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## Why Are Young Westerners Drawn to Terrorist Organizations Like ISIS?

by Omar Sultan Haque, MD, PhD, MTS, Jihye Choi, Tim Phillips,  
and Harold Bursztajn, MD

The relatively sudden rise of the terrorist group ISIS in the Middle East has surprised many in the West. Equally surprising is that financially stable foreigners from the West are over-represented among ISIS fighters.<sup>1</sup> As helpless observers of the inhumane and disproportionate violence that ISIS has exacted on the people of the Middle East and the rest of the world, it is easy to wonder: what could possibly be the appeal of such a murderous, intolerant, and authoritarian organization to so many young people in the West?

This question is easier to answer when imagining the motives and rationales of locals in Iraq and Syria. Perhaps these locals join in what they believe to be a righteous cause. They may want to fight their perceived enemy in a global war, just as many Americans join the US Armed Forces to fight ISIS and other perceived enemies. But what could possibly compel otherwise financially stable young Westerners (non-Muslim as well as Muslim) to leave their families, friends, and home culture, and take up an uncertain future by joining a terrorist organization like ISIS?

ISIS provides existential fast food, and for some of the most spiritually hungry young Westerners, ISIS is like a Big Mac amidst a barren wasteland of an existence.

### It's not about poverty or religion

Clearly, poverty is not causing people to join ISIS, neither is religion. The vast majority of the West's 50 million Muslims do not join terrorist groups.<sup>2</sup> Even among those with radical Islamic beliefs, only a very few act on those beliefs and join a terrorist organization.<sup>3</sup> Background beliefs do not explain the motivation that compels people to join such



groups—even as fundamentalist organizations go, ISIS is particularly extreme. It has been roundly condemned by many prominent Islamic institutions across the world as illegitimate, in violation of Islamic Law, and as not a part of Islam; it has even been rejected by the quite radical group Al-Qaeda.<sup>4</sup>

The true answer is more disturbing and psychological, and has little to do with evil psychopaths finding their true home in ISIS, or of innocent youths being brainwashed into mindless soldiers. Rather, it involves the interaction of conscious and unconscious processes with unique features of ideologies like ISIS, and existential (but not material) vulnerabilities inherent in contemporary American life. One way to summarize our answer is that as an ideology, ISIS provides existential fast food, and for some of the most spiritually hungry young Westerners, ISIS is like a Big Mac amidst a barren waste-

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## Drawn to Terrorism

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land of an existence. Much of the worldview of ISIS appears intellectually vapid and brittle, even silly when seriously considered as religious or philosophical propositions. Just as a person can get lost, a religious movement can also get lost in a forest of bad ideas. But most people do not get a PhD in philosophy of religion before deciding what to believe. The heart's longings lead the mind, and the existential filler of ISIS nourishes the desperate and vulnerable soul, however much one is surrounded by material comfort.

Who actually joins ISIS? Not psychopaths or the brainwashed, but rather everyday young people in social transition, on the margins of society, or amidst a crisis of identity. According to anthropologist and psychologist Scott Atran who has studied the motivations and demographics of terrorists, it is mostly youth in transitional stages in their lives—immigrants, students, those between jobs or girlfriends, or those who left their homes and are looking for new families. For the most part they have no traditional religious education and are “born again” to religion. They are self-seekers who have found their way to jihad in myriad ways.<sup>5</sup>

### Why join ISIS?

Have you ever purchased junk food when tired, irritable, and jet-lagged at an airport? For lonely young people in transition, ISIS provides a quick fix to the perennial problems of human life. Vulnerable people don't tend to fact check when existential relief is easily and cheaply attained with little effort. Specifically, the relief in question concerns the human desire for identity, certainty, social connection, meaning, the optimal amount of freedom, and glory.

At crucial developmental periods in adolescence and early adulthood, the formation of one's identity is a primary concern, and a riddle to be solved. These years are a time for figuring out who one is, where one belongs, what one values and finds meaningful, and what one can become and prove to the world.<sup>6</sup> These years are also a time of increasing awareness of an exciting yet frightening internal world with conscious and unconscious conflicts around envy, competition, self-control, and self-esteem.<sup>7</sup> For youths on the margins of Western society, and in transition from one community to the next, this process of identity formation can become a hopeless task. When one has become a fringe member of one's home community in America during

crucial phases of identity formation, it is very tempting to join what appears to be a righteous struggle against one's oppressive community. Even superficial Internet exposure (much less direct marketing) can convince the young that they too may participate in a world-historical narrative in which the enemy of America is a beacon of hope for solidifying their emerging self. This may evolve into a counterphobic attitude toward the society in which they feel helplessness, with a full embrace of a cult of death such as ISIS.<sup>8</sup>

Humans tend to live with a quest for certainty in their hearts, and uncertainty is experienced as aversive.<sup>9,10</sup> Whatever its factual merits, a pluralistic worldview denies its adherents the delights of absolute certainty, and it takes much cognitive effort to maintain. ISIS provides an ideology in which the world is divided into absolute good and evil, no compromises are possible, radical Islam is the solution to all human problems, and any other interpretation of Islam is unthinkable. Why settle for shades of grey in a messy world when “The Truth” is packaged and delivered in under 30 seconds via Internet sound bites? This black and white picture of truth may seem simplistic for the critically minded, but it can provide epistemological crème brûlée for drifting and unanchored Western youths. These youths are looking for answers to existential questions within a home culture perceived to be permissive and relativistic. In the midst of all this, an ideology that does not compromise the quest for certainty can be very appealing to the most vulnerable.

### The underside of individualism

Americans pride themselves on their individualism, but the underside of individualism is loneliness.<sup>11</sup> The desire for social connection is a human need as basic as food and sex, and the most obvious source of terrorist seduction for the lonely hearted.<sup>12</sup> Social networks construct the web by which individuals are drawn to action, and social connection is a common attraction for everyday wholesome clubs as well as nefarious cults of all persuasions. Terrorist organizations are no exception, and most people join due to the influence of friends, kin, and others in a social network.<sup>13,14</sup>

Although joining based on the influence of one's friends and kin is a primary factor, recruitment from ISIS also occurs. ISIS has initiated a number of systematic online efforts to target and respond effectively to young Westerners in transition at the margins of society, who can be easily tempted

by the false allure of quick and easy social connections amidst an individualistic society from which they feel alienated.<sup>15</sup> Rather than contemplating and deciding whether the ideas within the ideology of ISIS are rational and worthy of assent, the young are more likely to be drawn in by attachments to those already embedded in ISIS as a way to thwart loneliness.

By most accounts, Americans are happy people, and the pursuit of happiness is enshrined in the American Declaration of Independence. But Western definitions of happiness tend toward happiness as present pleasure and self-expression, rather than happiness as meaning, moral struggle and sacrifice, and aligning oneself with sacred purposes beyond the self.<sup>16,17</sup> The latter meaning-oriented definition of happiness is more crucial for mental and physical health, but it is more common in non-secular cultures (and in the religious traditions within secular societies).<sup>18</sup> For Western youths drifting between communities and belief systems amidst pluralistic America, the allure of a powerful, simple ideology with a crystal-clear elaboration of the transcendent meaning for their lives and struggles would be akin to an ice cream cone on a hot July afternoon. This desire for meaning—to be a part of something much larger than oneself, especially if it is transcendent—is a very deep wish in human nature, and not the same as routine motivations concerning status or in-group preferences (ethnicity, race, or religion).<sup>19,20</sup> Thus the same need for meaning that propels a youngster to want to join ISIS can also lead an American businessman who achieves financial success to yearn for something beyond the accumulation of wealth, to something more meaningful and significant such as philanthropy, political office, or supporting a war.<sup>21</sup>

Relatedly, as Atran notes, people join ISIS because they seek adventure and want glory. ISIS presents to the bored, secure, and the uninspired in Western liberal democracies a “thrilling cause and call to action that promises glory and esteem in the

eyes of friends. Jihad is an egalitarian, equal-opportunity employer: fraternal, fast-breaking, glorious and cool. . . Many are just ‘vacationers’ for jihad, going to Syria over school breaks or holidays for the thrill of adventure and a semblance of glory.”<sup>25</sup>

A seemingly paradoxical reason some Westerners join ISIS and other totalitarian organizations is that too much freedom can be experienced as burdensome. In 1941, the psychologist Erich Fromm in *Escape From Freedom*<sup>22</sup> explained why so many were attracted to the Nazi ideology in Germany by pointing to a feature of human nature that is afraid of being free and thus would rather submit to authority than be responsible for creating a life of one's own. As in 1941 for Nazism, so also in 2015 for ISIS. Clearly, being a slave is no fun. But maximal freedom may also not be ideal, and humans vary in the degree to which additional freedom is experienced as beneficial. For someone who is socially integrated and stable, and more willful by nature, more autonomy can be a liberating means to self-create a life amidst hospitable institutions. In contrast, young adults in transition or on the margins of society may experience freedom as oppressive, since they lack the personal or social means for actually using a high degree of freedom to improve their lives. A totalitarian cult such as ISIS, which promises a strict ideology, rules, and a social order to which one can bind and submerge oneself, appeals to youths, especially those on the fringes of Western society for whom high amounts of freedom do not feel liberating but instead, oppressive.

Finally, these many vulnerabilities to joining terrorist organizations are combined with a deep but selective empathy. For example, an Iraqi-American youngster who perceives that Iraqis are persecuted by Americans might expand his empathy for suffering Iraqis over Americans and decide to join ISIS. Alternatively, a 5th-generation Italian-American

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### LEARN MORE

#### The Making of a Homegrown Terrorist

By Peter A. Olsson, MD

The author applies psychodynamic psychology to understand and recognize so-called “homegrown” terrorists—individuals who are familiar with American culture and thus more difficult to detect.

<http://www.psychiatrictimes.com/trauma-and-violence/making-homegrown-terrorist>

#### Immigration and Post-Adolescent Psychology of Young Terrorists

By Peter Barglow, MD

Radicalization by Norwegian converts to the Prophet's Ummah produced massive and terrible social consequences. The explanations offered may be pertinent to the current attraction that ISIS offers for too many young persons in many Western countries.

<http://www.psychiatrictimes.com/trauma-and-violence/immigration-and-post-adolescent-psychology-young-terrorists>

## Drawn to Terrorism

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youngster could find himself on the fringe of American society and start to develop deep empathy with the sufferings of America's perceived enemies. Empathy is indeed a source of joining terrorist groups. The same empathy we may feel for the cherished victims of our favorite causes,

others may feel for non-Americans. Empathy can be free of this paradoxical effect and fulfill its ethical possibilities only when empathy is generalized to all humans who suffer, not just to those in our in-group.

The reasons that youths join terrorist organizations such as ISIS have little to do with being poor, brainwashed, a Muslim, or a psychopath, and more to do with vulnerabil-

ities in human nature exacerbated by aspects of Western societies. This diagnosis is echoed by journalists who have interviewed many ISIS fighters; a recent analysis of ISIS fighters remarks that "what draws people to ISIS could easily bring them to any number of cults or totalitarian movements, even those ideologically contradictory to Salafist Jihadism."<sup>23</sup>

If we Westerners are lucky, we have identities, certainties, social connections, meanings, generalized empathies, freedoms, and individual pursuits of glory that can be taken for granted. However, for those Westerners in transition, marginalized, lonely, lost, bored, uncertain, spiritually or existentially dispossessed, burdened by too much freedom, and empathically selective, ISIS and oth-

APTENSIO XR™ (methylphenidate hydrochloride extended-release) Capsules, for oral use, CII Rx only

**BRIEF SUMMARY:** Consult Full Prescribing Information for Complete Product Information

**WARNING: ABUSE AND DEPENDENCE**

**CNS stimulants, including APTENSIO XR, other methylphenidate-containing products, and amphetamines, have a high potential for abuse and dependence. Assess the risk of abuse prior to prescribing, and monitor for signs of abuse and dependence while on therapy.**

**INDICATIONS AND USAGE**

APTENSIO XR is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).

**CONTRAINDICATIONS**

Hypersensitivity to methylphenidate or other components of the product. Hypersensitivity reactions such as angioedema and anaphylactic reactions have been reported in patients treated with methylphenidate products.

Concomitant treatment with monoamine oxidase inhibitors, and also within 14 days following discontinuation of treatment with a monoamine oxidase inhibitor, because of the risk of hypertensive crisis.

**WARNINGS AND PRECAUTIONS**

**Potential for Abuse and Dependence** CNS stimulants, including APTENSIO XR, other methylphenidate-containing products, and amphetamines, have a high potential for abuse and dependence. Assess the risk of abuse prior to prescribing, and monitor for signs of abuse and dependence while on therapy.

**Serious Cardiovascular Events** Sudden death, stroke and myocardial infarction have been reported in adults with CNS stimulant treatment at recommended doses. Sudden death has been reported in pediatric patients with structural cardiac abnormalities and other serious heart problems taking CNS stimulants at recommended doses for ADHD. Avoid use in patients with known structural cardiac abnormalities, cardiomyopathy, serious heart arrhythmia, coronary artery disease, and other serious heart problems. Further evaluate patients who develop exertional chest pain, unexplained syncope, or arrhythmias during APTENSIO XR treatment.

**Blood Pressure and Heart Rate Increases** CNS stimulants cause an increase in blood pressure (mean increase approximately 2 to 4 mmHg) and heart rate (mean increase approximately 3 to 6 bpm). Individuals may have larger increases. Monitor all patients for hypertension and tachycardia.

**Psychiatric Adverse Reactions** **Exacerbation of Pre-Existing Psychosis** CNS stimulants may exacerbate symptoms of behavior disturbance and thought disorder in patients with a pre-existing psychotic disorder. **Induction of a Manic Episode in Patients with Bipolar Disorder** CNS stimulants may induce a manic or mixed episode in patients. Prior to initiating treatment, screen patients for risk factors for developing a manic episode (e.g., comorbid or history of depressive symptoms or a family history of suicide, bipolar disorder, or depression). **New Psychotic or Manic Symptoms** CNS stimulants, at recommended doses, may cause psychotic or manic symptoms (e.g., hallucinations, delusional thinking, or mania) in patients without a prior history of psychotic illness or mania. If such symptoms occur, consider discontinuing APTENSIO XR. In a pooled analysis of multiple short-term, placebo-controlled studies of CNS stimulants, psychotic or manic symptoms occurred in approximately 0.1% of CNS stimulant-treated patients, compared to 0 in placebo-treated patients.

**Priapism** Prolonged and painful erections, sometimes requiring surgical intervention, have been reported with methylphenidate products, in both pediatric and adult patients. Priapism was not reported with drug initiation but developed after some time on the drug, often subsequent to an increase in dose. Priapism has also appeared during a period of drug withdrawal (drug holidays or during discontinuation). Patients who develop abnormally sustained or frequent and painful erections should seek immediate medical attention.

**Peripheral Vasculopathy, including Raynaud's Phenomenon** Stimulants, including APTENSIO XR, used to treat ADHD are associated with peripheral vasculopathy, including Raynaud's phenomenon. Signs and symptoms are usually intermittent and mild; however, very rare sequelae include digital ulceration and/or soft tissue breakdown. Effects of peripheral vasculopathy, including Raynaud's phenomenon, were observed in post-marketing reports at different times and at therapeutic doses in all age groups throughout the course of treatment. Signs and symptoms generally improve after reduction in dose or discontinuation of drug. Careful observation for digital changes is necessary during treatment with ADHD stimulants. Further clinical evaluation (e.g., rheumatology referral) may be appropriate for certain patients.

**Long-Term Suppression of Growth** CNS stimulants have been associated with weight loss and slowing of growth rate in pediatric patients. Closely monitor growth (weight and height) in pediatric patients treated with CNS stimulants, including APTENSIO XR. Careful follow-up of weight and height in pediatric patients ages 7 to 10 years who were randomized to either methylphenidate or

non-medication treatment groups over 14 months, as well as in naturalistic subgroups of newly methylphenidate-treated and non-medication treated pediatric patients over 36 months (to the ages of 10 to 13 years), suggests that consistently medicated pediatric patients (i.e., treatment for 7 days per week throughout the year) have a temporary slowing in growth rate (on average, a total of about 2 cm less growth in height and 2.7 kg less growth in weight over 3 years), without evidence of growth rebound during this period of development. Published data are inadequate to determine whether chronic use of amphetamines may cause a similar suppression of growth, however, it is anticipated that they likely have this effect as well. Therefore, growth should be monitored during treatment with stimulants, and patients who are not growing or gaining height or weight as expected may need to have their treatment interrupted.

**ADVERSE REACTIONS**

**Clinical Trial Experience** Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice. **Clinical Trials Experience with Other Methylphenidate Products in Children, Adolescents, and Adults with ADHD** Commonly reported ( $\geq 2\%$  of the methylphenidate group and at least twice the rate of the placebo group) adverse reactions from placebo-controlled trials of methylphenidate products include: decreased appetite, decreased weight, nausea, abdominal pain, dyspepsia, dry mouth, vomiting, insomnia, anxiety, nervousness, restlessness, affect lability, agitation, irritability, dizziness, vertigo, tremor, blurred vision, increased blood pressure, increased heart rate, tachycardia, palpitations, hyperhidrosis, and pyrexia. **Clinical Trials Experience with APTENSIO XR in Pediatric Patients with ADHD** The safety data in this section is based on data from two one-week controlled clinical studies of APTENSIO XR in pediatric patients with ADHD, one in children ages 6 to 12 years (RP-BP-EF001, hereafter "Study 1"), and one in children and adolescents ages 6 to 17 years (RP-BP-EF002, hereafter "Study 2"). Two APTENSIO XR clinical studies evaluated a total of 256 patients with ADHD. Two hundred and forty-three (243) patients participated in the double-blind phase of these two clinical studies. Study 1 was a randomized, double-blind, single center, placebo-controlled, flexible-dose, cross-over study to evaluate the time of onset, duration of efficacy, tolerability and safety of APTENSIO XR 15 mg, 20 mg, 30 mg, or 40 mg administered for one week in 26 pediatric patients aged 6 to 12 years who met DSM-IV criteria for ADHD. **Most Common Adverse Reactions** (incidence of  $\geq 5\%$  and at a rate at least twice placebo): abdominal pain, pyrexia and headache. **Adverse Reactions Leading to Discontinuation:** No subjects discontinued due to adverse reactions during the double-blind phase of this study. Study 2 was a randomized, double-blind, multicenter, placebo-controlled, parallel group, fixed-dose study of 10 mg, 15 mg, 20 mg, and 40 mg of APTENSIO XR administered for one week in 221 pediatric patients (6 to 17 years of age) who met DSM-IV criteria for ADHD. **Most Common Adverse Reactions** (incidence of  $\geq 5\%$  and at a rate of at least twice placebo): abdominal pain, decreased appetite, headache and insomnia. **Adverse Reactions Leading to Discontinuation:** Two patients (4.4%) in the APTENSIO XR 40 mg group discontinued due to insomnia, nausea and rapid heart rate, respectively during the double-blind phase of the study.

**Table 1: Common Adverse Reactions Occurring in  $\geq 2\%$  of Pediatric Patients (6 to 17 years of age) with ADHD Taking APTENSIO XR and at a Rate Greater than Placebo (Study 2)**

| Symptom Organ Class Adverse Reaction | Aptensio XR (n= 183) | Placebo (n=47) |
|--------------------------------------|----------------------|----------------|
| <b>Nervous System Disorders</b>      |                      |                |
| Headache                             | 10.9%                | 8.5%           |
| Insomnia                             | 9.8%                 | 2.1%           |
| Dizziness                            | 2.2%                 | 2.1%           |
| <b>Gastrointestinal Disorders</b>    |                      |                |
| Abdominal pain upper                 | 8.2%                 | 0%             |
| Nausea                               | 3.8%                 | 2.1%           |
| Vomiting                             | 3.8%                 | 0%             |
| <b>Metabolism and Nutritional</b>    |                      |                |
| Decreased Appetite                   | 4.9%                 | 0%             |

**Postmarketing Experience** The following adverse reactions have been identified during post approval use of methylphenidate products. Because these reactions are reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency or establish a causal relationship to drug exposure. These adverse reactions are as follows:

**Blood and Lymphatic System Disorders:** Pancytopenia, Thrombocytopenia, Thrombocytopenic purpura  
**Cardiac Disorders:** Angina pectoris, Bradycardia, Extrasystole, Supraventricular tachycardia, Ventricular extrasystole  
**Eye Disorders:** Diplopia, Mydriasis, Visual impairment

er shallow but contagious ideologies will remain tempting as quick fixes for the deep predicaments inherent to the human condition.

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**General Disorders:** Chest pain, Chest discomfort, Hyperpyrexia  
**Immune System Disorders:** Hypersensitivity reactions such as Angioedema, Anaphylactic reactions, Auricular swelling, Bullous conditions, Exfoliative conditions, Urticarias, Pruritus NEC, Rashes, Eruptions, and Exanthemas NEC  
**Investigations:** Alkaline phosphatase increased, Bilirubin increased, Hepatic enzyme increased, Platelet count decreased, White blood cell count abnormal  
**Musculoskeletal, Connective Tissue and Bone Disorders:** Arthralgia, Myalgia, Muscle twitching, Rhabdomyolysis  
**Nervous System Disorders:** Convulsion, Grand mal convulsion, Dyskinesia  
**Psychiatric Disorders:** Disorientation, Libido changes  
**Skin and Subcutaneous Tissue Disorders:** Alopecia, Erythema

## DRUG INTERACTIONS

**Clinically Important Interactions with APTENSIO XR Monoamine Oxidase Inhibitors (MAOIs)** Do not administer APTENSIO XR concomitantly or within 14 days after discontinuing MAOI treatment. Concomitant use of MAOIs and CNS stimulants can cause hypertensive crisis. Potential outcomes include death, stroke, myocardial infarction, aortic dissection, ophthalmological complications, eclampsia, pulmonary edema, and renal failure.

## USE IN SPECIFIC POPULATIONS

**Pregnancy Risk Summary** Limited published studies report on the use of methylphenidate in pregnant women; however, the data are insufficient to inform any drug-associated risks. No teratogenic effects were observed in embryo-fetal development studies with oral administration of methylphenidate to rats and rabbits during organogenesis at doses 2 and 11 times, respectively, the maximum recommended human dose (MRHD). However, spina bifida was observed in rabbits at a dose 40 times the MRHD. A decrease in pup body weight was observed in a pre- and post-natal development study with oral administration of methylphenidate to rats throughout pregnancy and lactation at doses 4 times the MRHD. The background risk of major birth defects and miscarriage for the indicated population are unknown. However, the background risk in the U.S. general population of major birth defects is 2% to 4% and of miscarriage is 15% to 20% of clinically recognized pregnancies. **Clinical Considerations** *Fetal/Neonatal adverse reactions* CNS stimulants, such as APTENSIO XR, can cause vasoconstriction and thereby decrease placental perfusion. No fetal and/or neonatal adverse reactions have been reported with the use of therapeutic doses of methylphenidate during pregnancy; however, premature delivery and low birth weight infants have been reported in amphetamine-dependent mothers. **Data Animal Data** In studies conducted in rats and rabbits, methylphenidate was administered orally at doses of up to 75 and 200 mg/kg/day, respectively, during the period of organogenesis. Teratogenic effects (increased incidence of fetal spina bifida) were observed in rabbits at the highest dose, which is approximately 40 times the maximum recommended human dose (MRHD) on a mg/m<sup>2</sup> basis. The no effect level for embryo-fetal development in rabbits was 60 mg/kg/day (11 times the MRHD on a mg/m<sup>2</sup> basis). There was no evidence of specific teratogenic activity in rats, although increased incidences of fetal skeletal variations were seen at the highest dose level (7 times the MRHD on a mg/m<sup>2</sup> basis), which was also maternally toxic. The no effect level for embryo-fetal development in rats was 25 mg/kg/day (2 times the MRHD on a mg/m<sup>2</sup> basis). When methylphenidate was administered to rats throughout pregnancy and lactation at doses of up to 45 mg/kg/day, offspring body weight gain was decreased at the highest dose (4 times the MRHD on a mg/m<sup>2</sup> basis), but no other effects on postnatal development were observed. The no effect level for pre- and postnatal development in rats was 15 mg/kg/day (equal to the MRHD on a mg/m<sup>2</sup> basis).

**Lactation Risk Summary** Limited published literature, based on breast milk sampling from five mothers, reports that methylphenidate is present in human milk, which resulted in infant doses of 0.16% to 0.7% of the maternal weight-adjusted dosage and a milk/plasma ratio ranging between 1.1 and 2.7. There are no reports of adverse effects on the breastfed infant and no effects on milk production. However, long-term neurodevelopmental effects on infants from stimulant exposure are unknown. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for APTENSIO XR and any potential adverse effects on the breastfed infant from APTENSIO XR or from the underlying maternal condition. **Clinical Considerations** Monitor breastfeeding infants for adverse reactions, such as agitation, anorexia, and reduced weight gain.

**Pediatric Use** The safety and effectiveness of APTENSIO XR in pediatric patients under six years have not been evaluated. The safety and effectiveness of APTENSIO XR have been established in pediatric patients ages 6 to 17 years in two adequate and well-controlled clinical. The long-term efficacy of methylphenidate in pediatric patients has not been established. **Long Term Suppression of Growth** Growth should be monitored during treatment with stimulants, including APTENSIO XR. Pediatric patients who are not growing or gaining weight as expected may need to have their treatment interrupted. **Juvenile Animal Data** Rats treated with methylphenidate early in the postnatal period through sexual maturation demonstrated a decrease in spontaneous locomotor activity in adulthood. A deficit in acquisition of a specific learning task was observed in females only. The doses at which these findings were

observed are at least 6 times the maximum recommended human dose (MRHD) on a mg/m<sup>2</sup> basis. In the study conducted in young rats, methylphenidate was administered orally at doses of up to 100 mg/kg/day for 9 weeks, starting early in the postnatal period (postnatal day 7) and continuing through sexual maturity (postnatal week 10). When these animals were tested as adults (postnatal weeks 13-14), decreased spontaneous locomotor activity was observed in males and females previously treated with 50 mg/kg/day (approximately 6 times the maximum recommended human dose [MRHD] on a mg/m<sup>2</sup> basis) or greater, and a deficit in the acquisition of a specific learning task was observed in females exposed to the highest dose (12 times the MRHD on a mg/m<sup>2</sup> basis). The no effect level for juvenile neurobehavioral development in rats was 5 mg/kg/day (half the MRHD on a mg/m<sup>2</sup> basis). The clinical significance of the long-term behavioral effects observed in rats is unknown.

**Geriatric Use** Clinical trials of APTENSIO XR did not include any patients aged 65 years and over. In general, dose selection for an elderly patient start at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function and of concomitant disease or other drug therapy.

## DRUG ABUSE AND DEPENDENCE

**Controlled Substance** APTENSIO XR contains methylphenidate a Schedule II controlled substance.

**Abuse** CNS stimulants including APTENSIO XR, other methylphenidate-containing products, and amphetamines have a high potential for abuse. Abuse is characterized by impaired control over drug use despite harm, and craving. Signs and symptoms of CNS stimulant abuse include increased heart rate, respiratory rate, blood pressure, and/or sweating, dilated pupils, hyperactivity, restlessness, insomnia, decreased appetite, loss of coordination, tremors, flushed skin, vomiting, and/or abdominal pain. Anxiety, psychosis, hostility, aggression, suicidal or homicidal ideation have also been observed. Abusers of CNS stimulants may chew, snort, inject, or use other unapproved routes of administration which can result in overdose and death. To reduce the abuse of CNS stimulants including APTENSIO XR, assess the risk of abuse prior to prescribing. After prescribing, keep careful prescription records, educate patients and their families about abuse and on proper storage and disposal of CNS stimulants, monitor for signs of abuse while on therapy, and re-evaluate the need for APTENSIO XR use.

**Dependence Tolerance** Tolerance (a state of adaptation in which exposure to a drug results in a reduction of the drug's desired and/or undesired effects over time) can occur during chronic therapy with CNS stimulants including APTENSIO XR. **Dependence** Physical dependence (a state of adaptation manifested by a withdrawal syndrome produced by abrupt cessation, rapid dose reduction, or administration of an antagonist) can occur in patients treated with CNS stimulants including APTENSIO XR. Withdrawal symptoms after abrupt cessation following prolonged high-dosage administration of CNS stimulants include extreme fatigue and depression.

## OVERDOSAGE

**Signs and Symptoms** Signs and symptoms of acute methylphenidate overdose, resulting principally from overstimulation of the CNS and from excessive sympathomimetic effects, may include the following: nausea, vomiting, diarrhea, restlessness, anxiety, agitation, tremors, hyperreflexia, muscle twitching, convulsions (may be followed by coma), euphoria, confusion, hallucinations, delirium, sweating, flushing, headache, hyperpyrexia, tachycardia, palpitations, cardiac arrhythmias, hypertension, hypotension, tachypnea, mydriasis, dryness of mucous membranes, and rhabdomyolysis.

**Management of Overdose** Consult with a Certified Poison Control Center (1-800-222-1222) for up-to-date guidance and advice on the management of overdose with methylphenidate. Provide supportive care, including close medical supervision and monitoring. Treatment should consist of those general measures employed in the management of overdose with any drug. Consider the possibility of multiple drug overdoses. Ensure an adequate airway, oxygenation, and ventilation. Monitor cardiac rhythm and vital signs. Use supportive and symptomatic measures.

Gastric contents may be evacuated by gastric lavage as indicated. Before performing gastric lavage, control agitation and seizures if present and protect the airway. Other measures to detoxify the gut include administration of activated charcoal and a cathartic. Intensive care must be provided to maintain adequate circulation and respiratory exchange; external cooling procedures may be required for pyrexia.

## Drawn to Terrorism

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## NEWS

# Use of a Nasal Naloxone-Containing Kit in the Transition From Regional Psychiatric Hospital to Community Care: A 1-Year Follow-up Study

by Justin J. Trevino, MD and James Raia, PhD

Unintentional drug overdose deaths have increased exponentially in the past decade. Ohio experienced a 366% increase in drug overdose deaths from 2000 to 2012. Over much of this 12-year period, prescription drugs were involved in the majority of unintentional drug overdose deaths. However, the 2012 Ohio overdose data, which included 1914 deaths, revealed a significant shift in this trend; there was an apparent leveling off of prescription opioid-related overdose deaths, accompanied by a large increase in non-prescription opioid, mainly heroin-related, deaths.

In terms of saving lives from opioid overdose, Nora Volkow, MD, Director of the National Institute on Drug Abuse (NIDA), highlighted the value of naloxone as an opioid antagonist, noting NIDA's support of projects to develop intranasal delivery systems.<sup>1</sup> She emphasized that naloxone has a high safety profile and no abuse potential and thus can be part of an effective approach to address the opioid overdose epidemic.

The Project DAWN (Deaths Avoided With Naloxone) kit is a component of the Overdose Education and Naloxone Distribution Program (OENDP) of the Ohio Department of Health in which participants receive training on drug overdose situations and the administration of intranasal naloxone to themselves and others.<sup>2,3</sup>

**TABLE 1** Survey findings of the 343 eligible OSAMI patients: reasons for accepting or declining the Project DAWN kit

| Reasons for participating   | n (%)      | Reasons for declining to participate  | n (%)      |
|---|------------|---|------------|
| The DAWN kit will save my life if I overdose                        | 69 (34)    | The DAWN kit and its process are too complicated for me to understand and use   | 51 (37)    |
| The DAWN kit will save the life of a friend if he or she overdoses  | 55 (27)    | I won't be able to remember how to put the DAWN kit together if I need it       | 36 (26)    |
| The DAWN kit will be my safeguard in case I relapse                 | 41 (20)    | If the police stop me and see the DAWN kit, I will be identified as a drug user | 27 (20)    |
| I will keep the DAWN kit as a reminder not to use opioids again     | 20 (10)    | I don't have a serious enough problem to need a DAWN kit                        | 13 (9)     |
| It makes sense to carry the DAWN kit with me just in case I need it | 19 (9)     | My problems are mental and not drug abuse; I don't need a DAWN kit              | 12 (8)     |
| Total OSAMI patient participants                                    | 204 (59.4) | Total OSAMI patient non-participants  | 139 (40.6) |

DAWN, Deaths Avoided With Naloxone; OSAMI, opioid substance abuse and mental illness.

### Project DAWN protocol

In March of 2014, the Twin Valley Behavioral Healthcare regional psychiatric hospital developed a protocol for the distribution of Project DAWN kits upon hospital discharge to patients identified with opioid substance abuse and mental illness (OSAMI). The protocol consists of 7 steps:

**Step 1:** All admitted patients are screened for substance use issues; those with patterns of regular opioid use are designated as OSAMI patients and the information is communicated to related treatment teams.

**Step 2:** An individualized treatment plan that integrates opioid and other substance use problems into the overall plan of care is completed.

**Step 3:** The Screening, Brief Intervention, and Referral to Treatment (SBIRT) evidence-based practice model<sup>4</sup> offers OSAMI patients participation in specific substance abuse treatment interventions, including individual and/or group therapy and on-site recovery group participation, and scheduling them to meet with licensed independent chemical dependency counselors. The counselors subsequently collaborate with the patient and his or her treatment team to identify resources that can promote recovery and provide referral to community treatment and recovery resources for those patients desiring such services.

**Step 4:** All OSAMI patients are

invited to participate in an educational session covering the general goals of Project DAWN and specific information about the Project DAWN kit.

**Step 5:** Completion of overdose risk assessment and a more detailed substance use assessment by the chemical dependency counselor assigned to the case for those patients participating in the educational session (Step 4).

**Step 6:** Patients sign a consent acknowledging their willingness to participate in the Project DAWN program and receive additional education and training on overdose situations and naloxone storage/se-

(Please see Nasal Naloxone-Containing Kit, page 38)