



CONTROVERSIAL THERAPIES FOR LEARNING AND ATTENTION DISORDERS

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I do intend to discuss an unapproved/investigative use of a commercial product/device in my presentation.





*At the end of this activity,
participants will be able to...*



- recognize general characteristics of controversial therapies,
- use print and web-based resources to identify treatments that are unproven, and
- understand how to advise families.



Legal, Medical and Ethical Issues of Unproven Therapy Use for Learning and Attention Disorders in Children



Legal requirements for evidence-based educational practice (No Child Left Behind 2002; IDEA Reauthorization 2005).

Ineffective treatments may cause harm directly (toxicity, nutrition, interrupt/delay) or indirectly (time, financial burden, guilt, inaccurate attributions).

Obligation to provide information about the risks and benefits of treatments.

Higher ethical standard than for adult patients because children do not decide on what treatments they receive.



DEFINITIONS OF TERMS

Alternative medicine:

Interventions not typically taught in U.S. medical schools, not available in hospitals, not reimbursed by insurance, or lacking scientific evidence to support its use.

Complementary medicine:

Therapies used in conjunction with but not replacing scientific medicine.

Integrative medicine:

Inclusion of CAM into the fold of scientific medicine.





Complementary and Alternative Medicine (CAM) Use in Children



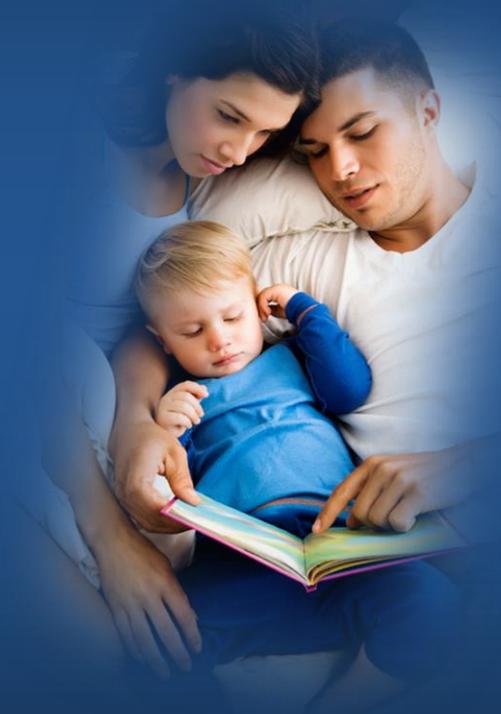
- More than 50% of children with chronic medical conditions use CAM and CAM use is increasing.
- Parents and patients often do not tell their clinicians about CAM use.
- CAM is not covered widely or systematically in pediatric residency education.
- 50% of pediatricians would consider recommending CAM for their patients.



Why Do Families Choose CAM?



- mistrust and misunderstanding of conventional medicine/intervention
- desire to do all that is possible
- conventional treatment is ineffective
- preference for more “natural” intervention
- attempt to gain sense of control





Unproven Therapies for Learning and Attention Disorders: A Partial List



- Colored overlays/Tinted lenses
- Optometric visual training
- Fast Forward
- Computer-based cognitive training (Cogmed, BrainBuilder)
- Dietary supplements (megavitamins, minerals, amino acids, omega-3 fatty acids, herbs)
- Dietary restriction (sugar, food allergens, additives)
- Neurotherapy (EEG biofeedback)
- Sensory integration therapy
- Auditory integration therapy (The Listening Program)
- Auditory Trainer (CAPD)
- Dore-DDAT (Dyslexia, dyspraxia and attention treatment)
- Cerebellar-vestibular treatment (anti-motion sickness medication)
- Patterning (Doman-Delacato)
- Interactive metronome therapy
- Chiropractic cure for dyslexia
- Davis dyslexia correction method



Conventional Treatments are Performance-Based



Direct Instruction or Intervention –
targeting deficient “high level” cognitive ability

(e.g. component reading skills for dyslexia
and language skills for specific language
impairment, etc.)



CAM or Controversial Treatments are Process-Focused



Indirect Approach –

Targeting lower level perceptual (e.g. auditory, tactile, visual) or motor ability

Correcting underlying cause improves higher aspect of cognition (e.g. reading, language, attention, etc.)

Pennington (2009)



Empirical Criteria for CAM (Process-Focused) Treatments



Lower level deficit is present in children with the disorder

Treatment improves the lower level deficit

Reducing the lower level deficit remediates the disorder (**transfer**)



Level of Evidence for Studies of Treatment Efficacy

1. meta-analysis of >1 RCT
2. RCT
3. quasi-experimental study (controlled without randomization)
4. non-experimental study (pre-post without control group or randomization)
5. committee or consensus conf. report, clinical experience of respected experts
6. unsystematic clinical observations (anecdotes)



Magnitude of Treatment Efficacy: Effect Size (ES)

$$ES = \frac{(\text{mean expt gp}) - (\text{mean control gp})}{\text{Standard Deviation}}$$

<u>Cohen's d ES</u>	<u>Effect</u>
.2	Small
.5	Medium
.8	Large



CAM Research Issues

Many CAM therapies have not been evaluated and there are relatively few random control trials (RCTs) in peer-reviewed journals.

Limited interest and expertise in CAM at conventional institutions are potential barriers to experimental studies.

Publication bias in CAM research may be opposite of conventional medicine (i.e. negative results published).



IS THE THERAPY PROVEN?



- consistent with pathophysiologic processes
- randomized and comparison-group controlled trials
- accumulated evidence
- peer-reviewed publication





IS THE THERAPY PROVEN?



Consistent with pathophysiologic processes

Randomized and comparison-group controlled trials

Accumulated evidence

Peer-reviewed publication





Parents of a five year old with attention-deficit/hyperactivity disorder claim their son's behavior is highly influenced by what he eats. They have observed that he "gets hyper" when he consumes foods high in sugar, artificial additives, and peanuts. They are hesitant to use stimulant medication after reading about growth problems and sudden death. In magazines and on the internet they have read about the safety and effectiveness of restrictive diets and nutritional supplements. They are reluctant to use any form of treatment until they weigh the pros and cons.



GENERAL POINTS REGARDING CONTROVERSIAL THERAPIES



**Controversial therapies first appear
in non-peer-reviewed literature.**

**Natural substances or exercises are
relied upon and are said to cause no
adverse effects.**

**Powerful placebo or Hawthorne
effects convince proponents that the
treatment is effective and worthwhile.**



IRLEN COLORED OVERLAYS/LENSES



In 1983, during a presentation at the annual meeting of the American Psychological Association, Helen Irlen proposed a treatment of dyslexia using tinted (colored) overlays or lenses. The lenses treat a condition called scotopic sensitivity syndrome (SSS) that is said to be a visual defect related to difficulties with light source, glare, luminance, wave length and black/white contrast. Without publishing research on the condition or efficacy of the treatment, she claimed in the newsletter of her institute (2001) that tinted lenses have also successfully treated individuals suffering from light sensitivity and distortions caused by head injuries, migraine headaches, cataracts, fibromyalgia, depression and perceptual problems.

irlen.com/newsletter-archive



IRLEN COLORED OVERLAYS/LENSES, cont...



The assessment for SSS involves questions about eye fatigue, blurred vision, words “running off the page” and visual tasks with overlays of 7 different colors. During the tasks, individuals answer questions about visual discomfort and clarity while interpreting geometric figures and reading text. Fifty percent of individuals with dyslexia are said to have SSS and derive immediate improvement in word reading accuracy and efficiency when their specific tint is used. The Irlen Institute was the original fabricator of tinted glasses. Schools may now support the use of overlays by screening and supplying the needed tint. Parents who were convinced their children benefited from colored overlays organized an effort that made colored overlays an allowable accommodation for the Texas state assessment (STAAR).



GENERAL POINTS ABOUT CONTROVERSIAL THERAPIES



**Clients recruited
from schools**

**Advocates are
organized in lay
groups**

**Theory not
based on
recognized
pathophysiology**

**Treatment
promises high
success rate for
diverse
problems**



IRLEN COLORED OVERLAYS/LENSES DO NOT ALLEVIATE READING DIFFICULTIES (RD)



Sixty-one school children (aged 7 – 12) with R D

Irlen diagnosticians diagnosed SSS in .77

No difference in reading (WRRT, GORT) among those with and without SSS using prescribed color, non prescribed color and clear overlay

Two of three children who knew their SSS diagnosis and tint had higher Wilkins Rate of Reading Test (WRRT) scores with the prescribed overlay

A clumsy first grader with sloppy paper-pencil skills has just finished a year of occupational therapy at school. He was said to make good progress with treatment and his printing, to your estimate, now appears age appropriate. The school O.T. recommends continuing weekly individual therapy to help with his inattention and slow development of reading proficiency. She states that he has tactile defensiveness, shortened duration of post-rotatory nystagmus, and gravitational insecurity. The child's mother is concerned about the effect of pulling her child out of the classroom two hours weekly for therapy. She was forewarned of physician bias against it.



GENERAL POINTS ABOUT CONTROVERSIAL THERAPIES



Studies that do not support the controversial treatment are discounted as biased, controlled by uninformed physicians.

Unproven therapies often have the endorsement of school officials and are incorporated into school programs.



COUNSEL FAMILIES ABOUT CONTROVERSIAL THERAPIES



- C**over - clinical course of the condition
- O**bserve - response to unproven therapy
- U**nderscore - their role in management
- N**otice - and control your reaction
- S**end - them resources and support groups
- E**ducate - them to recognize unproven treatments
AAP – CCWD (2001) and Kemper et al. (2008)
- L**isten - to their concerns



Characteristics of Unproven Therapies

**Promise
success rate
much
greater than
validated
treatments**

**Effective for
multiple
unrelated
disorders**

**Based on
novel theory
inconsistent
with
established
concepts**

**Supported
only by
anecdotes,
testimonials;
no RCT or
control
comparison
trial**

**Providers
make
substantial
profit**



Visit web-based Resources for Evaluating Controversial, Complementary and Alternative Therapies



Cochrane Collaboration:

www.cochrane.org



National Council Against Health Fraud:

www.quackwatch.org

**National Center for Complementary and Alternative
Medicine – National Institute of Health:**

www.nccam.nih.gov



AAP Section on Integrative Medicine:

www.aap.org



Understood.org:

www.understood.org

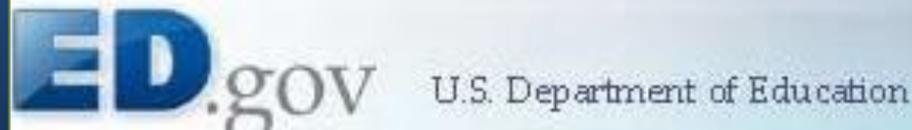


Use Guidelines to Help Evaluate Research Reports



USDOE-IES: Identifying and Implementing Educational Practices Supported by Rigorous Evidence

www.ed.gov/about/offices/list/ies/news.html#guide





A Commonsense Guide to Complementary and Alternative Medicine Treatment Recommendations



		Is the therapy effective?	
		Yes	No
Is the therapy safe?	Yes	Recommend	Tolerate
	No	Monitor closely or discourage	Discourage

From Kemper K. Cohen M. *Contemp. Pediatrics*. 2004; 21:65



CLOSING THOUGHTS ON CONTROVERSIAL THERAPIES



- ❖ Become familiar with and use objective sources of information about complementary and alternative treatments.
- ❖ Look carefully for characteristics of quackery/pseudoscience.
- ❖ Determine if scientific research has shown that the therapy is evidence-based (quality of evidence, strength of treatment).



The absence of evidence is not evidence of absence
Carl Sagan

Thank You!

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