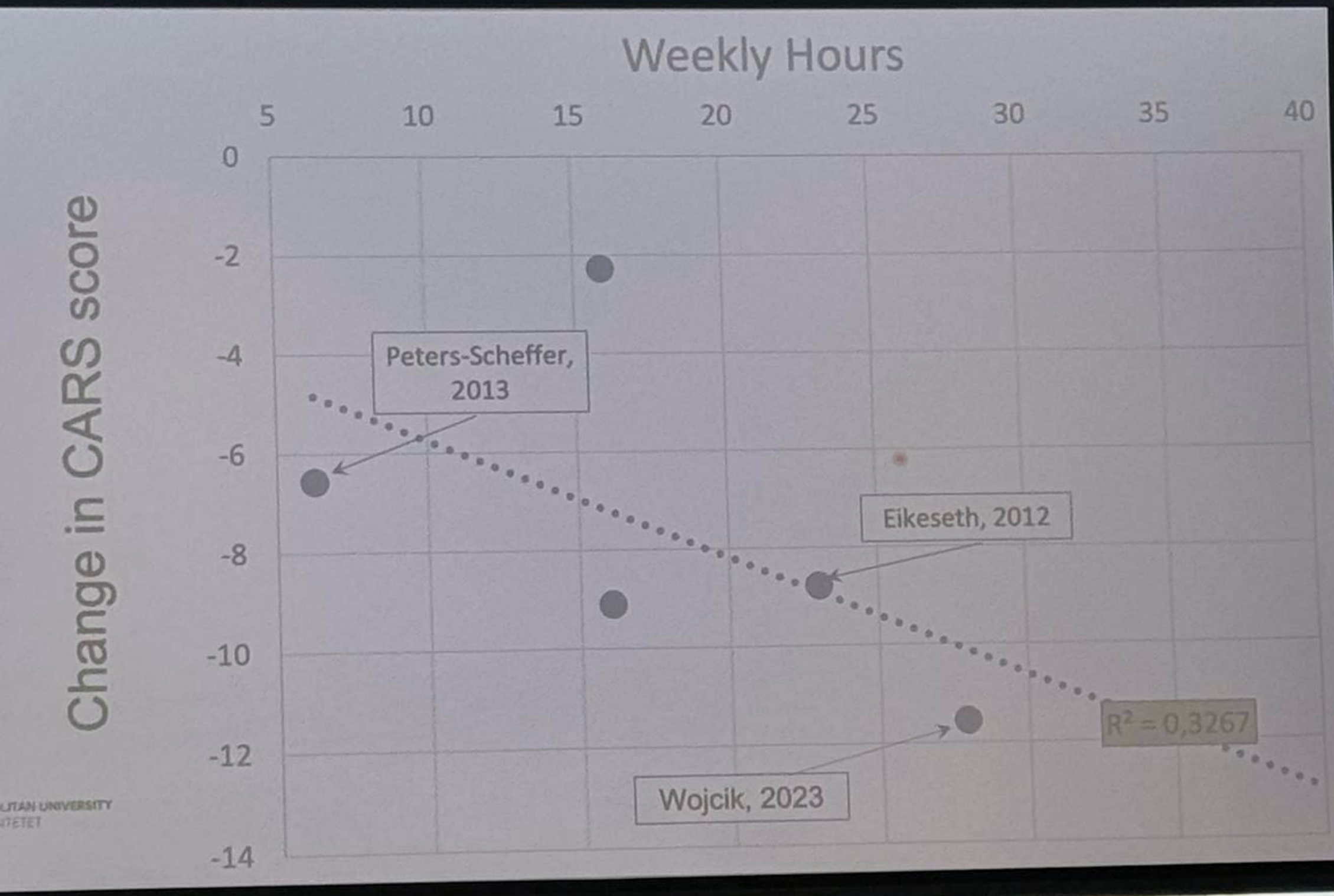

Intellectual Functioning in the Normal Range
60
50
40
30
20
10
0
Percent
Low 5-12 w/hrs (n=59)
Moderate 13-25 w/hrs (n=111)
High 26-40 w/hrs (n=133)
Normal IQ pre
Normal IQ post

CARS severity groups

SEVERITY GROUP

- ☐ **Minimal-to-No Symptoms of Autism Spectrum Disorder**
  (15–29.5; *15–27.5 for ages 13+*)
- ☐ **Mild-to-Moderate Symptoms of Autism Spectrum Disorder**
  (30–36.5; *28–34.5 for ages 13+*)
- ☐ **Severe Symptoms of Autism Spectrum Disorder**
  (37 and higher; *35 and higher for ages 13+*)


Change in IQ score
35
30
25
20
15
10
5
0
5
10
15
20
25
30
35
40
Weekly Hours
Howard, 2014
Wojcik, 2023
Waters, 2018
R² = 0,347
Peters-Scheffer, 2013
Lovaas, 1987


Weekly Hours
5
10
15
20
25
30
35
40
0
-2
-4
-6
-8
-10
-12
-14
Change in CARS score
Peters-Scheffer, 2013
Eikeseth, 2012
Wojcik, 2023
R² = 0,3267

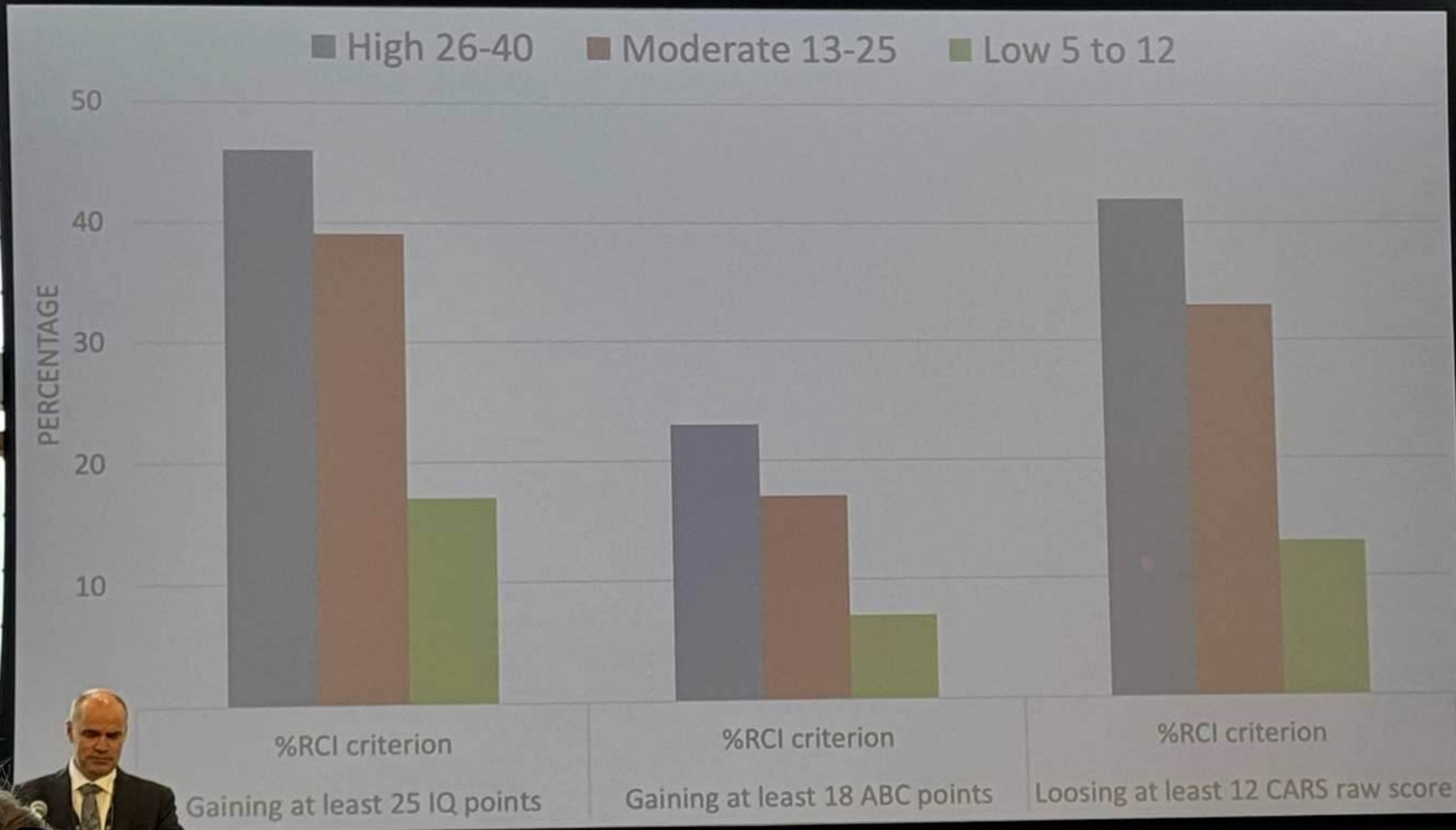
Formula that computes the change needed to show that effects are not due to measurement error, variation in sample etc, with 95% certainty – statistically reliable

For the present analysis the RCIs were:

25 IQ points

18 ABC points

-12 CARS raw score


High 26-40
Moderate 13-25
Low 5 to 12
50
40
30
20
10
PERCENTAGE
%RCI criterion
Gaining at least 25 IQ points
%RCI criterion
Gaining at least 18 ABC points
%RCI criterion
Loosing at least 12 CARS raw score

	Mean IQ Change	Mean ABC Change	Mean CARS Change
High 26-40	22	9	-11
Moderate 13-25	15	5	-9
5 to 12	11	2	-6

ABA CODING COALITION 2025 GOALS

- Continue to evaluate the readiness of 0362T and 0373T (assessment and treatment of destructive behavior) codes to be elevated to Category I status with the CPT Editorial Panel.
- Update the Model Coverage Policy, including integration of the updated CASP Guidelines.
- Continue evaluating ways to obtain coverage of / reimbursement for non-face-to-face QHP activities that are integral to ensuring quality treatment.
- Continue monitoring MUE barriers and working with CMS on both MUE and NCCI edits that are causing issues for providers.
- Continue payer and provider education around the CPT code set, including webinars, conference presentations, answering portal inquiries, and updating the ABACC website.

CMS TELEHEALTH COVERAGE

In the NPRM, CMS noted that *they do not have the authority to expand the list of eligible Medicare telehealth practitioners to include therapists after 2024 (citing regulations 87 FR 69449 – 69451) because the federal Consolidation Appropriations Act (CAA) of 2023 did not change the list of practitioners who can furnish and bill for telehealth services permanently.*

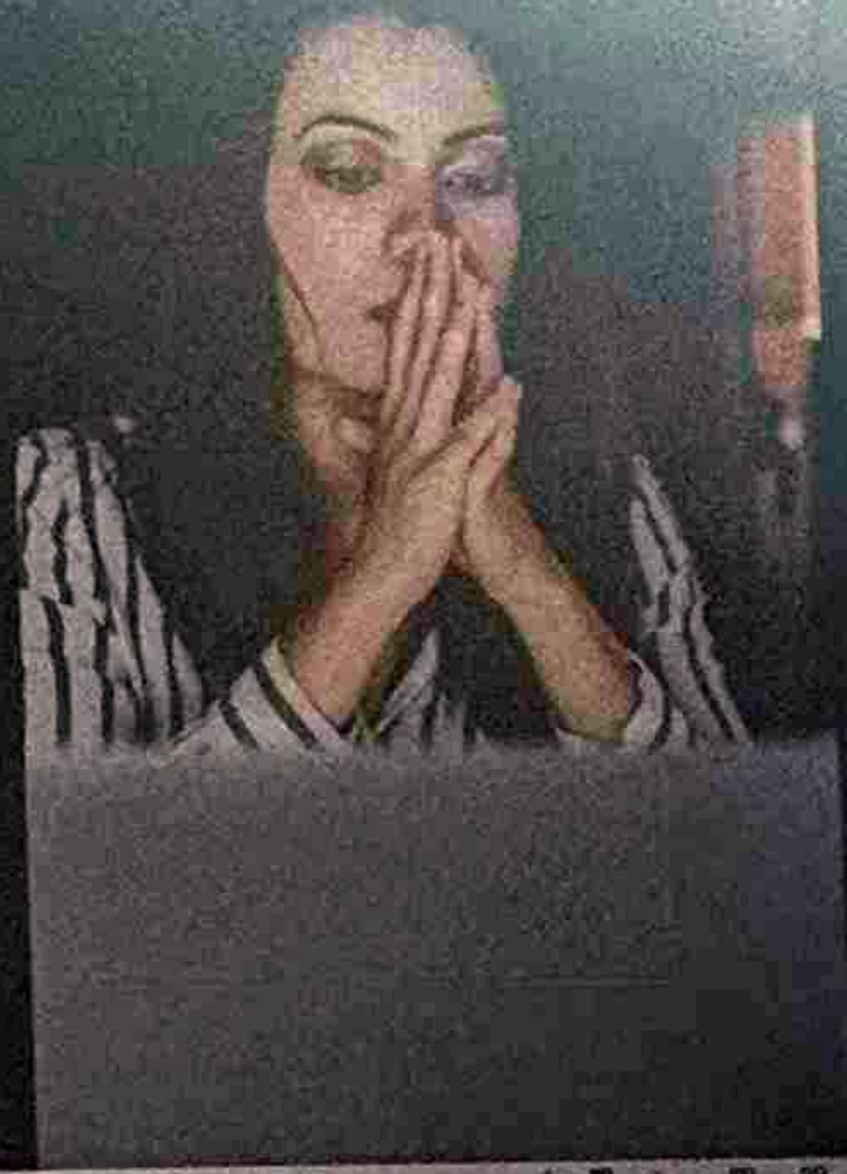
Rather, the CAA extended current telehealth flexibilities through the end of 2024. *Therefore, CMS proposes to retain all CPT codes for therapeutic services as telehealth Category 3 (temporary) through December 31, 2024. That includes the adaptive behavior/ABA services codes (97151-97158, 0362T, 0373T).*

IS CONCURRENT BILLING ALLOWED?

- The AMA CPT® book includes no exclusionary parentheticals indicating that these services may not be reported concurrently.
- The November 2018 AMA CPT® Assistant article specifies that code 97155 (adaptive behavior treatment with protocol modification administered by QHP; may include simultaneous direction of technician) is intended to be reported with 97153 (adaptive behavior treatment by protocol administered by technician) when the QHP directs a technician who is implementing a protocol with a patient.
- Also see the Supplemental Guidance Article at www.abacodes.org
- The services represented by 97155 and 97153 are separate and distinct, so billing them concurrently does not constitute duplication.

WHAT ARE INDIRECT SERVICES?

- Examples of indirect services include activities like updating written protocols and treatment plans, graphing data, writing session notes, and preparing or cleaning up the treatment space/room.
- There is no separate code for indirect services in the 2019 CPT code set (nor was there in the Category III CPT code set).
- Some payers may supplement the CPT codes with a HCPCS or other CPT code (e.g., H0032, G9012, H2019) for reporting indirect activities.
- If a payer does not, activities that occur prior to and after face-to-face time should not be reported, rather it's INCLUDED in the reimbursement for the face-to-face time you reported.



NATIONAL CORRECT CODING INITIATIVE EDITS

The NCCI quarterly edits set procedure to procedure edits (i.e., what services/codes can be billed together on a given date of service).

Some examples include limitations on ABA and speech or psychotherapy services being billed for the same patient, on the same day. This is NOT CONCURRENT.

Reports of these issues are really ramping up!

WHAT IS ADAPTIVE BEHAVIOR SERVICE PROTOCOL MODIFICATION?

(a) adjustments to specific components of a protocol (e.g., treatment targets, treatment goals, observation and measurement, reinforcers, reinforcer delivery, prompts, instructions, materials, discriminative stimuli, contextual variables);

(b) observations to determine if the protocol components are functioning effectively for the patient or require adjustments;

(c) active direction of a technician while the technician delivers a service to a patient to ensure that the procedures are being implemented correctly, to correct errors in implementation, or to train the technician to implement a modified protocol; and

(d) QHP implementation of the protocol with the patient to determine if changes are needed to improve patient progress or to test a modified protocol.

Cold Probe

- Medicaid cannot pay for ABA therapy in schools because this would constitute improper double billing.
- A school has no obligation to allow a child to access ABA in school settings unless the child's IEP team concludes that this is necessary to provide a FAPE to the child.
- Schools cannot allow in outside ABA providers because this would violate FERPA.
- Insurers are not obligated to cover ABA in school settings; this is educational ABA and is the school's responsibility.
- Medicaid reimbursable services in school settings are limited to services provided by schools (Medicaid school-based services programs).

Education versus Medical Treatment:
Different standards, rights, providers, purposes.

Education

Sufficient special education and related services to provide a FAPE

- Behavior support, behavior management

School Personnel

Education standard (Endrew F,: related services necessary for appropriately ambitious educational goals in light of the child's circumstances)

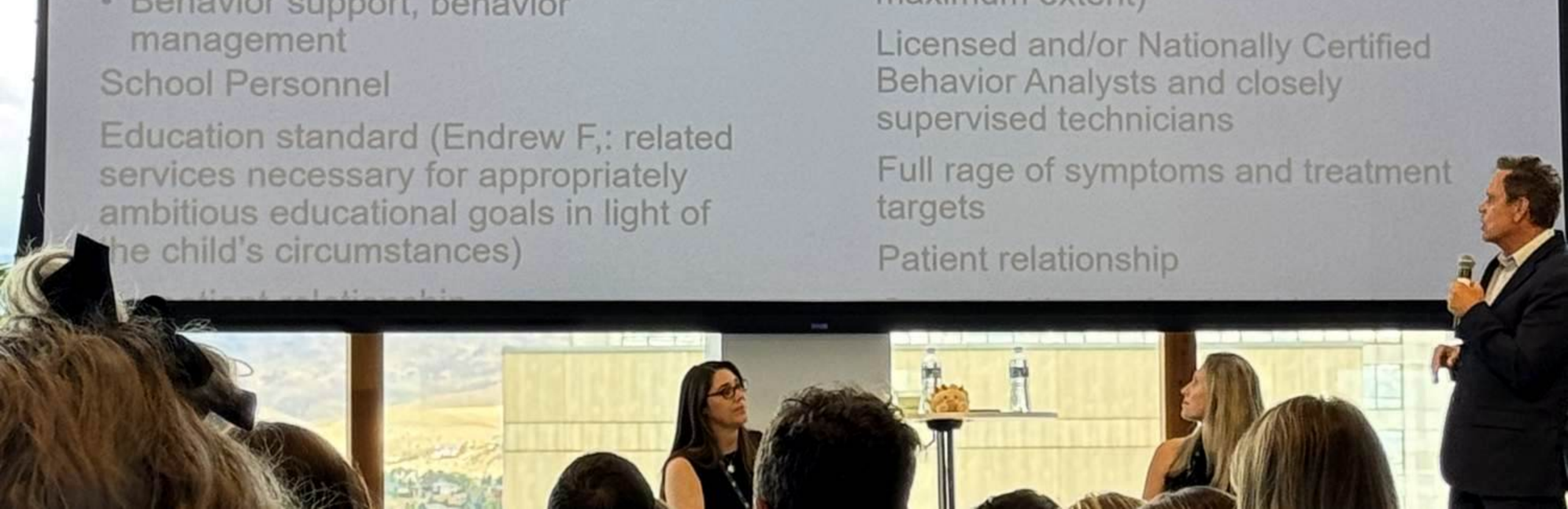
Medical treatment

Medical standard (Correct or ameliorate all impairing ASD symptoms to the maximum extent)

Licensed and/or Nationally Certified Behavior Analysts and closely supervised technicians

Full rage of symptoms and treatment targets

Patient relationship



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gets

ient relationship

It's Not Either/Or

- Both systems important and child's rights under both should be vindicated.
- Work to be done under Endrew F. to access sufficient education.
- Work to be done under ADA to access sufficient healthcare treatment. For purposes of today we will focus on this important area.
- Child's right to access medically necessary care is not limited to what school personnel believe is necessary for an appropriate education.

Background to the Issue

- ASD is a global developmental disorder involving impairments in social interaction, communication, and behavior, and children with ASD frequently have *difficulty generalizing behaviors across settings*.
- Because of this and because the primary evidence-based treatment for ASD, applied behavior analysis (ABA), involves the interaction between behavior and environment, it is **medically necessary for some children with ASD to receive behavioral health treatment across a variety of settings, including school settings**, to successfully treat their condition and achieve maximum functioning.

edical Treatment Generally Accepted Standards of Care

CASP The Council of Autism

Applied Behavior Analysis Practice Guidelines for the Treatment of Autism Spectrum Disorder

Guidance for Healthcare Funders, Regulatory Bodies, Service Providers, and Consumers

THIRD EDITION

"ABA treatment must not be restricted a priori to specific settings but instead should be delivered in the settings that maximize treatment outcomes for the individual patient. It may be medically necessary for a patient to receive services in a particular location for a variety of reasons, including but not limited to generalization needs, the impact of interactions in this environment on skill building or behavioral targets in the treatment program, or to access the required intensity of services for the patient. For example, treatment in various community settings such as daycare, school, or a recreational activity may be medically necessary to promote social-emotional reciprocity, nonverbal communicative behaviors, and the development and maintenance of relationships." P.39

Medically Necessary ABA in School Settings

- ABA may be medically necessary for some children in the school setting.
  - Generalization of skills, treatment consistency, and fidelity
  - Deficiencies or inconsistencies in one setting can affect the child's entire treatment program
  - Challenging behaviors
  - Behavioral, social communication amelioration of deficits
  - Social deficits/interaction not progressing is school setting
  - Independence and safety,
  - Long term functioning
- As with any medically necessary care, if they do not receive it, it negatively impacts their current functioning across settings, their overall treatment program, and their future health and functioning. In short, there are lifelong consequences beyond the quality of their education.

Legal Basis for Medicaid and Insurance Funding in School Settings

- Mandates
- MHPAEA (Federal mental health parity)
- State mental health parity laws
- Contract
- Medicaid EPSDT

Insurance-Mandates - *Burke v. IBC* (Pa. 2017)

- Medically necessary care had to be provided in school setting notwithstanding general exclusion in policy.
- 40 Pa. Cons. Stat. § 764h(c) Coverage under this section shall be subject to copayment, deductible and coinsurance provisions and any other general exclusions or limitations of a health insurance policy or government program to the same extent as other medical services covered by the policy or program are subject to these provisions.
- 40 Pa. Cons. Stat. § 764h(f)(1) "Applied behavioral analysis" means the design, implementation and evaluation of environmental modifications, using behavioral stimuli and consequences, to produce socially significant improvement in human behavior or to prevent loss of attained skill or function, including the use of direct observation, measurement and functional analysis of the relations between environment and behavior.

Insurance-Mandates

- "As Mr. Burke stresses and the Law explicitly recognizes, ABA is an environmentally sensitive form of therapy. Ultimately, we simply do not believe that the Legislature intended to permit insurers to exclude coverage in the sensory-laden educational environment where children spend large portions of their days, or to require families to litigate the issue of medical necessity discretely in individual cases to secure such location-specific coverage for the treatment." *Burke v. IBC*, 642 Pa. 691, 710 (Pa. 2017)

Insurance-Federal Mental Health Parity (MHPAEA)

- Excluding coverage of ABA services in locations where they are medically necessary is a Nonquantitative treatment limitation subject to the federal Mental Health Parity and Addiction Equity Act. 29 U.S.C. §1185a; 42 U.S.C. § 300gg-26.
  - Cannot have a treatment limitation that applies only to MH condition. 29 U.S.C. § 1185a(a)(3)(A)(ii).
  - Cannot have a non quantitative treatment limitation (NQTL) imposed on MH unless the processes, strategies, evidentiary standards or other factors used in applying the NQTL to MH/SUD benefits are comparable to and applied no more stringently than for medical/surgical benefits. 29 U.S.C. § 1185a(a)(3)(A)(ii).
    - Application of generally accepted standards of care to MH and M/S
    - Restrictions on medically necessary settings

tate Mental Health Parity Acts: California SB 855

- Insurer must follow [illegible] accepted standards [illegible] and clinical practice guidelines [illegible] relevant nonprofit health care [illegible] professional associations [illegible] making medical necessity [illegible] of care decisions.
- Prohibits exclusion [illegible] position that [illegible] could be covered [illegible] entitlement program [illegible], but not limited to, special education or an individualized education program.

Insurance-Contract

- Exclusions for special education services provided by school personnel do not exclude medically necessary behavioral health treatment being delivered in this setting in similar fashion to other community settings.

Medicaid EPSDT

- Medicaid agency has obligation to cover all coverable medically necessary care for Medicaid eligible children under 21 based on individualized determinations of medical necessity regardless of whether such care is currently in the State Plan. 42 U.S.C. §1396d(r)(5).
- Colorado
- Missouri
- Kansas

Schools' Obligation to Allow Access to Medically Necessary ABA under ADA and Section 504

- Section 504 of the federal Rehabilitation Act applies to entities which receive federal financial assistance and prohibits discrimination of the basis of disability.
- The ADA (Americans with Disabilities Act) was passed after Section 504 and applies to private institutions, workplaces, state-funded entities and other institutions that were not covered under section 504

The Americans with Disabilities Act (ADA)

- Public schools receive federal financial assistance making them subject to both Section 504 of the Rehabilitation Act and the ADA.
- When care is medically necessary for a student in the school setting, being deprived of this care results in impediments to access and access that is not equivalent to that of nondisabled students who do not face these heightened health risks in attending and participating in school programs, activities, and services.
  - For this reason, it is well established that students using service dogs to increase their independence by assisting them in activities and interactions are entitled to this access in school settings just as they are in other community settings.
  - Similarly, students who require support from medical professionals to safely attend schools without compromising their current and long-term treatment and prognosis are entitled to reasonable accommodations to address their healthcare needs.

ADA/504 ABA in Schools Not Limited by FAPE

- Do not have to proceed under IDEA per Supreme Court decision in *Fry v. Napoleon Comm. Sch. Dist.* (2017)
- Plaintiffs in *Fry* sought relief under Section 504 for school's refusal to allow child to attend school with her prescribed service dog did not have to exhaust administrative remedies under the IDEA. Supreme Court held that plaintiffs could proceed in federal court without going through IDEA dispute resolution. Gravamen of complaint was something other than denial of a free and appropriate education (FAPE) required by IDEA.
- Clues: Could First, could the plaintiff have brought essentially the same claim if the alleged conduct had occurred at a public facility that was not a school—say, a public theater or library? And second, could an adult at the school—say, an employee or visitor—have pressed essentially the same grievance?

ADA/504 ABA Medically Necessary ABA in Schools

- ADA requires school to make reasonable accommodation to allow child access to medically necessary care in the school setting.
- *K.M. v. Tehachapi School Dist.* (E.D. Ca. 2018) (denying motion to dismiss ABA claims where school refused access to medically necessary ABA; court noted allegations showing a lack of investigation to determine whether the accommodation requested was reasonable).

Z.W. v. Horry County School District, 68 F. 4th 915 (4th Cir. 2023)

- The school had used "ABA-like" strategies in response to ongoing regression. MUSC Neurodevelopmental pediatrician prescribed intensive ABA program provided by BACB-certified or registered personnel across settings, including school, as medically necessary. School refused to consider access claiming that its program was meeting child's educational needs.
- "[The "essence" of Z.W.'s beef with the school district is its refusal to permit him to bring his privately supplied and funded ABA therapist to school with him. Z.W. could file essentially the same claim against a library, a museum, or a summer camp. What is more, a non-student visitor (say, a friend, sibling, or other relative) could make a largely identical claim against the school district if it refused to permit an ABA therapist to accompany the visitor to Z.W.'s school."
- Also, "[b]ecause Z.W.'s complaint requests nothing that would be "provided at public expense . . . and without charge" to him and his parents, § 1401(9), its "essence" or "crux" does not appear to "concern[] the denial of a FAPE" in either "surface" or "substance," quoting *Fry*, 580 U.S. at 169, 171, 172.)

Louisiana Act 696—Access to Medically Necessary Behavioral Health Services in Schools

- §173. Behavioral health services for students
- 10 (A)(1) A public school governing authority shall not prohibit a behavioral health provider from providing behavioral health services to a student at school during school hours if the student's parent or legal guardian requests such services from the provider.
- (2) Not later than January 1, 2019, each public school governing authority shall adopt a policy to implement the provisions of this Section . . . .
- Not explicitly cover ABA/LABAs, constraints on time/location interfere with access based on nature of ABA

Florida HB 1401

- ABA Techs included in personnel who can provide services in school pursuant to Florida's statute on Collaboration of public and private instructional personnel. Fla. Stat. § 1003.572.
- Florida HB 1401 passed House last session.
- Previously passed legislation clarifying broad scope of Medicaid's coverage obligations.
- Other states looking at legislation.

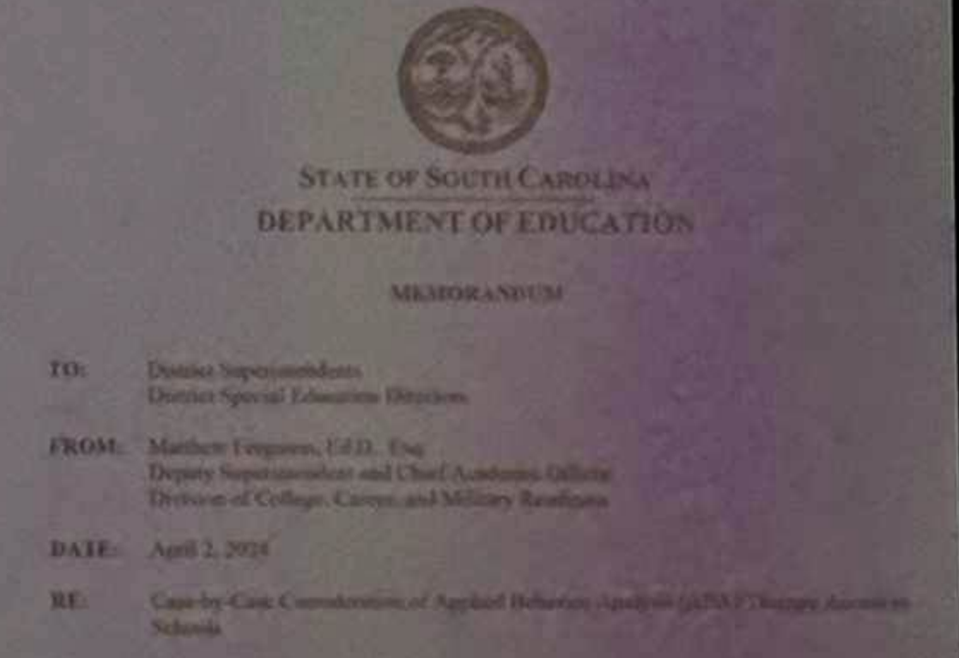
Colorado HB22-1260-Codified at Colo Rev. State § 22-20-121

- Preamble recognizes that generally accepted standards of care require that ABA treatment be available across settings, including schools; that insurance and Medicaid have obligations to cover medically necessary care in school settings; that no family should have to choose between a child attending public school or receiving access to medically necessary services; and that ensuring that children have access to these services will also improve the efficacy of their treatment and their integration into the community, as well as reduce long-term costs to the state.
- Children have a right to reasonable accommodations allow access to prescribed medical care necessary for the child to attend school without risks to his or her health and functioning
- Statute requires that SDs must have policy that addresses process in which a private health care specialist may observe the student in the school setting, collaborate with instructional personnel in the school setting, and provide medically necessary treatment in the school setting as required by [section 504} and {the ADA]

SDs must provide data indicating number of requests for access by private health care providers and whether access was approved or denied.

S.C. Dep't of Education Memorandum

- Acknowledges difficulties of families in obtaining ACCESS.
- Acknowledges the applicability of the ADA and Section 504.
- Addresses requests for the STUDENT'S qualified healthcare provider to provide treatment in the school setting.
- Requires comprehensive case-by-case consideration of the accommodation request.
- Prohibits blanket denials of this type of request.
- Encourages collaboration so students can reach their FULL potential.



STATE OF SOUTH CAROLINA
DEPARTMENT OF EDUCATION

MEMORANDUM

TO: District Superintendents
District Special Education Directors

FROM: Matthew Ferguson, Ed.D., Esq.
Deputy Superintendent and Chief Academic Officer
Division of College, Career, and Military Readiness

DATE: April 2, 2024

RE: Case-by-Case Considerations of Applied Behavior Analysis (ABA) Therapy Access in Schools

The Process for Requesting Access

- Parent identifies child as a person with a disability seeking accommodations under the ADA/504 to access medically necessary care prescribed in the school setting by a qualified healthcare practitioner.
- Parents must request access for their child's qualified health provider to provide medically necessary treatment (ABA) in the school setting.
  - Reference ADA and any applicable state law or guidance
  - Demonstrate medical necessity.
  - Define the access requested.
    - The initial request for access is likely necessary to assess medical necessity and design appropriate programming in the school setting.
  - Have an insurance/Medicaid-funded provider ready/willing/able to provide the treatment.
- Schools are then to consider and engage in interactive process to investigate and determine how the request can reasonably be accommodated.(classroom procedures, insurance, background checks, etc.)

Individual considerations regarding medically necessary access to care in school settings

Some examples:

- Lack of skill acquisition in shared treatment domain areas (e.g., AAC, ADLS, etc.)
- Social deficits that are improving in ABA but not "keeping up" in school
- Safety concerns not successfully remediated by the IEP goals/IEP services
- Interfering behaviors are reduced/stabilized in the home, community, and center but occur at high rates in school
- Generalization barriers not remediated with care coordination with the IEP team
- Behavioral contrast not successfully remediated without direct Clinical ABA intervention
- Clinical ABA would increase student independence and/or reduction of severe behavior
- Clinical ABA would remediate barriers that reduce adult placement options (e.g., limited living situation options)

Behavioral Contrast

Non Treatment Setting

Attention is still given for the behavior.

Oppositional behavior increases

Treatment Setting

Attention is withheld for behavior

Oppositional behavior decreases

Medical Necessity for ABA in school assessment tool

Case of Entry	Metric	Response
CE 1	Can reasonable accommodations meet the needs of the student (See "Reasonable Accommodations" tab)	
CE 2	Is the Clinical ABA treatment plan in aligned with symptoms presented from the diagnosis	
CE 3	Should Dir treatment be necessary across all settings (ie. the public library test)	
CE 4	Are the ABA treatment plan goals contextually appropriate to be run in the school setting?	
CE 5	Do you have a medical referral from the pls across stating that Clinical ABA is medically necessary in the school setting for the prescribed dosage as outlined in your treatment plan?	
CE 6	Has the Clinical ABA treatment (or school treatment) been approved as medically necessary by another party (ie. Kaiser, pre-certs...)?	
	TOTAL SCORE	

Medical Necessity Criteria	Metric	Response
MN1	Is the student experiencing a lack of skill acquisition in the treatment domain areas shared (e.g. AAC, ADLS, etc) in the ABA Treatment Plan in the school setting (e.g. not meeting at least 50% of IEP goals but making significant progress on similar domain area ABA Treatment Plan goals such as at least 70% of short term benchmarks)?	
MN2	Is the student experiencing social deficits at school that are making adequate progress on the ABA treatment plan (e.g. how to address bullying) but remains a barrier in school?	
MN3	Does the student experience safety concerns in the school setting that are not successfully addressed?	
MN4	Are maladaptive or interfering behaviors reduced in other settings but still occur at high rates in the school setting due to environment staff or peer reinforcement?	
MN5	Are generalization barriers not successfully remediated through at least 3 months of care coordination with IEP team?	
MN6	Is there evidence of behavioral contrast (e.g. behaviors only occurring in non clinic settings) that are not being successfully remediated without direct intervention from ABA team?	
MN7	Would the addition of Clinical ABA treatment in the school setting result in increased student independence and or reduction of severe behavior?	
MN8	Would the addition of Clinical ABA treatment result in remediation of barriers that reduce adult placement options for the student?	

Instructions for Observation Data Sheet
1. **Teacher Contacts:** Collect data based on observation in school for the indicated session below. Record % observed behaviors by teacher (e.g. clearly stated expectations, corrective feedback delivered vs praise positive acknowledgement delivered)
2. **Client Performance:** Collect data on the following prerequisite skills for success in a classroom environment without 1:1 support. Record % independence for each target skill
3. Attempt to get at least 3 observations scheduled for your assessment when possible to identify a trend. If you cannot get 3 observations due to feasible limitations or district limitations, one observation still suffice. Continue to collect data on these metrics throughout the time you are related at least quarterly to measure progress/ generalization of you are NOT treating in school. If you are treating in school, consider whether or not these are realistically necessary goals for the client and assess the IEP does not duplicate any of your goals to avoid feasible violations

Observation Data Sheet	Observation 1	Observation 2	Observation 3
Teacher Contacts: [description]	Date:	Date:	Date:
1. Clearly stated expectations delivered			
2. Corrective Feedback delivered			
3. Praise delivered/ Positive acknowledgement			
Client Performance:			
1. Follows Individual Instructions (1:1 time)			
2. Follows Whole Group Instructions (1:n time)			
3. Observational Learning (look to peers for direction)			
4. On Task (stay in Class)			
5. Engages in self advocacy appropriately			

ABC Data	Antecedent	Context	Consequence
Behavior 1:			
Behavior 2:			
Behavior 3:			
Behavior 4:			

Common Denial Reasons for Clinical ABA in School

Concerns Expressed by Some Schools	Rebuttal
1. ABA as a pull out service is disruptive to the classroom and will interfere with educational progress	ABA is mostly a push in service and is no more disruptive than related service providers delivering treatment on a push in model (e.g. OT, Speech). There is ample research supporting the effectiveness of a push in model. RBTs are not more disruptive than paraeducators in a classroom.
2. This ABA schedule will interfere with other related services/school activities/teaching time	Treatment is often delivered in a school setting in addition to being an effective treatment model in medical settings. Many students receiving intensive, clinical grade treatment engage in interfering behaviors in related service sessions, reducing progress which can be successfully remediated by partnering with the clinical ABA team.
3. We cannot allow your staff in because of FERPA concerns	FERPA The IEP is separate for medical services and should not does not preclude a student's right to access medical treatment. Progress on IEP goals does not have any correlation to medical necessity as we cannot share IEP medical goals. IEP goals do not address underlying of medical diagnosis. They address showing a student is able to access their education for "merely more than de minimis educational benefit" and does not guarantee any remediation of medical conditions. Ask them to define adequate progress and for a copy of their policy that outlines how they determine whether a student is making adequate progress.
4. The student does not need clinical ABA in school because they are progressing making adequate progress on their IEP goals	Treatment vs Clinical ABA Evaluate the school program to determine if the school "ABA" services meet the same criteria as the clinical ABA services.
5. We already provide ABA in school/We have a BCBA on staff/RBT in the classroom so we don't need you	What are your processes for your volunteers? We are happy to accommodate those processes.
6. We cannot allow your staff in due to confidentiality/privacy concerns for the other students	ABA providers will need to add school locations to their liability insurance policies. Provide a copy to the district as this should satisfy this requirement. (See model policy)
7. We cannot allow ABA in school due to liability issues	ABA providers should provide background checks or offer to have them fingerprinted using whatever system the district uses. (See model policy) "Just how consistent, safe/teachers, we are vetted and offer to do the same or equivalent.
8. We cannot allow your staff in as we have not vetted them. This is a safety concern to allow non-district staff in the classroom	Has your nurse spoken with the student's physician and does the nurse disagree with the physician and diagnostician's prescription and diagnosis?
9. Our nurse does not agree this service is medically necessary	It is inequitable to expect this student to attend school without addressing their medical needs, especially when other students' needs are being met by default (i.e., not requiring medical support).
10. It would be inequitable to other students to allow this student access to clinical ABA in the classroom	This violates LRE. Clinical ABA is no more intrusive than adding SLP or OT services to an IEP and should not constitute a change of placement especially as ABA will allow students to access even less restrictive settings and gain skills necessary to move to a less restrictive setting. Clinical ABA is proven to reduce the need for additional IEP services over time, potentially resulting in exiting an IEP.
11. Rather than adding clinical ABA, we should be discussing a change of placement to a more restrictive setting	

The Interactive Process under ADA/504

- The obligation is to make reasonable accommodations and modifications to policies. Good-faith dialogue.
- Section 504 and the ADA allow public institutions to deny requests for accommodation where the accommodation would impose an undue hardship or a direct threat to the safety of employees or others.
- Allowing outside providers to deliver services in schools is not uncommon
- If issues are raised, get clarification and details as specific as possible
- Compare and contrast to other scenarios
  - What other third parties are allowed in the building?
  - What do you require of those people before entering? (background checks, bonding?)
- Offer ways to ameliorate named concerns. Work collaboratively on logistics that do not interfere with the accomplishment of treatment goals.

Working in school settings as an outside healthcare provider

- First impression is key
- Be warm, appreciative, and engaging.
  - How you first present will set the groundwork for how the IEP team responds to your presence and your suggestions.
- Ensure the team knows you're not there to judge their performance; you are providing medical treatment to a child.
- Make your end goal known.
  - The goal is for students to be self-sufficient and for us to exit the "medical" support

Skills needed for effective collaboration

Cultural awareness of clients and their circle of supports
- Schools and classrooms are their own cultures

→ Be a good listener
- Active listening is a skill many are not taught

→ Be a good observer
- Be a behavioral detective

→ Think/act like a behavior analyst

↓

Be critical of immediate results without clear rationales

→ Be analytical

→ Stay current with research on trauma

→ Continue to challenge yourself and what you know about trauma assumed care

Pat Martelle, LCSW

Moderator

doff, Esq

Associate Director, Idaho Lega

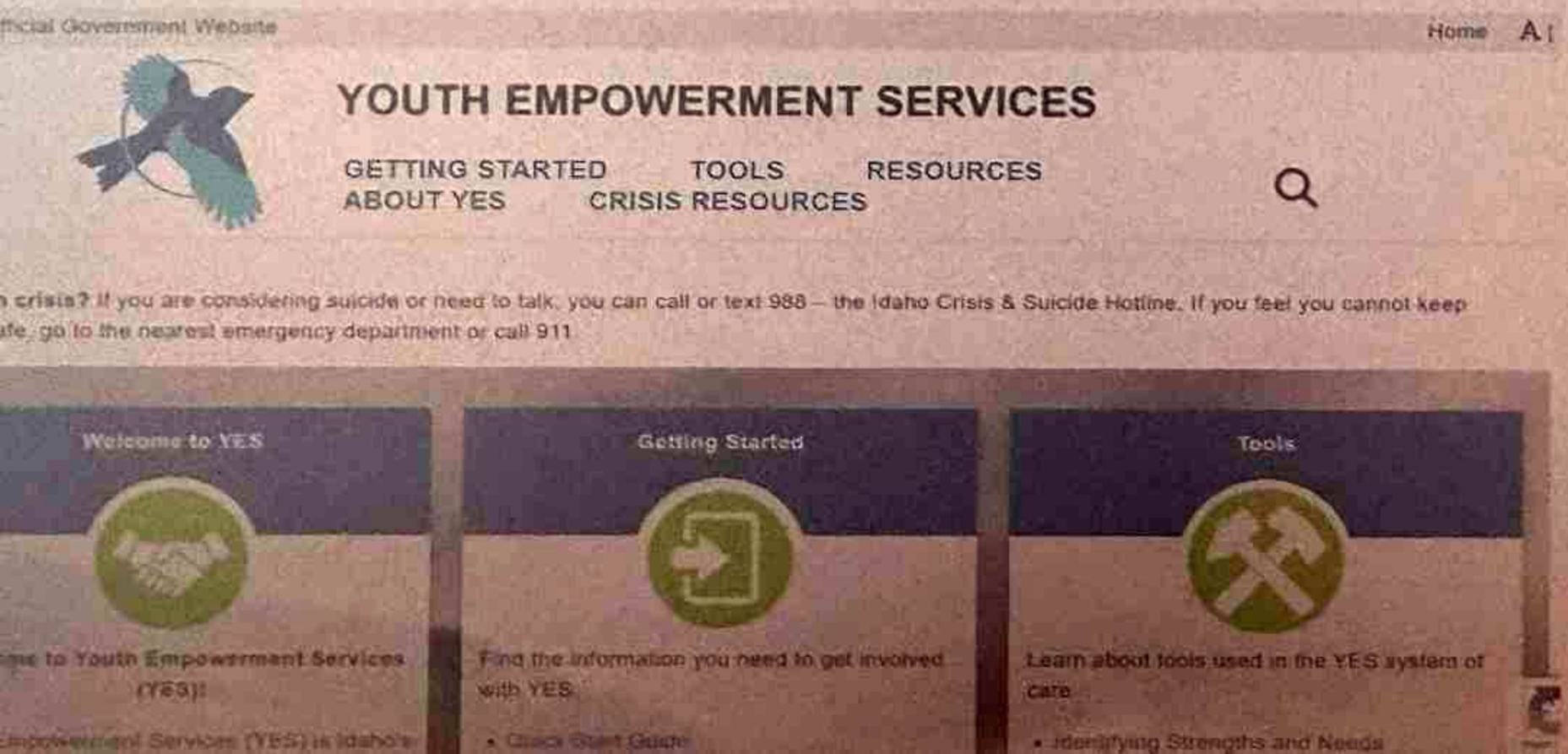
Brittany Shipley,

Child and Family Advoca

yes.idaho.gov

SCAN ME

TO SUBMIT A QUESTIO



THE SETTINGS RULE – SOME BACKGROUND

In 2014, the Centers for Medicare and Medicaid Services (CMS) published a final rule with new requirements for home- and community-based services (HCBS) waiver programs.

What are HCBS waiver programs?

- States have the option to develop HCBS waiver programs to meet the needs of people who need long-term care services and support in their homes or communities rather than institutional settings.
- Upon demonstrating that the waiver program meets requirements, the States can "waive" certain other Medicaid program requirements.
- States can develop HCBS waiver programs targeting groups of people that would otherwise be at risk of institutionalization, such as the elderly or individuals with intellectual disability or autism.
- Several million people receive benefits through HCBS waiver programs.

HCBS WAIVER PROGRAMS AND THE SETTINGS RULE

The acronym here matters: HOME—and COMMUNITY-Based Services

- The waiver programs are intended to allow individuals to receive long-term services and support in their home and community rather than in an institutional setting if they prefer.
- The final rule published in 2014 seeks to ensure and emphasize that individuals are to receive these services in the most integrated setting appropriate for their needs.
- This focus on the "setting" is the reason for the 2014 rule's shorthand name: The Settings Rule.

THE SETTINGS RULE

Choice

- Selection of residence from among options
- Autonomy and independence in life decisions
- Choice in services and the providers thereof

INDIVIDUAL RIGHTS:
Privacy, Dignity, Respect, Freedom from Coercion/ Restraint

Access

- Integrated into the greater community
- Support full access to the resources and opportunities of the greater community

SETTINGS RULE REQUIREMENTS

Funding through an HCBS waiver requires that beneficiaries have:

- a lease or other legally enforceable agreement providing similar protections;
- privacy in their unit, including lockable doors, choice of roommates, and freedom to furnish or decorate the unit;
- control over his/her own schedule, including access to food at any time;
- the ability to have visitors of their choosing at any time; and
- a setting that is physically accessible.

The rule additionally requires a person-centered approach to participant care plans, in which the participant's goals and preferences guide the delivery of services.

SETTINGS RULE – PRESUMED INSTITUTIONS

A setting is presumed to be an institution rather than a home or community setting if:

- The setting is located in a building that provides inpatient institutional treatment;
- The setting is located in a building on the grounds of, or immediately adjacent to, a public institution or
- The setting has the "effect of isolating" individuals receiving HCBS from the broader community.
  - The setting is designed to provide people with disabilities with multiple types of services and activities on-site;
  - People in the setting have limited interaction with the broader community;
  - The setting uses/authorizes interventions that are used in institutional settings, such as seclusion or
  - The setting is gated/secured only for residents with disabilities and the staff working with them, and the majority of their residential, day supports, and other services are provided within the perimeters of the setting.
- See CMS guidance here.

SETTINGS RULE – HEIGHTENED SCRUTINY OF PRESUMED INSTITUTIONS

Identifying settings that are presumed institutions is not the end of the inquiry:

- States have the opportunity to collect evidence and submit it to CMS for "heightened scrutiny" to determine whether the presumed institutional setting actually functions as a home- and community-based setting.
- CMS has indicated that settings should be considered on a case-by-case basis and that outcomes take precedence over location, geography, or physical characteristics–choice, access, and individual rights.

SETTINGS RULE – TIMELINE

2014: Publication of the Settings Rule

- Newly approved settings must meet the requirements
- Five-year transition period for existing HCBS settings to comply

2017: CMS extends the transition period to 2022 (instead of 2019)

2020: CMS again extends the transition period to March 2023 due to impacts from the COVID-19 Pandemic

2022: CMS announces the option for states to apply for a Corrective Action Plan (CAP) in circumstances where additional time is needed to obtain full compliance.

March 2023: The Settings Rule is in Effect**

**Some States/Waivers continue to operate under their CAPs. CAPs are publicly available and provide customized/specific timelines for programs to move toward full compliance.

Summary here with table of state status as of December 2023.

SETTINGS RULE – HEIGHTENED SCRUTINY DURING THE TRANSITION

- During the transition period, states created and made progress toward compliance under Statewide Transition Plans (STPs).
- This process required that states publish and submit for public comment, among other things, their methodology for identifying presumptively institutional settings and their methodology for reviewing those settings for compliance.
- That done, states were later required to publish the names of settings identified as presumptively institutional that were reviewed, as well as their findings after that review. This also was subject to public comment.
- All evidence for a setting believed to have overcome the presumption is submitted to CMS for a final decision/ruling.

A more detailed summary is here, but note that the document was last updated in 2020.

THE SETTING RULE TODAY

- For the past decade, the primary focus has been on the transition and bringing waiver programs (their approved providers) into compliance.
- It is clear that all newly approved providers must comply with the Settings Rule.
- It is less clear how that process occurs moving forward.
  - Public comment periods?
- And how that process works for a newly developed community.
  - CMS previously indicated that a setting presumed to have the qualities of an institution cannot be determined to be compliant until it is operational and occupied by beneficiaries receiving services there–outcomes take precedence.*
  - As such, CMS conceded that the rule is intended to discourage constructing settings that fall within the presumption of an institutional setting.*
    - *These statements appeared in a previously released FAQ document that CMS has since removed from its website.

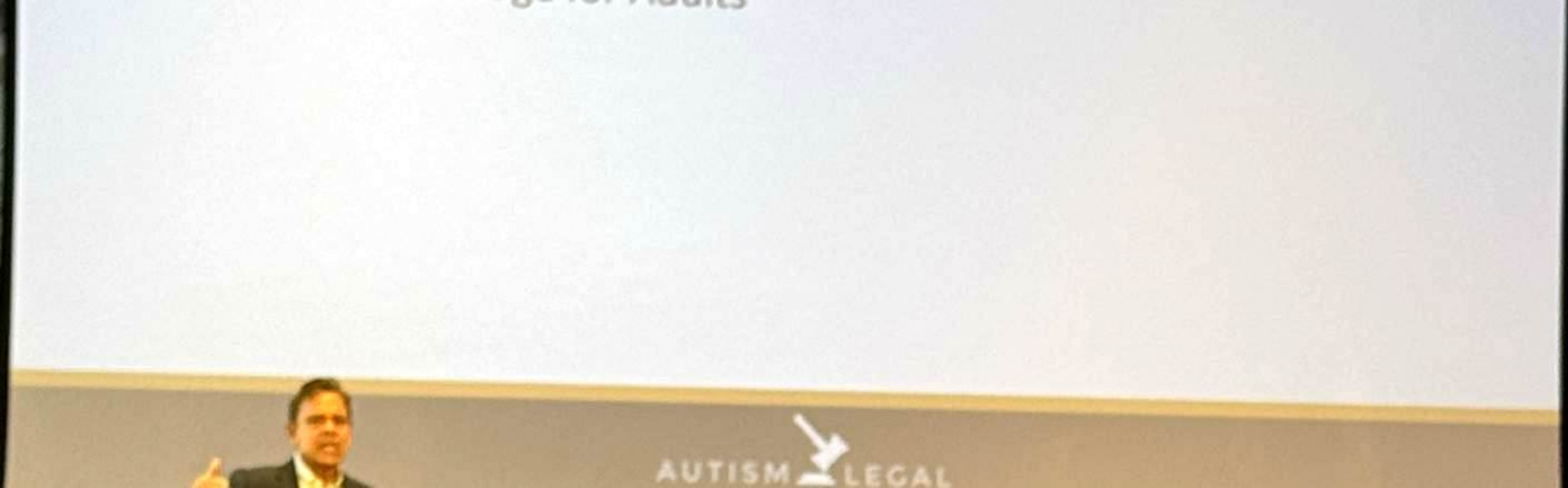
Commercial Insurance

- State mandates
- State mental health parity
- Federal mental health parity
  - Age cap in state mandate unenforceable per MHPAA
- ACA.

AUTISM LEGAL RESOURCE CENTER

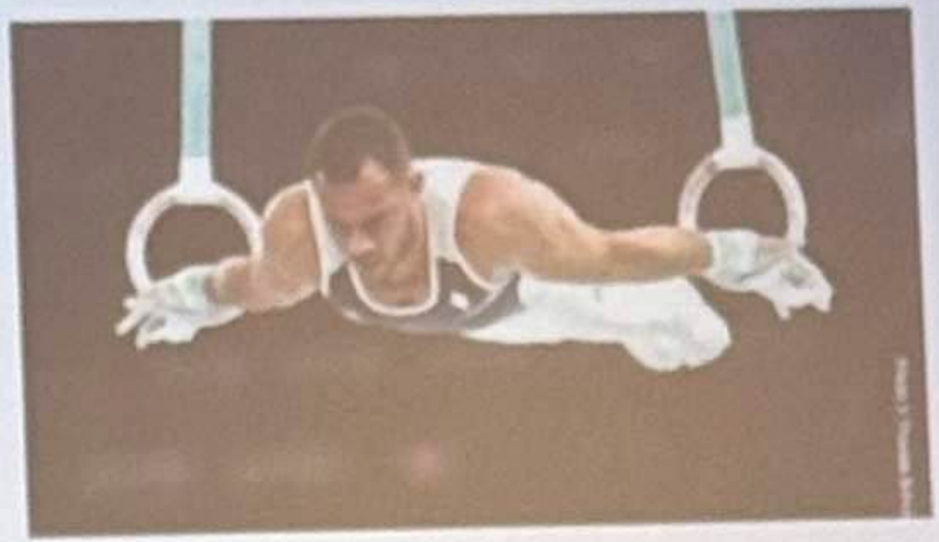
Medicaid

- EPSDT through 21 (all coverable services regardless of whether in current State Plan)
- State Plan Coverage for Adults



Medicaid Coverage of ABA for Adults

- **By litigation (MHPAEA, ADA, State APA and other laws applicable to Medicaid):**
  - *Blessing v. Ind. Family and Social Servs. Admin.*, No. 06C01-2007 (Ind. Cir. Ct., May 21. 2021), affirmed, No. 21A-PL-1707, 186 N.E.3d 626 (Ct. App. Table)* (Mar. 28, 2022)(agency's actions were arbitrary and capricious and otherwise contrary to law and therefore invalid under the state administrative procedures act.)
- ACA Section 1557 (prohibition on the basis of age or disability in benefit design)



Medicaid Coverage of ABA for Adults

- By Statute
  - New Mexico HB322 (2019)
  - Utah SB204 (2023)
  - New York SB1578 (2023) (Budget)
- By Policy
  - Arizona (no age limits in ABA policy)
  - North Carolina (SPA) ABA/RB-BHT covered for adults supported by credible scientific or clinical evidence as appropriate for the treatment of ASD and the individual's age range). NC Medicaid SPA 2021-0023, Attachment 3.1-A.1 Page 15-A.1.
- Arguments, cost savings, necessary to comply with MHPAEA. ACA

AUTISM LEGAL

Medicaid Coverage of ABA for Adults

- **By litigation (MHPAEA, ADA, State APA and other laws applicable to Medicaid):**
  - *Camp v. Wash. State Health Care Auth.*, 20-2-0183-34 (Wa. Superior Ct., Dec. 11, 2020) (state Medicaid administrative rules excluding coverage of ABA for adults used by MCOs to deny coverage were invalid and exceeded the statutory authority of agency because they violated federal and state parity acts.). Note: MHPAEA applies to Medicaid if any portion of services is delivered by MCOs. Coverage of services beyond what is currently in State Plan allowed if necessary to comply with MHPAEA.

AUTISM LEGAL RESOURCE CENTER

Medicaid Coverage of ABA for Adults

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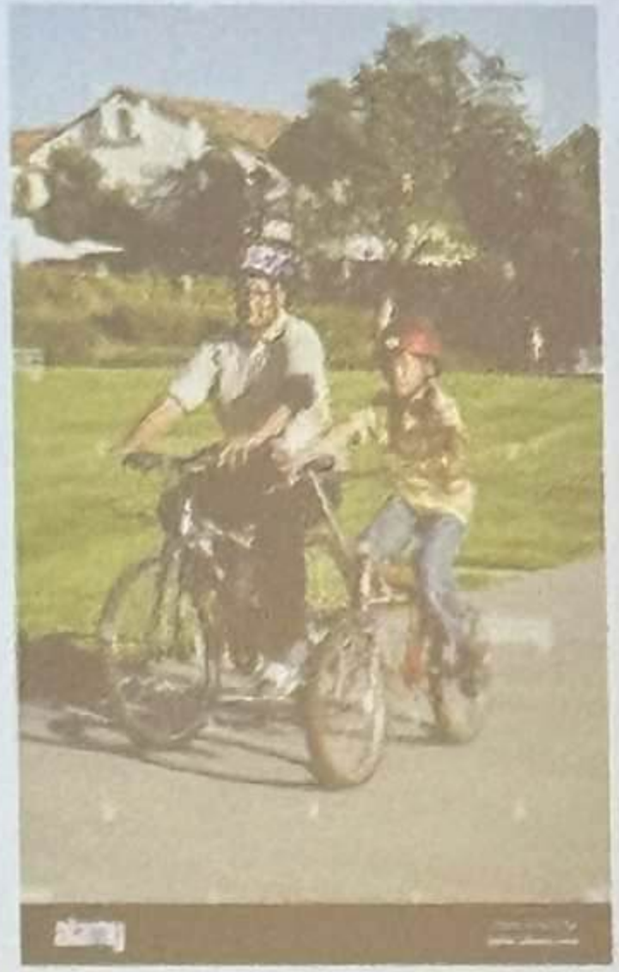


AUTISM LEGAL RESOURCE CENTER

Medicaid Coverage of ABA for Adults

- By professional licensing and designation of behavior analysts as approved providers
- Other licensed professional, State Plan category of medical assistance
- Kentucky example

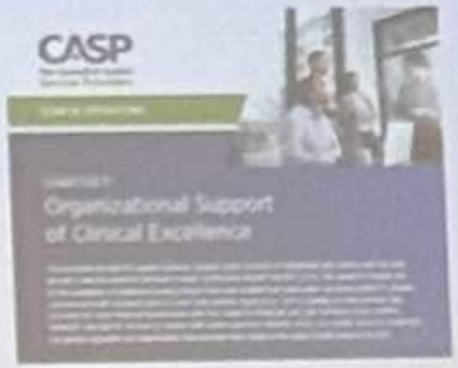
AUTISM LEGAL RESOURCE CENTER

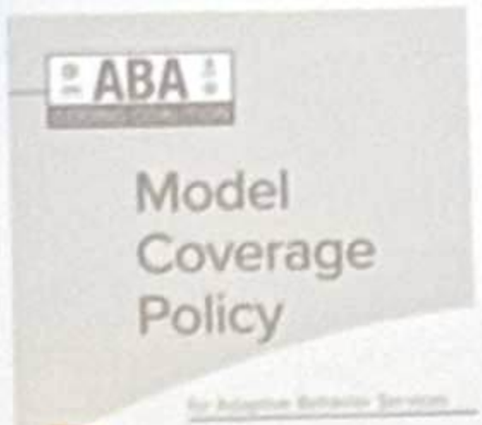
Coverage beyond basic healthcare

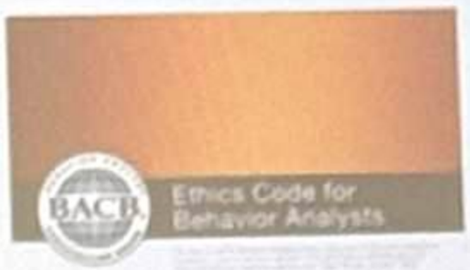
- HCBS waivers, housing supports and independent living
- VR programs, employment training and supports
- Emergency/crises stabilization situations
- Legal theories and analysis, antidiscrimination, look for systems where services available but not adapted for people needing ABA

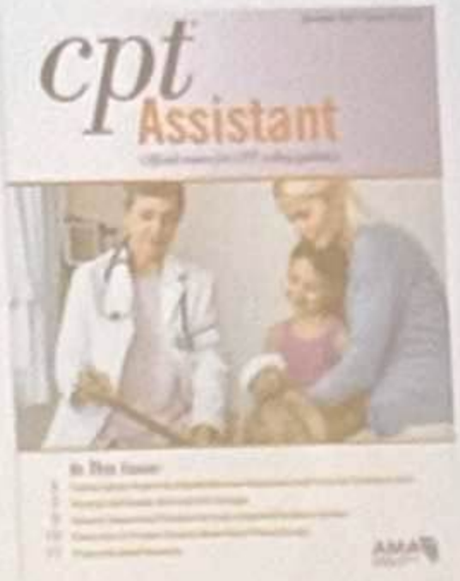
Resources

- Stakeholders who read session notes
- Clinical decision making
- Continuity of care
- Facilitate transition

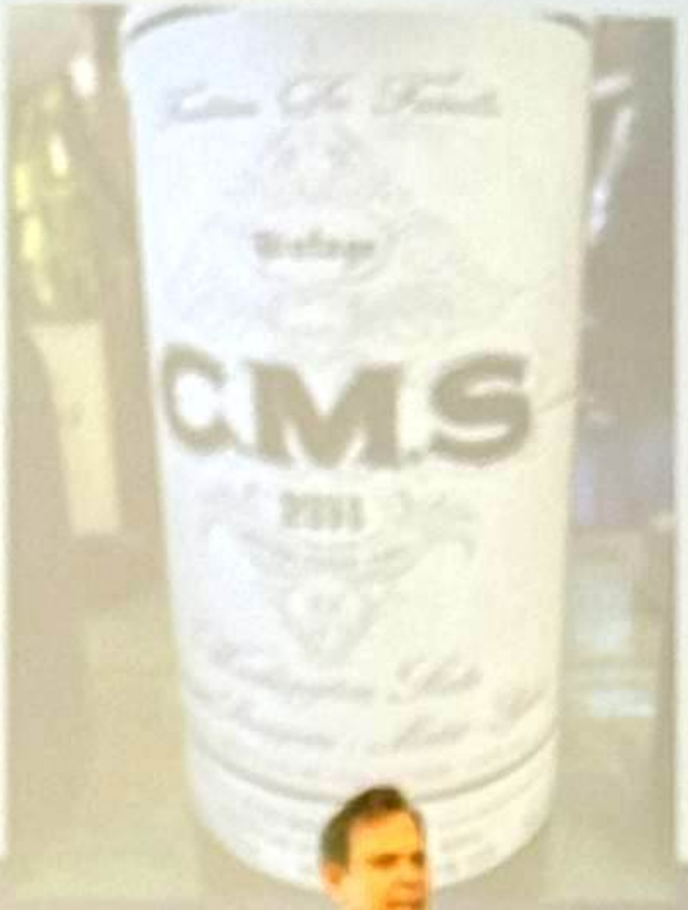








EPSDT Medicaid Coverage



- Still some coverage issues (Oklahoma)
- Continuing Issues with utilization management
- School services
- Rates
- MHPAEA,
- EPSDT
- Reasonable promptness

HDRC v. Kishimoto (9th Cir. 2023) (pending)

- Claim against Hawaii DOH and DOE for failing to provide ABA in schools under IDEA or EPSDT and failing to allow access to outside providers of medically necessary ABA under ADA. DOH as state Medicaid agency had "delegated" responsibility for providing ABA to schools which in turn limited ABA to what was educationally necessary and further limited access to any ABA to addressing challenging behavior after other behavioral interventions had failed).
- Argued October 4, 2023.

Perez v. Sturgis Pub. Schools (S. Ct. 2023) Progeny

- *Nagel v. Cloverleaf Local Sch. Dist.* (N.D. Ohio 2024) Student with autism denied aide overwelmed by actions of another student, physically assaulted the student and was then suspended and denied access to programs
- Sued for compensatory damages under the ADA

A word about MUEs

- Preventing Insurance Denials of Applied Behavior Analysis Treatment Based on Misuse of Medically Unlikely Edits (MUEs), Kornack, Unumb, Williams, Behavior Analysis in Practice (October 2023)
- NCCI guidance—payors using MUEs should ensure consistent with coverage obligations
- Adjudication Indicator 3

Case updates MHPAEA

- *Ryan S. v. United Health Group*, (9th Cir. 2024
- Plaintiff stated a claim for MHPAEA violation based on allegations that insurer applied a more stringent internal review process of MH as compared to M/S. Allegations also supported by report from DMHC. On MH side had algorithm system (ALERT system) that imposed certain progress criteria and if criteria not met flagged cases for peer review and potential denial, no similar system and requirements imposed on M/S services.
- Even if all those denials were independently valid, the mere fact that the reasons to deny coverage were identified only because the MH/SUD claims were subjected to an additional layer of scrutiny could violate the Parity Act.

Case updates MHPAEA

- *K.D. v. Anthem BCBS (D. Utah 2023)*
- Health plan violated MHPAEA where MCG guidelines used by insurer were more restrictive for MH than for M/S.
- Beneficiaries subject to discharge from residential MH facility when they met certain discharge criteria but M/S patient in residential facility not considered for discharge until they progressed through various stages of care in their treatment plan and demonstrated an ability to transition out of treatment show progression.

Wellstone-Domenici Mental Health Parity and Addiction Equity Act (MHPAEA)

- Coverage of mental health conditions should be on par with/no more restrictive than coverage of medical/surgical conditions.
- Broad Application (fully insured, self-funded, FEHB, Medicaid, CHIP, Non-Federal Government plans, ERISA plans, small group and individual through ACA).

MHPAEA:

- Prohibits treatment limitation applicable solely to Mental Health condition(s) (ASD).
- Prohibits quantitative treatment limitations unless imposed on substantially all medical surgical/conditions in same classification (outpatient services). (e.g., ST,OT,PT; 97151 caps)
- Prohibits nonquantitative treatment limitations unless as written or in operation applied no more restrictively to MH than to medical/surgical.
  - NQTLs include prior authorization requirements, diagnostic and other gatekeeping requirements, progress requirements, service locations, treatment plans, medical necessity criteria, provider networks admission requirements, rates, etc.
  - Insurer must have done and make available upon request a sufficient analysis demonstrating that as written and in operation the processes, strategies, evidentiary standards, or other factors used in applying the NQTL to mental health or substance use disorder benefits in the classification are comparable to, and are applied no more stringently than the processes, strategies, evidentiary standards, or other factors used in applying the limitation to medical/surgical conditions.

Definition of Mental Health Condition

- Defined by insurer/plan issuer but "any condition defined by the plan as being or as not being a mental health condition must be defined consistent with generally recognized independent standards of current medical practice." The prior language that determinations consistent with "State guidelines" are also acceptable has been eliminated.
  - Ensures greater consistency with federal law and prevents improper limitations
  - Avoids conflicts between generally recognized independent standards of current medical practice and State guidelines
- Must include all conditions that fall under any of the diagnostic categories listed in the mental, behavioral and neurodevelopmental disorders chapter . . Of the most current version of the ICD or that are listed in in the most current version of the DSM

Opt out for non-Federal Government Plans Eliminated

- Implements sunset provision for self-funded non-Federal government plans to opt out of MHPAEA plans as adopted in CAA for 2023.

No Change Re: QTLs

- Substantially all test applies.
- Relevant category for comparison is the applicable statutory classification. See 29 CFR 2590.712(c)(2)(ii)(A). No other classsifications are permissible. The relevent statutory classification for ABA benefits for ASD are in-network outpatient out of network outpatient.
- Applying substantially all test to ST, OT, PT when used to treat ASD limits on ST, OT, PT cannot be applied when they are used to treat ASD.
- Limits on specific services are QTLs (e.g., 97151)

No Treatment Limitations only on MH

- Prohibition on separate nonquantitative treatment limitations applicable only to mental health benefits. 29 C.F.R. § 2590.712 (c)(4)(iv).
- Corresponds to current law.

Meaningful Benefits

- If plan provides benefits for a MH condition in any classification, it must provide meaningful benefits for that condition in every benefit classification where it provides meaningful benefits for one or more M/S conditions.
- Meaningful benefits include coverage of core treatments for a condition.
- ABA is a core treatment for ASD. *Doe v. UBH*, 523 F.Supp.3d 1119 (N.D. Cal. 2021)

Revisions to NQTL Rule

- An NQTL imposed on MH benefits cannot be more restrictive as written or in operation than the predominant NQTL of that type that applies to substantially M/S benefits in the same classification
- Final Rule did not adopt for NQTLs the mathematical "substantially all" test used for QTLs.
- The Rule imposes two sets of requirements that an NQTL must meet:
- It applies the "no more restrictive test" on design and application requirements for NQTLs, and it includes a new prohibition on use of discriminatory factors and evidentiary standards in NQTL design.
- It also imposes data collection and evaluation requirements to assess the impact of the NQTL and whether it is more restrictive in operation in a manner that limits access to MH benefits compared to M.S benefits.

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NQTL No More Restrictive Rule

- Must show that any NQTL applied to MH both as written and in operation is designed and applied based on processes, strategies , evidentiary standards and factors that are comparable to and not more strictly applied than the processes, strategies , evidentiary standards and factors used in designing and applying the NQTL to M/S.

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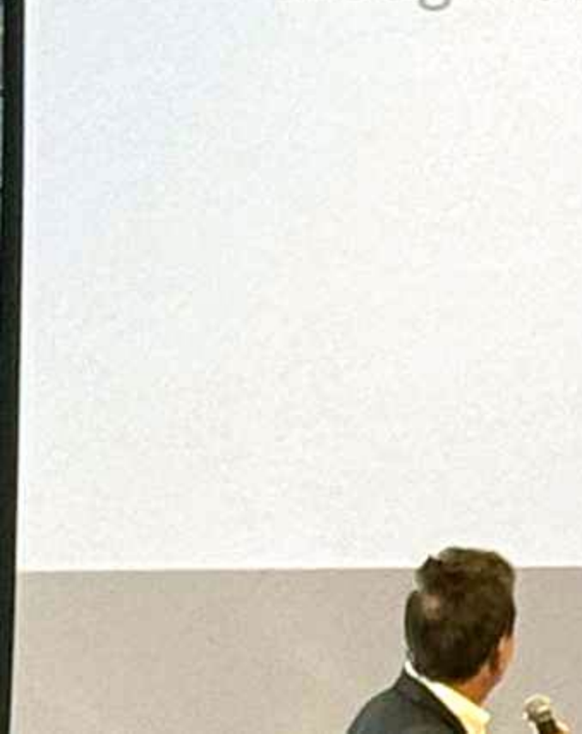
New/Additional Definitions of NQTL Terms

- **Evidentiary Standards** considered by plan in designing or applying a **Factor** with respect to an NQTL
- **Factors** are information including **processes** and **strategies** considered in designing an NQTL or determining whether or how the NQTL applies to particular benefits. Include provider discretion in determining diagnosis or type or length of treatment, severity or chronicity of condition, geographic location.
- **Strategies** are methods the insurer uses to design an NQTL.
- **Processes** are steps insurer uses to apply the NQTL

- Don't panic
- Practical what, why, when, how
- DOL self-compliance tool
- Prior authorization

Example: more stringent application

- Exclusion for experimental/investigative applied more stringently to ABA. As written exclude M/S or M/H if no clinical guidelines and fewer than 2 RCTs. In operation exclude ABA as experimental even though it meets these requirements.



Prohibition on Discriminatory Factors and Standards

- In designing NQTLs, the insurer cannot use factors or standards that are discriminatory. Factors or standards are discriminatory if the information or sources on which they are based are biased or not objective in a manner that discriminates against MH versus M/H benefits.
- Plans may take measures to correct for this bias
- Historical data from when plan as not subject to or in compliance with MHPAEA is presumed to be biased if it systematically disfavors MH access or is designed to disfavor access and has not been corrected for this.

Example Discriminatory Factor

- Step therapy protocol with exception for severe or irreversible consequences.
- Methodology developed by external third-party organization.
- Methodology identifies instances in which delay of prescribed drug could result in either severe **or** irreversible consequences.
- For MH, however, methodology only identifies instances where delay could result in severe **and** irreversible consequences.

Data Collection and Evaluation requirement

- Must collect and evaluate data in a manner reasonably designed to assess the impact of the NQTL on relevant outcomes related to access to MH services.
- Relevant data includes number and percentage of claims denials. Regulators can request additional data they determine is relevant to an NQTL
- If data suggests NQTL contributes to material differences in access this will be considered a strong indication of a MHPAEA violation. Insurer must take reasonable action to address material differences in access between MH and M/S and bring plan into compliance.

Data Collection and Evaluation requirement- Network Composition

- For NQTLs related to network composition relevant data may include in-network and out-of-network utilization rates, network adequacy metrics, provider reimbursement rates for comparable services or as benchmarked to a standard. For network composition must collect and evaluate data in a manner designed to assess the aggregate impact of all NQTLs. Corrective actions may include recruitment of providers, increasing compensation, streamlining credentialing.

Special Rules Re: NQTLs Based on Generally Recognized Independent Professional Medical or Clinical Standards

- Independent Professional Standards when are presumed to be unbiased, objective and not discriminatory when used to design or apply NQTLs.
- Independent standards include peer-reviewed scientific studies and medical literature, formal published recommendations of Federal Government agencies, drug labeling approved by the United States Food and Drug Administration (FDA), and recommendations of relevant nonprofit health care provider professional associations and specialty societies, including, but not limited to, patient placement criteria and clinical practice guidelines.

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Special Rules re: use of Carefully Designed and Circumscribed Measures to Detect, Prevent or Prove Fraud or Abuse

- Carefully designed and circumscribed fraud prevention measures that appropriately minimize negative impacts on access to MH are not considered to be biased or unobjective in a way that discriminates against MH when they are used to design NQTLs and differences in outcome evaluation data attributable to such measures are not considered material.
- But, as with generally accepted independent medical/clinical standards, such measures must still meet the general design and application requirements for NQTLs requiring that they not be more restrictive as written or in operation than those measures used for M/S benefits and that the design and application factors and standards be comparable to and no more stringent than those used in designing and applying the limitation with respect to M/S benefits ion the same classification,

Requirement to Conduct and Document the NQTL Analysis

- Insurer must perform and document a comparative analysis of the design and application of each NQTL used.
- Must **identify and describe each NQTL**, including terms, where it appears in documents, benefits it applies to, ad classification of such benefits.
- Must **identify and define each factor** and evidentiary standard (and its source) considered or relied on to design or apply NQTL
- Describe how plan has taken steps to cure any biased information or standards used

Requirement to Conduct and Document the NQTL Analysis

- Must demonstrate meeting of comparability and stringency requirements for processes, strategies, standards for NQTL **in operation**, including how the plan evaluates whether processes, standards, strategies or other factors used for MH are comparable to and no more stringently applied than those for the NQTL as applied to M/S, including methodology and data used to design, apply and evaluate the NQTL.
- Must demonstrate satisfaction of the **data collection and evaluation** requirements including resulting outcomes information, explanation of material differences and discussion of corrective actions to address material differences in access indicated by the data.
- Must include **findings add conclusions** identification of reviewers and consultants and certification by fiduciaries that they have engaged in a prudent process to select any qualified service providers retained to perform and document the NQTL analysis.

Requirements to Produce NQTL Analysis to Regulators and Respond to Findings

- NQTL analysis must be prepared before imposing NQTL
- NQTL must be provided to DOL within 10 business days of their request. NQTL's must also be provided to any appliable State authorities on their request.
- If DOL determines the initial response is insufficient, additional information must be provided within 10 business days of the DOL's follow-up request.
- If the DOL makes an initial determination of noncompliance, then the plan has 45 additional days to address the findings; and
- If the DOL makes a final determination of noncompliance, then the plan has 7 business days to notify all individuals covered under the plan of that finding.

Requirement to Produce NQTL Comparative Analysis to Plan Beneficiaries.

- NQTL analyses must be produced to beneficiaries within 30 days of request pursuant to ERISA Section 104 as they are part of plan documents (instruments that operate the plan)
- NQTL analyses must be provided to beneficiaries who have received an adverse benefit determination.

Result if NQTL analysis is deficient

- DOL (or state regulators) may order or accept corrective actions
- DOL (or state regulators) may but are not required to order that NQTL can not be used and may take various factors into account in making that decision
- If it is determined that the NQTL violates the substantive "no more restrictive" requirements at (4)(c)(i)(design and application) and 4(c)(iii) (required use of outcomes data), the plan cannot apply the unlawful NQTL. DOL and state regulators have authority to take enforcement action to prohibit insurer from continuing to impose it.

Effective Dates

- Generally effective for plan years beginning on or after January 1, 2025
- Meaningful benefits standard, prohibition on discriminatory factors and evidentiary standards relevant data evaluation requirements and related provisions in comparative analysis requirements are not in effect until plan years beginning o or after January 1, 2026.

Elimination of *Chevron* Deference

- Pro
- Con

Nuts and Bolts

- Credentialing delays
  - Agency credentialing
  - Retroactive effect
- Prepayment Reviews
- Disconnect between clinical/authorization and claims/audit
  - Supervision issues and documentation
  - Multiple sessions, same day, different locations, different provide
  - MUEs