THINK **BIGGER** DO **GOOD**
POLICY SERIES

Policy and Practice Innovations to Improve Prescribing of Psychoactive Medications for Children

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Dear Reader,

Now is the time to solve the growing behavioral health needs in our country by advancing public policies that transform the delivery of mental health and substance use disorder services and address outdated funding mechanisms.

This paper is part of Think Bigger Do Good, a series of papers launched in 2017 through the support and leadership of the Thomas Scattergood Behavioral Health Foundation and Peg's Foundation. While the paper topics continue to evolve, our goal to develop a policy agenda to improve health outcomes for all remains constant.

In partnership with national experts in behavioral health, including our editors, Howard Goldman and Constance Gartner, we identified seven critical topics for this third series of papers. Each paper identifies the problem and provides clear, actionable solutions.

We hope you join us in advocating for stronger behavioral health policies by sharing this paper with your programmatic partners, local, state, and federal decision makers, advocacy organizations, and voters. To learn more about Think Bigger Do Good and to access the other papers in the series, visit **www.thinkbiggerdogood.org**

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1 / Introduction

Psychoactive medications are the most expensive and fastest-growing class of pharmaceutical agents for children. The four drugs prescribed to children with the highest Medicaid cost are all psychoactive medications (1, 2). Stimulants alone account for 20.6% of all pediatric drug expenditures. At the same time, psychoactive medications have extensive and expensive side effects and frequently have minimal monitoring. For example, although metabolic monitoring through laboratory assessments is recommended for all children and adolescents taking antipsychotics, less than one-fifth of children receive such monitoring (1). Studies of prescribing practices and their costs, both economically and medically, have raised concerns among clinicians, patient advocates, and agencies with accountability for insuring children and adolescents that psychoactive medications are often used inappropriately.

We briefly review prescribing for three classes of psychoactive drugs—stimulants, antidepressants, and antipsychotics—and then discuss current system approaches to improving appropriateness of prescribing.

Here, we briefly review prescribing for three classes of psychoactive drugs—stimulants, antidepressants, and antipsychotics—and then discuss current system approaches to improving appropriateness of prescribing. System approaches include monitoring guideline concordance or lack thereof, and new but untested pharmaceutical policies and implementation of prescribing strategies to improve appropriateness. Inappropriate prescribing is difficult to define except on a case-by-case basis. Therefore, we refer to the broader category of potentially inappropriate prescribing as "questionable prescribing practices." Both refer to the prescription of drugs in patterns that appear incongruous with clinically accepted, evidence-based guidelines. (For convenience, we sometimes use the word "children" to refer to children and adolescents.)

2 Stimulant Prescribing

One of the most challenging areas of psychotropic prescribing involves children and adolescents diagnosed as having attention-deficit hyperactivity disorder (ADHD). Although the American Academy of Pediatrics (AAP) continues to update clinical guidelines for the treatment of ADHD (3), there remains debate among providers about the accuracy of diagnosis, because many disruptive or impulsive behaviors attributed to ADHD can overlap with normative behavior among young children or may be a manifestation of trauma history or other psychosocial challenges.

Multiple challenges exist in connecting children to services, including substantial differences in access to treatment for vulnerable groups.

Nevertheless, overall diagnosis rates for ADHD are increasing, and prescribing has followed in tow. By 2011, one in nine parents of youths ages 4–17 reported a history of ADHD diagnosis among their children, up more than 40% from the prior decade (4). ADHD stimulant use has similarly risen, reaching one in 15 of all youths, up 25% during the same period (4). One in three ADHD diagnoses occurs among preschool children, and diagnoses have climbed among younger children since the AAP issued new guidelines in 2011 (4, 5). At the same time, diagnosis and treatment have not been consistent across all groups of children.

In particular, children in Medicaid and African-American and Latino children lag behind white children in diagnosis rates and access to many kinds of behavioral treatments (6). Meanwhile, as diagnoses have climbed for older youths, so have concerns about overdiagnosis and increasing trends in illegal diversion of medication from youths with prescribed stimulants to their fellow high school and college students (7).

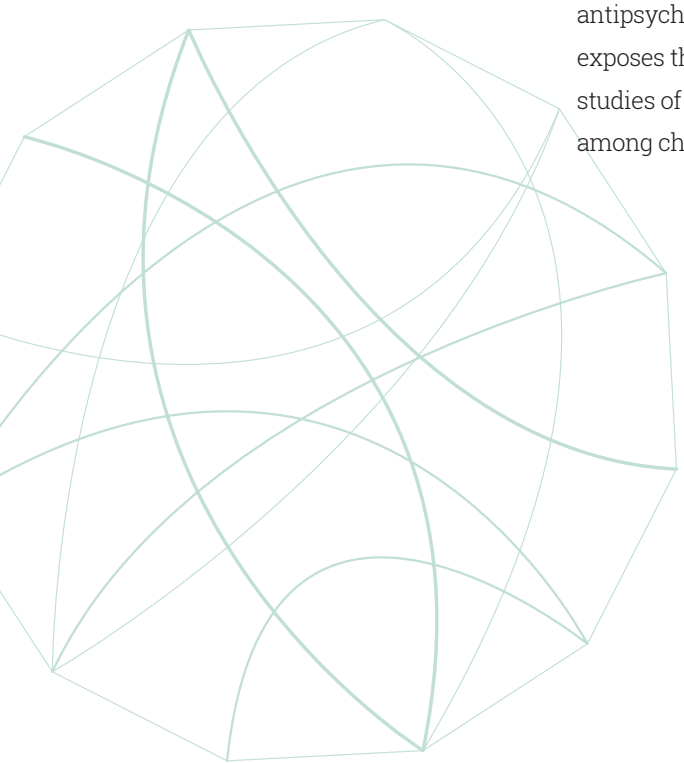
The result has been a highly variable treatment environment in which many children may be at risk of overdiagnosis and treatment; however, we are also mindful that many children continue to be undertreated. In fact, half of the estimated 7.7 million U.S. children with a treatable mental disorder do not obtain necessary treatment (8). Multiple challenges exist in connecting children to services, including substantial differences in access to treatment for vulnerable groups. Insurance coverage, race-ethnicity, income, gender, and geography all affect children and families' access to mental health services (9), and reactions to overtreatment, as evidenced here, should be anchored in this acknowledgment.

The response among the pediatric community to questionable prescribing, both over- and undertreatment, has led to calls to standardize care and to an emphasis on the value of shared decision making between providers and caregivers. The AAP guidelines seek to clarify the treatment environment for children and adolescents with ADHD (3). These guidelines endorse behavior therapy as the primary line of therapy for preschool children, and medications and behavior therapy are endorsed, with clinical equipoise, for school-age children. The guidelines emphasize medication treatment as a primary indication for older children.

3 Antipsychotic Prescribing

The story is different for antipsychotics. The largest part of antipsychotic pediatric use is off-label use for nonpsychotic disorders, primarily for ADHD and other externalizing symptoms (10–12). In a large study by the Mental Health Research Network, a consortium of 13 healthcare delivery systems across the United States, 66% of boys ages 6–11 who were prescribed an antipsychotic medication did not have a psychotic disorder or other indication approved by the U.S. Food and Drug Administration (FDA). In the American Psychiatric Association's Choosing Wisely recommendations, the fifth recommendation is, "Don't routinely prescribe an antipsychotic medication to treat behavioral and emotional symptoms of childhood mental disorders in the absence of approved or evidence supported indications" (13).

Another concerning trend is that antipsychotics are disproportionately given to children in foster care, most commonly for disruptive behaviors (14). Giving antipsychotics to foster care children not only increases risks of side effects but also exposes the developing brain to medications for which there have been no long-term studies of outcomes. Antipsychotics are also associated with increased risk of death among children (15).



4 Antidepressant Prescribing

A large, annual U.S. survey, the National Survey on Drug Use and Health, reported increased use from 2005 to 2014 of prescription medication by adolescents with major depressive episodes.

In the United States, national patterns of prescribing antidepressants to youths have been trending upward. A large, annual U.S. survey, the National Survey on Drug Use and Health, reported increased use from 2005 to 2014 of prescription medication by adolescents with major depressive episodes (16). This trend is consistent with epidemiologic data on the development of depression among youths (i.e., antidepressant use tends to increase with age for children [17]). Antidepressant medication prescribing for youths has also been on the rise internationally (18).

Only a small portion of U.S. youths—3.4% of those ages 12–19—used an antidepressant (19), compared with the prevalence rates of major depressive episodes among U.S. males (6.8%) and females (20%) of the same age (20). Reasons likely include lingering concerns by primary care providers about the risk of suicidality, despite mixed evidence (21–25), and providers' lack of training and confidence in identifying and treating depression among youths (26–28). In addition, limited numbers of effective coordinated care models between primary care and mental health services are deployed (29).

5 Current Policies to Address Questionable Prescribing Practices

The high rates of questionable prescribing of psychoactive medications for children have raised concerns among advocates, agencies accountable for children in custody, Medicaid programs, and clinicians.

Federal and State Policies

These concerns are reinforced by federal policy efforts encouraging states to address antipsychotic use among foster care children. Public Law (PL) 110–351 in 2008 required states to develop oversight plans for overall mental health services for child welfare agencies, PL 112–34 in 2012 required states to have a protocol for oversight of psychoactive drugs for children in foster care, and the 2012 Because Minds Matter Summit coordinated state Medicaid and child welfare agencies in a meeting about psychoactive medication oversight for children in foster care, with an emphasis on second-generation antipsychotics.

However, altering prescriber behavior is difficult. Simply providing physicians with information about available prescribing algorithms and guidelines is not an effective strategy (30–32). Simple practice alerts are often ignored (33). A targeted implementation strategy that includes a care pathway and clinical workflow is necessary (34, 35), but success requires concerted effort by leadership and staff at all levels of specialty practice. In addition, some of these tools are necessary in primary care practice, where prescribing psychoactive drugs may not occur routinely.

Delivery system enhancements to improve prescribing include increasing the quality and availability of psychotherapy services as an alternative to psychoactive medications.

Academic outreach with specialists or primary care physician opinion leaders used in some states can be highly effective at changing prescribing practices (32, 36–38). Unfortunately, such an approach requires review of individual prescribing decisions by trained peers, either in one-on-one arrangements or in small groups, and thus is very expensive.

System-Level Interventions

Because the approaches to individual clinicians noted above are expensive and inconsistently effective, policy makers have looked for system-level interventions to address questionable prescribing. These system-level policies generally fall into three categories: delivery system enhancements, clinician prescribing enhancements, and monitoring programs.

Delivery system enhancements

Delivery system enhancements to improve prescribing include increasing the quality and availability of psychotherapy services as an alternative to psychoactive medications. For ADHD (3) and many externalizing behaviors (39, 40), psychotherapy or behavioral services are recommended as first-line treatments with or without medications. However, inadequate supply and perceived cost and stigma barriers preclude their common use (9). In addition, delivery system enhancements include electronic health record reminders, increased care coordination for families, and cross-sector (e.g., foster care and behavioral health) collaboration. Making alternative treatments more accessible to patients and prescribing clinicians is part of the underlying premise in the current National Institute of Mental Health contract, Safer Use of Antipsychotics for Youth (SUAY) (41), being conducted as a randomized trial in five large health systems across the country. The intervention employs a best-practice alert for prescribers, care navigators for families, and rapid access to therapists on site or by video conference, all linked in a coordinated program. SUAY also incorporates a postprescribing consultation with an expert clinician for prescribers. Results of the trial are expected in early 2021.

Clinician prescribing enhancements

Clinician prescribing enhancements for psychoactive medications include standardizing treatment and emphasizing the value of shared decision making between providers and caregivers. For example, efforts involving antipsychotic prescribing and antidepressant prescribing have been organized by states and provider groups. These include Minds Matter (42), which is focused on antipsychotics; and Guidelines for Adolescent Depression in Primary Care (GLAD-PC-II), which provides guidance on managing adolescent depression in primary care, which is endorsed by the AAP. The American Academy of Child and Adolescent Psychiatrists and BEST, a compilation of best practices by Cincinnati Children's Medical Center, have similar depression guidelines, both recommending medication (selective serotonin reuptake inhibitors) or psychotherapy for depression. Guidelines from the United Kingdom suggest sequencing of medication and psychotherapy, and the National Institute for Health Care and Excellence urges providers to consider combined therapy (fluoxetine and psychological therapy) for initial treatment of moderate to severe depression among young people (ages 12–18) (43).

There are fundamental gaps in understanding how to implement such guidelines, including how to support clinicians most effectively in following the algorithms and how to increase access to psychosocial primary treatments that most of the existing guidelines recommend as part of first-line treatment (in addition to medications other than antipsychotics). New algorithms, however, are likely to be ignored without targeted implementation strategies (44–51) that include attention to challenges of changing prescribing practices addressed in the academic-detailing literature (36, 52–58).

One form of support with growing evidence for short-term clinician behavior changes is the use of large collaboratives for improving the quality and safety of pediatric care, such as Children's Hospital's Solutions for Patient Safety (59). Collaboratives have been shown to decrease inappropriate prescribing of both ADHD stimulant medication and antipsychotics in pediatric networks (42). It is less clear whether changes resulting from clinician prescribing enhancements can be sustained over the long term. In other words, when the enthusiasm for the quality collaborative ends or when it changes topics, will practices revert to prior patterns of prescribing? It is also unclear whether learning collaboratives, which can be expensive, are preferable to targeted consultation by experts in the content area (60).

Elective psychoactive consultation is sometimes considered an alternative to large collaboratives as a form of delivery system enhancement. The use of psychiatrist "second opinion" consultations is a middle alternative between academic outreach and retrospective claims monitoring. Consults can be low cost (conducted by phone or staff message) and yet allow the prescribing clinician to review the clinical rationale for the prescription and get support from a colleague. Using a peer-to-peer model, prescribing clinicians consult with on-call specialists provided across regions or networks addressing not only prescribing but system management and referrals. The best known of these models is the Massachusetts Child Psychiatry Access Project, which has yielded promising results, although a substantial infusion of state funds has been required to support the model (61, 62).

The use of psychiatrist "second opinion" consultations is a middle alternative between academic outreach and retrospective claims monitoring.

A reduction in potentially inappropriate prescribing from 29% to 12% among participating pharmacists was a larger change than found in previous studies of physician prescribing.

Monitoring programs

The most studied policy approaches to decreasing inappropriate prescribing are state or insurance programs that monitor prescribing either retrospectively or prospectively. The former refers to drug utilization review programs, whereby postprescription records are reviewed to identify trends in patterns suggestive of inappropriate prescribing (63, 64). Prescribing clinicians are notified about their overall patterns and often about specific patients who appear to have been prescribed medications that are contraindicated or likely inappropriate. Retrospective drug utilization review has a mixed record in studies (65). It can have modest effects in reducing inappropriate prescribing, although there are few studies related to pediatric psychoactive prescribing. In addition, it is less effective than concurrent drug utilization review, when compared head to head. A recent alternative to drug review of prescribers is drug utilization review for dispensing pharmacists. A reduction in potentially inappropriate prescribing from 29% to 12% among participating pharmacists was a larger change than found in previous studies of physician prescribing (66).

Peer review programs or oversight by other clinicians is also effective for child psychoactive medications. One of the best known such programs for child psychiatry is the Partnership Access Line (PAL) and Second Opinion program operated for the Washington State Medicaid program.

Prospective monitoring programs include prior authorization policies in combination with or without mandatory peer review. Prior authorization is the preapproval of care to the prescribing clinician by a payer agent for the use of expensive forms of care (67–69). Prior authorization for child psychiatry has negative connotations for many clinicians, who report large number of hours and staff to deal with prior authorizations for child psychoactive medications. In one report, child psychiatrists reported annual costs of more than $80,000 per clinician for addressing prior authorization requirements. Nevertheless, it appears to be modestly effective in reducing prescribing of some agents (70) and for improving overall implementation of antipsychotic prescribing guidelines (71). However, prior authorization policies can increase the prescribing of agents that are not on the prior authorization lists, because clinicians often seek to prescribe agents that have a lower administrative burden for their practices. This is called the spillover effect.

Peer review programs or oversight by other clinicians is also effective for child psychoactive medications. Probably the best known such program for child psychiatry is the Partnership Access Line (PAL) and Second Opinion program operated for the Washington State Medicaid program. Implementation of this program in Washington resulted in a 50% reduction in antipsychotic medication use among Medicaid-insured youths over its first 4 years. Second-opinion reviews have generated a 51% decrease in outlier ADHD stimulant medication prescribing, coupled with a 10:1 return on investment (72). PAL differs from MCPAP and other programs in its narrower focus on specific prescriptions rather than broad management and referrals of patients. Similar peer consultation programs were shown to be effective in other settings (73, 74). In its current form, the Washington State program requires an outpatient pharmacist to hold a prescription awaiting Medicaid authorization for an antipsychotic outside an established state guideline until there is documentation of a consultation between the prescribing provider and a child psychiatrist. Providers can also electively reach out to the team's consultants via the PAL service line to discuss best-practice care in a statewide rapid access program staffed by child psychiatrists. Several of these state initiatives for improving psychoactive drug prescribing for children are being examined in an ongoing study funded by the Patient-Centered Outcomes Research Institute; findings are expected to be released in 2020 (75).

The FDA has also intervened in a way that dramatically altered prescribing. In response to a 34-study meta-analysis of efficacy trials focused on child and adolescent antidepressant use, the FDA concluded that adolescents who were prescribed newer antidepressants had an uncommon but significantly increased risk of suicidal behavior and issued a black box warning. Antidepressant prescribing for adolescents dropped by 60% while adult prescribing changed little. Clinicians who were aware of the warning reported altering their prescribing practices (76, 77). The concerns resulting from the FDA's black box warning have been tempered by the finding of Gibbons et al. (78) of no significant effects of antidepressant treatment on suicidal thoughts and behaviors. This result was from a reanalysis that used longitudinal suicidal event data from a sample of 708 youths across published and unpublished placebo-controlled randomized controlled trials of fluoxetine. No evidence of increased suicide risk was observed among youths receiving active medication (versus placebo), and depression responded to treatment.

6 Innovations That Might Improve Appropriateness of Prescribing

Current U.S. pharmaceutical and healthcare systems encourage the use of psychoactive medications and are opaque about the overall costs and incentives among the various players, which include rebates to Medicaid agencies and managed care organizations, profits among pharmacy benefit managers that exceeded those of health insurers in the past few years, and incentives to specialty physicians for trying new agents. For example, numerous states contract with pharmacy benefit managers to receive rebates for the use of psychiatric drugs that may or may not be the best value for children. Some policies have been proposed but not tested that might influence this complex system, such as transparency in prices and incentives among insurers, public agencies, and pharmacy benefit managers. Similarly, direct negotiations between state Medicaid agencies and drug manufacturers, as has already been done by the U.S. Department of Veterans Affairs, might also greatly reduce costs and inappropriate incentives. Finally, the spread of value-based purchasing and specifically value-based payment for medications appears to be a promising avenue (79). Payment for value (outcomes related to costs) would focus less on high-cost medications and more on changes in outcome for dollars spent.

Of course, no thoughtful piece on children would be complete without discussion about preventive interventions. The explosion of promotion and prevention science for child and adolescent disorders over the past 2 decades means that there are now multiple evidence-based programs that decrease the overall need for psychotropic medications when such programs are put in place. Evidence that parent training, a well-documented preventive intervention, reduces the dosage of medication needed for children with serious behavior problems suggests that targeted preventive or psychosocial interventions can both improve children's outcomes and reduce the need for medication treatments (80). However, targeted and high-fidelity implementation of these interventions is needed to achieve the desired effect. Current evaluations are examining whether a corresponding reduction in medication use is also occurring. The advent of alternative therapies, preventive interventions, and psychosocial supports to reduce the dosage of and need for medications needs further examination, but these approaches to the problem of questionable prescribing of psychoactive medications for children are promising.

Evidence that parent training, a well-documented preventive intervention, reduces the dosage of medication needed for children with serious behavior problems suggests that targeted preventive or psychosocial interventions can both improve children's outcomes and reduce the need for medication treatments.

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