

and education, initial disbursement of convertible seats beginning at birth, reinvestment for booster seats at age 4 years, and a 5% annual replacement rate. It was assumed that the program would increase appropriate CRS use for low-income children by 23% for 0- to 3-year-olds and by 35% for children aged 4-7 years. Under these assumptions, implementation of the program would prevent 63 injuries and 2 deaths per 100,000 children. Over the course of 8 years, it would prevent 400 injuries and 17 deaths, resulting in 564 life-years saved, Mr. Goldstein reported.

Without the proposed program, annual crash-related outcome costs were estimat-

ed at \$4.2 million in medical costs, \$350,000 in parental work loss, and \$8.3 million in future victim productivity per 100,000 children. Implementation of CRS disbursement and education would reduce annual medical costs by about \$1 million, parental work loss costs by \$100,000, and future productivity costs by \$2.7 million.

Over the 8-year projection, the program would save nearly \$7 million in medical costs. At the same time, program administration costs were estimated at \$6 million for the first year and \$10 million cumulatively.

From the societal perspective (including all medical and nonmedical costs), the program would be cost-saving. From Medic-

aid's perspective—including only medical costs—the program would need to spend \$17,000 to save one life-year. "This value is well below the threshold of \$50,000-\$80,000 that most are willing to pay for an added year of life," Mr. Goldstein noted.

Indeed, a CRS disbursement/education program falls into the lower-cost end of the list of vaccines currently funded under VFC, well below the cost per life-year saved for varicella vaccine (\$19,700 or \$65,000, depending on the vaccine price estimate), hepatitis B vaccine (\$26,000), and pneumococcal vaccine (\$147,000). Only *Haemophilus influenzae* type b (cost saving to insurer) and measles-mumps-

rubella (\$6,000) were more cost effective.

Several states have programs that supply child safety seats among low-income populations using a variety of funding mechanisms, but most do not involve Medicaid.

A legislative proposal in Illinois would increase seatbelt violation fines from the current \$25 to \$200 to provide child safety seats on a sliding-scale fee to low-income families. It also would allow Medicaid to reimburse the time of certified child passenger safety technicians at eligible locations to educate families who receive sliding-fee child safety seats, said Jahari Piersol of the Illinois Department of Transportation. ■

ADVERSE EVENTS

Clinical Trials - OMNICEF Capsules (Adult and Adolescent Patients):

In clinical trials, 5093 adult and adolescent patients (3841 US and 1252 non-US) were treated with the recommended dose of cefdinir capsules (600 mg/day). Most adverse events were mild and self-limiting. No deaths or permanent disabilities were attributed to cefdinir. One hundred forty-seven of 5093 (3%) patients discontinued medication due to adverse events thought by the investigators to be possibly, probably, or definitely associated with cefdinir therapy. The discontinuations were primarily for gastrointestinal disturbances, usually diarrhea or nausea. Nineteen of 5093 (0.4%) patients were discontinued due to rash thought related to cefdinir administration.

In the US, the following adverse events were thought by investigators to be possibly, probably, or definitely related to cefdinir capsules in multiple-dose clinical trials (N = 3841 cefdinir-treated patients):

ADVERSE EVENTS ASSOCIATED WITH CEFDINIR CAPSULES US TRIALS IN ADULT AND ADOLESCENT PATIENTS (N=3841)^a

Incidence × 1%	Diarrhea	15%
	Vaginal moniliasis	4% of women
	Nausea	3%
	Headache	2%
	Abdominal pain	1%
	Vaginitis	1% of women
Incidence <1% but >0.1%	Rash	0.9%
	Dyspepsia	0.7%
	Flatulence	0.7%
	Vomiting	0.7%
	Abnormal stools	0.3%
	Anorexia	0.3%
	Constipation	0.3%
	Dizziness	0.3%
	Dry mouth	0.3%
	Asthenia	0.2%
	Insomnia	0.2%
	Leukorrhea	0.2% of women
	Moniliasis	0.2%
	Pruritus	0.2%
	Somnolence	0.2%

^a 1733 males, 2108 females

The following laboratory value changes of possible clinical significance, irrespective of relationship to therapy with cefdinir, were seen during clinical trials conducted in the US:

LABORATORY VALUE CHANGES OBSERVED WITH CEFDINIR CAPSULES US TRIALS IN ADULT AND ADOLESCENT PATIENTS (N=3841)

Incidence × 1%	δ Urine leukocytes	2%
	δ Urine protein	2%
	δ Gamma-glutamyltransferase ^a	1%
	α Lymphocytes, δ Lymphocytes	1%, 0.2%
	δ Microhematuria	1%
Incidence <1% but >0.1%	δ Glucose ^a	0.9%
	δ Urine glucose	0.9%
	δ White blood cells, α White blood cells	0.9%, 0.7%
	δ Alanine aminotransferase (ALT)	0.7%
	δ Eosinophils	0.7%
	δ Urine specific gravity, α Urine specific gravity ^a	0.6%, 0.2%
	α Bicarbonate ^a	0.6%
	δ Phosphorus, α Phosphorus ^a	0.6%, 0.3%
	δ Aspartate aminotransferase (AST)	0.4%
	δ Alkaline phosphatase	0.3%
	δ Blood urea nitrogen (BUN)	0.3%
	α Hemoglobin	0.3%
	δ Polymorphonuclear neutrophils (PMNs), α PMNs	0.3%, 0.2%
	δ Bilirubin	0.2%
	δ Lactate dehydrogenase ^a	0.2%
	δ Platelets	0.2%
	δ Potassium ^a	0.2%
	δ Urine pH ^a	0.2%

^a N<3841 for these parameters

Clinical Trials - OMNICEF for Oral Suspension (Pediatric Patients):

In clinical trials, 2289 pediatric patients (1783 US and 506 non-US) were treated with the recommended dose of cefdinir suspension (14 mg/kg/day). Most adverse events were mild and self-limiting. No deaths or permanent disabilities were attributed to cefdinir. Forty of 2289 (2%) patients discontinued medication due to adverse events considered by the investigators to be possibly, probably, or definitely associated with cefdinir therapy. Discontinuations were primarily for gastrointestinal disturbances, usually diarrhea. Five of 2289 (0.2%) patients were discontinued due to rash thought related to cefdinir administration.

In the US, the following adverse events were thought by investigators to be possibly, probably, or definitely related to cefdinir suspension in multiple-dose clinical trials (N=1783 cefdinir-treated patients):

ADVERSE EVENTS ASSOCIATED WITH CEFDINIR SUSPENSION US TRIALS IN PEDIATRIC PATIENTS (N=1783)^a

Incidence × 1%	Diarrhea	8%
	Rash	3%
	Vomiting	1%
Incidence <1% but >0.1%	Cutaneous moniliasis	0.9%
	Abdominal pain	0.8%
	Leukopenia ^b	0.3%
	Vaginal moniliasis	0.3% of girls
	Vaginitis	0.3% of girls
	Abnormal stools	0.2%
	Dyspepsia	0.2%
	Hyperkinesia	0.2%
	Increased AST ^b	0.2%
	Maculopapular rash	0.2%
	Nausea	0.2%

^a 977 males, 806 females

^b Laboratory changes were occasionally reported as adverse events.

NOTE: In both cefdinir- and control-treated patients, rates of diarrhea and rash were higher in the youngest pediatric patients. The incidence of diarrhea in cefdinir-treated patients A2 years of age was 17% (95/557) compared with 4% (51/1226) in those >2 years old. The incidence of rash (primarily diaper rash in the younger patients) was 8% (43/557) in patients A2 years of age compared with 1% (8/1226) in those >2 years old.

The following laboratory value changes of possible clinical significance, irrespective of relationship to therapy with cefdinir, were seen during clinical trials conducted in the US:

LABORATORY VALUE CHANGES OF POSSIBLE CLINICAL SIGNIFICANCE OBSERVED WITH CEFDINIR SUSPENSION US TRIALS IN PEDIATRIC PATIENTS (N=1783)

Incidence × 1%	δ Lymphocytes, α Lymphocytes	2%, 0.8%
	δ Alkaline phosphatase	1%
	α Bicarbonate ^a	1%
	δ Eosinophils	1%
	δ Lactate dehydrogenase	1%
	δ Platelets	1%
	δ PMNs, α PMNs	1%, 1%
	δ Urine protein	1%
Incidence <1% but >0.1%	δ Phosphorus, α Phosphorus	0.9%, 0.4%
	δ Urine pH	0.8%
	α White blood cells, δ White blood cells	0.7%, 0.3%
	α Calcium ^a	0.5%
	α Hemoglobin	0.5%
	δ Urine leukocytes	0.5%
	δ Monocytes	0.4%
	δ AST	0.3%
	δ Potassium ^a	0.3%
	δ Urine specific gravity, α Urine specific gravity	0.3%, 0.1%
	α Hematocrit ^a	0.2%

^a N=1387 for these parameters

Postmarketing Experience

The following adverse experiences and altered laboratory tests, regardless of their relationship to cefdinir, have been reported during extensive postmarketing experience, beginning with approval in Japan in 1991: Stevens-Johnson syndrome, toxic epidermal necrolysis, exfoliative dermatitis, erythema multiforme, erythema nodosum, serum sickness-like reactions, conjunctivitis, stomatitis, acute hepatitis, cholestasis, fulminant hepatitis, hepatic failure, jaundice, increased amylase, shock, anaphylaxis, facial and laryngeal edema, feeling of suffocation, acute enterocolitis, bloody diarrhea, hemorrhagic colitis, melena, pseudomembranous colitis, pancytopenia, granulocytopenia, leukopenia, thrombocytopenia, idiopathic thrombocytopenic purpura, hemolytic anemia, acute respiratory failure, asthmatic attack, drug-induced pneumonia, eosinophilic pneumonia, idiopathic interstitial pneumonia, fever, acute renal failure, nephropathy, bleeding tendency, coagulation disorder, disseminated intravascular coagulation, upper GI bleed, peptic ulcer, ileus, loss of consciousness, allergic vasculitis, possible cefdinir-diclofenac interaction, cardiac failure, chest pain, myocardial infarction, hypertension, involuntary movements, and rhabdomyolysis.

Cephalosporin Class Adverse Events

The following adverse events and altered laboratory tests have been reported for cephalosporin-class antibiotics in general:

Allergic reactions, anaphylaxis, Stevens-Johnson syndrome, erythema multiforme, toxic epidermal necrolysis, renal dysfunction, toxic nephropathy, hepatic dysfunction including cholestasis, aplastic anemia, hemolytic anemia, hemorrhage, false-positive test for urinary glucose, neutropenia, pancytopenia, and agranulocytosis. Pseudomembranous colitis symptoms may begin during or after antibiotic treatment (see WARNINGS).

Several cephalosporins have been implicated in triggering seizures, particularly in patients with renal impairment when the dosage was not reduced (see OVERDOSAGE). If seizures associated with drug therapy occur, the drug should be discontinued. Anticonvulsant therapy can be given if clinically indicated.

OVERDOSAGE

Information on cefdinir overdosage in humans is not available. In acute rodent toxicity studies, a single oral 5600-mg/kg dose produced no adverse effects. Toxic signs and symptoms following overdosage with other ϵ -lactam antibiotics have included nausea, vomiting, epigastric distress, diarrhea, and convulsions. Hemodialysis removes cefdinir from the body. This may be useful in the event of a serious toxic reaction from overdosage, particularly if renal function is compromised.

Rx only

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Limiting Topics During Visit Aids Retention

When providing parents with anticipatory guidance, less is apparently more.

Parental recall of topics discussed during a well-child visit dwindles as the number of topics increases, Dr. Shari L. Barkin and her associates reported: Parents absorb the information best when physicians limit their discussions to less than nine subjects.

"Limiting the number of topics discussed, rather than attempting to squeeze more informational content into the visit, might lead to increased retention, a necessary starting point for behavior change," wrote Dr. Barkin of Wake Forest University, Winston-Salem, N.C., and her colleagues (*Ambul. Pediatr.* 2005;5:372-6).

The investigators examined provider-parent agreement and parental recall of subjects discussed during 861 well-child visits. Most of the parents surveyed were mothers (90%), and most of the mothers (59%) reported at least a high school education.

The most discussed topics were car restraints, nutrition, dental care, and reading aloud. Other topics included exercise, firearms, smoking, and media use. Most providers (454) discussed 5-8 topics; 158 covered 1-4 topics, and 249 did 9-13 topics.

Immediately after the visit, parents and providers filled out surveys about the discussions. There was good agreement (at least 70%) about what was and was not discussed, but overall, parents reported discussing slightly fewer topics than did providers (mean topics 6.33 vs. 6.9, respectively). The best agreement between parents and providers occurred when five to eight topics had been discussed. When there were fewer than five topics, parents reported having discussed more topics than providers reported; in discussions of more than nine topics, parents recalled fewer topics than providers recalled.

Parental recall dwindled with time, the investigators wrote. One month after the visit, parents who heard the fewest subjects recalled discussing more than their providers had reported post visit (mean 5.58 vs. 3.12, respectively).

Parents who heard the most topics recalled fewer topics than their providers had reported post visit (mean 8.63 vs. 10.16, respectively).

—Michele G. Sullivan