Understanding ADHD: Should ADHD, Emotional Dysregulation Type, be added to the DSM-5 in its next Text Revision.

Retrospective Study: Comparing the Effects of Memantine (NAMENDA) and Aripiprazole (ABILIFY) in the Treatment of Irritability in Autistic Spectrum Disorder (ASD) Patients

Puget Sound Psychiatric Center SUBOXONE Treatment Protocol (Outpatient Induction and Maintenance treatment for Opioid-Dependent Adults)
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Understanding ADHD: Should ADHD, Emotional Dysregulation Type, be added to the DSM-5 in its next text revision

Pelin Hattatoglu, PhD, Syed Jamal Mustafa, MD

ABSTRACT:
ADHD is a universal phenomenon afflicting millions of individuals, young and old. Over the years through meticulous and painstaking review and research of available data, the field of Psychiatry has been fortunate to come to an understanding of the basics of the condition. However much still remains to be discovered and understood. DSM-III, DSM-IV, and DSM-5 all have had the commonly known sub-types of ADHD into Hyperactive and Inattentive forms. We propose that another subset be added to the ADHD spectrum, i.e. Emotional Dysregulation type. This article is a review of 41 psychological assessment evaluations for the verification attention-deficit hyperactivity disorder (ADHD) diagnosis based on DSM-5/DSM-IV-TR (Diagnostic and Statistical Manual of Mental Disorders, Edition-5 & 4th Edition Text Revised) criteria for children between ages 6 through 17, conducted over the period a two year period. These individuals were not only evaluated for a diagnosis of ADHD, but also differential diagnosis of various behavioral, neurodevelopmental, intellectual developmental, anxiety, mood, substance use, psychotic, and personality disorders were investigated. Results showed that 70% of children who were suspected of having ADHD by their parents did not meet the DSM criteria for ADHD with its existing sub-types. The finding of our study was that the single most common diagnosis observed in these children who were referred for ‘ADHD assessment” was Parent-Child Relationship Problem (34.1%), followed by Mood Disorders (31.7%) and Other Behavior Disorders (24.9%). These results are consistent with the studies investigating whether ADHD should constitute a separate clinical entity with disruptive disorders (oppositional defiant disorder (ODD) or conduct disorder (CD)), with the internalizing disorders (anxiety and/or depression), or all of the above. The meaning of high co-morbidity of ADHD with ODD, which can be anticipated to be as high as up to 30%- 60%, is commonly discussed in clinical and academic circles. It is thought that perhaps we are overlooking a large part of the ADHD spectrum disorders by not including ADHD; Emotional Dysregulation Type, in the DSM. We recommend that the next DSM revision committee on ADHD, consider this as an option.

Introduction
This study evaluates the diagnosis for children between ages 6 through 17 who came to an outpatient psychiatric clinic with a presenting attention problems to identify their ongoing service needs. 60 school aged children aged 6 through 17 years were assessed in the Puget Sound Psychiatric Clinic Assessment Center in Bothell, WA over the period between January 2011 and December 2013. The reasons for these psychological assessments were diagnostic clarifications for ADHD, Behavioral Problems, Autistic Spectrum Disorders, Social and Academic Problems, and Thought Disorders.

It is to note that during the compilation and analysis of the data the DSM IV-TR changed to DSM-5. And although there have been some positive changes in the new edition of the DSM, the authors feel that perhaps still a portion of ADHD patients; especially the subtype of Emotional Dysregulation Type have been left out.

A total of 41 cases out of total of over 100 assessments were chosen for further analysis. By eliminating the other cases, it was the attempt of the authors to try to keep the cases being studied as free from confound and bias as much as possible. The chosen cases had come only for the assessment of an ADHD diagnosis. Presenting symptoms included persistent inattention and/or hyperactivity that interfered with their daily activity and academic functioning and development. Because of the above mentioned symptoms, the subjects also reported experiencing adjustment and relational problems at school and at home.

Psychological assessments included clinical interview, intelligence testing, personality assessment batteries and task-oriented computerized assessments. Additionally parent and teacher report questionnaires were also reviewed to gather more information.

An additional add on observation of this review turned out be to analyze the validity and uniformity of Diagnosis of ADHD, or lack thereof in the current literature; as the results in our review indicated only one third of referrals received a valid ADHD diagnosis based on DSM Diagnostic Criteria. Adelman & Taylor (2010) point out that the increasing concern among professional and policymakers about large numbers of false positive diagnoses resulting from indiscriminate use and classification practices. There are multiple reports cited of older students feigning symptoms of Learning Disability (LD) and ADHD to obtain special accommodations in the classroom and in academic testing situations (Harrison, Edwards, & Parker, 2007, 2008; Harrison & Rosenblum, 2010; Sullivan, May, & Gabally, 2007).

Observations of various clinicians at the clinic also confirmed authors concerns. It was pointed that some children as young as 10 years old, endorse and report symptoms to get stimulant medications. Being that these individuals were of such tender age and not yet fully cognitively or emotionally mature, we have been very cautious to avoid diagnostic labels such as Malinger. However reportedly, when these young individuals were questioned about the symptoms that they endorsed to request stimulant medications, they acknowledged that they had overheard that these medications cause weight loss or give (enjoyable) euphoric effects. It was also noted that some parents were of the belief that their child would benefit academically, if they were to be placed in a special education classes for lack of academic success, and they would want to regard their child’s academic problems due to ADHD, rather than issues related to hard work, discipline or cognitive abilities. We also encountered multiple instances, where an
ADHD diagnosis is sought in order not to face the more stigmatized truths of family systems problems or intellectual disabilities. To investigate this issue further we reviewed our cases to identify patterns of ADHD diagnosis clarification referrals.

**Literature Review**

The ongoing debate on the over diagnosis of ADHD in the U.S. has been an interest of mental health research. Based on 2011-2012 National Survey of Children’s Health of Centers for Disease Control, an estimate of 6.4 million children in the U.S. ages 4 to 17 had been diagnosed with ADHD at some point, a 53 percent increase over the past decade. Approximately two-thirds of those currently diagnosed have been prescribed drugs (Centers for Disease Control, 2013). According to Adelman & Taylor (2010), current estimates are that about 5% of school-aged children are diagnosed with ADHD and core symptoms being (1) not paying attention, (2) being highly active, and (3) acting impulsively when it is deemed inappropriate. Approximately 75% of those diagnosed are male. In the past, it has been estimated that less than half of those diagnosed will continue to show such symptoms as adults (McCann & Roy-Byrne, 2004) however, current postsecondary institutions are reporting a dramatic increase in students with recent ADHD diagnoses who are seeking special institutional and testing accommodations (Harrison & Rosenblum, 2010).

Some researchers pointed the role of diagnostic criteria differences in the significantly higher rates of ADHD in the U.S. relative to the other Western countries. For example, Singh (2008) cites studies indicating that a diagnosis of ADHD is 3-4 times more likely when criteria specified in the DSM -IV are used, as contrasted with criteria delineated in the ICD-10 (International Classification of Diseases -10) for diagnosing Hyperkinetic Disorder. Moreover, the fact that in the U.S. the majority of ADHD cases were diagnosed by general practitioners, including primary-care physicians, is recited among the reasons for over diagnosis (Leslie, 2002; Singh, 2008). The insurance system in the US were also pointed for this dilemma, as care used for symptom management is reimbursed by third party payors only if a current ICD-9 diagnosis is given. This fact forces the clinicians to give an ADHD diagnosis to sub-clinical cases.

Cox, Motheral, Henderson & Mager (2003) reported prevalence differs among states (e.g., ranging from 5 to 15% of school aged children). These differences have raised concern that in some communities whether these substantial over diagnosis were primarily due to ADHD look-a-like misbehavior, a simple immaturity, or a self-regulation problem with different etiology that were misdiagnosed as ADHD. For example, a study by Elder (2010) suggests that nearly 1 million children in the U.S. may be misdiagnosed as ADHD because they are the youngest and most immature in their kindergarten class. Role of pharmaceutical companies, diet, and chemical exposure are also debated factors on the discussion of increased diagnosis of ADHD in the U.S. (Vallee, 2009). Concerns about ADHD overdiagnosis and misdiagnosis increases because most of these diagnoses lead to prescribing medication. Reports also suggest that ADHD medication is being overprescribed (Volknow & Swanson, 2003; Zito, Safer, dos Reis, et al., 2000) and indicate that about two-thirds of the 4-17 year old diagnosed group were on medication.

Policy makers also seemed to be concerned with the role of schools play in promoting ADHD diagnoses and recommending parents to seek medication (Adelman & Taylor, 2010). It is a fact that most schools have inadequate resources to attend to the special needs of every individual child however the question is why schools or teachers are promoting the ADHD medication to the parents of hard to manage or underperforming children by pointing their short-term positive effects on academic performance. Both parent and schools should be aware that there is some advocacy for making these “cognitive enhancers” available to non-ADHD children as an aid in enhancing their attention and focus on school tasks without being aware of their potentially serious side effects of ADHD medications (i.e., the U.S. Food and Drug Administration warns about possible cardiovascular effects, growth suppression, and development of other psychiatric conditions; other social concerns).

On the other hand, there is a long standing controversy on whether or not ADHD is a purely biological disorder and a focus on why it is more prevalent in the US if it has solely biological roots (Vallee, 2009). We now know that there is complex etiology of ADHD and current research on etiology of ADHD has shifted its focus to the identification of specific genetic and environmental factors which increase susceptibility to ADHD (Willcutt et al., 2011). The question turned out to be, identifying the roles of biology and environment more clearly in the equilibrium of ADHD. In this debate two topics stands out in the recent literature namely; executive function and self-regulation problems.

Executive functioning is an umbrella term that is defined as neuropsychological processes needed to sustain problem-solving toward a goal that involves the use of working memory, inhibitory control, and cognitive flexibility. Self-regulation refers to the capacity to control one’s impulses and behaviors intentionally towards achieving a desired goal.

Barkley (1997, 2006), argues executive function and self-regulation are not casually related but they are essentially the same thing. He argues that self-awareness, self-motivation, self-instruction, self-inhibition, or self-directed action are really just another name for executive function components of working memory, cognitive flexibility, and inhibitory control. According to Barkley (1997), ADHD posits problems to sustained attention, persistence towards goals, resisting distractions, and inhibiting actions, words, thoughts, and emotions are direct correlates of self-regulation and executive functioning problems. He further asserts that ADHD is a disorder of self-regulation and self-regulation requires that a person have intact executive functions. The executive functions are specific types of self-regulation or self-directed actions that people use to manage themselves effectively in order to sustain their actions and (problem-solving) toward their goals and the future.
Barkley (2006) argued that children with ADHD tend to have stressful and conflict prone interactions with their parents, which makes it difficult for them to establish and maintain strong parent–child attachments. Pianta (1997) pointed that this fact of failure to establish strong attachments with caregivers may contribute to self-regulation deficits. This information highlights reported high comorbidity between ADHD and internalizing disorders and ADHD with ODD/CD. The European ADORE (Attention-deficit/hyperactivity Disorder Observational Research in Europe) study clinically referred oppositional defiant disorder (ODD) (67%), and conduct disorder (CD) (46%) as the most common psychiatric comorbidities for ADHD (Steinhausen, Novik 2006). The emphasis given to the research on comorbid disorders with ADHD may reflect the role of emotional-regulation in child’s clinical profile currently reflected as an ADHD with an additional affective or behavioral diagnosis. Along with these studies Barkley’s work reflects that we cannot separate ADHD from emotional dysregulation and view ADHD only as an executive functioning deficit. This makes us wonder whether we are truly aware of ADHD and all its sub-types. Or more specifically, if we have identified all the various types of ADHD. Despite advancement via of significant research, ADHD is still full of mysteries. Researchers like us, may still find themselves having more questions than answers even when confronted with a small set of data like our study.

Results

Our study shows that a significant percentage of assessment requests were for the diagnostic confirmation of ADHD (68.3%) for the age group of 6 to 17. However, of these individuals who were assessed for ADHD, many (38.3%) did not meet the DSM criteria of ADHD, and despite having all the symptoms of “Clinical ADHD”, they tested positive for diagnosis of mood, anxiety or other disorder indicating Emotional Dysregulation, instead. Table 1 summarizes the total of 60 cases that have been reviewed in the 2 year research period. The most prominent diagnosis category was Mood Disorders, which included Depressive and Bipolar disorders per the DSM criteria, followed by Behavioral Disorders, which included Impulse Control, Oppositional Defiant Disorder (ODD) and Conduct Disorder. Parent-Child Relationship Problems as identified as a V-code in DSM followed as third frequent diagnosis among total referrals.

Table 2 shows the distribution of diagnoses for those who came to clinic to specifically identify whether their child meet the criteria of ADHD. A significant percentage of total referrals were referral for ADHD diagnostic clarification (68.3%). Only one third of these referrals received a diagnosis of ADHD based on DSM diagnostic criteria. Parent-Child Relational Problems were the most prominent single diagnosis among those who came with an ADHD suspicion (34.1%). Mood, Anxiety and Depressive Disorders (based on DSM) together constituted almost half of the diagnosis (46.3%). Other Behavior Disorders had almost one fourth of the weight among all diagnosis. It is important to note that, 17.1% of the children who were suspected to have ADHD had lower than average IQ levels.

It is important to mention that most of the participants have multiple provisional diagnoses and Table 3 summarizes comorbidity with ADHD. Results show that 40% of ADHD cases have either Parent-Child Relational problems or Behavior Disorders, or both.

These results are consistent with existing research that has proposed higher comorbidities between ODD and ADHD.

Discussion

For the past numerous years, the overwhelming majority of people whose lives are affected by ADHD (parents, patients, teachers and providers); all have come to identify ADHD with medications such as Stimulants or non-Stimulants affecting the neurotransmitter pathways, e.g. Dopaminergic or Nor-Adrenergic. By formulating a simplified view of ADHD, as being only of Hyperactive/Impulsive or Inattentive types, a sizeable number of patients (up to 30-40%) who have neither of the above mentioned sub-types confirmed by standardized testing, may be slipping through the cracks, and not be able to avail the resources present for patient of ADHD, and consequently perhaps are getting sub-optimal care by...
being labelled as having an Emotional or Behavioral Disturbance; or somethings else. Perhaps being open minded about the sub-types of ADHD, and including the Emotional Dysregulation type may be the missing link in not only our understanding of the complete psychopathology of, but also in compassionate care for patient who truly suffer from ADHD and its sequelae. By acknowledging the Emotional Dysregulation subtype of ADHD, we are also looking at perhaps changing the practice parameters for treatment of ADHD and its sub-types.

This review shows that even though two-thirds of total referrals inquired about ADHD, however only one-third of these inquiries received an ADHD diagnosis based on DSM-IV-TR criteria. The results indicate that large portion of parents and care givers are confused about addressing mood and behavioral (emotional dysregulation) problems within an ADHD diagnosis. It is also noted that there is a large relational component either preceding or following the reported onset of problems of these individuals. These results confirm a clear confusion on the part of parents on what ADHD is. Our literature review also shows that, the mental health community, its researcher and clinicians, as well as teachers have no clear answers about this specific subject.

As clinicians in the USA and also many other parts of the world, we base and match our diagnosis to the current taxonomies of the DSM. These diagnostic manuals offer choices only among categorical labels that cater to measurable dysfunctions in established categories, and for the most part especially in the case of ADHD, have not been able to offer a solution to the repeated observation that numerous patient with “Clinical ADHD Syndrome” also have an Emotional Dysregulation Sub-Type.

It is then natural to look at the diagnostic code source (DSM) to get guidance in identifying the various sub-types and clarifying the confusion. It very heartening to note that DSM-5 now has more lenient criteria such as being more inclusive by changing age cut-offs, as well as other issues such as lack of clinically significant impairment requirement, and inclusion of comorbidity with Autistic Disorders. This broader definition predisposes American clinicians to diagnose a larger percentage of children with ADHD. However it is still leaving outside the box, a substantial subset of patients with the subtype of ADHD which predominantly present with Emotional Dysregulation leading to the constellation of ADHD symptoms.

When we look at the Inhibition Deficits of ADHD, we see that part of the problem may also be the emotional inhibition. These individuals have impaired inhibition of inappropriate behavior related to strong emotions, low frustration tolerance, they are impatient, quick to anger, hot tempered, easily annoyed, and have greater emotional excitability and reactivity. It is no wonder that in our analysis, 34% of the attention problems showed a clear configuration of parent-child relational problem, which is coded as a V-Code in the DSM. We believe even this attempt at clarifying the classification only partially reflects the interaction between their attention problems and the nature of developmental and environmental maladjustments that they experience in growing up and its consequent emotional dysregulation manifestation.

Since they are deficient in effortful, cognitive “top-down” regulation of induced emotions, they have difficulties self-regulating emotional reactions and have hard time in self-soothing, and hence refocusing attention. Such difficulties in inducing positive, more acceptable mood states make it more difficult to differentiate between the mood problems from ADHD symptoms. Emotional dysregulation problems not only explain the confusion in parents regarding relational and mood problems with ADHD but also explains the high comorbidity with behavior problems. Once again our study concurs with contemporary research indicating high comorbidity between ADHD and Oppositional Defiant Disorder (ODD).

According to Angold, A. Costello, J., Erkanli (1999), ADHD cases have 11 times greater risk for ODD and may develop it within 2 years of ADHD onset, furthermore it has also been reported that the genetic contributions to ODD and Conduct Disorder (CD) are shared with (same genes as) that of ADHD (Tuvblad, 2009). This makes us wonder whether we are looking at not just comorbidity but a sub-type variant of ADHD with Emotional Dysregulation diagnosis. The emotional impulsiveness of ODD is shared with ADHD and on top of

<table>
<thead>
<tr>
<th>Table 2: Diagnostic Distribution of ADHD Referrals</th>
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<tr>
<td>Referral for ADHD</td>
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<tr>
<td>ADHD Diagnosis</td>
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<tr>
<td>Learning Disability</td>
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<tr>
<td>Borderline Intellectual Funt. (70&lt;IQ&lt;85)</td>
</tr>
<tr>
<td>Intellectual Disability (IQ&lt;70)</td>
</tr>
<tr>
<td>Parent-Child Relational Problems</td>
</tr>
<tr>
<td>Mood Disorder</td>
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<tr>
<td>Anxiety Disorders</td>
</tr>
<tr>
<td>Behavior Disorders incl. ODD &amp; Conduct</td>
</tr>
<tr>
<td>Personality Disorder or Features</td>
</tr>
<tr>
<td>Other</td>
</tr>
</tbody>
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Note: Most of the participants have multiple diagnoses.
that ODD has defying, annoying, arguing, and blaming social components. That itself implies biological component of emotional impulsiveness is compounded with learned behavior from the environment in the ODD and ODD comorbid with ADHD. Emotional dysregulation component predicts later depression and anxiety disorders and social conflict component predicts later Conduct Disorder (Barkley, 2006). We also know that the role of early environment and parental emotional dysregulation on child’s emotion regulation (Han & Shaffer, 2013). As executive functioning of a child develops hierarchical levels; mastering sequential behavior on top of environmental influence added on to the genetic structure of the children, warrants for multi-pronged approach to treatment for those children with ADHD and Emotional Dysregulation.

The authors strongly urge clinicians and thought leaders to pay particular attention in the interlocking biology and environmental influences in identifying ADHD symptoms and sub-types. It appears that parental confusion detected in our case study was not an anomaly for the fact that ADHD has an emotional dysregulation component as well as some pure environmentally caused emotional dysregulation in children appear like ADHD. It is also important to recognize and then discern, that emotional impulsivity and deficient emotional self-regulation is central to ADHD, and also that ADHD look-a-like symptoms apparently can be a result of reactions to environmental influences. This differentiation may help clinicians identifying the disorder.

**Conclusion**

It is the conclusion of the authors that unless we make Emotional Dysregulation a sub-type of the ADHD diagnosis at par with Hyperactive/Impulsive Type and Inattentive Type, confusion about the true nature of ADHD will continue. Not fully recognizing and addressing the Emotional Dysregulation Type of ADHD, will continue to lead to increasing medication consumption with the hope that all symptoms will come under control with medications alone. However understanding psycho-social aspects of the Emotional Dysregulation Problem would help further our understanding of diagnosing and treating ADHD. Treating ADHD; Emotional Dysregulation Type, with behavioral and supportive interventions will not only be cost effective but may also improve the quality of life of these individuals and decrease the stigma associated with a “willful behavioral dysfunction syndrome”. Horwitz (2002) proposes a more nuanced conceptualization of mental disorders, in which biological contribution is considered less salient in conditions such as ADHD, than the most severe disorders like Schizophrenia. In these disorders Horwitz et al (2002) points out the need for the understanding the role of cultural constructions as well as its biological reality.

Emotional dysregulation is a predictor of social rejection and academic problems as well as cause of immense parenting stress and family conflict. It also predicts anger and can also be related to adult issues, such as, road rage, speeding, job dismissals, workplace behavior problems, relational or marital dissatisfaction. Emotional dysregulation can then in turn be a catalyst for disorders like depression, anxiety, suicidality, learning disorders, and personality disorders.

APA Practice Guidelines (Parameters) discuss in detail ADHD related emotional impulsivity and emotional dysregulation problems improved with ADHD medications; and the secondary consequences of ADHD related self-regulatory problems or ADHD look-a-like emotional dysregulation problems addressed by behavioral interventions. However the drawback that we are observing is that since Emotional Dysregulation is not currently an integral part of the ADHD spectrum, the APA Practice Parameter Guidelines mainly focus on the treatment and management of the core symptoms of ADHD, and then leaving residual Emotional Dysregulation to be dealt with as the clinical need is deemed fit.

The authors propose that at the first point of contact with a patient suspected of ADHD, after confirmation of the Diagnosis of ADHD, and its sub-type i.e. either Hyperactive/Impulsive Type; Inattentive Type; Emotional Dysregulative Type; or Combined Type; a robust treatment regime should be instituted with Medications, Family and Individual Support, Educational/Vocational Support and accommodation as well as a modular therapy approach for Emotional Dysregulation Management be instituted.

**References:**


Retrospective Study Comparing the Effects of Memantine (NAMENDA) and Aripiprazole (ABILIFY) In the Treatment of Irritability in Autistic Spectrum Disorder (ASD) Patients

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ABSTRACT:

Autistic Spectrum Disorders are very common, and also very complex. At present, unfortunately, there are no medications that definitively treat the autistc spectrum disorders. Awareness about “autism” is increasing very rapidly. And, with the increase in awareness it is also becoming painstakingly clear that despite all the advancements we still do not have a clear understanding as to the etiology, pathophysiology, and most importantly treatment/management of this condition. There are medications that have been approved by the FDA for treatment of irritability symptoms and autistic disorder patients. Along with those medications, there are also anecdotal reports of numerous other “off-label medications”, “remedies”, “naturapathic medications”, “diets”, “supplements” etc., which might be of benefit in treatment of those patients who have autistic disorders. Commenting on the full spectrum of the possibilities of treatment, is beyond the scope of this article. However, the authors attempted to look into two medications (ABILIFY and NAMENDA) and compared them side-by-side to see if one of the two medications stands out as being of more benefit than the other. The choice of taking either of the two medications was based on the parent and patient preference, psychiatrist’s recommendation, insurance coverage and cost. At the end, the results indicates that both medications were equally effective not only as judged by the parents/caregivers, but also by clinicians who are monitoring the symptoms on a fairly regular basis, using standardized methods (parent rated scale Aberrant Behavior Checklist (ABC), and clinician rated CGI-I). There are a number of limitations in this study, however, it does make us aware that ASD is complex disorder with diverse symptomatology that may change over time. It also opens our mind to the fact that there might be more than one solution to a common problem, and that as clinicians, it is our duty and responsibility to continue to search for not just the treatment, but the best treatment option available for patients. The results show the separation Therefore further research is needed to explore efficacious and safer treatment options for ASD.

INTRODUCTION:

Autism and autistic disorders have a high prevalence in the general population, some studies put it at 1 out 166 school going children in the USA have Autistic Disorders. According to 2010 estimates from CDC's Autism and Developmental Disabilities Monitoring (ADDM) Network, about 1 in 68 or 14.7 per 1,000 children has been identified with ASD. ASD is almost 5 times (1 in 42 boys and 1 in 189 girls) more common among boys. (Jon Baio, 2014).

Although much has been written about it, Autism is still an emerging field of study. Autism spectrum disorder is a neurodevelopmental disorder of childhood onset that persists throughout the lifespan of affected individual and is characterized by deficit in socialization, difficulties in language and speech and restricted, repetitive pattern of behavior or activities. (Benjamin James Sadock, 2007) (Fine, 2013).

However a large proportion of the patients with AUTISM also have externalized irritability which negatively affect their socialization skills, and also at times effects their abilities to interact with peers, teachers, family etc. Additionally, these symptoms can also have a negative effect on the patient’s abilities to learn in a classroom or outside the classroom settings. Finding a cure for Autism has alluded researchers for a long time. The most realistic treatment option that we are able to provide our patients is symptomatic relief.

There are reports that up to 20% of children with ASD have symptoms of irritability including impulsivity, aggressiveness, self-injurious behavior, and temper tantrums. (Lecavalier [2006] J. Autism Dev. Disord. 36:1101–1114.) (Robb, 2010). The term “irritability” is used to describe severe behavioral difficulties, e.g., verbal and physical aggression, deliberate self-injurious behavior temper tantrum and, quickly changing mood. (Gabriels et al., 2005; Johnson, 2007)

Behavioral therapy, educational and supportive programs remain the mainstay in the management of ASD. Despite the traditional treatment programs, problematic behaviors like aggression and violence tend to remain a challenge. Although irritability is not a core feature for diagnosis of ASD, it is a disruptive symptom and limits the learning, educational and behavioral intervention. It is hypothesized that treating irritability may potentially mitigate core symptoms and often improves socialization.

Till date two medications have been approved by the FDA to treat Irritability in patients who have AUTISM (RISPERDAL and ARIPIPRAZOLE). There are also anecdotal reports that other medications have been tried and used by various physicians with varying reports of benefits or otherwise.

One such medication, MEMANTINE (NAMENDA) has a mechanism of action different from both, RISPERDAL or ABILIFY.

Some investigators propose connection between Alzheimer’s disease and autism. (Sokol DK, 2011). Memantine partially block NMDA receptor thus protect cell against excess glutamate. Increased Glutamate level leads to neurotoxicity and neurodegeneration and increased receptor density. Excess glutamate overstimu-
lates NMDA receptors to allow too much Calcium into the nerve cell leading to cell death. Aripiprazole is a modulator, rather than blocker, acting on both postsynaptic D2 receptor and presynaptic autoreceptor. Thus it addresses excessive limbic dopamine (hyperdopaminergic) activity and decreased dopamine (hypodopaminergic) activity in frontal and prefrontal areas. (Stahl, 2013)

Effects of Memantine have also been written about by numerous authors with varying results (Chez MG1, 2007) (Ritter M, 2014) (Ephraim Katz, April 8, 2014 )

In our clinical setting, there were a number of parents who came to the clinic requesting that their children who had pre-existing diagnosis of “AUTISM” be treated with MEMANTINE. These parents came with the knowledge that MEMANTINE is being used off-label.

It is to be noted that MEMANTINE (NAMENDA) has also been studied in two clinical trial conducted by Forest Pharmaceuticals, in a double-blind, placebo-controlled method to see if it is beneficial in control of the symptoms.

In many clinical setting physicians use ABILIFY to control Irritability/externalized symptoms in patients with Autism.

The use of Namenda was novel to our clinic, however it was noted that parents and caregivers were mostly satisfied with the results, and per their report it appeared that they were getting the results that they were expecting. Therefore the authors decided to analyze data comparing the effects of NAMENDA with ABILIFY. It is to be noted that the comparison was not with placebo. And the purpose of the study was to see how these two medications compared to each other in a clinical setting.

METHOD:

A retrospective chart review of patients in an out-patient clinical setting was conducted. We studied patient who had a diagnosis of Autism and whose primary focus for being in treatment was to address their irritability. The diagnosis were confirmed by DSM criteria and Autistic Diagnostic Interview-Revised (ADI-R) or Autism Diagnostic Observation Schedule (ADOS), conducted by trained professionals (Psychiatrist or Psychologist).

Our data sources were the caregivers, the patients themselves, and chart documentation by the treating psychiatrist. To minimize confound, charts of patients who had any other acute or ongoing psychiatric, neurological or any other physical conditions; or who were on other psychiatric medications were excluded from review. 20 patient charts chosen for review, it was noted that the gender ratio was nineteen males to one female patient. The age range of these patients was from 7 to 14 years.

Of the 20 patients, 13 were on Memantine and 7 were on Aripiprazole. The authors observed that the gender and treating medication ratios are skewed; there were more male patients and more patients on Memantine, however this was not by design.

It was accepted that Autism is more prevalent in males, and may have more externalized behaviors such as irritability. It was also hypothesized that that there were more patients on MEMANTINE as compared to ABILIFY, because of reports in the media at that time, about the possibility of Memantine being beneficial in the treatment of ASD irritability. Parents/guardians all were aware of the various medication options, and were well versed with treatment options, having their preferences for medications. The choice of using either Aripiprazole or Memantine was made collaboratively in a treatment team approach by prescriber and parents/guardians, with appropriate informed consent.

The severity, improvement and progress of the ASD patients regarding their irritability had been followed by the standardized measures such as parent/caregiver reported Aberrant Behavior Checklist- irritability subscale (ABC) and Clinician Rated Clinical Global Impression (Severity and Improvement) scales. It was noted that the same parent/caregiver and clinicians completed the forms, such as the ABC and CGI throughout the observation and review period.

The Aberrant Behavior Checklist (ABC), is a parent/
ABC consists of 58 items, organized within five subscales. Each item is scored on a scale from zero (no problems) to three (severe problems). A low score correlates with less symptoms, and a high score correlates with more symptoms in that category. ABC Irritability Subscale has 15 items, maximum 45 points. Symptoms assessed on this 15-item subscale include self-injurious behaviors, physical aggression towards others, screaming, yelling, temper tantrums, demanding behaviors, mood changes, and crying in response to minor annoyances (Aman MG 1994). The Clinical Global Impression Scale is a global rating scale that measures illness severity (CGI-S) and global improvement (CGI-I). CGI-S AND CGI-I are scales which are rated one through seven. For CGI-S, one would be considered being normal, four being moderately ill, and seven being most severely ill. And for CGI-I, a score of one would be considered very much improved, four meaning no change and seven being very much worse. Thus, a decrease in scores for both CGI-S and CGI-I, indicates an improvement in disease state.

RESULTS:

At the onset it was noted that both group of patients, i.e. those who chose to be on ABILIFY and those who chose to be on Namenda had very similar ABC-I subscale scores at the starting point (mean score for ABILIFY subgroup was 14 and mean score for NAMENDA subgroup was 12) as well as at the end of the observation period week 52 (mean score for ABILIFY subgroup was 14 and mean score for NAMENDA subgroup was 11). The mean scores for CGI-S scores for both subgroups was also very similar (at the start of the observation period the score was 4.31 for both groups; and at week 52 the mean score was 3.2 for the ABILIFY subgroup and the NAMENDA subgroup had a mean score of 2.8). The results of the data show that both ABILIFY and NAMENDA decreased the severity of the targeted symptoms as noted by CGI-I, indicating an improvement in the clinical picture. However the ABC-I subgroup scores showed no statistically significant change from the start of the study. Aripiprazole is effective medication in reducing irritability. Chart review indicated that both medications were well tolerated by the patients with no adverse events warranting the discontinuation of the treatment regime.

DISCUSSION:

The results that we got by analyzing the data were very interesting. It is to be noted that at the beginning of the chart review the authors were of considering that the results might indicate Abilify being much more effective than Namenda. It was expected that Abilify would do very well based on its past performance in double-blind, placebo-controlled pivotal studies based on which the FDA gave its approval to Abilify for use in Autistic patients with Irritability, and the reports regarding Meman-
tine have been that it has been reported to both either improve or worsen irritability in its double-blind placebo controlled trials.

The authors tried to decrease bias and confound by having strict criteria for inclusion or exclusion of charts in that were selected for review. Hence the small number of patients whose charts were reviewed. Even though this is one of the limitations of our study, i.e. a small sample size. However, it also appears to be one of the strengths of our review that con found was minimized. At the end of our analysis, it is interesting to note that both ABILIFY and NAMENDA did equally well and there was no statistical difference. Once again we have to point out that the limit of our study was the small sample size and it is possible that if the sample size was larger, we could have seen a significant statistical difference between the two subgroups of patients. However, this can be considered a typical setting in a clinic where the number of patients with autistic spectrum disorder are not in the thousands, especially when we take into account all the compounds. It also emphasizes the already known fact that medications alone are not the answer and along with medications. We do need treatment regimens, which include, psychoeducation, supportive therapy, behavioral interventions, as well as family support groups. More research is needed not only in order to find better treatment options, but also to compare different medications that are either approved by the FDA for certain conditions, or are commonly being used in the community as part of the standard of care doctrine.

The result that we got may be interpreted as implying that there might be subgroups of children with ASD that respond optimally to Memantine or to Abilify. Clearly larger, well-designed, and blinded studies are needed to further evaluate the efficacy of medications in children with ASD as well as a need to define the subgroups that might optimally respond to this or other medication. (Daniel A. Rossignol1, 2014)

With the information available to us from this study, and other such studies we in the scientific community need to come up with a treatment algorithm for patients with various subtypes of the autistic spectrum disorder. In a way this would mean that we are treating patients symptoms rather than their diagnoses, which is already the standard of care.

References
Puget Sound Psychiatric Center (PSPC) SUBOXONE TREATMENT PROTOCOL (PSTP): Out-patient SUBOXONE Induction, Maintenance and Taper for Opioid-Dependent Adults

Syed Jamal Mustafa, MD, Syed Kamal Mustafa, MD

ABSTRACT:

The Puget Sound Psychiatric Center has been using SUBOXONE for the treatment of Opiate Dependence for many years. Over the years the PSPC SUBOXONE TREATMENT PROTOCOL (PSTP) has evolved into its current form. A vast majority of patients have enjoyed huge successes by following this structured and easy to follow treatment protocol. The objective of this paper is to outline the PSPC SUBOXONE Treatment Protocol (PSTP), currently used in clinical practice at the Puget Sound Psychiatric Center (PSPC). The PSTP, is based broadly off the Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction Treatment Improvement Protocol (TIP – 40) a publication of the USDA SAMHSA. The current version of the treatment protocol went through a number of evolutionary changes in the past decade or so, to come to its current version. In its current state of the art form, it is a formidable protocol. However, it is expected that as our knowledge regarding opiate addiction, as well as comorbidities improves we will further improve our protocols. As in other treatment centers, it has also been observed at our opiate dependence treatment center that patients who have opiate dependence have better outcomes with a structured protocol. Another item that was of great clinical importance was the observation that patients who are in regular meaningful psychotherapy have a much better overall response to the treatment protocol. The outcome measures of the treatment protocol (which are beyond the scope of this article) were determined through relapse rates (RR) within one year of starting the protocol, and the time to relapse (TTR) after start of the treatment protocol. It is the experience of the author that this protocol has been easy to use in clinical practice. It is also the opinion of the author that results seen when using this protocol are at least equal to, if not better than any other treatment protocol currently in use.

INTRODUCTION:

SUBOXONE for the treatment of Opiate Dependence, is recognized as an important addition to the repertoire of the treatment options. Yet, at the same time, there have been many struggles faced by SUBOXONE prescribing physicians, mainly because of the absence of a well-established universally accepted SUBOXONE Treatment Protocol.

Over the years numerous variations to the SAMHSA TIP 40 (TIP 40: Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction; SMA07-3939, 09/2004) guidelines have been proposed and used by different SUBOXONE prescribing physicians. The presence of so many, similar albeit differing treatment protocols prompted the author at the Puget Sound Psychiatric Center, to formulate a simple to understand and easy to implement treatment protocol, best suited for the needs of the PSPC and the patient population that we help.

The starting point of the Treatment Protocol, was the recognition that any Chemical Dependency treatment protocol has to be well structured, with minimal discretionary changes allowed; including the timing of the follow-up appointments, participation in therapy and the dosing by the treating physician.

PSTP has incorporated structure as the main modality in the Treatment protocol. Also incorporated in the treatment protocol along-with mandatory therapy, was the equally important mandatory abstinence of all other substances including THC, and disallowing use of Benzodiazepines.

In a structured approach the patients who come for treatment, as well as the clinicians prescribing and administering treatment are all aware of the protocol; also the expectations from the prescribers, as well as the patients are very clear and it is very rare that a deviation would occur because of some misunderstanding.

It is to be clarified that deviations from the protocol can and do happen on occasions, but this is the exception and not the rule. Any deviations from the protocol are on a case by case basis, and for only the best clinical interest of the patient.

We are cognizant that patients who have Opiate Dependence, and come for treatment with SUBOXONE can be confused and even disoriented in treatment settings and may not be able to follow complex protocols. We are also aware that some patient on the other hand may have manipulative or even abrasive behaviors. In many instances, patients with opiate dependence have been using various forms of opiates for long durations, sometimes at high dosages. A common concern that comes across from many patients is that do not want to go through painful withdrawals. Psycho-education, it is extremely important to educate and inform the patient about their condition and to continue to do so throughout the course of their treatment. It is equally important to encourage the patient to ask questions, vent their concerns about the process and be actively involved in their treatment process.

The PSTP also works with the assumption that most if not all patients with Opiate Dependence (American Psychiatric Association DSM-5, 2014) have co-occurring
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psychiatric conditions, which need to be assessed and treated appropriately, even though use of medications may not be necessary for all such co-occurring conditions.

Our current treatment protocol (PSTP) has been in use for the past almost a decade at the Puget Sound Psychiatric Center with remarkable success. We have noticed that not only have the relapse rates within the first year gone down, but also the time to relapse has dramatically been prolonged as well. In addition to this, the Patient Reported Quality Of Life Assessment (PROOLA) indicates that the patient’s have better self-esteem, less symptoms such as related to mood, anxiety, sleep, and attention: majority of patients also reported improvement in relationship issues (significant others, offsprings, parents, peers, and coworkers).

**Phases of PSTP:**

Phase 1: Patient Selection & Evaluation.
Phase 2: Induction & Titration of SUBOXONE.
Phase 3: Stabilization Phase on SUBOXONE.
Phase 4: Maintenance Phase on SUBOXONE.
Phase 5: Titrations & Discontinuation of SUBOXONE.
Phase 6: Follow-up.

**PHASE 1: Patient Selection & Evaluation.**

The most important aspect of any protocol and its success hinges on appropriate patient selection followed by an even more exhaustive Evaluation process. The Evaluation process not only includes determining treatment goals, objectives and modalities for the patient, but also evaluating the person for appropriateness of inclusion in the protocol.

A number of things are considered when we are contacted by potential patients.

It is very appropriate for patients to either a referral for a SUBOXONE treatment facility or to “Google search” for doctors in the area listed on the “SUBOXONE website”. Frequently patients/potential patients call a number of clinics and doctors listed on that website trying to get in for the earliest appointment time. Patients also want to consider the cost commitment, and want a easy to follow treatment protocol.

Unfortunately the sad news for many patients is that SUBOXONE treatment is not easy or is not as convenient as they would want it to be.

The recommendation of the US DHHS SAMHSA TIP – 40, and the DEA expectations, mean that every patient on SUBOXONE should be provided the opportunity of therapy.

Patients call and try to negotiate protocols, sometimes mentioning that there are doctors who only require the patient to come, hand over the money and walk out with a prescription of SUBOXONE.

Whenever I hear such a statement, I take it with a grain of salt, knowing that many patients would want to find the least inconvenient way of getting the treatment that they think they want.

There are also instances, when patients call to inquire about SUBOXONE protocol, and become irritated about not getting “good customer service”, after being informed of the protocol requirements and expectations. There obviously are some concierge establishments which offer a customized almost gourmet treatment menus for their “clients”; however I am not aware of any these facilities publishing data or for these establishments having a better outcome than any regular treatment facility.

I have heard about irate patient who wants the so-called “combo number one” of “only SUBOXONE.”

A person who is impatient, impulsive, demanding and perhaps even somewhat entitled might indeed be deserving of SUBOXONE treatment, however management of such a person can be challenging. Therefore for the treatment to be successful for such patients, these issues need to be discussed in detail in therapy.

In this day and age of rising expectations of physician productivity, I still recommend that patient needs to be thoroughly screened for appropriateness of inclusion into a treatment protocol. It is important for the treatment facilities to identify patients that can be best served therapeutically and ethically. And not to take on patients to fulfill management imposed quota requirements.

This is not to say that all patients do not deserve our full expertise equally, however this is to acknowledge the limitations of individual clinics.

Therefore, it is extremely important to keep in mind that patient selection is extremely important.

Once patient selection has been completed. We go to the second part of the first phase, i.e. a comprehensive evaluation.

It is important to explore many details about the patient’s history. A thorough history gives us a good insight into the patients psychological predisposing, precipitating and perpetuating factors. In the evaluation process co-occurring substance use and dependency issues, as well as co-occurring psychiatric co-morbidities also need to be given due consideration.

Initial laboratory and toxicology examination is also completed at this time.

When satisfied that the patient is a good faith participant in treatment, the patient has been evaluated for psychiatric and co-occurring chemical dependency issues; and laboratory and toxicology examination do not exclude the patient from participating in treatment, psycho-education is begun, with a thorough explanation of the protocol and what to expect. As the patient gives consent to start treatment, the patient is told to abstain from all substances, especially OPIATES. All other substances, such as Benzodiazepines, etc. are also not allowed.
# PSPC SUBOXONE TREATMENT PROTOCOL

<table>
<thead>
<tr>
<th>Phase</th>
<th>Event</th>
<th>Symptoms</th>
<th>Status of Opiate Use</th>
<th>time line</th>
<th>Resc. Medication(s)</th>
<th>Psych Med(s)</th>
<th>Medication Management</th>
<th>Therapy (As Clinically Appropriate)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evaluation</td>
<td>Point of first contact with clinic</td>
<td>No Symptoms</td>
<td>Actively Using</td>
<td>Evaluation Day 1</td>
<td>Not Required, if requested</td>
<td>Yes, if needed</td>
<td>SUBOXONE</td>
<td>Psychiatry</td>
</tr>
<tr>
<td>Abstinence</td>
<td>Before start of induction</td>
<td>Partial withdrawal symptoms</td>
<td>Advised to Refrain from Use</td>
<td>SUBOXONE Day 0 to -1</td>
<td>Rescue Medications Started</td>
<td>Yes, if needed</td>
<td>SUBOXONE Initiated</td>
<td>Initiated</td>
</tr>
<tr>
<td>Induction</td>
<td>Start of SUBOXONE and titration up</td>
<td>Partial withdrawal symptoms</td>
<td>Advised to Refrain from Use</td>
<td>SUBOXONE Day 0 to Day 4</td>
<td>No Rescue Medications Continued</td>
<td>Yes, if needed</td>
<td>SUBOXONE Titrated up to 8 mg / day</td>
<td>Continued</td>
</tr>
<tr>
<td>Stabilization</td>
<td>Continue SUBOXONE, slight adjustment of dose if needed</td>
<td>No Physical Symptoms, Some Psychological Symptoms</td>
<td>Advised to Refrain from Use</td>
<td>SUBOXONE Day 0 to Day 30</td>
<td>Not Required, if requested</td>
<td>Yes, if needed</td>
<td>SUBOXONE Titrated from 4 mg / day</td>
<td>Continued</td>
</tr>
<tr>
<td>Maintenance</td>
<td>Continue SUBOXONE, at stable dose</td>
<td>No Physical Symptoms, Some Psychological Symptoms</td>
<td>Advised to Refrain from Use</td>
<td>SUBOXONE Day 1 to Day 30</td>
<td>1-90 Days</td>
<td>Not Required, if requested</td>
<td>SUBOXONE Medication at Stabilization Dose</td>
<td>Continued</td>
</tr>
<tr>
<td>Taper</td>
<td>SUBOXONE Titrated down slowly</td>
<td>No Physical Symptoms, Some Psychological Symptoms</td>
<td>Advised to Refrain from Use</td>
<td>End of Maintenance Phase + 120 days</td>
<td>Rescue medications, if needed and requested by patient</td>
<td>Yes, if needed</td>
<td>SUBOXONE Taper: at a rate of 2 mg drop in daily dose per month</td>
<td>Continued</td>
</tr>
<tr>
<td>Follow-Up</td>
<td>No SUBOXONE</td>
<td>No Physical Symptoms, Some Psychological Symptoms</td>
<td>Advised to Refrain from Use</td>
<td>End of Active SUBOXONE Phase + 90 Days</td>
<td>Not Required, if requested</td>
<td>Yes, if needed</td>
<td>No SUBOXONE</td>
<td>Continued</td>
</tr>
</tbody>
</table>
Treatment Protocol Review

The patient is then started on a "RESCUE MEDICATION COCKTAIL". The Cocktail includes; NEURONTIN 100 mg TID; SEROQUEL 50 mg QHS; Clonidine 0.1 mg TID, Baclofen 10 mg BID (for a maximum of 5 Days); and if needed for Diarrhea LOMOTIL is prescribed at a max of 4 doses over 48 hours.

Psycho Education and Supportive Therapy is initiated during this phase.

Random Toxicology test can be performed, to confirm presence of SUBOXONE, absence of OPIATES BENZODIAZEPINES and other substances

Phase 2: Induction & Titration of SUBOXONE.

Once the patient has started to exhibit symptoms of partial withdrawal from opiates (SUBOXONE Day 1), as evidenced by the Clinical Opiate Withdrawal Scale (COWS) (Wesson DR, 1999), which can be within 24-48 hours (1-2 days) of the last use of short acting opiates or as long as up to 168 Hours (7 days) from the last use of a long acting opiates, the first dose of SUBOXONE 2mg/0.5mg is given, the next day (SUBOXONE Day 2) the patient is given a dose of SUBOXONE 4 mg/1mg. On SUBOXONE Day 3, a SUBOXONE dose of 6 gm /1.5 mg is given. On SUBOXONE Day 4, the patient is given SUBOXONE 8 mg /2 mg.

During these four days, the patient is encouraged to continue to take the Rescue Medication Cocktail.

Regular weekly Supportive Therapy and Psycho-education is continued, and Motivational Therapy is started. The patient is also encouraged to join a support group. Patient is advised to maintain abstinence from all substances.

Random Toxicology test can be performed, to confirm presence of SUBOXONE, absence of OPIATES BENZODIAZEPINES and other substances

Phase 3: Stabilization on SUBOXONE.

Once the patient has successfully progressed beyond the Induction and Titration Phase, during the next 3 weeks, the patient has an appointment every 1-2 week for evaluation and assessment of the medications dose, his response to the medication, his commitment to abstinence and also to address co-morbid psychiatric concerns.

It is during this phase that the dose of SUBOXONE may be adjusted from the 8 mg/ 2 mg daily dose to as low as a dose of 4 mg/1 mg daily to as high as 12 mg / 3 mg daily dose, depending on the patient clinical and subjective response and tolerability.

Supportive Therapy, Psycho-education, and Motivational Therapy are continued. The patient is also encouraged to join a support group. Patient is advised to maintain abstinence from all substances. Psychotherapy is initiated. Random Toxicology test are be performed, to confirm presence of SUBOXONE, absence of OPIATES BENZODIAZEPINES and other substances.

Phase 4: Maintenance on SUBOXONE.

This is the longest of the treatment phases, and usually lasts approximately 12 months (+/- 3 months). During this period the patient continues on the same dose of once daily SUBOXONE that was established during the Stabilization phase. Patient is evaluated at least once a month by the prescribing physician. Regular monthly and unscheduled random toxicology tests are performed, to confirm presence of SUBOXONE, absence of OPIATES, BENZODIAZEPINES and other substances.

Co-occurring psychiatric and other substance use issues are actively treated.

Regular weekly Supportive Therapy, Psycho-education, Motivational Therapy and Psycho-therapy are continued. The patient is also encouraged to join a support group. Patient is advised to maintain abstinence from all substances.

Phase 5: Titration & Discontinuation of SUBOXONE.

At the successful completion of Phase 4, the patient goes into a slow titration phase. The dose of SUBOXONE is decreased every month by 2 mg/0.5 mg daily dose increments, till the final month. In the last month the dose of SUBOXONE is decreased by 1 mg/0.5 mg every 15 days. E.g. if the patient had entered Phase 5 on a daily dose of 8 mg/2 mg, then in three months he would be completely weaned off.

Co-occurring psychiatric and other substance use issues are actively treated.

Regular weekly Supportive Therapy, Psycho-education, Motivational Therapy and Psycho-therapy are continued. The patient is also encouraged to join a support group. Patient is advised to maintain abstinence from all substances.

Patient is evaluated at least once a month by the prescribing physician. Regular monthly and unscheduled random toxicology tests are performed, to confirm presence of SUBOXONE, absence of OPIATES, BENZODIAZEPINES and other substances

Phase 6: Follow-up.

90 days after successful completion of the SUBOXONE protocol, the patient is contacted for follow-up. Patient is assessed and evaluated.

Patient is advised to continue Motivational Therapy and Psycho-therapy. The patient is also encouraged to maintain connection with a support group. Patient is advised to maintain abstinence from all substances.

CONCLUSION:

As has been referenced previously in this article, it is very important at very beginning to establish a good therapeutic alliance with the patient.
For the success of the treatment it is important, to establish at the very beginning, a good therapeutic alliance with the patient. Therapeutic alliance should mean not only establishing boundaries with the patient, but also at the same inculcating a therapeutic bond of mutual respect between the clinician and the patient. The therapeutic alliance is based on the best clinical interest of the patient, while adhering to the principles of medical practice and care of the patient at its highest regard.

The clinical determination of whether the patient is in partial withdrawals can be aided by the use of COWS (Clinical Opiate Withdrawal Scale) (Wesson DR, 1999), sometimes patients are asked to report their experiences by filling out SOWS (Subjective Opiate Withdrawal Scale) (Handelsman et al., 1987).

Using these two scales together gives us some level of reliability and correlation of validity of the subjective opiate withdrawal scale. It is well accepted that many with opiate dependence issues tend to exaggerate the extent and frequency of their use, as well as the symptoms that they experience. Using the clinical opiate withdrawal scale (COWS) may give us an objective assessment of what the patient may be experiencing.

It is to be noted that there are some clinics, which use COWS in determining the dose of SUBOXONE for the induction and maintenance phases, the PSTP does not utilize COWS to determine the dose of SUBOXONE that used for induction or maintenance. Our dose range strictly kept between 8mg/2mg to 12mg/3mg per day.

The support groups such as AA and NA, serve a vital and important function in the recovery process of the patients. However, they are no substitute for regular and ongoing chemical dependency/mental health psychotherapy.

Lastly, an essential part of the treatment protocol for patients who are on SUBOXONE is the fact that they need to be financially responsible for not only their appointments, but also for their missed appointments. Patients who have chemical dependency issues tend to have a history of irresponsible actions, not only financially, but also in their judgment regarding use of substances, and management of their time. By requiring patient’s to be responsible their time and money, the patients learn important skills helping them succeed in life.

The PSTP

References
