Evidence Based Use and Possible Solutions to the Overuse of Psychiatric Medication For Children in Foster Care

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Background

Approximately 500,000 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 children in foster care have been abused and / or neglected by their biological parents. Placement in foster care, while necessary for safety and protection, subjects children to additional 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 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 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 if possible 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.

Treatment considerations: what you need to understand about psychiatric medication

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 residential care for the adults (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 Tofranil is an effective antidepressant in adults but is proven to be ineffective in children. Prozac is less effective in children than in adults. Medication that is safe in adults may not be safe in children. Again clinical experience should not override science. Tofranil causes sudden death in children. 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. Gabetin, an anti-seizure medication, causes seizures when used as a mood stabilizer. Topamax, an anti-seizure medication frequently used as a mood stabilizer despite little evidence, causes metabolic acidosis.

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. Risperidone causes significant increase in cerebral-vascular events including fatalities in the demented elderly. 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. There are serious side effects reported with the combination of Ritalin and Clonidine although causality has not been determined. 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 Clonidine, the Ritalin should be discontinued. A subsequent trial on Clonidine alone improved the impulsivity and not focused attention. Other alternative treatments for ADHD such as Strattera or Tofranil were ineffective. At that point it would be reasonable to prescribe both Ritalin and Clonidine.

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.

Appendix 1 provides suggestions 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 the

risk substantial. 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.

<u>Quality assurance</u>

In order to insure appropriate use of psychiatric medication for children in residential treatment, 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 residential treatment for the many reasons. The biological parents may have abused or neglected their children and may have a history of mental illness or substance abuse and are therefore less able to be expected to make the informed judgment about their children's needs. 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 be obtained from the local department of social service commissioner or designee plus the biological parents if possible. The child should always be included in the process.

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 every medications is a task that would require sponsorship of a coalition of agencies or a national organization such as yours. But at minimum a consent form that meets the minimum standards set by JCAHO for true informed consent should be used.

Conclusions

It clearly is possible to reduce the over use of psychiatric medications for children in foster care through better understanding of the psychopathology of the youngsters in residence and of the benefits and risks of the medications. Improved quality assurance and informed consent would further contribute to continuous quality improvement. If we help foster parents or residential center staff to master the techniques of avoiding power struggles and improve the child's attachments and interpersonal relatedness while simultaneously teach children social, emotional, coping and problem solving skills, both aggression and utilization of psychiatric medication will decrease. Even more important, we will have given the children the skills and self-reliance to face their future.

Example of Consent Forms

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1 South Broadway
Hastings-On-Hudson, NY 10706
(914) 478-1100

Medication Consent
Prozac (fluoxetine)

Dr _____, one of our staff psychiatrists, is requesting your permission to treat your child, _____, (date of birth: _____) with the above medication at the following dose range, _____. A thorough evaluation has revealed that your child is suffering from _____. We will know if the medication is working if hopefully there is improvement in the following target symptoms: _____.
In addition your child is currently on the following medications: _____.
The plan for these medications is as follows: _____.

Possible benefit

Prozac is the only anti-depressant approved for depression in children and adolescents. It is not approved for any other indication in children. It helps about 1/3 of kids who try it. The medication works best for moderate to severe depression that seems to come from within. The medication works less well in mild to moderate depression that seems to be a reaction to real life events in your child's life. In many cases this kind of depression can be treated with therapy and counseling and does not require a medication. Prozac is also used to target anxiety in children but there is no proven effectiveness for anxiety in this age group.

Possible risks

Prozac like all anti-depressants can activate your child. Your child may suddenly become agitated, speeded up, irritable, aggressive, suicidal or manic or have a sudden personality change, and is different from what your child was experiencing before starting the medication. These symptoms occur in about 1 out of 20 kids on this medication usually soon after starting the medication or soon after a dose change. The risk can be minimized if your doctor sees your child frequently usually within 1-2 weeks after starting the medication or changing the dose. The risk can also be minimized if the provider has educated the adults taking care of your child to monitor the above symptoms and if there is a concern to temporarily stop the medication and immediately notify the psychiatrist. If these side effects are picked up early and medication is stopped, these behavioral and emotional side effects usually disappear within a few days and before they cause your child any harm. Appropriate monitoring by the physician and caretakers is key to safety.

Alternatives

If your child is not currently in therapy, it may be reasonable to first try therapy or counseling for a few months before trying medication especially for depression / anxiety that seems to be a reaction to real life events.

If your child needs medication for OCD or other forms of anxiety, Zoloft is an alternative that is approved by the FDA as a treatment for OCD, an anxiety disorder, in children and adolescents.

If Prozac is being added to other psychiatric medications, it is possible that the original medications may be contributing to the depression or anxiety or that the original medications were not all that effective. It may be reasonable to first try to lower or stop the original medication and if symptoms still persist to substitute one medication that might be good enough used alone.

Risk / benefit ratio

If you are convinced that the benefits of medication outweigh the risks and that the medication is the best alternative for your child at this point in time, you should go ahead and sign the consent below. On the other hand, if you have reservations about the medication or prefer to explore one of the above alternatives before trying this medication, please contact your caseworker who will put you in touch with the doctor.

Parents as partners in helping to monitor the medication

We welcome your participation in your child's treatment with medication. In order to make the best decisions about continuing or stopping the medication or changing the dose, we need your input. If you see that the medication is helping your child, improving the target symptoms listed at the top of the form, or if you do not see the medication as effective since the target symptoms have not changed, please let us know. Also if you think that your child is having side effects to the medication (see paragraph on risks) or have any other concerns about the medication, please contact us.

Consent

I agree to the use of the above medication at the above dose range. I understand that I may withdraw this consent at any time.

Signature:
Date:
Relationship to the child:

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1 South Broadway
Hastings-On-Hudson, NY 10706
(914) 478-1100

Medication Consent
Zoloft (sertraline)

Dr _____, one of our staff psychiatrists, is requesting your permission to treat your child, _____, (date of birth: _____) with the above medication at the following dose range, _____. A thorough evaluation has revealed that your child is suffering from _____. We will know if the medication is working if hopefully there is improvement in the following target symptoms: _____.
In addition your child is currently on the following medications: _____.
The plan for these medications is as follows: _____.

Possible benefit

Zoloft does help depression in adults. However, it is not approved by the Food and Drug Administration (FDA) as a treatment for depression in children and adolescents and has no proven effectiveness as a treatment for depression in this age group. The scientific studies have either not been done of if done do not show that Zoloft works in children and adolescents with depression. It is still possible that it may work in your child. Trying Zoloft may also be reasonable if your child has already been tried on Prozac, the only anti-depressant approved by the FDA for depression in children and adolescents, and it did not work.

Zoloft is approved as a treatment of obsessive-compulsive disorder, an anxiety disorder, in children and therefore may also have some effectiveness in other forms of anxiety. But studies show that certain targeted cognitive behavioral psychotherapies may be more effective than medication long term.

Possible risks

Any anti-depressants can activate your child. Your child may suddenly become agitated, speeded up, irritable, aggressive, suicidal or manic or have a sudden personality change, and is different from what your child was experiencing before starting the medication. These symptoms occur in about 1 out of 20 kids on this medication usually soon after starting the medication or soon after a dose change. The risk can be minimized if your doctor sees your child frequently usually within 1-2 weeks after starting the medication or changing the dose. The risk can also be minimized if the provider has educated the adults taking care of your child to monitor the above symptoms and if there is a concern to temporarily stop the medication and immediately notify the psychiatrist. If these side effects are picked up early and medication is stopped, these behavioral and emotional side effects usually disappear within a few days and before they cause your child any harm. Appropriate monitoring by the physician and caretakers is key to safety.

Alternatives

If your child is not currently in therapy, it may be reasonable to first try therapy or counseling for a few months before trying medication for depression / anxiety that seems to be a reaction to real life events or for OCD.

If your child needs medication for depression, Prozac is an alternative that is approved by the FDA as a treatment for depression in children and adolescents.

If Zoloft is being added to other psychiatric medications, it is possible that the original medications may be contributing to the depression or anxiety or that the original medications were not all that effective. It may be reasonable to first try to lower or stop the original medication and if symptoms still persist to substitute one medication that might be good enough used alone.

Risk / benefit ratio

If you are convinced that the benefits of medication outweigh the risks and that the medication is the best alternative for your child at this point in time, you should go ahead and sign the consent below. On the other hand, if you have reservations about the medication or prefer to explore one of the above alternatives before trying this medication, please contact your caseworker who will put you in touch with the doctor.

Parents as partners in helping to monitor the medication

We welcome your participation in your child's treatment with medication. In order to make the best decisions about continuing or stopping the medication or changing the dose, we need your input. If you see that the medication is helping your child, improving the target symptoms listed at the top of the form, or if you do not see the medication as effective since the target symptoms have not changed, please let us know. Also if you think that your child is having side effects to the medication (see paragraph on risks) or have any other concerns about the medication, please contact us.

Consent

I agree to the use of the above medication at the above dose range. I understand that I may withdraw this consent at any time.

Signature:
Date:
Relationship to the child:

Graham-Windham
1 South Broadway
Hastings-On-Hudson, NY 10706
(914) 478-1100

Medication Consent
Paxil (paroxetine)

Dr _____, one of our staff psychiatrist's, is requesting your permission to treat your child, _____, (date of birth: _____) with the above medication at the following dose range, _____. A thorough evaluation has revealed that your child is suffering from _____. We will know if the medication is working if hopefully there is improvement in the following target symptoms: _____.
In addition your child is currently on the following medications: _____.
The plan for these medications is as follows: _____.

Possible benefit

Paxil does help depression and anxiety in adults. However, it is not approved by the Food and Drug Administration (FDA) as a treatment for depression or anxiety in children and adolescents and has no proven effectiveness as a treatment for depression or anxiety in this age group. The scientific studies have either not been done or if done do not show that Paxil works in children and adolescents.

Possible risks

Any anti-depressants can activate your child. Your child may suddenly become agitated, speeded up, irritable, aggressive, suicidal or manic or have a sudden personality change, and is different from what your child was experiencing before starting the medication. These symptoms occur in about 1 out of 20 kids on this medication usually soon after starting the medication or soon after a dose change. The risk can be minimized if your doctor sees your child frequently usually within 1-2 weeks after starting the medication or changing the dose. The risk can also be minimized if the provider has educated the adults taking care of your child to monitor the above symptoms and if there is a concern to temporarily stop the medication and immediately notify the psychiatrist. If these side effects are picked up early and medication is stopped, these behavioral and emotional side effects usually disappear within a few days and before they cause your child any harm. Appropriate monitoring by the physician and caretakers is key to safety.

Paxil more than the other anti-depressants may dangerous during pregnancy and therefore should probably not be used if there is a risk that your child might become pregnant.

Paxil may be more difficult to come off of compared to other anti-depressants.

Alternatives

It may be reasonable to first try therapy or counseling for a few months before trying medication especially for depression / anxiety that seems to be a reaction to real life events.

If your child needs medication for depression, Prozac is an alternative that is approved by the FDA as a treatment for depression in children and adolescents and Zoloft is an alternative that is approved by the FDA as a treatment for OCD, an anxiety disorder, in children and adolescents.

If your child has already tried one anti-depressant and not responded, Prozac, Zoloft, Celexa and Lexapro may be a safer alternative to Paxil.

Risk / benefit ratio

In general, the risks of Paxil may outweigh the benefits when given to children. However if you are convinced that the benefits of medication outweigh the risks and that the medication is the best alternative for your child at this point in time, you should go ahead and sign the consent below. On the other hand, if you have reservations about the medication or prefer to explore one of the above alternatives before trying this medication, please contact your caseworker who will put you in touch with the doctor.

Parents as partners in helping to monitor the medication

We welcome your participation in your child's treatment with medication. In order to make the best decisions about continuing or stopping the medication or changing the dose, we need your input. If you see that the medication is helping your child, improving the target symptoms listed at the top of the form, or if you do not see the medication as effective since the target symptoms have not changed, please let us know. Also if you think that your child is having side effects to the medication (see paragraph on risks) or have any other concerns about the medication, please contact us.

Consent

I agree to the use of the above medication at the above dose range. I understand that I may withdraw this consent at any time.

Signature:
Date:
Relationship to the child:

Graham-Windham
1 South Broadway
Hastings-On-Hudson, NY 10706
(914) 478-1100

Medication Consent

Lexapro (escitalopram) or Celexa (citalopram)

Dr _____, one of our staff psychiatrists, is requesting your permission to treat your child, _____, (date of birth: _____) with one of the above medications, _____, at the following dose range, _____. A thorough evaluation has revealed that your child is suffering from _____. We will know if the medication is working if hopefully there is improvement in the following target symptoms: _____. In addition your child is currently on the following medications: _____. The plan for these medications is as follows: _____.

Possible benefit

Both help depression and anxiety in adults. However, they are not approved by the Food and Drug Administration (FDA) as a treatment for depression or anxiety in children and adolescents and have no proven effectiveness in this age group. The scientific studies have either not been done of if done do not show that these medications works in children and adolescents. It is still possible that it may work in your child. Trying Celexa or Lexapro may also be reasonable if your child has already been tried on Prozac, the only anti-depressant approved by the FDA for depression in children and adolescents or Zoloft for OCD, an anxiety disorder, and it did not work.

Possible risks

Any anti-depressants can activate your child. Your child may suddenly become agitated, speeded up, irritable, aggressive, suicidal or manic or have a sudden personality change, and is different from what your child was experiencing before starting the medication. These symptoms occur in about 1 out of 20 kids on this medication usually soon after starting the medication or soon after a dose change. The risk can be minimized if your doctor sees your child frequently usually within 1-2 weeks after starting the medication or changing the dose. The risk can also be minimized if the provider has educated the adults taking care of your child to monitor the above symptoms and if there is a concern to temporarily stop the medication and immediately notify the psychiatrist. If these side effects are picked up early and medication is stopped, these behavioral and emotional side effects usually disappear within a few days and before they cause your child any harm. Appropriate monitoring by the physician and caretakers is key to safety.

Alternatives

If your child is not currently in therapy, it may be reasonable to first try therapy or counseling for a few months before trying medication especially for depression / anxiety that seems to be a reaction to real life events.

If your child needs medication for depression, Prozac is an alternative that is approved by the FDA as a treatment for depression in children and adolescents.

If your child needs medication for OCD or other forms of anxiety, Zoloft is an alternative that is approved by the FDA as a treatment for OCD, an anxiety disorder, in children and adolescents.

If Lexapro or Celexa are being added to other psychiatric medications, it is possible that the original medications may be contributing to the depression or anxiety or that the original medications were not all that effective. It may be reasonable to first try to lower or stop the original medication and if symptoms still persist to substitute one medication that might be good enough used alone. Where you given this option?

Risk / benefit ratio

If you are convinced that the benefits of medication outweigh the risks and that the medication is the best alternative for your child at this point in time, you should go ahead and sign the consent below. On the other hand, if you have reservations about the medication or prefer to explore one of the above alternatives before trying this medication, please contact your caseworker who will put you in touch with the doctor.

Parents as partners in helping to monitor the medication

We welcome your participation in your child's treatment with medication. In order to make the best decisions about continuing or stopping the medication or changing the dose, we need your input. If you see that the medication is helping your child, improving the target symptoms listed at the top of the form, or if you do not see the medication as effective since the target symptoms have not changed, please let us know. Also if you think that your child is having side effects to the medication (see paragraph on risks) or have any other concerns about the medication, please contact us.

Consent

I agree to the use of the above medication at the above dose range. I understand that I may withdraw this consent at any time.

Signature:
Date:

Relationship to the child:

Graham-Windham
1 South Broadway
Hastings-On-Hudson, NY 10706
(914) 478-1100

Medication Consent
Wellbutrin (bupropion)

Dr _____, one of our staff psychiatrists, is requesting your permission to treat your child, _____, (date of birth: _____) with the above medication at the following dose range, _____. A thorough evaluation has revealed that your child is suffering from _____. We will know if the medication is working if hopefully there is improvement in the following target symptoms: _____.
In addition your child is currently on the following medications: _____.
The plan for these medications is as follows: _____.

Possible benefit

Wellbutrin does help depression in adults. It is also used off label, without FDA approval, to target ADHD. However, it is not approved by the Food and Drug Administration (FDA) as a treatment for depression or for ADHD in children and adolescents and has no proven effectiveness in this age group. The scientific studies have either not been done of if done do not show that it works in children and adolescents. It is still possible that it may work in your child.

Possible risks

Any anti-depressants can activate your child. Your child may suddenly become agitated, speeded up, irritable, aggressive, suicidal or manic or have a sudden personality change, and is different from what your child was experiencing before starting the medication. These symptoms occur in about 1 out of 20 kids on this medication usually soon after starting the medication or soon after a dose change. The risk can be minimized if your doctor sees your child frequently usually within 1-2 weeks after starting the medication or changing the dose.

Wellbutrin is especially dangerous and may cause seizures in adolescents who binge drink or have eating disorders. Both are common in this age group but adults may not know about it.

Alternatives

It may be reasonable to first try therapy or counseling for a few months before trying medication especially for depression that seems to be a reaction to real life events

If your child needs medication for depression, Prozac is an alternative that is approved by the FDA as a treatment for depression in children and adolescents. If your child has already tried Prozac and not responded, Zoloft, Celexa and Lexapro may be a safer alternative.

If your child needs medication for ADHD, Ritalin, Concerta or Adderall are alternatives that are approved by the FDA as a treatment for ADHD in children and adolescents. If your child has been on a stimulant and not done well, Strattera and Clonidine are also reasonable alternatives.

Risk / benefit ratio

In general the risks of the use of Wellbutrin in children may outweigh the benefits. However if you are convinced that the benefits of medication outweigh the risks and that the medication is the best alternative for your child at this point in time, you should go ahead and sign the consent below. On the other hand, if you have reservations about the medication or prefer to explore one of the above alternatives before trying this medication, please contact your caseworker who will put you in touch with the doctor.

Parents as partners in helping to monitor the medication

We welcome your participation in your child's treatment with medication. In order to make the best decisions about continuing or stopping the medication or changing the dose, we need your input. If you see that the medication is helping your child, improving the target symptoms listed at the top of the form, or if you do not see the medication as effective since the target symptoms have not changed, please let us know. Also if you think that your child is having side effects to the medication (see paragraph on risks) or have any other concerns about the medication, please contact us.

Consent

I agree to the use of the above medication at the above dose range. I understand that I may withdraw this consent at any time.

Signature:
Date:
Relationship to the child:

Graham-Windham
1 South Broadway
Hastings-On-Hudson, NY 10706
(914) 478-1100

Medication Consent for Stimulants
Ritalin, Concerta, Methadate or Methylin (methylphenidate)
Dexedrine or Adderall (amphetamine salts)
Focalin (dexmethylphenidate)

Dr _____, one of our staff psychiatrists, is requesting your permission to treat your child, _____, (date of birth: _____) with one of the above medications, _____, at the following dose range, _____. A thorough evaluation has revealed that your child is suffering from _____. We will know if the medication is working if hopefully there is improvement in the following target symptoms: _____. In addition your child is currently on the following medications: _____. The plan for these medications is as follows: _____.

Possible benefit

All the stimulants are approved for ADHD in children and adolescents. Stimulants help about 45% of kids who try it but only if they truly have ADHD. ADHD is characterized by impulsivity, hyperactivity, inattention and distractibility that begins early in life, is present both at home and at school and is not caused by such other factors as depression, anxiety, exposure to violence, reaction to traumatic events such as abuse, extremely stressful home environment or placement in foster care. Cases of mild ADHD can be treated with behavior therapy, counseling and placement in a very structured home environment and may not require a medication. When there are elements of multiple psychiatric disorders, in order to make the diagnosis of ADHD your child requires a comprehensive evaluation possibly including a continuous performance test, a computer test that measures your child's inattention, impulsivity and distractibility compared to other children his or her age.

If you think that your child has ADHD, that your child's behaviors are not caused by other factors mentioned above, occur both at home and at school, began before age 8, that your child received a thorough evaluation and other non-medical intervention tried first, then a trial of stimulant medication is justified with a reasonable likelihood of benefit.

Possible risks

Stimulants can cause increased heart rate, abnormal hear rate or increased blood pressure. There have been rare reports of sudden death in children on stimulants, about one in a million. The danger is greatest if your child has heart disease. To reduce the risk your child should have an EKG and thorough pediatric examination.

Stimulants can also activate your child. Your child may become agitated, speeded up, irritable, aggressive, suicidal, manic, and paranoid or hear voices. These symptoms occur in about 1 out of 20 kids on this medication. The risk can be minimized if your doctor sees your child frequently and catches the side effect soon after it starts, well before the activation causes your child major problems. In most cases, these symptoms will disappear after the medication is stopped. Stimulants can be abused. Some adolescents can become dependant on stimulants. Some adolescents sell their medication, breaking the law.
If you have concerns about these issues, you may prefer alternative medications such as Strattera or Clonidine.

Alternatives

It may be reasonable to first try behavioral interventions for a few months before trying medication.

At school, it may be reasonable to first try behavioral interventions in the regular classroom or special education placement for a few months before trying medication.

If your child needs medication for ADHD, Strattera or Clonidine are alternative treatments for ADHD in children and adolescents.

If a stimulant is being added to other psychiatric medications, it is possible that the original medications may be contributing to the ADHD-like symptoms or that the original medications were not all that effective. It may be reasonable to first try to lower or stop the original medication and if symptoms still persist to substitute one medication that might be good enough used alone.

Risk / benefit ratio

If you are convinced that the benefits of medication outweigh the risks and that the medication is the best alternative for your child at this point in time, you should go ahead and sign the consent below. On the other hand, if you have reservations about the medication, prefer to explore one of the above alternatives before trying this medication or your child has a heart murmur, heart disease or an abnormal EKG, please contact your caseworker who will put you in touch with the doctor.

Parents as partners in helping to monitor the medication

We welcome your participation in your child's treatment with medication. In order to make the best decisions about continuing or stopping the medication or changing the dose, we need your input. If you see that the medication is helping your child, improving the target symptoms listed at the top of the form, or if you do not see the medication as effective since the target symptoms have not changed, please let us know. Also if you think that your child is having side effects to the medication (see paragraph on risks) or have any other concerns about the medication, please contact us.

Consent

I agree to the use of the above medication at the above dose range. I understand that I may withdraw this consent at any time.

Signature:
Date:
Relationship to the child:

Graham-Windham
1 South Broadway
Hastings-On-Hudson, NY 10706
(914) 478-1100

Medication Consent
Strattera (atomoxetine)

Dr _____, one of our staff psychiatrists, is requesting your permission to treat your child, _____, (date of birth: _____) with the above medication at the following dose range, _____. A thorough evaluation has revealed that your child is suffering from _____. We will know if the medication is working if hopefully there is improvement in the following target symptoms: _____.
In addition your child is currently on the following medications: _____.
The plan for these medications is as follows: _____.

Possible benefit

Strattera is approved for ADHD in children and adolescents. It is not approved for depression or any other use. Strattera helps about 40% of kids who try it but only if they truly have ADHD. ADHD is characterized by impulsivity, hyperactivity, inattention and distractibility that begins early in life, is present both at home and at school and is not caused by such other factors as depression, anxiety, exposure to violence, reaction to traumatic events such as abuse, extremely stressful home environment or placement in foster care. In cases mild ADHD can be treated with behavior therapy, counseling and placement in a very structured home environment and does not require a medication. When there are elements of multiple psychiatric disorders, in order to make the diagnosis of ADHD your child requires a comprehensive evaluation possibly including a continuous performance test, a computer test that measures your child's inattention, impulsivity and distractibility compared to other children his or her age.

If you think that your child has ADHD, that your child's behaviors are not caused by other factors mentioned above, occur both at home and at school, began before age 8, that your child received a thorough evaluation and other non-medical intervention tried first, then a trial of stimulant medication is justified with a reasonable likelihood of benefit.

Possible risks

Strattera can also activate your child. Your child may become agitated, speeded up, irritable, aggressive or manic. There is also in increased risk of suicidal behavior or thoughts occurring in about 1 out of 25 kids on this medication. The risk can be minimized if your doctor sees your child frequently. The recently revised medication label approved by the FDA recommends that follow-up be weekly for the first 4 weeks, biweekly for the next 4 weeks and then monthly.

There have been extremely rare reports of serious liver damage with Strattera, approximately one in a million. Since this rate of liver damage is less than the rate of serious liver damage in the general population, it is not even clear that the problem is caused by the medication.

Alternatives

It may be reasonable to first try behavioral interventions for a few months before trying medication.

At school, it may be reasonable to first try behavioral interventions in the regular classroom or special education placement for a few months before trying medication.

If your child needs medication for ADHD, stimulants such as Concerta or Adderall are usually the first choice treatments for ADHD in children and adolescents.

If Strattera is being added to other psychiatric medications, it is possible that the original medications may be contributing to the ADHD-like symptoms or that the original medications were not all that effective. It may be reasonable to first try to lower or stop the original medication and if symptoms still persist to substitute one medication that might be good enough used alone.

Risk / benefit ratio

If you are convinced that the benefits of medication outweigh the risks and that the medication is the best alternative for your child at this point in time, you should go ahead and sign the consent below. On the other hand, if you have reservations about the medication or prefer to explore one of the above alternatives before trying this medication, please contact your caseworker who will put you in touch with the doctor.

Parents as partners in helping to monitor the medication

We welcome your participation in your child's treatment with medication. In order to make the best decisions about continuing or stopping the medication or changing the dose, we need your input. If you see that the medication is helping your child, improving the target symptoms listed at the top of the form, or if you do not see the medication as effective since the target symptoms have not changed, please let us know. Also if you think that your child is having side effects to the medication (see paragraph on risks) or have any other concerns about the medication, please contact us.

Consent

I agree to the use of the above medication at the above dose range. I understand that I may withdraw this consent at any time.

Signature:
Date:
Relationship to the child:

Graham-Windham
1 South Broadway
Hastings-On-Hudson, NY 10706
(914) 478-1100

Medication Consent
Risperidal (risperidone)

Dr _____, one of our staff psychiatrists, is requesting your permission to treat your child, _____, (date of birth: _____) with the above medication at the following dose range, _____. A thorough evaluation has revealed that your child is suffering from _____. We will know if the medication is working if hopefully there is improvement in the following target symptoms: _____.
In addition your child is currently on the following medications: _____.
The plan for these medications is as follows: _____.

Possible benefit

Risperidal is an atypical anti-psychotic medication. It is approved by the FDA for treatment of schizophrenia and bipolar mania in adults. It is not approved for use in children except for autism, nor is any other similar medication. It is however frequently prescribed for children and adolescents with schizophrenia, mania, paranoia, mood swings, and excessive anger with severe aggression. Although not enough to gain FDA approval, there is some evidence to suggest that Risperidal may be somewhat effective for these conditions in children. In addition, there appears to be more evidence for Risperidal's effectiveness in children than for other similar medications in the same class making it the drug of choice compared to the other atypical anti-psychotics such as Zyprexa, Seroquel or Abilify. The use of an anti-psychotic medication such as Risperidal is clearly justified if your child is psychotic or schizophrenic and is hearing voices, delusional and having trouble with logical thinking. Risperidal's other uses are more controversial and although treatment with Risperidal may be helpful, its benefits must be carefully weighed against its risks. Mania is often misdiagnosed or over diagnosed in children especially those in the foster care system, who are angry (and have reasons to be angry) and have behavioral difficulties due to their negative, traumatic and stressful life experience, which frequently includes abuse, exposure to violence, and frequent placements. Mood swings can be seen in typical adolescents. Frequently, Risperidal is used for less severe anger and aggressive behavior, where the medication may not be all that effective or necessary and that might be better handled with behavioral treatments and teaching of anger management skills and techniques.

Possible risks

Risperidal is very well tolerated short term. It may cause sedation or weight gain but on average less than Zyprexa or Seroquel.

Risperidal increases the risk of your child developing diabetes, a serious life-long medical disease, in the future. So far, the risk appears to be less than for similar drugs such as Zyprexa or Seroquel. Most of the risk is due to weight gain, which can be monitored closely. However there is still some risk that is not due to weight gain. There is little risk in the short term but most children who are put on anti-psychotic medications tend to remain on them for years.

Risperidal may increase cholesterol and triglyceride levels. Although this does not pose an immediate problem to your child, long term elevations of these levels increases the risk of heart disease and strokes. Risperidal increases these levels less than similar medications such as Zyprexa and Seroquel.

Risperidal after long term use at high doses may cause Tardive Dyskinesia, a permanent, chronic and disabling movement disorder. The risk appears to be equal for Zyprexa and Seroquel. The risk increases over time. There is little risk in the short term but most children who are put on anti-psychotic medications tend to remain on them for years.

Risperidal may cause milk leakage in adolescent girls or breast enlargement in adolescent boys in less than 1% or children. When this occurs, if the medication is stopped, these side effects usually resolve.

Alternatives

Although in schizophrenia ancillary therapies increase the level of recovery, there are no treatments that can substitute for medication.

When Risperidal is recommended for mood swings, anger or behavior, it may be reasonable to first try counseling, anger management or behavioral therapies for a few months before trying medication.

If your child needs medication for anger or behavior, there are other possible choices such as Clonidine or lithium.

If Risperidal is being added to other psychiatric medications, it is possible that the new medication is being recommended to counteract side effects of the original medications or because the original medication is not all that effective. If so, given the long-term risks associated with Risperidone and the lack of proven efficacy or safety when multiple drugs are given together to children, it may be reasonable to first try to lower or stop the original medication and if symptoms still persist to substitute one medication that might be good enough used alone.

Risk / benefit ratio

If you are convinced that the benefits of medication outweigh the risks and that the medication is the best alternative for your child at this point in time, you should go ahead and sign the consent below. On the other hand, if you have reservations about the medication or prefer to explore one of the above alternatives before trying this medication, please contact your caseworker who will put you in touch with the doctor.

Parents as partners in helping to monitor the medication

We welcome your participation in your child's treatment with medication. In order to make the best decisions about continuing or stopping the medication or changing the dose, we need your input. If you see that the medication is helping your child, improving the target symptoms listed at the top of the form, or if you do not see the medication as effective since the target symptoms have not changed, please let us know. Also if you think that your child is having side effects to the medication (see paragraph on risks) or have any other concerns about the medication, please contact us.

Consent

I agree to the use of the above medication at the above dose range. I understand that I may withdraw this consent at any time.

Signature:
Date:
Relationship to the child:

Graham-Windham
1 South Broadway
Hastings-On-Hudson, NY 10706
(914) 478-1100

Medication Consent
Zyprexa (olanzapine) or Seroquel (quetiapine)

Dr _____, one of our staff psychiatrists, is requesting your permission to treat your child, _____, (date of birth: _____) with one of the above medications,_____ at the following dose range, _____. A thorough evaluation has revealed that your child is suffering from _____. We will know if the medication is working if hopefully there is improvement in the following target symptoms: _____. In addition your child is currently on the following medications: _____. The plan for these medications is as follows: _____.

Possible benefit

Zyprexa and Seroquel are atypical anti-psychotic medications, approved by the FDA for treatment of schizophrenia and bipolar mania in adults. They are not approved for use in children, nor are any other similar medication except for Risperidal, which is approved for autistic youngsters. They are however frequently prescribed for children and adolescents with schizophrenia, mania, paranoia, mood swings, and excessive anger with severe aggression. There is some evidence to suggest that Zyprexa or Seroquel may be somewhat effective for these conditions in children. However the evidence is less than that available for Risperidal, a similar drug in the same class. The use of an anti-psychotic medications are clearly justified if your child is psychotic or schizophrenic and is hearing voices, delusional and having trouble with logical thinking. There is even less evidence supporting other and although treatment with anti-psychotic medication may be helpful, its benefits must be carefully weighed against its risks. Mania is often misdiagnosed or over diagnosed in children especially those in the foster care system, who are angry (and have reasons to be angry) and have behavioral difficulties due to their negative, traumatic and stressful life experience, which frequently includes abuse, exposure to violence, and frequent placements. Mood swings can be seen in typical adolescents. Frequently, Zyprexa or Seroquel is used for less severe anger and behavior, where the medication may not be all that effective or necessary and that might be better handled with behavioral treatments and teaching of anger management skills and techniques. Zyprexa or Seroquel might be useful for children who were already tried on Risperidal and it was not effective.

Possible risks

Zyprexa or Seroquel can cause significant sedation or weight gain. The risk on Risperidal is less.

Zyprexa or Seroquel increase the risk of your child developing diabetes, a serious life-long medical disease, in the future. Most of the risk is due to weight gain, which can be monitored closely. However there is still some risk that is not due to weight gain. The risk on Risperidal is less. There is little risk in the short term but most children who are put on anti-psychotic medications tend to remain on them for years.

Zyprexa or Seroquel may increase cholesterol and triglyceride levels. Although this does not pose an immediate problem to your child, long term elevations of these levels increases the risk of heart disease and strokes. The risk on Risperidal is less.

Zyprexa or Seroquel after long-term use at high doses may cause Tardive Dyskinesia, a permanent, chronic and disabling movement disorder. The risk is the same for Risperidal. The risk increases over time. There is little risk in the short term but most children who are put on anti-psychotic medications tend to remain on them for years.

Seroquel causes cataracts in animals. It is not known if it increases the risk of cataracts in humans. This risk is unique to Seroquel. However to be safe, the FDA recommends eye examinations before starting Seroquel and every six months while on Seroquel. There have been no reports of cataracts in children. The frequent eye examinations may not be necessary in children but since the FDA does not approve this medication for children, it did not make a specific follow up recommendation for children.

Alternatives

Although in schizophrenia ancillary therapies increase the level of recovery, there are no treatments that can substitute for medication.

When Zyprexa or Seroquel is recommended for mood swings, anger or behavior, it may be reasonable to first try counseling, anger management or behavioral therapies for a few months before trying medication.

If your child needs medication for anger or behavior, there are other possible choices such as Risperidal, Clonidine or lithium.

If Zyprexa or Seroquel are being added to other psychiatric medications, it is possible that the new medication is being recommended to counteract side effects of the original medications or because the original medication is not all

that effective. If so, given the long-term risks associated with these medications and the lack of proven efficacy or safety when multiple drugs are given together to children, it may be reasonable to first try to lower or stop the original medication and if symptoms still persist to substitute one medication that might be good enough used alone.

Risk / benefit ratio

If you are convinced that the benefits of medication outweigh the risks and that the medication is the best alternative for your child at this point in time, you should go ahead and sign the consent below. On the other hand, if you have reservations about the medication or prefer to explore one of the above alternatives before trying this medication, please contact your caseworker who will put you in touch with the doctor.

Parents as partners in helping to monitor the medication

We welcome your participation in your child's treatment with medication. In order to make the best decisions about continuing or stopping the medication or changing the dose, we need your input. If you see that the medication is helping your child, improving the target symptoms listed at the top of the form, or if you do not see the medication as effective since the target symptoms have not changed, please let us know. Also if you think that your child is having side effects to the medication (see paragraph on risks) or have any other concerns about the medication, please contact us.

Consent

I agree to the use of the above medication at the above dose range. I understand that I may withdraw this consent at any time.

Signature:
Date:
Relationship to the child:

Graham-Windham
1 South Broadway
Hastings-On-Hudson, NY 10706
(914) 478-1100

Medication Consent

Abilify (aripiprazole)

Dr _____, one of our staff psychiatrists, is requesting your permission to treat your child, _____, (date of birth: _____) with the above medication at the following dose range, _____. A thorough evaluation has revealed that your child is suffering from _____. We will know if the medication is working if hopefully there is improvement in the following target symptoms: _____.
In addition your child is currently on the following medications: _____.
The plan for these medications is as follows: _____.

Possible benefit

Abilify is an atypical anti-psychotic medication, approved by the FDA for treatment of schizophrenia and bipolar mania in adults. It is not approved for use in children, nor is any other similar medication except Risperidal, which is approved for autistic youngsters. It is however frequently prescribed for children and adolescents with schizophrenia, mania, paranoia, mood swings, and excessive anger with severe aggression. Abilify is a relatively new medication. Compared to similar medications in the same class such as Risperidal, Zyprexa or Seroquel, there is little scientific evidence or long term track record to suggest that is safe or effective for these conditions in children. In addition, mania is often misdiagnosed or over diagnosed in children especially those in the foster care system, who are angry (and have reasons to be angry) and have behavioral difficulties due to their negative, traumatic and stressful life experience, which frequently includes abuse, exposure to violence, and frequent placements. Mood swings can be seen in typical adolescents. Frequently, Abilify is used for less severe anger and behavior that might be better handled with behavioral treatments and teaching of anger management skills and techniques. Given its lack of proven efficacy, safety or long-term clinical experience, Abilify probably should not be used as a first choice medication. However, it does offer an advantage over similar medications. Abilify causes less weight gain, over sedation or elevated cholesterol levels. Therefore Abilify might be useful for children who were already tried on Risperidal and it was not effective or the child was too sedated or gained too much weight.

Possible risks

All atypical anti-psychotic medications may cause tardive dyskinesia and increase the risk of developing diabetes if used long term. It appears that Abilify may have a lower incidence of these problems than Risperidal, Zyprexa or Seroquel. However, since these side effects take years to develop and Abilify is much newer than the other 3 medications, the full risk will not be know for many more years. With a new medication, there is also the possibility that other long-term side effects that we do not know about yet will still appear in the future.

Alternatives

Although in schizophrenia ancillary therapies increase the level of recovery, there are no treatments that can substitute for medication.

When Abilify is recommended for mood swings, anger or behavior, it may be reasonable to first try counseling, anger management or behavioral therapies for a few months before trying medication.

If your child needs medication for anger or behavior, there are other possible choices such as Risperidal, Clonidine or lithium. Has your child already been on these medications?

If Abilify is being added to other psychiatric medications, it is possible that the new medication is being recommended to counteract side effects of the original medications or because the original medication is not all that effective. If so, given the long-term risks associated with Risperidone and the lack of proven efficacy or safety when multiple drugs are given together to children, it may be reasonable to first try to lower or stop the original medication and if symptoms still persist to substitute one medication that might be good enough used alone.

Risk / benefit ratio

If you are convinced that the benefits of medication outweigh the risks and that the medication is the best alternative for your child at this point in time, you should go ahead and sign the consent below. On the other hand, if you have reservations about the medication or prefer to explore one of the above alternatives before trying this medication, please contact your caseworker who will put you in touch with the doctor.

Parents as partners in helping to monitor the medication

We welcome your participation in your child's treatment with medication. In order to make the best decisions about continuing or stopping the medication or changing the dose, we need your input. If you see that the medication is helping your child, improving the target symptoms listed at the top of the form, or if you do not see the medication as effective since the target symptoms have not changed, please let us know. Also if you think that your child is having side effects to the medication (see paragraph on risks) or have any other concerns about the medication, please contact us.

Consent

I agree to the use of the above medication at the above dose range. I understand that I may withdraw this consent at any time.

Signature:
Date:
Relationship to the child:

Graham-Windham
1 South Broadway
Hastings-On-Hudson, NY 10706
(914) 478-1100

Medication Consent
lithium

Dr _____, one of our staff psychiatrists, is requesting your permission to treat your child, _____, (date of birth: _____) with the above medication at the following dose range, _____. A thorough evaluation has revealed that your child is suffering from _____. We will know if the medication is working if hopefully there is improvement in the following target symptoms: _____.
In addition your child is currently on the following medications: _____.
The plan for these medications is as follows: _____.

Possible benefit

Lithium is a proven and accepted treatment for bipolar disorder or mania in adults and adolescents. Although not approved for children under 12, its use is justified in children who have classical cycles of mania with symptoms of euphoria, grandiosity, racing thoughts, excess energy, not needing sleep and impulsivity. Unfortunately, bipolar disorder is difficult to diagnose in children. Many children prescribed lithium do not exhibit classical mania but instead exhibit irritability, mood swings, and excessive anger with severe aggression. These symptoms can easily be mislabeled as mania especially in children in the foster care system, who are angry (and have reasons to be angry) and have behavioral difficulties due to their negative, traumatic and stressful life experience, which frequently includes abuse, exposure to violence, and frequent placements. Mood swings also can be seen in typical adolescents. In addition, lithium may be used for less severe anger and behavior, where the medication may not be all that effective or necessary and that might be better handled with behavioral treatments and teaching of anger management skills and techniques. Although there is some evidence to suggest that lithium may have anti-aggressive properties and may be somewhat effective for irritability, anger, aggression and mood swings in children, its benefits must be carefully weighed against its significant risks especially if your child is not exhibiting classical mania.

Possible risks

Lithium is a difficult medication to use. Frequent blood tests are required. Initially, it is likely to cause stomach upset. At therapeutic doses, your child is likely to have increased urination, increase thirst, and some shakiness. If your child becomes dehydrated due to fever, diarrhea, or vomiting, does not drink enough water either because he or she is uncooperative or the adults who supervise the child do not allow for enough breaks or your child sweats a lot and does not replenish fluids especially after being active in a hot summer day, your child can become quickly toxic. Toxicity can be recognized by lack of coordination, confusion, tremors, and sedation and if caught early can easily be reversed with fluids and skipping a few doses of medication. However if not identified, it can lead to seizures, coma, the need for kidney dialysis and possibly death. But to put this in perspective, if the adults in your child's life including foster family, cottage staff, teachers, case managers, case workers etc are educated to recognize the side effects and enforce fluid intake, lithium can be used safely and may be of significant benefit.

Lithium may cause thyroid problems. Thyroid hormone levels can be monitored through blood tests and if caught early and the medication is stopped is reversible. However if not caught early or the medication is not stopped, permanent thyroid disease will likely occur. The thyroid disease caused by lithium is not dangerous if your child is cooperative and takes thyroid replacement medication for the rest of his or her life.

Alternatives

Although in classical bipolar disorder ancillary therapies increase the level of recovery, there are no treatments that can substitute for medication.

When lithium is recommended for mood swings, anger or behavior, it may be reasonable to first try counseling, anger management or behavioral therapies for a few months before trying medication.

If your child needs medication for anger or behavior, there are other possible choices such as Clonidine or Risperidal.

If lithium is being added to other psychiatric medications, it is possible that it is being recommended because the original medication is not all that effective. If so, given the long-term risks and the lack of proven efficacy or safety when multiple drugs are given together to children, it may be reasonable to first try to stop the original medication and then substitute lithium so that the child is only on one medication.

Risk / benefit ratio

If you are convinced that the benefits of medication outweigh the risks and that the medication is the best alternative for your child at this point in time, you should go ahead and sign the consent below. On the other hand, if you have reservations about the medication or prefer to explore one of the above alternatives before trying this medication, please contact your caseworker who will put you in touch with the doctor.

Parents as partners in helping to monitor the medication

We welcome your participation in your child's treatment with medication. In order to make the best decisions about continuing or stopping the medication or changing the dose, we need your input. If you see that the medication is helping your child, improving the target symptoms listed at the top of the form, or if you do not see the medication as effective since the target symptoms have not changed, please let us know. Also if you think that your child is having side effects to the medication (see paragraph on risks) or have any other concerns about the medication, please contact us.

Consent

I agree to the use of the above medication at the above dose range. I understand that I may withdraw this consent at any time.

Signature:
Date:
Relationship to the child:

Graham-Windham
1 South Broadway
Hastings-On-Hudson, NY 10706
(914) 478-1100

Medication Consent
Depakote (valroic acid)

Dr _____, one of our staff psychiatrists, is requesting your permission to treat your child, _____, (date of birth: _____) with the above medication at the following dose range, _____. A thorough evaluation has revealed that your child is suffering from _____. We will know if the medication is working if hopefully there is improvement in the following target symptoms: _____.
In addition your child is currently on the following medications: _____.
The plan for these medications is as follows: _____.

Possible benefit

Depakote is an anti-seizure medication that is also a proven and accepted treatment for bipolar disorder in adults. Although not approved for children for psychiatric indications (it is approved for treatment of seizures in children), its use is justified in children who have classical cycles of mania with symptoms of euphoria, grandiosity, racing thoughts, excess energy, not needing sleep and impulsivity. Unfortunately, bipolar disorder is difficult to diagnose in children. Many children prescribed Depakote do not exhibit classical mania but instead exhibit irritability, mood swings, and excessive anger with severe aggression. These symptoms can easily be mislabeled as mania especially in children in the foster care system, who are angry (and have reasons to be angry) and have behavioral difficulties due to their negative, traumatic and stressful life experience, which frequently includes abuse, exposure to violence, and frequent placements. Mood swings also can be seen in typical adolescents. In addition, Depakote may be used for less severe anger and behavior, where the medication may not be all that effective or necessary and that might be better handled with behavioral treatments and teaching of anger management skills and techniques. Although there is some evidence to suggest that Depakote may be somewhat effective for irritability, anger, aggression and mood swings in children, its benefits must be carefully weighed against its significant risks especially if your child is not exhibiting classical mania.

Possible risks

Depakote is a difficult medication to use. At therapeutic doses, your child may experience significant over sedation and weight gain. Frequent blood tests are required to prevent toxicity.

There is a serious risk to the fetus should an adolescent girl become pregnant. Since many teen age girls who are prescribed this medication are sexually active and do not routinely use birth control, this medication may not be the best choice for a teenage girl.

In very rare instances, Depakote can cause liver damage, pancreatitis and in adolescent girls polycystic ovaries.

Alternatives

Although in classical bipolar disorder ancillary therapies increase the level of recovery, there are no treatments that can substitute for medication.

When Depakote is recommended for mood swings, anger or behavior, it may be reasonable to first try counseling, anger management or behavioral therapies for a few months before trying medication.
If your child needs medication for anger or behavior, there are other possible choices such as Clonidine, Risperidal or lithium.

If Depakote is being added to other psychiatric medications, it is possible that it is being recommended because the original medication is not all that effective. If so, given the long-term risks and the lack of proven efficacy or safety when multiple drugs are given together to children, it may be reasonable to first try to stop the original medication and then substitute Depakote so that the child is only on one medication.

Risk / benefit ratio

If you are convinced that the benefits of medication outweigh the risks and that the medication is the best alternative for your child at this point in time, you should go ahead and sign the consent below. On the other hand, if you have reservations about the medication or prefer to explore one of the above alternatives before trying this medication, please contact your caseworker who will put you in touch with the doctor.

Parents as partners in helping to monitor the medication

We welcome your participation in your child's treatment with medication. In order to make the best decisions about continuing or stopping the medication or changing the dose, we need your input. If you see that the medication is helping your child, improving the target symptoms listed at the top of the form, or if you do not see the medication as effective since the target symptoms have not changed, please let us know. Also if you think that your child is having side effects to the medication (see paragraph on risks) or have any other concerns about the medication, please contact us.

Consent

I agree to the use of the above medication at the above dose range. I understand that I may withdraw this consent at any time.

Signature:
Date:
Relationship to the child:

Graham-Windham
1 South Broadway
Hastings-On-Hudson, NY 10706
(914) 478-1100

Medication Consent
Clonidine

Dr _____, one of our staff psychiatrists, is requesting your permission to treat your child, _____, (date of birth: _____) with the above medication at the following dose range, _____. A thorough evaluation has revealed that your child is suffering from _____. We will know if the medication is working if hopefully there is improvement in the following target symptoms: _____.
In addition your child is currently on the following medications: _____.
The plan for these medications is as follows: _____.

Possible benefit

Clonidine is a blood pressure medication that has been used in child psychiatry for over 20 years to target ADHD, the tics associated with Tourette's s syndrome, anger / aggression, and hyperarrousal / over reactivity. It is not FDA approved for psychiatric usage since it is a generic drug that does not have the backing of a major pharmaceutical firm that is needed to submit the appropriate documentation to the FDA. Despite its lack of approval, there is reasonable evidence for its effectiveness and safety plus years of clinical experience when used in children to target ADHD, Tourette's, anger / aggression, and hyperarrousal / over reactivity. On the other hand, when used once per day for sleep, the benefits of Clonidine may not outweigh the risks.

Possible risks

Clonidine frequently causes over sedation. To minimize the sedation, it should be started at a small dose and gradually increased.

As a short acting blood pressure medication, Clonidine lowers blood pressure. If taken 3-4 times per day as recommended, blood pressure will likely be stable but lower than baseline. Having a stable lowered blood pressure should not pose a risk. If anything having low blood pressure is probably a long-term protective factor, decreasing the chance of developing cardio-vascular disease.

Since Clonidine is a short acting blood pressure medication, when it is taken once per day usually at night for sleep or to counteract the insomnia caused by stimulants such as Ritalin, Concerta or Adderall, it causes significant blood pressure fluctuations. The blood pressure initially goes down and then as the

single dose wears off, the blood pressure rebounds probably even higher than the baseline. This kind of yo-yo blood pressure is not healthy. (This is not a problem if the medication is taken 3-4 times per day.)

Clonidine requires a great deal of compliance. It cannot be stopped suddenly. If suddenly stopped because a child refuses to take it or runs away, there may be a dramatic rebound in blood pressure that could potentially be dangerous.

Overall, if your child's baseline blood pressures and pulse, physical examination and EKG are within normal limits, the medication is given in 3-4 doses per day and these parameters are repeated periodically while on medication, Clonidine is a reasonably safe medication.

Alternatives

When Clonidine is recommended for impulsivity, anger or behavior, it may be reasonable to first try counseling, anger management or behavioral therapies for a few months before trying medication.

If your child needs medication for anger or behavior, there are other possible choices such as Risperidal or lithium.

If your child needs medication for ADHD, there are other possible choices such as Ritalin, Concerta or Adderall.

If Clonidine is being added to other psychiatric medications, it is possible that it is being recommended because the original medication is not all that effective or caused side effects. If so, given the long-term risks and the lack of proven efficacy or safety when multiple drugs are given together to children, it may be reasonable to first try to stop the original medication and then substitute either Clonidine or another medication targeting the original symptoms so that the child is only on one medication.

Risk / benefit ratio

If you are convinced that the benefits of medication outweigh the risks and that the medication is the best alternative for your child at this point in time, you should go ahead and sign the consent below. On the other hand, if you have reservations about the medication or prefer to explore one of the above alternatives before trying this medication, please contact your caseworker who will put you in touch with the doctor.

Parents as partners in helping to monitor the medication

We welcome your participation in your child's treatment with medication. In order to make the best decisions about continuing or stopping the medication or changing the dose, we need your input. If you see that the medication is helping your child, improving the target symptoms listed at the top of the form, or if you do not see the medication as effective since the target symptoms have not changed, please let us know. Also if you think that your child is having side effects to the medication (see paragraph on risks) or have any other concerns about the medication, please contact us.

Consent

I agree to the use of the above medication at the above dose range. I understand that I may withdraw this consent at any time.

Signature:
Date:
Relationship to the child:

Appendix 2: QA and CQI program to monitor use of psychiatric medication

In order to insure appropriate use of psychiatric medication, a quality assurance and continuous quality improvement program 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.

Initial psychiatric evaluation
QA officer will review all initial evaluation and treatment plans for

Evidence that past records reviewed including analysis of accuracy of past diagnoses and effectiveness of all past medications

Input from teachers, cottage staff, and clinicians

Mental status exam

Support of current diagnosis including further work up of rule outs

Bio-psychosocial formulation that integrates all of the above

Comprehensive treatment plan that discusses reason, goal, objectives and duration for each treatment including other therapies, plus school and cottage interventions. Recommendations seem to flow from formulation.

Justification for new medication
QA officer will review all psychiatric record for

Is medication indicated for diagnosis and age? (If no, go to next section)

Is there evidence to support diagnosis?

Is a rationale provided for proposed treatment?

Have reasonable non medical interventions been tried and failed

Is there an analysis of benefits vs. risks? Are risks and benefits reasonable?

Are reasonable alternatives offered?

Have appropriate medical procedures been obtained? Are results documented?

Does the child have other disorders or take other drugs contraindicating med?

Has informed consent been obtained?

Non-FDA approved medication
QA officer will review all records for the items under justification for new medication plus added justification for use of non-approved medication.

Are there FDA approved alternatives?

If yes, why not chose the approved medication?

If there are no approved alternatives is there a more detailed discussion documenting evidence of the meds effectiveness and safety in children for the proposed usage?

If there is little evidence of safety and effectiveness in children is there a more detailed discussion of rationale for use and lack of other alternatives?

Multiple medications

QA officer will review all records to determine if there is adequate justification for the addition the new medication based on the 2 above sections plus added justification to add it on top of current medications.

Why is the first medication not being discontinued?

Have all reasonable alternative medications that might be good enough use alone been tried? Why not?

Are there potential drug-drug interactions?

Weight gain and lab abnormalities possibly due to psychiatric medication

QA officer will review all charts for adequate follow up. If weight has increased more than 5% in 3 months following start of a new medication, if child is overweight based on growth charts or if there are lab abnormalities, QA officer to check to determine if abnormality plus an action plan to correct abnormality is documented by psychiatrist. If documentation is absent or abnormality persists for longer than 2 months, case should be red flagged.

Continued need for medication

For each medication that has been used for over one year, QA officer will review

Is there documented evidence that medication was truly effective?

Is there documented evidence of absence of serious side effects?

Has medication been used longer than initial expected duration? Why?

Is there a plan to taper, discontinue or reevaluate the need for the medicine?

What is the justification for continuing the medication?

Restarting a medication after attempt to discontinue it

QA officer will review documentation that original target symptoms are still present 2 months after stopping medication or rationale that symptoms are not temporary, likely to be due to withdrawal or likely to be short lived plus the criteria for starting a new medication.