Promoting and Monitoring Evidenced-Based Antipsychotic Prescribing Practices in Children and Adolescents: Florida Medicaid Initiatives

Mary Elizabeth Jones, Pharm BSc, RPh
Senior Pharmacist
AHCA Pharmacy Services
Outline of Presentation

- Evidenced-Based Prescribing Practices
- Classes of psychotherapeutic medications prescribed to children
- Special focus on antipsychotic medications
- Quality Improvement of Antipsychotic Prescribing Practices
Definition of Evidence Based Practice

Evidence Based Practice is “the conscientious, explicit and judicious use of current best evidence in making decisions about the care of the individual patient.

It means integrating individual clinical expertise with the best available external clinical evidence from systematic research.”

(Sackett D, 1996)

Levels of Evidence

- Large randomized controlled studies (RCT)
  - Most scientific rigor, multiple trials
- Smaller trials and case studies
- Expert Opinion
  - Consensus
- Clinical Experience
Evidenced Based Practice

• Prescribing practices are traditionally informed by
  – Medical education (training)
  – Clinical practice (experiential)
  – Evidenced-Based Literature Review
  – Best Practice Guidelines

• Practices lag behind current Evidence-Based Literature
  – Information explosion
  – Busy providers, little time
  – Slow to change
Evidence Based Prescribing Practices

Integrates the best research evidence with clinical expertise and patient values

Pediatric Age Descriptions

• Preschool Child – less than 6 years
• Child – 6 to 12 years
• Adolescent – 13 to 17 years
Most Common Medication Classes Prescribed to Children and Adolescents

• Stimulants
• Other ADHD medications
• Antipsychotics
  – Typical
  – Atypical*
• Antidepressants
• Anticonvulsants
Atypical Antipsychotics Prescribed in Children and Adolescents

- Risperidone*
- Aripiprazole*
- Quetiapine
- Paliperidone
- Olanzapine
- Ziprasidone
- Newer Agents; lurasidone, asenapine, iloperidone

*most FDA indications and evidence-based data in children
Diagnoses Associated with Antipsychotic Prescribing

- Autism/Pervasive Developmental Disorders
- ADHD alone and comorbid
- Mood Disorders
  - Disruptive mood dysregulation, Bipolar d/o, depressive d/o
- Conduct Disorder
- Oppositional Defiant Disorder
- Obsessive-Compulsive Disorder
- Tourette’s Syndrome
- Schizophrenia and other psychotic disorders
Symptoms Targeted with Antipsychotic Medications

- Severe aggression (impulsive)
- Self-injurious Behaviors
- Extreme Irritability (Autism)
- Extreme Impulsivity
- Mood instability
- Psychosis (positive symptoms)
- Repetitive movements, Tics
Potential Adverse Effects of Antipsychotic Medications

• Metabolic side effects
  – Weight gain, lipid dysregulation, obesity, diabetes
• Neurological side effects
  – Sedation, seizures
• Motor side effects
  – Restlessness, tremor, tardive dyskinesia
• Cardiovascular side effects
  – Hypotension, arrhythmias
• Prolactin elevation
  – Breast milk production, male breast development
Antipsychotic Prescribing Trends in the Early to Mid-2000’s

• The MDTMP tracked the use of antipsychotics in children and findings included
  – Increased utilization in children
  – Use in preschool children (< 6 years of age)
  – More than 1 antipsychotic prescribed concomitantly
  – Other psychotherapeutic medications prescribed concomitantly
  – Findings prompted further study focused on children < 6 years of age
Related Quality Concerns

• Limited data to guide use in children
  – Limited FDA indications; off-label prescribing
  – Data from adult studies not applicable

• Some benefits to use
  – Improved symptoms; quality of life

• Some risks to use; safety and tolerability concerns
  – Side effects
  – Prescribed concurrently with psychotherapeutic medication classes increases risks
  – Emerging data on the long-term effects
Policy Considerations and Development

- AHCA collaborated with DCF and the MDTMP to develop policy regarding oversight of antipsychotic medications in preschoolers
- The Florida Medication Guidelines provided the evidence-based support for policy development
- Initiatives to Ensure Appropriate Use
  - Strengthen Process of Informed Consent
  - Distribute Guidelines and Provide Education
  - Monitor prescribing practice
- Child psychiatrists from the expert panel provide expert opinion and participate in interventions
Informed Consent for Psychotherapeutic Medication

• Effective September 1, 2011

• Pursuant to statute 409.912(51) The Agency may not pay for a psychotropic medication prescribed for a child in the Medicaid program without the express and informed consent of the child's parent or legal guardian. The physician shall document the consent in the child's medical record and provide the pharmacy with a signed attestation of this documentation with the prescription.

• Florida Statute 394.492(3) “Child” means a person from birth until the person’s 13th birthday.
Florida Panel Recommendations

• Use psychosocial treatment prior to medication
• Benefits of medication treatment must outweigh the risks
• Start with one medication
• Individualized treatment
• Involve family in decision making
  – Informed consent
General Statement Regarding Use of Antipsychotics in Preschool Children

The use of antipsychotic medications in preschoolers (children less than six years of age) which is generally “off-label”, is not recommended and should only be considered under the most extraordinary circumstances.
Antipsychotic Prior Authorization
Implemented April 2008

• Preschool children less than 6 years of age
• New prescriptions require review by a board certified child psychiatrist (expert opinion)

• Guiding principles for the review
  – Appropriate & Safe medical care a priority
  – Adherence to Florida Medication Guidelines

• Goal of 24 hour turnaround for review
Documentation Required for Review

• Antipsychotic Prior authorization form
• Prescription copy
• Diagnostic Evaluation
• Current progress notes
• Height, weight, BMI
• Previous therapies
• Target symptoms
• Date of follow-up visit
Antipsychotic Review Considerations

• Diagnosis
• Target symptoms
• Level of functional impairment
• Previous medication trials
• Previous behavioral therapies
• Is the dosing appropriate?
• Is the monitoring plan sufficient?
Review Options

• New Requests
  – Approve
    • Maximum six months
    • Average three months
  – Deny
  – Request additional documentation

• Continuation Requests
  – Reviewed for dose appropriateness, monitoring
  – Trial off medication sometimes recommended
  – Denials rare
Feedback to Prescriber

- Essentially, a second medical opinion is provided
  - Comments, recommendations
  - Requirements for approval consideration

- Recommendations may include
  - Dosing/titration
  - Reduction of polypharmacy
  - Rating scales, monitoring scales
  - Lab studies, ECG, Genetic workup
  - Specific behavioral therapies
  - Coordination of care
Early Prior Authorization Review Results (Age < 6 years)

• 50% reduction in the number of requests
• Use of more than one antipsychotic stopped.
• Reduction in the proposed doses
• Improvements in prescribing practices prompted additional initiatives in older children
Prior Authorization Changes

• Antipsychotic prior authorization for children greater than 6 years of age implemented
  – No FDA indication, evidence lacking
  – High Dose
• Prior authorization for children 6 to 12 years of age implemented November 2010
• Prior authorization for adolescents 13 to 17 years of age implemented April 2011
Additional Prior Authorization Requirements for Safety Monitoring

• Metabolic labs
  – Fasting glucose
  – Fasting lipids

• Tardive Dyskinesia screen
  – AIMS
  – DISCUS

• USF website provides
  – Access to forms
  – Access to rating scales
Compliance with Monitoring

• Initial percent compliance compared to 2013
  – (2008) BMI = 11%
  – (2013) BMI% = 94%
  – (2010) Labs = 11%
  – (2013) Labs = 41%
  – (2010) TD screen = 6%
  – (2013) TD screen = 54%
Recent Quality Improvements

• Better adherence to guidelines
• Reduction in polypharmacy
• Improved metabolic monitoring
• Improved tracking of BMI and BMI%
• Improved Tardive Dyskinesia monitoring
• Improved acceptance of child psychiatrist recommendations
Summary

- Adherence with Evidenced-Based Practices improves care to children and adolescents prescribed psychotherapeutic medications
  - Promotes safe, effective treatments
  - Promotes individualized, measured-based care
  - Promotes family involvement and informed consent