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Practices Eye Playing Field for Accountable Care Organizations

BY MARY ELLEN SCHNEIDER

The medical model of "the more you do, the more you make" is out, according to Dr. William Chin, and so is the idea that the physician needs to do everything personally. If a service can be provided more efficiently by a nurse or social worker, that may be the way to go under the next big thing in health care – the accountable care organization.

Dr. Colleen Kraft, a pediatrician for Carilion Clinic in Roanoke, Va., has participated in an integrated health system since 2007. The Epic care system links the Carilion Clinic's pediatric specialists with a hospital, therapists, and care coordinators.

While participating in an ACO-modeled system, Dr. Kraft said she has noticed a significant improvement in quality of care.

"Our ability to communicate with each other about common patients is extensive and streamlines patient care, especially for children with special health care needs," Dr. Kraft said. "Parents from all socioeconomic groups are better informed about following asthma action plans, healthy eating, and the importance of prevention. This makes compliance with medications and anticipatory guidance much easier."

Dr. Chin, executive medical director for HealthCare Partners, an independent physician association

See **ACOs** page 6



COURTESY DR. JUSTIN WILKIN

"Physicians who choose to become part of an ACO have to want to work more collaboratively. Technology alone doesn't provide better patient care; physicians who ... communicate with each other as well as the families improve patient care," according to pediatrician Colleen Kraft.

Teen Vaccine Recs Had Little Impact on Preventive Visits

BY DOUG BRUNK

FROM THE ANNUAL MEETING OF THE PEDIATRIC ACADEMIC SOCIETIES

DENVER – Although new adolescent vaccine recommendations disseminated between 2005 and early 2007 for meningococcal, tetanus-diphtheria-pertussis, and human papillomavirus vaccines were anticipated to increase the proportion of adolescents with an annual preventive visit, no such impact has occurred, results from a large national survey demonstrated.

However, the rates of vaccination-only visits did increase, researchers led by Christina S. Albertin, reported during a poster session at the meeting.

The findings suggest that patterns of primary care delivery did not appear to change as a result of the new recommendations for this population.

"Additional methods, such as reminder and recall interventions for annual well care



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The percentage of teens who reported a visit with a vaccination increased from 8% to 11%, according to the national survey findings.

visits, may be needed to bring additional adolescents in for recommended preventive care," the researchers wrote.

Ms. Albertin and her associates from

"The data seem to show ... pediatricians focused on fitting vaccinations into existing visits."

the division of general pediatrics at the University of Rochester (N.Y.) analyzed Medical Expenditure Panel Survey data for any medical visits, well-care visits, and vaccine-only visits made by adolescents, aged 11-21 years, during two time periods: 2004-2005 (before the vaccine recommendations) and 2007-2008 (after the recommendations).

They compared visit rates overall and by age group (11-13 years, 14-17 years, and 18-21 years), sex, race/ethnic group, insurance status, and household income. They used chi square

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Vaccine-Only Visits Jumped

Vaccine Recs from page 1

analysis to compare rates between the two time periods, controlling for the complex sample design.

Ms. Albertin presented findings from 2,693 adolescents studied in 2004-2005 and 1,988 adolescents studied in 2007-2008.

Between the two time periods, no significant changes in the percentage of adolescents with any medical visit overall were observed (73% vs. 72%,

respectively), nor were any changes seen among any of the subgroups following the recommendations, the researchers reported.

In addition, the percentage of well-child visits did not change significantly overall (they remained at 41% for both time periods), or among any of the subgroups.

The average number of visits with a vaccination overall increased signifi-

cantly from 0.08% in 2004-2005 to 0.14% in 2007-2008.

Likewise, the percentage of adolescents who reported a visit with a vaccination increased from 8% to 11%.

The subgroups with significant increases included adolescents aged 14-17 years, females, whites, those who were privately insured, and those from

families with the highest income level.

“The data seem to show that in the initial 21 months or so following the recommendations, pediatricians focused on fitting vaccinations into existing visits, not expanding the number of [patient] visits,” Ms. Albertin said

in an interview.

“I’m surprised by the results given



‘I’m surprised by the results given that there are Tdap vaccine requirements in many states.’

MS. ALBERTIN

KAPVAY (clonidine hydrochloride) extended-release tablets, oral, Rx only INDICATIONS AND USAGE

KAPVAY™ is a centrally acting alpha₂-adrenergic agonist indicated for the treatment of attention deficit hyperactivity disorder (ADHD) as monotherapy or as adjunctive therapy to stimulant medications. (1)

The efficacy of KAPVAY is based on the results of two clinical trials in children and adolescents. (14) Maintenance efficacy has not been systematically evaluated, and patients who are continued on longer-term treatment require periodic reassessment. (1)

This extended-release formulation of clonidine hydrochloride is also approved for the treatment of hypertension under the trade name JENLOGA. (1)

CONTRAINDICATIONS

KAPVAY should not be used in patients with known hypersensitivity to clonidine.

WARNINGS AND PRECAUTIONS

Hypotension/Bradycardia

Treatment with KAPVAY can cause dose related decreases in blood pressure and heart rate. In patients that completed 5 weeks of treatment in a controlled, fixed-dose monotherapy study in pediatric patients, during the treatment period the maximum placebo-subtracted mean change in systolic blood pressure was -4.0 mmHg on KAPVAY 0.2 mg/day and -8.8 mmHg on KAPVAY 0.4 mg/day. The maximum placebo-subtracted mean change in diastolic blood pressure was -4.0 mmHg on KAPVAY 0.2 mg/day and -7.3 mmHg on KAPVAY 0.4 mg/day. The maximum placebo-subtracted mean change in heart rate was -4.0 beats per minute on KAPVAY 0.2 mg/day and -7.7 beats per minute on KAPVAY 0.4 mg/day.

During the taper period of the fixed-dose monotherapy study the maximum placebo-subtracted mean change in systolic blood pressure was +3.4 mmHg on KAPVAY 0.2 mg/day and -5.6 mmHg on KAPVAY 0.4 mg/day. The maximum placebo-subtracted mean change in diastolic blood pressure was +3.3 mmHg on KAPVAY 0.2 mg/day and -5.4 mmHg on KAPVAY 0.4 mg/day. The maximum placebo-subtracted mean change in heart rate was -0.6 beats per minute on KAPVAY 0.2 mg/day and -3.0 beats per minute on KAPVAY 0.4 mg/day.

Measure heart rate and blood pressure prior to initiation of therapy, following dose increases, and periodically while on therapy. Use KAPVAY with caution in patients with a history of hypotension, heart block, bradycardia, or cardiovascular disease, because it can decrease blood pressure and heart rate. Use caution in treating patients who have a history of syncope or may have a condition that predisposes them to syncope, such as hypotension, orthostatic hypotension, bradycardia, or dehydration. Use KAPVAY with caution in patients treated concomitantly with antihypertensives or other drugs that can reduce blood pressure or heart rate or increase the risk of syncope. Advise patients to avoid becoming dehydrated or overheated.

Sedation and Somnolence

Somnolence and sedation were commonly reported adverse reactions in clinical studies. In patients that completed 5 weeks of therapy in a controlled fixed dose pediatric monotherapy study, 31% of patients treated with 0.4 mg/day and 38% treated with 0.2 mg/day vs 7% of placebo treated patients reported somnolence as an adverse event. In patients that completed 5 weeks of therapy in a controlled flexible dose pediatric adjunctive to stimulants study, 19% of patients treated with KAPVAY+stimulant vs 8% treated with placebo+stimulant reported somnolence. Before using KAPVAY with other centrally active depressants (such as phenothiazines, barbiturates, or benzodiazepines), consider the potential for additive sedative effects. Caution patients against operating heavy equipment or driving until they know how they respond to treatment with KAPVAY. Advise patients to avoid use with alcohol.

Abrupt Discontinuation

No studies evaluating abrupt discontinuation of KAPVAY in children with ADHD have been conducted. In children and adolescents with ADHD, physicians should gradually reduce the dose of KAPVAY in decrements of no more than 0.1 mg every 3 to 7 days. Patients should be instructed not to discontinue KAPVAY therapy without consulting their physician due to the potential risk of withdrawal effects. In adults with hypertension, sudden cessation of clonidine hydrochloride extended-release formulation treatment in the 0.2 to 0.6 mg/day range resulted in reports of headache, tachycardia, nausea, flushing, warm feeling, brief lightheadedness, tightness in chest, and anxiety.

In adults with hypertension, sudden cessation of treatment with immediate-release clonidine has, in some cases, resulted in symptoms such as nervousness, agitation, headache, and tremor accompanied or followed by a rapid rise in blood pressure and elevated catecholamine concentrations in the plasma.

Allergic Reactions

In patients who have developed localized contact sensitization to clonidine transdermal system, continuation of clonidine transdermal system or substitution of oral clonidine hydrochloride therapy may be associated with the development of a generalized skin rash.

In patients who develop an allergic reaction from clonidine transdermal system, substitution of oral clonidine hydrochloride may also elicit an allergic reaction (including generalized rash, urticaria, or angioedema).

Patients with Vascular Disease, Cardiac Conduction Disease, or Renal Failure

Clonidine hydrochloride should be used with caution in patients with severe coronary insufficiency, conduction disturbances, recent myocardial infarction, cerebrovascular disease or chronic renal failure.

Other Clonidine-Containing Products

Clonidine, the active ingredient in KAPVAY, is also approved as an antihypertensive. Do not use KAPVAY in patients concomitantly taking other clonidine-containing products, (e.g. Catapres®).

ADVERSE REACTIONS

Clinical Trial Experience

Two KAPVAY ADHD clinical studies evaluated 256 patients who received active therapy, in one of the two placebo-controlled studies (Studies 1 and 2) with primary efficacy end-points at 5-weeks.

Study 1: Fixed-dose KAPVAY Monotherapy

Study 1 was a multi-center, randomized, double-blind, placebo-controlled study with primary efficacy endpoint at 5 weeks, of two fixed doses (0.2 mg/day or 0.4 mg/day) of KAPVAY in children and adolescents (6 to 17 years of age) who met DSM-IV criteria for ADHD hyperactive or combined inattentive/hyperactive subtypes.

Commonly observed adverse reactions (incidence of ≥ 2% in either active treatment group and greater than the rate on placebo) during the treatment period are listed in Table 2.

Table 2 Common Adverse Reactions in the Fixed-Dose Monotherapy Trial- Treatment period (Study 1)

Preferred Term	Percentage of Patients Reporting Event		
	KAPVAY 0.4 mg/day N=78	KAPVAY 0.2 mg/day N=76	Placebo (N=76)
Somnolence ¹	31%	38%	5%
Headache	19%	29%	18%
Upper Abdominal Pain	13%	20%	17%
Fatigue ²	13%	16%	1%
Upper Respiratory Tract Infection	6%	11%	4%
Irritability	6%	9%	3%
Throat Pain	6%	8%	3%
Nausea	8%	5%	4%
Nightmare	9%	3%	0
Dizziness	3%	7%	5%
Insomnia	6%	4%	1%
Emotional Disorder	5%	4%	1%
Constipation	6%	1%	0
Dry Mouth	5%	0	1%
Nasal Congestion	5%	3%	1%
Body Temperature Increased	1%	5%	3%
Gastrointestinal Viral	0%	7%	4%
Diarrhea	1%	4%	3%
Ear Pain	0	5%	1%
Nasopharyngitis	3%	3%	1%
Abnormal Sleep-Related Event	1%	3%	0
Aggression	1%	3%	1%
Asthma	1%	3%	1%
Bradycardia	4%	0	0
Enuresis	4%	0	0
Influenza like Illness	3%	1%	1%
Tearfulness	3%	1%	0
Thirst	3%	1%	0
Tremor	3%	1%	0
Epistaxis	0	3%	0
Lower Respiratory Tract Infection	0	3%	1%
Pollakiuria	0	3%	0
Sleep Terror	0	3%	0

1. Somnolence includes the terms “somnolence” and “sedation”.

2. Fatigue includes the terms “fatigue” and “lethargy”.

Commonly observed adverse reactions (incidence of ≥ 2% in either active treatment group and greater than the rate on placebo) during the taper period are listed in Table 3.

Table 3 Common Adverse Reactions in the Fixed-Dose Monotherapy Trial- Taper period* (Study 1)

Preferred Term	Percentage of Patients Reporting Event		
	KAPVAY 0.4 mg/day N=78	KAPVAY 0.2 mg/day N=76	Placebo (N=76)
Abdominal Pain Upper	6%	0	3%
Headache	2%	5%	3%
Gastrointestinal Viral	5%	0	0
Somnolence	3%	2%	0
Heart Rate Increased	3%	0	0
Otitis Media Acute	0	3%	0

*Taper Period: 0.2 mg dose, week 8; 0.4 mg dose, weeks 6-8; Placebo dose, weeks 6-8

Study 2: Flexible-dose KAPVAY as Adjunctive Therapy to Psychostimulants

Study 2 was a multi-center, randomized, double-blind, placebo-controlled study, with primary efficacy endpoint at 5 weeks, of a flexible dose of KAPVAY as adjunctive therapy to a psychostimulant in children and adolescents (6 to 17 years) who met DSM-IV criteria for ADHD hyperactive or combined inattentive/hyperactive subtypes. KAPVAY was initiated at 0.1 mg/day and titrated up to 0.4 mg/day over a 3-week period. Most KAPVAY treated patients (75.5%) were escalated to the maximum dose of 0.4 mg/day.

Commonly observed adverse reactions (incidence of ≥ 2% in the treatment group and greater than the rate on placebo) during the treatment period are listed in Table 4.

that there are Tdap vaccine requirements in many states,” the investigator commented.

She went on to explain that through 2008, only 16 states had school requirements for the Tdap vaccine.

“Now, projected through 2011 it looks like that’s going to more than double,” she said.

“As a result, I think that we will slowly see an increase in both immunization-only and preventive visits,” Ms. Albertin noted.

Ms. Albertin said she had no relevant financial conflicts to disclose. ■

Long-Acting Beta-Agonists Plus Inhaled Steroids Combo Appears Safe for Kids

BY DOUG BRUNK

FROM THE ANNUAL MEETING OF THE AMERICAN ACADEMY OF ALLERGY, ASTHMA, AND IMMUNOLOGY

SAN FRANCISCO – Adding long-acting beta-agonists to a regimen consisting of inhaled corticosteroids did not increase the rate of admissions to the

pediatric intensive care unit, results from a year-long study showed.

“This supports the guidelines from the National Asthma Education and Prevention Program,” Dr. Tammy S. Jacobs said in an interview during a poster session at the meeting. “When you fail to have adequate control with inhaled corticosteroids alone, long-

acting beta-agonists can be a very good medication to add.”

While results from the U.K. Serevent Nationwide Surveillance study and the U.S. Salmeterol Multicenter Asthma Research trial suggested that long-acting beta-agonists (LABAs) increase the risk of asthma-related mortality, neither trial was adequately powered to study the safety of LABAs when used in conjunction with inhaled corticosteroids (ICS), said Dr. Jacobs, a resident at Children’s Hospital of Pittsburgh.

In an effort to evaluate the impact of LABA use in conjunction with inhaled corticosteroids on the risk of near-fatal asthma in children, she and her associates reviewed the medical charts of 363 children aged 4-18 years who were admitted for asthma exacerbations to Children’s Hospital of Pittsburgh in 2005.

Cases and controls were determined by pediatric intensive care unit (PICU) and floor admissions, respectively. Exposure

Table 4 Common Adverse Reactions in the Flexible-Dose Adjunctive to Stimulant Therapy Trial- Treatment Period (Study 2)

Preferred Term	Percentage of Patients Reporting Event	
	KAPVAY+STM (N=102)	PBO+STM (N=96)
Somnolence ¹	19%	8%
Fatigue ²	16%	4%
Abdominal Pain Upper	12%	7%
Nasal Congestion	6%	5%
Throat Pain	6%	3%
Decreased Appetite	5%	4%
Body Temperature Increased	4%	2%
Dizziness	4%	2%
Insomnia	4%	2%
Epistaxis	3%	0
Rhinorrhea	3%	0
Abdominal Pain	2%	1%
Anxiety	2%	0
Pain in Extremity	2%	0

1. Somnolence includes the terms: “somnolence” and “sedation”.

2. Fatigue includes the terms “fatigue” and “lethargy”.

Commonly observed adverse reactions (incidence of $\geq 2\%$ in the treatment group and greater than the rate on placebo) during the taper period are listed in Table 5.

Table 5 Common Adverse Reactions in the Flexible-Dose Adjunctive to Stimulant Therapy Trial- Taper Period* (Study 2)

Preferred Term	Percentage of Patients Reporting Event	
	KAPVAY+STM (N=102)	PBO+STM (N=96)
Nasal Congestion	4%	2%
Headache	3%	1%
Irritability	3%	2%
Throat Pain	3%	1%
Gastroenteritis Viral	2%	0
Rash	2%	0

*Taper Period: weeks 6-8.

Most common adverse reactions, defined as events that were reported in at least 5% of drug-treated patients and at least twice the rate as in placebo patients, during the treatment period were somnolence, fatigue, upper respiratory tract infection, irritability, throat pain, insomnia, nightmares, emotional disorder, constipation, nasal congestion, increased body temperature, dry mouth, and ear pain. The most common adverse reactions that were reported during the taper phase were upper abdominal pain and gastrointestinal virus.

Adverse Reactions Leading to Discontinuation

Thirteen percent (13%) of patients receiving KAPVAY discontinued from the pediatric monotherapy study due to adverse events, compared to 1% in the placebo group. The most common adverse reactions leading to discontinuation of KAPVAY monotherapy treated patients were from somnolence/sedation (5%) and fatigue (4%). Less common adverse reactions leading to discontinuation (occurring in approximately 1% of patients) included: formication, vomiting, prolonged QT, increased heart rate, and rash. In the pediatric adjunctive treatment to stimulants study, one patient discontinued from KAPVAY + stimulant group because of bradypnea.

Effects on Laboratory Tests, Vital Signs, and Electrocardiograms

KAPVAY treatment was not associated with any clinically important effects on any laboratory parameters in either of the placebo-controlled studies.

Mean decreases in blood pressure and heart rate were seen [see Warnings and Precautions (5.1)].

There were no changes on ECGs to suggest a drug-related effect.

DRUG INTERACTIONS

No drug interaction studies have been conducted with KAPVAY in children. The following have been reported with other oral immediate release formulations of clonidine.

Interactions with CNS-depressant Drugs

Clonidine may potentiate the CNS-depressive effects of alcohol, barbiturates or other sedating drugs.

Interactions with Tricyclic Antidepressants

If a patient is receiving clonidine hydrochloride and also taking tricyclic antidepressants the hypotensive effects of clonidine may be reduced.

Interactions with Drugs Known to Affect Sinus Node Function or AV Nodal Conduction

Due to a potential for additive effects such as bradycardia and AV block, caution is warranted in patients receiving clonidine concomitantly with agents known to affect sinus node function or AV nodal conduction (e.g., digitalis, calcium channel blockers and beta-blockers).

Use with other products containing clonidine

Do not use KAPVAY concomitantly with other products containing clonidine (e.g., Catapres®).

Antihypertensive Drugs

Use caution when KAPVAY is administered concomitantly with antihypertensive drugs, due to the potential for additive pharmacodynamic effects (e.g., hypotension, syncope) [see Warnings and Precautions (5.2)].

USE IN SPECIFIC POPULATIONS

Pregnancy

Pregnancy Category C: Oral administration of clonidine hydrochloride to pregnant rabbits during the period of embryo/fetal organogenesis at doses of up to 80 mcg/kg/day (approximately 3 times the oral maximum recommended daily dose [MRHD] of 0.4 mg/day on a mg/m² basis) produced no evidence of teratogenic or embryotoxic potential. In pregnant rats, however, doses as low as 15 mcg/kg/day (1/3 the MRHD on a mg/m² basis) were associated with increased resorptions in a study in which dams were treated continuously from 2 months prior to mating and throughout gestation. Increased resorptions were not associated with treatment at the same or at higher dose levels (up to 3 times the MRHD) when treatment of the dams was restricted to gestation days 6-15. Increases in resorptions were observed in both rats and mice at 500 mcg/kg/day (10 and 5 times the MRHD in rats and mice, respectively) or higher when the animals were treated on gestation days 1-14; 500 mcg/kg/day was the lowest dose employed in this study. No adequate and well-controlled studies have been conducted in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should not be used during pregnancy unless clearly needed.

Nursing Mothers

Since clonidine hydrochloride is excreted in human milk, caution should be exercised when KAPVAY is administered to a nursing woman.

Pediatric Use

A study was conducted in which young rats were treated orally with clonidine hydrochloride from day 21 of age to adulthood at doses of up to 300 mcg/kg/day, which is approximately 3 times the maximum recommended human dose (MRHD) of 0.4 mg/day on a mg/m² basis. A slight delay in onset of preputial separation was seen in males treated with the highest dose (with a no-effect dose of 100 mcg/kg/day, which is approximately equal to the MRHD), but there were no drug effects on fertility or on other measures of sexual or neurobehavioral development.

KAPVAY has not been studied in children with ADHD less than 6 years old.

Patients with Renal Impairment

The impact of renal impairment on the pharmacokinetics of clonidine in children has not been assessed. The initial dosage of KAPVAY should be based on degree of impairment. Monitor patients carefully for hypotension and bradycardia, and titrate to higher doses cautiously. Since only a minimal amount of clonidine is removed during routine hemodialysis, there is no need to give supplemental KAPVAY following dialysis.

Adult Use in ADHD

KAPVAY has not been studied in adult patients with ADHD.

DRUG ABUSE AND DEPENDENCE

Controlled Substance

KAPVAY is not a controlled substance and has no known potential for abuse or dependence.

OVERDOSAGE

Symptoms

Clonidine overdose: hypertension may develop early and may be followed by hypotension, bradycardia, respiratory depression, hypothermia, drowsiness, decreased or absent reflexes, weakness, irritability and miosis. The frequency of CNS depression may be higher in children than adults. Large overdoses may result in reversible cardiac conduction defects or dysrhythmias, apnea, coma and seizures. Signs and symptoms of overdose generally occur within 30 minutes to two hours after exposure.

Treatment

Consult with a Certified Poison Control Center for up-to-date guidance and advice.

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When you fail to have adequate control with inhaled steroids alone, LABAs can be a very good medication to add.

DR. JACOBS

was defined by LABA use in combination with ICS vs. ICS alone.

After exclusion of patients with non-asthma-indicated admissions, complicated pneumonias, debilitating comorbid disorders, and multiple admissions, 85 PICU admissions and 96 floor admissions were included in the final analysis. The mean age of patients was 9 years, 54% were male, and 51% were white.

Dr. Jacobs reported that the use of LABA in conjunction with ICS did not significantly increase the risk of PICU admissions (odds ratio, 1.07), compared with ICS alone. After the researchers adjusted for demographics, asthma severity, history of PICU admissions, and concurrent infection, they found that the use of LABA in conjunction with ICS may have decreased the risk of PICU admission, compared with ICS alone (OR, 0.85). No deaths occurred during the study period.

“Although this [study] does not directly evaluate increase in mortality (as in previous trials), risk of ICU admission may actually be a more clinically relevant outcome to evaluate LABA safety,” the researchers concluded in their poster. “Findings are generalizable to a population of children with relatively higher-risk asthma/poorer asthma control since all subjects were admitted, and no outpatient subjects were included.”

Dr. Jacobs acknowledged certain limitations of the study, including the fact that it was a retrospective chart review with the potential for missing data.

She said that she had no relevant financial conflicts to disclose. ■