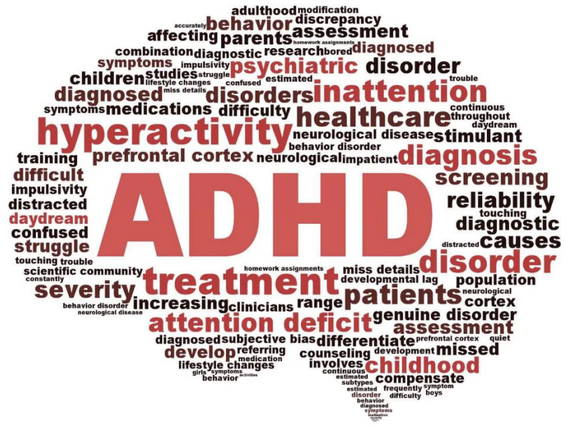
Stay Focused! ADHD Management Updates for Pharmacy Team



Jeanlouis Betancourt Gaztambide, Pharm.D., MBA, MPH
Pharmacy Manager - Farmacia Caridad
Conference #15

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Objectives

- By the end of this conference, participants should be able to:
- Describe ADHD diagnostic criteria, pathophysiology and epidemiology.
- Compare stimulant vs non-stimulant therapies.
- Identify place in therapy of ADHD medications based on guidelines.
- Evaluate ADHD medication safety, monitoring parameters, and misuse risks.
- Apply evidence-based ADHD management using case scenarios.
- Recognize pharmacist roles in ADHD care optimization.

Epidemiology, etiology & risk factors

ADHD

ADHD is the **most common neurodevelopmental disorder in children**.

- Occurs in 5-10% of children and approximately 2.5-5% of adults

Chronic illness that can cause symptoms throughout adolescence and adulthood

Characterized by symptoms of inattention, hyperactivity and impulsivity

More prevalent in males than females

- 2:1 in children
- 1.6:1 in adults

In 2016, 6.1 million children in the US (9.4% of 2-17 year old) were diagnosed with ADHD

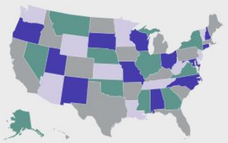
Genes involved in ADHD are present in schizophrenia and other disorders

PREVALENCIA Y EPIDEMIOLOGÍA DE TDAH EN NIÑOS

ASSMCA

Mundial

Según Ayano et al. (2023), la prevalencia global de TDAH en niños es un 8%, siendo el doble en masculinos (10%) que en femeninas (5%).



Estados Unidos

Según Danielson et al. (2024), en los Estados Unidos la prevalencia de diagnóstico actual es 10.5% de niños entre 3-17 años.

Puerto Rico

Según el reporte reciente de Perfil Sociodemográfico y Clínica de Población de Niños y Adolescentes atendidos (SEPS) (AF 2021-2022), se identifica que 41.2% de los niños atendidos tenían un diagnóstico de TDAH.

National Survey of Children Health (NSCH)

7 años

es la edad promedio que se presentan los **síntomas**.

4 años

es la **edad promedio** para diagnosticar **TDAH severo**.

Niños (14.7%)

mayor prevalencia que

Niñas (8.1%)

Bajo Tratamiento

TDAH severo **(77.9%)**
TDAH moderado **(59.7%)**
TDAH leve **(39.7%).**

Se estima que en Puerto Rico, la prevalencia de niños que tienen TDAH es entre **3-5%.**

Grant 15PBJA-21-GG-02600

ADHD - Prevalence

In the U.S.

- Age group 12-17 years with highest prevalence (13.2%)
- 6-11 years (10%)
- 3-5 years (2.2%)

For those with a lifetime diagnosis of ADHD

- Males
- Children 12-17 years of age
- Afro-Americans
- Non-Hispanic children
- Households living < 200% below the federal poverty level
- Children of parents with a high school education
- Children with public insurance
- Living in rural areas

ADHD - Genetic Factors

Genetic Factors

- ADHD has **high heritability (~70–74%)**.
- Risk is **2–8 times higher** if a parent or sibling has ADHD.
- Multiple genes involved in:
  - Brain development
  - Neuronal communication
  - Dopamine and norepinephrine pathways

ADHD is **multifactorial**, not caused by a single gene.

Environment & Prenatal Risk Factors

Strong Association

- Family history of ADHD
- Prematurity
- Maternal smoking during pregnancy

Moderate Association

- Low birth weight
- Perinatal stress or complications
- Advanced maternal age → ≥35 years
- Young maternal age: → < 20 years
- Lead exposure

Limited Evidence

- Maternal alcohol use during pregnancy
- Toxins exposure
- Antidepressants use during pregnancy
- Single mothers

Environmental factors increase risk but are not sufficient alone

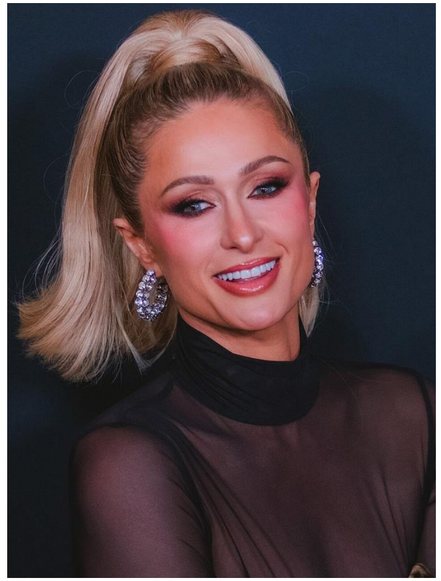
Famous and Historical Figures with ADHD

Michael Phelps

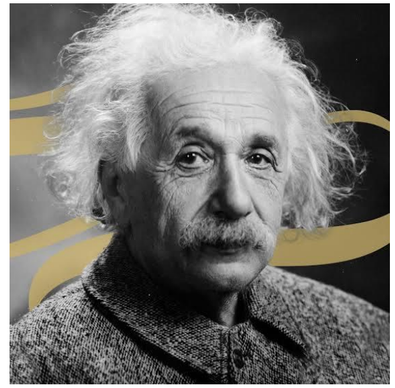
Justin Timberlake

Adam Levine

Tom Holland



Paris Hilton



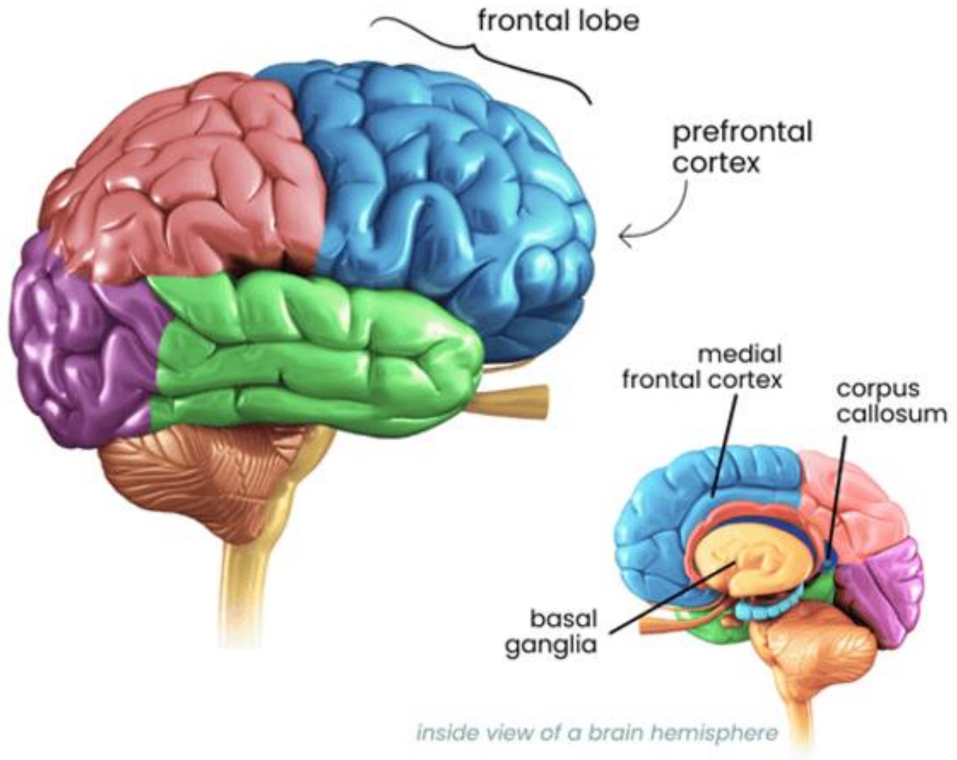
Albert Einstein

Benjamin Franklin

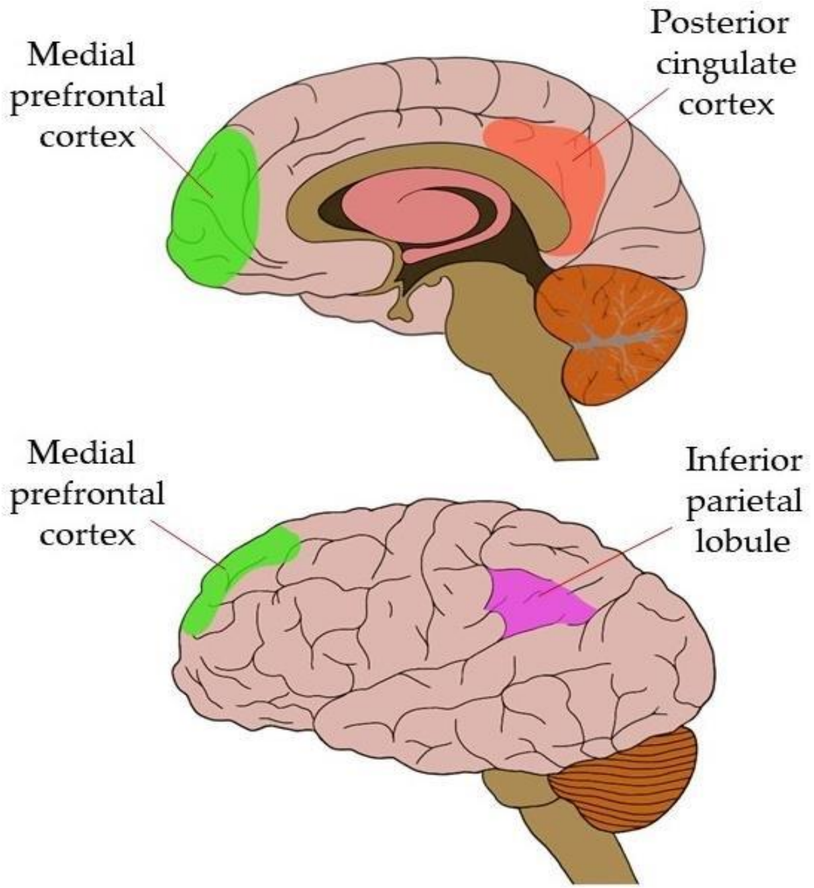
Pathophysiology Review

Pathophysiology: structural brain differences

- Reduction in gray matter volume in cortical and subcortical areas.
- Reduced maturation rate of **prefrontal cortex.**
  - Regulates attention, behavior, and emotion
  - In ADHD, there is a 2–3-year delay in reaching peak cortical thickness



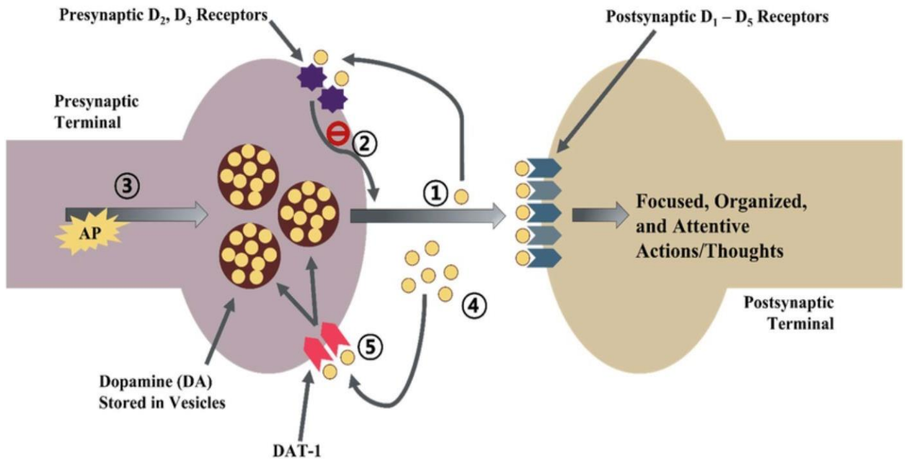
Pathophysiology: The Default Mode Network



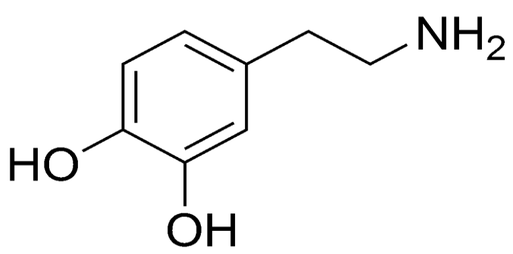
- The default mode network (DMN) is a large-scale brain network that supports internally focused mental processes such as **mind-wandering, introspection, and self-referential cognition**.
- The DMN theory of ADHD proposes that altered DMN activity and its dysfunctional interactions with task-positive networks underlie core ADHD symptoms, particularly **inattention and distractibility.**

Pathophysiology: Neurotransmitter Dysfunction

- Defects in the dopamine pathways that regulate reward anticipation and emotional self-regulation can play a role in ADHD.
- Balance of both dopamine and norepinephrine is required for proper prefrontal cortex functioning.



Pathophysiology: Neurotransmitter Dysfunction



Dopamine receptors play critical roles in ADHD pathophysiology through their effects on prefrontal cortical function, striatal circuits, and reward processing.

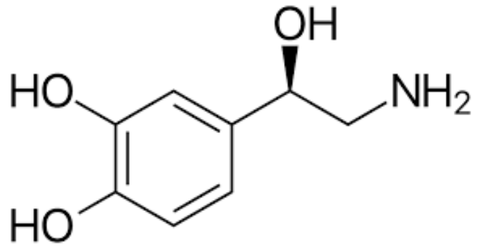
D1 receptor is the most important regulator of cognitive functions:

- Spatial learning
- Working memory
- Executive function

Pathophysiology: Neurotransmitter Dysfunction

Norepinephrine works alongside dopamine to help with focus and alertness.

Norepinephrine modulates prefrontal cortical function.



Pathophysiology: catecholamine hypothesis

The catecholamine hypothesis of ADHD proposes that dysregulation of dopamine and norepinephrine neurotransmission, underlies the core symptoms **of inattention, impulsivity, and hyperactivity**.

The hypothesis centers on suboptimal catecholamine levels in the prefrontal cortex.

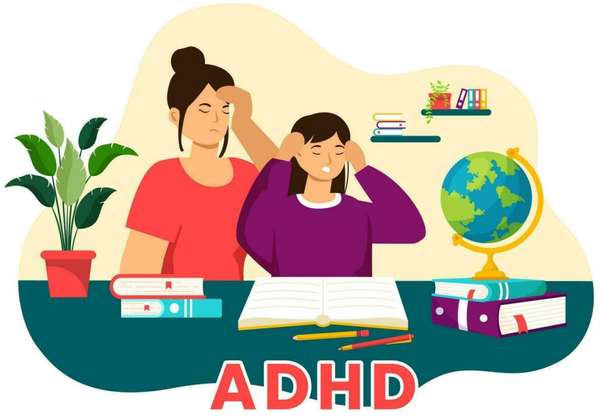
This hypothesis emerged from observations that all effective ADHD medications enhance catecholamine signaling.

Clinical Presentation & Diagnostic Criteria

Clinical Presentation

- ADHD is characterized by **academic or behavioral problems** and symptoms of **inattention, hyperactivity, or impulsivity**
- Onset of symptoms must be before 12 years of age
- Symptom manifestation varies based on age group
  - Preschoolers (3 to 5 y/o)
  - School Age (6 to 11 y/o)
  - Adolescents (12 to 18 y/o)
  - Adults

Clinical Presentation



Inattention

- Inability to stay on task
- Seeming not to listen (inattentive)
- Losing materials necessary for tasks
- Forgetful
- Poor organization skills
- Avoids mentally engaging tasks
- Easily distracted
- Doesn't follow instructions
- Careless mistakes/ overlooks details

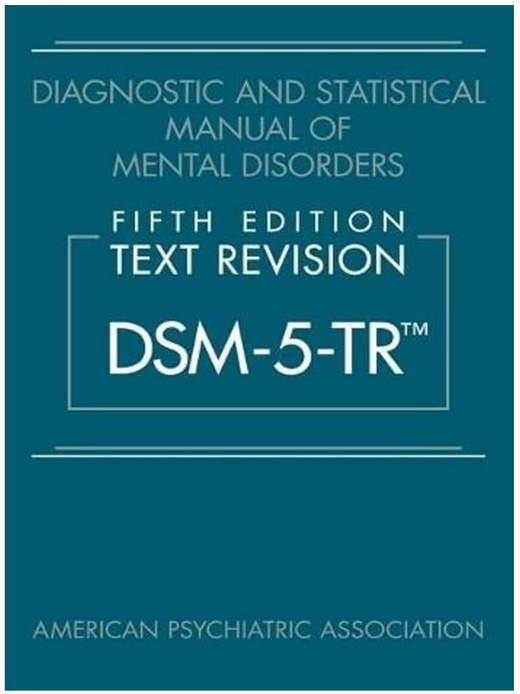
With increasing age, inattention and impulsivity can remain and hyperactivity can decrease

Clinical Presentation

Hyperactivity/Impulsivity
• Overactivity • Fidgeting • Inability to stay seated • Intruding into other's activities • Inability to wait • Struggles to keep quiet • Restless • Talks before others finish • Unable to play quietly • Likes to keep moving

With increasing age, inattention and impulsivity can remain and hyperactivity can decrease

Diagnostic criteria



I. Persistent pattern of **inattention** and/or **hyperactivity-impulsivity**, as characterized by age:
   A. Inattention:
      1. If ≤ 16 y/o = ≥ 6 of the inattentive symptoms have persisted for at least 6 months.
      2. If ≥ 17 y/o = ≥ 5 of the inattentive symptoms have persisted for at least 6 months.
   B. Hyperactivity and impulsivity:
      1. If ≤ 16 y/o = ≥ 6 of the inattentive symptoms have persisted for at least 6 months.
      2. If ≥ 17 y/o = ≥ 5 of the inattentive symptoms have persisted for at least 6 months.

Diagnostic Criteria

Six or more symptoms must be present for at least 6 months

Significant impairment must be seen in **two or more settings**

- Ex. home and school

Symptoms must be documented by parent, teacher, and clinician

Only **five** symptoms are required in older adolescents and adults (17 years of age and older)

Symptoms should be persistent, inconsistent with developmental level, and negatively impact social, academic, and occupational functioning

Symptoms are not solely a manifestation of another psychiatric disorder, Substance use disorder or medical condition

Specify Presentation Type

Predominantly Inattentive

- Meets criteria for inattention only
- Example: forgetful, distracted, disorganized

Predominantly Hyperactive-Impulsive

- Meets criteria for hyperactivity/impulsivity only
- Example: restless, interrupts others, cannot wait turn

Combined Presentation

- Meets criteria for both domains

Comorbid Conditions

- Comorbidities occur in nearly two-thirds of children with current ADHD diagnosis

MOST COMMON

Disruptive behavior disorders (52%)
- **Oppositional Defiant Disorder & Conduct Disorder**

Anxiety disorders (33%)

Depression disorder (17%)

Autism spectrum disorder (20-50%)

Tourette's disorder (20%)

Seizure Disorders 2-3x more likely

OTHERS

Bipolar Disorder

Substance Use Disorders

Eating Disorders

Aggression

Sleep disorders

When selecting treatment, the predominance and urgency of symptoms **must** guide the medication selection process

Practice question #1

1. A 4-year-old child exhibits severe hyperactivity at preschool and is asked to leave preschool due to aggression, impulsivity, and not following directions. Which of the following statements describes an additional diagnostic criterion needed for a diagnosis of ADHD?

   A. The symptom duration would need to be 6 weeks.
   B. These impairing symptoms are also present at home.
   C. The patient must be at least 6 years old.
   D. Learning disability needs to be ruled out.

Treatment

Guideline

Pediatrics (2019) 144 (4): e20192528

CLINICAL PRACTICE GUIDELINE

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN™

Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents

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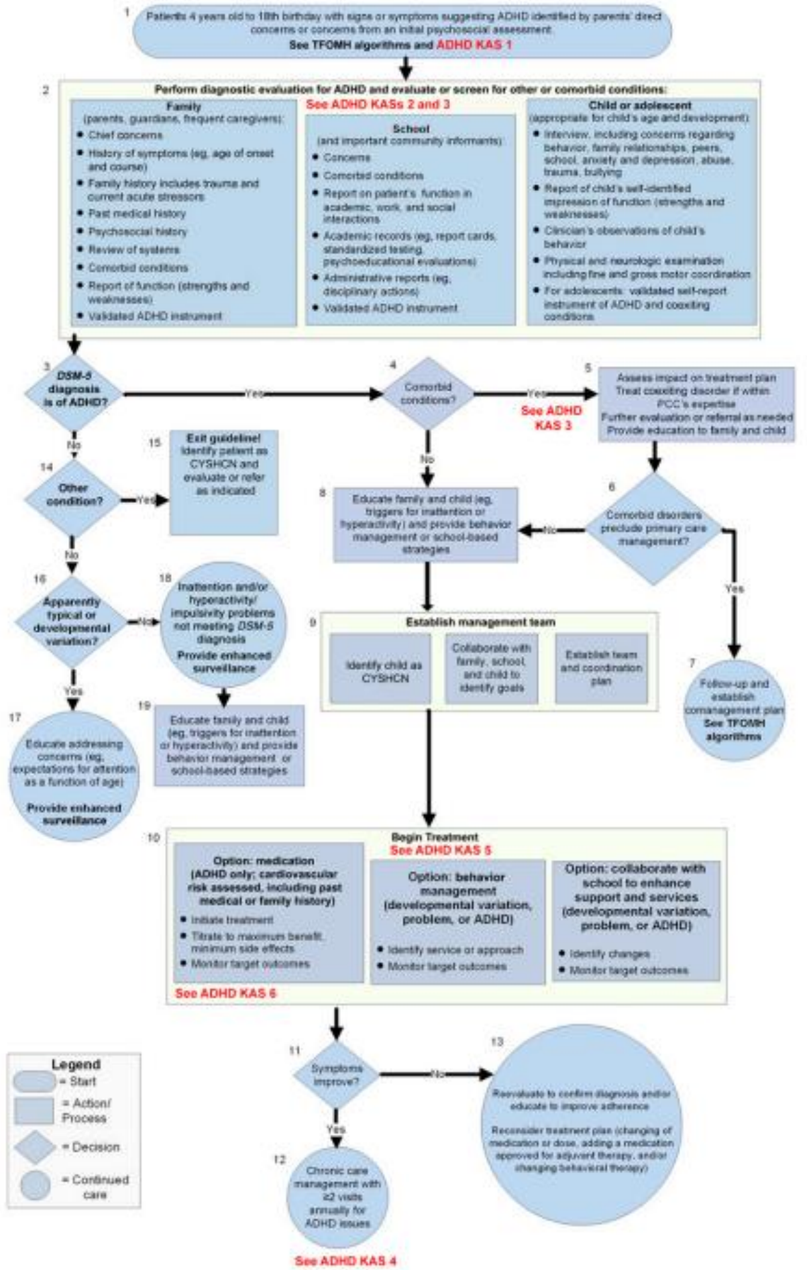


SUPPLEMENTAL FIGURE 2

ADHD care algorithm. CYSHCN, children and youth with special health care needs; TFOMH, Task Force on Mental Health.

2

Perform diagnostic evaluation for ADHD and evaluate or screen for other or comorbid conditions:

Family
(parents, guardians, frequent caregivers):

- Chief concerns
- History of symptoms (eg, age of onset and course)
- Family history includes trauma and current acute stressors
- Past medical history
- Psychosocial history
- Review of systems
- Comorbid conditions
- Report of function (strengths and weaknesses)
- Validated ADHD instrument

See ADHD KASs 2 and 3

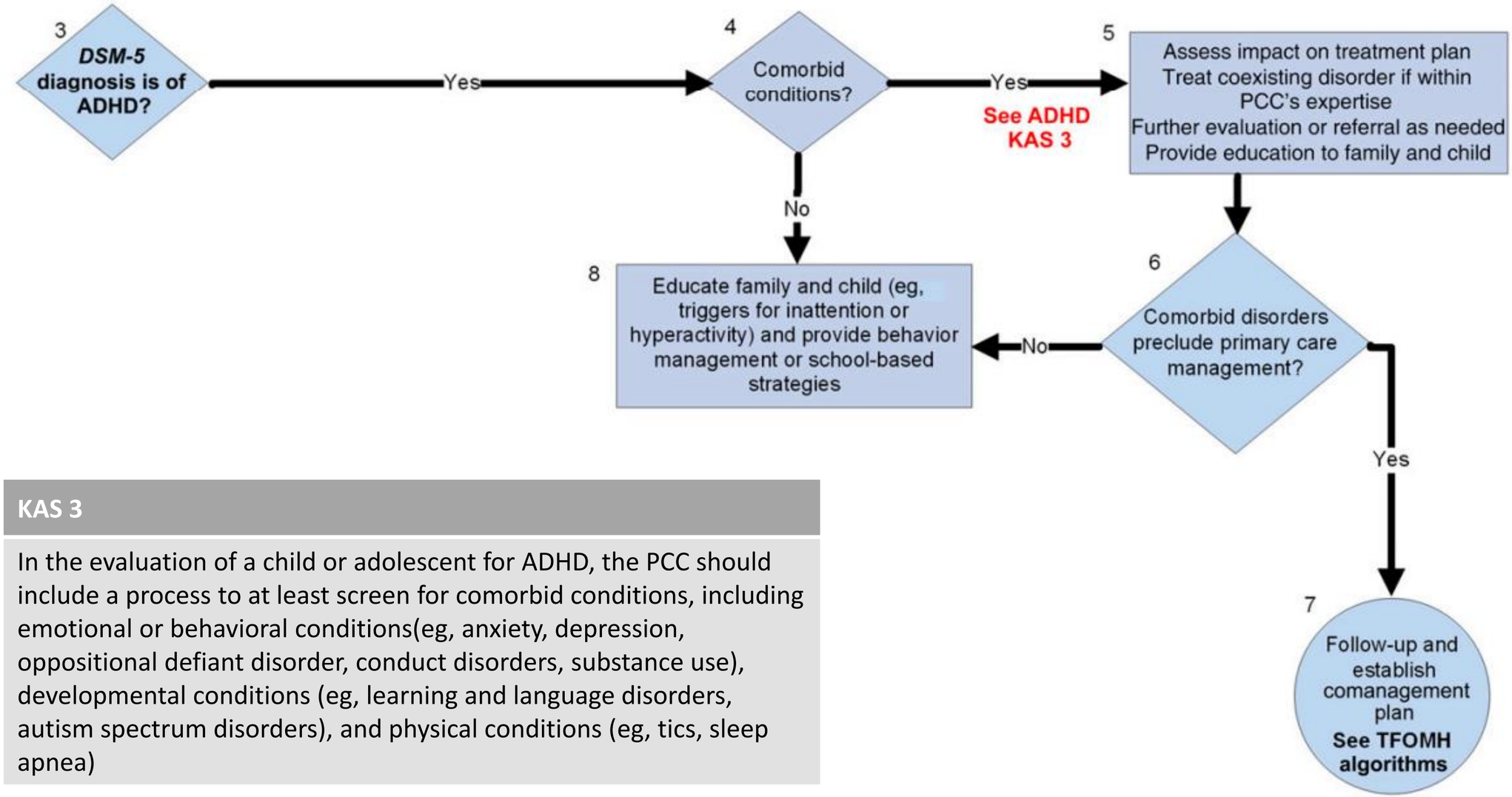
School
(and important community informants):

- Concerns
- Comorbid conditions
- Report on patient's function in academic, work, and social interactions
- Academic records (eg, report cards, standardized testing, psychoeducational evaluations)
- Administrative reports (eg, disciplinary actions)
- Validated ADHD instrument

Child or adolescent
(appropriate for child's age and development):

- Interview, including concerns regarding behavior, family relationships, peers, school, anxiety and depression, abuse, trauma, bullying
- Report of child's self-identified impression of function (strengths and weaknesses)
- Clinician's observations of child's behavior
- Physical and neurologic examination includes fine and gross motor coordination
- For adolescents: validated self-report instrument of ADHD and coexisting conditions

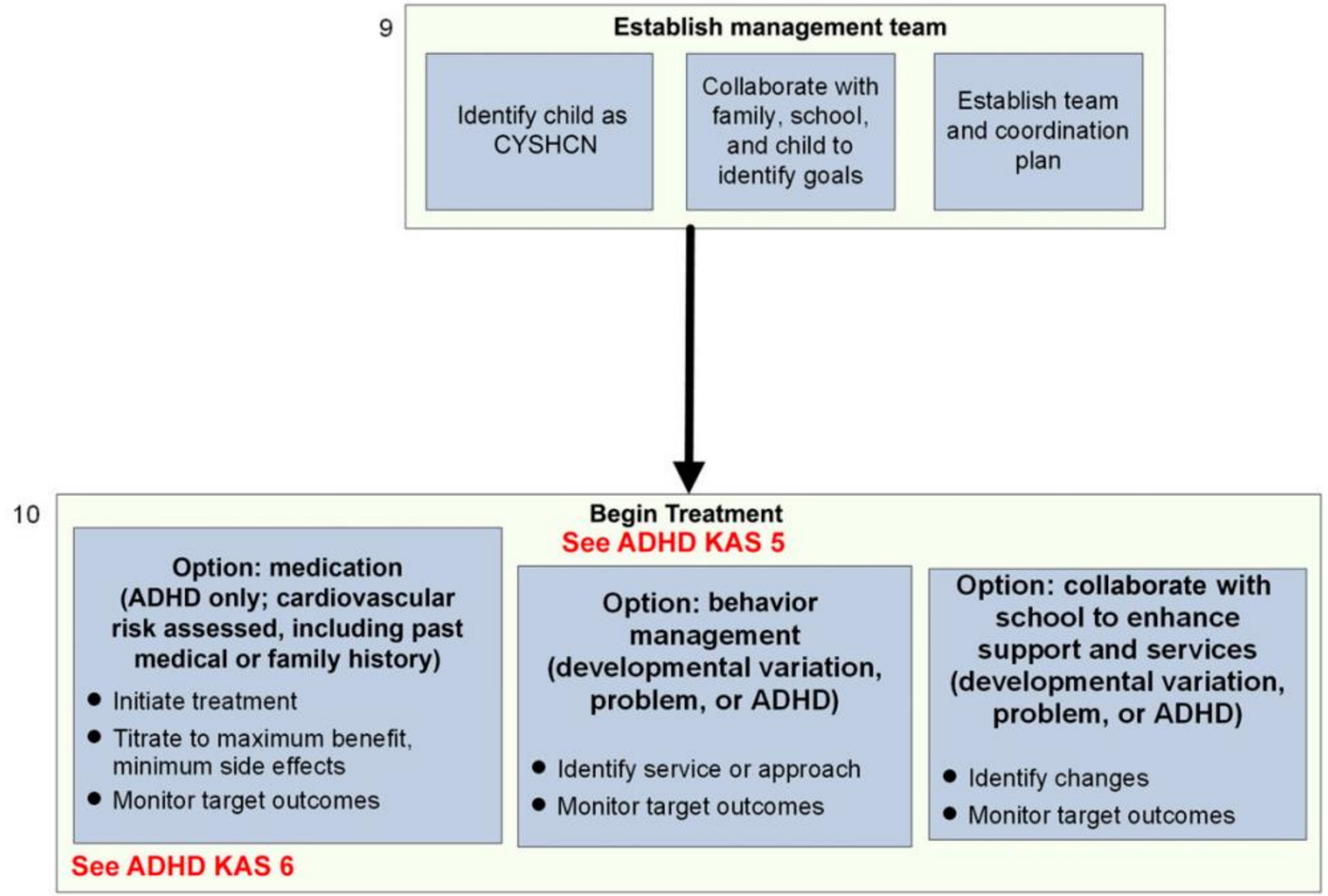
SUPPLEMENTAL FIGURE 4
Perform a diagnostic evaluation for ADHD and evaluate or screen for comorbid disorders



KAS 3

In the evaluation of a child or adolescent for ADHD, the PCC should include a process to at least screen for comorbid conditions, including emotional or behavioral conditions(eg, anxiety, depression, oppositional defiant disorder, conduct disorders, substance use), developmental conditions (eg, learning and language disorders, autism spectrum disorders), and physical conditions (eg, tics, sleep apnea)

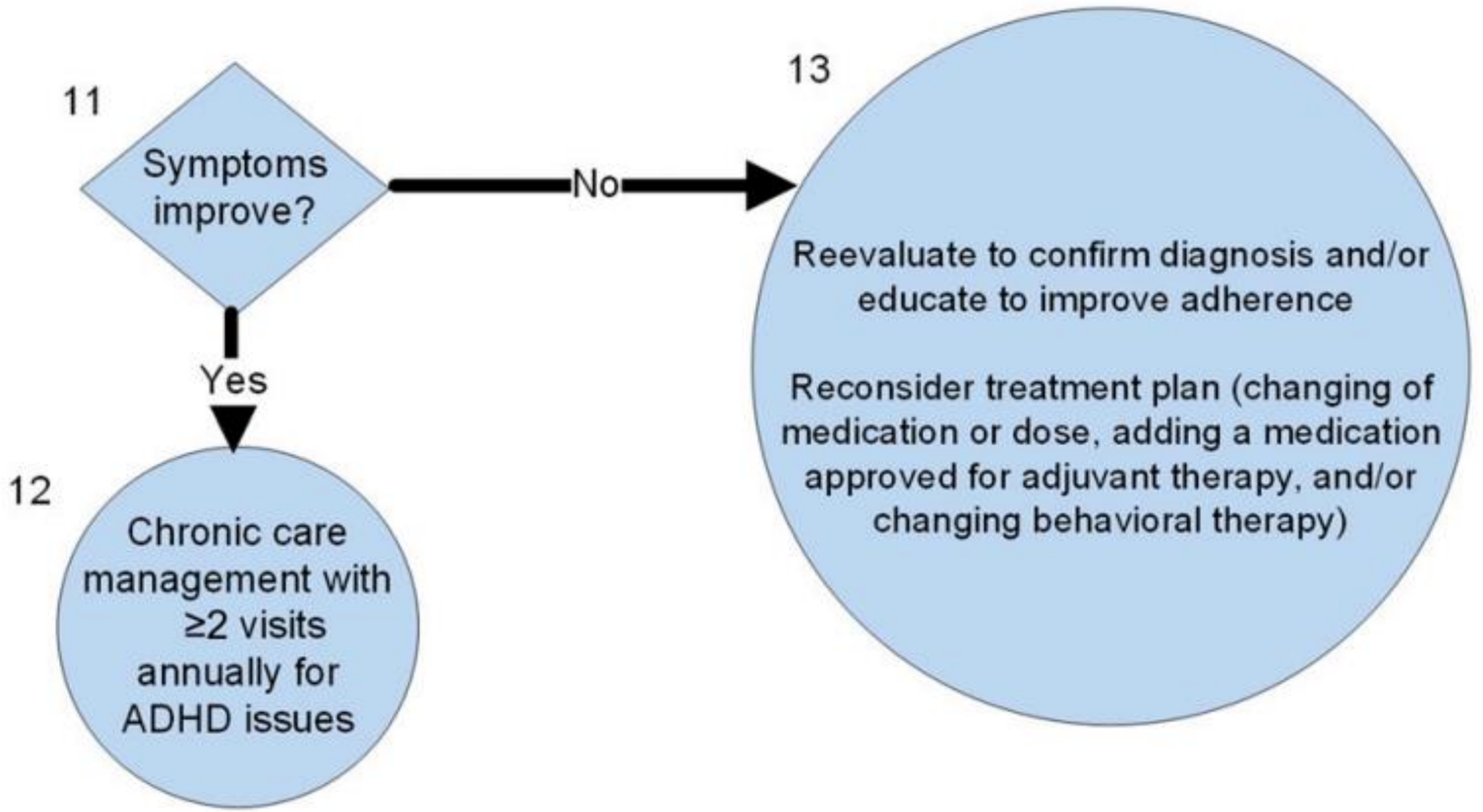
SUPPLEMENTAL FIGURE 6
Consideration of comorbid conditions. TFOMH, Task Force on Mental Health.



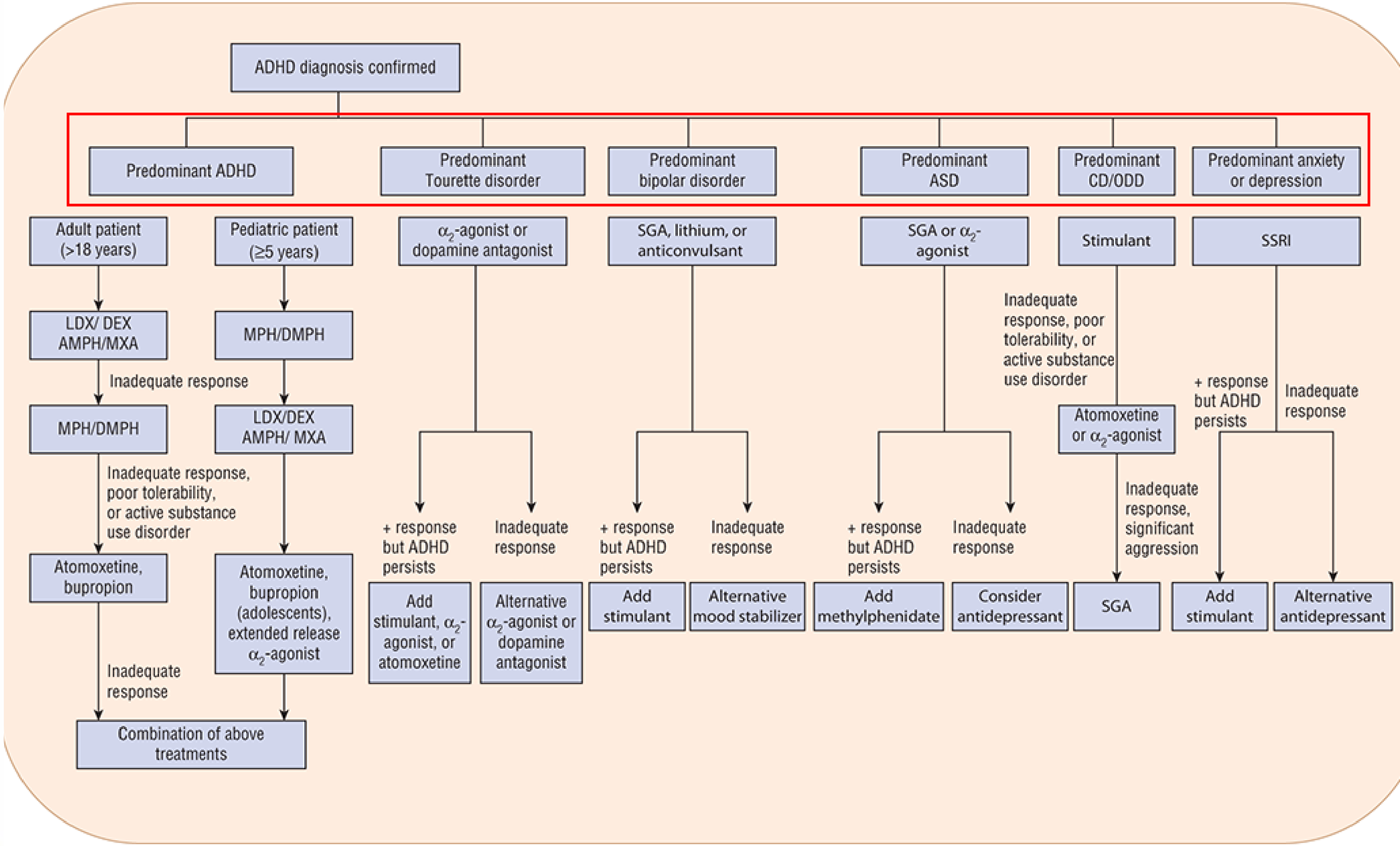
UPPLEMENTAL FIGURE 7
'eatment. CYSHCN, children and youth with special health care needs.

KAS 5	
Preschool 4-6 y/o	First-line: evidence-based PTBM and/or behavioral classroom interventions Second-line: Add methylphenidate
School aged 6-12 y/o	FDA-approved medications for ADHD + PTBM and/or behavioral classroom intervention
Adolescents 12-18 y/o	FDA-approved medications for ADHD with the adolescent's assent Evidence-based training interventions and/or behavioral interventions – **encouraged**

KAS 6
Titrate doses of medication for ADHD to achieve maximum benefit with tolerable side effects



SUPPLEMENTAL FIGURE 8
Monitoring.


ADHD diagnosis confirmed
Predominant ADHD
Predominant Tourette disorder
Predominant bipolar disorder
Predominant ASD
Predominant CD/ODD
Predominant anxiety or depression
Adult patient (>18 years)
Pediatric patient (≥5 years)
α2-agonist or dopamine antagonist
SGA, lithium, or anticonvulsant
SGA or α2-agonist
Stimulant
SSRI
LDX/ DEX AMPH/MXA
MPH/DMPH
Inadequate response
MPH/DMPH
LDX/DEX AMPH/ MXA
Inadequate response, poor tolerability, or active substance use disorder
Atomoxetine, bupropion
Atomoxetine, bupropion (adolescents), extended release α2-agonist
Inadequate response
Combination of above treatments
+ response but ADHD persists
Inadequate response
Add stimulant, α2-agonist, or atomoxetine
Alternative α2-agonist or dopamine antagonist
+ response but ADHD persists
Inadequate response
Add stimulant
Alternative mood stabilizer
+ response but ADHD persists
Inadequate response
Add methylphenidate
Consider antidepressant
Inadequate response, poor tolerability, or active substance use disorder
Atomoxetine or α2-agonist
Inadequate response, significant aggression
SGA
+ response but ADHD persists
Inadequate response
Add stimulant
Alternative antidepressant

Treatment Goals:

Improve academic performance

Improve relationship with peers

Controlling impulsive behavior

Meet family and academic behavior expectations

- Families should establish individual goals attainable with their routine and responsibilities
- Charts and clear expectations are beneficial for treatment efficacy evaluation

Non-Pharmacological Treatment

Non-Pharmacological therapy:

Behavioral Interventions

- First-line in **preschool children (<6 yr)**
- Adjunct in **school-age children & adults**
- Essential when meds contraindicated or poorly tolerated

Age	Description of Intervention	Typical Outcomes
Preschool and School Age	Behavioral Parent Training (BPT) - Parent-Child Interaction Therapy - Parent Management Training	Improved parental understanding and satisfaction Improved compliance with parental demands
	Behavioral Classroom Management (BCM)	Improved teacher satisfaction ↓ disruptive behavior, ↑ academic productivity
Adolescent	School modifications: Breakup homework assignments into manageable segments. Structured schedule; organizer	Completion of assignments improves; improved self-esteem and sense of self
Adolescent and Adult	ADHD-specific cognitive behavioral therapy (CBT)	Improved productivity and vocational success
	Behavioral Peer Interventions (BPI)	Improved relationships

- The AAP recommends a 6-month trial of behavioral classroom interventions and parent training in behavioral management **prior** to pharmacotherapy in children **less than 6 years old**

Non-Pharmacological therapy:
Game-based digital therapeutic device

EndeavorRx®

First ever prescription videogame

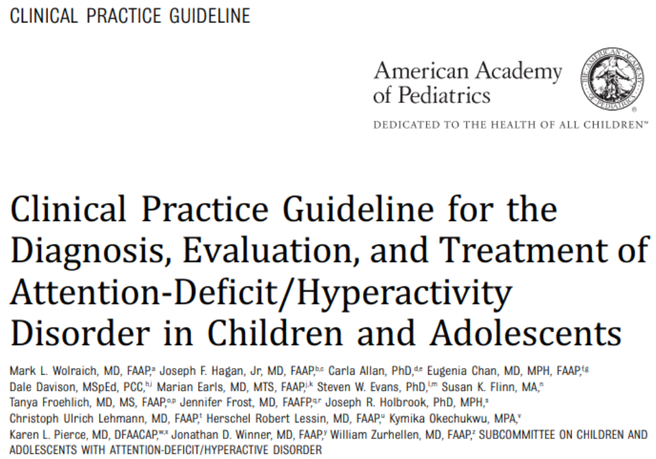
- **First FDA approved non-medication option (2020)** for improving attention symptoms in children **8–12 years** with inattentive or combined-type presentations
- **Use in combination with behavioral or pharmacologic treatments.** Designed to be played **25 minutes per day five days a week.** A lock-out occurs after **30 minutes.**
- Uses coordinated hand-eye movements to stimulate specific neural pathways involved in attention.
- Common adverse effects included frustration, headache, dizziness, emotional reaction, and aggression.
- EndeavorOTC (2023), for adults **≥18 years)** with ADHD symptoms, available at App Store and Google Play.

Non-Pharmacological therapy:
Game-based digital therapeutic device

Natural Products Interventions

Polyunsaturated Fatty Acids	• Omega-3 and Omega-6 may decrease in ADHD • May improve ADHD symptoms, but limited data; safe profile
Vitamin D	• Showed decrease in ADHD symptoms in a systemic review meta-analysis
Melatonin	• Improves sleep delay and extends overall sleep duration in people with ADHD
Ginkgo Bilboa	• May help reduce side effects of methylphenidate
St. John’s Wort	• No data demonstrating benefit
Iron, Magnesium and Zinc supplementation	• May enhance the therapeutic benefit of stimulants

Pharmacological therapy Guidelines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1) American Academy of Pediatrics (AAP) - 2019

2) Canadian ADHD Resource Alliance (CADDRA) - 2018

3) National Institute for Health and Care Excellence (NICE) ADHD - 2018

4) European Consensus Statement for Adult ADHD - 2019

Pharmacological Therapy Guidelines

Canadian ADHD Resource Alliance (CADDRA) - 2018

Canadian ADHD Resource Alliance (CADDRA), 2018 — Favors long-acting formulations first-line across ages.

National Institute for Health and Care Excellence (NICE) ADHD - 2018

Covers children, young people, and adults. Emphasizes a **stepwise approach**: ADHD-focused parent training/environmental modification first, then medication (methylphenidate → lisdexamfetamine → atomoxetine/guanfacine) if impairment persists.

European Consensus Statement for Adult ADHD - 2019

Pharmacological Therapy Guidelines

European Consensus Statement for Adult ADHD - 2019

- Pharmacotherapy first-line for moderate–severe adult ADHD
- First choice: lisdexamfetamine or methylphenidate
- Second-line: atomoxetine (preferred first-line if comorbid substance use disorder)
- Combine with evidence-based non-pharmacologic interventions

Pharmacological Therapy Guidelines

Guideline	First-line (school-age children)	First-line (adults)	Formulation stance
CADDRA 2018 (Canada)	Long-acting stimulants (LA amphetamine salts, LA methylphenidate, or lisdexamfetamine)	Long-acting stimulants (same agents)	Long-acting preferred across all ages
NICE 2018 (UK)	Methylphenidate → lisdexamfetamine → atomoxetine/guanfacine	Lisdexamfetamine or methylphenidate → atomoxetine	Agent-based order; formulation not the primary axis
AAP 2019 (US)	Stimulants → atomoxetine → XR-guanfacine → XR-clonidine	Not addressed	Evidence-strength order by drug class
European Consensus 2019	Not addressed	lisdexamfetamine or methylphenidate	Severity-stratified

Pharmacological Treatment

Pharmacological therapy

Stimulants are the most effective medication treatment options

Stimulants are divided into two main chemical classes:

- Methylphenidate
- Amphetamines

Non-stimulants are less effective but may be used as monotherapy or in combination with stimulants for improving overall response and for managing behavioral symptoms and insomnia associated with ADHD

Pharmacological therapy

Stimulants

- **Methylphenidates**
  - Dexmethylphenidate
- **Amphetamines**
  - Lisdexamfetamine
  - Dextroamphetamine
  - Mixed amphetamine salts

Serotonin Norepinephrine Reuptake Inhibitors

- Atomoxetine
- Viloxazine
- Bupropion

Alpha Adrenergic Agonists

- Clonidine ER
- Guanfacine ER

Antipsychotics

- Aripiprazole
- Haloperidol
- Olanzapine
- Quetiapine
- Risperidone
- Ziprasidone

Stimulants

Methylphenidate

- First line for children/adolescents
- DA/NE reuptake inhibitor

Amphetamines

- First line for adults
- DA/NE reuptake inhibitor and enhances release of DA/NE

*__IMPORTANT__: All stimulants are controlled substances (C-II)

- Limited to 30-day supply
- No refills

Methylphenidate Products

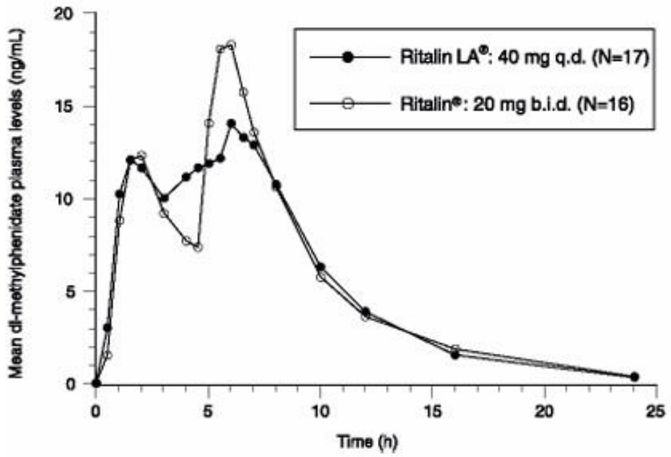
Methylphenidate (C-II)

- **Brand Name(s): Ritalin©**, Methylin©, Metadate©
- **Immediate release formulations**
  - **tablet, oral solution, and chewable tablet**
- **Dosing**:
  - Children: 2.5-5 mg twice daily [Max 60 mg/day or 2 mg/kg/day]
  - Adults: 10-20 mg/day in divided doses [Max: 60 mg/day]
- T½ of ~3 hours → dosed 2-3 times daily
- Onset 20-60 mins, duration 3-5 hours

Methylphenidate Slow-Release

- **Brand Name(s):** Ritalin SR©, Methylin ER©, Metadate ER©
- **Intermediate-acting extended release, tablets**
- Total daily IR dose is equivalent to ER/SR dose
- Onset 60-180 mins, duration ~8 hours

Figure 1. Mean plasma concentration time-profile of methylphenidate after a single dose of Ritalin LA® 40 mg q.d. and Ritalin® 20 mg given in two doses four hours apart



Brand Name(s): Ritalin LA©
Metadate CD©

Biphasic release, capsules

Total Daily IR is equivalent to LA/CD dose

Onset 20-60 mins, duration 8+ hours

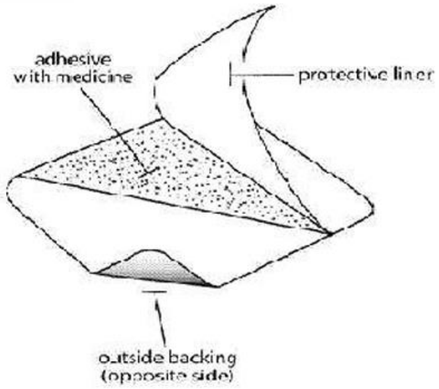
Methylphenidate Slow-Release (cont.)

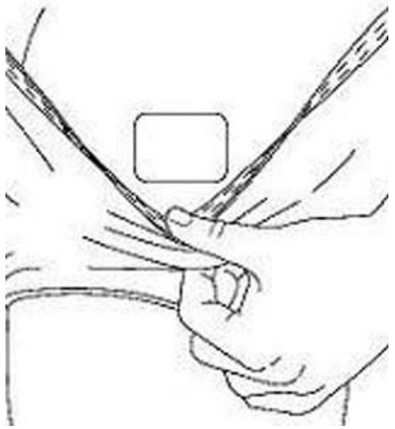
Table 1 DAYTRANA - Recommended Titration Schedule (Patients New to Methylphenidate)

Upward Titration, if Response is Not Maximized				
	Week 1	Week 2	Week 3	Week 4
Transdermal System Size	12.5 cm^2	18.75 cm^2	25 cm^2	37.5 cm^2
Nominal Delivered Dose* (mg/9 hours)	10 mg	15 mg	20 mg	30 mg
Delivery Rate*	(1.1 mg/hr)*	(1.6 mg/hr)*	(2.2 mg/hr)*	(3.3 mg/hr)*

*Nominal *in vivo* delivery rate in children and adolescents when applied to the hip, based on a 9-hour wear period.

Patients converting from another formulation of methylphenidate should follow the above titration schedule due to differences in bioavailability of DAYTRANA compared to other products.





- **Brand Name(s): Daytrana©**
- **Transdermal patch**
- **Dosing:** initial:10 mg TD daily, applied to hip 2 hours before needed and **removed after 9 hours**
- **Alternate hips daily and discard used patches by flushing down the toilet**
- **Titration required for higher doses even if converting from other formulations**
- Onset 60 mins, duration 10-12 hours
- Patient Education: instructions-for-use.pdf (daytrana.com)

Methylphenidate Slow-Release (cont.)

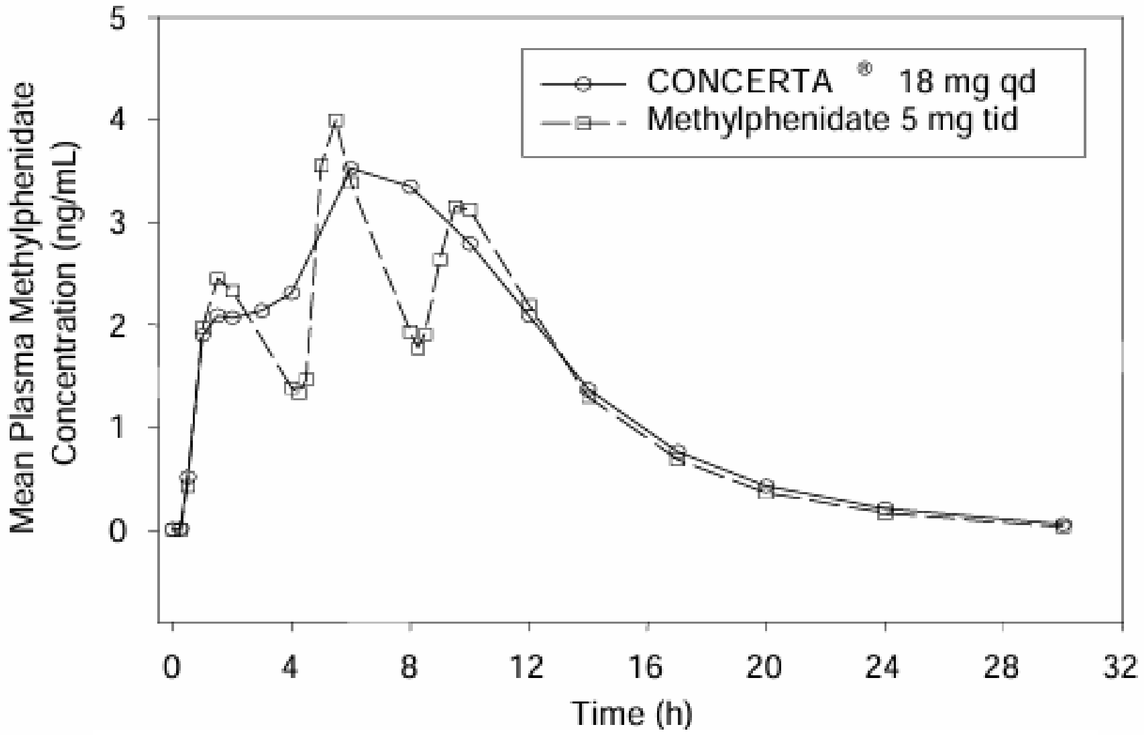
QuillivantXR©

- 5 mg/mL extended-release oral suspension
- **Dosing:** 20 mg/day [Max. 60 mg/day]
- Onset 60 mins, duration 10-12 hours
- T½ of ~5 hours
- Consider for children who do not want to take tablets
- Patient education: QuillivantXR_pi.pdf (trispharma.com)

QuilliChew ER©

- Extended-release chewable tablet
- Cherry Flavored
- **Dosing:** 20 mg/day [Max. 60 mg/day]

Methylphenidate Long-Acting



Mean methylphenidate plasma concentrations in 36 adults, following a single dose of CONCERTA® 18 mg qd and immediate-release methylphenidate 5 mg tid administered every 4 hours

- **Brand Name(s):** Concerta©
- **Long-acting extended release**
  - **Osmotic-Controlled Release Oral (OROS) Delivery System**
  - Outer coat dissolves fast for quick action, the rest is release slowly
  - Can see ghost tablet in stool
  - Hard to crush to ↓ abuse potential
- **Dosing:** 18mg/day, [Max. 54 mg/day (children) or 72 mg/day (adolescents and adults)]
- Onset 20-60 mins, duration 10-12 hours
- T½ of ~3.5 hours

Source: 021121s014lbl.pdf (fda.gov)

Methylphenidate Long-Acting (cont.)

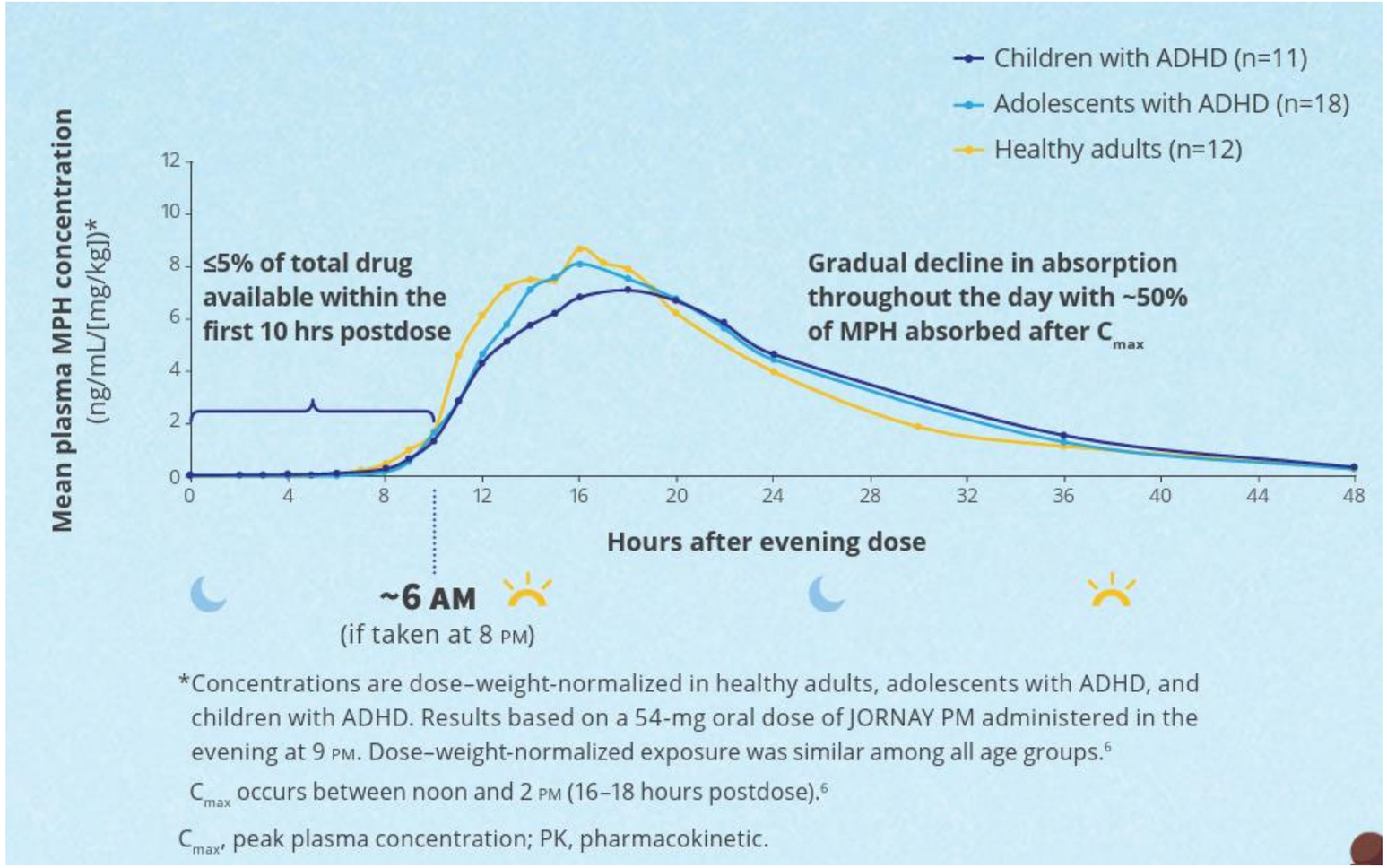
TABLE 4: Recommended Dose Conversion from Methylphenidate Regimens to CONCERTA®

Previous Methylphenidate Daily Dose	Recommended CONCERTA® Starting Dose
5 mg Methylphenidate bid or tid	18 mg q am
10 mg Methylphenidate bid or tid	36 mg q am
15 mg Methylphenidate bid or tid	54 mg q am

Source: 021121s014lbl.pdf (fda.gov)

Methylphenidate Long-Acting (cont.)

- **Brand Name(s):** Jornay PM©
- **Long-acting extended release, delayed release formulation to take in the evening**
  - Take 12 hours before waking/need symptom coverage
- **Dosing:** 20 mg daily HS/PM, [Max 100 mg/day]
- T½ of ~6 hours
- Capsules can be opened and sprinkled into food, but not crushed



Source: JORNAY PM Peds Detail Aid Leave-Behind Digital (Update Oct 2021).pdf (jornaypm-pro.com)

Dexmethylphenidate

Focalin©

- IR tablet
- Dosed 2-3 times daily
- 2.5 mg twice daily [Max. 20 mg/day]
- Given at least 4 hours apart
- Onset 1-2 hours, duration 3-5 hours
- T½ of ~3 hours

Focalin XR©

- ER capsule
- Dosed once daily
- 5mg daily (children) 10 mg daily, [Max 40 (adults) or 30 (children) mg/day
- Onset 1-2 hours duration 9-12 hours
- T½ of ~3 hours
- Total daily IR dose is equivalent to XR dose, adjust to appropriate frequency

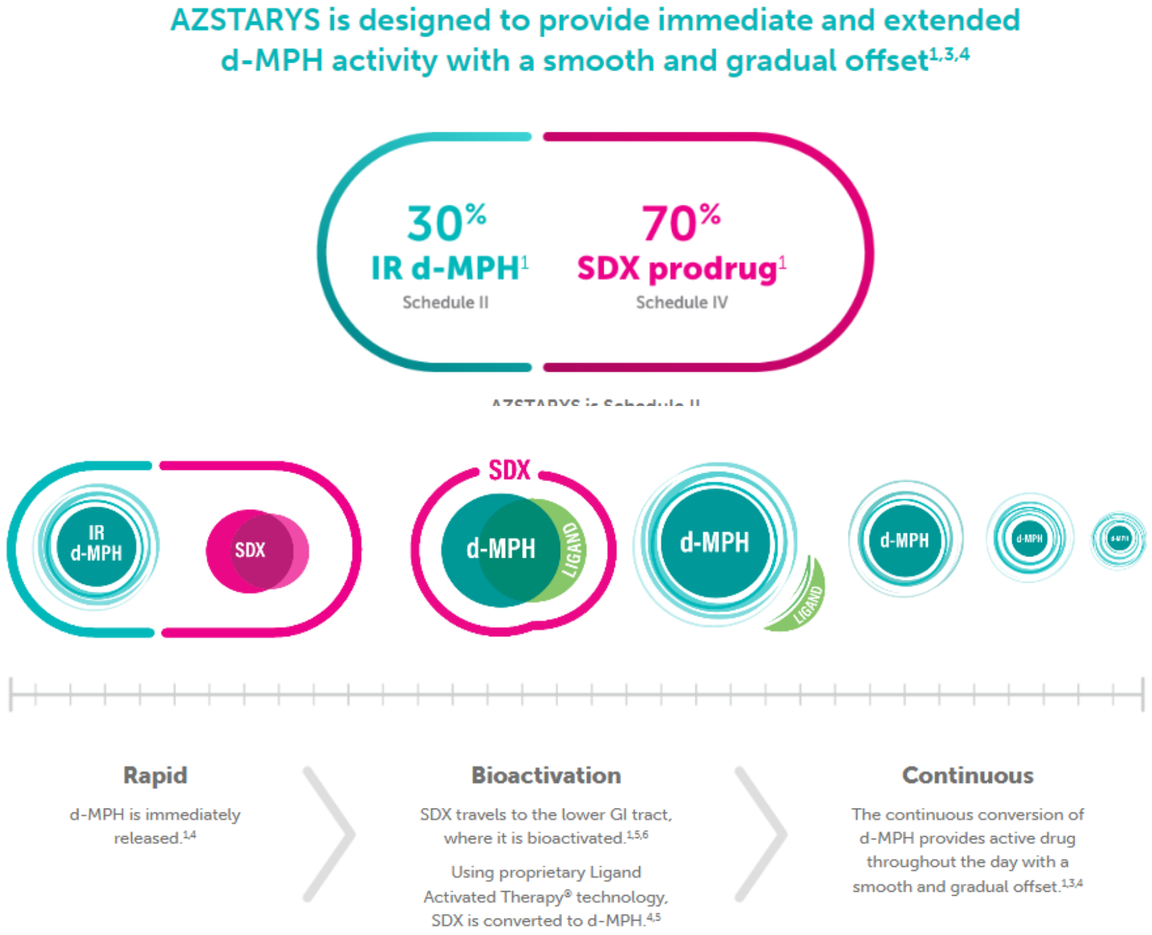
Dosing Conversions:

Methylphenidate to dexmethylphenidate:

- Initiate dexmethylphenidate IR or ER at one-half the total daily dose of racemic methylphenidate

Serdexmethylphenidate and dexmethylphenidate

- **Brand Name(s):** Azstarys©
- **Dosing:** 39.2 mg/7.8 mg daily, [Max. 52.3 mg/10.4 mg daily; 26.1 mg/5.2 mg daily if necessary (6-12 years)
- T½ of 5.7 hours (Serdexmethylphenidate) and 11.7 hours (dexmethylphenidate)
- **Serdexmethylphenidate is a prodrug of dexmethylphenidate**
- Onset 1-2 hours, duration 10+ hours
- If converting from methylphenidate, discontinue medication and initiate titration



Source: [ADHD Medication Mechanism of Action | AZSTARYS® HCP (azstarys-pro.com)]

Amphetamine Products

Dextroamphetamine Immediate-Release

Zenzedi©

- FDA approved 3-16 years
- Immediate-release tablets
- Dosing: 2.5 mg/day (3-5 years) or 5 mg/day (6-16 years), [Max 40 mg/day in 2-3 doses]
- T½ of ~12 hours
- Guidelines do not recommend use in children ≤5 years of age due to insufficient evidence

ProCentra©

- Flavored oral solution 5 mg/mL
- Same dosing as Zenzedi©
- Duration 4-8 hours

Dextroamphetamine sustained-release

Dexedrine Spansule©

- FDA approved 6-16 years
- Extended-sustained release capsules
- T½ of ~12 hours
- Dosing: 5 mg 1-2 times daily, [Max. 40 mg/day] in 1-2 divided doses

Amphetamine Salts

Adzenys ER©, Adzenys XR-ODT©

- Dosing: 6.3 mg daily (6-17 years) or 12.5 mg daily (adults), max dose 18.8 mg daily (6-12 years) or 12.5 mg daily (13+ years)
- Orange flavored suspension 1.25 mg/mL
- If transitioning from a different product, then discontinue and start titration

Table 1: Equivalent Doses of ADZENYS XR-ODT and ADDERALL XR (Mixed Salts of a Single-Entity Amphetamine Product) Extended-Release Capsules

ADZENYS XR-ODT Amphetamine extended-release orally disintegrating tablets	3.1 mg	6.3 mg	9.4 mg	12.5 mg	15.7 mg	18.8 mg
ADDERALL XR Mixed salts of a single-entity amphetamine product extended-release capsules (MAS ER)	5 mg	10 mg	15 mg	20 mg	25 mg	30 mg

Source: https://aytubio.com/downloads/Adzenys/Adzenys_PI.pdf

Amphetamine ER Suspension

Dyanavel XR©

- Dosing: 2.5-5 mg daily, max 20 mg/day
- Extended-Release Suspension 2.5 mg/mL & Extended-Release Tablet
- T 1⁄2 10-12 hours (6-12 years) and 12-15 hours (adults)
- Onset 1 hour, duration 10-13 hours
- DYANAVEL XR oral suspension **can be substituted** with DYANAVEL XR tablets on a milligram per milligram basis

Do not take with acidic food which ↓ absorption

Amphetamine salts

Evekeo IR©, Evekeo ODT©

- Dosing: 2.5 mg daily (3-5 years) or 5 mg 1-2 times daily (6 ≥ to ≤ 17 years), max dose not specified by not recommended > 40 mg/day

Mixed Amphetamine salts dextroamphetamine/Amphetamine

Adderall©

- IR tablet
- Approved for children ≥ 3 years
- Dosing: 5mg 1-2 times daily (≥ 6 years) or 2.5 mg daily (3-5 years), max 40 mg/day in divided doses
- Duration 4-6 hours
- Can give 1-3 times daily

Adderall XR©

- Dosing: 10 mg daily (6-17 years) or 20 mg daily (adults), max 30 mg daily (6-17 years)
- Duration 8-12 hours
- Tmax prolonged by food by 2-3 hour

Do not take with acidic food which ↓ absorption

Mixed Amphetamine salts dextroamphetamine/Amphetamine

Mydayis©

- Extended-release capsule
- Dosing: 12.5 mg daily, max 50 mg/day (adults) or 25 mg/day (13-17 years)
- FDA-approved for 13+

Lisdexamfetamine

- **Brand Name(s): Vyvanse©**
- **Chewable tablet or capsule**
- **Dosing:** 30 mg/day, max 70 mg/day
- T½ 10-13 hours
- Renal dose adjustments for GFR < 30 mL/min/1.732
- Lower risk for abuse
  - Lisdexamfetamine is a prodrug of dextroamphetamine

Stimulant side effects

- **Black Box Warning**
  - High misuse potential
    - Prolonged administration may lead to dependence

Stimulant side effects

- **Psychiatric**:
  - The FDA has added warnings to the labeling of all ADHD medications regarding three broad categories of psychiatric adverse effects:
    - Psychosis
    - Mood disturbances (ie, irritability, lability, or depression)
    - Severe anxiety or panic attacks
  - FDA Communication May 2023: https://www.fda.gov/media/168066/download?attachment

Stimulant side effects

- **Cardiac**:
  - Stimulants, atomoxetine, viloxazine, and α2-adrenergic agonists have well-described cardiac and cardiovascular adverse reactions that are not significant for most youth, but can be intolerable in some, particularly in those with existing cardiac/cardiovascular disease
  - Increased heart rate by 3 to 10 beats/min and/or increased systolic or diastolic blood pressure by 2 to 14 mm Hg
  - The American Heart Association recommends careful screening of all children and adolescents prior to initiating pharmacologic therapy for ADHD, including a medical and family history and physical examination
  - Baseline ECG and consultation with cardiologist if family history of cardiovascular disease is present

Stimulant side effects

- **Growth**:
  - Growth effects are less apparent when stimulants are not used consistently, medication holidays and only using for school management are techniques that may be evaluated

Stimulant Adverse Reactions

Common Side Effects

- Reduced appetite, weight loss
- Stomach ache
- Insomnia
- Headache
- Rebound Symptoms
- Irritability/jitteriness

Rare but Serious Side Effects

- Dysphoria
- Skin discoloration
- Zombie-like state
- Tics or abnormal movements
- Priapism
- Hypertension, pulse fluctuations
- Hallucinations
- Peripheral vasculopathy

Additional counseling with stimulants

- Stimulants should not be taken at night (except Jornay PM®) to avoid insomnia
- Avoid within 14 days of an MAO inhibitor
- Consider any history of drug or alcohol abuse
- Caution in patients with anxiety, agitation, psychosis, seizures, or cardiac related comorbidities
- Patients might be subjected to drug testing from provider
- Only IR products may be crushed or chewed

Practice Question

2. Which statement should be included when counseling a family on the risks of stimulant therapy for ADHD?

A. The risk of an adverse cardiac event is two times greater in a child taking stimulant compared to an untreated child.
B. Stimulant therapy for ADHD increases the risk of accidental injury, including the risk of severe brain injury.
C. The risk of decreased growth and insomnia is greater with immediate-release stimulants.
D. Stimulants are more likely to be associated with severe liver injury compared to atomoxetine.

Non-Stimulant Treatment Options

Norepinephrine Reuptake Inhibitor

First non - stimulant FDA Approved (2002)

- **Atomoxetine (Strattera©)**
  - **Capsules**
- Weight based dosing:
  - ≥70 kg: start 40 mg PO QAM (or divided BID); max 100 mg/day
  - <70 kg: start 0.5 mg/kg QAM (or divided BID); max 1.4 mg/kg/day or 100mg/day
- Generally reserved for patients with a history of substance use disorder or those who cannot tolerate or do not have a sufficient response to preferred agents
- SE: Increased BP/HR, insomnia, fatigue, suicidality, anorexia, and liver injury (rare), **do not open the capsule (ocular irritant)**
- Contraindications: Narrow-angle glaucoma, MAOI use within the past 14 days, pheochromocytoma
- Black Box waring: Rick of suicidal ideation
- Slower onset of therapeutic effect
  - 2-4 weeks vs 1-2 hours with an effective stimulant dose
  - full benefit may not be seen for 6 to 12 weeks

Norepinephrine Reuptake Inhibitor

- Viloxazine (Qelbree ©)
- Extended-release capsule
  - Capsule can be opened and contents sprinkled on 1tsp of pudding or applesauce
- Dosing: 100 mg daily (6-11 years) or 200 mg daily (12+ years), max 400 mg/day (12-17 y/o) 600 mg/day (adults)
- Compared to atomoxetine, **viloxazine is a less potent inhibitor** of the norepinephrine transporter. In addition to norepinephrine reuptake inhibition, viloxazine **increases 5-HT levels in the prefrontal cortex via modulation of serotonin receptors**.
- SE: increased SBP, tachycardia, headache, drowsiness

Alpha-2 Adrenergic agonists (IR)

- Central *alpha*$_2$-adrenergic agonists
  - Act pre-synaptically to inhibit norepinephrine release and post-synaptically to increase blood flow in the prefrontal cortex, which enhance working memory and executive functioning

Guanfacine (Tenex ©)

- **Dosing**: 0.5mg once or twice daily; can increase as tolerated to 1-4 mg/day; Max: 4 mg/day in children/adolescents
- Duration: 18 hours
- Less sedation and dizziness
- May be used as adjunct to stimulants
- Off-label

Clonidine (Catapres ©)

- **Dosing**: 0.05 mg two or four times daily; can increase as tolerated to 0.1-0.4 mg/day
- Duration: 12 hours
- May be used as adjunct to stimulants
- Off-label

Alpha-2 Adrenergic agonists (XR)

Guanfacine (Intuiv ©)

- **Dosing**: 1 mg in the AM; titrate weekly to response; Max: 4 mg/day in children; 7 mg/day in adolescents

Clonidine (Kapvay ©)

- **Dosing**: 0.1 mg at bedtime; may increase by 0.1 mg weekly; maximum: 0.4 mg/day given twice a day if dose >0.2 mg/day

- **Common Side Effects:**
  - Sedation, dizziness, heart block (check ECG), constipation, headache, upper abdominal pain
  - **FDA approved for ADHD**
  - **Do not chew, crush or cut tablets; and do not take with a high fat meal**
  - **Do not discontinue abruptly because of rebound HTN may occur**

Alpha-2 Adrenergic agonists (XR)

ONYDA XR (Clonidine)

Clonidine hydrochloride extended-release oral suspension

0.1 mg/Start: 0.1 mg PO **once nightly at bedtime**
Titration: ↑ by 0.1 mg/day at weekly intervals
Maximum: 0.4 mg once nightly

First **once-nightly extended-release liquid clonidine** for ADHD

Approved for pediatric patients **≥6 years**

Can be used as **monotherapy** or **adjunctive therapy with CNS stimulants**

Common/clinically important effects include:

- Somnolence / sedation
- Fatigue
- Dizziness
- Decreased appetite
- Hypotension & bradycardia

Practice question

3. Potential advantages of *alpha*$_2$-adrenergic agonists over stimulants for ADHD include:

A. More rapid onset of therapeutic effect
B. Less insomnia, anorexia, and growth effects
C. Greater efficacy for inattentive symptoms
D. Effective for children, teens, and adults

Centanafadine (SIMTRIYO®): A New Non-Stimulant for ADHD

FDA Approved: **July 24, 2026**

Adults and pediatric patients **≥6 years**

Pediatric patients must weigh **≥20 kg**

First and only **norepinephrine, dopamine, and serotonin reuptake inhibitor (NDSRI)** approved for ADHD

Non-stimulant treatment option

Medication	Primary reuptake inhibition
Atomoxetine (Strattera®)	Norepinephrine
Viloxazine (Qelbree®)	Norepinephrine + Serotonin
Centanafadine (SIMTRIYO®)	**Norepinephrine + Dopamine + Serotonin**

Centanafadine (SIMTRIYO®): A New Non-Stimulant for ADHD

Clinical Evidence

- Four pivotal **Phase 3 trials** supported FDA approval
- Significant improvement in **ADHD symptoms**
- Benefit demonstrated in both **adult and pediatric populations**
- Onset of clinical benefit reported at approximately **1–2 weeks**

Common Adverse Effects

- Decreased appetite
- Nausea
- Headache
- Rash

Potential Advantages

- Non-stimulant alternative with a **novel mechanism**
- Relatively rapid onset compared with some traditional non-stimulants
- Potential tolerability advantages based on **indirect comparisons**

Bupropion

- Brand name: **Wellbutrin©**
- Weak DA and NE reuptake inhibitor
- Not FDA approved for ADHD
- Bupropion has been found beneficial for adolescents with depression and ADHD and causes less appetite suppression and weight loss compared with stimulants, but it has a greater risk of seizures
- SE: tachycardia, weight loss, diaphoresis, N/V, xerostomia, headache, agitation, insomnia

TRICYCLIC ANTIDEPRESSANTS

- Not FDA approved for ADHD, off-label for children twelve years and older
- Takes up to four weeks to see maximum effects in ADHD
- SE: anticholinergic effects, HR fluctuations, sudden cardiac death

Additional medications used in ADHD

Antipsychotics (for comorbid aggression, mood disorders, tics, or irritability associated with ASD)		
Aripiprazole (Abilify)	2-5 mg daily; can titrate weekly as tolerated to response (usual range: 5-20 mg/day)	Nausea, restlessness, insomnia extrapyramidal symptoms, dizziness, sedation
Haloperidol[a] (Haldol)	0.5-1 mg twice daily; can titrate every 3-4 days as tolerated to response (usual range: 0.5-5 mg/day)	Extrapyramidal symptoms, dizziness, ↑ serum prolactin, sedation
Olanzapine[a] (Zyprexa)	2.5-5 mg every day; can titrate every 3-4 days as tolerated to response (usual range: 7.5-15 mg/day)	Sedation, severe weight gain, restlessness, extrapyramidal symptoms
		Diabetes, marked hyperlipidemia (never a first-line treatment)
Quetiapine[a] (Seroquel)	25-50 mg twice daily; can titrate every 3-4 days as tolerated to response (usual range: 200–600 mg/day)	Sedation, dizziness, weight gain, diabetes, hyperlipidemia
Risperidone[a] (Risperdal)	0.25-0.5 mg twice daily; can titrate every 3-4 days as tolerated to response (1-4 mg/day)	Extrapyramidal symptoms, dizziness, ↑ serum prolactin, decreased skeletal bone mass, hepatotoxicity, weight gain
		Diabetes, hyperlipidemia
Ziprasidone[a] (Geodon)	10-20 mg twice daily; can titrate every 3-4 days as tolerated to response (usual range: 40-160 mg/day)	Nausea, restlessness, insomnia extrapyramidal symptoms, sedation, QTc prolongation

Antipsychotics

- First-generation antipsychotics (chlorpromazine and haloperidol) can improve symptoms of hyperactivity and impulsivity in children with ADHD, but their negative effects on learning, cognitive functioning, and the significant risk of extrapyramidal adverse reactions **limit their usefulness**
- Second-generation antipsychotics such as **risperidone, olanzapine, quetiapine, ziprasidone, and aripiprazole** have been used to control **severe aggression** in refractory cases of ADHD, particularly if CD or bipolar disorder coexists
- Risperidone is the most well studied for **aggression associated with ADHD**

Special populations

Pregnancy

- **Stimulants** (e.g., Methylphenidate, Adderall XR)
  - Associated with **premature birth, low birth weight, neonatal withdrawal**
  - Use **only if benefits outweigh risks**
- **Non-stimulants** (Atomoxetine, Viloxazine, Guanfacine ER, Clonidine ER)
  - Limited pregnancy data → **use with caution**

Lactation

- Stimulants may **reduce milk production** and cause infant irritability
- Methylphenidate appears in breast milk in **low amounts** → monitor infant
- Atomoxetine/Viloxazine: unknown excretion
- Guanfacine: monitor infant sedation

Geriatrics

- Stimulants and non-stimulants **not well studied in elderly**
- Increased risk of **cardiovascular events, renal/hepatic impairment**
- Use lower doses and monitor BP, HR, and tolerability.

Practice Question

4. A 10-year-old with ADHD and conduct disorder with severe aggression is taking 54 mg of osmotically released oral delivery system (OROS) methylphenidate. BP is 116/68, pulse 60, weight is 50 kg (110 lb). What intervention has the most evidence for efficacy in managing aggression in this patient?

A. Increase dose of OROS methylphenidate to 72 mg
B. Add guanfacine 1 mg twice daily
C. Change from OROS methylphenidate to atomoxetine
D. Add risperidone 0.5 mg twice daily

Mini Case

- JJ 16-year-old male diagnosed with ADHD at age 11. He has been taking methylphenidate ER 36 mg every morning for the past year. His parents report significant improvement in attention and school performance; however, over the last several months he has experienced decreased appetite, a 7-lb weight loss, and difficulty falling asleep.
- His BP and HR are slightly increased from baseline but remain within normal limits. He denies substance use, and his family reports good medication adherence. Because of the persistent adverse effects, the patient and his parents ask whether a non-stimulant medication could be considered.

Mini Case

1. Which medication would be an appropriate non-stimulant alternative?

A. Lisdexamfetamine
B. Atomoxetine
C. Dexmethylphenidate
D. Mixed amphetamine salts

2. What parameters should the pharmacist monitor after changing therapy?

A. Renal function and electrolytes
B. Blood glucose and A1C
C. ADHD symptoms, BP/HR, weight, and adverse effects
D. INR and liver enzymes only

Mini Case

3. Which finding would indicate that the treatment change is effective?

A. Increased heart rate
B. Additional weight loss
C. Improved attention with better appetite and sleep
D. Development of daytime sedation

Pharmacist Role: Evaluate treatment response and tolerability, recommend appropriate alternatives, educate the patient/family, and monitor outcomes during therapy changes.

Role of the Pharmacist

Medication Management

- Evaluate **stimulant vs. non-stimulant** treatment options
- Optimize **dose, formulation, and administration timing**
- Identify **drug–drug interactions** and contraindications
- Support medication switching and titration

Monitoring & Safety

- Monitor **efficacy and functional improvement**
- Assess adverse effects: appetite/weight, sleep, mood, BP & HR
- Screen for **misuse, diversion, and inappropriate stimulant use**
- Promote appropriate monitoring and follow-up

Patient & Caregiver Education

- Set expectations regarding **onset and duration of effect**
- Counsel on adherence and proper medication administration
- Educate about adverse effects and when to seek care
- Address misconceptions and stigma surrounding ADHD medications

Collaborative Care

- Collaborate with **psychiatry, primary care, pediatrics, psychology, and schools**
- Recommend evidence-based pharmacotherapy adjustments
- Help manage **psychiatric and medical comorbidities**
- Improve continuity of care and medication access

Controlled-Substance Stewardship

- Verify appropriate stimulant prescribing and dispensing
- Review **PDMP** in every prescription.
- Educate on **safe storage and disposal**
- Navigate shortages, insurance barriers, and therapeutic alternatives

POST TEST

ADHD is mainly characterized by which three symptom groups?

- Anxiety, depression, insomnia
- Inattention, hyperactivity, impulsivity
- Psychosis, mania, panic
- Memory loss, tremor, confusion

POST TEST

Non-stimulant medications are always more effective than stimulant medications for treating ADHD symptoms.

a)True

b)False

POST TEST

A 6-year-old boy has symptoms of ADHD at home and school, and behavioral therapy did not improve his symptoms. Which of the following is the most appropriate first medication to start for ADHD?

a)Ritalin

b)Atomoxetine

c)Guanfacine ER

d)EndeavorRx

POST TEST

A mother asks about instructions for ADHD medications. Which of the following counseling statements is INCORRECT?

a)The Daytrana patch should be placed on the hip.

b)Seeing an empty Concerta tablet shell in the stool is normal.

c)Jornay PM should be taken in the evening.

d)Adderall XR works better when taken with orange juice.

POST TEST

A 27-year-old man with ADHD has a history of opioid use disorder in remission. The doctor wants a stimulant with a lower risk of misuse. Which of the following medications is the most appropriate option?

a)Adderall IR

b)Dexedrine

c)Vyvanse

d)Ritalin IR

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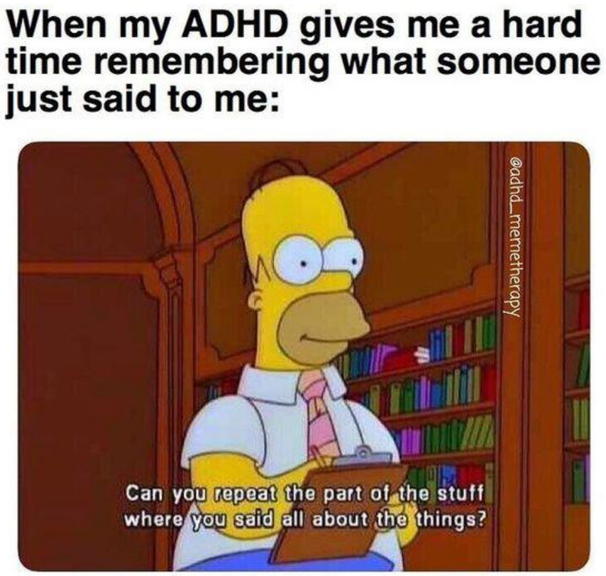

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Pharmacy Manager - Farmacia Caridad

jeanlouis.betancourt@gmail.com