

ADD Basics 301

Rationale for Clinically Necessary Off-Label Use of Stimulant Medications in the Treatment of Attention Deficit Disorder/ Attention Deficit Hyperactivity Disorder (ADD/ADHD)

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Abstract

State of the art care for Attention Deficit Disorder/Attention Deficit Hyperactivity Disorder (ADD/ADHD) frequently requires doses/dosage regimens of stimulant medications that are at variance with FDA approved manufacturer's guidelines (i.e., off-label). Lack of training and experience about ADD/ADHD and its pervasive nature, limited experience with the medications used to treat it, and a misunderstanding/misinterpretation of the intent of the FDA approved guidelines promotes fear of off-label use of stimulant medications in patients and many professionals. As a result, many patients who could greatly benefit from proper treatment receive sub-therapeutic dosage regimens or no treatment at all.

The medical literature provides ample support for the safe use of off-label doses/dosage regimens of stimulants in children and adults with ADD/ADHD when tailored to a patient's individual needs. A national

survey of family physicians, pediatricians, developmental pediatricians, and child/adult psychiatrists has shown that greater than 45% have prescribed stimulant medications for ADD/ADHD off-label.

By using a systematic protocol that involves a comprehensive multidisciplinary assessment to first establish a valid ADD/ADHD diagnosis and identify related co-morbidities, objective in office medication trial testing, and ongoing supportive counseling, we have safely incorporated off-label dosing regimens of stimulant medications when needed to help our ADD/ADHD patients function effectively in all life spheres.

Introduction

ADD/ADHD has been a provocative topic in lay and professional communities for decades: What is it? Does it really exist? What causes it? How is it diagnosed? Is it over-diagnosed? Is it really a significant health issue? Why are so many people being diagnosed with it?

A key driver behind many of these questions is the fact that effective treatment of ADD/ADHD more often than not necessitates the use of controlled substances to treat a problem that just does not seem that serious to many individuals. The front-line medications for ADD/ADHD, the methylphenidate and amphetamine based stimulants, provoke strong feelings, namely, worry and fear in most patients and, unfortunately, in many professionals involved in their care.

Because of these fears, some well founded and some not, many patients with legitimate concerns go undiagnosed while others do not get treated or are treated with sub-therapeutic dosage regimens. As a result, their short and long term outcomes are not optimal and the chances of developing significant secondary co-morbidities increase.

Over the past 35 years, in our ADD/ADHD specialty practice in Pittsburgh and at various satellite locations, we have diagnosed and successfully treated more than 10,000 patients (greater than a 90% success rate). We have accomplished this high degree of success by rigidly adhering to a comprehensive, multidisciplinary approach that is individualized to the needs of each patient. We have created systematic evidence-based

protocols which we have refined by consistently applying them to our patients and continuously assessing their efficacy and cost effectiveness/efficiency.

We have developed a particular expertise in the use of medication in the treatment of ADD/ADHD. To achieve a high degree of success when it comes to medication treatment for ADD/ADHD we have found that it is commonly necessary for us to use off-label medication doses and regimens (i.e., for any medication dosage form, dosage regimen, population, or other use presently not mentioned in the FDA approved manufacturers' marketing guidelines). Predictably this can magnify the inherent fear many patients, family members, uninformed physicians, and pharmacists have about the stimulant medications and can put us at odds with insurance companies that are increasingly restricting their formularies for ADD/ADHD medications by imposing arbitrary quantity limits for these medications and failing to reimburse off-label uses of stimulant medications to treat ADD/ADHD.

Targeted Audiences

The purpose of this white paper is to present our rationale for clinically necessary off-label use of stimulant medications in the treatment of ADD/ADHD. Our targeted audiences are:

- Lay audiences who are concerned about taking doses (amount/frequency) of stimulant medications beyond FDA approved manufacturer's marketing guidelines
- Practitioners confused/fearful about prescribing controlled substances beyond FDA approved manufacturer's marketing recommendations
- Practitioners whose patients are not doing well on current once per day dosage regimens but are hesitant to prescribe additional dosages beyond the FDA approved manufacturer's marketing guidelines
- Practitioners frustrated with insurance companies that have set arbitrary quantity limits for stimulant medications or in other ways refused to reimburse off-label use of stimulant medications justified by invoking FDA approved manufacturer's marketing guidelines and who are attempting to appeal/advocate for their patient's needs for higher doses or multiple doses during the waking day

- Insurance company medical directors, pharmacy directors, pharmacy and therapeutics committee members faced with making responsible insurance plan formulary decisions, particularly those who are interested in making decisions that minimize overall costs of care or lack of care of ADD/ADHD not just medication costs
- Pharmacists who feel uncomfortable filling prescriptions for ADD/ADHD patients that are beyond FDA approved manufacturer's marketing guidelines
- Insurance agents/brokers and HR directors looking to find optimal plans for individuals with ADD/ADHD
- Media tasked with reviewing and interpreting studies and policy decisions about ADD/ADHD and its medication treatment

Key Background Facts

- Manufacturer labeling including dosage guidelines for Ritalin and Dexedrine, the early forerunners of the methylphenidate and amphetamine-based stimulants of today, were initially approved by the FDA many decades ago. This was at a time prior to the more rigid approval standards used today. Original documents used by the manufacturers to support their prescribing guidelines (which were ultimately approved) provided no scientific basis for the recommendations made, but rather, anecdotal feedback from a small collection of physicians who had experience prescribing the medications at that time.
- These approved labels including manufacturer's prescribing guidelines were subsequently grandfathered in when the United States Federal Food, Drug and Cosmetic Act (FD&C) was updated and amended. Therefore, books, clinical articles, professional society association pamphlets, drugstore/pharmacist printouts, package inserts, and other materials which use the FDA approved manufacturer's marketing guidelines (i.e., the PDR) as the basis for their recommendations are probably the least scientifically reliable and valid pieces of information available to physicians to use in making informed decisions about stimulant medication dosages.
- The manufacturer of a newer methylphenidate formulation, Concerta, worked out agreements with the FDA to get approval for its labeling and dosage guidelines without having to undergo extensive and expensive dosing studies provided that it adhered to dose recommendations that were equivalent to the FDA approved, yet unscientifically-determined, dosage recommendations for Ritalin. This means that the FDA approved manufacturer's prescribing guidelines for one of the most popular medications used to treat ADHD, Concerta, are more than 50 years out of date.
- The FDA has set a standard for medications used to treat ADD/ADHD that, to receive approval, manufacturers must demonstrate a 30% reduction in core symptomatology in blinded controlled trials in groups of individuals with and without ADD/ADHD using responses on FDA approved questionnaires or through behavior ratings from structured observations of subjects. The goal for pharmaceutical companies is to generate data to meet this standard for approval by using the lowest dose that shows *group* efficacy and the lack of deleterious side effects not what was the most effective dosage for *individual* participants. While this standard may be appropriate for manufacturers with regards to approval for marketing their products to the masses, it is out of sync with the real world realities of finding and using the most effective dosing regimens to

properly treat an individual with ADD/ADHD. Most experts now agree that clinicians treating individuals with ADD/ADHD should be striving to provide 100% symptom relief (i.e., remission) throughout the entire waking day. Logically, this means that many ADD/ADHD patients might require dosages that are at variance with FDA approved manufacturer's marketing guidelines in order to receive optimal care.

- Once a drug is approved for use, it would be illegal for a pharmaceutical company to market it or make recommendations that are at variance with the original FDA approved guidelines even when years of clinical practice and the medical literature might suggest significant variations are warranted. Furthermore, senior management of pharmaceutical companies have told us and others that there is no incentive, in fact, significant disincentives, (i.e., exorbitant costs of conducting additional research to meet current FDA requirements and enhanced liability exposure) for them to generate more data with costly new trials to support approval of secondary indications or expanded dosages when off-label use is so common (40-60% of all prescriptions written) and sales of these products are so strong.
- FDA approval of manufacturer's marketing guidelines sets the parameters by which pharmaceutical companies can market their products to physicians and the public. However, they are not intended to dictate medical care. **In fact, by the provisions of the FD&C Act, once a medication is approved by the FDA for marketing, physicians can prescribe it off-label for whatever conditions and at whatever dosage schedule they deem necessary to meet a given patient's needs.** In fact, off-label use of medications is an accepted and valuable part of quality care of a patient when used by physicians ethically and according to their best knowledge and judgment. Many organizations and experts have weighed in on the off-label use of medications and the consensus would appear to be that it represents good medical practice when the following pre-requisites are met:
 1. The prescriber has experience and familiarity with the medication and the patient being treated
 2. No other alternatives are available
 3. Sound medical evidence in the published literature and/or other expert physicians support the intended use
 4. Efficacy and safety are closely monitored and documented

Therefore, off-label use of stimulants above or outside of the FDA approved manufacturer's recommended dosage schedule in marketing materials by experienced healthcare providers is not only permissible, but could actually be indicated to meet certain individual patient needs when there is either justification in the medical literature or evidence that peers with similar training and experience are prescribing them in this fashion. We will provide information in this white paper that confirms that both of these criteria are met when it comes to off-label use of stimulant medications for ADD/ADHD.

- As our knowledge and understanding about ADD/ADHD have expanded over the past several decades, prescribing patterns of specialists in the field have changed dramatically. We have become aware that ADD/ADHD is more than a behavior or academic problem identified at school. It is clear that this genetically-based neurological disorder can impact significantly on all spheres of life throughout the day and across the life span. As a result, most knowledgeable specialists now prescribe stimulant medications in a fashion that provides the patient therapeutic benefits for the entire waking day, seven days a week, 365 days a year across the lifespan. This means using short-acting medications 3 or 4 times per day or combinations of long-acting and short-acting medications in order to provide 14 to 18 hours of coverage per day. It should be noted that none of the currently available long-acting stimulants provide unequivocal therapeutic efficacy beyond 12-14 hours.
- We now look for outcome measures other than school performance to judge therapeutic efficacy of ADD/ADHD treatments. In fact, school might be the easiest place to manage the impulsivity, distractibility, and short attention span that are characteristic of ADD/ADHD. For example, we have taken care of hundreds of ADD/ADHD patients who have experienced profound behavior control difficulties which resulted in serious problems like bicycle and automobile accidents, unplanned pregnancies, and criminal activity when they were not treated with medication during non-school hours. Failure to provide proper all day coverage also puts the ADD/ADHD child or adult at much greater risk for unbalanced, unhealthy lifestyles which we now know places them at greater risk for obesity, hypertension, type 2 diabetes, and coronary artery disease, behavior control problems that can precipitate a variety of mental health disorders including depression, anxiety, suicidality, and substance use disorders, and pragmatic language difficulties which lead to communication, relationship, and social problems. This means that today, more commonly than in the past, proper care of the individual with ADD/ADHD often requires higher or additional

doses that might be above or outside of the FDA approved manufacturer's marketing guidelines. Given our current state of knowledge about the ADD/ADHD disease state, it could be argued that physicians and others who fail to provide all day symptom relief to their ADD/ADHD patients place themselves at significant medico-legal risk.

- We now recognize that individuals with genetically-based ADD/ADHD do not outgrow the problem. Nationwide, millions of adults are now being treated with a variety of stimulant medications for ADD/ADHD. At one time, people felt adults did not respond to these medications when, in reality, they were being given non-scientifically established dosages intended for children. A large percentage of the ADD/ADHD adults that we treat require doses significantly higher than the FDA approved manufacturer's marketing recommendations in order to have an optimal clinical response.
- As health care providers in an ADD/ADHD specialty practice, we have large numbers of ADD/ADHD patients referred to us who have been previously treated by other physicians including pediatricians, family practitioners, internists, and psychiatrists. Commonly, these patients give histories of being non-responders or of having adverse negative effects with stimulants. Upon careful probing, the key reason for these declarations of non or adverse response frequently turn out to be the use of sub-therapeutic doses of medication that fall within the FDA approved manufacturer's marketing guidelines. More often than not, these individuals can be helped to have significant improvement in overall life functioning when the doses of stimulants are carefully and systematically titrated to more clinically appropriate levels which commonly turn out to exceed the FDA approved manufacturer's marketing guidelines.
- In our specialty practice, the most common reasons for ADD/ADHD patients to experience apparent "side effects" with stimulant medications are:
 - 1) The persistence of ADHD symptoms misinterpreted as "side effects" in individuals who are taking **sub-therapeutic** dosages.
 - 2) The unpleasant consequences of increased **self-awareness** (e.g., anxiety, intense emotionality, the physiological consequences of the mobilization of the stress response, or tuning into the sensations associated with somatic dysfunctions like constipation) that can accompany **proper** medication therapy (i.e., using whatever dosage level is needed and tolerated by the patient).

The former (1) is managed by carefully adjusting the dose of medication which often means exceeding the FDA approved manufacturer's marketing guidelines or changing the specific medication being used. The later (2) is addressed by *always* providing close professional, supportive counseling to the individual starting medication therapy in order to guide them in interpreting and managing the complex behavioral changes that invariably occur.

Support in the Medical Literature

There are a wide variety of articles in the medical literature which support the use of off-label dosages of stimulant medication. The following is a small sample of some of the articles (arranged chronologically) that we have found most helpful in understanding this issue and developing a rationale for prescribing stimulants at dosages which are at variance with the FDA approved manufacturer's marketing guidelines.

Rapport MD et al: Attention Deficit Disorder and Methylphenidate: A Multilevel Analysis of Dose-Response Effects on Children's Impulsivity Across Settings. J Am Acad Child Adolesc Psychiatry 27:60-69,1988.

Davy T and Rodgers CL: Stimulant Medication and Short Attention Span: A Clinical Approach. Develop Beh Ped 10:313-317,1989.

Spencer T et al: A Double-Blind, Crossover Comparison of Methylphenidate and Placebo in Adults with Child-Onset Attention Deficit Hyperactivity Disorder. Arch Gen Psychiatry 52:434-443,1995.

Kessler S: Drug Therapy in Attention Deficit Hyperactivity Disorder. Southern Med J 89:33-38, 1996.

Biederman JT: Academic Highlights: Determining and Achieving Therapeutic Targets in Attention – Deficit /Hyperactivity Disorder. J of Clin Psychiatry 64(3):265-72, 2003.

Stevens JR, George RA, Fusillo S, Stern TA, Wilens TE: Plasma Methylphenidate Concentrations in Youths Treated with High-Dose Osmotic Release Oral System Formulation. J Child Adolesc Psychopharmacol. Feb20(1):49-54, 2010.

Dodson, William: Real World Office Management of ADHD in Adults. <http://www.addresources.org/ADHD%20Off%20Management>. Accessed 11/20/13.

Surman Craig: (editor Jerrold F. Rosenbaum, MD) ADHD in Adults: A Practical Guide to Evaluation and Management. New York: Humana Press, 2013.

Goodman David: Sustained Treatment Effect in Attention Deficit Hyperactivity Disorder: Focus on Long-term Placebo Controlled Randomized Maintenance Withdrawal and Open Label Studies. Ther Clin Risk Manag 9:121-130, 2013.

Froehlich T, Delgado SV, Anixt JS: Expanding Medication Options for Pediatric ADHD. Current Psychiatry 12(12):20-29, 2013.

Stevens JR, Wilens TE, Stern T: Using Stimulants for Attention Deficit/Hyperactivity Disorder: Clinical Approaches and Challenges. Prim Care Companion CNS Disorder 15(2),2013.
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3733520/> Accessed 2/21/14.

Surman Craig: Medscape Psychiatry: Correct Stimulant Dose for Adults; Interactions Between SSRIs and Stimulants. <http://www.medscape.org/viewarticle/553351>. Accessed 2/21/14.

In general, the medical literature demonstrates that for most patients there is a linear dose-response curve with regards to stimulant medications. This means the higher the dose the greater the response. Other patients show no response at lower doses but require substantially more robust doses before they show any positive benefits.

These differences in medication responsiveness appear to reflect genetically-based individual differences in factors that affect how an individual metabolizes these drugs. We now have genetic testing that can facilitate a better understanding of why certain patients appear to be outliers when it comes to medication effectiveness and adverse effects.

Therefore, in the presence of continued dysfunction in an ADD/ADHD individual, medication can legitimately be increased to the point that all day clinical efficacy is achieved or side effects become intolerable or unmanageable. In our experience, this later issue is oftentimes very complicated. Clearly, the ADD/ADHD field could benefit from much more research into the use of medication and dosage levels in particular. We feel that the major limitation of current medical literature is the significant heterogeneity of the ADD/ADHD population in terms of the degree of their problem and profile of underlying attentional weaknesses and executive dysfunctions along with the presence of individual differences in temperament and/or co-morbid conditions that have not been accounted for in study designs.

National Physician Survey Results

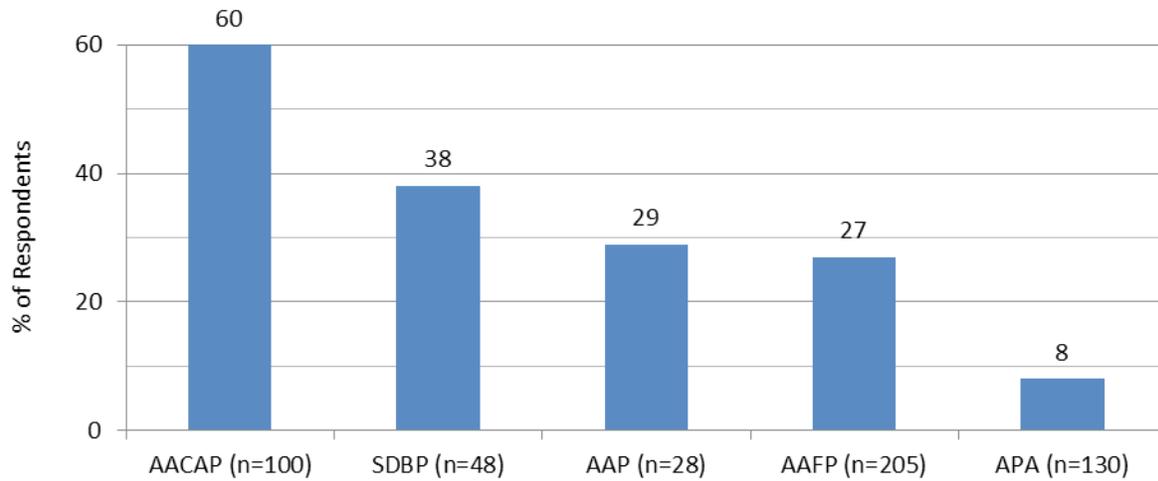
We have conducted a national survey of physicians regarding their prescribing practices with regards to ADD/ADHD. We obtained randomized samples (including geographic area) of membership lists from the American Academy of Family Practitioners (AAFP), the American Academy of Pediatrics (AAP), the American Psychiatric Association (APA), the Society of Developmental and Behavioral Pediatrics (SDBP), and the American Academy of Child and Adolescent Psychiatry (AACAP). Each physician was asked to complete a detailed questionnaire designed by a research psychologist with a strong background in marketing surveys.

Results indicate that approximately 45% of all physicians responding had used stimulants in treating ADD/ADHD at dosages greater than the FDA approved manufacturer's marketing guidelines. Furthermore, as training and experience with ADD/ADHD increases, the percentage of physicians using higher doses increases (see tables on the next page). Our interpretation would be that as physicians get more training and more experience with ADD/ADHD, they come to recognize that it is frequently necessary to exceed FDA approved manufacturer's marketing guidelines for stimulants in order to properly manage their patients in all life spheres throughout the working day.

Percent in Professional Organizations saying they were comfortable prescribing a single dose of Ritalin that exceeded 20 mg



Percent in Professional Organizations saying they were comfortable prescribing a daily dose of Ritalin that exceeded 60 mg



Our Approach

In our specialty practice, we have now had the opportunity to care for more than 10,000 patients with ADD/ADHD over the past 35 years. Our youngest patient is 3 years old and our oldest well into her 90's. We have had the unique opportunity to watch ADD/ADHD across the lifespan from early childhood to late adolescence, from young adult life to mid-adult life, and from mid-adult life to the senior years. We know of very few individuals or medical practices in the world who have had the same extensive clinical experience with ADD/ADHD and the stimulant medications as we have had.

Several years ago, Dr. Liden was asked to present a peer reviewed paper at the first International Conference on Attention Deficit Disorders in Jerusalem, Israel sponsored by the Hebrew University of Jerusalem, entitled: "TRANSACT: Toward a Standard of Care for ADD." Our approach to diagnosis and treatment including the use of medication was the only multidisciplinary clinical program selected for presentation at this first International Conference on ADD/ADHD. We received uniformly positive feedback from other physicians attending this conference.

Since 1980, we have conducted hundreds of lectures and workshops for physicians and other health related professionals from across the country and around the world regarding ADD/ADHD and the use of medication. Dr. Liden has presented testimony to the U.S. Congressional Oversight Committee regarding the proper use of medication in ADHD. He has also sat on advisory boards for several pharmaceutical companies and has served on the board of ADDA, the national advocacy group for adults with ADD/ADHD.

Based upon years of clinical experience and research and a review of the medical literature, we have developed a highly systematic protocol for the use of stimulants in treating patients with ADD/ADHD. The following are key features of our approach:

1. All patients must first have a comprehensive, multidisciplinary evaluation (3 hours) that includes use of parent, child, and school questionnaires that survey the presenting concerns, efforts to address them, key life arenas where problems are appearing along with a review of the patients' temperamental traits, readiness skills, attention and executive functioning, current and past health and mental health status, family history, attitudes, values and beliefs and a delineation of current daily routines for sleep, exercise, eating, stress management and other activities of

daily living. This is supplemented with a structured interview that probes areas of uncertainty from the questionnaire and delineates the course of the problem(s) over time. All new patients participate in a neurodevelopmental survey of neuromaturational functioning, attention/executive functioning, expressive, receptive and pragmatic language skills, memory, problem-solving, and basic academic skills in reading, spelling, math, and written language. All new patients undergo a targeted physical examination during which their mental status is also assessed.

At the conclusion of testing, patients/families meet with one of our medical directors to establish the ADD/ADHD diagnosis (if appropriate), identify any co-existing problems and generate a holistic profile of the individual's strengths and weaknesses physically, emotionally, behaviorally, and educationally that helps develop a comprehensive treatment plan of which **medication is only one part**. All patients receiving the ADD/ADHD diagnosis meet the DSM criteria at a minimum but also our refined criteria: chronic inattention and executive dysfunction, inattention and executive dysfunction apparent in multiple life spheres, evidence of attentional weaknesses and/or executive dysfunction on objective testing and the presence of neuromaturational delay (by history or through direct assessment using a standardized battery of "soft" neurological signs).

2. All patients who are prescribed medication must be involved with ongoing follow-up sessions with a professional counselor that are directed at improving self-awareness and self-control, establishing healthy daily routines, developing compensating strategies, and providing on-going emotional support. We *never* prescribe stimulant medication in isolation or as the sole mode of treatment for ADD/ADHD. We insist that our patients participate in the supportive follow-up visits on at least a monthly basis (or more frequently as needed) as a prerequisite for us to continue to write prescriptions for their ADD/ADHD medications.
3. After the initial comprehensive evaluation, all patients for whom stimulant medication is indicated are required to go through systematic medication trial testing in our office. This involves taking a dose of medication at home and coming into the office for an appointment at a time that corresponds to when the effect of that dose should be at its peak. While in the office, they undergo objective testing of attention using the FACES, a distinctive feature analysis task we have developed, or other objective measures of attention. Results are compared to a previous baseline performance without medication. At the time of the medication trial visit, a physical

assessment including vital signs and behavioral observations are made while the patient is on the medication to monitor for any adverse effects.

In conducting these trial tests, we use a set of prescribing guidelines from the American Academy of Pediatrics (2000) based on mg of generic, short-acting methylphenidate/kg body weight/dose, not on unsubstantiated absolute dosage limits as a *starting point* to select the initial dose for in-office trial testing. Using this basic formula, we calculate the equivalent mg/kg ratio for other medications that are not short-acting methylphenidate (e.g., Concerta, 18 mg = 5 mg methylphenidate, b.i.d.). The Academy's position on medication is a reflection of many clinician's experiences and the medical literature which shows increasing positive attention benefits as one moves up in the mg/kg ratio (i.e., .7 mg/kg dose has a greater positive effect than .3 mg/kg dose). These guidelines have been signed off by all the major professional organizations including the FDA. We inform all of our patients when the dosage we recommend via the Academy's guidelines exceed the FDA approved manufacturer's marketing guidelines and have them sign an informed consent.

Generally, we conduct the first trial test with a dose of the medication that falls around 0.3 mg/kg body weight with allowances made for the severity of the patient's ADD/ADHD, his/her specific profile of attentional weaknesses, the presence of co-morbid conditions, and his/her previous experience with medication among other things. We repeat trial tests in the office until we find the lowest possible dose that gives significant positive objective benefits without adverse side effects.

Once the medication trials are complete, we have patients begin a 1-2 week clinical trial on what appears to be the optimal dose in order to assess the effectiveness of the medication in the real world and its duration of action. We may elect to begin the clinical trial with what was determined to be the "optimal dose" during the trials or we may elect to start at a lower dose and gradually titrate upwards using the "optimal dose" from the trials as a final "target." Three days into the clinical trial we have a brief phone follow-up with the patient or significant other to assess the initial response to the medication and identify any untoward effects that need to be addressed.

At the end of the 2-week clinical trial period, we receive feedback from patients, parents, spouses, teachers, and/or employers, as the case may be, during in-office interviews and through objective feedback forms sent to schools. We make adjustments in the medication regimen accordingly to ensure optimal coverage for the waking day and to eliminate or reduce any negative side effects.

Using this approach, the overwhelming majority of our patients take doses of the medicine that fall within the 2000 AAP Guidelines (i.e., 0.3 to 0.8 mg/kg/dose). Interestingly, many of these same doses which are within the Academy's Guidelines fall outside the FDA approved manufacturers, non-scientific-based marketing recommendations. Many other specialists in the treatment of ADD/ADHD have shared with us that they have had similar experiences. For example, Dr. Til Davy from the Toronto Sick Children's Hospital, a world class pediatric facility, has published a lead article in the Journal of Developmental and Behavioral Pediatrics, a specialty journal, describing his experience. Dr. Davy summarizes some of the key issues with stimulant dosing and states that in his experience some children with attention weaknesses require doses of Ritalin in excess of 300 mg per day and tolerate them well. He adds that there is no reason to view this as a maximum.

We are seeing an increasing number of adults with ADD/ADHD and they participate in the same structured protocol as above. In general, it has been our experience that adults with ADD/ADHD uniformly require higher absolute doses of medication compared to children though the mg/kg ratio per dose is oftentimes somewhat lower. We find that while weight can help point one in the right direction (perhaps as a reflection of brain size) it is the severity of the individual's attentional problem that seems to have the biggest impact on determining the most appropriate dose.

Other specialists treating ADD/ADHD adults have also found the need to use higher doses than the manufacturer's recommendations. Dr. Daniel Amen, a nationally recognized researcher and clinician in the area of ADD/ADHD, has written to us describing his experience with medication doses and it is very similar to the one that we have experienced. Similarly, Drs. Marc and Nicolas Schwartz who see large numbers of adults with ADD/ADHD have studied optimal stimulant dosing in their private practice and have found adults require optimal doses of all stimulants that fall above FDA-approved manufacturers' guidelines.

4. Once we have started patients on medication, we conduct a one-hour medication review visit every three to four months. At these visits, we re-assess attention either on or off medication to document continued efficacy, monitor improvement and verify the need for continued use of the medicine. We also conduct an interview with the patient and significant others to monitor progress, identify problems, and respond to concerns. A targeted physical assessment including vital signs is conducted to monitor for any adverse effects. At the end of this visit, decisions are made about the medication (dosage, schedule, etc.) and the overall treatment plan is revised. We

look for every opportunity, if possible, to discontinue medication, but, not surprisingly, most of our patients seem to have significant problems which require long-term medication treatment. In carefully monitoring our patients, we have not identified any significant negative side effects with the stimulants that could be conclusively attributed to an off-label dosage/dosage regimen of medication prescribed. We have found that most of the common side effects that occur with stimulants can be mitigated by adjusting the timing of medication, switching to another attention medication, helping patients establish and maintain balanced healthy daily routines, and providing ongoing supportive counseling in parallel with the medication.

We take our responsibility as health care providers extremely seriously and when applied to the management of ADD/ADHD, we feel that we are on the cutting edge. We have taken care to do things properly and have even submitted our approach to the State of Pennsylvania Medical Board, which found it to be in accordance with appropriate medical practice as defined by state statutes. We feel very confident and comfortable with the approach that we take with our ADD/ADHD patients.

Summary

As advocates for patients and families living with ADD/ADHD, we are very concerned when physicians, pharmacists, and insurance companies make decisions about stimulant medication doses relying on out-of-date, non-scientific data (i.e., FDA approved manufacturer's marketing guidelines). This seems to be an untenable position with what we now know scientifically and clinically about ADD/ADHD and the medications used to treat it. It has become increasingly clear that untreated and/or sub-therapeutically treated ADD/ADHD is a contributor to many of the most serious and costly health care problems we face today including drug and alcohol abuse, obesity, hypertension, chronic constipation and related bowel problems, chronic mental health problems, and poor treatment compliance let alone a variety of educational, vocational, and social difficulties. We worry about who takes responsibility when a patient with ADD/ADHD flunks out of college, loses a job, develops anxiety and depression, get in a serious automobile accident, becomes obese and hypertensive, gets pregnant at age 15, impulsively steals, or commits suicide as a consequence of inattentiveness resulting from an inadequate regimen of medication.

Our sense is that appropriate treatment of ADD/ADHD with *proper* dosing of medication is going to emerge as a significant health care issue. We are eager to work with others to resolve this important health care problem. We are confident that if we work together we can come up with a more appropriate set of guidelines for the use of stimulant medications in the treatment of ADD/ADHD so that these individuals can receive a higher quality of medical care and better long-term outcomes. We believe that cost effective and efficient management of a common problem like ADD/ADHD, such as we provide with our approach, can be a cornerstone to reducing overall health care costs.

About the Authors

Craig B. Liden, MD

Craig B. Liden is an internationally recognized expert in the diagnosis and treatment of ADD/ADHD. He is a board certified pediatrician who graduated from the University of Michigan and the Ohio State University College of Medicine. He completed his pediatric training and postdoctoral fellowship at the Harvard University Medical School/Children's Hospital Medical Center in Boston. Dr. Liden previously served on the faculty at the University of Pittsburgh School of Medicine.

Since the 1980s, Dr. Liden has been in private practice and has treated more than 10,000 patients with ADD/ADHD and a variety of other developmental and behavioral health issues. He is currently the Senior Medical Director of the Being Well Center (www.thebeingwellcenter.com) in Pittsburgh, Pennsylvania. The BWC's transdisciplinary team provides diagnostic and treatment services to people with ADD/ADHD across the lifespan. The BWC offers special programs for college students (Confidence@College), overweight individuals (Transforming U), and for people who live far away from Pittsburgh (Long Distance Services).

Dr. Liden has lectured to lay and professional audiences across the country and around the world about ADD/ADHD. He has written extensively about ADD/ADHD and is author of the acclaimed book *Pay Attention! Answers to common questions about the diagnosis and treatment of Attention Deficit Disorder* and the newly released *Accommodations for Success: A Guide for Creating 504 Agreements and IEP's for Children with ADD/ADHD*.

Terri West, PA-C

Terri West is a NCCPA board certified Physician Assistant who received her training at Gannon University. She has over 20 years of experience in working with patients across the lifespan in a variety of settings including pediatrics, family practice, gynecology, surgery, and a breast cancer specialty practice where she gained a keen insight into women's health issues. This diverse experience coupled with her leadership and teaching skills ideally matches with The Being Well Center's commitment to identify and manage the health consequences of undiagnosed or improperly treated ADHD, its integration of preventative care into a continuous support model, and its goal to support patients in independently managing their health.

About TRANShealth, Inc.

TRANShealth, Inc. is a non-profit organization committed to playing a key role in developing more accurate, cost-effective, and efficient treatment of ADD/ADHD for the 21st century. We intend to impact children, adults, and their families with complex health care problems and educational needs related to ADD/ADHD. We strive to raise public and professional awareness of the virtues of treating the whole person, not just the disorder of ADD/ADHD.

About ADDBasics.org

ADDBasics.org compiles smart, trusted resources for people living with ADD/ADHD. At ADDBasics.org, we love people with ADD/ADHD. We celebrate the unique qualities of individuals with ADD/ADHD. We imagine a future where accurate diagnosis and effective treatment for ADD is the norm. ADD Basics seeks to educate, inform, guide, and cheerlead individuals pursuing a path to overcome the challenges of ADD/ADHD.