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Treatment Efficacy in Autism Spectrum Disorders

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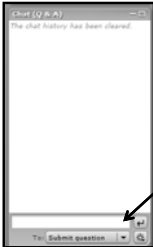
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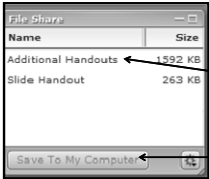
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Treatment Efficacy in Autism Spectrum Disorders

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Evidence and its Detractors

- Which of these seems plausible? Which do you use/recommend? Which do you believe in?
 - MMR vaccine causation theory of ASD
 - Dolphin assisted therapy for language development treatment
 - Gluten-free casein-free diet
 - Sensory integration training
 - Early intensive behavioral intervention
 - Traditional speech-language intervention
 - Picture exchange communication system
 - Social stories
 -

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Evidence-based Practice (EBP)

- What is it?
 - Using best available scientific evidence for clinical decision-making
- Who is responsible for it?
 - Every individual clinician must be able to defend intervention choices

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How to go about EBP

- ▶ 1. Frame an answerable question.
 - Examples of questions you might have as a clinician
 - How can I improve reading comprehension in children with ASD?
 - Are naturalistic interventions appropriate for children with ASD?
 - How could you go about getting evidence to answer them?

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EBP, cont.

- ▶ Importance of asking answerable questions
- ▶ ASHA's suggestion: PICO format for questions
 - Population
 - Intervention
 - Comparison
 - Outcome
 - <http://www.asha.org/members/ebp/>

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EBP, cont.

- ▶ PICO example
 - Population
 - Preschoolers with ASD, ages 36 to 60 months
 - Intervention
 - Naturalistic, child-centered, social-interactionist
 - Comparison
 - Behavior modification
 - OR MAYBE
 - No treatment, alternating treatments
 - Outcome
 - Improved formal test scores?
 - Improved functioning (e.g., increased MLU in language samples? increase in vocabulary size?) Increased joint attention? Increased social engagement?
 - ????

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Now What?

- ▶ Find search terms
 - ASD
 - Intervention, treatment
 - Outcomes
 - Naturalistic language intervention
 - Social interactionist
 - Child-centered
- ▶ Find articles....
- ▶ Read articles....
- ▶ Decide if they are any good....
- ▶ Make decision....

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What is Good Evidence?

- ▶ RCT
 - Randomized Controlled Trial
 - Random assignment to treatment condition
 - Blinding
 - Considered "Gold Standard"
- ▶ High quality, controlled studies
 - Group designs
 - Single participant designs
- ▶ Case reports, program reviews
- ▶ Expert opinions
 - Based on what?

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ASHA Levels of Evidence

- ▶ Ia Well-designed meta-analysis of more than 1 randomized controlled trial
- ▶ Ib Well-designed randomized controlled study
- ▶ IIa Well-designed controlled study without randomization
- ▶ IIb Well-designed quasi-experimental study
- ▶ III Well-designed non-experimental studies, i.e., correlational and case studies
- ▶ IV Expert committee report, consensus conference, clinical experience of respected authorities
 - <http://www.asha.org/members/ebp/assessing.htm>

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Problems with EBP

- ▶ For some topics, little information available
- ▶ For others, lots of information
 - Challenge: sifting and weighing it!
- ▶ Obligation to clinicians
 - Ethically bound to use EBP information when available
 - E.g., incorporate results into clinical practice if randomized controlled trials available

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ASD and Pseudoscience

- Autism: ripe ground for unsubstantiated claims
 - No obvious physical differences
 - Developmental trajectory very individual
 - A child could make spontaneous large gains for no known reason
 - Subtle anomalies present early may go unnoticed
 - Only when later development not on target are differences noted
- Evidence that appears scientific often is not
 - <http://www.autismweb.com/diet.htm>

Characteristics of Science

- Hypothesis generation and testing
- (Usually) slow accumulation of evidence
 - Rarely “proof”
- Often, studies produce conflicting results
 - Why?
 - Design
 - Interpretation
 - Variability of phenomenon
 - (Rarely, I hope) scientific fraud

Distinguishing between Science and Pseudoscience

- Clinicians must differentiate between scientific and pseudoscientific claims of treatment efficacy
- Look for warning signs
 - Untestable
 - Unchanged
 - Confirming evidence
 - Anecdotal evidence
 - Inadequate evidence
 - Avoiding peer review
 - Disconnected
 - New terms
 - Grandiose outcomes
 - Holistic

(Finn, Bothe, & Bramlett, 2005)

Methodological Issues in Intervention Research

- Selecting appropriate population to study
 - Criteria used to select participants?
 - Ability levels?
 - What control groups were used?
- Controlling for alternative explanations: Internal validity
 - Normal development & change
 - Something else introduced at same time
 - Diet, drugs, medical changes, school placement
 - Placebo effect
 - Belief of participant that treatment is helpful results in change
 - May apply when treatments judged by non-blinded caregivers
 - Hawthorne effect
 - Tendency of participants to improve behavior when they are being studied
 - Possible corollary: People may interact differently with children known to be undergoing treatment believed to be effective

Error Sources Undermining Validity

- Measurement error
 - Inaccurate (reliability of measurement)
 - Raters blind to treatment condition?
 - Inter-rater, intra-rater agreement measured?
 - Validity of sample of behavior?
 - Natural variability in some behaviors
 - Inappropriate measurement tools (construct, content validity)
 - Tools must accurately measure outcomes
 - IQ?
 - Formal language tests?
 - Language or behavioral sampling?
 - School placement?
 - Caregiver ratings?
 - Can measure pick up subtle changes?
 - If use pre- and post-testing
 - Are changes within Standard Error of Measure of test?

Evaluating Research Designs

- Group designs
 - Double-blind, placebo-controlled study, random assignment to treatment conditions
 - E.g., Bettison (1996)
 - Placebo-controlled
 - May use alternating treatments
 - Random assignment to treatment conditions?
 - » “convenience” samples
 - Treatment, no treatment
 - Delayed treatment

Issues with group designs

- ▶ Heterogeneity of population
 - Was group appropriately homogeneous?
 - If *too* homogeneous, may also be a problem
 - Can only generalize results to subset of population with ASD
 - Individual differences in response not always clear
 - Statistical tests on group means
 - Some researchers mention individual differences informally
 - For ideal treatment effectiveness, should be able to predict whether group results apply to particular individual cases
 - Some kids may have improved when no statistically significant group changes found
 - Other kids may have showed no change, even if group means went up

An alternative to group designs

- ▶ Single case design
 - Experimental design using participant as his or her own control
 - Often confused with case studies
 - Establish experimental control by
 - Withdrawal design (simplest—ABA)
 - Establish baseline behavior rate—A
 - Introduce treatment—B
 - Withdraw treatment --A
 - Multiple baseline (hold one behavior in baseline while treating another)
 - Use of visual significance
 - Replication important (across at least 3 participants)
 - Other issues
 - Variable or increasing baseline?
 - Control for normal development?

More Aspects of Validity

- External
 - In intervention research, applicability of treatment to real world conditions
 - E.g., Can research protocol be replicated by families?
 - Well-controlled study may still lack external validity
- Other threats to validity
 - Scientific consensus re: theory behind treatment
 - Sometimes called “content validity”
 - 7 Warning Signs of Bogus Science
 - › <http://www.quackwatch.org/01QuackeryRelatedTopics/signs.html>
 - Need for documenting effectiveness of components of intervention
 - Interventions needing

Other Issues in Evaluating Scientific Research

- › Importance of *replication*
 - Problem: Study with apparent validity that cannot be replicated
- › Publication in *peer-reviewed* media
- › Are claims made for treatment aligned with *current knowledge* of autism?
 - Miracle cures....?
 - Autism known to be developmental disability affecting many brain systems
 - Sudden cures or huge change in short time unlikely
 - Scientific literature supports gradual change
 - Are proposed etiologies out of line with current biomedical knowledge?
- › Do proponents have a financial interest in their treatment methods?

The Big Divide: Behaviorist vs. Social Interactionist Approaches

- › Claim:
 - The only evidence-based approach to intervention for children with ASD is intensive behavioral intervention
 - This is false.
- › Claim:
 - Behaviorism is an old-fashioned and discredited means of language intervention.
 - This is also false.

Early Intensive Behavioral Intervention

- ▶ UCLA Young Autism Project: Lovaas (1987)
 - Participant selection
 - Young children with autism referred to clinic
 - Assigned to intensive or less intensive treatment based on therapist availability
 - Basic Theory
 - Children with autism need special learning environments
 - Teaching of basic skills in small stepwise increments
 - Imitation very important
 - Generalization to natural environments
 - Intensive, early intervention allows brain plasticity to overcome learning problems (Lovaas, 2000).

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EIBI, cont.

- ▶ Treatment method
 - Behavioral methods
 - Including discrete trial teaching
 - Planned generalization
 - Highly trained and well-monitored consultants & trainers
 - Parent involvement
 - Intensive: 40 hours per week
- ▶ Outcome measures
 - IQ tests
 - School placement
 - Note: long term follow-up measures looked at wider range of measures

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How well does it hold up?

- ▶ Many severe criticisms have been leveled at this study
 - Not all have held up over time
 - E.g., charge that assignment to treatment group non-random somewhat serious
 - But no autism intervention study meets this criterion
 - Lovaas has denied his participant selection was biased (Lovaas, 2000)

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Strengths of study

- Theoretical basis has support in literature
- Degree of effects shown hard to explain away by normal variation in population
 - Almost half of 19 participants functioning in typical range of IQ at close of study
 - Two control groups, one receiving 10 hours per week of treatment, the other a community sample receiving typical (unspecified) treatments available in the community
 - Neither exhibited gains shown by experimental group
- Careful adherence to study protocol
- In general, as carefully done as any relatively large-scale treatment study
 - Few competitors in realm of autism treatment research

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Weaknesses of study

- ▶ Number one weakness: failure to replicate
 - Multi-site replication study under way
- ▶ Current protocol differs from YAP protocol
 - Punishment no longer used
- ▶ External validity questionable
 - Difficult to replicate results in community
 - Lovaas himself criticizes poorly run interventions claiming to use his protocol (Lovaas, 2000)
 - Lack of trained personnel
 - Lack of necessary intensity
 - Lack of careful generalization phases

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Weaknesses, cont.

- ▶ Small *n* problematic
- ▶ Failure to use control group receiving comparably intensive treatment
 - Which is key: intensity or behavioral training?
- ▶ Theory weakened by lack of discussion of how/when natural learning takes over from training
 - Impossible to train all grammatical structures, all vocabulary, all pragmatic competence to within normal limits
 - Natural learning a logical necessity
 - Not addressed in behavioral literature

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Another problem with EIBI and YAP

- ▶ E stands for Early, Y for Young!
 - This protocol not validated for older children
 - Behavioral approaches do have validation for older children, but....
 - Enrolling school age children in a version of the YAP is not hypothesized by its developers to result in outcomes similar to those achieved by the youngest children

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Recent Critical Reviews & Comparative Studies

- One meta-analysis found intensive behavioral intervention to result in large to moderate gains in IQ & adaptive functioning
 - Eldevik et al. (2009)
- Another systematic review found some improvement but few RCT's and methodological limitations that impede confidence in results
 - Reichow & Wolery (2009)
- One recent study found EIBI more effective than school-based services
 - Cohen et al. 2006
- Another found no difference between standard preschool-based treatments and EIBI
 - Magiati, Charman, & Howlin (2007)

Lovaas-based EIBI: Conclusion

- ▶ Supporting evidence is good
- ▶ BUT: not as strong as supporters claim
- ▶ Must be implemented consistently by trained personnel

Picture Exchange Communication System: A Behavioral Approach

- ▶ Augmentative approach rooted in behavioral philosophy (Bondy & Frost, 1994)
- ▶ Popular
 - BUT often modified from original behavioral format
- ▶ Evidence
 - Several case studies, single participant studies
 - RCT Howlin et al. (2007) found modest gains in symbol use
 - No language gains
 - No improvements in social-adaptive functioning
 - RCT Yoder & Stone (2006)
 - Prelinguistic Milieu Teaching vs. PECS
 - PECS superior at developing generalized requesting
 - Milieu superior at increasing jt. attention & turn-taking
 - Meta-analysis (Flippin, Reszka, & Watson, 2010) found weak evidence for small/moderate gains in communication, negative to no evidence for gains in speech

Naturalistic Behaviorism: Pivotal Response Training/Teaching

- ▶ Outgrowth of behaviorist theory
 - (Koegel et al., 1999; Koegel & Koegel, 2006)
 - Concerns
 - avoid prompt dependency
 - explicitly teach skills that foster independent learning

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Pivotal Response Training, cont.

- Pivotal skills:
 - Responsivity to multiple cues
 - Motivation to initiate and respond appropriately to social and environmental stimuli
 - Self-regulation of behavior

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Pivotal Response Training, cont.

- Approaches:
 - Teach responding to multiple cues by prompting, conditional discrimination.
 - Motivate child by:
 - offering choice
 - use of natural (intrinsic) reinforcers
 - interspersed maintenance trials
 - reinforcing attempts

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PVT Evidence

- ▶ Single participant design studies with small N (but adequate replication) find increases in adaptive functioning
- ▶ No RCT's

D.I.R., Floortime (Greenspan & Wieder, 2000)

- ▶ 2 to 5 hours per day of home-based intervention.
- ▶ Provide interactive experiences known as "Floor-time", using DIR Model
 - Developmental
 - Individualized
 - Relationship-based

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Floortime (Greenspan & Wieder, 2000)

- ▶ Key concepts in developmental hierarchy:
 - Attention & focus
 - Engaging & relating
 - Nonverbal gesturing
 - Affect cuing
 - Complex problem-solving
 - Symbolic communication
 - Abstract & logical thinking

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Floortime (Greenspan & Wieder, 2000)

- ▶ Goal: Mediate environment to provide natural input from caregivers, taking into account:
 - Child's neurobiological readiness
 - Family patterns
 - Larger society patterns
- ▶ Some efficacy data, long-term, uncontrolled, case review-based
- ▶ Solomon et al. (2006) pilot study found 90% parent satisfaction and moderate gains in social functioning

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SCERTS

- SCERTS (Social Communication Transactional Regulation & Social Support) model (Prizant, Wetherby, Rubin, & Laurent, 2006)
 - Comprehensive curriculum
 - Developmental
 - Naturalistic
 - Focus on modifying environment and activities
- Wetherby & Woods (2006) preliminary study of 17 two-year-olds found improvements using a version of the SCERTS model
- O'Neil et al. (2010) Case report of implementation for 4 students in school setting
 - Argues that SCERTS is a model for implementing best practice, not single intervention

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Hanen Program

- ▶ Parent training based
 - Video feedback
 - Developmental
 - Naturalistic, child-centered
- ▶ Girolametto, Sussman, & Weiszman (2007) 3 case studies: Found parent improvement in interaction; child improvement in social functioning and language use
 - Earlier studies included children with ASD but did not separate them from others with different developmental disorders
 - Other work by this group has documented parent change in behavior without measuring child change

Joint Attention Intervention

- ▶ Kasari et al. (2007): RCT
 - Theory: Social engagement needed for language development to progress normally
 - Background: Numerous studies show deficit in joint attention in children with ASD
 - Joint attention is foundation of social engagement, so increasing it should remediate and/or prevent some of the social and language impairments in ASD
 - Intervention trains parents to engage children in play-based joint attention interactions
 - (note similarity to Floortime, SCERTS)
 - Finding: Increased joint attention AND increased vocabulary
 - Smith et al. (2011) systematic review
 - naturalistic, play-based approaches to teaching jt. attention appear to facilitate generalization

Bottom Line on Social Interactionist & Naturalistic Approaches

- ▶ Evidence beginning to accrue
 - Kasari et al. among best to date
- ▶ Some very popular approaches have never been carefully studied on a large scale
 - Casenhiser et al. just completed RCT on Floortime/DIR—results not yet published, but promising
 - <http://www.mehri.ca/research/clin.html>
- ▶ Strengths
 - Tied to scientific facts of language development
 - Literally impossible to train all words and all language structures
 - If properly implemented, can be intensive without being financially as burdensome as EIBI
 - Family-centered, parent training based

Older children and adults with ASD

- ▶ Much less research
- ▶ Most approaches have no large clinical trials
- ▶ Examples
 - Winner's Social Thinking model has some preliminary evidence
 - Crooke, Hendrix, & Rachman (2008)
 - Social stories have some preliminary evidence
 - Scatone et al. (2002)
 - Focus on decreasing disruptive behavior, not language or social development

Final Thoughts

- ▶ Treatment research is difficult and expensive
- ▶ Can take years and have little to show for your work
- ▶ Developing the rigor needed for a controlled study is extremely difficult, esp. when outcomes are difficult to measure
 - Increase in social behavior
 - Increase in joint attention
 - Improved functional communication
- ▶ For quickly locating the latest, most relevant info/abstracts, try Google Scholar.

Questions?

- ▶ For any references or articles, feel free to e-mail me at:
 - lhewitt@bgsu.edu
- ▶ Check out ASHA Group 1: Language Learning and Education for information on child language and ASD
- ▶ Thank you!
