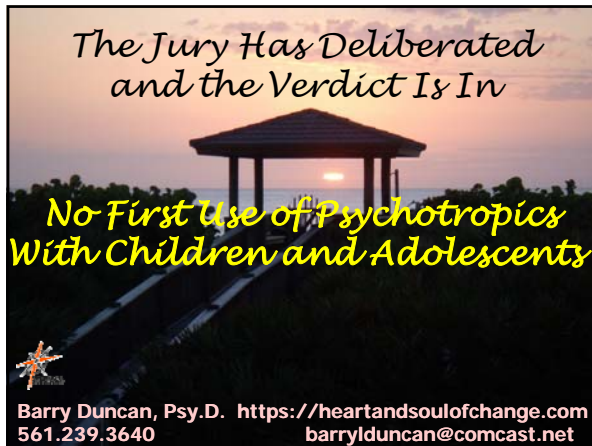


*The Jury Has Deliberated
and the Verdict Is In*

**No First Use of Psychotropics
With Children and Adolescents**

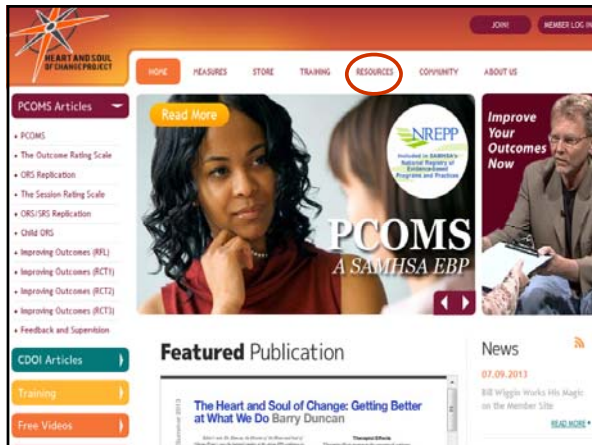


Barry Duncan, Psy.D. <https://heartandsoulofchange.com>
561.239.3640 barrylduncan@comcast.net

Disclosures

The presenter DOES have an interest in selling a technology, program, product and/or service to CME/CE professionals.

Dr. Duncan is a co-holder of the copyright of the Outcome Rating Scale/Session Rating Scale family of measures. The measures are free for individual use but Duncan receives royalties from licenses issued to groups and organizations. In addition, a Web-based system that uses the measures and analyzes the data is a commercial product and he receives royalties based on sales.



HEART AND SOUL OF CHANGE PROJECT

HOME MEASURES STORE TRAINING **RESOURCES** COMMUNITY ABOUT US

PCOMS Articles

- PCOMS
- The Outcome Rating Scale
- ORS Replication
- The Session Rating Scale
- ORS/SRS Replication
- Child ORS
- Improving Outcomes (IRL)
- Improving Outcomes (RCT1)
- Improving Outcomes (RCT2)
- Improving Outcomes (RCT3)
- Feedback and Supervision

Featured Publication


The Heart and Soul of Change: Getting Better at What We Do Barry Duncan

Youth Prescription Rates Increasing Globally



In the US, spending for meds for child behavior problems eclipsed any other drug category, including antibiotics

While the US leads the world in psychotropic prescriptions to youth, global use of stimulants has significantly increased and antipsychotics have doubled across Europe




Study of poor children found that 26% on antipsychotics; Poor children 4 times more likely to be on antipsychotics

57% of foster children are taking 3 or more psychiatric drugs, 6 times national average


Apparently, children are vulnerable to psychotropics used as interventions of control rather than therapy.

The Questions Children and Psychiatric Drugs

- Are the skyrocketing rates of prescription justified by clinical trial evidence?



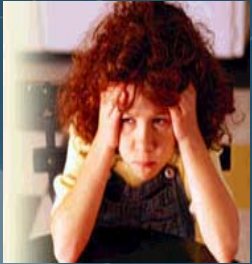
SSRIs: Antidepressants The Risks and the Black Box



FDA study of 4400 youth revealed a risk of suicidality of 4% in SSRI patients, twice that of placebo; a follow up analysis of 22 RCTs reported similar findings; Finally, the FDA meta-analyzed 372 RCTs and reported that suicide risk increased as age under 25 decreased

SSRIs: Antidepressants The Benefit


Of 15 published and unpublished clinical trials, only 3 show superiority to placebo on primary measures; none on patient or parent measures.



Antidepressants carry at least double the chance for suicidal ideation and behavior...Black box warning...Nicole

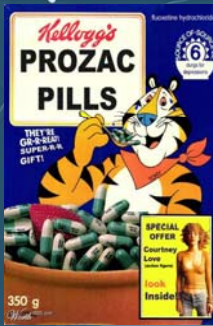


Risk/Benefit Analysis: TADS (Treatment of Adolescent Depression Study)



- Multicenter, randomized, effectiveness trial funded by NIMH. N=432
- Short term (12-weeks) & long-term (36-weeks) of adols. diagnosed w/MDD
- 4 groups: Prozac, placebo, CBT, Prozac + CBT

SSRIs TADS: The Benefit



✓CBT alone had comparable outcome at 30 weeks while the antidepressant treatment groups had significantly more psychiatric adverse events;

✓What about Suicide Risk?

Suicide Related Events (SREs) and Suicide Attempts (SAs) in TADS (Vitiello et al., 2009)

Treatment	N	SREs	%	SAs
Placebo	103	3	3	0
CBT	108	5	5	1
Fluoxetine alone	109	16	15	6
Combination	107	9	8	3
Placebo switched to fluoxetine or combination	9	9	100	6
CBT switched to fluoxetine or combination	3	2	67	2
Total Non-SSRI	211	8	4	1
Total SSRI	228	36	19	17

Outside the Box: Re-assessing Pediatric Antidepressant Prescription

Jacqueline A. Sparks PhD, Barry L. Duncan PhD

Abstract

Objective: The purpose of this review is to discuss further evidence regarding a biological mechanism for pediatric antidepressant use and re-evaluation of the risks. **Methods:** The review examines studies supporting the potential to treat anxiety or related conditions and the role of neurotransmitters, particularly serotonin, in the pathophysiology of anxiety, depression, and related conditions. **Results:** Pediatric antidepressant prescription is on the rise, and there is growing concern about the potential for adverse effects, particularly in the form of suicidal ideation. **Conclusions:** The use of antidepressants in children and adolescents is a complex issue that requires careful consideration. **Keywords:** antidepressants, anxiety, chronic administration, suicidal ideation.

Keywords: antidepressants, anxiety, chronic administration, suicidal ideation.

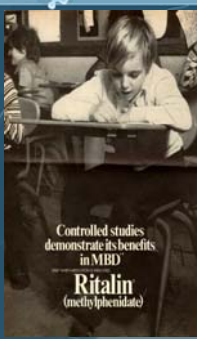
Objective: Given that a goal of practice is to ensure provision of care that is evidence-based, it is important to understand the risks of antidepressant use in children. **Methods:** In this review, the authors discuss the potential for adverse effects of antidepressant use in children, including suicidal ideation, and the role of neurotransmitters, particularly serotonin, in the pathophysiology of anxiety, depression, and related conditions. **Results:** Pediatric antidepressant prescription is on the rise, and there is growing concern about the potential for adverse effects, particularly in the form of suicidal ideation. **Conclusions:** The use of antidepressants in children and adolescents is a complex issue that requires careful consideration. **Keywords:** antidepressants, anxiety, chronic administration, suicidal ideation.

With the rapid acceleration of selective serotonin reuptake inhibitor (SSRI) prescriptions in youth from 1992 to 2004 (Chen, Cui, & Saxe, 2006; Saxe, 2006), SSRI use has become a prominent clinical phenomenon. In a review of the literature, Saxe (2006) found that the number of SSRI prescriptions for youth increased from 1992 to 2004, with a 100% increase in the number of prescriptions for youth aged 12 to 17. In addition, the US Food and Drug Administration (FDA) issued a warning of adverse effects associated with SSRI use in children and adolescents in a black box warning for all antidepressants for these youth age 12 (FDA, 2005, October 15).

A review article issued in the UK, The Medicines and Healthcare Products Regulatory Agency (MHRA) (2006) also found a 100% increase in SSRI prescriptions for youth under 18 with the exception of fluoxetine, which could only be used for those over age eight (MHRA, 2006). In addition, the US Food and Drug Administration (FDA) issued a warning of adverse effects associated with SSRI use in children and adolescents in a black box warning for all antidepressants for these youth age 12 to 17 (FDA, 2005, October 15).

**University of North Carolina, Chapel Hill, NC, USA
Barry L. Duncan, PhD, Director, Center for the Study of Emotion and Behavior, University of North Carolina, Chapel Hill, NC, USA
Contact: blduncan@unc.edu
DOI: 10.1177/1063426913501891**

Stimulants: The Multimodal Treatment Study of Children w/ADHD (MTA)




- Large 14 mo comparison of managed med v. BT v. combined v. TAU (medicated)
- 19 outcome measures
- All 4 groups improved
- Concluded that MM superior to BT & Combined brought no advantages

Stimulants


MTA: The Benefit

- Found advantage to med group on 3 of 19 measures
- At 36 months, groups did not differ.




Stimulants

MTA: The Risk—Adverse Events



- 64% of the children experienced ADRs; 11% were rated as moderate, and 3% as severe.
- Follow-up reveals sig. growth reduction with no rebound

Antipsychotics: Treatment of Early Onset Schiz. Spectrum Disorders (TEOSS)




- TEOSS compared two SGAs (Risperdal & Zyprexa) to a FGA (Molan).
- At the end of eight weeks, the "response" rate was 50% for those treated with Molan, 46% for Risperdal, and 34% for Zyprexa; 41% didn't complete 8 weeks.

Minimal improvement on the PANSS counted as "response"

Antipsychotics

TEOSS: The Risks—Suicide




- 1 suicide & 8 (8%) were hospitalized for suicidality or worsening psychosis—at risk excluded.
- Weight gain resulted in suspension of Zyprexa arm.
- Adverse events "frequent." "May place many youth at risk for diabetes and cardiovascular problems."

Antipsychotics

TEOSS: Ultimate Risk and Benefit

- The 54 who “responded” during the initial 8 weeks entered into the 44-week maintenance study
- 40 of 54 dropped out for “adverse effects” or “inadequate response.” Only 14 of 116 youth responded and stayed on the med for one year—only 12%.



Psychotropic Medications

The Risks That Don't Make the Ads



Antidepressant Risks: Mania—5 times the rate of placebo; ‘Warning’ for suicidal behavior—at least twice the rate of placebo; stunted growth

Stimulant Risks: ‘Warnings’ for suicide and cardiac risk; loss of 1 cm and 2.7 kg per yr; Mania, psychosis, cardiac sudden death; 64% report adverse reactions


Antipsychotic Risks: Diabetes, obesity; EPS, tardive dyskinesia, neuroleptic malignant syndrome, **suicide**, akathisia

There is no informed consent with children. Parents and helpers need to know

Conclusions

A Risk Benefit Analyses

- Does not support meds as a first intervention;
- Offer alternatives: community, spiritual & counseling in concert w/values, culture, and preferences.
- Where there are no options, create them



Where Children Are Concerned

The Stakes Are Higher

Do not have a voice to say no and depend on adults to safeguard wellbeing; poor children have fewer adults watching over them and are vulnerable to dangerous drugs used for control rather than therapy. **It's up to us to ensure their safety.**



Now That You Know

The Risk/Benefit Analyses

Having heard this, you may choose to look the other way, but you can never say again that you did not know.

William Wilburforce, Address to the English Parliament regarding the Slave Trade

- I hope when you leave tomorrow you will take with you a skepticism of commercial interests with little conscience, a keen attention to the evidence, and a desire for ongoing study of broadening psychosocial options, including a follow up conference.


The Evidence and Ethics Demand

A Higher Standard of Care



- 1) Psychosocial intervention first—especially to the poor
- 2) No off label prescribing;
- 3) No polypharmacy
- 4) Separate pharmaceutical company influence from science and practice
- 5) Monitor treatment response with patient rated measures

Gabriel, foster care child, was on Vyvance, Lexapro, Zyprexa, Symbyax, and Adderal; died at age 7



“Children are like rivers: You can’t step in the same river twice.”

- Children change with changes in context
- Children change as they develop
- Children’s identities are impressionable and mutable



Questions for the Presenters

Rules of Engagement

1. Appreciate your comments but please keep them brief, just a couple of sentences—then ask your question, identifying to whom it is addressed
2. Up to two additional panel members may respond. Please keep all responses under 3 minutes