Rotavirus

Infectious Diseases

Winter and early spring.”

We, Indianapolis. “We

James Whitcomb Riley Hospital

for Children, Indianapolis. “We

อธิполитическical division of the micro-

biology and infectious diseases at the Na-

tional Institute of Allergy and Infectious

Diseases in Bethesda, Md. Referring to

RotaTeq, she said, “I remember what we

all lived through.”

The pediatricians plan to monitor ongoing intussus-

ception risk through a 28,000-infant study at a

managed care organization. But the panel

also urged the company to more closely

examine whether the vaccine is safe for

all infants, an outcome that has

already been associated with either of the

two new rotavirus vaccines now being

licensed, said Dr. Richard L. Ward, a pro-

fessor of pediatrics at the University of

Cincinnati who was a pioneering devel-

oper of another rotavirus vaccine, Rota-

rix, which is made and sold by Glaxo-

SmithKline outside the United States.

The Merck and GlaxoSmithKline vac-

cines appear to be less apt to cause prob-

lems in their human hosts, Dr. Ward said in an

terview.

In the Merck study, overall, there were

13 cases of intussusception up to 1 year

after the first dose, compared with 19 for

the placebo group. On first look, there

appeared to be a clustering of cases after

the second dose, but both the FDA and its

advisers agreed that there seemed to

be no pattern that would implicate the

vaccine.

Even with what appears to be a large

margin of safety, it is not clear that physi-

cians will use the vaccine if it is approved.

(Ninety-four percent of those responding to

a small survey published in 2003 said they

would use a new rotavirus vaccine if it

proved to be safer than RotaShield and

if the American Academy of Pediatrics and

the CDC’s Advisory Committee on Immu-

nization Practices recommended the

vaccine.

The survey was conducted by re-

searchers at the Rollins School of Public

Health at Emory University in Atlanta

(Pediatrics 2003;112:e10-14).

Dr. Demnesy said the vaccine’s main ad-

vantage would be in curbing those hospi-

tal and physician visits. Merck said that

among its study population, there was

an 80%-90% reduction in emergency depart-

ment and physician office visits and hos-

pitalizations.

Despite the intussusception problem with RotaShield and the perception that physicians are more comfortable with the new vaccine. Merck was reassured by its phase

II data and decided to pursue the U.S. mar-

ket, Dr. Penny Heaton, director of clinical

research at Merck, said at the advisory pan-

el meeting.

So far, however, GlaxoSmithKline has not

sought FDA approval for Rotarix. It

launched the vaccine in Mexico in January

and received backing from the European

Union’s Committee for Medicinal Prod-

ucts for Human Use in December, paving

the way for European Commission ap-

proval.

Vaccine to Curb ER, Office Visits

Rotavirus from page

“The data as presented to me are very reassuring with regard to

intussusception,” said Dr. Gary Overturf, the panel’s chair.

“I think a lot of pediatricians are going to be cautious and want to see the data.”

said Dr. Penelope Denney, division di-

rector for pediatric infectious diseases at

Hasbro Children’s Hospital in Providence, R.I., and a member of the American Acad-

emy of Pediatrics’ committee on infec-

tious diseases.

One study indicates that pediatricians

might be ready to use such a vaccine.

BY DOUG BRUNK

San Diego Bureau

LAS VEGAS — Respiratory syncytial virus infection is a clin-

ical diagnosis based on patient history, physical exam, and the

season of the year, Dr. Veda L. Ackerman said at a meeting spon-

sored by the American Academy of Pediatrics’ California Chapters

1, 2, 3, and 4 and the AAP.

“Is it or are you trying to tell me that you have a baby who is RSV pos-

itive on July 4th in your practice, I’m going to tell you that your RSV test has cross-reacted with

another virus,” said Dr. Ack-

erman, of the section of pul-

monology and critical care in the

department of pediatrics at the

James Whitcomb Riley Hospital for

Children, Indianapolis. “We do not see RSV in the summer in the

United States. It peaks in mid-

winter and early spring.”

You can use RSV rapid tests to

make a diagnosis, but these “have both a high degree of false- neg-

ative and a high degree of false-

positives,” she said. “You have to

take that into consideration.”

Even with viral cultures—

which are traditionally the pre-

ferred method—there is a high false-negative rate due to the la-

bility of the virus. “So you can’t

take RSV positive or negative as a very good guideline for what you
do,” she explained. “As ther-

apy is largely supportive, proving

that the baby has RSV really

shouldn’t matter to you, except

for potential infection control.”

By age 2 years, 99% of children

who have been infected with RSV at

least once and 36% have had a

least two infections. This makes

RSV “as contagious as varicella, and it has significant impact on

missed days of school and missed days of work.”

Factors that increase one’s risk of

acquiring RSV infection in-

clude maternal education of
grade 12 or less, day care attend-
ence, school-age siblings, lack of

breast-feeding, two or more peo-

dlesharing a bedroom, multiple

births, passive smoke exposure, and birth within 6 months before

onset of RSV infection.

Obvious risk factors for better
delivering your baby in March or

April than you are in December,”

Dr. Ackerman said. “You’re less

likely to have that baby acquire RSV.”

Clinical features of RSV infec-

tion include nasal flaring; chest

wall retractions; tachypnea with

apneic episodes; expiratory wheezing; prolonged expiration;
rules and rhonchi; cough; and

hypoxemia and cyanosis. Tiny babies infected with RSV may

present only with apnea.

In a study of 213 infants younger than 13 months who had

bronchiolitis, the best predictor of

more severe disease was an oxy-

gen saturation level of less than


“A baby with RSV may present only with apnea.”

If you “have to happen not to

have [pulse] oximetry in your office, I

urge you that it is one of the things

that will help you tremon-

dously, both in figuring out what to

do with the child with asthma and

what to do with the child with

bronchiolitis,” Dr. Ack-

erman said.

Treatment for RSV infection is

mainly supportive and includes

supplemental humidified oxygen,

IV hydration if needed, proper

nutrition, and ventilatory assis-

tance for respiratory failure.

A trial of bronchodilators is

appropriate, “but to continue

them if there’s no response is not

appropriate,” she warned.

Corticosteroids are not cur-

rently indicated for RSV infection

but Dr. Ackerman said she would

use them in a 9-month-old infant

with a second or third episode of

wheezing who happens to have

RSV. “That’s an asthmatic and that’s a baby [in whom] I would

use corticosteroids.”

She also said they would use them in a

baby with RSV and heart failure.

Efforts to delay RSV spread in-

clude limiting contact with in-

fected people, enrolling your

child in a day care facility with

few children, and washing hands

frequently.

The James Whitcomb Riley Hospital for Children is in the midst of a handwashing cam-

paign. Parents are given a

brochure on admission which

urges them to ask, “Doctor, have

you washed your hands?” every
time they see a physician touch

their child. “My answer is sup-

posed to be, ‘Yes, I have. Thank

you for asking.’” she said.

Other efforts to prevent spread

include disinfecting surfaces ex-

posed to infectious secretions,

grouping hospitalized patients

with RSV, and promoting breast-

feeding.

One strategy to prevent in-

fection in high-risk premature

infants is to administer palivizumab (Synagis), which has been shown to reduce RSV-

related hospitalizations in this

patient population by more than

90%. “The downside of Synagis

is you have to give it before ex-

posure and you have to give it
every 30 days,” Dr. Ackerman

commented. “This is really a

problem because you have to
give it before you’re ever ex-

posed and you have to give it fre-

quently.”

She also noted that there are

no data to address the use of

palivizumab in children older

than 2 years of age or in those

with cerebral palsy, neuromotor

disease, metabolic disease, or

immunodeficiency.

Dr. Ackerman disclosed that she is a speaker’s bureau for

Glaxo-SmithKline Inc., maker of

Zovirax (generic name acyclovir)

and for AstraZeneca.