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WMJ

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Volume 111, no. 6 • December 2012

WMJ

COVER THEME
Roots of change: Improving health through better access, education, and food policy

Ours is an overweight community and becoming more so, a risk factor for many chronic health conditions. In this issue of *WMJ,* two articles explore comprehensive approaches that seek not only to address the root causes of overweight and obesity, but also explore effective approaches to solve the problem of both eating too much and eating too much of the wrong things.

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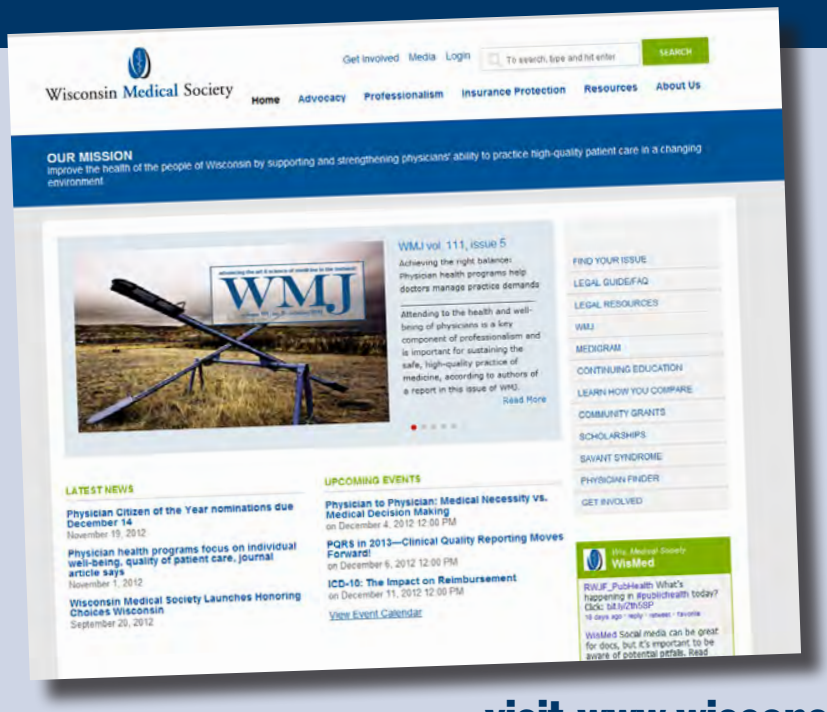

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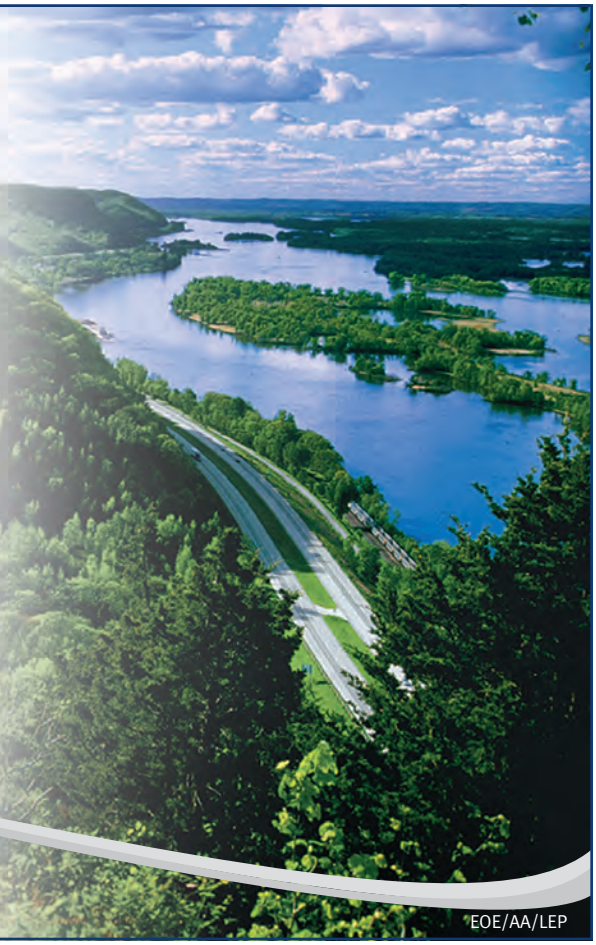

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VIIBRYD:
Approved to treat Major Depressive Disorder (MDD) in adults

Important Safety Information

WARNING: SUICIDALITY AND ANTIDEPRESSANT DRUGS
Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of Major Depressive Disorder (MDD) and other psychiatric disorders. Anyone considering the use of VIIBRYD or any other antidepressant in a child, adolescent, or young adult must balance this risk with the clinical need. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction in risk with antidepressants compared to placebo in adults aged 65 and older. Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide. Patients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. VIIBRYD is not approved for use in pediatric patients.

Contraindications

- VIIBRYD must not be used concomitantly in patients taking MAOIs or in patients who have taken MAOIs within the preceding 14 days due to the risk of serious, sometimes fatal, drug interactions with serotonergic drugs. Allow at least 14 days after stopping VIIBRYD before starting an MAOI.

Warnings and Precautions

- **All patients treated with antidepressants should be monitored appropriately and observed closely for clinical worsening, suicidality, and unusual changes in behavior, especially during the first few months of treatment and when changing the dose.** Consider changing the therapeutic regimen, including possibly discontinuing the medication, in patients whose depression is persistently worse or includes symptoms of anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsivity, akathisia, hypomania, mania, or suicidality that are severe, abrupt in onset, or were not part of the patient's presenting symptoms. **Families and caregivers of patients being treated with antidepressants should be alerted about the need to monitor patients daily.** Prescriptions for VIIBRYD should be written for the smallest quantity of tablets consistent with good patient management, in order to reduce the risk of overdose.
- The development of potentially life-threatening serotonin syndrome or Neuroleptic Malignant Syndrome (NMS)-like reactions has been reported with antidepressants alone, but particularly with concomitant use of serotonergic drugs (including triptans) with drugs which impair metabolism of serotonin (including MAOIs), or with antipsychotics or other dopamine antagonists. Symptoms of serotonin syndrome were noted in 0.1% of patients treated with VIIBRYD. Serotonin syndrome symptoms may include mental status changes (eg, agitation, hallucinations, coma), autonomic instability (eg, tachycardia, labile blood

Please see brief summary of Prescribing Information on following pages.
Please also see full Prescribing Information at www.viibrydhcp.com.

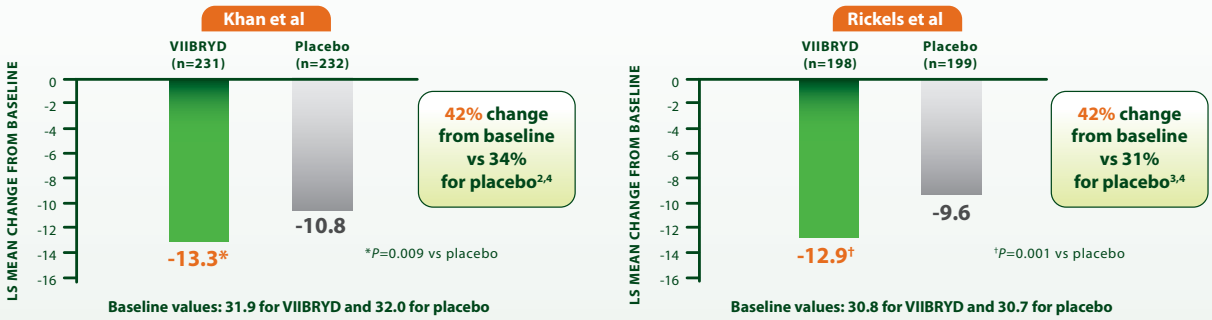
The first and only SSRI and 5-HT$_{1A}$ receptor partial agonist[1]

- While the MOA is not fully understood, it is thought to be related to enhancement of serotonergic activity
- The role of 5-HT$_{1A}$ partial agonist activity on serotonergic transmission and antidepressant effect is unknown

Proven efficacy in adults with MDD[1–4]

- Significant improvement vs placebo in Montgomery-Asberg Depression Rating Scale (MADRS) total score in two 8-week, randomized and controlled studies ($P<0.01$)
  - At week 8, least squares (LS) mean difference from placebo in change from baseline in MADRS total score was -2.5 in Khan et al and -3.2 in Rickels et al

MADRS mean total score reduction from baseline at week 8[2-4]



Randomized, double-blind, placebo-controlled, multicenter, 8-week clinical trials to determine the efficacy and safety of VIIBRYD in adults aged 18 to 70 years in Khan et al, and in adults aged 18 to 65 years in Rickels et al, who were diagnosed with MDD. Patients were randomized to receive VIIBRYD (n=231) or placebo (n=232) in Khan et al, and VIIBRYD (n=198) or placebo (n=199) in Rickels et al. Last observation carried forward analysis shown.[1-3]

The primary efficacy endpoint was the change from baseline in MADRS total score to week 8 (ITT population).

The LS mean difference (95% confidence interval) from placebo in change from baseline in MADRS total score was -2.5 (-4.4, -0.6) in Khan et al and -3.2 (-5.2, -1.3) in Rickels et al.

VIIBRYD treatment was initiated once daily at 10 mg for 7 days, followed by 20 mg for another 7 days, and 40 mg thereafter until the end of week 8. VIIBRYD was administered with food.[1-3]

pressure, hyperthermia), neuromuscular aberrations (eg, hyperreflexia, incoordination) and/or gastrointestinal symptoms (eg, nausea, vomiting, diarrhea). Patients should be monitored for the emergence of serotonin syndrome or NMS-like signs and symptoms while treated with VIIBRYD.

- Like other antidepressants, VIIBRYD should be prescribed with caution in patients with a seizure disorder.
- The use of drugs that interfere with serotonin reuptake, including VIIBRYD, may increase the risk of bleeding events. Patients should be cautioned about the risk of bleeding associated with the concomitant use of VIIBRYD and NSAIDs, aspirin, warfarin, or other drugs that affect coagulation or bleeding.
- Symptoms of mania/hypomania were noted in 0.1% of patients treated with VIIBRYD in clinical studies. As with all antidepressants, VIIBRYD should be used cautiously in patients with a history or family history of bipolar disorder, mania or hypomania.
- Prior to initiating treatment with an antidepressant, patients with depressive symptoms should be adequately screened to determine if they are at risk for bipolar disorder. VIIBRYD is not approved for use in treating bipolar depression.
- Discontinuation symptoms have been reported with discontinuation of serotonergic drugs such as VIIBRYD. Gradual dose reduction is recommended, instead of abrupt discontinuation, whenever possible. Monitor patients when discontinuing VIIBRYD. If intolerable symptoms occur following a dose decrease or upon discontinuation of treatment, consider resuming the previously prescribed dose and decreasing the dose at a more gradual rate.
- Advise patients that if they are treated with diuretics, or are otherwise volume depleted, or are elderly, they may be at greater risk of developing hyponatremia while taking VIIBRYD. Although no cases of hyponatremia resulting from VIIBRYD treatment were reported in the clinical studies, hyponatremia has occurred as a result of treatment with SSRIs and SNRIs. Discontinuation of VIIBRYD in patients with symptomatic hyponatremia and appropriate medical intervention should be instituted.

Adverse Reactions

- The most commonly observed adverse reactions in MDD patients treated with VIIBRYD in placebo-controlled studies (incidence ≥5% and at least twice the rate of placebo) were: diarrhea (28% vs 9%), nausea (23% vs 5%), insomnia (6% vs 2%), and vomiting (5% vs 1%).

References: 1. Viibryd (vilazodone HCl) [package insert]. St Louis, MO: Forest Pharmaceuticals, Inc.; 2011. **2.** Khan A, Cutler AJ, Kajdasz DK, et al. A randomized, double-blind, placebo-controlled, 8-week study of vilazodone, a serotonergic agent for the treatment of major depressive disorder. *J Clin Psychiatry.* 2011;72:441-447. **3.** Rickels K, Athanasiou M, Robinson DS, Gibertini M, Whalen H, Reed CR. Evidence for efficacy and tolerability of vilazodone in the treatment of major depressive disorder: a randomized, double-blind, placebo-controlled trial. *J Clin Psychiatry.* 2009;70:326-333. **4.** Data on file. Forest Laboratories, Inc.

Viibryd™
vilazodone HCl
10 mg, 20 mg, 40 mg tablets

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47-12000115-PRR1 10/11

VIIBRYD (vilazodone HCl) **Rx Only**
Tablets for oral administration

Brief Summary of full Prescribing Information

Initial U.S. Approval: 2011

WARNING: SUICIDALITY AND ANTIDEPRESSANT DRUGS

Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of Major Depressive Disorder (MDD) and other psychiatric disorders. Anyone considering the use of VIIBRYD or any other antidepressant in a child, adolescent, or young adult must balance this risk with the clinical need. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction in risk with antidepressants compared to placebo in adults aged 65 and older. Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide. Patients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. VIIBRYD is not approved for use in pediatric patients [*see Warnings and Precautions, Use in Specific Populations, and Patient Counseling Information*]

INDICATIONS AND USAGE: VIIBRYD is indicated for the treatment of major depressive disorder (MDD). The efficacy of VIIBRYD was established in two 8-week, randomized, double-blind, placebo-controlled trials in adult patients with a diagnosis of MDD *[see Clinical Studies]*. Major depressive disorder consists of one or more major depressive episodes. A major depressive episode (DSM-IV-TR) implies a prominent and relatively persistent (nearly every day for at least 2 weeks) depressed or dysphoric mood that usually interferes with daily functioning, and includes at least 5 of the following 9 symptoms: depressed mood, loss of interest in usual activities, significant change in weight and/or appetite, insomnia or hypersomnia, psychomotor agitation or retardation, increased fatigue, feelings of guilt or worthlessness, slowed thinking or impaired concentration, or a suicide attempt or suicidal ideation.

CONTRAINDICATIONS: Monoamine Oxidase Inhibitors - VIIBRYD must not be used concomitantly in patients taking MAOIs or in patients who have taken MAOIs within the preceding 14 days due to the risk of serious, sometimes fatal, drug interactions with serotonergic drugs. These interactions have been associated with symptoms that include tremor, myoclonus, diaphoresis, nausea, vomiting, flushing, dizziness, hyperthermia with features resembling neuroleptic malignant syndrome, seizures, rigidity, autonomic instability with possible rapid fluctuations of vital signs, and mental status changes that include extreme agitation progressing to delirium and coma. Allow at least 14 days after stopping VIIBRYD before starting an MAOI *[see Drug Interactions]*.

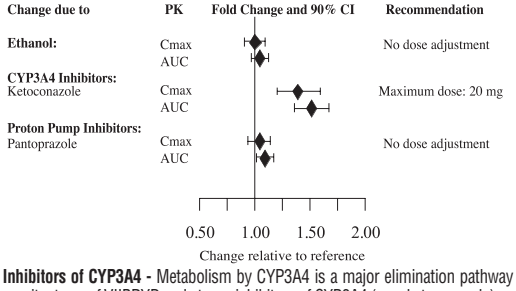
WARNINGS AND PRECAUTIONS: Clinical Worsening and Suicide Risk - Patients with major depressive disorder (MDD), both adult and pediatric, may experience worsening of their depression and/or the emergence of suicidal ideation and behavior (suicidality) or unusual changes in behavior, whether or not they are taking antidepressant medications, and this risk may persist until significant remission occurs. Suicide is a known risk of depression and certain other psychiatric disorders, and these disorders themselves are the strongest predictors of suicide. There has been a long-standing concern, however, that antidepressants may have a role in inducing worsening of depression and the emergence of suicidality in certain patients during the early phases of treatment. Pooled analyses of short-term placebo-controlled studies of antidepressant drugs (selective serotonin reuptake inhibitors [SSRIs] and others) showed that these drugs increase the risk of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults (ages 18-24) with MDD and other psychiatric disorders. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction with antidepressants compared to placebo in adults aged 65 and older. The pooled analyses of placebo-controlled studies in children and adolescents with MDD, obsessive compulsive disorder (OCD), or other psychiatric disorders included a total of 24 short-term studies of 9 antidepressant drugs in over 4,400 patients. The pooled analyses of placebo-controlled studies in adults with MDD or other psychiatric disorders included a total of 295 short-term studies (median duration of 2 months) of 11 antidepressant drugs in over 77,000 patients. There was considerable variation in risk of suicidality among drugs, but a tendency toward an increase in the younger patients for almost all drugs studied. There were differences in absolute risk of suicidality across the different indications, with the highest incidence in MDD. The risk differences (drug vs. placebo), however, were relatively stable within age strata and across indications. These risk differences (drug-placebo difference in the number of cases of suicidality per 1000 patients treated) are provided in Table 1. There were 14 additional cases reported in patients under the age of 18, while 5 additional cases were reported in patients between 18 and 24 years of age. Patients between 25 and 64 years of age reported 1 fewer case of suicidality, while patients 65 years of age and over reported 6 fewer cases. No suicides occurred in any of the pediatric studies. There were suicides in the adult studies, but the number was not sufficient to reach any conclusion about drug effect on suicide. It is unknown whether the suicidality risk extends to longer-term use, i.e., beyond several months. However, there is substantial evidence from placebo-controlled maintenance studies in adults with depression that the use of antidepressants can delay the recurrence of depression. **All patients being treated with antidepressants for any indication should be monitored appropriately and observed closely for clinical worsening, suicidality, and unusual changes in behavior, especially during the initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases.** The following symptoms, anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsivity, akathisia (psychomotor restlessness), hypomania, and mania, have been reported in adult and pediatric patients being treated with antidepressants for major depressive disorder as well as for other indications, both psychiatric and nonpsychiatric. Although a causal link between the emergence of such symptoms and either the worsening of depression and/or the emergence of suicidal impulses has not been established, there is concern that such symptoms may represent precursors to emerging suicidality. Consideration should be given to changing the therapeutic regimen, including possibly discontinuing the medication, in patients whose depression is persistently worse, or who are experiencing emergent suicidality or symptoms that might be precursors to worsening depression or suicidality, especially if these symptoms are severe, abrupt in onset, or were not part of the patient's presenting symptoms. If the decision has been made to discontinue treatment, medication should be tapered, as rapidly as is feasible, but with recognition that abrupt discontinuation can be associated with certain symptoms [*see Warnings and Precautions and Dosage and Administration*]. Families and caregivers of patients being treated with antidepressants for major depressive disorder or other indications, both psychiatric and nonpsychiatric, should be alerted about the need to monitor patients for the emergence of agitation, irritability, unusual changes in behavior, and the other symptoms described above, as well as the emergence of suicidality, and to report such symptoms immediately to healthcare providers. Such monitoring should include daily observation by families and caregivers. Prescriptions for VIIBRYD should be written for the smallest quantity of tablets consistent with good patient management, in order to reduce the risk of overdose *[see also Patient Counseling Information]*. **Screening patients for bipolar disorder -** A major depressive episode may be the initial presentation of bipolar disorder. It is generally believed (though not established in controlled studies) that treating such an episode with an antidepressant alone may increase the likelihood of precipitation of a mixed/manic episode in patients at risk for bipolar disorder. Whether any of the symptoms described above represent such a conversion is unknown. However, prior to initiating treatment with an antidepressant, patients with depressive symptoms should be adequately screened to determine if they are at risk for bipolar disorder; such screening should include a detailed psychiatric history, including a family history of suicide, bipolar disorder, and depression. It should be noted that VIIBRYD is not approved for use in treating bipolar depression. **Serotonin Syndrome or Neuroleptic Malignant Syndrome (NMS)-like Reactions -** The development of a potentially life-threatening serotonin syndrome or Neuroleptic Malignant Syndrome (NMS)-like reactions has been reported with antidepressants alone, but particularly with concomitant use of serotonergic drugs (including triptans) with drugs that impair metabolism of serotonin (including MAOIs), or with antipsychotics or other dopamine antagonists. Symptoms of serotonin syndrome were noted in 0.1% of patients treated with VIIBRYD. Serotonin syndrome symptoms may include mental status changes (e.g., agitation, hallucinations, coma), autonomic instability (e.g., tachycardia, labile blood pressure, hyperthermia), neuromuscular aberrations (e.g., hyperreflexia, incoordination) and/or gastrointestinal symptoms (e.g., nausea, vomiting, diarrhea). Serotonin syndrome, in its most severe form can resemble NMS, which includes hyperthermia, muscle rigidity, autonomic instability with possible rapid fluctuation of vital signs, and mental status changes. Patients should be monitored for the emergence of serotonin syndrome or NMS-like signs and symptoms. The concomitant use of VIIBRYD with MAOIs intended to treat depression is contraindicated *[see Contraindications]*. If concomitant treatment of VIIBRYD with a 5-hydroxytryptamine receptor agonist (triptan) is clinically warranted, careful observation of the patient is advised, particularly during treatment initiation and dose increases *[see Drug Interactions]*. The concomitant use of VIIBRYD with serotonin precursors (such as tryptophan) is not recommended *[see Drug Interactions]*. Treatment with VIIBRYD and any concomitant serotonergic (SSRI, serotonin–norepinephrine reuptake inhibitor [SNRI], triptan, buspirone, tramadol, etc.) or antidopaminergic drugs, including antipsychotics, should be discontinued immediately if the above events occur and supportive symptomatic treatment should be initiated. **Seizures -** VIIBRYD has not been systematically evaluated in patients with a seizure disorder. Patients with a history of seizures were excluded from clinical studies. Like other antidepressants, VIIBRYD should be prescribed with caution in patients with a seizure disorder. **Abnormal Bleeding -** The use of drugs that interfere with serotonin reuptake inhibition, including VIIBRYD, may increase the risk of bleeding events. Concomitant use of aspirin, nonsteroidal anti-inflammatory drugs (NSAIDS), warfarin, and other anticoagulants may add to this risk. Case reports and epidemiological studies (case-control and cohort design) have demonstrated an association between use of drugs that interfere with serotonin reuptake and the occurrence of gastrointestinal bleeding. Bleeding events related to SSRIs have ranged from ecchymosis, hematoma, epistaxis, and petechiae to life-threatening hemorrhages. Patients should be cautioned about the risk of bleeding associated with the concomitant use of VIIBRYD and NSAIDs, aspirin, or other drugs that affect coagulation or bleeding. **Activation of Mania/Hypomania -** Symptoms of mania/hypomania were reported in 0.1% of patients treated with VIIBRYD in clinical studies. Activation of mania/hypomania has also been reported in a small proportion of patients with major affective disorder who were treated with other antidepressants. As with all antidepressants, use VIIBRYD cautiously in patients with a history or family history of bipolar disorder, mania, or hypomania. **Discontinuation of Treatment with VIIBRYD -** There have been reports of adverse events occurring upon discontinuation of serotonergic antidepressants, particularly when discontinuation is abrupt, including the following: dysphoric mood, irritability, agitation, dizziness, sensory disturbances (e.g., paresthesia, such as electric shock sensations), anxiety, confusion, headache, lethargy, emotional lability, insomnia, hypomania, tinnitus, and seizures. While these events are generally self-limiting, there have been reports of serious discontinuation symptoms. Monitor patients for these symptoms when discontinuing VIIBRYD. Reduce the dose gradually whenever possible. If intolerable symptoms occur following a decrease in the dose or upon discontinuation of treatment, consider resuming the previously prescribed dose. Subsequently, the dose may be decreased, but at a more gradual rate *[see Dosage and Administration]*. **Hyponatremia -** Although no cases of hyponatremia resulting from VIIBRYD treatment were reported in the clinical studies, hyponatremia has occurred as a result of treatment with SSRIs and SNRIs. In many cases, hyponatremia appears to be the result of the syndrome of inappropriate antidiuretic hormone secretion (SIADH). Cases with serum sodium lower than 110 mmol/L have been reported. Elderly patients may be at greater risk of developing hyponatremia with SSRIs. Also, patients taking diuretics or who are otherwise volume depleted can be at greater risk. Discontinuation of VIIBRYD in patients with symptomatic hyponatremia and appropriate medical intervention should be instituted. Signs and symptoms of hyponatremia include headache, difficulty concentrating, memory impairment, confusion, weakness, and unsteadiness, which can lead to falls. Signs and symptoms associated with more severe and/or acute cases have included hallucination, syncope, seizure, coma, respiratory arrest, and death.

ADVERSE REACTIONS: Clinical Studies Experience - The most commonly observed adverse reactions in VIIBRYD-treated MDD patients in placebo-controlled studies (incidence ≥5% and at least twice the rate of placebo) were: diarrhea, nausea, vomiting, and insomnia. **Patient Exposure -** The safety of VIIBRYD was evaluated in 2,177 patients (18-70 years of age) diagnosed with MDD who participated in clinical studies, representing 552 patient-years of exposure. In an open-label 52 week study at 40 mg daily, 599 patients were exposed to VIIBRYD for a total of 348 patient-years. The information presented in these sections was derived from studies of VIIBRYD 40 mg daily in major depressive disorder including: 1) 2 placebo-controlled 8-week studies in 861 patients, including 436 receiving vilazodone; and 2) an open-label 52-week study of 599 patients. These studies included a titration period of 10 mg daily for 7 days followed by 20 mg daily for 7 days. In these clinical trials, VIIBRYD was administered with food. Because clinical trials are conducted under widely varying conditions and varying lengths of time, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical studies of another drug and may not reflect rates observed in practice. **Adverse reactions reported as reasons for discontinuation of treatment -** In the placebo-controlled studies of MDD there was no single adverse reaction leading to discontinuation in > 1% of the patients. Overall, 7.1% of the patients who received VIIBRYD discontinued treatment due to an adverse reaction, compared with 3.2% of placebo-treated patients in these studies. **Common adverse reactions in placebo-controlled MDD studies -** Table 2 shows the incidence of common adverse reactions that occurred in ≥2% of VIIBRYD-treated MDD patients (and greater than in placebo-treated patients) in the placebo-controlled studies. The first value displays the number of patients exhibiting the adverse reaction while receiving VIIBRYD 40 mg/day (N = 436) and the second value is the number of patients exhibiting the adverse reaction while receiving Placebo (N = 433). **Gastrointestinal disorders:** Diarrhea (28, 9); Nausea (23, 5); Dry mouth (8, 5); Vomiting (5, 1); Dyspepsia (3, 2); Flatulence (3, 2); Gastroenteritis (3, <1); **Nervous system disorders:** Dizziness (9, 5); Somnolence (3, 2); Paresthesia (3, 1); Tremor (2, 0); **Psychiatric disorders:** Insomnia (6, 2); Abnormal dreams (4, 1); Libido decreased (4, <1); Restlessness* (3, <1); Orgasm abnormal** (3, 0); **General disorders:** Fatigue (4, 3); Feeling jittery (2, <1); **Cardiac disorders:** Palpitations (2, <1); **Musculoskeletal and connective tissue disorders:** Arthralgia (3, 2); **Reproductive system and breast disorders:** Delayed ejaculation*** (2, 0); Erectile dysfunction*** (2, 1); **Metabolism and nutrition disorders:** Increased appetite (2, 1). *Includes restlessness, akathisia, and restless legs syndrome; **Includes orgasm abnormal and anorgasmia; ***Male patients only (Placebo n=182; VIIBRYD n=170). Table 3 shows the percentages of Sexual Adverse Reactions in the Placebo-Controlled Studies. The first grouping shows the percentages in Males with VIIBRYD (N=170) and Placebo (N=182). The second grouping shows the percentages in Females with VIIBRYD (N=266) and Placebo (N = 251). Decreased libido (5,0)/(3,<1); Abnormal orgasm* (4,0)/(2,0); Delayed ejaculation (2,0)/(–,–); Erectile dysfunction (2,1)/(–,–); Sexual dysfunction (2,0)/(<1,<1). – Not applicable; *Includes

anorgasmia. **Laboratory Tests** - VIIBRYD has not been associated with any clinically important changes in laboratory test parameters in serum chemistry (including liver function tests), hematology and urinalysis, as measured in placebo-controlled studies. These studies include analysis of (1) mean change from baseline and (2) the proportion of patients meeting criteria for potentially clinically significant changes from baseline. Results from a 52-week open-label study were consistent with the findings from the placebo-controlled studies. **ECG** - VIIBRYD has not been associated with any clinically significant effect on ECG parameters, including QT, QTc, PR and QRS intervals, or with any arrhythmogenic potential. ECGs were evaluated in a thorough QTc study at doses up to 80 mg daily with food and in the placebo-controlled studies *[see Clinical Pharmacology]*. **Vital Signs** - VIIBRYD has not been associated with any clinically significant effect on vital signs, including systolic and diastolic blood pressure and heart rate, as measured in placebo-controlled studies. These studies included analyses of (1) change from baseline, and (2) the proportion of patients meeting criteria for potentially clinically significant changes from baseline. Results from a 52-week open-label study were consistent with the findings from the placebo-controlled studies. **Weight -** VIIBRYD had no effect on body weight as measured by the mean change from baseline in the 8-week, placebo-controlled studies. The mean changes in weight were +0.16 kg in the VIIBRYD group and +0.18 kg in the placebo group. The proportions of patients with a weight gain ≥7% were 0.9% in the VIIBRYD group and 1.2% in the placebo group.The proportions of patients with a weight decrease ≥7% were 1.4% in the VIIBRYD group and 1.4% in the placebo group. **Other adverse reactions observed in clinical studies** - The following listing does not include reactions: 1) already listed in previous tables or elsewhere in labeling, 2) for which a drug cause was remote, 3) which were so general as to be uninformative, 4) which were not considered to have significant clinical implications, or 5) which occurred at a rate equal to or less than placebo. Reactions are categorized by body system according to the following definitions: *frequent* adverse reactions are those occurring in at least 1/100 patients; *infrequent* adverse reactions are those occurring in 1/100 to 1/1000 patients; *rare* reactions are those occurring in fewer than 1/1000 patients; Cardiac disorders: *infrequent*: ventricular extrasystoles; Eye disorders: *frequent:* vision blurred, dry eye; *infrequent:* cataracts; General disorders: *infrequent*: feeling abnormal; Metabolism and nutrition disorders: *frequent*: decreased appetite; Nervous System: *frequent*: sedation, migraine; *infrequent*: dysgeusia; Psychiatric disorders: *infrequent*: panic attack, mania; Renal and Urinary disorder: *infrequent*: pollakiuria; Skin and subcutaneous tissue disorders: *frequent*: hyperhidrosis, night sweats

DRUG INTERACTIONS: Central Nervous System (CNS)-Active Agents - The risk of using VIIBRYD in combination with other CNS-active drugs has not been systematically evaluated. Consequently, use caution when VIIBRYD is prescribed in combination with other CNS-active drugs. **Monoamine Oxidase Inhibitors (MAOI) -** Adverse reactions, some of which are serious or fatal, can develop in patients who use MAOIs or who have recently been discontinued from an MAOI and started on antidepressant(s) with pharmacological properties similar to VIIBRYD (e.g. SSRIs), or who have recently had SSRI therapy discontinued prior to initiation of an MAOI. Do not prescribe VIIBRYD concomitantly with an MAOI or within 14 days of discontinuing or starting an MAOI *[see Contraindications]*. **Serotonergic Drugs -** Based on the mechanism of action of VIIBRYD and the potential for serotonin toxicity, also known as serotonin syndrome, caution is advised when VIIBRYD is coadministered with other drugs that may affect the serotonergic neurotransmitter systems (e.g., MAOI, SSRIs, SNRIs, triptans, buspirone, tramadol, and tryptophan products etc.) *[see Warnings and Precautions]*. **Drugs that Interfere with Hemostasis (e.g., NSAIDs, Aspirin, and Warfarin) -** Serotonin release by platelets plays an important role in hemostasis. Epidemiological studies of case-control and cohort design have demonstrated an association between use of psychotropic drugs that interfere with serotonin reuptake and the occurrence of upper gastrointestinal bleeding. These studies have also shown that concurrent use of an NSAID or aspirin may potentiate this risk of bleeding. Altered anticoagulant effects, including increased bleeding, have been reported when SSRIs and SNRIs are coadministered with warfarin. Patients receiving warfarin therapy should be carefully monitored when VIIBRYD is initiated or discontinued *[see Warnings and Precautions]*. **Potential for Other Drugs to Affect Vilazodone**

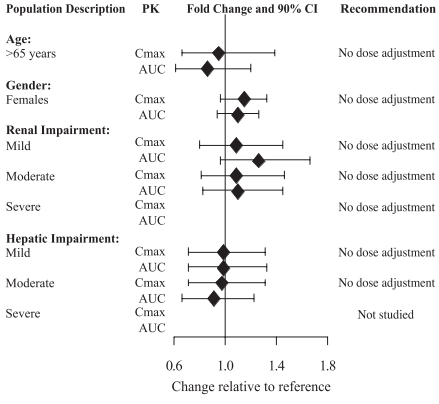
Figure 1. Impact of Other Drugs on Vilazodone PK



Inhibitors of CYP3A4 - Metabolism by CYP3A4 is a major elimination pathway for vilazodone. Concomitant use of VIIBRYD and strong inhibitors of CYP3A4 (e.g., ketoconazole) can increase vilazodone plasma concentrations by approximately 50% (see Figure 1). The VIIBRYD dose should be reduced to 20 mg if co-administered with a strong inhibitor of CYP3A4. During co-administration with moderate inhibitors of CYP3A4 (e.g., erythromycin), the VIIBRYD dose should be reduced to 20 mg for patients with intolerable adverse events. No dose adjustment is recommended when VIIBRYD is co-administered with mild inhibitors of CYP3A4 (e.g., cimetidine). **Inducers of CYP3A4 -** Concomitant use of VIIBRYD with inducers of CYP3A4 has the potential to reduce vilazodone systemic exposure. However, the effect of CYP3A4 inducers on vilazodone plasma concentrations has not been evaluated. **Inhibitors of other CYP enzymes -** Concomitant administration of VIIBRYD with inhibitors of CYP2C19 and CYP2D6 is not expected to alter plasma concentrations of vilazodone. These isoforms are minor elimination pathways in the metabolism of vilazodone. *In vitro* studies have shown that CYP1A2, CYP2A6, CYP2C9 and CYP2E1 have minimal contribution to the metabolism of vilazodone. **Potential for Vilazodone to Affect Other Drugs - Drugs metabolized by CYP1A2, CYP2C9, CYP2D6, CYP3A4 or CYP2C19.** Coadministration of VIIBRYD with substrates for CYP1A2, CYP2C9, CYP3A4, or CYP2D6 is unlikely to result in clinically significant changes in the concentrations of the CYP substrates. A study in healthy subjects found that VIIBRYD (20 mg/day for 8-10 days) had no effect on the pharmacokinetics of caffeine, flurbiprofen, nifedipine or debrisoquine, probes for CYP1A2, CYP2C9, CYP3A4, and CYP2D6, respectively. VIIBRYD coadministration with mephenytoin to healthy subjects resulted in a small (11%) increase in mephenytoin biotransformation, suggestive of a minor induction of CYP2C19. *In vitro* studies have shown that VIIBRYD is a moderate inhibitor of CYP2C19 and CYP2D6. **Drugs metabolized by CYP2C8 -** Coadministration of VIIBRYD with a CYP2C8 substrate may lead to an increase in concentration of the other drug. *In vitro* studies suggest that VIIBRYD may inhibit the biotransformation of substrates of CYP2C8. The effect of VIIBRYD on CYP2C8 activity has not been tested *in vivo*. **Induction of CYP isoforms -** VIIBRYD did not induce CYP1A1, 1A2, 2A6, 2B6, 2C9, 2C19, 2D6, 2E1, 3A4 or 3A5 in an *in vitro* study in cultured human hepatocytes. Chronic administration of vilazodone is unlikely to induce the metabolism of drugs metabolized by these major CYP isoforms. **Drugs Highly Bound to Plasma Protein -** The interaction between vilazodone and other highly protein-bound drugs has not been evaluated. Because vilazodone is highly bound to plasma protein, administration of VIIBRYD to a patient taking another drug that is highly protein bound may cause increased free concentrations of the other drug.

USE IN SPECIFIC POPULATIONS: Pregnancy, Teratogenic Effects - Pregnancy Category C - Vilazodone caused some developmental toxicity in rats, but was not teratogenic in rats or rabbits. There are no adequate and well-controlled studies of VIIBRYD in pregnant women. When treating pregnant women with VIIBRYD, carefully consider whether the potential benefits outweigh the potential risks of treatment. No teratogenic effects were observed when vilazodone was given to pregnant rats or rabbits during the period of organogenesis at oral doses up to 200 and 36 mg/kg/day, respectively. These doses are 48 and 17 times, in rats and rabbits, respectively, the maximum recommended human dose (MRHD) of 40 mg on a mg/m^2 basis. Fetal body weight gain was reduced, and skeletal ossification was delayed in both rats and rabbits at these doses; these effects were not observed at doses up to 10 times the MRHD in rats or 4 times the MRHD in rabbits. When vilazodone was administered to pregnant rats at an oral dose of 30 times the MRHD during the period of organogenesis and throughout pregnancy and lactation, the number of live born pups was decreased. There was an increase in early postnatal pup mortality, and among surviving pups there was decreased body weight, delayed maturation, and decreased fertility in adulthood. There was some maternal toxicity at this dose. These effects were not seen at 6 times the MRHD. **Nonteratogenic Effects -** Neonates exposed to serotonergic antidepressants late in the third trimester have developed complications requiring prolonged hospitalization, respiratory support, and tube feeding. Such complications can arise immediately upon delivery. Reported clinical findings have included respiratory distress, cyanosis, apnea, seizures, temperature instability, feeding difficulty, vomiting, hypoglycemia, hypotonia, hypertonia, hyperreflexia, tremor, jitteriness, irritability, and constant crying. These features are consistent with either a direct toxic effect of serotonergic antidepressants or, possibly, a drug discontinuation syndrome. It should be noted that, in some cases, the clinical picture is consistent with serotonin syndrome *[see Warnings and Precautions]*. **Labor and Delivery -** The effect of VIIBRYD on labor and delivery in humans is unknown. VIIBRYD should be used during labor and delivery only if the potential benefit outweighs the potential risk. **Nursing Mothers -** Vilazodone is excreted into the milk of lactating rats. The effect of VIIBRYD on lactation and nursing in humans is unknown. Breast feeding in women treated with VIIBRYD should be considered only if the potential benefit outweighs the potential risk to the child. **Pediatric Use -** Clinical studies on the use of VIIBRYD in pediatric patients have not been conducted; therefore, the safety and effectiveness of VIIBRYD in the pediatric population have not been established. VIIBRYD is not approved for use in pediatric patients *[see Boxed Warning and Warnings and Precautions]*. **Geriatric Use -** No dose adjustment is recommended on the basis of age (see Figure 2). Results from a single-dose (20 mg) pharmacokinetic study in elderly (> 65 years-old) vs. young (24-55 years-old) subjects demonstrated that the pharmacokinetics were generally similar between the two age groups. Of the 2177 patients in clinical studies with VIIBRYD, 37 (1.7%) were 65 years of age or older, and 272 (12.5%) were 55 to 64 years of age. Greater sensitivity of some older individuals cannot be ruled out *[see Dosage and Administration]*. Serotonergic antidepressants have been associated with cases of clinically significant hyponatremia in elderly patients, who may be at greater risk for this adverse event *[see Warnings and Precautions]*. **Hepatic Impairment -** Vilazodone is eliminated primarily by hepatic metabolism. In mild and moderate hepatic impairment, no dose adjustment is necessary (see Figure 2). VIIBRYD has not been studied in patients with severe hepatic impairment *[see Dosage and Administration]*. **Renal Impairment -** In mild, moderate, and severe renal impairment, no dose adjustment is necessary (see Figure 2 below) *[see Dosage and Administration]*. **Gender Effect -** After adjustment for body weight, the systemic exposures between males and females are similar (see Figure 2) *[see Dosage and Administration]*.

Figure 2. Impact of Intrinsic Factors on Vilazodone PK



The data shown for elderly subjects (>65 years) are relative to younger subjects (24-55 years).
The data shown for female subjects are relative to male subjects.
The data shown for renal and hepatic impairment are relative to subjects with normal renal and hepatic function, respectively.

OVERDOSAGE: Human Experience - There is limited clinical experience regarding human overdosage with VIIBRYD. Four patients and 1 patient's child experienced an overdose of VIIBRYD; all recovered. The adverse reactions associated with overdose of VIIBRYD at doses of 200-280 mg as observed in clinical trials included serotonin syndrome, lethargy, restlessness, hallucinations, and disorientation. **Management of Overdose -** Consult a Certified Poison Control Center for up-to-date guidance and advice. Telephone numbers for certified poison control centers are listed in the Physicians' Desk Reference® (PDR). No specific antidotes for vilazodone are known. In case of an overdose, provide supportive care, including close medical supervision and monitoring. Treatment should consist of those general measures employed in the management of overdosage with any drug. Consider the possibility of multiple drug overdose. Ensure an adequate airway, oxygenation, and ventilation. Monitor cardiac rhythm and vital signs. General supportive and symptomatic measures are also recommended. Gastric lavage with a large-bore orogastric tube with appropriate airway protection, if needed, may be considered. Removal of vilazodone by dialysis has not been studied; however, the high volume of distribution of vilazodone suggests that dialysis will not be effective in reducing vilazodone plasma concentrations.

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‘Retro’ ads reflect decades-old issue

Editor’s note: The ads on this page were published in WMJ, *Volume 63, 1962, demonstrating that overweight and obesity are issues not new to medicine.*

WMJ

Thank you to our reviewers

The *WMJ* would like to thank everyone who served as manuscript reviewers in 2012. Manuscript review is an important collegial act and is essential to the integrity of *WMJ*. We are grateful for the assistance of these individuals in ensuring authors receive prompt, objective, and insightful feedback on their work.

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Families and Food

John J. Frey, III, MD, Medical Editor

It would be helpful if both clinicians and the public understood that obesity and elevated cholesterol are risk factors, not diseases. That understanding might change the conversation from the medicalizing and commercialization of modern life (more pills, more TV ads) to thinking about situations in families and communities that might improve conditions that predispose us to problems like diabetes and heart disease. (The "Looking Back" feature for this issue goes to ads in the *WMJ* from 50 years ago when "speed" helped with weight loss—no kidding!—and we were already trying canned diet food. Safflower oil did endure, though.) The term "epidemic" is convenient for both clinicians and the media, but carries a great deal of blame when applied to being overweight. The horrifying red maps of obesity put out by the Centers for Disease Control and Prevention are splashed across media sites and newspapers to alert us to what we already know—we are an overweight country becoming more so.[1] Of course, we are a more sedentary society, a society that has marketed nutrients rather than food, and a society that points fingers at—depending on who is doing the pointing—individuals, families, and economic factors such as poverty, education, and the politics of food as the causes of the problem. The correct answer is "all of the above." Now, what to do?

Two articles in this issue of the *WMJ* begin to take a more comprehensive approach that deals with root causes and tries to create or prescribe effective approaches that begin to move toward a more healthy solution to both eating too much and eating too much of the wrong things. Ziebarth and colleagues[2] remind us that, in large part, the social context in which we live determines how we live, and describe targeted efforts to change one group–Hispanic children. They translated the "We Can!" curriculum from the US Department of Agriculture into Spanish and adapted it, with substantial input from the Latino community, into a series of family activities that educated families and provided cooking programs that focused on healthier food choices, engaged in group exercise programs, and used incentives such as YMCA memberships and group dinners and celebrations to get the whole family involved. Along with the improvement in understanding in both adults and children about eating better, some of the effects of the program on the larger community may have the most enduring long-term consequences. The authors describe changes—a local Mexican café adding lower-calorie dishes, pressure to change traffic intersections to be more walking friendly, discounted memberships to the YMCA for low-income families, and increased drinking water options in the local school—that cannot be attributed directly to the intervention, but no doubt have come about because of the increased county-wide awareness that the program created.

Hood and colleagues[3] move the conversation to state-level food policy and clearly outline the current status and history of efforts to change the economics of food. Agriculture is still the largest export in this country and is growing. The corporate/local struggle in agriculture continues, and the family farms and local cooperatives that typically have been the tradition in Wisconsin dairy are, like so much of the agriculture in this country, beginning to accrete into very large farms with a more industrial quality to them. While going across the road to get milk from the farm next door as we did in my childhood is virtually impossible today, local food sources are becoming more available to consumers, including low-income consumers who are more likely to have difficulty buying fresh food. It makes sense for all sorts of reasons to create local economies that support small farmers and provide quality products. But, as Hood and her colleagues point out, the case for connecting local consumers, particularly those with limited food budgets, and local farmers sits in the midst of a vast array of regulatory issues that often make medical regulations pale by comparison. Their sug-

The term "epidemic" is convenient for both clinicians and the media, but carries a great deal of blame when applied to being overweight.

gestion, reflected in the experience of other Midwestern states, is for establishing a state-level food policy council where the goal is to guide policy that will benefit farmers and consumers, but just as importantly, create a broad policy conversation that can overcome the stuckness of tradition and offer innovative ideas about improving healthy eating for all of us.

Family matters as well when it comes to issues of low birth weight babies and the subsequent risk of infant mortality. The article by Schlenker and colleagues[4] describes how "intensive" support for high-risk pregnancies in the African-American community of Dane County contributed to the decrease in low birth weight babies over the decade from 1997 to 2007. Clinicians, public health professionals, food programs, and community support and awareness are all necessary for successful improvement. However, the increase in black infant mortality in Dane County in the past 4 years, an unhappy trend, indicates how hard it is to attribute outcomes to anything other than the complex interrelationship between societal and medical effects.

All clinicians who care for children know that family risk factors—both behavioral such as eating habits, and genetic such as elevated lipids—add to the potential for the development of chronic health problems. Sometimes we might wish that obesity was as simple to affect as cholesterol, but we know that neither is that easy. While laboratory testing for lipids has vastly improved over the last 40 years, the guidelines for who should be tested and when, especially children, remains problematic—particularly with an approach that says "everyone," as described by Peterson and McBride.[5] The unanswered questions that follow from universal screening are: what should we do differently with "positive" results; will "positive" results motivate children and their families to change risk factors they control; should we be using medications in children and if so, what is the evidence of long term affects on morbidity and mortality; and what is the cost effectiveness and the number needed to treat of universal, in contrast to selective, screening?[6,7]

Finally, the case report from Garcia-Rodriguez and colleagues[8] reinforces that a careful physical exam of the head and neck in someone reporting problems with snoring and swallowing may lead to some unusual findings!

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A Community-Based Family Intervention Program to Improve Obesity in Hispanic Families

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ABSTRACT

Introduction: The Waukesha County Division of Public Health and Waukesha Memorial Hospital developed a social-ecological approach to diminish the incidence of overweight and obesity in Hispanic families in Waukesha County.

Program Description: A sample of Waukesha County children and their families participated in an 8-week program that promoted awareness of healthy food choices and the importance of physical activity. The program was selected, translated, and adapted for the Hispanic community. Weekly sessions included nutrition classes, physical activity, and a healthy meal for participating families. Biometric data were collected pre- and post-program, including blood pressure, cholesterol, glucose, weight, height, and waist measurement. A pre- and post-program knowledge test regarding nutrition, food labels, and physical activity was administered.

Results: A total of 47 Hispanic families participated throughout the course of the program. Biometric measures and tests of nutrition knowledge and attitudes of participants consistently showed improvements. In addition, changes occurred in the community system structure, which positively affected the built environment by improving access to parks, YMCA, and schools for family physical activity.

Conclusion: The translated curriculum was successful in reducing cardiac and diabetes risk factors in Hispanic adults by increasing knowledge and positive attitudes about healthy behaviors.

INTRODUCTION

Obesity is common among many ethnic groups, but is even more so among the Hispanic population.[1-3] There are few healthy lifestyle programs available in Spanish that incorporate valued cultural characteristics. In 2008, the Women, Infant, and Children Program (WIC) in Wisconsin reported that 24% of black participants aged 2 to 4 years were overweight or obese.[4] For white and Asian participants in the same age group, the percentages were 27% and 31%, respectively.[4] The rate of overweight or obesity in Hispanic children aged 2 to 4 years was 37%.[4] Since children's diet and activity levels are typically dictated by the adult members of the household, the need for a program involving the entire family was evident.

Two of the overarching goals of Healthy People 2020 are to be free of preventive diseases related to weight and diet and to eliminate health disparities.[5-7] In Waukesha County, Wisconsin, located 25 miles west of Milwaukee, the Hispanic community continues to grow and is in the top 10 counties for Hispanic population growth in Wisconsin.[8] Social service agencies have estimated there are 15,000 Hispanic residents in Waukesha County. The county includes several densely populated clusters and census track areas where nearly 30% of the residents are of Hispanic origin.[8] It is estimated that over 75% of Waukesha Hispanic residents are of Mexican descent. Mexican Americans have the lowest completed education level, lowest family income, and the largest family size of all the Hispanic subgroups.[9] "Familismo" is central to Hispanic culture, meaning that family is the center of daily life.[9] It was essential to develop a healthy lifestyle program that incorporated this important cultural characteristic.

The Waukesha County Division of Public Health invited the Hispanic Community Health Resource Center (HCHRC), a community benefit initiative of Waukesha Memorial Hospital, to partner to decrease the incidence of overweight and obesity in Hispanic families in Waukesha County. A culturally acceptable, family-based diet and exercise program was key. The Ways to Enhance Children's Activity and Nutrition (We Can!) curriculum, an outreach program of the US Department of Health and Human Services,[10] was selected, translated, and supplemented to address the needs of entire Hispanic fami-

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Table 1. Nutrition Session Themes

Week 1	Program Overview
Week 2	Energy Balance
Week 3	Body Mass Index and Portion Control
Week 4	Energy In* and Reading Nutrition Labels **Energy In is the amount of calories consumed through dietary intake.*
Week 5	Energy In and Healthy Substitutions
Week 6	Energy Out* and the Importance of Physical Activity in Energy Balance **Energy Out is the amount of calories burned through physical activities and normal daily functions.*
Week 7	Decreasing Screen Time
Week 8	Program wrap-up with post-test, evaluation and program surveys

lies in order to diminish health disparities such as those seen between the Hispanics and non-Hispanic whites in the areas of obesity. This article describes the study and specific individual and community outcomes.

METHODS

Where there are many lifestyle programs for children, few involve the full family unit and take the Hispanic culture into consideration. For example, the Fit Kids Program[11] was structured with primarily the English-speaking child in mind and had a program fee. Given the high percentage of low-income Hispanic families in Waukesha, any program fee or language barrier could economically or socially exclude participation. The We Can! curriculum promotes awareness of healthy food choices and discusses the importance of physical activity with a particular focus on energy balance and family.[10,12] It is available online at no cost, and the first 2 weeks of materials were already translated into Spanish. The curriculum is endorsed by the National Heart, Lung, and Blood Institute[10,12] and strives to further the Healthiest Wisconsin 2020 focus areas and objectives regarding nutrition, healthy foods, and physical activity.[13] It also addresses important overarching goals of Healthy People 2020 to reduce obesity and disparities.[6,7]

The Waukesha County Public Health Division collaborated with the Hispanic Community Health Resource Center to facilitate the We Can! curriculum in a series of nutrition and exercise classes. After translating the remaining curriculum into Spanish and including other culturally appropriate supplemental handouts, a family exercise component was added to each class. Community partnerships were sought to host activities, promote participation, and provide support for sustainability. Partners included White Rock Public Elementary School, La Casa de Esperanza (community center) and the local YMCA.

Participants were recruited through convenience sampling using community outreach methods at local churches, medical clinics, schools, self-service laundries, and community programs. Publicity was primarily in the form of posters, announcements, and word of mouth. Families with school-age children were encouraged to enroll. Families with children younger than school age were offered on-site childcare.

The 8-week program included a 40-minute classroom component followed by a 40-minute physical activity session that concluded with a healthy family dinner to promote good eating habits. The classroom program was based upon the 3 crucial components used in the We Can! curriculum and became program objectives. Program objectives helped families: (1) improve food choices; (2) increase physical activity; and (3) reduce screen time. Screen time is the amount of time a person spends in front of a television, computer, or video game screen. Because many of the household decisions regarding television viewing, food preparation, and recreational activities are made by adults, the program was designed to present parallel messages to both the adults and children. The overall goal of the program was to encourage additional communication between parents and their children, leading to cooperative decision-making involving nutrition and physical activities for all family members.

The educational component was divided into 2 groups, one consisting of adults and the other of school-age children. Adult educational programming was presented in Spanish by a bilingual health educator and a bilingual registered nurse. All written materials were made available in Spanish and English, with literacy level considerations. Children's classes were presented in English. Bilingual staff included a registered nurse and exercise instructor from the HCHRC and a health educator from the Waukesha Public Health Division. Although the adults and children attended separate nutrition lessons, both discussed the importance of making healthy food choices and being active. A variety of activities and games were incorporated into the curriculum to strengthen the understanding of the lesson objectives (Table 1).

All family members participated in the same exercise/physical activity session. The sessions were taught by the bilingual health promoter, a certified, bilingual exercise instructor. Physical activities proved to be a very popular component for all family members and strengthened the concept of being active together and enjoying physical activity. Participants had different levels of mobility and the exercises were selected with that in mind.

The exercise sessions had 3 distinct dimensions: warm-up, exercise, and cool down. Physical activity included aerobic/cardiovascular (endurance), anaerobic (speed/strength), flexibility, and coordination exercises. The physical exercise equipment consisted of fun and inexpensive materials that many families already have at home, such as balls, jump ropes, hula hoops,

Table 2. Biometric Results for Adults

	Program Year	Unit of Measure	Sample Size	Pre-program Average	Post-program Average	Change	*P*-value[a]
Systolic blood pressure	2006-2010	mm Hg	50	108.34	104.84	decrease 3.5	0.0132[a]
Diastolic blood pressure	2006-2010	mm Hg	50	67.84	65.48	decrease 2.36	0.0357[a]
Cholesterol	2006-2010	mg/dL	52	174.96	170.79	decrease 4.17	0.3616[a]
HDL	2006-2010	mg/dL	52	44.94	46.52	increase 1.58	0.2663[a]
LDL	2006-2010	mg/dL	48	104.71	97.44	decrease 7.27	0.1157[a]
Triglycerides	2006-2010	mg/dL	50	145.92	154.36	increase 8.44	0.4678[a]
Glucose	2006-2010	mg/dL	52	96.62	93.54	decrease 3.08	0.0253[a]
Waist	2006-2010	inches	52	37.33	36.79	decrease 0.54	0.0345[a]
Weight	2006-2009	pounds	37	156.97	154.95	decrease 2.03	0.0024[a]
Body mass index	2006-2009		37	27.97	27.62	decrease 0.35	0.0103[a]
Knowledge test	2006-2010	percent correct	57	38%	88%	increase of 50 percentage points	0.0001[b]

[a]Statistical significance tested using paired *t* test
[b]Statistical significance tested using unpaired *t* test

balloons, spoons and eggs, and foam pool toys. The participants were able to take home elastic bands to continue exercises taught.

A family dinner encouraged participants to implement some of the strategies and decision-making skills covered in each week's lesson. Demonstration and participation in snack and meal preparation encouraged participants to use healthy ingredients and substitutions. The participants practiced portion control and had many opportunities to experience new healthy foods.

A closing ceremony anchored the last class, at which each participant's accomplishments were recognized with a certificate of completion. Program incentives were awarded upon successful program completion and included YMCA memberships at a discounted rate. As an incentive for children, $50 was given toward the purchase of a bicycle to further promote physical activity. The program educators secured and fitted bicycle helmets for each child participant. Participants were encouraged to suggest any changes or to share any thoughts. Participants who completed the program were encouraged to register for other exercise classes and community health programs available at the HCHRC.

For this study, data was collected before and at the conclusion of the 8-week program. Progress toward program objectives was measured through knowledge testing, lifestyle surveys, and biometric testing. Pre- and post-program lifestyle surveys, and knowledge and biometric testing for adults were facilitated. Testing and surveys were available in Spanish and English. In addition, adult test questions and response choices were read aloud at both pre- and post-assessments to ensure understanding.

Children were given pre- and post-program survey questions that reflected the lifestyle behaviors of children participants. These were administered by a public health educator, with the intent of measuring behaviors about healthy choices in nutrition and activity. Children also were asked true and false knowledge questions in a group setting, which included knowledge about nutrition labels, portions, physical activity, and general health. No biometric blood testing was done with children. Child participants were measured for height, weight, and body mass index (BMI) percentile pre-program and post-program.

RESULTS

The program served 47 families: 57 adults and 54 children. The average age for adults was 32 years. Of the adults, 89% were women and 11% men. One 16-year-old participant was given a choice to participate in the adult or the children's educational component. He chose to attend the adult class; however, a decision was made not to participate in biometric testing.

The survey included assessment of families' habits related to food choices, sweetened beverage consumption, physical activity, and screen time. Adult health risk assessments (HRAs) were performed approximately 1 week prior to the start of each program and 1 week following. HRA assessments included biometrics: total cholesterol, LDL cholesterol, HDL cholesterol, triglycerides, fasting glucose, height, weight, BMI percentile, waist circumference and blood pressure. The HCHRC hosted all screenings and offered a post-screening healthy breakfast.

The biometric testing in the adults' post-program intervention showed some improvements in reducing cardiac and diabetes risk factors (Table 2). This included improvements in systolic and diastolic blood pressure, glucose, weight, BMI, and waist circumference. Blood pressure data collection averaged a 3.5 mm Hg decrease systolically ($P = .0132$) and decreased

Figure 1. Knowledge Testing Results for Adults by Program Year

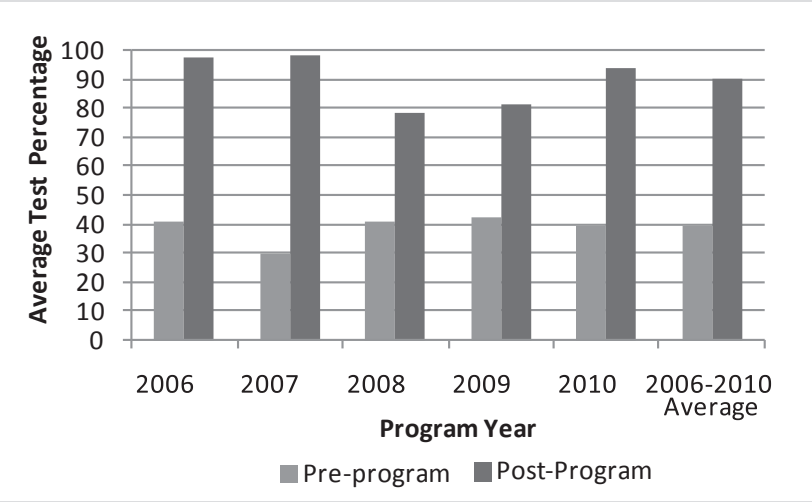

Table 3. Participant Comments

Participant 1	"I loved the program because it gave me the opportunity to be with my children. Also I learned that exercising as a family is fun."
Participant 2	"I am very pleased that there are programs like this because, aside from learning about good nutrition and health, we spent time as a family discussing what we want to do in the future."
Participant 3	"It seemed to be a great program, very complete for health. I loved that there are people concerned about the health of others. Thank you with all my heart. It also served to unite our family on what we should eat and how to exercise as a family."

2.36 mm Hg diastolically ($P = .0357$). Blood glucose decreased by 3.08 points ($P = .0253$) comparing pre-program and post-program collections. Weight decreased by 2.03 pounds overall ($P = .0024$) and BMI decreased by 0.35 ($P = .0103$). Waist circumference decreases over the 4-year period averaged .54 inches ($P = .0345$).

Each of the core evaluation measurements was linked to one of the program objectives in order to measure the program's effectiveness. The first objective to improve food choices was measured through didactic testing of both adults and children. Comparisons of pre-program to post-program knowledge testing for adults revealed an average of a 50 percentage point increase over the span of the program. In 2008, there was a 50% decrease in soda consumption among adults. In 2009 and 2010, there was a 20% decrease of soda consumption among adults post program (Figure 1).

For children, pre-program nutrition knowledge scores for children averaged 20%, while post-program knowledge scores averaged 80%. There was a 33% decrease in soda consumption among children in year 2008. In 2009 and 2010, there was a 40% decrease in soda consumption among children.

The second program objective was to increase physical activity. In an analysis of pre-program and post-program data, there was an average 60% drop in adult participants reporting lack of motivation as a barrier to physical activity.

For the third program objective, decreased screen time, lifestyle surveys for adults in 2008 showed that prior to program participation, 100% of participants reported watching more than 2 hours of television per day. Post-program, that number dropped to 47%. In 2009, participants viewing more than 2 hours of television per day dropped by 34% by the program completion. Reportedly, in 2010, the number of participants watching more than 2 hours of television dropped by 65% at the end of the program. The children's scores yielded similar findings.

An overall goal of the study was to increase communication between parents and their children to facilitate cooperative decision-making involving nutrition and physical activities. Anecdotal evidence obtained through parent's comments suggests that increased family communication of nutrition and physical activities had occurred. (Table 3)

The HCHRC created a monthly support exercise group post program in response to participants' comments. It reinforced nutrition and exercise concepts previously learned in the program and encouraged families to continue exercising together. Program participants led this exercise support group, which evolved into a monthly "Family Exercise Night" that is held during the winter months. In addition, a total of 16 walking sessions are offered as a counterpart during the summer months. Participants of all ages continue to walk together and numbers have surpassed 100 walkers.

Other programmatic outcomes included a culturally appropriate We Can! curriculum translated into Spanish and available for use as well as pre-screening and post-screening HRA forms, Release of Information for HRA's form, Release of Liability form, and a Photo Consent form, all translated into Spanish.

COMMUNITY OUTCOMES

The We Can! program served not only to improve the knowledge and individual behaviors of the participants, but it also

facilitated a variety of systems changes in the community due to its collaborative nature. For example, the local YMCA provided gym memberships at a discounted rate, which were awarded upon successful program completion. This encouraged families to maintain an active lifestyle post-program. Bilingual program staff interpreted and oriented one family to the gym equipment and activities at the YMCA. That family in turn oriented and interpreted for the remaining participants. Through this, the YMCA was made aware of the need for bilingual signage and staff. They have since hired 3 bilingual individuals to improve access for Spanish speakers.

Meals were served by a local Hispanic café, which agreed to create some dishes especially for the program. The meals were so popular with program participants that the café added a healthy-options section to its menu, featuring many of the program entrées.

System changes occurred in the built environment (community structures). After a report to the Waukesha Collaborative Hispanic Network, a community stakeholder group comprising 23 organizations, a call was made to city leaders to ask for improvements to a neighborhood intersection. The 5-way intersection was perceived by local residents as unsafe and created a barrier to a local park. Pedestrian-friendly lights were installed with audible cues.

A partnership with a local elementary school and a well-known water systems company resulted in the promotion and increased consumption of drinking water in schools. The Waukesha Public Health Department staff assisted the School District of Waukesha in their development of a school wellness policy. The HCHRC staff worked with County Parks and Recreation Department to assist with Spanish translation of their children's program brochure.

DISCUSSION

The adapted We Can! curriculum, when combined with a physical activity and meal preparation component, showed some evidence in decreasing cardiac and diabetes risk factors in Hispanic families. Some biometric improvements were achieved, such as lowering BMI. Surveys pre- and post-program showed increased knowledge relating to energy balance and nutrition and revealed positive attitude changes regarding healthy behaviors.

Limitations included the lack of a control group with which to compare the program's effects, and the inability to control variables such as other sources of education from media or reading nutrition education materials that may have affected learning. There were no follow-up biometric measures planned beyond those of post-program. Collecting biometric measures at 6 months and 12 months post-program could yield additional evidence of long-term clinical impact.

The community was involved in every step of the program, including program development, system changes and sustainability. A community approach was necessary to change both individual eating and exercise habits as well as to diminish environmental barriers to achieve a healthy and active lifestyle. Time for community conversations, strategic partnerships and grant writing became the first steps in developing community programs that address health disparities of minority populations. Collaboration between key community organizations and health institutions was essential in improving health in a social ecological approach. A strong collaboration between leadership at the Waukesha Public Health Division and management at Waukesha Memorial Hospital provided the framework to explore new ways to improve Hispanic health in Waukesha County. With hospital restructuring, health care reform, and state budget reductions, finding future funding for multiple year prevention programming may be challenging.

The intent of this initiative was to provide a community-based program to diminish the incidence of overweight and obesity in Hispanic families by promoting awareness of healthy food choices and the importance of physical activity in a culturally acceptable fashion with a particular focus on energy balance. Using the We Can! curriculum and intervening at an individual, family, and community level, program goals were achievable. The ability to replicate the program year after year has resulted in additional programmatic and system changes. Changes occurred in community systems, which positively affected the built environment with increased availability of and improved access to safe places for family physical activity. The results of this program evaluation are encouraging. This program has had a meaningful impact on the participating community members and the community at large.

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Additional Information: Ms. Ziebarth currently is a PhD student at the University of Wisconsin-Milwaukee. She was involved in the development of this program in her previous position as Manager of Community Benefit Outreach at ProHealth Care, Inc, Waukesha Memorial Hospital, Waukesha, Wis.

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The Effect of Prenatal Support on Birth Outcomes in an Urban Midwestern County

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ABSTRACT

Objectives: In Dane County, Wisconsin, the black-white infant mortality gap started decreasing from 2000 and was eliminated from 2004 to 2007. Unfortunately, it has reappeared since 2008. This paper examines risk factors and levels of prenatal care to identify key contributors to the dramatic decline and recent increase in black infant mortality and extremely premature birth rates.

Methods: This retrospective cohort study analyzed approximately 100,000 Dane County birth, fetal, and infant death records from 1990 to 2007. Levels of prenatal care received were categorized as "less-than-standard," "standard routine" or "intensive." US Census data analysis identified demographic and socioeconomic changes. Infant mortality rates and extremely premature (≤ 28 weeks gestation) birth rates were main outcome measures. Contributions to improved outcomes were measured by calculating relative risk, risk difference and population attributable fraction (PAF). Mean income and food stamp use by race were analyzed as indicators of general socioeconomic changes suspected to be responsible for worsening outcomes since 2008.

Results: Risk of extremely premature delivery for black women receiving standard routine care and intensive care decreased from 1990-2000 to 2001-2007 by 77.8% (95% CI = 49.9-90.1%) and 57.3% (95% CI = 27.6-74.8%) respectively. Women receiving less-than-standard care showed no significant improvement over time. Racial gaps in mean income and food stamp use narrowed 2002-2007 and widened since 2008.

Conclusions: Prenatal support played an important role in improving black birth outcomes and eliminating the Dane County black-white infant mortality gap. Increasing socioeconomic disparities with worsening US economy since 2008 likely contributed to the gap's reappearance.

INTRODUCTION

The Dane County, Wisconsin black infant mortality rate dropped from 3 times that of whites prior to 2002 to approximately the same as whites from 2004-2007.[1] During the years 2002-2007, 34 babies that otherwise would have died, survived, and 45 babies that would have been born at or before 28 weeks gestation were born later.[1] In contrast, black infant mortality rates remained high in the rest of Wisconsin and nationally during this time period.[2] Unfortunately, the black-white infant mortality gap has reappeared in Dane County. This paper analyzes primarily the disappearance of the black-white infant mortality gap from 2000-2007 and also offers preliminary observations on the resurgence of excess black infant mortality since 2008 with suggestions for further research.

There is a long history in the United States of racial disparities in infant mortality, which makes it all the more notable that Madison and Dane County managed to close the infant mortality gap. High levels of infant mortality were attributed to overcrowding in urban housing and unsanitary environments, which included lack of access to clean water and ventilation. Other factors included contaminated milk supplies, generally insufficient diets and high rates of contagious diseases. Since the Civil War, US urban and state public health officials have developed programs designated as "child-saving" to deal with increasingly high rates of infant mortality, which grew as industrial cities expanded. One such program, notable in its success and in its very brief life, occurred in Milwaukee, Wisconsin's south side immigrant neighborhood, where health officers, partnering with local midwives and the local parish priest, were able—within 1 year,

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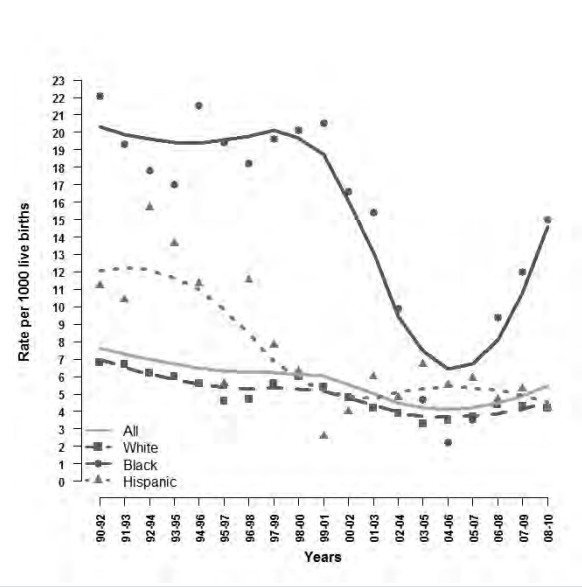
Table 1. Modified Kotelchuck Index of Prenatal Care

Intensive
Care initiated by the 4th month and at least 110% of the expected visits
Standard routine
Care initiated by 4th month and 50% - 109% of the expected visits
Less-than-standard
Care initiated after the 4th month or less than 50% of the expected visits

Figure 1. Infant Mortality Rates by Race, Dane County 1990-2010



Three-year moving average infant mortality rates fitted with a locally weighted regression (loess).

1911—to decrease infant mortality rates from 125/1000 live births to 44/1000.[3] Mortality rates for black children throughout the United States were always higher, sometimes as much as double the rates of white children.[4] By 1920, black infants died at a rate 60% higher than white children.[4] Efforts to close this gap included the Sheppard Towner Act—which provided federal dollars to establish educational programs focusing on maternal and infant health—in the 1920s and ongoing efforts throughout the 20th century after those funds were no longer available. Despite these efforts, enormous racial disparities continued, and black children continued to face almost twice the risk of mortality and morbidity of white children.[5] The longstanding history of racial disparities underscores just how impressive the closing of the racial gap in Dane County infant mortality was. This study was designed to test the hypothesis that prenatal care (in a broad sense) played a significant role in lowering the Dane County black prematurity and infant mortality rates from 2002-2007.

METHODS

Birth and Infant Death Records

Investigators analyzed over 100,000 Dane County, Wisconsin linked birth and death records provided by the Bureau of Health Information and Policy of the Wisconsin Department of Health Services (DHS) for the period 1990-2007. We present infant mortality rates with 3-year rolling averages to minimize the effect of year-to-year variability and a locally weighted regression (LOESS) to smooth the trend curve.

US Census

US Census data were obtained for the period 1990-2010, including data from the American Community Survey (ACS) for the years 2007-2010. Despite a change in sampling rate from a 1 in 6 sample used in the Long Form Census of 1990 and 2000 to a 1 in 11 sample in the ACS, the currency and refresh of these data, along with the lack of Long Form Census tabulations, make the ACS data the logical comparative in a time series of this nature. The ACS data informed yearly estimated trends over this later period of our study (2007-2010).

US Census data obtained for Dane County, Wisconsin were analyzed visually for relevant contextual factors relating to the observed changes in the birth outcome data. Data tables were produced through the American Factfinder website (www.factfinder.census.gov). Data were converted to percentage of the population values.

Vital record data for the majority of data in this paper defines black and white as non-Hispanic black and non-Hispanic white. However, US Census data used in median income calculations do not have a separate category for Hispanic and includes those of Hispanic ethnicity in black and white statistics. Race and ethnicity are now appreciated as social, rather than biological, constructs.[6] In light of that, some epidemiologists are suggesting that studies omit data about race and replace it with relevant socioeconomic data. However, as Nancy Kreiger suggests, to omit "race" and rely solely on "class" ignores the persistence of racism and also evidence that interpersonal and structural discrimination can harm health.[7] Thus, we have decided to continue to use data collected about race and add to it wherever possible information about various social and economic factors that impact health.

Outcome and Selected Determinants

The main outcome of interest was extremely preterm birth, defined as birth through 28 weeks of gestation, and how it related to prenatal support provided.[8]

Prenatal care utilization was quantified using a modified Kotelchuck Index[9] and its components (Table 1). With the Kotelchuck Index, the level of prenatal care category is based on the expected number of visits given the month prenatal care

was initiated and the length of the pregnancy. Therefore, the level of prenatal care is not affected by a shorter pregnancy.

The Kotelchuck Index was modified slightly for this paper. In the original index, the expected number of visits is reduced when care is initiated late. In the modified index, the expected number of visits is only adjusted for gestational age at delivery. Therefore, in the original index, a woman would be expected to have fewer visits if she started prenatal care late and her level of care could be misclassified as adequate. With our modification, a woman starting prenatal care late is more likely to have fewer than expected visits and a lower category of care.

One other adjustment we made to the original Kotelchuck Index was to expand the category of standard routine care to include the Kotelchuck category of "intermediate care." The purpose of the modifications is to minimize misclassification into the intensive care category by assuming high risk or complicated pregnancy for women with generally routine pregnancies.

Although our prenatal care metric is based only on number of physician/nurse practitioner/midwife visits and time of initiation, the concept of prenatal support, as discussed in this study, extends beyond quantifying clinical care and includes both quality of care and other kinds of support derived from nursing case management and home visiting, Special Supplemental Nutrition Program for Women, Infants and Children (WIC), mom- and baby-oriented community services and other systems.

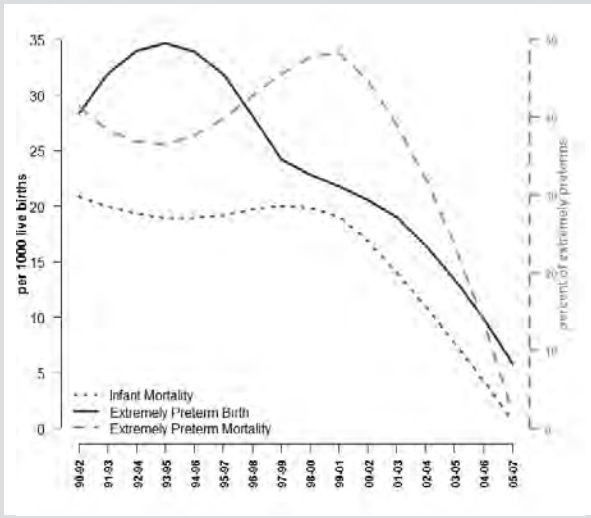
Statistical Analysis

The study design was retrospective cohort. We assessed the association between various risk factors (medical condition, previous preterm delivery, age, marital status, tobacco use, previous pregnancy termination, and previous child death) and outcomes using crude and adjusted relative risks (RR). Crude RR confidence intervals (CIs) were calculated by Wald normal approximation. For adjustment of relative risk regression we used family quasipoisson and the link log from R general linear modeling.

Selection of risk factors to be included in regression analysis was made according to their relative association in our study population with extremely premature birth rates with some allowance for those factors frequently mentioned in the literature. Exact Wilcoxon Mann-Whitney Rank Sum Test was used to assess differences in mean gestational age.

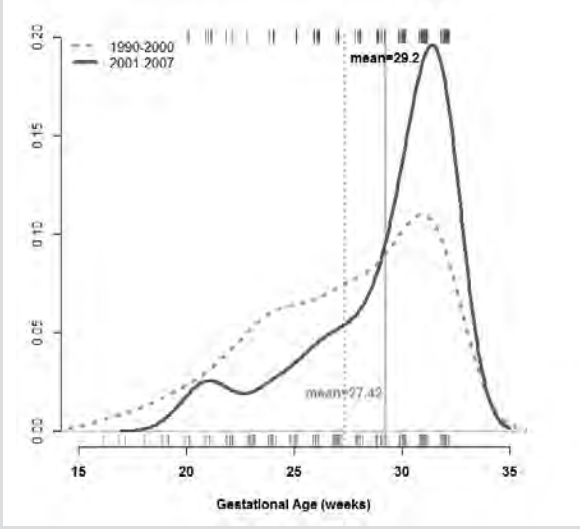
The 95% CI for the prevalence and risk measures were calculated using Wilson confidence's limit for binomial. The impact of selected risk factors was assessed with population attributable fraction (PAF) using the Levin's formula expressed in percents with appropriate modification for the polytomous variables. The statistical analysis was conducted using R, a Language and Environment for Statistical Computing (R Foundation for Statistical Computing, Vienna, Austria). The missing or implausible birth weights were imputed using the R package Amelia.

Figure 2. Comparison of Trends in Infant Mortality, Extremely Preterm Birth (≤ 28 weeks of Gestational Age) and Mortality Among Extremely Preterms, Dane County Black Infants 1990 to 2007



Only extremely preterm mortality (dashed line) is expressed in percents on the right vertical axis. The other 2 rates are per 1000 on the left axis. All the lines are smoothed with a locally weighted regression (loess).

Figure 3. Distribution of Gestational Ages of Preterm Births. Dane County Black Infants 1990-2000 and 2001-2007

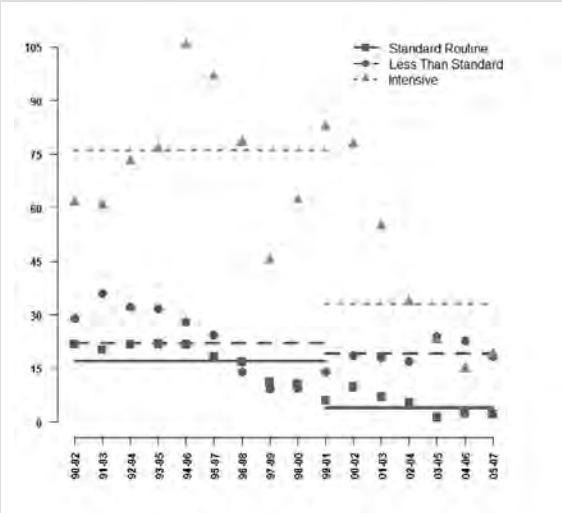


In addition to the density curves, the small bar plots at the bottom and at the top of the figure represent the individual very preterm births for the respective periods of bottom (1990-2000) and top (2001-2007). The small bar plots are jittered to minimize overlapping.

RESULTS

Infant mortality rates for whites, blacks, and Hispanics in Dane County improved from 1990 to 2007 (Figure 1). The 57.4% (95% CI = 32.6-73.1) decline in black infant mortality rates from 1990-2001 to 2002-2007 corresponded with a 53.9%

Figure 4. Birth ≤ 28 Weeks Gestation Rates and Averages by Category of Prenatal Care, Dane County Black Infants 1990-2007



The horizontal segments represent the average risk of extremely preterm for the 2 periods of 1990-2000 and 2001-2007 by prenatal care category.

(95% CI = 33.5-68) decline in the black extremely premature birth (Figure 2). The mean gestational age of black babies born at very preterm (≤ 32 weeks of gestation) showed a statistically significant increase from 27.4 to 29 weeks of gestation, contributing to their increased survival (Figure 3). Based on Wisconsin Department of Health Services estimates of average Medicaid billings for children in the first 4 years of life by birth weight category, the reduction in extremely preterm would amount to $6.75 million in hospital charges averted.[10]

Black women who received "less-than-standard" care (Table 1), showed no significant improvement in rates of extremely premature birth over time: 2.2% (95% CI 1.4-3.5) in 1990-2000 compared with 1.9% (95% CI 1.1-3.3) in 2001-2007. Those who received "standard routine" care declined from 1.7% (95% CI 1.2-2.4) to 0.4% (95% CI 0.2-0.8) while "intensive" care declined from 7.6% (95% CI 5.7-10.1) to 3.3% (95% CI 2.1 to 5.0). Both were large and significant decreases (Table 2): risk of extremely premature delivery for black women receiving "standard routine" care and "intensive" care decreased from 1990-2000 to 2001-2007 by 77.8% (95% CI 49.9-90.1) and 57.3% (95% CI 27.6-74.8) respectively. "Standard routine" and "intensive" care also had improved risk ratios compared to "less-than-standard" care: from 0.8 (95% CI 0.4-1.4) to 0.2 (95% CI 0.1-0.5) for standard routine care and from 3.4(95% CI 2-5.9) to 1.7 (95% CI 0.8-3.6) for intensive care (Figure 4, Table 2).

The prevalence of most pregnancy risk factors (fewer previous preterm births, teenagers, smokers, and women with a previous child death) among black women decreased over time, while those diagnosed with medical conditions and delivering over age 35 increased. For all risk categories, except age, the risk ratio tended to decrease from 1990-2000 to 2001-2007, though not significantly based on the 95% confidence intervals. The PAF for black unmarried women and smokers was high because of the prevalence of these risk factors in the population (Table 3).

Regression analysis shows that after adjustment, risk of extremely preterm delivery is less likely for "standard routine" care and 2001-2007 time period, while it is more likely for intensive care, comorbid medical conditions, black and other race, maternal age less than 20, and previous preterm birth. Age over 35 was not significantly associated with the decrease in extreme premature birth rate (Table 4).

The Dane County black infant mortality rate increased to 12 (95% CI 7.6-18.8) for 2007-2009 and 15 (95% CI 10-22.4) for 2008-2010.

Analysis of Dane County economic data shows that black per capita income rose during the period of improved birth outcomes (2000-2007) and decreased over the time that the gap between black and white infant mortality returned (2008-2010) (Figure 5). This worsening of black economic conditions from 2008 also is demonstrated in a dramatic increase in the percentage of blacks in Dane County using food stamps (Figure 6).

DISCUSSION

The authors previously have reported that, for 4 years during the past decade, the black/white infant mortality gap in Dane County, Wisconsin disappeared. They further demonstrated that the 67% decline in black infant mortality rates (from 19.4 infant deaths per 1000 live births during 1990-2001 to 6.4 during 2002-2007) was largely attributable to the concomitant 61% decline in extremely premature births.[1] This report offers the additional findings that increased gestational age among premature babies was also a key factor in the reduction of black infant mortality and that prenatal support has a protective effect on extremely preterm birth.

Other studies have shown the link between premature birth and infant death and have offered evidence that various interventions can, despite social and economic deprivation, improve outcomes. These include increasing the number of primary care physicians, especially family physicians[11], WIC[12], breastfeeding[13], improved interconception care[14], greater access to contraception,[15] and more continuous, culturally specific and equitable care.[16-19] The "three delays" (seeking care, getting to a health facility, and receiving quality care once in a health facility) associated with maternal mortality in developing countries also may be relevant to decreasing infant mortality in the United States.[20]

Our findings suggest that prenatal support systems can

have great impact on black infant mortality and premature birth and that the effectiveness of such systems can significantly improve over a relatively short time period. In Dane County, prenatal support systems associated with "intensive" care for women with complicated pregnancies (a minority of women that contribute the majority of extremely premature births), dramatically increased their effectiveness over the past decade. Similarly, systems associated with "standard routine" care (the majority of women at lesser risk but who still contribute substantial numbers of extremely premature births), increased their effectiveness. Those who received "less-than-standard" care had no significant reduction in extremely premature birth over time, although the number of women receiving "less-than-standard" care declined significantly.

How and why prenatal support systems became so much more effective appears to be multifactorial (Table 4). Individual contributors can be explored further in future studies. We postulate that change came about through increased cooperation and collaboration among various system components, triggered by immigration (mostly from elsewhere in the United States) of racial and ethnic minorities beginning in the 1990s. Reports from the late 1990s suggest that forces were brought to bear on hospitals, primary care systems, public health, and community organizations to rethink care for a changing population of pregnant women and babies.[21] For example, the Harambee Center was established in 1995 to provide coordinated delivery of social services; original partners included Access Community Health Center, Madison and Dane County Health Departments, Planned Parenthood, the Early Childhood Family Enhancement Center and the Madison Public Library. BadgerCare (a state insurance program) began in 1999 to expand prenatal care coverage to those who earned too much

Table 2. Risk of Extremely Preterm Birth (≤ 28 Weeks Gestation) Among Blacks by Level of Prenatal Care

Dane County 1990-2000 and 2001-2007

Category of Care	Years	Prevalence (N)	Rate%(95%CI)	RR(95%CI)
Less-than-standard care	1990-2000	24.1 (810)	2.2 (1.4,3.5)	1
	2001-2007	19.5 (586)	1.9 (1.1,3.3)	1
Standard routine care	1990-2000	59.2 (1990)	1.7 (1.2,2.4)	0.8 (0.4,1.4)
	2001-2007	61.2 (1842)	0.4 (0.2,0.8)	0.2 (0.1,0.5)
Intensive Care	1990-2000	16.8 (564)	7.6 (5.7,10.1)	3.4 (2,5.9)
	2001-2007	19.4 (583)	3.3 (2.1,5)	1.7 (0.8,3.6)

Abbreviations: CI, confidence interval; RR, relative risk.
Rate is the percent of extremely preterm births in the category of care

Table 3. Determinants of Extremely Preterm Birth for Dane County Black Mothers 1990-2000 and 2001-2007

Factors	Years	Prevalence (N)	Rate% (95%CI)	RR (95%CI)	PAF
Unmarried	1990-2000	75% (2524)	3.2 (2.6,3.9)	1.8 (1,3.1)	36.9
	2001-2007	76.9% (2338)	1.4 (1,2)	1.7 (0.7,3.9)	33.5
Smoking	1990-2000	29.8% (1002)	4.6 (3.5,6.1)	2.2 (1.5,3.3)	26.6
	2001-2007	22.6% (678)	2.1 (1.2,3.4)	1.9 (1,3.7)	17.2
Previous termination	1990-2000	2.5% (84)	9.5 (4.9,17.7)	3.6 (1.8,7.2)	6.1
	2001-2007	2.8% (86)	3.5 (1.2,9.8)	2.9 (0.9,9.1)	5
Previous death	1990-2000	2.6% (86)	11.6 (6.4,20.1)	4.5 (2.4,8.3)	8.2
	2001-2007	1.8% (56)	5.4 (1.8,14.6)	4.4 (1.4,14)	6
Medical condition	1990-2000	49% (1649)	3.9 (3.1,4.9)	2.1 (1.4,3.3)	36
	2001-2007	57.9% (1761)	1.3 (0.9,2)	1.1 (0.6,2)	2.6
Previous premature	1990-2000	5.9% (198)	8.6 (5.4,13.3)	3.5 (2.1,5.8)	12.8
	2001-2007	4.8% (146)	2.1 (0.7,5.9)	1.6 (0.5,5.3)	3
Mother's age <20	1990-2000	25.9% (872)	3.4 (2.4,4.9)	1.3 (0.8,2)	7.1
	2001-2007	20.4% (622)	1.9 (1.1,3.3)	1.7 (0.9,3.4)	12.6
Mother's age >35	1990-2000	5% (169)	2.4 (0.9,5.9)	0.9 (0.3,2.4)	-0.5
	2001-2007	6.1% (185)	1.6 (0.6,4.7)	1.4 (0.4,4.8)	2.3

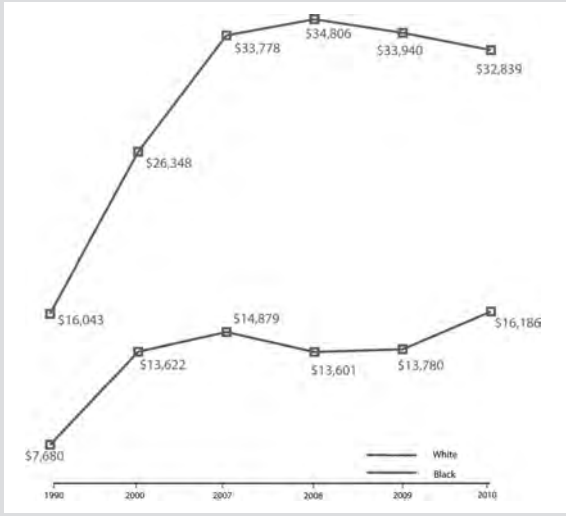
Abbreviations: CI, confidence interval; PAF, population attributable fraction; RR, relative risk.
"Rate is the percent of extremely preterm births in the risk factor

Table 4. Unadjusted and Adjusted Risk Ratios (RR), Prevalence, and *P*-value of Selected Determinants of Extremely Preterm Birth (≤ 28 weeks) in Dane County, 1990 to 2007

Predictors	Prevalence	Crude RR (95%CI)	Adjusted RR (95%CI)	*P*-value
Standard routine[1]	75.6	0.3 (0.2,0.3)	0.3 (0.2,0.3)	<0.001
Intensive[1]	17	2.4 (2.2,2.6)	2.1 (1.7,2.6)	<0.001
Medical[2]	37.1	2.1 (1.8,2.4)	1.4 (1.2,1.6)	<0.001
Previous preterm birth[3]	2.1	4.7 (3.6,6)	2.5 (1.9,3.2)	<0.001
Black race[4]	6.6	3.5 (2.8,4.2)	2.3 (1.9,2.8)	<0.001
Other race[4]	12	1.3 (1,1.6)	1.3 (1,1.6)	0.023
2001-2007[5]	42.1	0.8 (0.7,0.9)	0.6 (0.6,0.8)	<0.001
Mother's age < 20yrs[6]	5.9	2.4 (1.9,3)	1.7 (1.4,2.2)	<0.001
Mother's age > 35yrs[6]	12.3	1.1 (0.9,1.4)	1 (0.8,1.2)	0.936

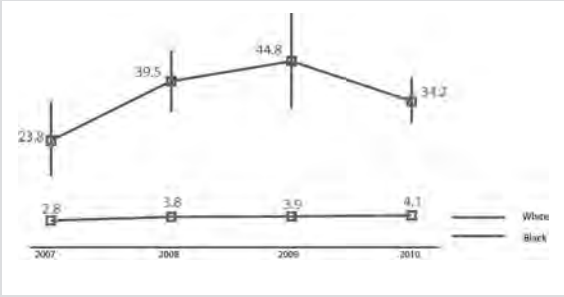
Adjustment for race and time period and the following predictors: level of prenatal care,medical history, previous preterm birth and mother's age. All the risk factors were still associated with extremely preterm birth after adjustment except age over 35 years, and the effect of time period was still significant.
Reference groups: 1 = less than standard; 2 = non-medical; 3= no previous preterm birth; 4 = white race; 5 = 1990-2000; 6 = Mother's age 20-35

Figure 5. Dane County Median Income by Race, 1990-2010



Top line = white. Bottom line = black.

Figure 6. Percent Food Stamp Participation by Race, Dane County 2007-2010



Top line = black. Bottom line = white.

to qualify for Medicaid. Both of these programs were affected by the economic downturn of recent years.

The return of excessive black infant mortality to Dane County is very disheartening. The great recession of 2008 that halted the rising economic tides of previous years appears to have broadly affected birth outcomes, most drastically for blacks. Local prenatal support systems and women's health programs may be key in confronting new challenges.

Wisconsin's birth cost recovery policies may be exacerbating racial disparities in birth outcomes, especially in hard economic times.[22] Birth cost recovery involves recouping Medicaid medical expenses related to pregnancy and delivery from unmarried fathers. Wisconsin is 1 of 9 states collecting birth cost recovery from Medicaid patients and one of the two most aggressive. Because unmarried women seeking Medicaid prenatal care coverage are forced to report the father of the baby, they may be less inclined to seek prenatal care. If they do report the father and are living with him out of marriage, money recouped from him is money upon which she may depend. Since, of 2007 Wisconsin births, 84% of white women compared with 27% of black women were married when they gave birth, this policy has a greater impact on black women and their families.[23]More research is needed on the impact of Wisconsin's birth cost recovery policies.

As key factors leading to the elimination and reappearance of the Dane County black-white infant mortality gap are identified, they may be exported elsewhere in Wisconsin and nationally. Ninety-one percent of Wisconsin black infant deaths occur in the cities of Beloit, Kenosha, Milwaukee and Racine.[24] An initiative funded by the Wisconsin Partnership Program, Lifecourse Initiative for Healthy Families (LIHF), is researching ways to impact the high black infant mortality rate in these 4 counties.[24,25] The life course perspective explains racial disparities in birth outcomes by the cumulative effect of lifetime exposure to more risk factors and fewer protective factors, especially at critical times.[26] The life course approach, "which has increasingly been advocated by researchers and health officials across the country, focuses on breaking the cycle of infant mortality by attacking poverty, racism and segregation, health care, chronic diseases, stress, low birth weight and a range of behaviors such as smoking."[27] The elimination of the Dane County black-white infant mortality gap demonstrates that change can be achieved and intensified research and support for prenatal care in a broad sense are essential. The association between worsening socioeconomic conditions and reappearance of the Dane County black-white infant mortality gap supports the LIHF approach.

CONCLUSIONS

In Dane County, Wisconsin, during 2000-2007, dramatic declines in black premature birth and increases in black infant survival were strongly associated with the growing effectiveness of local prenatal care systems. The reappearance of a large black/white infant mortality gap during 2008-2010, the years of a great recession that disproportionately affected blacks, suggests that socioeconomic factors predominate.

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A Review of Guidelines for Dyslipidemia in Children and Adolescents

Amy L. Peterson, MD; Patrick E. McBride, MD, MPH

ABSTRACT

The recent publication of new pediatric lipid screening guidelines represents a change in recommendations regarding lipid screening and management for pediatric patients that will affect all health care professionals who care for children and adolescents. The guidelines differ from the selective screening recommended by the 2007 US Preventive Services Task Force, instead recommending routine lipid screening for children and adolescents at ages 9-11 years and again at 17-21 years. Studies have shown that limiting lipid screening to patients with risk factors fails to identify many patients with genetic or acquired dyslipidemias. Without universal screening, many at-risk children will not be identified.

A CASE SCENARIO

An overweight 15-year-old male was referred to clinic after his father died suddenly at 33 years of age while working on an assembly line at a factory. Myocardial infarction was the confirmed cause of the father's death. The father's total cholesterol (TC) was greater than 300 mg/dL. A fasting lipid profile in the 15-year-old patient showed TC of 314 mg/dL, low-density lipoprotein (LDL) 254 mg/dL, high-density lipoprotein (HDL) 35 mg/dL, and triglycerides (TG) of 125 mg/dL, confirming a diagnosis of familial hypercholesterolemia (FH) along with features of familial combined hyperlipidemia (FCH).

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CME available. See page 282 for more information.

BACKGROUND

Significant lipid disorders in pediatrics commonly are missed.[1-4] Previous research on selected screening demonstrates that as many as half of children with genetic and acquired cholesterol disorders are missed without routine screening.[5,6] Publication of new pediatric lipid screening guidelines in the *Expert Panel on Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents: Summary Report*[7] in December 2011 representS a change in recommendations regarding lipid screening and management for pediatric patients that will affect all health care professionals who care for children and adolescents. The guidelines recommend universal lipid screening with a non-fasting TC, high-density lipoprotein (HDL), and non-HDL cholesterol at ages 9-11 years and again at 17-21 years in children and adolescents for routine screening. Children and adolescents with higher risk medical conditions or concerning family histories can be screened as young as 2 years old or at the time the medical condition or concerning family history is diagnosed. The screen should be considered every 5 years thereafter. These recommendations differ from the selective screening recommended by the 2007 US Preventive Services Task Force, which concluded that "the evidence was insufficient to recommend for or against routine screening for lipid disorders" in children and adolescents up to age 20.[8]

Overweight and obesity are well-established cardiovascular risk factors in adults, and pediatric obesity is linked to increased rates of dyslipidemia.[9] Unfortunately, the rising incidence of pediatric obesity in the United States is evident. Currently, approximately one-third of American children are overweight or obese.[10] Consequently, rates of pediatric dyslipidemia in the United States are rising.[11] Previously, pediatric cholesterol guidelines have focused on identifying children with elevated LDL or with FH. However, the most common pediatric dys-

lipidemia is now moderately to severely elevated TG, normal to mildly elevated LDL, and reduced HDL, most commonly seen in obese children and adolescents.

WHICH DYSLIPIDEMIAS ARE FREQUENTLY DIAGNOSED IN CHILDREN AND ADOLESCENTS?

Dyslipidemias are abnormal amounts of lipid (hydrophobic fat molecules such as cholesterol and fatty acids) and/or lipoprotein (aggregate molecules consisting of lipids and apolipoproteins that bind to lipids) in the blood. Levels of lipid and lipoprotein are a result of genetic and environmental contributions (diet, activity, etc). Normal ranges of lipids and lipoproteins have been established in the pediatric population. Dyslipidemias can be caused by primary genetic disorders or by secondary causes, the most common of which is obesity.

There are many described genetic dyslipidemia syndromes. The most common found in pediatric practice are FCH and FH.[12] Table 1 compares pediatric features of FCH and FH. FH occurs in 1 in 300-500 people in the US population and is inherited in an autosomal dominant pattern. FH patients present with severely elevated TC and LDL that is present from birth, and they typically have normal TG and HDL. Patients with FH develop premature cardiovascular disease, with 50% of men and 25% of women developing a cardiovascular event by 50 years old.[12]

FH is underdiagnosed and undertreated, particularly in the pediatric population. Some experts estimate that only 20% of patients with FH are diagnosed[1,2] and only a small percentage of those receive appropriate treatment.[2,13] FH guidelines do not require genetic testing to confirm the diagnosis, as it is unlikely to modify a patient's management approach at the current time.[14] FH should be suspected in a patient 20 years of age or younger if the untreated fasting LDL is ≥160 mg/dL or the non-HDL cholesterol is ≥190 mg/dL, values that are substantially above the 95th percentile.[3] The diagnosis is confirmed if the patient has a first-degree family member with premature atherosclerosis and an LDL > 200 mg/dL.

As with adults, FCH is the most common pediatric dyslipidemia seen in practice today, with some estimates of incidence as high as 1 in 100 children.[4] Pediatric patients have moderately to severely elevated TG, normal or mildly elevated LDL, and reduced HDL. It is most commonly associated with overweight or obesity, hypertension, and insulin resistance in the pediatric population.[4,15-19] Diagnostic criteria for FCH are less clear and the entity represents a much more heterogeneous population than does FH, making estimates of pediatric prevalence difficult.

Table 1. Features of Familial Combined Hyperlipidemia and Familial Hypercholesterolemia in the Pediatric Population

	Familial Combined Hyperlipidemia (FCH)	Familial Hypercholesterolemia (FH)
Incidence	~1:100	1:300-500
Inheritance Pattern	Polygenic	Monogenic (usually autosomal dominant)
Associated Conditions	Obesity, insulin resistance, hypertension	None
LDL Level	Normal	High
HDL Level	Low	Normal
TG Level	High	Normal

Abbreviations: LDL, low-density lipoprotein; HDL, high-density lipoprotein; TG; triglycerides.

Table 2. Risk Factors

High-Level Risk Factors

Hypertension requiring drug therapy (BP ≥ 99th percentile + 5 mmHg)
Current cigarette smoker
BMI ≥ 97th percentile
Presence of high-risk conditions
(Diabetes mellitus [DM] is also a high-level risk factor but it is classified here as a high-risk condition to correspond with Adult Treatment Panel III recommendations for adults that DM is considered a cardiovascular disease. equivalent.)

Moderate-Level Risk Factors

Hypertension not requiring drug therapy
BMI ≥ 95th percentile, < 97percentile
HDL-C < 40 mg/dL
Presence of moderate-risk conditions (Table 3)

Abbreviations: RF, risk factor; definitions for dyslipidemia algorithms (+) family history: myocardial infarction, angina, coronary artery bypass graft/stent/angioplasty, sudden cardiac death in parent, grandparent, aunt, or uncle, male <55 y, female < 65y

Adapted from: Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents. Report of the Expert Panel.[20]

Table 3. Special Risk Conditions

High Risk

Diabetes mellitus, type 1 and type 2
Chronic kidney disease/end-stage renal disease/post renal transplant
Post orthotopic heart transplant
Kawasaki disease with current aneurysms

Moderate Risk

Kawasaki disease with regressed coronary aneurysms
Chronic inflammatory disease (systemic lupus erythematosis, juvenile rheumatoid arthritis)
Human immunodeficiency virus infection
Nephrotic syndrome

Adapted from: Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents. Report of the Expert Panel.[20]

Table 4. Acceptable, Borderline-High, and High Plasma Lipid, Lipoprotein and Apolipoprotein Concentrations (mg/dL) For Children and Adolescents

Category	Acceptable	Borderline	High[a]
TC	< 170	170-199	≥ 200
LDL-C	< 110	110-129	≥ 130
Non-HDL-C	< 120	120-144	≥ 145
ApoB	< 90	90-109	≥ 110
TG			
0-9 years	< 75	75-99	≥ 100
10-19 years	< 90	90-129	≥ 130
Category	**Acceptable**	**Borderline**	**Low[b]**
HDL-C	>45	40-45	< 40
ApoA-I	>120	115-120	<115

Abbreviations: TC, total cholesterol; LDL-C, low-density lipoprotein cholesterol; HDL-C, high-density lipoprotein cholesterol; TG, triglycerides.
[a] Values for plasma lipid and lipoprotein levels are from the National Cholesterol Education Program (NCEP) Expert Panel on Cholesterol Levels in Children. Non-HDL-C values from the Bogalusa Heart Study are equivalent to the NCEP Pediatric Panel cut points for LDL-C. Values for plasma apoB and apoA-I are from the National Health and Nutrition Examination Survey III.
[b]The cut points for high and borderline-high represent approximately the 95th and 75th percentiles, respectively. Low cut points for HDL-C and apoA-I represent approximately the 10th percentile.

Adapted from: Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents. Report of the Expert Panel.[20]

Table 5. Recommended Cut Points for Lipid and Lipoprotein Levels (mg/dL) in Young Adults[a]

Category	Acceptable	Borderline High	High
TC	< 190	190-224	≥ 225
LDL-C	< 120	120-159	≥ 160
Non-HDL-C	< 150	150-189	≥ 190
TG	< 115	115-149	≥ 150
Category	**Acceptable**	**Borderline Low**	**Low**
HDL-C	>45	40-44	< 40

Abbreviations: TC, total cholesterol; LDL-C, low-density lipoprotein cholesterol; HDL-C, high-density lipoprotein cholesterol; TG, triglycerides.
[a]Values provided are from the Lipid Research Clinics Prevalence Study. The cut points for TC, LDL-C, and non-HDL-C represent the 95th percentile for 20- to 24 year old subjects and are not identical with the cut points used in the most recent NHLBI adult guidelines, ATP III, which are derived from combined data on adults of all ages. The age-specific cut points given here are provided for pediatric care providers to use in managing this young adult age group.
For TC, LDL-C, and non-HDL-C, borderline high values are between the 75th and 94th percentile, while acceptable are < 75th percentile. The high TG cut point represents approximately the 90th percentile with borderline high between the 75th and 89th percentile and acceptable <75th percentile. The low HDL-C cut point represents roughly the 25th percentile, with borderline low between the 26th and 50th percentile and acceptable > the 50th percentile.

Adapted from: Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents. Report of the Expert Panel.[20]

WHAT DO THE GUIDELINES RECOMMEND?

Cardiovascular Risk Factors

Guideline recommendations regarding frequency and type of lipid screening vary based on the presence of cardiovascular risk factors. Common risk factors encountered in pediatric practice include overweight and obesity, hypertension, and diabetes. A detailed listing of high-level and moderate-level risk factors is summarized in Tables 2 and 3.[20]

Children with no cardiovascular risk factors

Recent guidelines published by the National Cholesterol Education Program Expert Panel have endorsed universal screening of all children from 9 to 11 years old and again at 17 to 21 years old with a non-fasting lipid screen in order to identify children with dyslipidemias at a young age.[7] This recommendation is different from the 2007 US Preventive Services Task Force (USPSTF) recommendations regarding screening of children and adolescents for dyslipidemias. The USPSTF concluded "the evidence is insufficient to recommend for or against routine screening" in children and adolescents up to age 20 and instead endorsed selective screening of children and adolescents at increased risk for early cardiovascular disease[8]. Both sets of guidelines offered their recommendations as a level of evidence "C," reflecting expert consensus in the absence of data from large randomized controlled trials in children.

According to the NCEP Expert Panel, the initial screening test can be a non-fasting total and HDL cholesterol, which are accurate in the non-fasting state. The non-HDL cholesterol can then be calculated using the formula non-HDL=TC – HDL. Evidence supports that lipid levels drawn before puberty have a high correlation with adult levels and are stable, unlike levels drawn during puberty. During puberty, hormonal changes have been associated with a decrease in LDL levels, with fluctuations in HDL and TG. The Dietary Intervention Study in Children (DISC) showed an average decrease in LDL of 23.3 mg/dL in boys and 10.6 mg/dL in girls in Tanner stage 4 or 5 compared to their LDL level at Tanner stage 1.[21] As a result of these normal decreases in LDL during puberty, the sensitivity and specificity of predicting adult LDL levels based on levels obtained during puberty is compromised and indiscriminate testing leads to a high false negative rate of detection. For this reason, universal screening is not recommended during adolescence. Despite decreases in LDL levels during puberty, guidelines use the same reference ranges for lipid profiles in adolescents as they do in children. This is because the recommended thresholds to initiate lifestyle or medical therapy are the same for children and adolescents, regardless of pubertal status.

Universal screening is not recommended prior to age 9 due

Figure 1. Dyslipidemia Algorythm: TARGET LDL-C (Low-Density Lipoprotein Cholesterol)

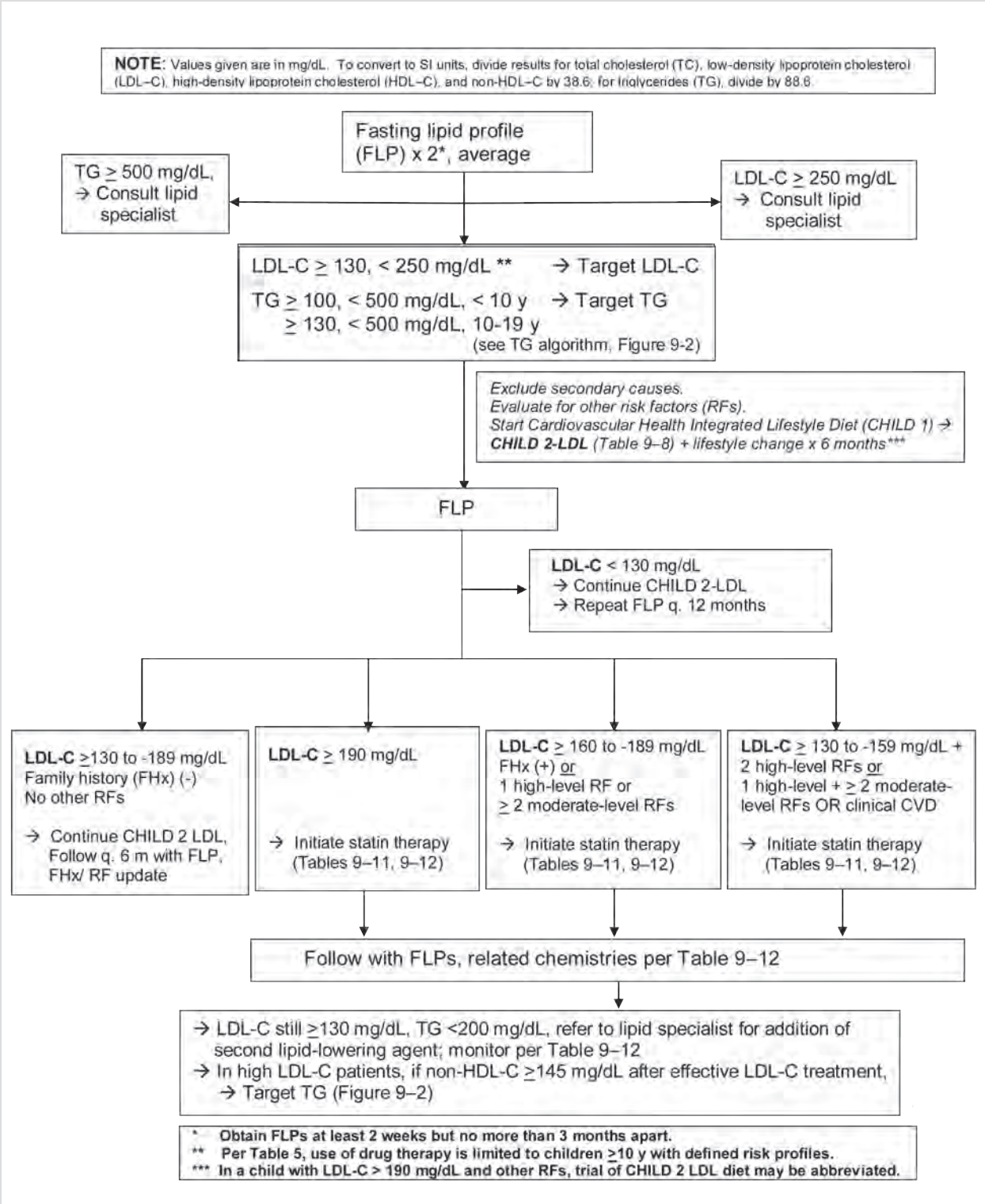

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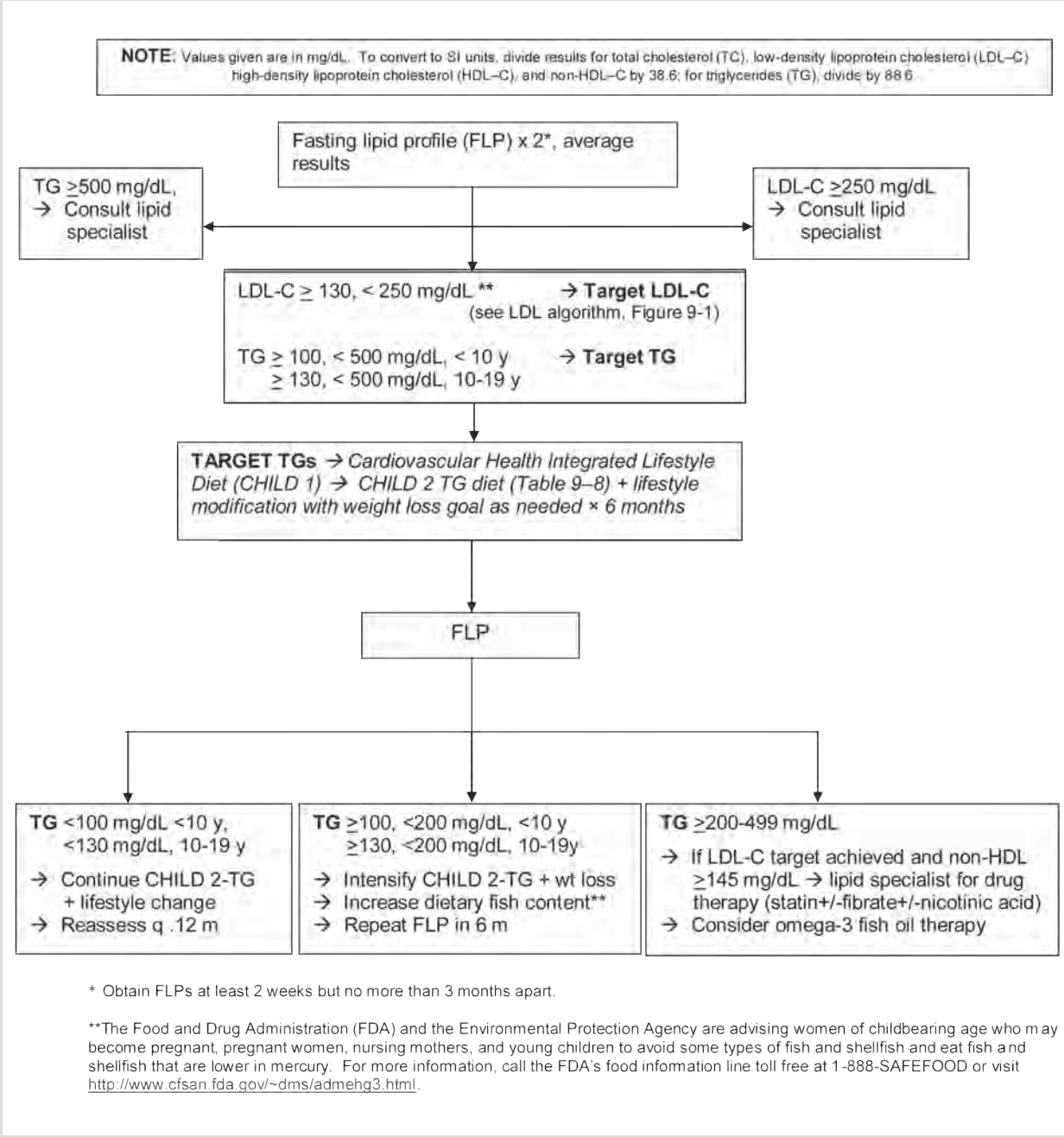
Figure 2. Dyslipidemia Algorythm: TARGET TG (Triglycerides)



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to the minimal data regarding medication use in children less than 8 years old. However, if new risk factors are identified between 10 and 17 years of age, then targeted screening with a fasting lipid profile may be appropriate.

Acceptable ranges for fasting and non-fasting lipid profiles for children, adolescents, and young adults are shown in Tables 4 and 5. If a non-fasting lipid screen is abnormal, 2 fasting lipid profiles (TC, LDL, HDL, and TG measured) should be performed, with the average result taken.[7]

Children with cardiovascular risk factors

Children with a family history of premature cardiovascular disease may be screened with a fasting lipid profile at an earlier age, as young as 2 years old if this would result in a change in management of the child and family. Deciding if a child has a

"strong" family history of "early" cardiovascular disease can be subjective, and so a definition for a positive family history of premature cardiovascular disease is given in Table 2. Children with conditions that predispose to dyslipidemia should be screened with a fasting lipid profile when the condition is diagnosed and every 5 years thereafter. Common medical conditions that predispose children to dyslipidemia are listed in Tables 2 and 3.

Treatment of dyslipidemias

Treatment of identified dyslipidemias is indicated for those children who are at higher risk for accelerated atherosclerosis. This is intended to prevent premature atherosclerosis in those at highest risk, and establish lifelong healthy practices. Suggested treatment algorithms for elevated LDL and elevated TG are shown in Figures 1 and 2, respectively. Lifestyle modification is first-line treatment for nearly all patients. This includes regular physical activity and limited "screen time" as well as a diet low in fat, saturated fat, and cholesterol. Controlling intake of refined carbohydrates is useful, particularly in the setting of hypertriglyceridemia. Appropriate caloric intake is also important, particularly if the child is overweight or obese. Referral to a dietician experienced in treating children and families for medical nutrition therapy can be very helpful. Regular follow-up is important, and if dyslipidemias persist, then pharmacologic treatment may be recommended after careful consideration of a child's family history and cardiovascular risk factors.

In general, children 9 years of age and younger should be offered only pharmacologic treatment under high-risk circumstances. Severe dyslipidemia, a high-risk medical condition, or evident cardiovascular disease may warrant medication, but this should be done under the care of a physician with significant experience in lipid disorders and treatment. For children and adolescents 10 years and older, consultation with a lipid specialist is recommended if the average LDL ≥ 250 mg/dL or if the average TG ≥ 500 mg/dL. Lipid profiles this markedly abnormal generally indicate a primary dyslipidemia. While lifestyle modification is important in the management of any dyslipidemia, these conditions invariably require treatment with one, if not several, medications.

For less severe dyslipidemias, lifestyle modifications and close monitoring are usually appropriate initial steps, but appropriate treatment of pediatric patients with persistently abnormal lipid profiles and/or cardiovascular risk factors may include medication. Consultation with the patient and family is important prior to the initiation of any medication.

DOES SCREENING MAKE A DIFFERENCE?

It is well-established that atherosclerosis begins in childhood.[22-24] The presence of fatty streaks in the arterial intima during childhood and the reversibility of these early atherosclerotic lesions lend support to the concept of early treatment, including lifestyle modification and medications.[25,26]

Screening and treating children for lipid disorders remains controversial because there are no studies demonstrating that treatment of dyslipidemias in childhood will prevent cardiovascular events later in life. While ideal, randomized controlled trials of screening and treating pediatric patients are not practical due to limitations of cost, study size, and length of follow-up required.[27] However, there is evidence that modifying established cardiovascular risk factors will delay the development and progression of atherosclerotic lesions in children.[28-32] The presence of atherosclerotic lesions, even in young adults, has been linked to a shorter life expectancy and an increase in cardiovascular events.

The presence or absence of cardiovascular risk factors alters a person's atherosclerotic burden, even in childhood. Young adults with no or minimal cardiovascular risk factors have less atherosclerosis, live longer, have fewer cardiovascular events, and have a better quality of life.[28,29] One trial showed that when healthy boys were fed a low saturated fat, low cholesterol diet from 7 months of age through 11 years, they were shown to have lower TC and LDL throughout childhood, and had better vascular endothelial function compared to controls. Girls following this diet had less obesity. Importantly, despite a low-fat diet starting at 7 months of age, cognitive, neurologic, and pubertal development were similar between the two groups.[30]

It has also been established that modification of preexisting cardiovascular risk factors can decrease a child's atherosclerotic burden. Children with very high LDL that are treated have less carotid atherosclerosis than those that are untreated. In those patients, if appropriate medical and lifestyle interventions are started at younger ages, the decrease in atherosclerosis is even greater.[31]

Why the argument for universal screening?

In response to concerns regarding pediatric obesity and associated pediatric dyslipidemia, in 2008 the American Academy of Pediatrics (AAP) revised its guidelines and recommended screening with a fasting lipid profile for all children between 2 and 10 years old with identified family history or patient risk factors. Recommendations indicated that a patient's family history should prompt screening if a parent, grandparent, aunt, or uncle had high cholesterol or cardiovascular disease, or if family history was unknown. Any patient with overweight or obesity, hypertension, tobacco use, or diabetes also met criteria for screening.[32]

However, in order for this type of selective screening program to work, the patients that meet screening criteria need to be properly identified. There are no clear standards for accurate

family histories, and accurate measurement and interpretation of blood pressure in children and adolescents can be challenging. In order to identify patients with cardiovascular risk factors, the risk factors themselves need to be identified.

In order for any selective screening program to work, the screening criteria need to be sensitive enough to detect affected patients. Unfortunately, this is not the case with pediatric dyslipidemias.[5,6,33-37] One study screened LDL in over 20,000 fifth graders. In that particular study, 71% of children met 2008 AAP screening criteria. Of those children, 8.3% had an abnormally elevated LDL, and 14% of children with an abnormal LDL required pharmacologic treatment. Of the 29% that did not meet screening criteria, 9.5% had an abnormal LDL, and 18% of those children with an abnormal LDL required pharmacologic treatment. Dyslipidemia requiring pharmacologic treatment was more common among children who did not meet screening criteria than among those who did.[5] Another study of 678 children found the 2008 AAP screening criteria were only 54%-66% sensitive in identifying children with a dyslipidemia.[6]

CONCLUSION

Dyslipidemias are common in pediatrics. They are increasing in incidence and frequently are missed with selective screening. It is important to identify common genetic risk factors. Identifying cardiovascular risk factors in children can be challenging, and risk factors often are missed. Even if risk factors are properly identified, studies have shown that limiting lipid screening to those patients with risk factors fails to identify many patients with genetic or acquired dyslipidemias. Without universal screening, many at-risk children will not be identified.

Atherosclerosis starts in the very young, and in rare cases of severe dyslipidemia where medical management is indicated, early intervention has been shown to improve vascular function and reduce risk for future disease. Initiation of medication is not and cannot be the first-line treatment: for all patients with dyslipidemia, lifestyle intervention is vital in the management of a disease process that eventually carries high morbidity and mortality. Ignoring genetic disease in children that predisposes them to early morbidity and mortality because 30-year results of randomized controlled trials are not available is unacceptable.

Development of medical guidelines is complex but serves an essential purpose: to provide recommendations for treatment based on evidence. Large, long-term trials in pediatric medicine are virtually nonexistent. With the creation of any guideline, evidence ratings are provided and potential conflicts of interest are disclosed to help clinicians make informed decisions regarding management of their individual patients. Controversies can and do arise when guidelines disagree; it is part of the art and science of medicine.

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CME

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Quiz: A Review of Guidelines for Dyslipidemia in Children and Adolescents

EDUCATIONAL OBJECTIVES

Upon completion of this activity, participants will be able to:

1. Understand the broad outlines of the current recommendations for screening for dyslipidemia in children and adolescents.
2. Recognize the levels of lipids that would trigger more aggressive treatment of dyslipidemia in children and adolescents.
3. Understand the diagnostic features of the two most common inherited forms of dyslipidemia in children and adolescents: Familial Combined Hyperlipidemia (FCH) and Familial Hypercholesterolemia (FH).

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QUESTIONS

1. Which of the following statements are true?
   - A. Approximately 20% of American children are overweight or obese.
   - B. As many as half of children with genetic and acquired cholesterol disorders are missed without routine screening.
   - C. Integrated guidelines for cardiovascular health and risk reduction in children and adolescents published by the National Heart, Lung and Blood Institute in December 2011 recommend universal lipid screening for all children ages 9 to 11 years and again at 17 to 21 years of age.
   - D. Children or adolescents with a LDL ≥ 250 mg/dL or triglycerides ≥ 500 mg/dL almost certainly have a primary dyslipidemia and should be considered for referral to a specialist with experience in treating pediatric lipid disorders.

   ❑ All of the above
   ❑ A and B only
   ❑ C and D only
   ❑ B, C, and D only
   ❑ A, B, and C only

• • •

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2. Which of the following statements concerning FH and Familial Combined Hyperlipidemia FCH are false?
   - A. The most common pediatric dyslipidemia seen practice today is FCH.
   - B. FCH is characterized by an elevated triglyceride level, a reduced HDL level, and a normal or mildly elevated LDL level.
   - C. The incidence of FCH is about 1 in 100, whereas the incidence of FH is about 1 in 300-500.
   - D. FC is under underdiagnosed and undertreated, particularly in the pediatric population.
   - E. FH should be suspected in a patient 20 years of age or younger if the untreated fasting LDL is greater than 160 mg/dL or the non-HDL cholesterol is greater than 190 mg/dL.

   ❑ A
   ❑ B
   ❑ C
   ❑ D
   ❑ E
   ❑ All statements are correct

3. Which of the following statements are true?
   - A. The screening test recommended for children and adolescents with no cardiovascular risk factors should be a total cholesterol, HDL, and non-HDL cholesterol.
   - B. If a nonfasting lipid screen is abnormal, 2 fasting lipid profiles should be performed, with the average result taken. Subsequent treatment decisions should be based on these values.
   - C. Lipid levels may be drawn during puberty since they are highly correlated with adult lipid levels.
   - D. Children with conditions that predispose them to dyslipidemia should be screened with a fasting lipid profile when the condition is diagnosed and every 5 years thereafter.
   - E. Children and adolescents with family histories strongly positive for cardiovascular disease can be screened as young as 2 years of age.

   ❑ All of the above
   ❑ None of the above
   ❑ A, B, and C only
   ❑ A, B, D, and E only
   ❑ D and E only

4. Patients with FH develop premature cardiovascular disease with 50% of men and women developing a cardiovascular event by 50 years of age.
   ❑ True
   ❑ False

Promoting Healthy Food Consumption: A Review of State-Level Policies to Improve Access to Fruits and Vegetables

Carlyn Hood, MPA, MPH; Ana Martinez-Donate, PhD; Amy Meinen, MPH, RD, CD

ABSTRACT

Research indicates poor nutrition is a leading determinant of the development of chronic disease, and increasing fruit and vegetable consumption is one method for decreasing obesity. Many policies have focused on increasing the demand for fruits and vegetables through price reductions and coupons. However, without ensuring a stable supply, increased demand can continue to raise prices, crowding out individuals who may otherwise have purchased fruits and vegetables and ultimately leading to continued disparities in access. This paper presents a review of selected state-level policy options recently proposed or implemented in states across the United States, and provides an evidence-based lens through which food access policy can be shaped in the Midwest. This review and potential framework uses Wisconsin to illustrate the feasibility of different state-level decisions and their potential impact on particular populations. Future supply-side policies to consider include expanding Electronic Benefit Transfer to the Special Supplemental Nutrition Program for Women, Infants and Children (WIC),program and farmers markets, incentivizing the purchase of locally grown produce, assisting local specialty farmers directly, and/or establishing a state-level food policy council. This review reveals that a food policy council would create a more sustainable policy analysis process to better ensure future policy adoption is truly comprehensive, encompassing the production, distribution and purchase of locally grown fruits and vegetables.

INTRODUCTION

One factor behind the high rate of obesity in the United States is that 86% of US adults and 91.5% of adolescents do not consume the 5 daily fruit and vegetable servings recommended for a healthy diet.[1] The implications of such poor dietary patterns extend beyond bad health outcomes. On a national scale, medical costs associated with treating preventable obesity-related diseases are estimated to increase by $48 billion to $66 billion per year, and the loss in economic productivity could be between $390 billion and $580 billion annually by 2030.[2]

While obesity rates are high for adults overall, some populations are disproportionately burdened with these higher costs than others. Obesity rates for African Americans are 49.5% compared to Mexican Americans (40.4%), all Hispanics (39.1%) and non-Hispanic whites (34.3%).[3] Research indicates race, income, and educational attainment all play a part in obesity,[3] highlighting the importance of interventions aimed at promoting equity. One objective in the national health plan—Healthy People 2020—is to reduce the proportion of all adults, adolescents, and children who are obese.[4] Increasing fruit and vegetable contribution and variety in the diets of all Americans by 2020[4]—a second national health plan objective—attempts to address the issue.

Various settings for interventions aimed at improving nutrition have been identified and proposed, including the home, child care and after school programs, work sites, restaurants and fast food outlets, and retail food stores.[5] The Social Ecological Model states that health behaviors may be influenced through changes at the individual, interpersonal, organizational, and community level, as well as changes in policies ranging from the local to federal levels.[6] According to this model, policy change may be one of the most effective strategies to increase access to fruits and vegetables at the population level.

Access to fruits and vegetables is the result of fluctuations in the economic market through both demand and supply. Demand is driven by income, prices, and consumer preferences. Supply is determined by the input costs to running a business, such as labor, land, equipment, transportation, stock-

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ing, and inventory. Many policies have focused on increasing the demand for fruits and vegetables through price reductions and coupons. However, without ensuring a stable supply, increased demand can continue to raise prices, crowding out individuals who may otherwise have purchased fruits and vegetables and ultimately leading to continued disparities in access. Failure to consider food access from the perspective of both consumers and suppliers may lead to inequalities in nutritional opportunities among populations.[7] Larger system and environmental policy change that supports increasing access to fruits and vegetables—from growth and production to purchasing and consumption—has the ability to empower all individuals to make healthier choices, reduce increasing rates of obesity and related chronic diseases, and promote health equity simultaneously. One example of such an approach, and the most sustainable method for continuing to analyze the connections between varying facets of the food system, is the establishment of a state-level food policy council.

Given the prevalence of obesity, increased state-level assistance is imperative in addressing inequitable access to fruits and vegetables. While some interventions operate at the local level, they are inherently more limited in reach[8] and potentially less cost effective than state- or federal-level policy change. This article presents an analysis of state-level policy alternatives recently proposed or implemented in states across the United States, and uses Wisconsin as a case study to provide an evidence-based lens through which food access policy can be shaped at the state level.

INFLUENCING DEMAND: USING FRUIT AND VEGETABLE VOUCHERS TO REDUCE PRICE BARRIERS

Economic theory assumes demand is determined by income, prices, and preferences. Multiple studies have shown that price reductions, be it through coupons, vouchers, discounts, or loans, can positively affect consumer demand for and consumption of healthy foods.[9] Comprehensive economic research estimates "a 10% reduction in the price of fruits and vegetables would increase purchases on average by 7.0% and 5.8%, respectively."[10] Furthermore, growing research on the way in which potential price changes improve dietary quality and obesity show particular implications for young people, lower income populations, and those most at risk for obesity.[11]

One example of an attempt to alter the level of income available for purchasing fruits and vegetables is Wisconsin's 2009 adoption of the Special Supplemental Nutrition Program for Women, Infants and Children (WIC), program's cash value vouchers. This program provides monthly supplementary checks of $6 (children) and $8 (women) solely for the purchase of fruits and vegetables at WIC participating stores.[12] It has been hypothesized that, given the WIC program serves over 9 million recipients, the voucher policy change has the potential to create significant new demand for foods that were previously lacking in the diets of low-income populations and in the stores that serve them.[13] While the impact of this intervention has not been fully evaluated, one study indicates 76.6% of eligible WIC participants in Wisconsin used their voucher checks at 18 months post implementation.[14] Additionally, participants noted the checks allowed them to buy a larger variety of fruits and vegetables than they would otherwise.[14]

Increasing the availability and variety of fruits and vegetables in food outlets serving a significant volume of WIC participants not only benefits WIC recipients, but increases access to non-WIC participants who shop in these outlets as well. In some locations across the country, 93% of WIC-certified retailers have reported adding new products in response to the WIC revisions.[13]

The voucher program's attempt to increase consumer demand of healthy foods is not without limitations. These include increased time required in processing WIC purchases,[13] difficulty and confusion for WIC participants in getting through the shopping and payment process, new redemption procedures requiring cashiers to monitor and enforce the program and its entitlements,[12] and difficulty for WIC stores in stocking requirements.[13]

The aforementioned program limitations have had little impact on the overall demand for healthy foods, however. In Wisconsin, one study noted more than 63% of WIC families using their vouchers purchased more fruits and vegetables than the maximum voucher value.[14] Several alternative policies, often implemented at the local level, have aimed to increase demand through disclosing nutritional content on menus or packaging or by educating individuals on the benefits of fruit and vegetable consumption. The results of such interventions have varied.[9] This review concentrates on one demand policy, the voucher program, which appears effective at the state level. Alternatives to increasing demand are not included, as economic models indicate that without also considering supply-side policies in the equation, demand policy may have potentially negative impacts for lower-income communities through increased prices, causing continued disparities in access.

INFLUENCING SUPPLY: AN ARRAY OF OPTIONS

Many supply-side policies for increasing access to fruits and vegetables have been suggested at the local, state, and federal levels. Those operating on the community level, while effective, may not have as broad an impact on a population as state or federal level policies. Others, implemented at the state level, can be restrained or made more complex by federal law and national regulation, such as creating healthy menu default options or zoning the development of chain restaurants.

Fortunately, unlike federal policies, state and local food policies benefit from the ability of communities and local officials to utilize institutions they have authority over, empowering them to take control. The following supply-side options are focused at the state level and have the potential to enhance the aforementioned demand-side policies, leading to more equitable access while at the same time assisting local fruit and vegetable producers.

Expanding Electronic Benefit Transfer to All Food Assistance Programs

One option is the subsidization and streamlining of Electronic Benefit Transfer (EBT) equipment for all food assistance programs in stores and farmers markets. EBT is an electronic system that replaces paper food checks or vouchers with a card for food benefit issuance and redemption.[15] In Wisconsin, the Department of Health Services declared as one of its state objectives that all people will have ready access to sufficient nutritious, high-quality, affordable foods and beverages.[16] Nationally, the use of EBT for Supplemental Nutrition Assistance Program (SNAP) benefits in stores has made leaps in obtaining this goal by improving program administration and creating better customer service for both retailers and participants.[17] Currently, the federal government supplies EBT equipment free of charge to SNAP retailers.[17] Streamlining the process to allow WIC participants to redeem benefits through EBT could have a large impact on the recipients of this food program as well. However, while the federal government subsidizes the cost of EBT equipment for retailers, it is not required to support wireless devices that could be used in farmers markets for either program.[17]

Due to large technical and financial costs associated with running EBT,[7] only 39 farmers markets in Wisconsin have capacity for these transactions.[18] The Food and Nutrition Service estimates that the cost to purchase and operate a wireless EBT terminal is roughly $1255 annually.[17] A University of Wisconsin-Extension and US Department of Agriculture pilot project on EBT use in 10 Wisconsin farmers markets has minimized this cost by using 1 terminal per market, increasing economies of scale and decreasing cost to each individual farmer. Preliminary results of this project indicate 87% of SNAP beneficiaries surveyed at Wisconsin farmers markets report that being able to use EBT at the market allowed them to purchase more fruits and vegetables (K. Krokowski, MS, e-mail communication, April 2012). Lack of EBT acceptance at farmers markets has been a substantial barrier to farmers market utilization by low-income residents eligible for food assistance nationwide.[7] As of 2011, California, Indiana, and Massachusetts had passed legislation mandating EBT use in farmers markets.[19]

Wisconsin has declared the proportion of farmers' markets that accept payment from EBT and WIC Farmers' Market Nutrition Program coupons as an indicator of the aforesaid Healthiest Wisconsin 2020 objective[16] and can be increased by creating grant programs and economic incentives to fund the establishment or renovation of farmers markets and roadside markets.[16] Expanding the ability and incentives for food assistance program recipients to redeem benefits in farmers markets and small stores has ramifications for the economy as well. One study found that every SNAP dollar spent generates $1.73 in real GDP increase and that expanding food stamps is the most effective way to "prime the economy's pump."[20] In neighboring Michigan, the Double Up Food Bucks program, which provides matched funds to food assistance beneficiaries for every dollar spent on Michigan grown fruits and vegetables at farmers markets, generated over $200,000 in 3 months with all of the money going directly into the pockets of Michigan growers and food businesses.[21]

Incentivize the Purchase of Locally Grown Fruits and Vegetables

A second supply-side alternative is to alter store and/or government agency stocking requirements to mandate or incentivize these establishments to stock a minimum percentage of locally produced fruits and vegetables. Current policy requires SNAP- and WIC-eligible stores to provide an allotted variety of foods. Expanding these requirements or more vigorously enforcing the existing requirements to ensure sufficient stocking of local fresh produce could improve the selection of healthy foods exactly where the populations most at need shop.[22] In Wisconsin, over half of WIC-eligible stores are small, and small stores are more likely to sell food of low nutritional value and little fresh produce[23] (C. Grover, e-mail communication, March 20, 2012). This suggests WIC participants are most likely to benefit from changes to WIC-eligible stores, and adapting store requirements to increase access to fruits and vegetables could have large ramifications in promoting healthy diets among the underserved. However, without concurrent demand-side programs to ensure increased sales of stocked fresh produce, such a policy might also make it harder for stores to operate profitably in low-income neighborhoods and make it difficult to sustain in the long run.[22]

In addition to stores, state agencies such as schools, work sites, hospitals, state government buildings, correctional facilities, colleges and universities, and group and family child care centers also can be critical in transforming the food system and helping minimize increased rates of obesity by modeling healthy nutrition practices. The Farm to School program is one program that promotes healthy eating and the reduction of childhood obesity by procuring locally grown produce from

farmers for use in school cafeterias, in-class educational cooking opportunities, and on-site school gardening activities.[24] In Wisconsin, over 100 public school districts purchase and serve locally grown fruits and vegetables through this initiative.[24] Expanding purchasing requirements to all state government agencies has the potential to improve the health of their employees as well as the citizens served by their agencies, at the same time ensuring that state-level spending benefits local citizens. Thirteen states have adopted procurement policies mandating that purchasing preferences be given to locally grown commodities.[19] The only Midwestern state to adopt this legislation was Iowa; however, as of 2006 this bill became inactive.[19]

Provide Assistance to Local Fruit and Vegetable Farmers

A third supply-side policy option is to assist local farmers directly. Agricultural business is extremely vulnerable to fluctuations in the market, weather and pests,[25] making financial assistance and insurance a lifeline for small farming ventures. However, federal funds do not currently support small and mid-sized growers of specialty crops such as fruits, vegetables, tree nuts, dried fruits, horticulture, and nursery crops.[26] In 2010, 90% of federal subsidies in Wisconsin supported the production of corn and soybeans.[27] These products are grown largely for use as sugar additives and oil, which have increased in the United States food supply 158% and 38% respectively since 2000.[25] Policies that impact the health of a state's citizens, small farmer livelihood, and economy can be improved and expanded at the state level. Some states have developed programs to support their small farmers through varying methods that include providing funding to assist in increasing the number and operation of farmer's markets; helping farmers absorb costs associated with food production, such as organic certification, distribution of grown goods, and subsidizing crop insurance for higher value horticultural crops; and funding marketing and promotional efforts.[11] This farm assistance was at one time provided federally through the Federal Farm Bill's Emergency Agricultural Appropriations Act.[28] If the National Farm Bill is renewed for 2012, funding will support specialty crops with a block grant of $101 million.[29] However, the Bill expired as of September 30, 2012. Without Congressional support, this policy alternately could be implemented at the state level, giving individual states the opportunity to develop innovative programs to support their local specialty producers.

ECONOMIC IMPACT OF SUPPORTING SUPPLY-SIDE POLICIES

Research indicates assisting with the local production of fruit and vegetables for local markets, and the promotion of direct farm-to-consumer supply chains, would be a wise investment in addressing unhealthy eating, obesity and related diseases.[30] Supporting local farmers not only potentially increases access to healthy foods, but can benefit individual state economies as well. One study found that by converting conventional crop production to fruit and vegetable production at a level to meet the existing demand for those products, the Midwest would benefit from a $1 billon increase in related economic activity.[20] In 2007 Michigan approved a resolution encouraging Congress and the US Department of Agriculture to implement food policies that "promote healthy food, farms, and communities by encouraging local production of fruits and vegetables by specialty crop farmers."[19] As of 2009, 4 states had passed legislation directly supporting their local farmers.[19]

DESIGNING INTEGRATIVE FOOD POLICIES: ESTABLISHING A WISCONSIN FOOD-POLICY COUNCIL

A fourth, more encompassing policy option is the establishment of a state-level food policy council. A food policy council can be defined as an officially sanctioned body of representatives from various segments of a food system—including public, private, and nonprofit officials—tasked with examining the operation of the local food system and providing ideas or recommendations for how it can be improved on both the supply and demand sides.[28] The council's initiatives and strategies attempt to draw on input from individuals in every component of the food system—consumers, farmers, grocers, chefs, food processors, distributors, antihunger advocates, educators, government, and consumers—to support and advise residents and government in developing policies and programs that look at how the local food system works[28] and the methods to increase access and availability of fruits and vegetables.[31]

Councils may be formed voluntarily, by an executive order of the governor, or through independent legislation. One benefit to government-mandated councils is that they often have a steady stream of funding and paid, dedicated council members. However, appointed memberships like this may not be fully representative of the entire food system. Non-government based food policy councils are more likely to have knowledgeable and invested members, but may not be financially sustainable.[31]

Food policy councils have many benefits, including bringing a broader array of interests and voices to the table, providing space for the questions that often do not get asked when the parties normally involved in developing farming and agricultural policies meet, and employing a more comprehensive approach to analyzing food issues, which recognizes the relationship between different parts of the food system and the need for coordination of actions if policy goals are to be met.[28]

The state of Connecticut was the first to create a state food

policy council in 1997.[28] As of 2011, 13 states had developed state-level food policy councils, including Michigan and Illinois.[19] While the establishment of state-level food policy councils is relatively new and evidence of effectiveness is still forthcoming, existing state-level food councils have initiated food policy changes in many areas, including purchasing of local fruits and vegetables for school lunches, promotion of sustainable agriculture, increased ease of access to food assistance programs and healthy foods for low-income individuals and seniors, increased opportunities for locally produced farm products, creation of community and school gardens and farm-to-school program education, creation of new forms of insurance for small producers, and implementation of farm-to-cafeteria and farm-to-school programs.[31] Many states, including Wisconsin, currently have local food networks, but there often is no formal body that meets consistently and has the personnel and resources to direct attention to more comprehensive development of state-level food policy.

CONCLUSION

Food systems are complex, and intervening at their multiple levels is a complicated task. Policy changes at the state level have been successful in significantly improving public health issues, such as tobacco use[32] and seat belt use.[33] Increasingly, obesity is seen as a problem requiring multilevel interventions, including changes in policies at the local, state, and federal level to increase access to healthy foods. Research suggests price changes combined with other regulations affecting the food environment may have a multiplicative effect that could significantly improve diets, particularly among at-risk populations.[11] Wisconsin's adoption of vouchers to decrease the price of fruits and vegetables relative to other goods is an example of a state-level policy that has shown preliminary success in increasing demand. Future supply-side policies could replicate the previously mentioned initiatives, such as expanding EBT to the WIC program and farmers markets, incentivizing the purchase of locally grown produce, and/or assisting local specialty farmers directly.

State-level interventions take into account that federal law and policy are only one component of the discussion, and while the framework for action may be set at the national level, federal law itself cannot provide a localized response.[31] This article has used Wisconsin as a case study to review state-level fruit and vegetable access policies, but it is by no means exhaustive. Obesity policy is an important and newly emerging issue, so much so that every state has become a testing ground for new interventions. However, due to the difficulty in evaluating the effectiveness of these programs in the short run, one method for continuing to apply evidence-based research is the establishment of a state-level food policy council. Each designated body would be beneficial not only in considering how future policy influences health, but also policy's impact on the state's economy and, in particular, the sustainability of local farms and small business owners. State policies can and should incorporate strategies to create demand and supply, and span the entire food process from seed to mouth, in assessing the health and economic impact of increasing access to locally grown fruits and vegetables.

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A Case of a Dermoid Cyst Compressing the Airway

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ABSTRACT

Introduction: In this report we discuss the etiology, common locations, diagnostic approach, and treatment of a dermoid cyst.

Case Presentation: A 22-year-old man arrived at the emergency department complaining of submental fullness, an increase in snoring, choking, gagging, and difficulty breathing. The patient was taken to the operating room for a complete resection of a large dermoid cyst that was compressing his airway.

Discussion: Dermoid cysts are uncommon head and neck tumors mainly presenting in patients aged 15 to 35. The origin of dermoid cysts is thought to be congenital in most cases, but they can also develop from acquired factors such as trauma or surgical implantation that forces epithelial cells into deep tissues.

Conclusion: Although benign and often asymptomatic, dermoid cysts may cause other associated symptoms due to compression of structures in the head and neck.

INTRODUCTION

Dermoid cysts are uncommon masses that can arise in the head and neck area, most commonly in people aged 15 to 35 years,[1] during a period of maximal epithelial activity.[2] They are thought to be congenital in origin, but the literature also indicates they can arise due to implantation.[1] Diagnostic modalities include imaging such as ultrasound, computed tomography (CT) scan, and magnetic resonance imaging (MRI). Dermoid cysts must be considered in the differential diagnosis of head and neck masses. In this report, we present a case of an acute growth of a neck mass in a 22-year-old man that resulted in airway compression and caused him to go to the emergency department (ED). As a case report, this project was exempt from Institutional Review Board approval.

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CASE PRESENTATION

A 22-year-old male presented to the emergency department with a 2-day history of increasing submental fullness and an associated increase in snoring, choking, gagging, and difficulty breathing. He reported a 2- to 3-year history of significant weight gain, up to 148.5 kg, which had caused him to develop a "double chin." However, after losing 15-20 kg over the past year, he became concerned because of persistent submental fullness. He had been sleeping propped up on pillows for the past year due to difficulty breathing at night, which he attributed to asthma. However, use of his albuterol inhaler did not alleviate his symptoms. Two days prior to his arrival at the ED, his primary care physician noted a submental mass and made an outpatient referral to our clinic for further evaluation. Instead, because of worsening respiratory symptoms in the interval, he presented to the ED for acute management.

Clinical examination of the patient's oral cavity and oropharynx was unremarkable. The floor of the mouth was soft and the tongue appeared normal with good mobility. Fiberoptic examination of the pharynx and larynx showed medial displacement of the left lateral pharyngeal wall and rightward deviation and rotation of the larynx. The airway was patent. Examination of the neck revealed a 10 x 15 cm soft neck mass extending from the submental region to the left mandibular angle and inferiorly just beyond the level of the hyoid. A contrast-enhanced CT scan of the neck was obtained (Figure 1), which was followed up by an ultrasound as recommended by radiology (Figure 2). An MRI was obtained to further define the location of the lesion with respect to adjacent musculature and other soft tissues (Figure 3).

Excision of the mass began with a skin crease incision followed by a subplatysmal flap elevated to the level of the mandible. The anatomy of the neck musculature was distorted due to stretching by the underlying mass. Dissection focused on establishing a plane between the mass and the surrounding

Figure 1. Post-contrast Axial CT Scan

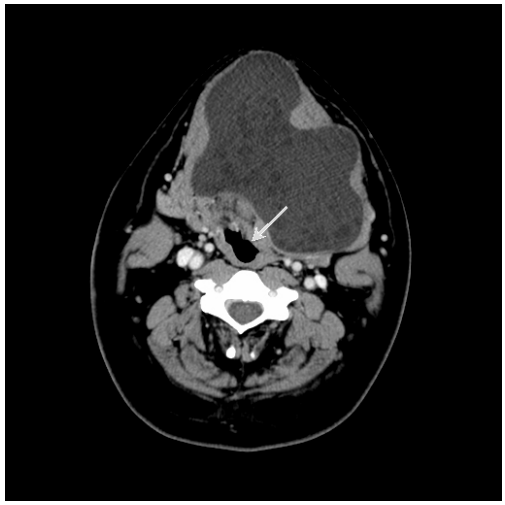


Image demonstrates a large, well-defined floor of mouth mass that is hypodense compared to adjacent musculature. Multiple low-attenuation, rounded foci are noted scattered throughout the lesion. Note slight mass effect upon the oropharyngeal airway (arrow).

Figure 2. Sagittal Ultrasound Image

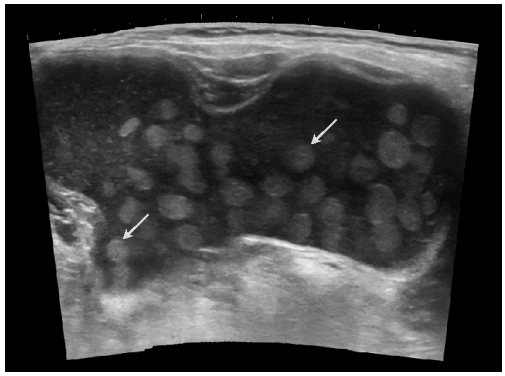


Image shows that the lesion is cystic, measures 13 x 8 x 5 cm, and contains multiple mobile, hyperechoic nodules (arrows) suspended within the fluid.

soft tissue. Dense musculature was dissected off the mass and retracted away. Once the plane around the mass was established, dissection was completed from lateral to medial and inferior to superior. The right marginal branch of the facial nerve and submandibular gland were identified and preserved. Once the mass was circumferentially exposed, it was delivered out of the neck, freeing it from its depths on the left side. The tissue tethering the mass to the neck was cut and the mass was delivered intact. Final inspection, irrigation, hemostasis, and drain placement were completed prior to closure.

Pathology revealed a cyst wall lined by focally keratinizing stratified squamous epithelium with underlying areas focally showing skin adnexae. The globules identified on the imaging studies were composed of keratinaceous debris with acute inflammation.

The postoperative course was rather eventful as the patient had submental swelling and drain output that exceeded the criteria for safe discharge. Drains remained in place for 3 days. Because of increasing swelling, his neck incision was reopened on postoperative day 5. Edema of muscle and soft tissue was present. The remainder of his recovery was uneventful. At follow-up 4 months later, he reported no problems with oral intake, articulation, or breathing. He no longer needed to sleep in a semi-recumbent position. He did not have asthma, and no longer required albuterol.

DISCUSSION

A dermoid cyst is an uncommon head and neck tumor that mainly presents in patients ages 15 to 35, with an equal distribution between males and females.[1] Depending on the source, the ratio of males to females can be 3:1.[3] It is thought that most are seen in this age range because of increased activity of epithelial tissues. With accelerated activity of hair follicles, sweat glands, dermis/epidermis, etc, there is increased filling of the cystic lumen, which is why these previously inconspicuous lesions are noticed with maturation of the patient.[2] One study analyzed 2063 neck masses, of which 252 (12%) turned out to be congenital.[4] Of these, dermoid cysts comprised 11% and thyroglossal duct cyst/fistulas represented 53%. Another study similarly reported that 9% of pediatric neck masses were dermoid cysts.[5]

The origin of dermoid cysts is thought to be congenital in most cases, but they also can be acquired. The congenital theory suggests that entrapped midline ectodermal tissue during fusion of the first (mandibular) and second (hyoid) branchial arches during the third and fourth week of fetal development result in a cystic structure.[1] Alternatively, the cysts may arise from the tuberculum impar of His, which forms the body of the tongue and floor of the mouth with each mandibular arch.[3] These cysts also can develop from acquired factors such as trauma or surgical implantation that forces epithelial cells into deep tissues.[1]

A review of 195 case reports indicated the most common location to be intraoral (58.3%), followed by sublingual (52%), and submental (26%).[1] From those case reports, it was also apparent that the vast majority of cysts were dermoid (72.9%), epidermoid (22.2%), and teratoma (4.9%). The simplest is an epidermoid cyst which is lined by simple stratified squamous epithelium. A dermoid cyst has the features of an epidermoid cyst, plus skin appendages such as hair, sweat glands, and seba-

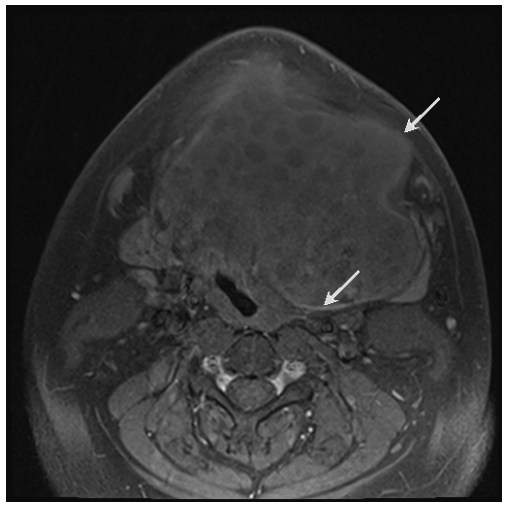
ceous glands. A teratoma is characterized by epidermoid and dermoid features, plus gastrointestinal or respiratory tissue and connective tissue derivatives.[1]

In the case described here, an axial CT scan with contrast (Figure 1) demonstrated a large hypodense floor of mouth mass centered to the left of the midline with numerous low-attenuation rounded foci within the lesion, which were thought to represent fat globules. The pathognomonic finding on CT scan and MRI is a "sack of marbles," the marbles indicating coalescence of keratinous material with lipid, which was seen on this image.[6] The exact location of the mass was difficult to determine on CT due to its large size, 10 x 12.6 x 6 cm, but was most likely located within the sublingual space as it crossed the midline in the anterior floor of mouth. There was mass effect on the oropharynx, hypopharynx, and supraglottic laryngeal airway, resulting in the patient's dyspnea, which was not alleviated by frequent albuterol use. A sagittal ultrasound image (Figure 2) showed a large ovoid cyst, 13 x 8 x 5 cm, with complex internal features. The lesion was filled with hypoechoic fluid with multiple well-defined hyperechoic nodules suspended within the fluid. The findings of the CT scan and ultrasound were consistent with a dermoid cyst. An axial-T1 weighted gadolinium-enhanced MRI with fat suppression, localized the mass to the sublingual space (Figure 3). The mylohyoid muscle sling was thinned and markedly peripherally displaced. The MRI demonstrated that the cyst was larger to the left of the midline, but crossed extensively into the right floor of mouth in the plane between the mylohyoid sling and the (superiorly displaced) geniohyoid muscles. The signal intensity within the fluid suggested that it was proteinaceous; however, the globules did not follow the signal intensity of mature fat. Figure 4 is an enlarged view of the cyst contents.

Similar cases have previously been reported in the literature with typical presentations such as a painless mass resulting in a double chin, dyspnea, dysphagia, or dysphonia. Recommended preoperative diagnosing techniques include ultrasound, CT scan, MRI, and fine needle aspiration biopsy.[3] MRI is usually necessary to determine the exact location within the surrounding soft tissues as the cyst wall may tightly adhere with its surroundings. Ultrasound is a reasonable initial imaging study as it is readily available, cost effective, and does not expose the patient to ionizing radiation. This is particularly helpful in the pediatric patient.[7]

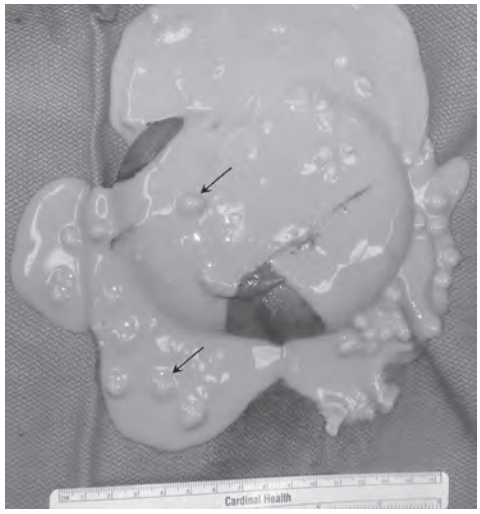
Most clinicians agree that treatment is complete surgical resection, and recurrence is rare if complete excision is achieved. To relieve symptoms of airway compromise prior to definitive treatment, aspiration may be attempted, although it may not be possible if the contents are too viscous. Prior to surgical intervention, if the mass is constricting the larynx and intubation is impossible, tracheotomy or decompression via aspiration may be necessary.[1] Complications can include infection, bleeding, anesthesia risk and incomplete resection, although some cases report no complications except moderate post-surgical edema, which also occurred in our patient.[3]

Figure 3. Axial T1 Weighted, Gadolinium-enhanced MRI with Fat Suppression



Shows no appreciable enhancement within the cyst, localization of the mass to the sublingual space. Minimal enhancement is noted at the periphery (arrows).

Figure 4. Cystic Contents Exposed after Resection of Mass



Globules are noted with arrows.

CONCLUSION

Dermoid cysts have characteristic clinical and radiographic fea-

tures that can aid in preoperative diagnosis. Although benign and often asymptomatic, dermoid cysts may cause other associated symptoms due to extrinsic compression of structures in the head and neck, including airway compromise. Currently, surgery is the mainstay of treatment and complete excision typically results in a very low recurrence rate.[2,3]

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IMPORTANT SAFETY INFORMATION

Contraindications

DALIRESP is contraindicated in patients with moderate to severe liver impairment (Child-Pugh B or C).

Warnings and Precautions

- DALIRESP is not a bronchodilator and should not be used for the relief of acute bronchospasm.
- Prescribers should advise patients, their caregivers, and families to be alert for the emergence or worsening of insomnia, anxiety, depression, suicidal thoughts or other mood changes, and if such changes occur, to contact their healthcare provider. Prescribers should carefully evaluate the risks and benefits of continuing treatment if such events occur. Before using DALIRESP in patients with a history of depression and/or suicidal thoughts or behavior, prescribers should carefully weigh the risks and benefits of treatment with DALIRESP.
  - Treatment with DALIRESP is associated with an increase in psychiatric adverse reactions. In controlled clinical trials 5.9% of patients treated with DALIRESP reported psychiatric adverse reactions vs 3.3% treated with placebo. The most common psychiatric adverse reactions were insomnia (2.4% vs 1.0%), anxiety (1.4% vs 0.9%), and depression (1.2% vs 0.9%). Three patients treated with DALIRESP experienced suicide-related adverse reactions (one completed suicide and two suicide attempts) compared to one patient (suicidal ideation) treated with placebo.
- Patients should have their weight monitored regularly. If unexplained or clinically significant weight loss occurs, weight loss should be evaluated and treatment discontinuation considered.
  - In addition to weight loss being reported as a common adverse reaction (7.5% of patients treated with DALIRESP vs 2.1% placebo), weight was prospectively assessed in two 1-year clinical trials. In these studies that compared DALIRESP to placebo, 20% vs 7% experienced moderate weight loss (5-10% of body weight) and 7% vs 2% experienced severe weight loss (>10% body weight). During the follow-up period after discontinuing DALIRESP, the majority of patients regained some of the weight they had lost.

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DALIRESP is indicated as a treatment to reduce the risk of COPD exacerbations in patients with severe COPD associated with chronic bronchitis and a history of exacerbations. DALIRESP is not a bronchodilator and is not indicated for the relief of acute bronchospasm.

- Use with strong cytochrome P450 enzyme inducers (eg, rifampicin, phenobarbital, carbamazepine, phenytoin) is not recommended, as they decrease the exposure and may reduce the therapeutic effectiveness of DALIRESP.

Adverse Reactions

In clinical trials the most common adverse reactions (≥2% and greater than placebo) were diarrhea (9.5% vs 2.7%), weight loss (7.5% vs 2.1%), nausea (4.7% vs 1.4%), headache (4.4% vs 2.1%), back pain (3.2% vs 2.2%), influenza (2.8% vs 2.7%), insomnia (2.4% vs 1.0%), dizziness (2.1% vs 1.1%), and decreased appetite (2.1% vs 0.4%).

Please see Brief Summary of full Prescribing Information on next page.

COPD=chronic obstructive pulmonary disease.

References: 1. DALIRESP (roflumilast) Prescribing Information. Forest Pharmaceuticals, Inc. St. Louis, MO. **2.** US Food and Drug Administration. FDA approves new drug to treat chronic obstructive pulmonary disease. March 1, 2011. http://www.fda.gov/NewsEvents/newsroom/PressAnnouncements/ucm244989.htm. Accessed October 19, 2011. **3.** Data on file. Forest Laboratories, Inc. **4.** Calverley PMA, Rabe KF, Goehring U-M, Kristiansen S, Fabbri LM, Martinez FJ; for the M2-124 and M2-125 study groups. Roflumilast in symptomatic chronic obstructive pulmonary disease: two randomised clinical trials. *Lancet.* 2009;374:685-694. **5.** US Food and Drug Administration. Atrovent approval history (NDA 019085, 1986). Drugs@FDA. http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm. Accessed October 19, 2011.

Daliresp® (roflumilast) tablets 500 mcg

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Initial U.S. Approval: 2011

INDICATIONS AND USAGE

DALIRESP® is indicated as a treatment to reduce the risk of COPD exacerbations in patients with severe COPD associated with chronic bronchitis and a history of exacerbations.

Limitations of Use

DALIRESP is not a bronchodilator and is not indicated for the relief of acute bronchospasm.

CONTRAINDICATIONS

The use of DALIRESP is contraindicated in the following conditions: Moderate to severe liver impairment (Child-Pugh B or C) [*see Clinical Pharmacology (12.3) and Use in Special Populations (8.6)*].

WARNINGS AND PRECAUTIONS

Treatment of Acute Bronchospasm

DALIRESP is not a bronchodilator and should not be used for the relief of acute bronchospasm.

Psychiatric Events including Suicidality

Treatment with DALIRESP is associated with an increase in psychiatric adverse reactions. In 8 controlled clinical trials 5.9% (263) of patients treated with DALIRESP 500 mcg daily reported psychiatric adverse reactions compared to 3.3% (137) treated with placebo. The most commonly reported psychiatric adverse reactions were insomnia, anxiety, and depression which were reported at higher rates in those treated with DALIRESP 500 mcg daily (2.4%, 1.4%, and 1.2% for DALIRESP versus 1.0%, 0.9%, and 0.9% for placebo, respectively) *[see Adverse Reactions (6.1)]*. Instances of suicidal ideation and behavior, including completed suicide, have been observed in clinical trials. Three patients experienced suicide-related adverse reactions (one completed suicide and two suicide attempts) while receiving DALIRESP compared to one patient (suicidal ideation) who received placebo.

Before using DALIRESP in patients with a history of depression and/or suicidal thoughts or behavior, prescribers should carefully weigh the risks and benefits of treatment with DALIRESP in such patients. Patients, their caregivers, and families should be advised of the need to be alert for the emergence or worsening of insomnia, anxiety, depression, suicidal thoughts or other mood changes, and if such changes occur to contact their healthcare provider. Prescribers should carefully evaluate the risks and benefits of continuing treatment with DALIRESP if such events occur.

Weight Decrease

Weight loss was a common adverse reaction in DALIRESP clinical trials and was reported in 7.5% (331) of patients treated with DALIRESP 500 mcg once daily compared to 2.1% (89) treated with placebo [*see Adverse Reactions (6.1)*]. In addition to being reported as adverse reactions, weight was prospectively assessed in two placebo-controlled clinical trials of one year duration. In these studies, 20% of patients receiving roflumilast experienced moderate weight loss (defined as between 5-10% of body weight) compared to 7% of patients who received placebo. In addition, 7% of patients who received roflumilast compared to 2% of patients receiving placebo experienced severe (>10% body weight) weight loss. During follow-up after treatment discontinuation, the majority of patients with weight loss regained some of the weight they had lost while receiving DALIRESP. Patients treated with DALIRESP should have their weight monitored regularly. If unexplained or clinically significant weight loss occurs, weight loss should be evaluated, and discontinuation of DALIRESP should be considered.

Drug Interactions

A major step in roflumilast metabolism is the N-oxidation of roflumilast to roflumilast N-oxide by CYP3A4 and CYP1A2. The administration of the cytochrome P450 enzyme inducer rifampicin resulted in a reduction in exposure, which may result in a decrease in the therapeutic effectiveness of DALIRESP. Therefore, the use of strong cytochrome P450 enzyme inducers (e.g. rifampicin, phenobarbital, carbamazepine, phenytoin) with DALIRESP is not recommended. [*see Drugs That Induce Cytochrome P450 (CYP) Enzymes (7.1) and Clinical Pharmacology (12.3)*].

ADVERSE REACTIONS

The following adverse reactions are described in greater detail in other sections:

- Psychiatric Events Including Suicidality *[see Warnings and Precautions (5.2)]*
- Weight Decrease *[see Warnings and Precautions (5.3)]*

Adverse Reactions in Clinical Studies

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 practice.

The safety data described below reflect exposure of 4438 patients to DALIRESP 500 mcg once daily in four 1-year placebo-controlled trials, two 6-month placebo-controlled trials, and two 6-month drug add-on trials *[see Clinical Studies (14.1)]*. In these trials, 3136 and 1232 COPD patients were exposed to DALIRESP 500 mcg once daily for 6 months and 1-year, respectively.

The population had a median age of 64 years (range 40-91), 73% were male, 92.9% were Caucasian, and had COPD with a mean pre-bronchodilator forced expiratory volume in one second (FEV_1) of 8.9 to 89.1% predicted. In these trials, 68.5% of the patients treated with DALIRESP reported an adverse reaction compared with 65.3% treated with placebo.

The proportion of patients who discontinued treatment due to adverse reaction was 14.8% for DALIRESP-treated patients and 9.9% for placebo-treated patients. The most common adverse reactions that led to discontinuation of DALIRESP were diarrhea (2.4%) and nausea (1.6%).

Serious adverse reactions, whether considered drug-related or not by the investigators, which occurred more frequently in DALIRESP-treated patients include diarrhea, atrial fibrillation, lung cancer, prostate cancer, acute pancreatitis, and acute renal failure.

Table 1 summarizes the adverse reactions reported by ≥ 2% of patients in the DALIRESP group in 8 controlled COPD clinical trials.

Table 1: Adverse Reactions Reported by ≥ 2% of Patients Treated with DALIRESP 500 mcg daily and Greater Than Placebo

	Treatment	
Adverse Reactions (Preferred Term)	**DALIRESP** (**N=**4438) n (%)	**Placebo** (**N=**4192) n (%)
Diarrhea	420 (9.5)	113 (2.7)
Weight decreased	331 (7.5)	89 (2.1)
Nausea	209 (4.7)	60 (1.4)
Headache	195 (4.4)	87 (2.1)
Back pain	142 (3.2)	92 (2.2)
Influenza	124 (2.8)	112 (2.7)
Insomnia	105 (2.4)	41 (1.0)
Dizziness	92 (2.1)	45 (1.1)
Decreased appetite	91 (2.1)	15 (0.4)

Adverse reactions that occurred in the DALIRESP group at a frequency of 1 to 2% where rates exceeded that in the placebo group include:

Gastrointestinal disorders - abdominal pain, dyspepsia, gastritis, vomiting

Infections and infestations - rhinitis, sinusitis, urinary tract infection,

Musculoskeletal and connective tissue disorders - muscle spasms

Nervous system disorders - tremor

Psychiatric disorders - anxiety, depression

DRUG INTERACTIONS

A major step in roflumilast metabolism is the N-oxidation of roflumilast to roflumilast N-oxide by CYP3A4 and CYP1A2 [*see Clinical Pharmacology (12.3)*].

Drugs That Induce Cytochrome P450 (CYP) Enzymes

Strong cytochrome P450 enzyme inducers decrease systemic exposure to roflumilast and may reduce the therapeutic effectiveness of DALIRESP. Therefore the use of strong cytochrome P450 inducers (e.g., rifampicin, phenobarbital, carbamazepine, and phenytoin) with DALIRESP is not recommended *[see Drug Interactions (5.4) and Clinical Pharmacology (12.3)]*.

Drugs That Inhibit Cytochrome P450 (CYP) Enzymes

The co-administration of DALIRESP (500 mcg) with CYP3A4 inhibitors or dual inhibitors that inhibit both CYP3A4 and CYP1A2 simultaneously (e.g., erythromycin, ketoconazole, fluvoxamine, enoxacin, cimetidine) may increase roflumilast systemic exposure and may result in increased adverse reactions. The risk of such concurrent use should be weighed carefully against benefit. *[see Clinical Pharmacology (12.3)]*.

Oral Contraceptives Containing Gestodene and Ethinyl Estradiol

The co-administration of DALIRESP (500 mcg) with oral contraceptives containing gestodene and ethinyl estradiol may increase roflumilast systemic exposure and may result in increased side effects. The risk of such concurrent use should be weighed carefully against benefit *[see Clinical Pharmacology (12.3)]*.

USE IN SPECIFIC POPULATIONS

Pregnancy

Teratogenic effects: Pregnancy Category C: There are no adequate and well controlled studies of DALIRESP in pregnant women. DALIRESP was not teratogenic in mice, rats, or rabbits. DALIRESP should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

DALIRESP induced stillbirth and decreased pup viability in mice at doses corresponding to approximately 16 and 49 times, respectively, the maximum recommended human dose (MRHD) (on a mg/m^2 basis at maternal doses > 2 mg/kg/day and 6 mg/kg/day, respectively). DALIRESP induced post-implantation loss in rats at doses greater than or equal to approximately 10 times the MRHD (on a mg/m^2 basis at maternal doses ≥ 0.6 mg/kg/day). No treatment-related effects on embryo-fetal development were observed in mice, rats, and rabbits at approximately 12, 3, and 26 times the MRHD, respectively (on a mg/m^2 basis at maternal doses of 1.5, 0.2, and 0.8 mg/kg/day, respectively).

Nonteratogenic effects: DALIRESP has been shown to adversely affect pup post-natal development when dams were treated with the drug during pregnancy and lactation periods in mice. These studies found that DALIRESP decreased pup rearing frequencies at approximately 49 times the MRHD (on a mg/mg^2 basis at a maternal dose of 6 mg/kg/day) during pregnancy and lactation. DALIRESP also decreased survival and forelimb grip reflex and delayed pinna detachment in mouse pups at approximately 97 times the MRHD (on a mg/m^2 basis at a maternal dose of 12 mg/kg/day) during pregnancy and lactation.

Labor and Delivery

DALIRESP should not be used during labor and delivery. There are no human studies that have investigated effects of DALIRESP on preterm labor or labor at term; however, animal studies showed that DALIRESP disrupted the labor and delivery process in mice. DALIRESP induced delivery retardation in pregnant mice at doses greater than or equal to approximately 16 times the MRHD (on a mg/m^2 basis at a maternal dose of > 2 mg/kg/day).

Nursing Mothers

Roflumilast and/or its metabolites are excreted into the milk of lactating rats. Excretion of roflumilast and/or its metabolites into human milk is probable. There are no human studies that have investigated effects of DALIRESP on breast-fed infants. DALIRESP should not be used by women who are nursing.

Pediatric Use

COPD does not normally occur in children. The safety and effectiveness of DALIRESP in pediatric patients have not been established.

Geriatric Use

Of the 4438 COPD subjects exposed to DALIRESP for up to 12 months in 8 controlled clinical trials, 2022 were > 65 years of age and 471 were > 75 years of age. No overall differences in safety or effectiveness were observed between these subjects and younger subjects and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out. Based on available data for roflumilast, no adjustment of dosage in geriatric patients is warranted *[see Clinical Pharmacology (12.3)]*.

Hepatic Impairment

Roflumilast 250 mcg once daily for 14 days was studied in subjects with mild-to-moderate hepatic impairment classified as Child-Pugh A and B (8 subjects in each group). The AUCs of roflumilast and roflumilast N-oxide were increased by 51% and 24%, respectively in Child-Pugh A subjects and by 92% and 41%, respectively in Child-Pugh B subjects, as compared to age-, weight- and gender-matched healthy subjects. The C_{max} of roflumilast and roflumilast N-oxide were increased by 3% and 26%, respectively in Child-Pugh A subjects and by 26% and 40%, respectively in Child-Pugh B subjects, as compared to healthy subjects. DALIRESP 500 mcg has not been studied in hepatically impaired patients. Clinicians should consider the risk-benefit of administering DALIRESP to patients who have mild liver impairment (Child-Pugh A). DALIRESP is not recommended for use in patients with moderate or severe liver impairment (Child-Pugh B or C) *[see Contraindications (4) and Clinical Pharmacology (12.3)]*.

Renal Impairment

In twelve subjects with severe renal impairment administered a single dose of 500 mcg roflumilast, the AUCs of roflumilast and roflumilast N-oxide were decreased by 21% and 7%, respectively and C_{max} were reduced by 16% and 12%, respectively. No dosage adjustment is necessary for patients with renal impairment *[see Clinical Pharmacology (12.3)]*.

OVERDOSAGE

Human Experience

No case of overdose has been reported in clinical studies with DALIRESP. During the Phase I studies of DALIRESP, the following symptoms were observed at an increased rate after a single oral dose of 2500 mcg and a single dose of 5000 mcg: headache, gastrointestinal disorders, dizziness, palpitations, lightheadedness, clamminess and arterial hypotension.

Management of Overdose

In case of overdose, patients should seek immediate medical help. Appropriate supportive medical care should be provided. Since roflumilast is highly protein bound, hemodialysis is not likely to be an efficient method of drug removal. It is not known whether roflumilast is dialyzable by peritoneal dialysis.

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