

Module 5

Specific Drug Classes: Use, Efficacy and Safety

Learning Goals

1. Name specific psychotropic drugs that are approved by the FDA for use with children and adolescents, and identify their specific indication(s).
2. Name specific psychotropic drugs that are *not* approved by the FDA for use with children and adolescents.
3. Explain “black box” warnings issued by the FDA for specific psychotropic agents used with children and adolescents.
4. Identify adverse effects associated with each of these specific psychotropic agents.
5. Reflect on implications of class-action litigation against drug makers concerning “hidden” data of adverse effects and off-label marketing.
6. Evaluate the state of the evidence concerning the safety and efficacy of psychotropic medication use with children and adolescents.

Questions for Practice, Supervision and Administration

1. Select two cases from your current case load and review the psychotropic medication regimen prescribed.
 - a. Are the drugs approved for use in that child’s age group?
 - b. Are any FDA warnings associated with any of the drugs prescribed? Has this warning been disclosed to parents?
 - c. Are the medications having the desired effect? How do you know? Identify other factors that could explain the observed effects. Explain your reasons for *excluding* these other factors as actual causes.
 - d. Have you carried out any formal assessment of adverse effects? How often? Using what methods or instruments? Are the medications having any adverse effects? If so, how are they being managed? Is it possible that previous adverse effects of medication were misrecognized?

- e. Do the observed benefits of the medication(s) outweigh the observed risks? Whose opinion and judgment is sought to answer that question? How exactly is the risk-benefit ratio assessed?
- f. Is the child participating in any concurrent psychosocial intervention?
- g. What alternatives exist to the use of medication(s)? Have these alternatives been attempted? Why or why not?
- h. Do you possess knowledge about this client's reaction to medications that are not documented anywhere?
- i. Would you presently feel comfortable justifying this client's medication regimen and other interventions to the client's parents? To a judge? To a state legislative committee? To a reporter? To a child advocate? To the child? Would you use different reasons for your justification with some of these players? Why or why not?