Antipsychotic Use in Children Twelve and Under – Do the Benefits Outweigh the Risks? A Review of the Literature

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Abstract

Antipsychotic medications are widely used in adult psychiatry, yet their use in children, particularly those aged twelve and under, raises serious clinical and ethical concerns. While some antipsychotics are approved for specific pediatric conditions such as early-onset schizophrenia, the majority of prescriptions in this age group are for off-label uses to target behavioral symptoms such as irritability, aggression, and hyperactivity. Evidence regarding safety, efficacy, long-term outcomes, and optimal dosing in young children remains limited. This literature review examines recent research on prescribing trends, efficacy, safety, monitoring practices, and potential benefits of antipsychotic use in children aged twelve and under. Findings highlight high rates of off-label prescribing, limited evidence for behavioral symptom management, and significant risk of metabolic, neurological, and cardiovascular adverse effects. Inadequate guideline-based monitoring, poor follow-up, and insufficient patient and family education further compound the potential for harm. Despite these concerns, short-term, closely-monitored use has been shown to provide benefit in exceptional cases. The review concludes that antipsychotic prescribing in young children should prioritize non-pharmacologic interventions, with medications being reserved for situations where the potential benefits clearly outweigh the substantial risks, and emphasizes the need for improved monitoring, education, and age-specific research to support safer, evidence-informed practice. .

Introduction

Antipsychotic medications play an important role in psychiatric treatment in adults, but their use in children, particularly those aged twelve and under, raises significant clinical and ethical concerns. While these medications are approved for some pediatric conditions such as early-onset schizophrenia, the majority of pediatric prescriptions are for off-label indications, including behavioral disorders, irritability, and aggression. Evidence about the safety, efficacy, and long-term outcomes of antipsychotic use in this population remains limited and children are especially vulnerable to the broad side-effect profile these medications carry (Hoekstra & Dietrich, 2022; Radojčić et al., 2023). Additionally, significant gaps in clinical monitoring, follow-up care, and patient and family education compound the potential for iatrogenic harm. This literature review examines the prescribing trends, efficacy, safety, monitoring practices, and potential benefits of antipsychotics in children aged twelve and under, arguing that, due to these risks and limitations, the therapeutic gain of these medications is often outweighed by the potential for harm.

Methods

This comprehensive literature review was conducted between September 16, 2025 and October 22, 2025. Electronic searches were completed using the following databases: (a) CINAHL, (b) PubMed, (c) PsycINFO, (d) Google Scholar, and (e) MacEwan University online library. A

preliminary review of abstracts was used to identify relevance to the research topic. Key search terms included: (a) antipsychotics, (b) children, (c) safety, (d) off-label, (e) efficacy, (f) alternatives, and (g) risk.

As research on pediatric antipsychotic use is rapidly evolving, priority was given to international literature published within the last five years. Sources were included if they examined antipsychotic prescribing trends, safety, efficacy, side effects, or clinical monitoring in children, with priority given to those focused specifically on children aged twelve and under. Sources were excluded if they focused solely on adult populations or did not discuss antipsychotic use in pediatric mental health contexts.

Results

Twenty-three total sources were included in this literature review. Of these, twenty sources published between 2020 and 2025 were reviewed and analyzed. These sources included seven quantitative analyses, five systematic reviews, three cross-sectional studies, one literature review, one critical review, one narrative review, one clinical reference overview, and one editorial. Two international studies and two multicenter European studies were included. In addition, four sources originated from the United States, two from Australia, two from the United Kingdom, two from France, one from Canada, one from Ireland, one from Turkey, one from Portugal, one from Italy, and one from India. The review also included three documents utilized for definitions and additional context. This included a clinical practice guideline from Canada (Pringsheim et al., 2011); an educational resource from the United States (National Alliance on Mental Illness [NAMI], 2025); and a public-information summary about the off-label use of medications from Germany (Institute for Quality and Efficiency in Health Care [IQWiG], 2022).

Antipsychotic Medications

Antipsychotics are a class of medications widely used in psychiatry to treat a range of mental health disorders. They are typically divided into two categories: first-generation (typical) antipsychotics, which act as dopamine receptor antagonists, and second-generation (atypical) antipsychotics, which act as serotonin-dopamine antagonists (Chokhawala & Stevens, 2023). These medications carry a broad side-effect profile, most notably extrapyramidal symptoms (EPS), which are movement-related symptoms that include involuntary muscle contractions, stiffness, and tremors (Chokhawala & Stevens, 2023). While first-generation antipsychotics are associated with significant EPS, second-generation antipsychotics have a lower EPS risk and are prescribed far more often, especially in the pediatric population (Chokhawala & Stevens, 2023). As such, this paper focuses specifically on second-generation (atypical) antipsychotic use in children aged twelve and under.

Indications

Clinical indications for antipsychotics include acute psychosis, schizophrenia and schizoaffective disorders, substance-induced psychotic disorders, acute mania, and major depressive disorder with psychotic features (Chokhawala & Stevens, 2023). Additionally, these medications are frequently prescribed for off-label uses. Off-label use refers to prescribing a medication for a population or condition that has not been approved by regulatory authorities (IQWiG, 2022).

Some off-label uses for antipsychotics include Tourette disorder and dementia (IQWiG, 2022). Given the limited regulatory approval of these medications for pediatric use in Canada, the majority of prescriptions in this population are considered off-label (Verdoux, 2025).

Side Effect Profile

Antipsychotic medications carry a broad side-effect profile with the potential to cause major metabolic, neurological, and cardiovascular complications with chronic use (Singappuli et al., 2022). Most notably, second-generation antipsychotics are associated with significant weight gain and the development of metabolic syndrome (Chokhawala & Stevens, 2023). Though less than that of first-generation antipsychotics, second-generation antipsychotics still contain risk for EPS and other neurological side effects (Chokhawala & Stevens, 2023).

Prescribing Trends

Most antipsychotics do not have approval for use in children and adolescents due to limited evidence about their safety, particularly for long term use (Lambert et al., 2018; Radojčić et al., 2023). Additionally, many of the conditions that these medications are typically indicated for, such as schizophrenia, are far less common in younger populations, with typical onset occurring in early adulthood (NAMI, 2025). Even for the few antipsychotic medications that do have approved pediatric indications, such as for early-onset schizophrenia, they are still more often being prescribed for entirely different purposes (Driscoll & McCarthy, 2024; Verdoux, 2025).

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Off-Label Use

Regardless of location, study type, or methodology, the literature consistently revealed that the vast majority of antipsychotic prescriptions in children and adolescents are for off-label uses (Driscoll & McCarthy, 2024; Taurines et al., 2025; Verdoux, 2025). In clinical practice, these medications are most often prescribed to youth to target specific behavioral symptoms, the most common being agitation and irritability, rather than for specific conditions like psychosis (Driscoll & McCarthy, 2024). The most common diagnoses associated with pediatric antipsychotic prescribing are behavioral disorders such as oppositional defiant disorder (ODD) and conduct disorder, followed by behavioral challenges related to autism spectrum disorder (ASD), intellectual disability, and attention deficit/hyperactivity disorder (ADHD) (Çakır et al., 2021; Driscoll & McCarthy, 2024). This demonstrates that the high rate of off-label antipsychotic prescribing in pediatrics is not only because of age, but because the indications themselves fall outside approved uses. Off-label use accounts for up to 92% of second-generation antipsychotic prescribing in children, with this rate of off-label use roughly equal between age groups both above and below twelve years old (Taurines et al., 2025). At least two-thirds of children and

adolescents receiving these medications have no approved indication for them at all (Verdoux, 2025).

A major issue raised by these prescribing practices is the exposure of youth with unapproved indications to medications that are known to carry substantial risks. Additionally, the symptoms that are most often being targeted, such as irritability, are subjective, context-dependent, and poorly defined. While such symptoms may be attributable to specific disorders such as ASD, the literature suggests that they more often reflect underlying relational, developmental, and environmental stressors that young children have difficulty expressing (Hoekstra & Dietrich, 2022). Instead of addressing these root causes, the child's behavioural response is being pathologized and medicated. Antipsychotics are therefore being used primarily as behaviour-management tools rather than treatments for clearly established psychiatric diagnoses, which intensifies concerns about risk, appropriateness, and long-term impact.

Efficacy

Despite behavioural symptoms being the primary reason antipsychotics are prescribed to children, evidence supporting their effectiveness for this purpose remains limited (Bushnell et al., 2021; Hoekstra & Dietrich, 2022). Psychosocial and behavioral interventions, especially those involving both the child and their parents, remain the most effective and appropriate first-line treatments for behavioural concerns in children aged twelve and under (Rajkumar, 2022). Once these interventions have been optimized, combining them with the short-term use of antipsychotic medication has been shown to help improve outcomes for difficult-to-treat patients in some cases (Sanfins et al., 2025; Singappuli et al., 2022). However, the use of antipsychotics extending beyond approximately 8-12 weeks is not associated with improved outcomes or effective prevention of a relapse of symptoms (Singappuli et al., 2022). Additionally, long term use is associated with increased risk, including worsening side effects and reduced quality of life (Radojčić et al., 2023; Singappuli et al., 2022). Long-acting antipsychotics, such as depot injections, show low efficacy in the pediatric population and their ability to tolerate these medications is much lower than adults (Benarous et al., 2022).

An additional concern is, due to the fact that the vast majority of pediatric antipsychotic prescriptions are off-label, there is limited evidence to guide age-specific pharmacokinetics and optimal pediatric dosing (Radojčić et al., 2023; Taurines et al., 2025). This increases the likelihood of suboptimal dosing, medication intoxication, ineffective treatment, and adverse drug reactions. These challenges directly impact the overall effectiveness of these medications, especially for children aged twelve and under, as the way antipsychotics are metabolized, absorbed, and tolerated in pediatric populations remains inadequately understood (Taurines et al., 2025). The lack of evidence supporting effectiveness in treating behavioral symptoms as well as concerns about proper pediatric dosing raises concerns about the ability of antipsychotics to reliably provide enough therapeutic value for children to justify the risk.

Side Effects

In addition to limited effectiveness, there is very strong evidence of iatrogenic harm caused by antipsychotic medication prescribed to children and adolescents (Mead et al., 2021). A large

portion of this is due to the broad side-effect profile that these medications carry, which includes metabolic, neurological, and cardiovascular complications (Singappuli et al., 2022). In children, the risk of serious adverse drug reactions was not significantly different between using antipsychotics off-label versus on-label (Egberts et al., 2022; Verdoux, 2025). Though this is reassuring, the question remains about the necessity of children being prescribed these medications for certain off-label uses at all, or if this risk could be eradicated altogether through the use of alternative therapeutic interventions.

Metabolic Effects

Second-generation antipsychotics are consistently associated with significant weight gain and the development of metabolic syndrome, a group of conditions that increase the risk of heart disease, stroke, and type 2 diabetes mellitus (Chokhawala & Stevens, 2023; Man et al, 2022). Concerningly, children and adolescents are particularly vulnerable to these effects, experiencing faster weight increases than adults as well as more pronounced lipid and glucose abnormalities (Çakır et al., 2021; Klau et al., 2025). There has been a large association found between second-generation antipsychotics and the development of type 2 diabetes mellitus in children taking these medications for longer than twelve months (Solmi et al., 2020). Additional endocrine and cardiometabolic complications, including dyslipidemia, hyperprolactinemia, hyperlipidemia, hyperglycemia, and prolonged QT interval are also well documented (Çakır et al., 2021; Chokhawala & Stevens, 2023; Klau et al., 2025; Man et al., 2022; Singappuli et al., 2022). Given the significant metabolic impact they have on children, there is growing concern that antipsychotics can subject children to lifelong health problems and even premature mortality (Klau et al., 2025).

Neurological Effects

Neurological side effects, including EPS and movement disorders, are also well-documented in pediatric populations (Solmi et al., 2020). They also carry the risk of the rare but fatal adverse effect called neuroleptic malignant syndrome (Chokhawala & Stevens, 2023). Antipsychotic use can put children at up to a four time increased risk of seizures, with this risk increasing with polypharmacy (Hoekstra & Dietrich, 2022). Sedation is also commonly associated with these medications, contributing to reduced alertness, blunted emotional responsiveness, and functional impairment in daily life (Singappuli et al., 2022; Solmi et al., 2020).

Emotional, Social, and Quality-of-Life Impacts

Beyond the physical risks, antipsychotic side effects also carry significant impacts for children's emotional wellbeing and social functioning. Antipsychotic induced weight gain places children at an increased risk of stigma, bullying, and negative educational outcomes (Mead et al., 2021). As a result, it is also considered a risk factor for mental illness. Additionally, because of their activity on dopamine pathways, antipsychotics are associated with decreased pleasure, motivation, and reward, a significant side effect that is difficult to measure and quantify but frequently reported as a reason for medication noncompliance/discontinuation (Singappuli et al., 2022). While sedation and blunted affect may reduce behavioural symptoms like irritability, this raises serious concerns about the broader cost to a child's emotional development and overall quality of life.

Safety

In addition to limited evidence about effectiveness and the risk of a broad range of side effects, there is also a concerning lack of evidence supporting the overall safety of antipsychotics in children (Bushnell et al., 2021). Though safety evidence has been growing in recent years, it still remains inadequate (Solmi et al., 2020). In children aged twelve and under, antipsychotic use alone does not appear to increase premature mortality (Ray et al., 2024). However, higher cumulative doses in young adults is linked to increased mortality risk, echoing concerns about the long-term implications of antipsychotic exposure that begins in childhood.

Prescribing Setting

Children admitted to an inpatient psychiatric unit are more likely to be prescribed antipsychotics for off-label uses, even if the severity of their symptoms is the same as their outpatient peers (Taurines et al., 2025). As symptom severity was not determined to be a contributing factor, the higher inpatient prescribing rate suggests that these medications are being used to manage children's behaviour rather than to treat more severe clinical presentations. The inconsistency between inpatient and outpatient prescribing and the pathologization of children's behavioral symptoms highlights the continued risk of iatrogenic harm with these medications. If patients are to be prescribed antipsychotics in an inpatient setting, it is important that they are connected with strong follow-up after discharge to ensure medication safety and effectiveness.

Continuity of Care

Inadequate Monitoring

If the benefits are considered to outweigh the risks and children are prescribed antipsychotics, close and ongoing monitoring is essential. Clinical guidelines such as the Canadian Alliance for Monitoring Effectiveness and Safety of Antipsychotics in Children (CAMESA) guideline have been developed to provide clear standards for the type and frequency of monitoring required to ensure safety for children being prescribed antipsychotics (Pringsheim et al., 2011).

Even with the development of tools such as the CAMESA guideline, the research consistently shows that recommended monitoring is often being insufficiently met in practice (Hoekstra & Dietrich, 2022). Despite children being particularly vulnerable to the metabolic effects of antipsychotics, rates of cardiometabolic monitoring by physicians remain far below guideline recommendations (Çakır et al., 2021; Klau et al., 2025; Mead et al., 2021). Concerningly, children aged twelve and under have an even lower likelihood of being monitored according to guidelines than their adolescent peers (Mead et al., 2021). Clinicians report high awareness of the risks associated with antipsychotics, therefore the reasons for poor adherence to guideline-based monitoring are unrelated to a lack of awareness or education (Mead et al., 2021).

The consequences of inadequate monitoring are significant. Children are often prescribed antipsychotics without structured follow-up, increasing the likelihood that they remain on these medications longer than recommended and increasing their exposure to preventable adverse effects. This risk is compounded for children in the inpatient setting, who are more likely to be started on antipsychotics and subsequently discharged to the community without sufficient

follow-up or access to adjunct psychosocial interventions (Rajkumar, 2022). Without proper monitoring and oversight, children are placed at an increased risk of ineffective treatment, adverse drug reactions, and a trajectory of harm that could have been prevented with appropriate clinical oversight.

Community Resources

Evidence supports the shortest effective duration of antipsychotic treatment in combination with psychosocial and behavioral interventions, along with close community monitoring (Rajkumar, 2022; Sanfins et al., 2025; Singappuli et al., 2022). However, even in high-income countries, up to 70% of children and adolescents on antipsychotics do not receive the psychosocial interventions they need (Rajkumar, 2022). Additionally, accessibility is a significant concern. Many of the environmental and social factors that place children at greater risk for developing behavioral disorders, such as low socioeconomic status, parental criminality, parental substance use, and placement in foster care, also pose barriers to engagement in effective psychosocial treatments (Bushnell et al., 2021; Rajkumar, 2022).

Patient and Family Education

Another major concern for prescribing children antipsychotics is evidence of a gross lack of awareness amongst patients and their families about why these medications are being prescribed and the associated risks (Hoekstra & Dietrich, 2022; McLaren et al., 2022). Caregivers frequently report seeking out information regarding side effects outside of clinical encounters, highlighting concern that patient/family education being provided during appointments is inadequate or inconsistent (McLaren et al., 2022). This gap in education has significant clinical implications. Due to a lack of education and follow-up, many caregivers consider stopping their children's antipsychotics on their own, raising concern about unsafe discontinuation in the community (McLaren et al., 2022). Additionally, for children who may benefit from the short-term use of antipsychotics, limited availability of safety data and education about these medications contributes to treatment delays or outright refusal by patients and their families (Solmi et al., 2020). Inadequate education, poor follow-up, and limited safety data place families in a difficult position of making decisions about high risk medications without the information and support that they need to effectively weigh the risks and benefits.

Benefits to Use

It is important to recognize that off-label prescribing is not inherently unethical, but the literature consistently highlights safer and more effective ways to use these medications to minimize iatrogenic harm and maximize therapeutic benefit.

Short Term Treatment

Antipsychotic medication in children can be effective for short-term management of behavioral symptoms like aggression when other treatment options have been exhausted (Sanfins et al., 2025; Singappuli et al., 2022). These medications are most effective when used in conjunction with psychosocial and behavioral interventions, and can serve as a bridge until these interventions are fully implemented and therapeutic engagement has begun (Hoekstra & Dietrich, 2022; Sanfins et al., 2025). When appropriately combined with evidence-based

approaches, short-term antipsychotic use can drastically improve outcomes for otherwise difficult-to-treat patients (Sanfins et al., 2025). Although risks remain, the potential benefits of carefully monitored, time-limited use should not be overlooked in cases where behavioral symptoms pose a serious strain on children and families and other treatment options have failed.

Alternative Interventions

If clinically necessary and carefully monitored, short-term use of antipsychotics should be combined with psychosocial and behavioral interventions to provide better outcomes (Hoekstra & Dietrich, 2022; Sanfins et al., 2025). Many alternative interventions have demonstrated success in the literature, including structured parent management training (PMT), cognitive behavioral therapy (CBT), school-based behavioural supports, and home-based behavioural interventions (Hoekstra & Dietrich, 2022; Rajkumar, 2022). PMT, in particular, has strong empirical support for reducing aggression and oppositional behaviours by equipping caregivers with consistent, developmentally appropriate behavioural management strategies. These interventions focus on modifying environmental triggers, strengthening caregiver-child attachment, and reinforcing adaptive behaviours rather than suppressing symptoms pharmacologically. However, a significant concern for many families is the availability, accessibility, and cost of these services, as well as challenges with engagement and compliance. For families facing these barriers, short-term medication may sometimes represent the only feasible option for managing behavioral symptoms (Rajkumar, 2022).

Benefits for Exceptional Cases

In certain exceptional cases, where all other evidence-based interventions have been exhausted or engagement with them is not realistic, antipsychotics may provide a beneficial option (Hoekstra & Dietrich, 2022). This can include situations such as severe aggression or violence related to non-verbal ASD where behavioral interventions alone are often insufficient (Driscoll & McCarthy, 2024; Hoekstra & Dietrich, 2022). In these carefully considered cases, short-term antipsychotic use can be necessary to manage acute risks and support safety for the child and their family.

Discussion

The findings of this comprehensive literature review highlight the complex balance between the potential benefits and significant risks associated with antipsychotic use in children aged twelve and under. While these medications can provide short-term symptom relief in exceptional cases, the overwhelming evidence suggests that off-label prescribing for behavioral symptoms is pervasive and often replaces evidence-based psychosocial interventions that address underlying developmental, relational, or environmental factors. Additionally, the safety concerns associated with these medications are significant. Children in this age group are particularly vulnerable to the metabolic, neurological, and cardiovascular side effects of antipsychotics, including rapid weight gain, metabolic syndrome, sedation, and movement disorders. Beyond physical risks, antipsychotic use can negatively impact emotional development, social functioning, and quality of life, contributing to stigma, reduced motivation, and social withdrawal.

Continued concerns are raised about current prescribing practices that are often influenced by systemic factors rather than clinical need. Children in inpatient settings receive antipsychotics more frequently despite having similar symptom severity to outpatient populations, suggesting that these medications are being used as behavior management tools rather than as targeted therapeutic interventions. The literature also identifies substantial gaps in monitoring and follow-up care, with children under twelve being even less likely than adolescents to receive guideline-based monitoring. Additionally, patients and their families are identified as having a gross lack of awareness about these medications, their use, and the potential for adverse effects.

Despite these significant concerns, antipsychotics have been shown to have benefits and their support in exceptional cases where children exhibit severe aggression, safety risks, or treatment-resistant behavioral symptoms should not be overlooked. Importantly, the literature emphasizes that time-limited use paired with appropriate monitoring and supportive interventions can maximize therapeutic outcomes and minimize harm. Overall, this comprehensive literature review highlights the need for cautious, evidence-informed prescribing in young children, with non-pharmacologic interventions being prioritized and antipsychotic use being reserved for cases where the potential benefits clearly outweigh the serious and well-documented risks.

Recommendations

To ensure safer and more accountable use of antipsychotics in young children, the following recommendations highlight important ways that these medications can be used to limit harm in this population. Evidence consistently supports non-pharmacologic interventions as first-line treatments for behavioral symptoms. Antipsychotics should only be considered after these interventions have been fully implemented and optimized. In order to effectively implement and optimize these interventions, clinicians and policymakers must work to improve equitable access to evidence-based psychosocial and behavioral interventions, especially for children in foster care, low-income households, and families with complex social stressors, to reduce reliance on pharmacologic treatments.

When medication is necessary, it should be prescribed for the shortest effective duration, ideally in combination with psychosocial interventions, and only in carefully considered situations where behavioral symptoms pose significant risks or functional impairment. Families should receive clear, consistent information about the purpose, risks, benefits, and expected outcomes of antipsychotic treatment. This education should include guidance on adherence, monitoring, and recognizing adverse effects to prevent unsafe discontinuation. Children prescribed antipsychotics require rigorous adherence to guideline-based monitoring, including metabolic, neurological, and cardiovascular assessments, with frequent follow-up in the community. Special attention should be given to children under twelve, who are less likely to receive adequate monitoring and may be more vulnerable to the adverse effects of antipsychotics. Lastly, further studies on age-specific pharmacokinetics, long-term efficacy, and the safety of antipsychotics in children aged twelve and under are essential to help inform evidence-based practice and minimize iatrogenic harm. By implementing these

recommendations, clinicians can better balance the therapeutic benefits of antipsychotics against their substantial risks, ensuring safer and more effective care for young children.

Suggestions for Future Research

There remains a significant gap in long-term safety data for antipsychotic use in children aged twelve and under, and much of the existing research combines them with adolescents despite clear developmental differences. Future studies should focus on independently examining how younger children absorb, metabolize, and respond to antipsychotic medications. This could include weight-based dosing research, developmental pharmacokinetics, and how these factors affect toxicity, adverse effects, and therapeutic benefit. Longitudinal studies are also essential to understand how chronic antipsychotic exposure influences children's health and development into adolescence and adulthood.

Although most current research focuses on objective adverse effects, there is a significant gap in understanding subjective factors of antipsychotic use. There is limited current research available on how young children and their families actually experience pediatric antipsychotic use and perceive changes in quality of life, daily functioning, and overall happiness. Qualitative research in this area could strengthen ethical guidance, highlight harms that are generally invisible in quantitative data, and inform more patient and family-centered prescribing practices.

Lastly, future research should also investigate why inpatient settings consistently show disproportionately high prescribing rates despite similar symptom severity to outpatient populations. This includes examining clinical decision-making, systemic pressures, and other factors that may influence prescribing trends to identify ways to reduce unnecessary use. Additionally, children who are more likely to receive antipsychotics, such as those living in poverty or the foster care system, often have the least access to psychosocial interventions. Research should focus on how to implement, adapt, and scale evidence-based psychosocial interventions for underserved groups to reduce inequities and reliance on medication.

Conclusion

A comprehensive review of current literature makes it clear that antipsychotic use in children aged twelve and under remains a high-risk, low-evidence practice. While these medications can offer short-term relief for some exceptional cases, the vast majority of prescriptions in this population continue to be off-label for behavioural symptoms that are better addressed through psychosocial interventions. Across all the literature, there are continued themes of limited evidence for long-term safety or efficacy, high rates of iatrogenic harm, poor continuity of care, and significant gaps in monitoring and education. These concerns are especially pronounced in younger children, who metabolize medications differently, experience more severe adverse effects, and are less likely to receive guideline-based follow-up. In conclusion, the current available research suggests that the potential therapeutic benefits rarely outweigh the substantial risks for the use of antipsychotics in children aged twelve and under.

Despite these challenges, it is important to note that the literature also reinforces that antipsychotics can be beneficial when used short-term while supported by close monitoring and

additional psychosocial interventions. The goal is not to eliminate antipsychotic use entirely, but to ensure that it is being used appropriately for cases where the significant risks can be justified and mitigated. Moving forward, improving access to evidence-based psychosocial interventions, strengthening patient and family education, and investing in age-specific research are essential to reducing unnecessary exposure to these medications. Ultimately, safer prescribing practices require the prioritization of children's long-term wellbeing over short-term symptom management and an understanding of the profound impact that early pharmacologic interventions can have.

References

Benarous, X., Cottin, G., Lahaye, H., De La Rivière, S. G., Guilé, J.-M., Speranza, M., Bonnot, O., & Cohen, D. (2022). Efficacy, tolerability, and acceptance of long-lasting antipsychotics in children and adolescents: A systematic review. *Journal of Child and Adolescent Psychopharmacology*, *32*(6), 312–327.https://doi.org/10.1089/cap.2021.0124

Bushnell, G. A., Crystal, S., & Olfson, M. (2021). Trends in antipsychotic medication use in young privately insured children. *Journal of the American Academy of Child & Adolescent Psychiatry*, *60*(7), 877–886. https://doi.org/10.1016/j.jaac.2020.09.023

Çakır, B., Yalın Sapmaz, Ş., & Kandemir, H. (2021). Use of antipsychotics: The experiences, views, and monitoring practices of child and adolescent psychiatrists in Turkey. *Journal of Child and Adolescent Psychopharmacology*, *31*(1), 73–78. https://doi.org/10.1089/cap.2020.0078

Chokhawala, K., & Stevens, L. (2023, February 26). Antipsychotic medications. In *StatPearls*. StatPearls Publishing. https://www.ncbi.nlm.nih.gov/books/NBK519503/

Driscoll, D. J. O., & McCarthy, S. (2024). Antipsychotic prescribing: National findings of children and adolescents attending mental health services in Ireland. *European Child & Adolescent Psychiatry*, *33*(11), 3861–3870. https://doi.org/10.1007/s00787-024-02428-4

Egberts, K. M., Gerlach, M., Correll, C. U., Plener, P. L., Malzahn, U., Heuschmann, P., Unterecker, S., Scherf-Clavel, M., Rock, H., Antony, G., Briegel, W., Fleischhaker, C., Häge, A., Hellenschmidt, T., Imgart, H., Kaess, M., Karwautz, A., Kölch, M., Reitzle, K., … Romanos, M. (2022). Serious adverse drug reactions in children and adolescents treated on- and off-label with antidepressants and antipsychotics in clinical practice. *Pharmacopsychiatry*, *55*(5), 255–265. https://doi.org/10.1055/a-1716-1856

Hoekstra, P. J., & Dietrich, A. (2022). First do no harm: Use off-label antipsychotic medication in children and adolescents with great caution. *European Child & Adolescent Psychiatry*, *31*(1), 1–3. https://doi.org/10.1007/s00787-022-01950-7

Institute for Quality and Efficiency in Health Care (IQWiG). (2022). In brief: "Off-label use": What to be aware of. In *InformedHealth.org*. https://www.ncbi.nlm.nih.gov/books/NBK279351/

Klau, J., Gonzalez-Chica, D., Raven, M., Aboustate, N., & Jureidini, J. (2025). Cardiometabolic monitoring in children and adolescents prescribed antipsychotics in Australian primary care, 2011 to 2017. *Australian & New Zealand Journal of Psychiatry*, *59*(9), 824–834. https://doi.org/10.1177/00048674251361696

Lambert, C., Panagiotopoulos, C., Davidson, J., & Goldman, R. D. (2018). Second-generation antipsychotics in children: Risks and monitoring needs. *Canadian Family Physician*, *64*(9), 660–662. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6135131/

Man, K. K. C., Shao, S.-C., Chaiyakunapruk, N., Dilokthornsakul, P., Kubota, K., Li, J., Ooba, N., Pratt, N., Pottegård, A., Rasmussen, L., Roughead, E. E., Shin, J.-Y., Su, C.-C., Wong, I., Kao Yang, Y.-H., & Lai, E. C.-C. (2022). Metabolic events associated with the use of antipsychotics in children, adolescents and young adults: A multinational sequence symmetry study. *European Child & Adolescent Psychiatry*, *31*(1), 99–120. https://doi.org/10.1007/s00787-020-01674-6

McLaren, J. L., Barnett, E. R., Acquilano, S. C., Concepcion Zayas, M. T., Drake, R. E., & Leyenaar, J. K. (2022). Psychotropic polypharmacy and antipsychotics in children: A survey of caregiver's perspectives. *Community Mental Health Journal*, *58*(3), 512–516. https://doi.org/10.1007/s10597-021-00845-2

Mead, L., Ayres, A., Blake, J. A., & Scott, J. G. (2021). Monitoring of metabolic side-effects in children and adolescents prescribed antipsychotic medication: A systematic review. *Australian & New Zealand Journal of Psychiatry*, *55*(8), 763–771. https://doi.org/10.1177/00048674211009620

National Alliance on Mental Illness. (2025). Schizophrenia: Symptoms, causes & treatment. https://www.nami.org/about-mental-illness/mental-health-conditions/schizophrenia/

Pringsheim, T., Panagiotopoulos, C., Davidson, J., Ho, J., & Canadian Alliance for Monitoring Effectiveness and Safety of Antipsychotics in Children guideline group. (2011). Evidence-based recommendations for monitoring safety of second generation antipsychotics in children and youth. *Journal of the Canadian Academy of Child and Adolescent Psychiatry*, *20*(3), 218–233. https://pubmed.ncbi.nlm.nih.gov/21804853/

Radojčić, M. R., Pierce, M., Hope, H., Senior, M., Taxiarchi, V. P., Trefan, L., Swift, E., & Abel, K. M. (2023). Trends in antipsychotic prescribing to children and adolescents in England: Cohort study using 2000–19 primary care data. *The Lancet Psychiatry*, *10*(2), 119–128. https://doi.org/10.1016/S2215-0366(22)00404-7

Rajkumar, R. P. (2022). Antipsychotics in the management of disruptive behavior disorders in children and adolescents: An update and critical review. *Biomedicines, 10*(11), Article 2818. https://doi.org/10.3390/biomedicines10112818

Ray, W. A., Fuchs, D. C., Olfson, M., Patrick, S. W., Stein, C. M., Murray, K. T., Daugherty, J., & Cooper, W. O. (2024). Antipsychotic medications and mortality in children and young adults. *JAMA Psychiatry*, *81*(3), 260-269. https://doi.org/10.1001/jamapsychiatry.2023.4573

Sanfins, N., Andrade, P., & Azevedo, J. (2025). Breaking the stigma: A systematic review of antipsychotic efficacy in children and adolescents with behavioral disorders. *Medicines*, *12*(3), Article 15. https://doi.org/10.3390/medicines12030015

Singappuli, P., Sonuga-Barke, E., & Kyriakopoulos, M. (2022). Antipsychotic long-term treatment in children and young people: A systematic review and meta-analysis of efficacy and tolerability across mental health and neurodevelopmental conditions. *CNS Spectrums*, *27*(5), 570–587. https://doi.org/10.1017/S1092852921000523

Solmi, M., Fornaro, M., Ostinelli, E. G., Zangani, C., Croatto, G., Monaco, F., Krinitski, D., Fusar‐Poli, P., & Correll, C. U. (2020). Safety of 80 antidepressants, antipsychotics, anti‐attention‐deficit/hyperactivity medications and mood stabilizers in children and adolescents with psychiatric disorders: A large scale systematic meta‐review of 78 adverse effects. *World Psychiatry*, *19*(2), 214–232. https://doi.org/10.1002/wps.20765

Taurines, R., Gerlach, M., Correll, C. U., Plener, P. L., Malzahn, U., Heuschmann, P., Scherf-Clavel, M., Rock, H., Briegel, W., Fleischhaker, C., Häge, A., Hellenschmidt, T., Imgart, H., Kaess, M., Karwautz, A., Kölch, M., Reitzle, K., Renner, T. J., Reuter-Dang, S.-Y., … Egberts, K. M. (2025). Off-label drug use in children and adolescents treated with antidepressants and antipsychotics: Results from a prospective multicenter trial. *Child and Adolescent Psychiatry and Mental Health*, *19*(1), Article 110. https://doi.org/10.1186/s13034-025-00957-7

Verdoux, H. (2025). Antipsychotic off-label use in the 21st century: An enduring public health concern. *Dialogues in Clinical Neuroscience*, *27*(1), 1–12. https://doi.org/10.1080/19585969.2025.2449833