Psychiatric Medication & Children in Foster Care

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Summary

Clinical Red Flags

- a child 13-17 is prescribed a 4th psychiatric medication
- a child 9-12 is prescribed a 3rd medication
- a child 6-8 or under is prescribed a 2nd medication
- a child 5 or under is prescribed any medication
- a child is prescribed 2 or more medications at the same time
- A child is prescribed a medication to treat side effects
- a child is prescribed an off label medication without previous trials of approved or safer medications - especially anti-psychotic medications
- a child has gained significant weight or has a BMI 30 or higher
- a child has significant lab abnormalities such as very low ANC while on anti-psychotic medication, elevated TSH while on lithium, or persistent elevated prolactin levels.
- a child of any age is prescribed a second medication in the same class as the child is currently taking (for example, a second anti-psychotic)
- a child is being prescribed Clozapine / Clozaril
- an adolescent or young adult woman being prescribed Depakote
- a child is prescribed medication without first having been treated with and not responded to psychotherapy
- a child who has failed multiple previous medication trials and is being treated by a nurse practitioner at a higher level of care such as in a hospital, residential or day treatment program
- a child is diagnosed with bipolar disorder or adjustment disorder and / or targeted symptoms are primarily behavior and anger

Consent Red Flags

- only one treatment alternative given
- side effects do not include or focus on black box warnings
- no mention of FDA approval or mention if medication is off label
- does not include likelihood of benefit
- does not discuss benefits or risks of alternatives
- parent did not meet of speak with prescriber
- parent has concerns that he or she feels have not been addressed

Background

Approximately 400,000 children in the United States live in the foster care system. Many of them come from communities and families that have inadequate access to education, employment, housing, health care, and social support. As many as 80% of foster children have developmental, learning or mental health problems. Many are exposed to adverse biological and psycho social risk factors that influence their mental, emotional and cognitive development including premature birth, prenatal drug and alcohol exposure, parents with mental illness or substance abuse, high levels of violence in their homes or communities, and child maltreatment: most often neglect secondary to poverty. Placement in foster care subjects children to additional tauma, stress, sadness and pain by disrupting critical attachments to family, friends and community.

It is therefore not surprising that children in placement may experience unhappiness, sadness, worry and anger that are an appropriate, understandable response to the reality of their lives. Their symptoms may be a manifestation of a generalized non-specific reaction to trauma, stress, loss, separation, abuse, neglect or adjustment to foster home or school placements. These states, which are frequently mislabeled as specific psychiatric disorders, may instead reflect attachment or relationship disturbances. Unhappiness is diagnosed as depression; realistic worry as anxiety; understandable anger as bipolar disorder; and non-specific nervousness as attention deficit hyperactivity disorder. The over medicalization of the problems of children in foster care is likely to result in frequent misdiagnosis - labeling of behavioral problems that result from trauma interpersonal difficulties, realistic feelings that are not excessive or out of proportion to the child's real life experiences, or reactions to current life stresses as major psychiatric disorders leading to unnecessary medical treatment. It is not uncommon for children even as young as 5 - 6 years of age to be on multiple medications, as many as 4 -5 at the same time. Most of the medications are not FDA approved for psychiatric usage in children and are not used for the approved indication. Some are not even approved for psychiatric usage in adults. These medications are essentially experimental. Neither efficacy nor safety has been demonstrated. Nor are these treatments benign. I have examined dozens of youngsters who were made so stuporous that they could not learn at school. Others were allowed to gain between 20 - 80 lbs further impairing their already fragile self-esteem and adding additional unnecessary stress. The high utilization of psychiatric medication to control behavior is justified by ascribing children's emotional and behavioral difficulties as symptoms of discrete psychiatric disorders, which are over diagnosed. The quality of psychiatric care received by many children is far from optimal.

Diagnostic principles and issues of psychopathology

A few examples of the failure to understand psychopathology and context resulting in over diagnoses and inappropriate medication treatment: a 7-year-old foster child who had ADHD and had been stable for months suddenly began acting up at school. His out patient psychiatrist based on a 15-minute medication follow up concluded that there was a re-emergence and worsening of the ADHD. The child's Ritalin was increased and he continued to deteriorate. A few weeks later, he was placed in residential treatment. I assumed his psychiatric care. Careful investigation of his history and interview with foster family and residential staff revealed that he was recently separated from his brother who was the only consistent person in his life and that he was constantly repeating to any one who would listen that "you were just going to get rid of me anyway." If a traumatized child does not believe that he is worthy of being loved and that no adult will ever keep him, why should he behave? From the child's perspective it makes sense to act out and get it over with – get kicked out. In fact if a child believes that it is inevitable that the placement will disrupt, it is preferable for the child to actively sabotage the placement that than wait, get attached and then be the victim of the adults actions. This child was not exhibiting breakthrough ADHD. He did not need more Ritalin. In fact the increase in Ritalin further activated him thereby causing the deterioration and subsequent disruption and new placement.

Like the child described above, many if not most children in placement exhibit moderate to severe attachment dysfunction. These children exhibit a very characteristic dance surrounding human relatedness. Like all of us they yearn to be loved resulting in a period where they seek out relationships, behave appropriately, try to be charming, and try to get close. However ultimately their belief that they are unlovable and they will be rejected takes over. Even a minimal failure on the part of the adults, a minor disappointment, serves as a reminder of what these children believe to be an eternal truth – rejection. They now cycle and act up. They push people away. For many this cycle is an automatic reaction that they cannot verbalize. Only a few can say as the above child did that "you were just going to get rid of me anyway." Because these children appear to have cycling anger, aggression and mood instability, this all too common presentation of a psychological problem with attachment is often overlooked in favor of diagnosing the child with bipolar disorder, a much more rare medical / psychiatric condition.

Optimal treatment including use of medication is predicated on complete and comprehensive evaluations leading to reliable, meaningful and valid diagnosis, case formulation and treatment recommendations. However, the diagnostic process is especially complicated in children in residential treatment for many reasons. Information about developmental, family and school history is often unavailable, spotty, or unreliable. Even when available, past evaluations may be incomplete, contradictory or provide erroneous conclusions. Children often switch from home to home and from school to school. They are often not in one place long enough to establish a history of baseline symptoms against which treatment changes can be judged. Because many

children in placement have been routinely bombarded with stress and trauma, their presenting symptoms may be non-specific manifestations of and reactions to abandonment, loss, and relationship disturbance plus adjustment and reaction to the new home and school environment. Even when in a stable foster home and school placement, children may still be experiencing a high level of continued stressful life events such as visits, court dates etc that account for at least some of their difficulties. Most of the children have developmental deficits in many areas of cognitive, emotional, coping, relationship, social and behavioral skills that may result in symptoms that appear to reflect major psychiatric disorder. There may be an immediate crisis that obscures baseline functioning.

Therefore, it is crucial to improve diagnostic accuracy. Many strategies are available. Try to obtain as much history as possible. It is usually possible to locate records from past school placements. Past school reports are less likely to be contaminated than reports from a biological parent especially if they have an adversarial relationship with the local child welfare agency. Review the details past records carefully for evidence supporting conclusions and recommendations. Evaluate and intervene if necessary to optimize the current home and school environment. Look for temporal patterns that may offer an alternative explanation for a child's symptoms such as the timing of visits. It is not uncommon to observe an increase of problems surrounding visits that significantly diminish or disappear between visits. Allow the child 3 - 4 months <u>if possible</u> to settle into a new placement and school before arriving at a final determination. It usually takes about that long for a placement to stabilize and the child to reach a new equilibrium that would indicate baseline symptoms.

<u>Treatment considerations: what you need to understand about psychiatric medication</u>

In weighing the use of medication against an alternative psychosocial treatment that is likely to be equally effective, the non-medical treatment may be preferable since it is less likely to have significant side effects. Non-medical treatment also encourages active mastery and the learning of other valuable skills. In addition the use of medication may also exacerbate the external locus of control already commonly seen in children in foster care. Psychoactive drugs are likely to have subtle effects on general neuropsychological functions especially on learning. Since most children in care are likely to be far behind in school, anything that interferes with their ability to learn will further compromise long term adjustment especially in light of the unproven positive effects.

Even proven effectiveness and FDA approval does not in and of itself mean that a treatment is a good one that should be widely used or that the treatment is the best choice for a given disorder. A recent study of Zoloft illustrates this. Immediately after the release of the study, the media hailed it as proof that Zoloft is an effective treatment for childhood depression. But is it? The study's overall conclusion, the punch line, is that there is a statistically significant difference between active drug and placebo. Granted that this also usually implies a clinical significance. But does the data support that Zoloft is a very effective treatment let alone the first choice treatment, where the

likelihood of the medication working clearly outweighs the likelihood of side effects? At first glance the article seems to "prove" the effectiveness of Zoloft. It is statistically better than placebo. But if you read the actual data and analyze the science you discover that 6 out of ten kids would respond without the medication. Three out of 10 do not respond and only one out of ten really responds to the medication. The magnitude of the response is also modest. Because of the number of kids in the study, the measures used and the arbitrary cutoffs that were picked, statistical significance is reached. However 6 times the number of kids responds to some non-biological or psychological factor inherent in the placebo intervention than respond to the pharmacological properties of the medication. But yet all kids 10 out of 10 are exposed to moderate side effects so that one kid can get a biological response to the medication. Nine out of 10 kids are put at risk for no gain. Based on this data, the authors who all make money from drug companies, the study was funded by the maker of Zoloft, claim to have proven the effectiveness of Zoloft in depressed kids. I think that a more realistic interpretation of the data is Zoloft is in fact modestly effective but for most kids should not be the treatment of first choice. Non-medical mental health interventions are more effective and should be tried first. One should have a healthy respect for the side effects of the medication and therefore not over rely on it. Overall the medication should be used the cautiously and only after other non-medical interventions have been tried and failed.

Medication may be abused or cause withdrawal or dependence.

Medication should generally not (except possibly in a crisis situation) be prescribed to control behavior, reduce an isolated symptom or induce sleep in the absence of a diagnosable disorder. Medication should only be prescribed following a complete evaluation. Crucial to the integrity of the evaluation and validity of its conclusions is obtaining input from the child, the child welfare or juvenile justice agency caseworker, the foster family or cottage staff, the therapist, the teacher and all other team members. A sincere effort should be made to involve the family.

Children should receive careful follow up. Follow up during the titration phase should be weekly. Once stabilized, follow up can be on a monthly basis. If a child has been stable for a period of time and is being treated with medications such as stimulants or SSRIs that do not require laboratory monitoring, follow up intervals can be gradually increased to quarterly. All visits for medication monitoring require the presence of the child and the primary caretaker (foster parent or residential staff). Input should also be obtained from the caseworker, teachers, therapists, biological parents when possible and other service providers. Without input from all these individuals, it is not possible to have the necessary detail to assess clinical response or side effects.

Updated psychiatric evaluations should be conducted at least once per year to address the need for continued treatment and to consider the possibility of reevaluating the need for the drug by attempting to taper and discontinue it.

Side effects that may be poorly tolerated by the youngsters need to be a major consideration in weighing the cost benefit ratio for continuing medication. It is not uncommon in foster care of residential care for the adults (foster parents, cottage staff, teacher, agency caseworker and the parent during visits) to be overly focused on behavioral improvement at the price of insensitivity to the child's experience of side effects especially over sedation and weight gain. The patient should be allowed major input. If side effects do not diminish over time and impair the child's functioning in other domains of his or her life, even if the medication is effective in reducing the target symptoms, strong consideration should be given to stopping the mediation and substituting another if needed.

Non-FDA approved medications

Many of the medications used to treat foster children are either not approved by the FDA for use in this age group or for the indication it is being prescribed. Non-FDA approved medications have no research or only minimal levels of evidence supporting their efficacy and safety and should therefore be used. The effects on development may be unknown. Therefore, a non-FDA medication should not be used if an alternate FDA approved medication is available unless there is a clear-cut justification that outweighs the added risk.

A primary justification given for use of medications that are not FDA approved for use in children is since the medicine is safe and effective in adults it is also safe and effective in children. Medication proven to be effective in adults may not be effective in children. Clinical experience should not override science. For instance, Prozac is less effective in children than in adults. Paxil is an effective anti-depressant in adults but not in children. Medication that is safe in adults may not be safe in children. Again clinical experience should not override science. The incidence of side effects in children on Zyprexa is 3 fold that of adults. Side effects may not appear for years in off label use of medication. Anti-psychotics cause increased death when used to treat behavior in the elderly.

Medication even if commonly used is not a guarantee of safety. Careful scientific study to gain FDA approval for a new indication has shown common medications to be dangerous even after years of use. SSRI anti-depressants cause increased suicidal ideation in teenagers and kids to the degree that the FDA has issued a black box warning.

Drug combinations

Children in residential placement are at high risk for difficult to manage behaviors reflecting loss, rejection, abuse, instability and relationship disturbance exhibiting symptoms that range across traditional diagnostic entities. Therefore, they are more likely to be placed on multiple medications. Drug combinations are generally ill advised for many reasons. No research exists that documents the efficacy or safety (short term or long term) of drug combinations in children and adolescents. Depekote combined with Zyprexa raise liver enzymes significantly more than either medication alone. The effects on development in general and brain development specifically of multiple medications that frequently have profound and sometimes contradictory neurochemical

effects are unknown. The use of multiple medications if likely to further increase the foster child's externalized locus of control. Preserving multiple medications increase the chance of administration mistakes. It is unlikely that children in care suffer from multiple discreet psychiatric disorders each requiring a separate treatment. Side effects are usually best handled by discontinuing the first medication and if needed substituting a new medication. If medicines such as stimulants or anti-depressants are activating, do not counteract the side effect by prescribing a sedative / downer. If a child becomes psychotic secondary to a stimulant, discontinue the stimulant instead of covering over the psychosis with a schizophrenia medication. Lastly, it is near impossible to evaluate the efficacy of a medication when a child's presentation is influenced by treatment with other medications.

However on occasion the use of multiple medications may be appropriate under the following conditions. All medications that offer reasonable likelihood of being good enough by itself have been tried. No medication by itself proved to be satisfactory at ameliorating the majority of target symptoms. In the process of trying other medications, one medication is effective on a certain group of symptoms while a second medication is effective on a different group of symptoms. With great care these medications may be combined provided that there are no known drug - drug interactions, overt contraindications or reason to expect commutative side effects to the combination. As an example, Ritalin improved a child with ADHD ability to focus and remain on task but did not result in improvement in impulsivity. Instead of adding Intuniv, the Ritalin should be discontinued. A subsequent trial on Intuniv alone improved the impulsivity and not focused attention. Other alternative treatments for ADHD such as Strattera or Wellbutrin have been tried when appropriate but were ineffective. At that point it would be reasonable to prescribe both Ritalin and Intuniv.

Some possible solutions: how to operationalize the above principles

Evidenced based treatment guidelines

Currently each agency and frequently each provider within an agency have their own standards of practice even if unstated. There are vast differences between agencies and providers in diagnostic patterns and overall use of medication, use of non FDA approved medication, use of medication to control behavior, use of multiple medications simultaneously, and use of alternative non medical interventions.

Even without knowing the "best practice," variations of this magnitude signify poor psychiatric care. Standardized treatment based on shared principles would solve a number of problems. Foremost, the quality of care is likely to improve if the practice guidelines are evidenced based. It is well known that physician decision-making is influenced more by the style of practice they were exposed to during residency and early career experiences than by current state of the art scientific research. It takes on average 8 years for scientific breakthroughs to be adopted in routine practice. Furthermore, the pharmaceutical industry with their massive budgets directed toward advertisements, free dinners (bribes?) for physicians and sales representatives influence prescribing habits.

For instance, in kids with very similar presentations, one psychiatrist will label the kid ADHD, another PTSD and yet a third adjustment disorder. Each diagnosis should lead to a vastly different treatment plan. It is impossible that all 3 children are getting optimal care. Abilify is now being frequently prescribed for acting out kids. It is a very new adult schizophrenia medication, heavily pushed by its manufacturer. Yet there is little to support its efficacy or safety when used in children especially non-psychotic children who are primarily being given the medication for behavior problems. Many of these kids have never been on more standard treatments with research supporting its efficacy and safety. The rationale may be that Abilify does not cause the weight gain frequently seen in its competitors. It is true that older more studied drugs in the same class may cause weight gain but in a controlled setting where staff can monitor diet and prevent weight gain, this particular side effect should not be a major factor when measured against the inherent unknown risk of using a new untested medication.

Part 2 provides information about evidenced based treatments. A few points need to be highlighted. A diagnosis cannot be made without careful review of past records and current reports from caretakers and teachers. Rule out that current symptoms are a non-specific manifestation of stress or reactivity to current life events. If a child has multiple diagnoses or is already on medication, do not assume that the diagnosis is correct or that the child requires medication. The diagnosis and medication effectiveness needs to be confirmed by careful examination of past records. If there is an objective measure of medication's effectiveness such as a continuous performance test on and off medication for ADHD, administer it. Also note that there are gold standard treatments, such as stimulants especially methylphenidate preparations for ADHD, which unless contraindicated should always be the treatment of first choice. When there is a new FDA approved medication, such as Strattera, since that long term safety has not been evaluated, the newer medication should mostly be used if the gold standard fails. Finally, there are alternative treatments with less proven efficacy and significant risks. In general these medication should only be used as a last resort and then only after careful assessment to minimize the risk. One of the alternatives for ADHD is especially problematic. The proven efficacy of Wellbutrin is minimal and may not outweigh the risks. There is a significant increase risk of seizures in individuals with eating disorders or binge drinkers. Adolescents are commonly binge drinkers. Eating disorders are endemic in adolescent girls. Both these conditions are usually hidden. Why should we be using Wellbutrin when there are safer alternatives? And yet, I review numerous cases of teenagers who are put on this medication without even being screened carefully for drinking or eating disorders. (The same reasoning hold true for Wellbutrin's use as an anti-depressant.)

Another example of a problematic choice of medication is the frequent use of Depekote for non-specific symptoms of anger, moodiness and irritability resulting in "unmanageable" behavior that may be mislabeled as bipolar disorder. The first consideration is that the child may not even be suffering from the disorder. Bipolar disorder also known as manic-depressive disorder is over diagnosed in children in foster care. Anger, moodiness and irritability are frequently presenting symptoms in

foster children. Bipolar disorder is rare in youngsters and the diagnosis should be reserved for the few children with strong family histories or clear-cut episodes of traditional mania alternating with depression or normal affective states. The symptoms sometimes attributed to mood disorder in foster children are likely to be reactions to or manifestations of attachment problems, abuse, neglect, loss, trauma etc. The second consideration is that even if the diagnosis is correct, is Depekote the best treatment. Side effects are significant. Sedation which is likely to contribute to decreased ability to learn is common as is significant weight gain which is unhealthy and contributes to further lowering of self esteem and increased social problems in youngsters who are already very vulnerable. Also can cause liver failure, acute pancreatitis, fetal abnormalities and polycystic ovaries. Do the benefits outweigh the risks? The answer is unlikely for use in children without bipolar disorder given the substantial risks and the unsubstantiated benefits. However for truly bipolar youngsters, the benefit can be substantial. The weight gain and sedation may be a reasonable trade off given the lack of alternatives to treat bipolar disorder. But what about the risk of adolescent girls developing polycystic ovaries that may lead to permanent infertility? Given the prevalence of fetal abnormalities, should we prescribe Depekote to sexually active adolescent girls? The decision to administer medications may have serious consequences that need to be considered. But commonly, the likelihood of benefit is exaggerated while the real risks are minimized.

Quality assurance

In order to insure appropriate use of psychiatric medication for children in foster care, a quality assurance and continuous quality improvement program that looks at content and not just process is crucial. QA should monitor and review the following: initial psychiatric evaluation including treatment plan, justification for a new medication, justification for a non-FDA approved medication, justification for multiple medications, follow up of weight gain, follow up of lab abnormalities and justification for continuation of medications that have been used for over a year.

Informed consent

Informed consent is one of the safeguards to ensure that treatment is needed, appropriate and safe. However, the information provided to the custodian signing the consent is usually inaccurate or misleading, increasing legal liability. Justification for use of medication is not given. There is no evidence to support the diagnosis. Reasonable alternatives are omitted. Benefits are inflated and risks are minimized. Just a few examples from consent documents I have reviewed. Celexa is described as an effective treatment for depression. This is a true statement for adults. The handout however does not mention that Celexa has not been proven to be effective or safe as a treatment for childhood depression. Nor does the consent form mention that Celexa is not FDA approved for use in children and that 2 alternative medications, Zoloft and Prozac, are approved and therefore have proven efficacy and safety specifically for children. A request for Depekote does not mention the risk of fetal abnormalities or of polycystic ovaries, which although low risk may lead to a catastrophic outcome - infertility, even though the medication is being prescribed to adolescent girls who are sexually active. A request to place a 4 year old on Klonipin did not include the possibility of withdrawal, dependence and addiction. Many other examples are available. These oversights can result in costly legal suits.

The level of informed consent needs to be higher for children in foster care for many reasons. The biological parents may not be given the necessary information. Because of legal involvement, they may feel that they have to consent or face further delay in getting their children back because they are deemed uncooperative. Since the legal guardian, in New York State the county commissioner of social service or designee, may not be the parent and may not even know the child, greater responsibility should be exercised in ensuring the welfare and best interest of the child. By the time the child has reached a higher level of care, the problems are complex as to require greater amounts of information to adequately weigh alternatives. Lastly, there is probably greater legal liability.

Informed consent should always be obtained from the biological parents if possible. The child should always be included in the process. Without assent from the child, non-compliance is likely and the probability that the medication is reduced.

Informed consent should include a rationale for treatment and its likely effectiveness, detailed side effects and their likely incidence, a discussion of costs vs. benefits, reasonable alternatives including pros and cons of the alternative compared to the recommended treatment, dosage range during the trial, dose for maintenance treatment and an expiration date.

If medication is not FDA approved for use in children or for the indication it is prescribed, this should be specifically indicated. A detailed explanation should

be given including why this particular drug was selected, why there is no FDA approved alternative, and why it is felt that this medication is safe.

If a second medication is being given to counteract the side effects of the first medication, this should be specifically indicated and a detailed rationale be given as to why the first medication is not being discontinued and an attempt be made to find one medication that is both effective and well tolerated.

If a second medication is being prescribed because the first medication is only partially effective, a rationale for not discontinuing the first medication and attempting a trial of another medication used alone should be provided.

If medication is being used to treat aggressive behavior that does not neatly fit in a diagnostic category, this should be specifically indicated. The lack of alternatives needs to be carefully documented. Both short term and long term costs vs. benefits should be weighed.

If the child is experiencing side effects and objects to the treatment, a compelling reason needs to be provided as to why the benefits to the child (as opposed to the benefit to the adults) exceeds the cost to the child of the poorly tolerated medication.

An initial consent for a trial of a new medication should expire within 3 months. At that time evidence for the medications effectiveness and lack of concerning side effects including a current weight should be provided along with a new consent to continue the medication for no more than one year. All further renewals of consent should be based on a reevaluation of the need to continue the medication that should periodically include the plan to attempt to taper and discontinue the medication followed by a reevaluation off medication.

Most consent forms and accompanying handouts were designed for either general medical usage, adult psychiatric usage or with the assumption that the parent has met with the medical provider. The vast majority of those that I have reviewed where designed to allow physicians wide latitude in prescribing medication and not to protect the safety of children in care. To my knowledge, there are no specific consent and information packets designed for psychiatric medication in children in general or for the special considerations in using psychiatric medication in the child welfare system. In order to improve risk management and overall level of psychiatric care, specific forms for each medication prescribed for psychiatric usage in children and adolescents should be designed. The consent document for each medication would discuss the likely effectiveness, risk / side effects, treatment considerations alternative treatments with risk benefit ratios specific for children and adolescents based on the available scientific literature. Since the knowledge base constantly changes, the form for each medication would be updated as new tends emerge, at least once per year. Designing specific consent forms and evidenced based handouts for