Piecing Together the Pharmacotherapy Puzzle for Children with Autism Spectrum Disorder

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Disclosure

- Faculty have nothing to disclose.

Objectives

- Design a medication regimen and monitoring plan for a pediatric patient with autism presenting with irritability.
- Make recommendations for the use and monitoring of stimulant drug therapy in a pediatric patient with attention-deficit hyperactivity disorder and inattention.
- Make recommendations for the use and monitoring of selective serotonin reuptake inhibitor therapy for depressive symptoms or repetitive behaviors in a pediatric patient with autism.

Introduction

- The prevalence of autism spectrum disorder (ASD) is approximately 1 in every 68 children
- Pharmacotherapy for comorbid conditions often involves psychotropic mediations
- An estimated 27 – 64 % of patients with ASD are on at least one psychotropic medication
  - And 4.5 – 15 % of patients may be on polypharmacy (three or more medications)

Center for Disease Control and Prevention. http://www.cdc.gov/ncbddd/autism/data.html (accessed 2016 Aug 20)

Coury DL, et al. *Pediatrics*. 2012;130:S69-S76.

Spencer D, et al. *Pediatrics*. 2013;132:833-40.

Introduction

- The amount of evidence-based data is increasing
- But psychotropic medications may be used off-label, in younger patients with limited data, and in combinations that may have unwarranted adverse effects (AEs)

Coury DL, et al. *Pediatrics*. 2012;130:S69-S76.

Spencer D, et al. *Pediatrics*. 2013;132:833-40.

Olfson, et al. *J Am Acad Child Adolesc Psychiatry.* 2010;49(1):13-23.

Case 1

- EM is a 6 year-old boy presenting to child psychiatry clinic for evaluation of impulsive and aggressive behaviors. Father desired an evaluation for autism.
- EM was born 38 weeks gestation due to placental abruption. Due to periventricular leukomalacia, he has cerebral palsy with spastic diplegia and epilepsy with focal seizures.

Case 1

- His communication skills have never been on par with his peers, but the family is able to identify what he needs. The differences between EM and his peers became more evident once he started school.

Case 1

- EM's aggressive behaviors (biting, kicking) occur when he has to stop an activity he likes.
- He 'acts out' when his 'ritual behaviors' are interrupted.
- When in group play with other children, he will not wait his turn and has difficulty focusing on an activity and staying seated.

Case 1

- The behavior outbursts are worsening and are occurring without an identifiable reason (to the father) and EM no longer can self-calm.
- The outbursts typically lasted five minutes, now they may last up to 20 minutes, even with interventions from the family.

Case 1

- EM's recent lab work shows complete blood count, chemistry panel, and liver enzymes all within normal limits. Current weight is 27.5 kg. Medications include:
  - Levetiracetam 500 mg, orally, twice a day
  - OnabotulinumtoxinA, intramuscular, every 3 months
  - Baclofen 10 mg, orally, three times a day

Case 1—Question 1

- The physician and father agree to initiate a second-generation antipsychotic to help with the worsening aggressive behaviors. What other baseline laboratory tests should be obtained prior to starting the antipsychotic?

Time for a Poll

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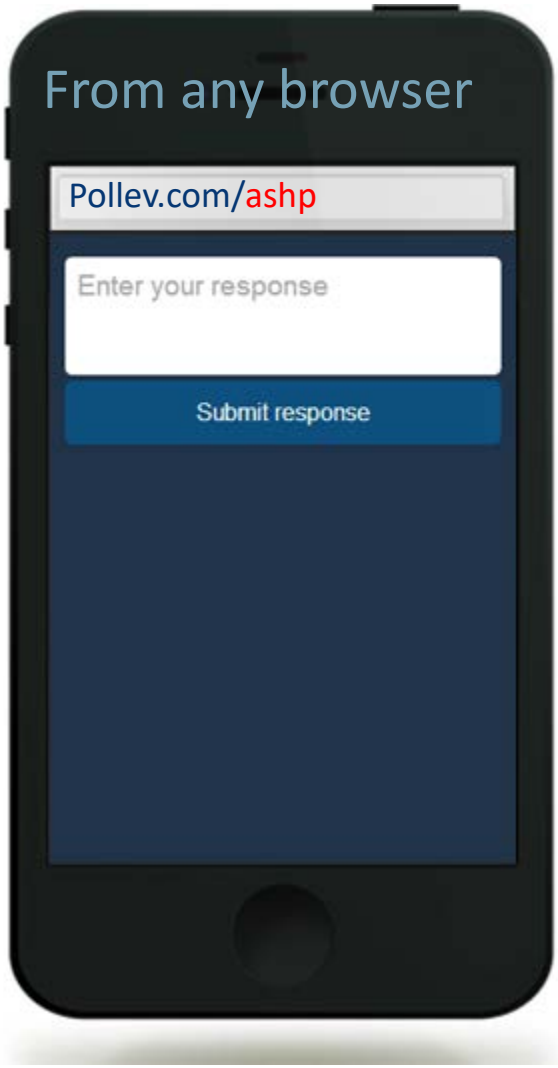
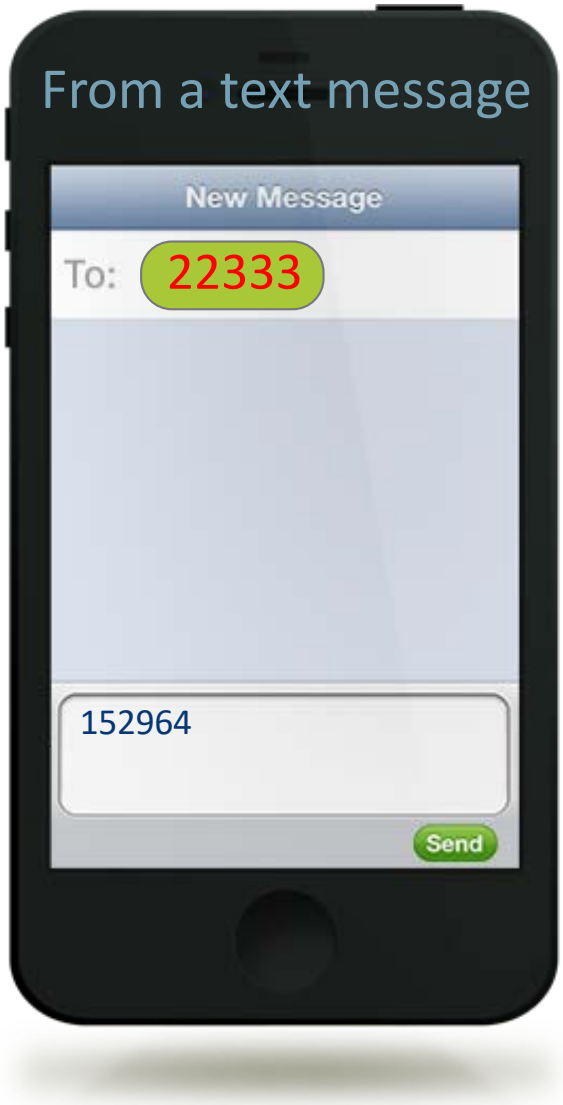
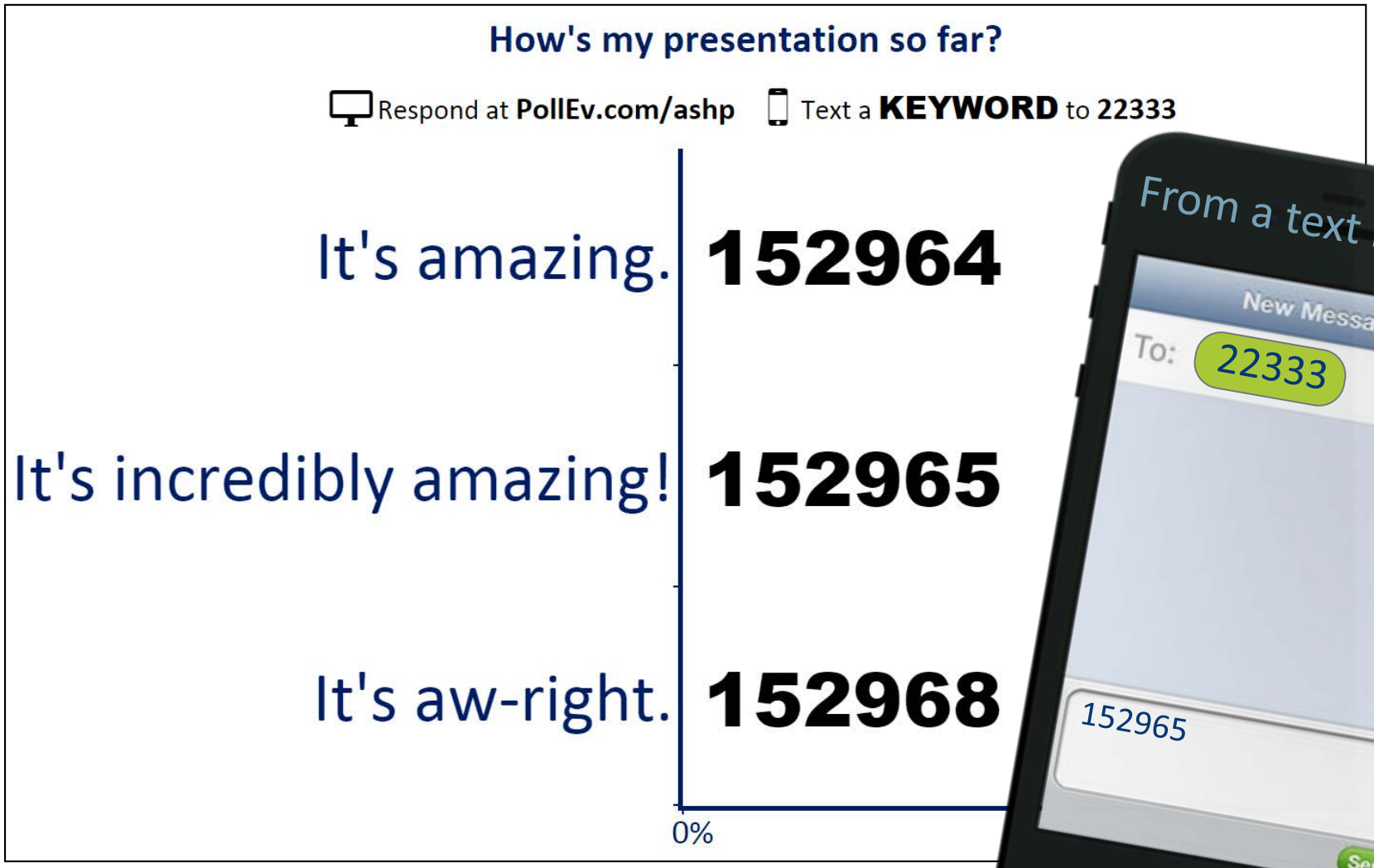
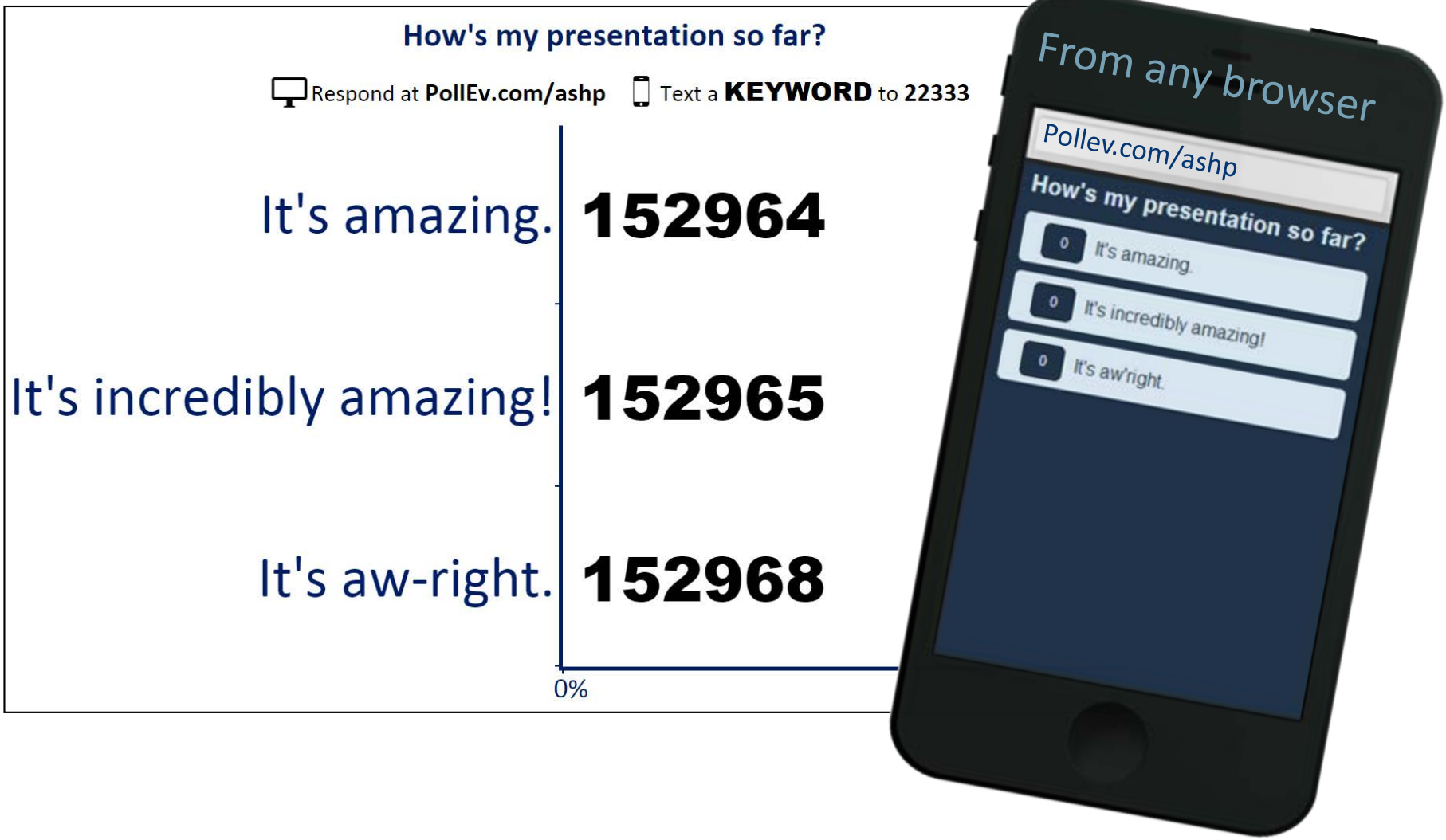




How to vote via text message



How to vote via the web



Case 1—Question 1

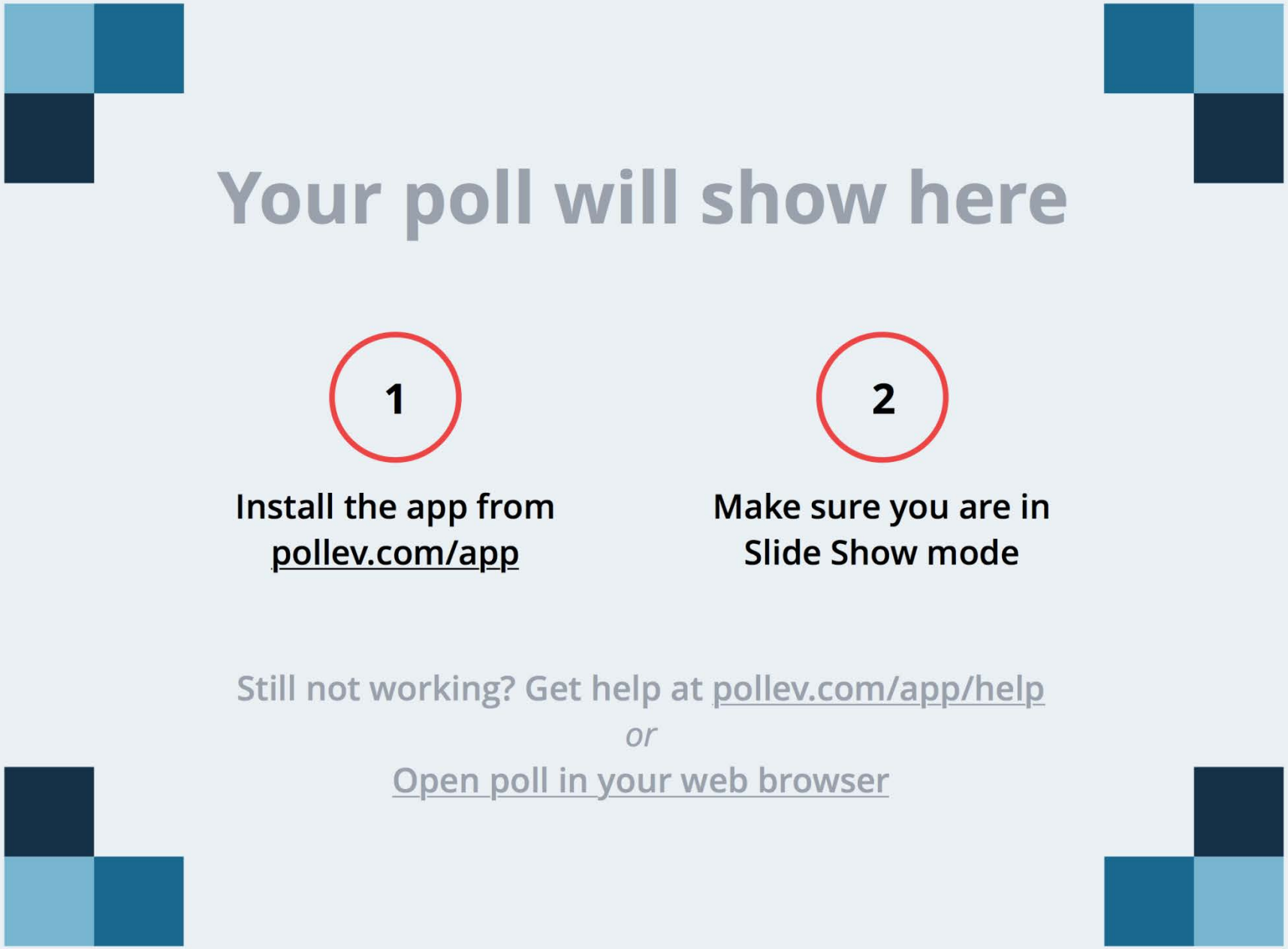
A Prolactin level

B Lipid panel

C Thyroid studies

D Prothrombin time/INR

Case 1—Question 1



Case 1—Question 1

A Prolactin level

B **Lipid panel**

C Thyroid studies

D Prothrombin time/INR

Case 1

- The decision is made to initiate risperidone at 0.5 mg PO at bedtime. Of note, the lipid panel did show an elevated LDL of 113 mg/dL and his current weight of 27.5 kg, which is ~95th percentile on the growth chart.

Risperidone for autistic behaviors

- Primary outcome at 8 weeks was assessed by:
  - Irritability subscale of the Aberrant Behavior Checklist (ABC) assessed by family/caregivers
  - Clinical Global Impressions—Improvement (CGI-I) assessed by clinician

Weight	Initial dose	Possible maximum dose
< 25 kg	0.25 mg QHS	1 mg QAM/1.5 mg QHS
25 – 45 kg	0.5 mg QHS	1 mg QAM/1.5 mg QHS
> 45 kg	0.5 mg QHS	1.5 mg QAM/2 mg QHS

Scahill L, et al. *N Engl J Med*. 2002; 347(5):314-12.

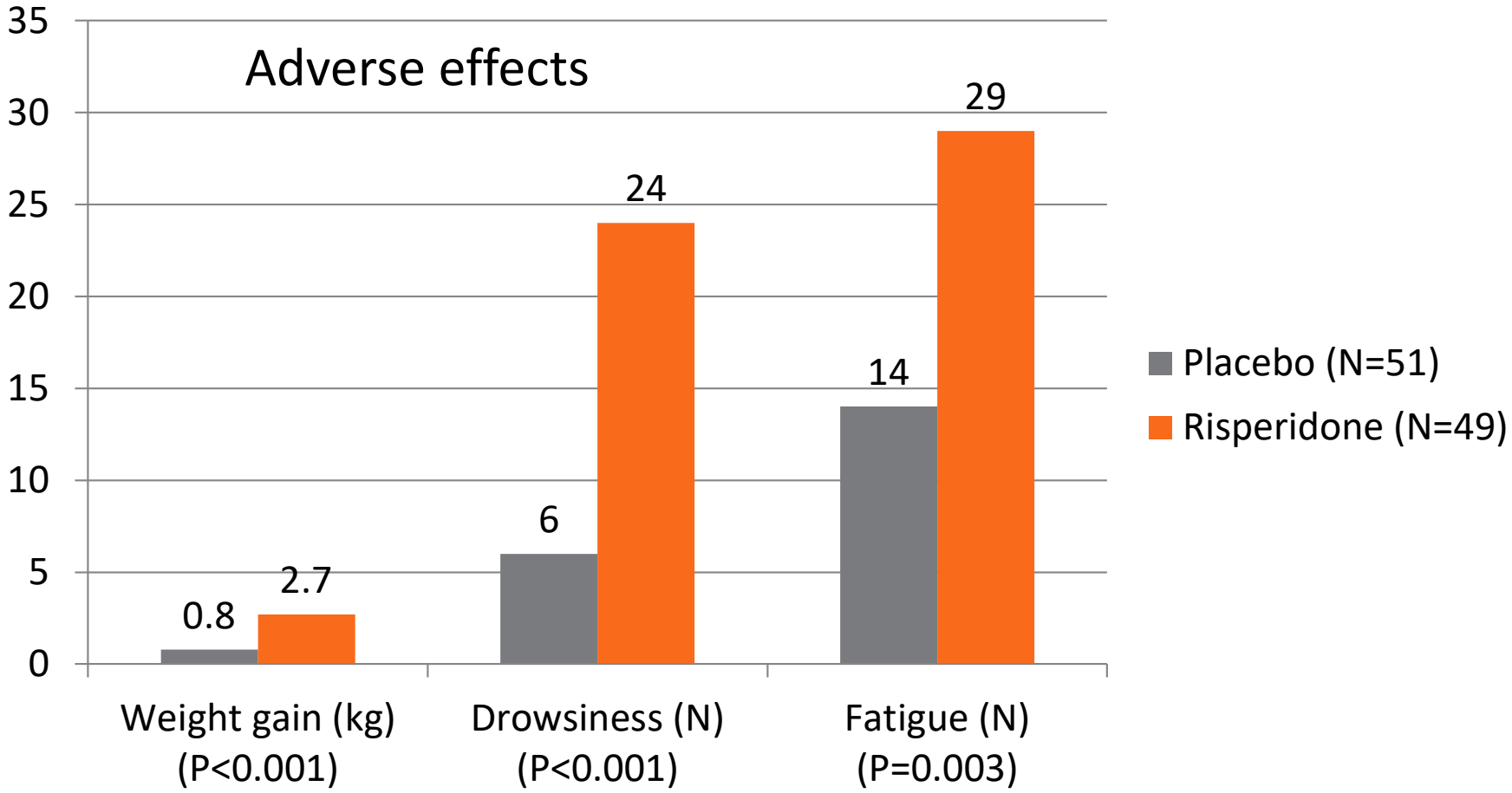
Risperidone for autistic behaviors

	Placebo	Risperidone	p-value
N	52	49	
Initial ABC score	25.5±6.6	26.2±7.9	
8-week ABC score	21.9±9.5	11.3±7.4	<0.001
Improvement in CGI-I	12%	69%	<0.001

- Children ages 5 – 17 years
- ABC assessment at least 18 at baseline

Scahill L, et al. *N Engl J Med*. 2002; 347(5):314-12.

Risperidone for autistic behaviors



Scahill L, et al. *N Engl J Med.* 2002; 347(5):314-12.

Cochrane review 2016: Aripiprazole for ASD

- Significant results for improvement of symptoms associated with ASD
  - ABC—Irritability and CGI—I scales
  - Hyperactivity and stereotypy
  - No improvement in social withdrawal or obsessive compulsive outcomes
- Potential for adverse effects: Sedation, drooling, weight gain, and tremor

Hirsch LE et al. Cochrane Database Syst Rev. 2016; (6):CD009043.

Potential AEs from antipsychotic agents

	Wgt gain	Diabetes	↑Lipids	↑Prolactin	Tardive Dyskinesia	Extra-pyramidal symptoms	↑QTc interval
Aripiprazole*	+	0	0	↓↓	**	+	0/+
Haloperidol	+	0	0	++	++	+++	0/+
Olanzapine	+++	+++	++	++	**	+	0/+
Paliperidone	++	+	+	+++	**	++	+
Quetiapine	++	++	+	++	**	0/+	+
Risperidone*	++	++	+	+++	0/+	++	+
Ziprasidone	+	0/+	0/+	+	+	+	++

*Approved by the FDA for the treatment of irritability associated with autistic disorder
**Limited or no long-term data in children/adolescents
Potential effect: 0/+ minimal, +mild, ++moderate, +++severe

Correll CU. *J Am Acad Child Adolesc Psychiatry*. 2008;47:9-20.
Caccia S. *Pediatr Drugs.* 2013;15:217-233.
Barrett E, et al. *Diabetes Care*. 2004;27(2):596-601.

Case 1

- At a 9 month follow-up visit, father reports some improvement in behaviors, especially after increasing the risperidone dose to 1 mg at bedtime.
- EM has gained weight since initiation of risperidone with no major changes in physical activity or diet. He currently weighs 29.3 kg.

Case 1

- The physician wishes to change risperidone to aripiprazole in an attempt to minimize the continued weight gain. EM is transitioned to a dose of 5 mg daily.
- While seizure control has been stable with levetiracetam (about 1 seizure a week that is self limited), the neurologist wishes to change antiepileptic therapy to determine if that may help with behavior improvements.

Case 1—Question 2

- Which antiepileptic would be an optimal choice to substitute the levetiracetam for treatment of EM's focal seizures?

Case 1—Question 2

A Carbamazepine

B Phenobarbital

C Valproic acid

D Topiramate

Case 1—Question 2

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Case 1—Question 2

A Carbamazepine

B Phenobarbital

C Valproic acid

D **Topiramate**

Pharmacokinetic considerations

	CYP3A4	CYP2D6	CYP1A2	UGT	Aldehyde Oxidase	T ½ (hr)	Protein Binding (%)
Aripiprazole	■	■				75	99
Olanzapine		∇	■	■		33	93
Paliperidone	∇	∇		■		24	74
Quetiapine	■	∇				6	83
Risperidone	∇	■				22	89
Ziprasidone	∇		∇		■	4-10	99

■ Extensive metabolism pathway

∇ Partial or minor metabolism pathway

Kennedy WK, et al. *CNS Drugs*. 2013;27:1021-48.
Caccia S. *Pediatr Drugs*. 2013;15:217-233.

Case 2

- LA is a 7-year-old boy diagnosed with autism at age 2 ½ years when he was not on par with peers with language and communication skills.
- LA's past medical history reveals nothing significant with birth history.
- Behavior changes started happening at age 4
  - Exaggerated reactions to being put in time out
  - Hitting his head with body rocking
  - Screaming

Case 2

- Behaviors started to escalate at age 5 when tantrums on the school playground were resulting in LA running off into the street. At that point, he was initiated on aripiprazole.
- Current medications (all oral): aripiprazole 5 mg daily, trazodone 25 mg at bedtime (sleep), loratadine 5 mg daily (allergy symptoms), senna 8.8 mg daily (constipation), gabapentin 100 mg at bedtime (leg pain)

Case 2

- Aripiprazole has helped with the tantrums and minimizing self-injurious behaviors.
- Now LA has difficulty focusing at school and he is easily distracted from tasks and will speak loudly out of turn in the classroom.
- Despite redirection and more 1:1 class/assistant time, LA is not able to focus on class work

Case 2

- LA's weight is 21.7 kg (~ 25th percentile) and height is 122 cm (~35th percentile)
- Lab work done about 3 months prior showed normal CBC and slightly hyponatremic (133 mmol/L)

Case 2—Question 3

- The family and physician agree medication is needed for LA's attention deficit-hyperactivity disorder. What would be the most appropriate initial medication for LA?

Case 2—Question 3

A Methylphenidate

B Amphetamine salts

C Atomoxetine

D Guanfacine

Case 2—Question 3

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Case 2—Question 3

A **Methylphenidate**

B Amphetamine salts

C Atomoxetine

D Guanfacine

Treatment recommendations

- While there are some data specifically evaluating treatment of ADHD in patients with ASD, recommendations are based on:
  - Existing data in treating patients with both conditions
  - Treating non-ASD patients with ADHD
  - Clinical experience

Mahajan R, et al. *Pediatrics*. 2012;130(suppl 2):S125-S138.

Wolraich M, et al. *Pediatrics*. 2011;128(5):1007-1022.

Methylphenidate in PDD with hyperactivity

- Enrolled patient with autistic disorder, Asperger disorder, or pervasive developmental disorder (PDD) not otherwise specified with interfering symptoms of hyperactivity and/or impulsiveness
- Comparing placebo with three different dosage levels of methylphenidate utilizing a double-blind, crossover phase study design

Posey DJ, et al. *Arch Gen Psychiatry*. 2005;62(11):1266-74.

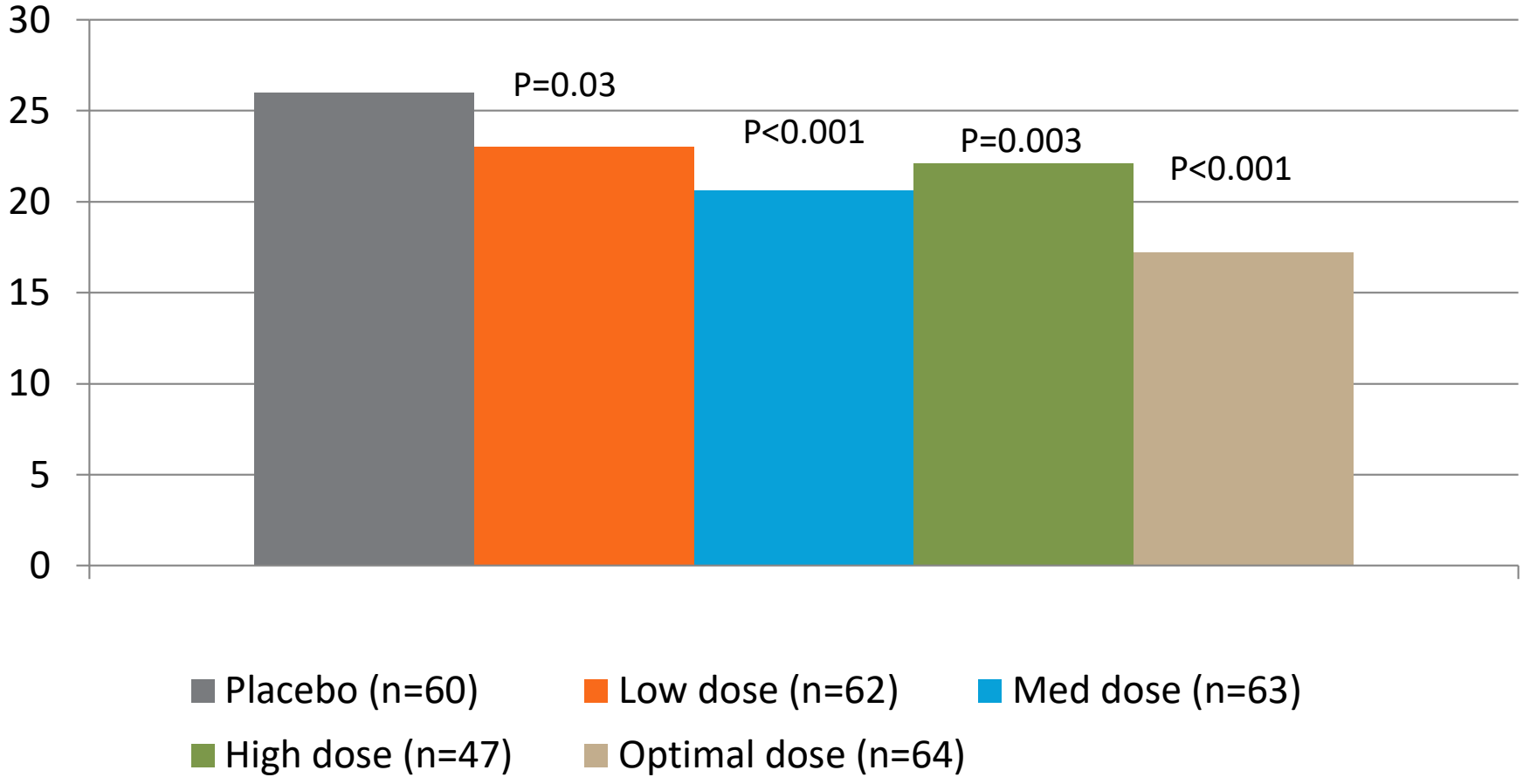
Methylphenidate in PDD with hyperactivity

Dosing schemes mg			
Weight group	Low dose	Medium dose	High dose
16 - < 24 kg n=29	2.5, 2.5, 2.5	5, 5, 2.5	10, 10, 5
24 – 34 kg n=20	5, 5, 2.5	10, 10, 5	15, 15, 10
>34 kg n=17	5, 5, 2.5	10, 10, 5	20, 20, 10

- Doses given 8 AM, 12 PM, and 4 PM
- Optimal dose defined as dose at which ABC hyperactivity subscale score was the lowest
- Initially enrolled 66 patients to the crossover phase

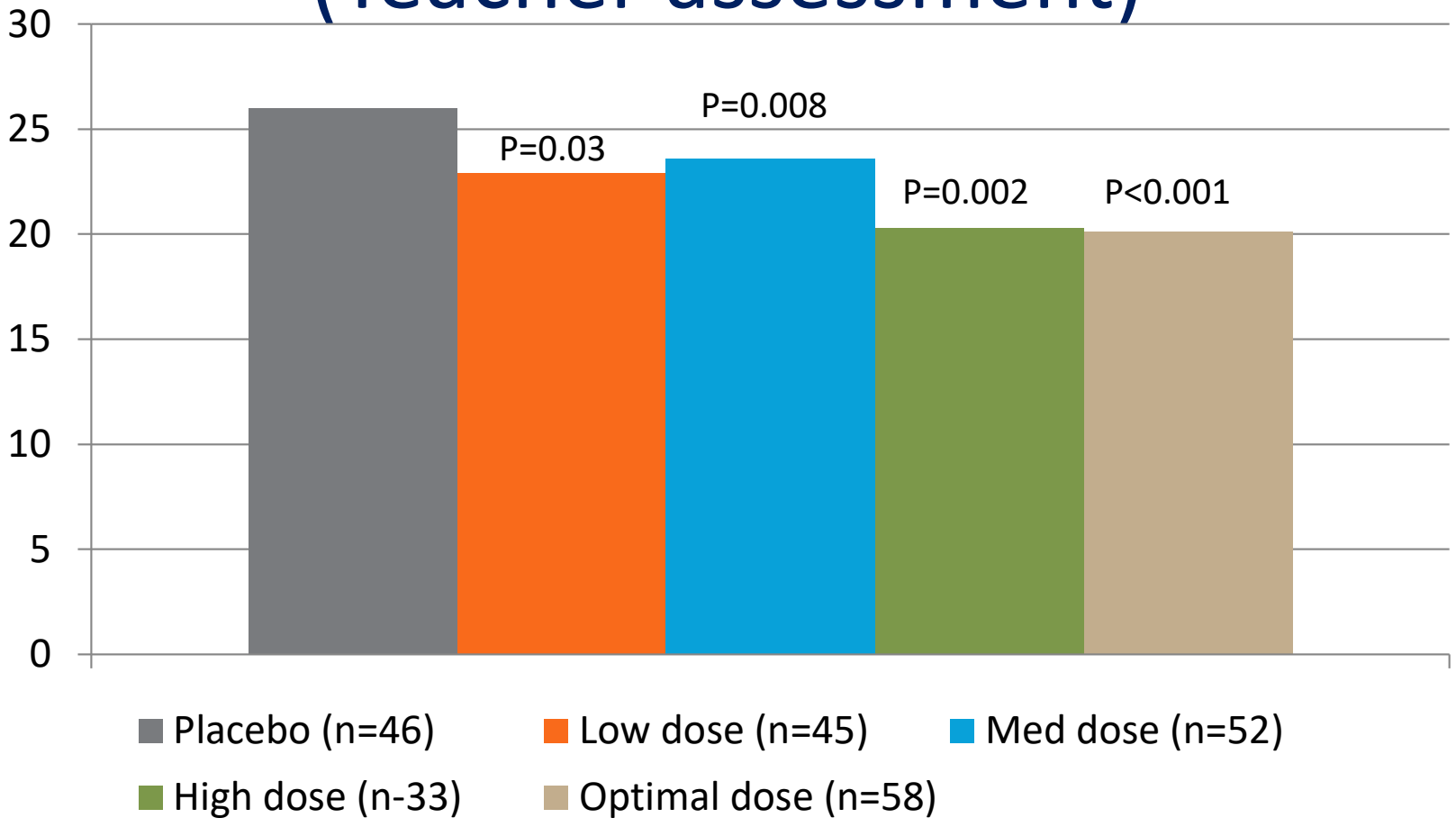
Posey DJ, et al. *Arch Gen Psychiatry*. 2005;62(11):1266-74.

ABC hyperactivity subscale score (Parent assessment)



Posey DJ, et al. *Arch Gen Psychiatry*. 2005;62(11):1266-74.

ABC hyperactivity subscale score (Teacher assessment)



Posey DJ, et al. *Arch Gen Psychiatry*. 2005;62(11):1266-74.

Case 2—Question 4

- What co-existing condition may be worsened for LA after starting methylphenidate for ADHD?

Case 2—Question 4

A Constipation

B Difficulty with sleep

C Hyponatremia

D Leg pain

Case 2—Question 4

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Case 2—Question 4

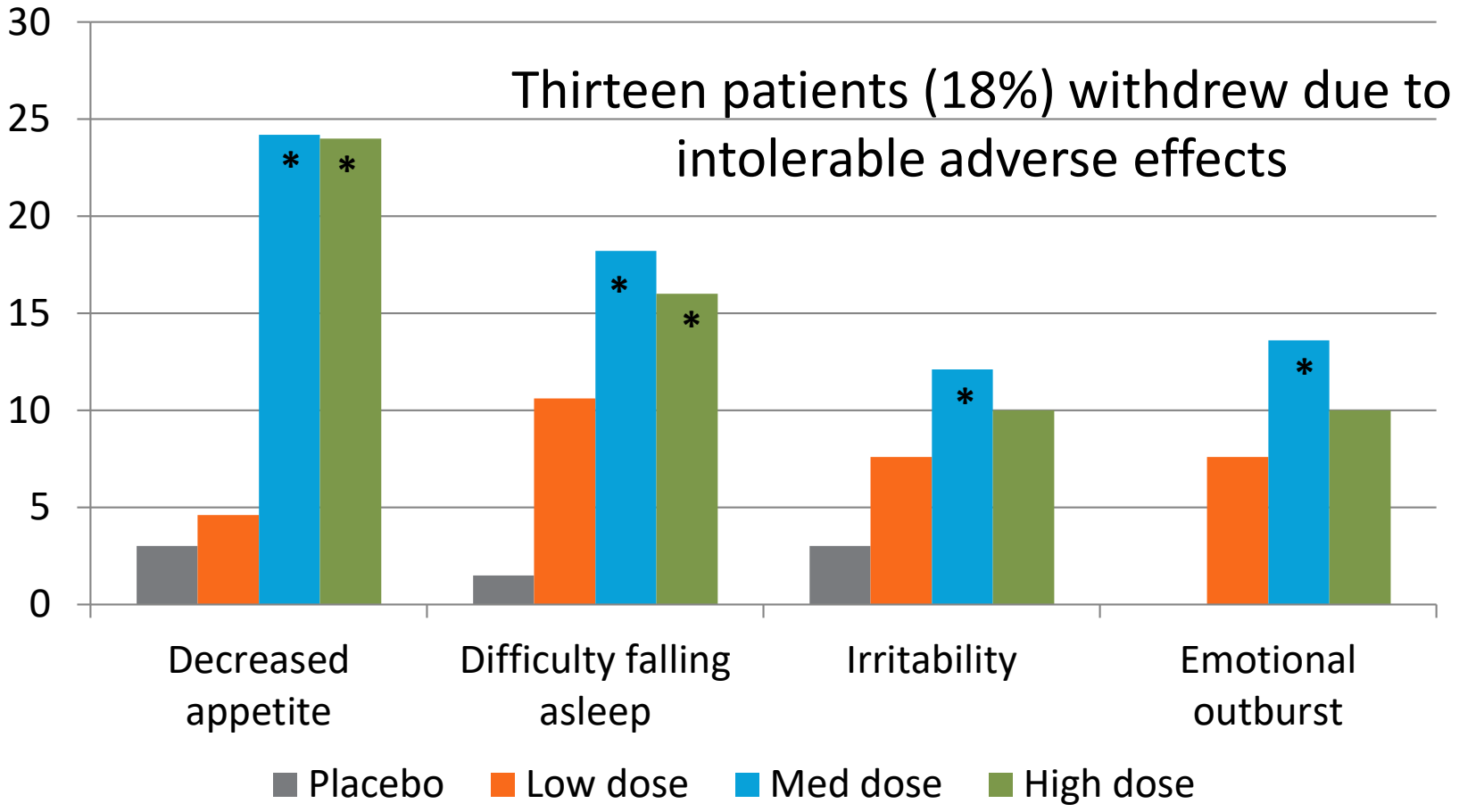
A Constipation

B **Difficulty with sleep**

C Hyponatremia

D Leg pain

Percent patients reporting AEs



* = statistically significant compared to placebo

Posey DJ, et al. *Arch Gen Psychiatry*. 2005;62(11):1266-74.

Methylphenidate in PDD with hyperactivity

- Response to methylphenidate not as robust compared to non-ASD patients
  - Response rate 49% compared to 70 – 80%
- Noted that non-ASD patients tolerated higher doses with lower drop out rate due to adverse effects
  - Study high dose ~0.625 mg/kg/dose versus 0.8 mg/kg/dose
  - Study dropout rate of 18% versus 1.4%

Posey DJ, et al. *Arch Gen Psychiatry*. 2005;62(11):1266-74.

Medication utilization for ADHD with ASD

Methylphenidate (first line)

Amphetamine salt (second line)

Atomoxetine -OR-

Guanfacine

Atypical antipsychotic

Mahajan R, et al. *Pediatrics*. 2012;130(suppl 2):S125-S138.

Medication use for ADHD symptoms

- Methylphenidate
  - Best evidence with pediatric patient population
  - Screen for cardiac abnormalities
  - Monitor appetite and sleep patterns
  - Several dosage forms with varying duration of action
- Amphetamine salts
  - If no significant benefit from methylphenidate or intolerable adverse effects from methylphenidate

Mahajan R, et al. *Pediatrics*. 2012;130(suppl 2):S125-S138.

Wolraich M, et al. *Pediatrics*. 2011;128(5):1007-1022.

Benvenuto A, et al. *Brain and Development*. 2013;35;119-27.

Medication use for ADHD symptoms

- Atomoxetine
  - Increased data to support use, better results in higher functioning ASD patients
  - Gastrointestinal symptoms (nausea, decreased appetite) common
  - Increases in irritability and moodiness

Mahajan R, et al. *Pediatrics*. 2012;130(suppl 2):S125-S138.

Wolraich M, et al. *Pediatrics*. 2011;128(5):1007-1022.

Benvenuto A, et al. *Brain and Development*. 2013;35;119-27.

Medication use for ADHD symptoms

- Guanfacine/Clonidine
  - Primarily used for hyperactivity and impulsivity, but may be beneficial with aggressive behaviors
  - May cause sedation (but may be beneficial for those patients with sleep issues)
  - Monitor blood pressure
  - Limited use for inattentiveness

Mahajan R, et al. *Pediatrics*. 2012;130(suppl 2):S125-S138.

Wolraich M, et al. *Pediatrics*. 2011;128(5):1007-1022.

Benvenuto A, et al. *Brain and Development*. 2013;35;119-27.

Medication use for ADHD symptoms

- Risperidone/Aripiprazole
  - In trials for treatment of irritability and agitation, did show an improvement of ADHD symptoms
  - ASD patients more sensitive to adverse effects
    - —Weight gain, metabolic syndrome
  - Reserved for patients with concomitant agitation, aggression, irritability or if the impulsivity actions are a safety concern

Mahajan R, et al. *Pediatrics*. 2012;130(suppl 2):S125-S138.
Wolraich M, et al. *Pediatrics*. 2011;128(5):1007-1022.
Benvenuto A, et al. *Brain and Development*. 2013;35;119-27.

Case 3

- AJ is a 10-year-old child with a history of epilepsy, autism, asthma, developmental delay, cerebral palsy and chromosomal 1p36 deletion. Developmentally, he functions at about a 3-year-old level.
- About 8 weeks ago, he needed a dental surgery to remove three teeth and have five teeth crowned.

Case 3—medications

- Albuterol 2.5 mg neb q4hr prn (asthma)
- Budesonide 0.5 mg neb twice a day (asthma)
- Cetirizine 10 mg G-tube daily (allergies)
- Cyproheptadine 2 mg G-tube twice a day (appetite)
- Lactobacillus 1 cap G-tube daily (regularity)
- Risperidone 2 mg G-tube twice a day (irritability)
- Clonidine 0.2 mg G-tube at bedtime (for sleep)
- Guanfacine 1 mg G-tube daily (irritability/focus)
- Levetiracetam 400 mg G-tube twice a day (epilepsy)
- Omeprazole 15 mg G-tube daily (reflux)

Case 3

- Since the dental procedure, AJ has started with a repetitive behavior of biting his hands. The family has tried to redirect him to other activities and follow up examination from the dental team shows the mouth healing well from the surgery. The family is concerned that the bite marks on the hand will lead to an infection and are seeking treatment for the repetitive behaviors.

Case 3

- Current weight is 20.4 kg (< 3rd percentile) and laboratory values obtained 3 months ago were within normal limits.
- The physician prescribes fluoxetine 5 mg G-tube daily for 7 days, then increase to 10 mg G-tube daily thereafter.

Case 3

- After 10 days on fluoxetine, AJ seems more irritable and is constantly moving about. He no longer will sit for any amount of time and the family can't seem to calm him down when he gets "worked up"
- The hand biting has not gotten any better and now he is flapping his hands throughout the day

Case 3—Question 5

- What is the most likely cause of AJ's acute akathisia?

Case 3—Question 5

A CYP3A4 inhibition of clonidine metabolism by fluoxetine

B Enhanced effect of fluoxetine with cyproheptadine

C CYP2D6 inhibition of risperidone metabolism by fluoxetine

D Enhanced paradoxical effect of cetirizine with fluoxetine

Case 3—Question 5

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Case 3—Question 5

A CYP3A4 inhibition of clonidine metabolism by fluoxetine

B Enhanced effect of fluoxetine with cyproheptadine

C **CYP2D6 inhibition of risperidone metabolism by fluoxetine**

D Enhanced paradoxical effect of cetirizine with fluoxetine

Case 3—Question 6

- After removal of the offending agent that induced the akathisia, which would be the best agent to use at home for short term management of akathisia symptoms in AJ?

Case 3—Question 6

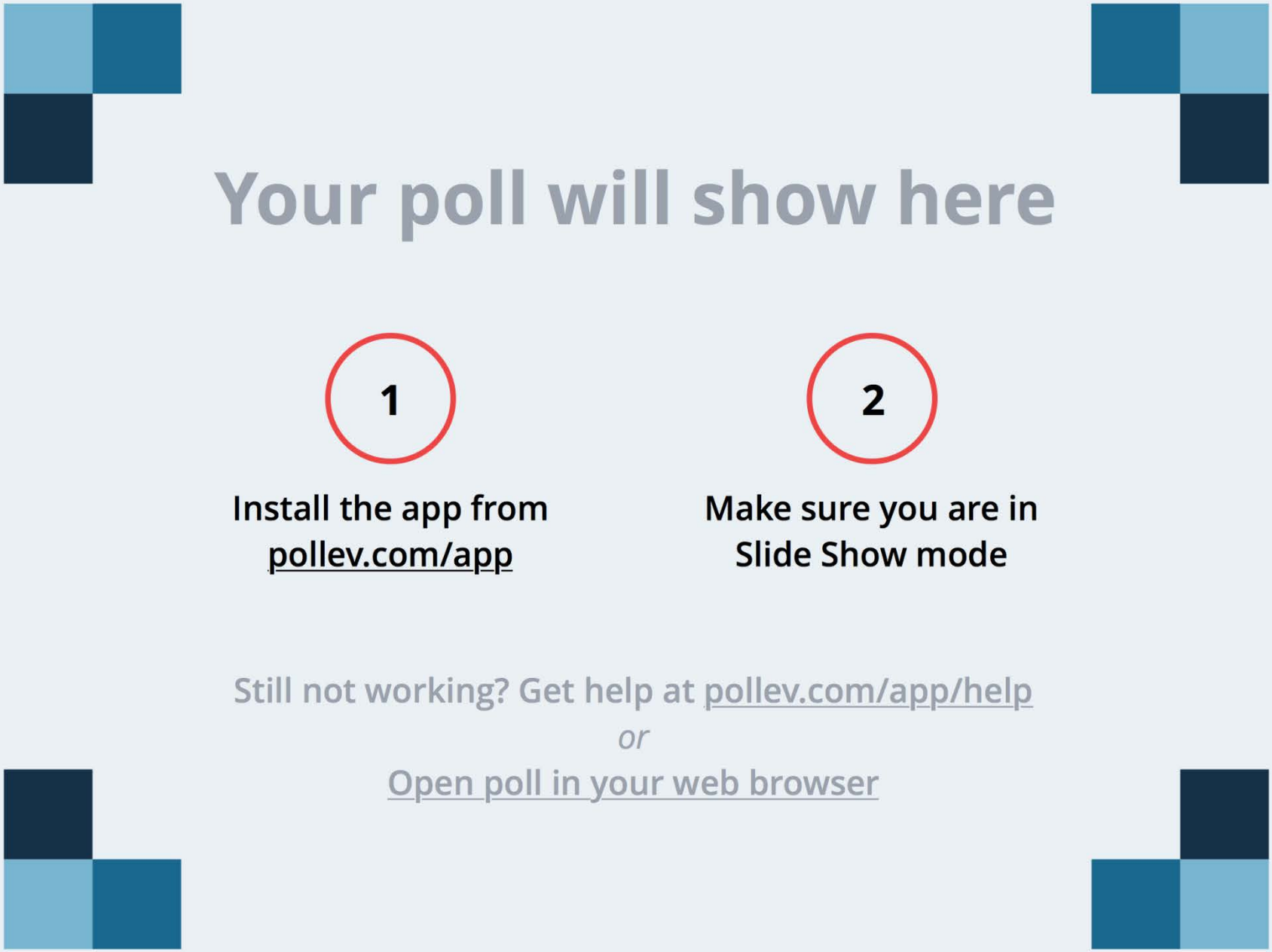
A Mirtazapine

B Propranolol

C Trihexyphenidyl

D Diphenhydramine

Case 3—Question 6



Case 3—Question 6

A Mirtazapine

B Propranolol

C Trihexyphenidyl

D **Diphenhydramine**

Potential SSRI Interactions

Drug and inhibitory effects on cytochrome P450 enzymes	CYP2D6	CYP2C9	CYP2C19	CYP3A4	CYP1A2
Citalopram	+				
Escitalopram	+				
Fluoxetine	+++	++	+	+/++	+
Fluvoxamine	+	+++		++	+++
Sertraline	+/++	+	+	+	+
Level of inhibition: +++ potent, ++ moderate, + weak					

Also consider additive effects of the safety profile (e.g., insomnia, EPS)

Spina E and de Leon J. *Expert Opin Drug Metab Toxicol.* 2014;10(5):721-46.

Potential utilization of SSRIs for pediatric patients

FDA labeled pediatric indications for SSRIs	Citalopram	Escitalopram	Fluoxetine	Fluvoxamine	Sertraline
Major depressive disorder	*	12 – 17 yr	8 – 17 yr		*
Obsessive compulsive disorder			7 – 17 yr	8 – 17 yr	6 – 17 yr
Depressive disorder with bipolar I disorder			10 – 17 yr		

*Not approved by FDA for pediatrics, but recommended by treatment algorithm

Hughes CW, et al. *J Am Acad Child Adolesc Psychiatry.* 2007;46(6):667-86.

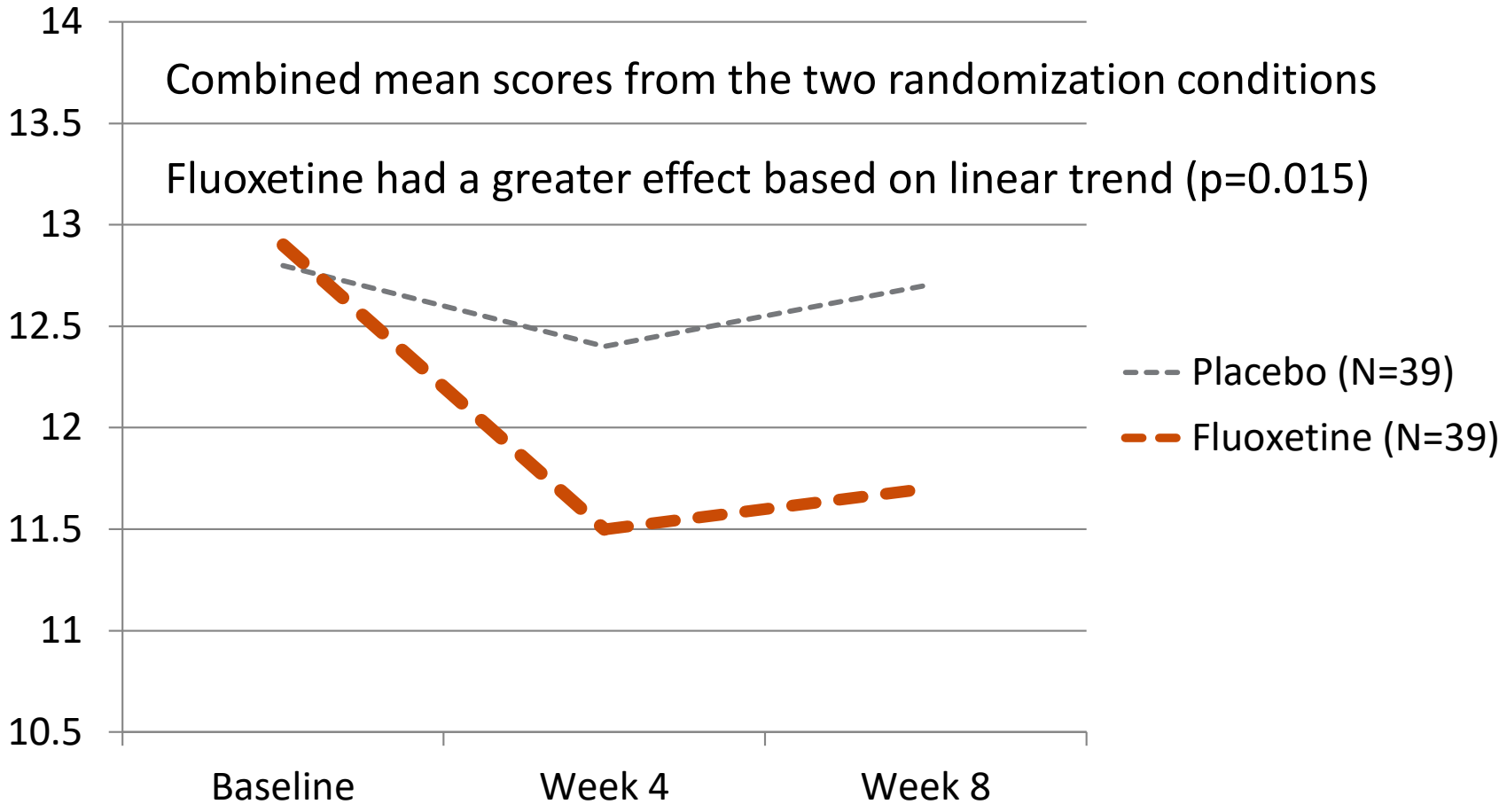
Individual drug monographs. www.dailymed.nlm.nih.gov. (Accessed 2016 Aug 6)

Fluoxetine for repetitive behaviors in autism patients

- Patient age 5 – 17 years meeting criteria for ASD
- Assessed using the Children's Yale-Brown Obsessive-Compulsion Scale, compulsions subscale (CY-BOCS)
- Initial fixed dose of fluoxetine 2.5 mg/day (then titrated up on a mg/kg dose)
  - Week 2→0.3 mg/kg/day
  - Week 3→0.5 mg/kg/day
  - Week 4-8→0.8 mg/kg/day maximum

Hollander E, et al. *Neuropsychopharmacology*. 2005;30:582-9.

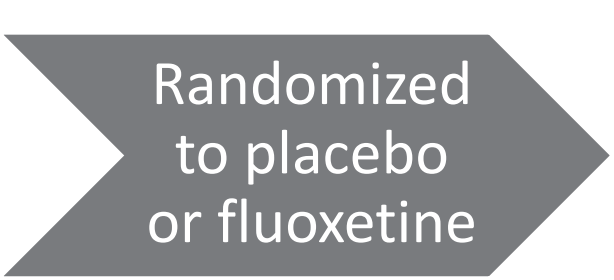
Mean CY-BOCS scores



Hollander E, et al. *Neuropsychopharmacology*. 2005;30:582-9.

Fluoxetine for repetitive behaviors in autism patients

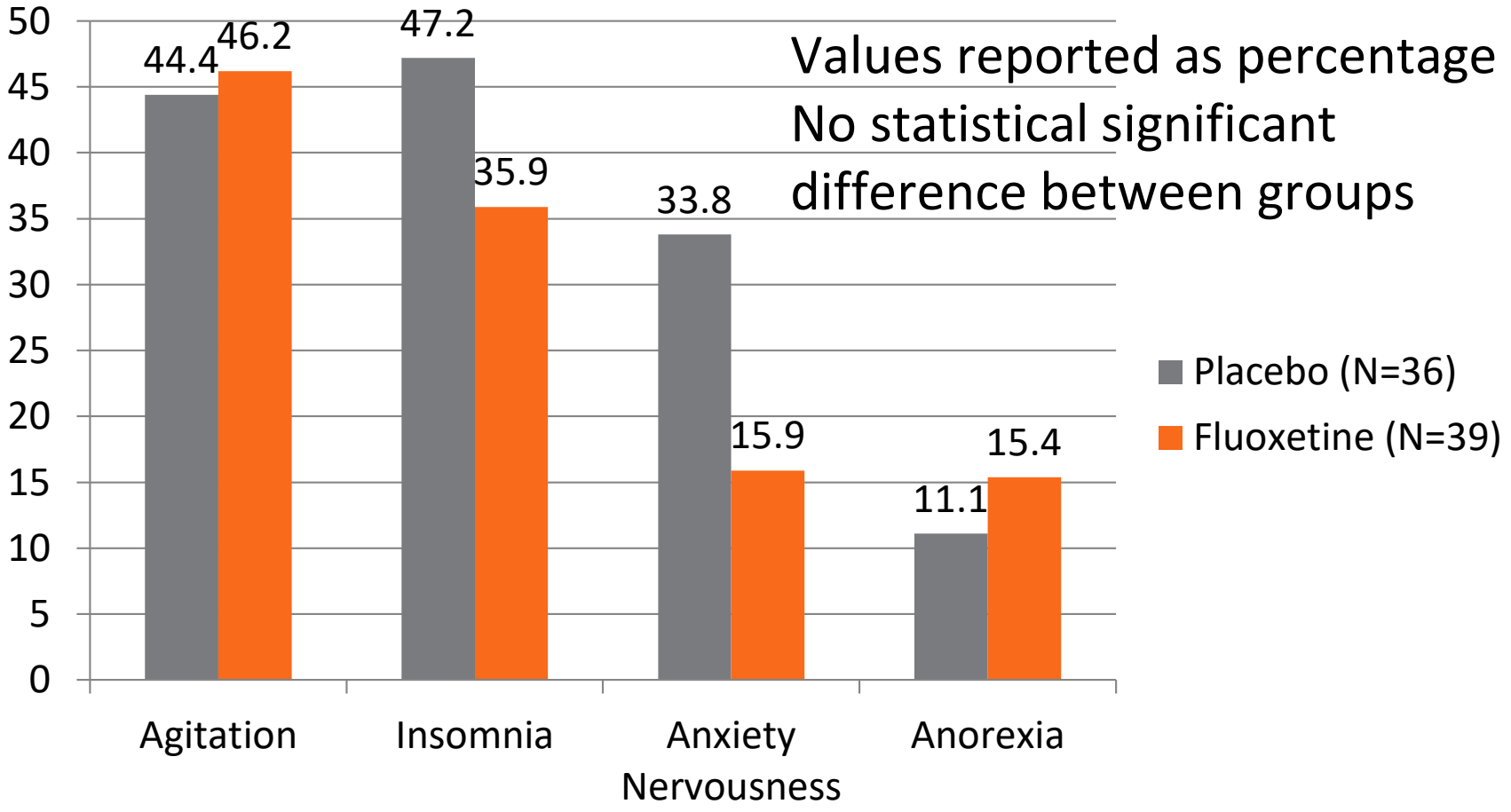
- Secondary analysis showed no statistically significant differences between groups using the Clinical Global Improvement Scale Adapted to Global Autism (CGI-AD)



- Noted in Cochrane analysis that when comparing data within a phase, there were no statistical differences

Hollander E, et al. *Neuropsychopharmacology*. 2005;30:582-9.
Williams K, et al. Cochrane Database Syst Rev. 2013; (8):CD004677.

Reported adverse events



Hollander E, et al. *Neuropsychopharmacology.* 2005;30:582-9.

Cochrane review (2013): SSRIs for ASD

- There were five studies with children and four studies with adults that met review criteria
- Due to different medications, small sample sizes (different patient ages), and various outcome measures, a meta-analysis was not possible
- Evaluated effect on core ASD features, non-core features and potential for adverse effects

Williams K, et al. Cochrane Database Syst Rev. 2013; (8):CD004677.

Cochrane review (2013): SSRIs for ASD

- Did not find significant data to support the use of SSRIs for core features (including repetitive behaviors) for children or adults
- SSRIs may be of benefit for adults patients in treating non-core symptoms (aggression, obsessive-compulsive disorder, anxiety)

Williams K, et al. Cochrane Database Syst Rev. 2013; (8):CD004677.

Cochrane review (2013): SSRIs for ASD

- Some patients did warrant a dose reduction of the SSRI due to adverse effects, and one patient had a prolonged seizure
- Conclusion: Decisions about the use of SSRIs for established clinical indications that may occur with autism, such as OCD, depression (in children and adults), or anxiety (adults), should be made on a case-by-case basis

Williams K, et al. Cochrane Database Syst Rev. 2013; (8):CD004677.

Treatment for depression

- If medication therapy warranted for a patient with ASD, utilize the current treatment algorithms for non-ASD patients
  - In conjunction with cognitive behavioral therapy

Hughes CW et al. *J Am Acad Child Adolesc Psychiatry.* 2007; 46:667-86.
Birmaher B et al. *J Am Acad Child Adolesc Psychiatry.* 2007; 46:1503-26.

Antidepressant efficacy and tolerability meta-analysis (2016)

- Limited efficacy in pediatric patients
  - Evaluated 34 trials with a combined 5260 patients utilizing 14 different antidepressants
  - Only fluoxetine showed significant efficacy versus placebo
  - Tricyclic antidepressants showed less efficacy compared to other agents and were not as well tolerated

Cipriani A, et al. *The Lancet*. 2016;388(10047):881-90.

SSRIs adverse effect considerations

- Potential increase in suicidality (boxed warning)
  - Highest risk in pediatric and young adult patients up to 24 years of age
- Potential adverse effect of 'behavioral activation'
  - Recurrence or worsening of agitation or irritability

Birmaher B et al. *J Am Acad Child Adolesc Psychiatry.* 2007; 46:1503-26.

U. S. Food and Drug Administration. Anti-depressant Drug Use in Pediatric Populations. http://www.fda.gov/newsevents/testimony/ucm113265.htm (accessed 2016 Aug 20)

Considerations in initiating an SSRI

- Initiate at a low dose and titrate up slowly
- Continue to monitor for general adverse effects
  - Gastrointestinal symptoms
  - Sleep disruption
  - Changes in appetite
- Counsel on potential severe adverse effects
  - Behavior activation
  - Serotonin syndrome

Birmaher B et al. *J Am Acad Child Adolesc Psychiatry.* 2007; 46:1503-26.

Earle JF. J Child Adolesc *Psychiatric Nursing*. 2016;29:62-71.

Conclusions

- Atypical antipsychotic agents are utilized for the irritability and aggression associated with ASD
  - Dose escalation
  - Baseline/follow-up laboratory monitoring
  - Drug/drug interactions

Conclusions

- Stimulant medications are the first-line therapy for ASD patients with ADHD symptoms
  - Proper dose initiation/escalation
  - Consider dosage forms for optimal efficacy and to minimize adverse effects
  - Consider other agents depending on clinical condition

Conclusions

- The utilization of SSRIs should be limited to specific indications and considered on a case-by-case basis
  - Diagnosis of depression or obsessive compulsive disorder
  - Consider drug/drug interactions and additive adverse effects
  - Monitor for increased risk of suicidality

Key Takeaways

- Key Takeaway #1
  - Medication management of non-core ASD symptoms is evolving with psychotropic medications and may involve polypharmacy
- Key Takeaway #2
  - Pharmacists can play a significant role in ensuring proper medication initiation, monitoring for drug/drug interactions, and counseling on potential adverse effects
- Key Takeaway #3
  - Updated clinical data can be found through American Academy of Pediatrics and the Autism Speaks Autism Treatment Network websites

Questions?