



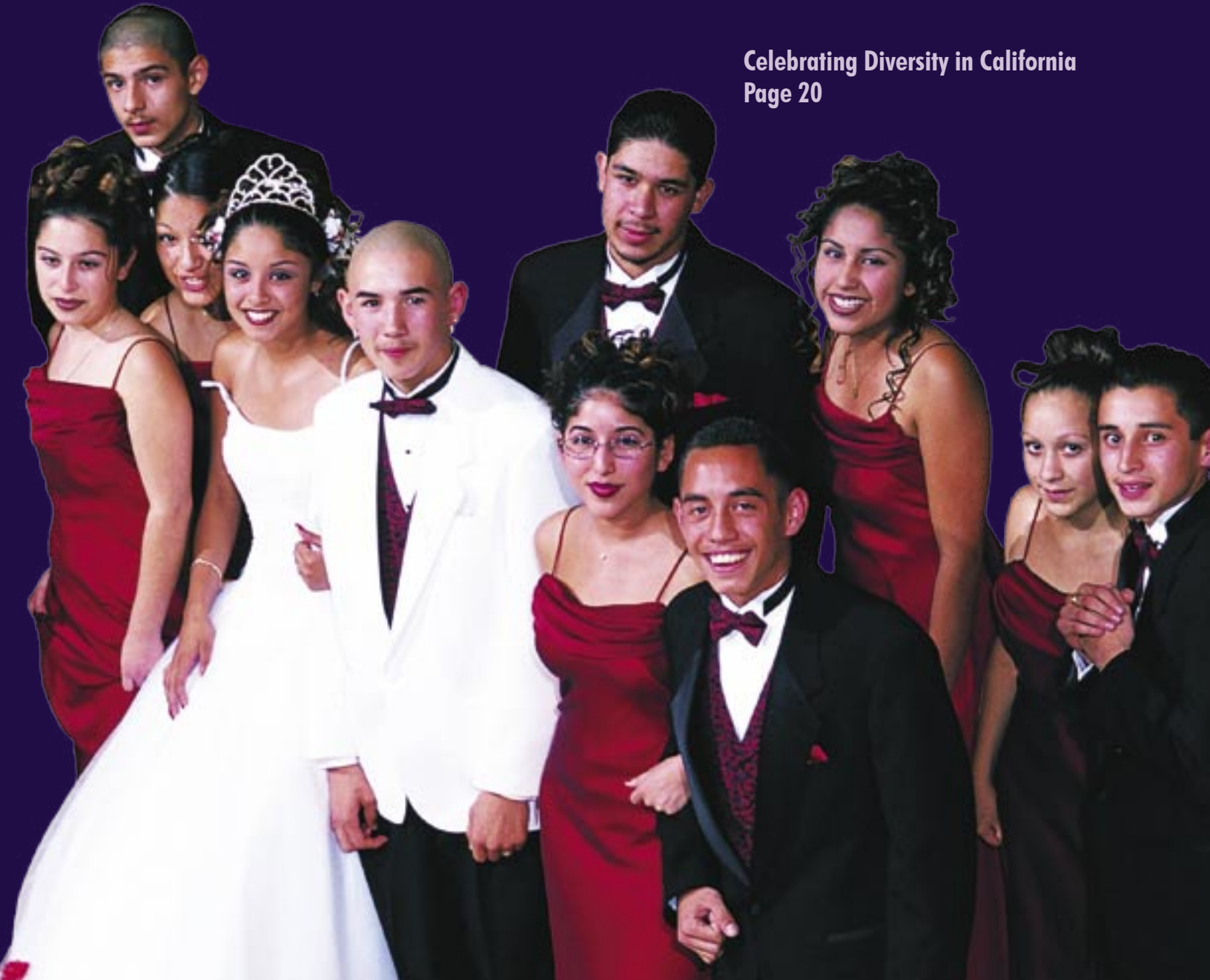
california

PEDIATRICIAN

Spring 2004

AMERICAN ACADEMY OF PEDIATRICS, CALIFORNIA DISTRICT IX

Celebrating Diversity in California
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July 3-9, 2004

University Childrens Medical Group and California Chapter 2, AAP
Pediatrics in the Islands...Clinical Pearls Hawaii
(323) 669-2305 or (800) 354-3263,
(800) 3-KID-CME www.ucmg.org

July 24, 2004

California Chapter 2, AAP
Coding for Dollars
Huntington Memorial Hospital,
Pasadena, CA
(714) 744-8245
or email kshematek@socal.rr.com

October 22-24, 2004

California Chapter 4, AAP
Current Advances in Pediatrics
Irvine Marriott Hotel, Irvine, California
(714) 971-0695 or
email ca4aap@sbcglobal.net

October 23-29, 2004

University Childrens Medical Group and AAP, California Chapter 2
Aloha Update: Pediatrics® Hawaii
(323) 669-2305, (800) 354-3263,
(800) 3-KID-CME www.ucmg.org

November 18-21, 2004

California Chapters 1, 2, 3, 4, AAP
26th Annual Las Vegas Seminars Pediatric Update
Venetian Hotel, Las Vegas
(310) 540-6240 or
email aapcach2@aol.com



December 4, 2004

California Chapter 1, AAP

Evaluation and Management of Pediatric Obesity
Laurel Heights Conference Center,
San Francisco
(415) 459-4775

January 2005

California Chapter 2, AAP
Is There Life After Residency?
Courtyard By Marriot,
Marina Del Rey, CA
(310) 540-6240 or
email aapcach2@aol.com

February 25-27, 2005

AAP, California Chapter 3 and Children's Hospital San Diego
Advances in Pediatrics
Hilton San Diego Resort on Mission Bay
San Diego, California
(858) 966-4072 or (888) 892-9249,
or e-mail vwillis@chsd.org
www.chsd.org/cme

March 3-6, 2005 (NEW DATES!)

California Chapter 2, AAP
Cosponsored by:
Los Angeles Pediatric Society
Combined Southern California Pediatric Postgraduate Meeting Clinical Pediatrics
Hilton Palm Springs Resort,
Palm Springs, CA
(310) 540-6240 or
email aapcach2@aol.com

April 14-17, 2005

California Chapter 2, AAP
Advances In Pediatrics, 17th Annual Las Vegas Postgraduate Meeting
Flamingo Hotel, Las Vegas, NV
(310) 540-6240 or
email aapcach2@aol.com

November 17-20, 2005

California Chapters 1, 2, 3, 4, AAP
27th Annual Las Vegas Seminars Pediatric Update
Venetian Hotel, Las Vegas
(310) 540-6240 or
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Cover Photo

We wish to acknowledge and thank Lawrence Migdale for permitting us to use his photograph of a quinceañera celebration for our cover. This photograph appears on the cover of *Celebrating a Quinceañera: A Latina's 15th Birthday Celebration* by Diane Hoyt-Goldsmith (New York, Holiday House) 2002. Hoyt-Goldsmith and Migdale have produced an excellent series for children and families about diversity in the United States. See www.holidayhouse.com.

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SARS (Severe Acute Respiratory Syndrome)

The First Mini-Pandemic of the 21st Century

James D. Cherry, M.D., M.Sc.

SARS (Severe Acute Respiratory Syndrome) was a new disease in the fall of 2002, which first occurred in Southern China and spread to 29 countries with 8422 cases and 916 deaths.¹ During the last year and a half, there have been over 1700 papers written about SARS but only 0.1% have been related to pediatric experiences. SARS spread to Hong Kong in February 2003 and the primary case was responsible for ten secondary cases who were guests in the same hotel where he stayed.² Infections in these persons plus the index case led directly to tertiary cases in two Hong Kong hospitals and outbreaks in Singapore, Toronto and Hanoi.

In March 2003, a novel coronavirus (SARS-CoV) was isolated from patients with SARS and subsequent study found that a similar virus was identified in animals (Himalayan palm civets and raccoon dogs) in a live animal market in Shenzhen, China.³

The epidemiology of SARS is fascinating. The ten secondary cases associated with the Hong Kong Hotel lead to worldwide dissemination of the disease. How the ten secondary cases acquired the disease is unknown, but it seems likely that an aerosol was created due to vacuuming in relation to cleaning up after the index patient had vomited. A point source outbreak of SARS was related to a housing complex in Hong Kong.⁴ The primary case relating to this was a man who lived in Southern China, who had chronic renal disease, and who frequently visited his brother in the housing complex. In mid-March this man visited his brother who lived in a flat in Block E of the housing complex. The patient had diarrhea at the time and a short time later an outbreak in the housing complex occurred and it had a point-source type distribution relating to Block E residents. Further study indicated that there had been aerosolization of contaminated sewage through floor vents when toilets were flushed and exhaust fans in bathrooms were switched on.

In the initial phases of the spread of SARS, a disproportionate number of health-care workers became ill.¹ The source of infection in these healthcare workers was often a case who appeared to be a "superspreader" (a single source patient responsible for multiple secondary cases). Later household contact

studies in Hong Kong and Singapore showed attack rates in family members of only 15% and 6% respectively. In retrospect, it appears that the disease gained a foothold because of aerosolization and in healthcare workers because they saw primary cases without carrying out respiratory infection control precautions. In March 2003, SARS spread throughout the world by infected persons traveling by airplane.⁵ With one exception, however, relatively few secondary cases were acquired by co-airline passengers.

The incubation period of SARS is two to ten days.¹ The attack rate in children is reported to be less than that of adults but Hong Kong data suggests that children have similar rates as adults when allowance is made for the large number of nosocomial cases. Disease in children is clearly less severe than that in adults. A review of 62 pediatric patients revealed the following findings: fever 100%, cough 63%, rhinorrhea 23%, myalgia 18%, chills 15%,

and headache 17%.⁶ In younger children (<10 years of age), the most common initial findings were fever and cough whereas in older children they also had headache, myalgia, sore throat, chills, and/or rigor. All children, however, had abnormal findings (patchy infiltrates, opacities, and/or areas of consolidation) on chest radiographs or CT studies. Virtually all children had absolute lymphopenia, although this was not always present at the time when the child was first seen. Nearly all children who were hospitalized with SARS were treated with intravenously or orally administered ribavirin and most children in Hong Kong but not those in Toronto were treated with steroids.

At the present time, the two key questions related to SARS are: 1). Will the disease reoccur; 2). And if it does, how should it be treated and contained? In retrospect, it would appear that the SARS pandemic of 2002/2003 occurred because of initial point-source outbreaks due to aerosolization of the virus and a large number of nosocomial infections. However, since disease has not recurred during the 2003/2004 season, the virus obviously did not gain a human foothold. It would appear that the SARS CoV is an animal virus, which, under normal conditions, does not spread well person-to-person. Therefore, it is reasonable to predict that it is unlikely to occur again with the same magnitude. However, since live animals and humans have close contact in Southern China and since infections with human CoVs

are common, it seems possible that dual infections with human and animal CoVs are possible. If this should occur, recombination might occur and this might lead to a catastrophic pandemic. In this regard, however, it is a far greater likelihood that a recombinant between a strain of avian influenza (such as H5N1) and a circulating human strain (such as H3N2) will occur in the near future. The initial therapy for SARS was developed on medical services in Hong Kong where both antiviral (ribavirin) and anti-inflammatory (steroids) treatment was employed. The rationale for steroid use was that some patients had ARDS and this was thought to be the result of "cytokine storm." However, subsequent studies in macaques suggest that the pulmonary pathology is due to a direct viral effect on type 1 pneumocytes. At the present time, in pediatrics it seems clear that there is no indication for routine treatment with steroids since children in Toronto who did not receive steroids did as well as those

At the present time, what seems most important in preventing a future epidemic or pandemic of SARS or epidemics or pandemics with other new viruses is sound public health policy and the use of standard infection control procedures as well as quarantine.

treated with steroids in Hong Kong. In regard to the use of the antiviral ribavirin, recent data suggest that blood levels that would inhibit the virus cannot be obtained.⁷ Studies have suggested that pegylated interferon- α and interferon- β might be useful therapeutic agents.

Although at the present time considerable effort is being made to develop a vaccine for SARS, it is my opinion that caution should be observed. If reoccurrence of pandemic disease should occur, it is likely that its origin will be from an animal so that a vaccine developed against the present human SARS-CoV would be unlikely to be effective against the new virus. A second concern is that previous experience with some candidate animal CoV vaccines have on occasion led to enhanced disease upon exposure.

At the present time, what seems most important in preventing a future epidemic or pandemic of SARS or epidemics or pandemics with other new viruses is sound public health policy and the use of standard infection control procedures as well as quarantine. In 2003, we were lucky in the United States because very few of the probable cases were actually infected with the SARS-CoV. In the spring of 2003, I surveyed a number of hospitals including our own and found that if a patient

CONTINUED ON PAGE 36
with SARS were to visit a clinic or emergency room, large numbers of persons would have

District Report

Burton Willis, M.D., District Chair and
Kris Calvin, M.A.,
District Executive Director

Politics matter for California pediatricians. This is true regardless of one's individual political perspective and affiliations. Nearly 40% of California's children receive state or federally funded healthcare. Many more are eligible for such care. Further, the statutes and regulations promulgated by policymakers increasingly dictate how medicine can be practiced. Recognizing that importance, AAP-CA, representing all four regional AAP Chapters, works diligently on your behalf to promote positive policies for children and pediatricians in California.

This year has been an unusual one politically. The second year of a two-year legislative session is generally the quiet one. Few new bill proposals are introduced. Focus can be given to those of primary importance. But for the recall, this would also have been the middle of the second term of a standing governor, whose appointees, processes and perspectives are well known to us. Instead, we have a new governor, known to all, but an unknown

quantity politically. This mid-stream change in leadership has brought with it a new cabinet, new department directors, and a host of new bills addressing new policy directions and reform proposals.

Nearing the six-month mark of the Schwarzenegger Administration, what is the picture for children and the practice of pediatricians in California? National and international press generally gives the governor and the Legislature good marks for breaking gridlock and beginning to address California's fiscal problems. The passage of Propositions 57 and 58 plugged this year's budget gap of nearly \$15 billion by borrowing. The governor has proposed a balanced budget for next fiscal year (05-06), while fulfilling his campaign promise of no new taxes. How does healthcare for children fare in this larger picture?

The governor's initial budget proposal in January contained deep cuts related to healthcare for children, including proposals to reduce physician reimbursement under Medi-Cal an additional 10% (over the 5% cut in Governor Davis' budget last year) and to cap enrollment in the Healthy Families Program and state-only CCS, potentially creating waiting lists. In addition to the proposed budget cuts, a parallel process to redesign Medi-Cal was initiated by the Administration. It was felt by many healthcare advocates that one goal for this redesign process was to find \$400 million in savings in the Medi-Cal budget for next year.

Since that time, AAP-CA has blitzed Sacramento policymakers with an unprecedented effort to protect and promote children's services in the budget. AAP-CA representatives have been at every major meeting and commented on every significant proposal where we have felt our input might have meaningful effects. We have worked in coalition with the California Medical Association, medical specialty societies and children's advocacy groups to leverage our efforts and make sure our voices were heard. In one of those partnerships we joined as a plaintiff in a CMA-led lawsuit against the state that was successful in blocking implementation of the current year budget's 5% physician reimbursement cuts for fee-for-service Medi-Cal. Further, we made it clear that we will take similar legal action relative to the proposed additional 10% cut in this year's January budget proposal.

As a result of these efforts, the efforts of others and an apparent commitment from this Administration and Legislature to the health of California's children, we are happy to report that the following positive changes occurred in the Governor's revised budget proposal of May 13th:

- The 10% Medi-Cal provider rate reductions in the original January budget have been withdrawn. (This is surely at least in part a result of the lawsuit AAP-CA par-

ticipated in which enjoined the 5% cuts proposed last year.)

- Enrollment caps and copayments for various health and human services programs, including CCS, Medi-Cal and Healthy Families, were also withdrawn.
- The governor also detached the Medi-Cal redesign project from the budget process. That proposal is now set for August 2nd, giving us more time to provide input. This is likely the result of all the work AAP-CA and others did in convincing the Governor and the Legislature that redesign of this scope needs more thought and time

Note that the above "May revise" is only a proposal, to be heard and acted upon by the legislature and then sent back to the governor for action. But compared to where we thought we would be this year, the picture is very positive. We will continue to advocate for children and for pediatricians in the hope that balancing the budget in California does not mean sacrificing care for children. (Note: Budget and other policy updates will be available at the AAP-CA website at www.aap-ca.org.)

NIH Internet Encopresis Study

Encopresis is estimated to affect more than two million children. Researchers at the University of Virginia have developed an intervention incorporating behavioral treatment and education with medical management. It has been found to be effective in clinical settings, and was recently transformed into an Internet intervention. The program has undergone successful pilot testing, and a national trial of this program is planned. Physicians who treat pediatric encopresis are needed to be a part of this NIH treatment outcome study. Physicians will continue to treat their patients, but half will be randomized to also receive access to the Web program. Both patients and physician offices will be financially compensated. To qualify, physicians must see at least four primary encopretic children between the ages of 6 to 12 each year. If you are interested in learning more, please call (434) 924-8020 or toll free at (800) 251-3627 (ext. 48020) or e-mail study@ucanpooptoo.com. HIC #9478.

Corrections

In the fall 2003 edition of *California Pediatrician*, "Painted Turtle: A Different Kind of Camp," the funding raised should have been \$23 million, not \$233 million.

In that article, the Figure 1 List of Founding Hospitals should have included:

- Loma Linda University Children's Hospital
- Los Angeles County and University of Southern California Medical Center Women's and Children's Hospital
- Lucile Salter Packard Children's Hospital at Stanford
- Mattel Children's Hospital at UCLA
- Miller Children's Hospital at Long Beach
- University of California at Davis School Medical Center
- University of California at Irvine Medical Center
- University of California at San Diego Medical Center
- UCSF Children's Hospital

California Pediatrician regrets the errors.

CONCERTA® (methylphenidate HCl) Extended-release Tablets

BRIEF SUMMARY: Please see full prescribing information.

DESCRIPTION

CONCERTA® is a central nervous system (CNS) stimulant. CONCERTA® is available in four tablet strengths. Each extended-release tablet for once-a-day oral administration contains 18, 27, 36, or 54 mg of methylphenidate HCl USP and is designed to have a 12-hour duration of effect.

CONTRAINDICATIONS

Agitation: CONCERTA® is contraindicated in patients with marked anxiety, tension, and agitation, since the drug may aggravate these symptoms.

Hypersensitivity to Methylphenidate: CONCERTA® is contraindicated in patients known to be hypersensitive to methylphenidate or other components of the product.

Glaucoma: CONCERTA® is contraindicated in patients with glaucoma.

Tics: CONCERTA® is contraindicated in patients with motor tics or with a family history or diagnosis of Tourette's syndrome (see ADVERSE REACTIONS).

Monamine Oxidase Inhibitors: CONCERTA® is contraindicated during treatment with monoamine oxidase (MAO) inhibitors, and also within a minimum of 14 days following discontinuation of a MAO inhibitor (hypertensive crises may result) (see PRECAUTIONS, Drug Interactions).

WARNINGS

Depression: CONCERTA® should not be used to treat severe depression.

Fatigue: CONCERTA® should not be used for the prevention or treatment of normal fatigue states.

Long-Term Suppression of Growth: Sufficient data on the safety of long-term use of methylphenidate in children are not yet available. Although a causal relationship has not been established, suppression of growth (ie, weight gain, and/or height) has been reported with the long-term use of stimulants in children. Therefore, patients requiring long-term therapy should be carefully monitored. Patients who are not growing or gaining weight as expected should have their treatment interrupted.

Psychosis: Clinical experience suggests that in psychotic patients, administration of methylphenidate may exacerbate symptoms of behavior disturbance and thought disorder.

Seizures: There is some clinical evidence that methylphenidate may lower the convulsive threshold in patients with prior history of seizures, in patients with prior EEG abnormalities in absence of seizures, and, very rarely, in absence of history of seizures and no prior EEG evidence of seizures. In the presence of seizures, the drug should be discontinued.

Potential for Gastrointestinal Obstruction: Because the CONCERTA® tablet is nondeformable and does not appreciably change in shape in the GI tract, CONCERTA® should not ordinarily be administered to patients with preexisting severe gastrointestinal narrowing (pathologic or iatrogenic, for example: esophageal motility disorders, small bowel inflammatory disease, "short gut" syndrome due to adhesions or decreased transit time, past history of peritonitis, cystic fibrosis, chronic intestinal pseudoobstruction, or Meckel's diverticulum). There have been rare reports of obstructive symptoms in patients with known strictures in association with the ingestion of drugs in nondeformable controlled-release formulations. Due to the controlled-release design of the tablet, CONCERTA® should only be used in patients who are able to swallow the tablet whole (see PRECAUTIONS: Information for Patients).

Hypertension and other Cardiovascular Conditions: Use cautiously in patients with hypertension. Blood pressure should be monitored at appropriate intervals in patients taking CONCERTA®, especially patients with hypertension. In the laboratory classroom clinical trials (Studies 1 and 2), both CONCERTA® and methylphenidate tid increased resting pulse by an average of 2-6 bpm and produced average increases of systolic and diastolic blood pressure of roughly 1-4 mm Hg during the day, relative to placebo. Therefore, caution is indicated in treating patients whose underlying medical conditions might be compromised by increases in blood pressure or heart rate, eg, those with preexisting hypertension, heart failure, recent myocardial infarction, or hyperthyroidism.

Visual Disturbance: Symptoms of visual disturbances have been encountered in rare cases. Difficulties with accommodation and blurring of vision have been reported.

Use in Children Under Six Years of Age: CONCERTA® should not be used in children under six years, since safety and efficacy in this age group have not been established.

DRUG DEPENDENCE

CONCERTA® should be given cautiously to patients with a history of drug dependence or alcoholism. Chronic abusive use can lead to marked tolerance and psychological dependence with varying degrees of abnormal behavior. Frank psychotic episodes can occur, especially with parenteral abuse. Careful supervision is required during withdrawal from abusive use since severe depression may occur. Withdrawal following chronic therapeutic use may unmask symptoms of the underlying disorder that may require follow-up.

PRECAUTIONS

Hematologic Monitoring: Periodic CBC, differential, and platelet counts are advised during prolonged therapy.

Information for Patients: Patients should be informed that CONCERTA® should be swallowed whole with the aid of liquids. Tablets should not be chewed, divided, or crushed. The medication is contained within a non-absorbable shell designed to release the drug at a controlled rate. The tablet shell, along with insoluble core components, is eliminated from the body; patients should not be concerned if they occasionally notice in their stool something that looks like a tablet.

Drug Interactions: CONCERTA® should not be used in patients being treated (currently or within the preceding 2 weeks) with MAO inhibitors (see CONTRAINDICATIONS, Monamine Oxidase Inhibitors). Because of possible increases in blood pressure, CONCERTA® should be used cautiously with vasopressor agents. Human pharmacologic studies have shown that methylphenidate may inhibit the metabolism of coumarin anticoagulants, anticonvulsants (eg, phenobarbital, phenytoin, primidone), and some antidepressants (tricyclics and selective serotonin reuptake inhibitors). Downward dose adjustment of these drugs may be required when given concomitantly with methylphenidate. It may be necessary to adjust the dosage and monitor plasma drug concentrations (or, in the case of coumarin, coagulation times), when initiating or discontinuing concomitant methylphenidate. Serious adverse

events have been reported in concomitant use with clonidine, although no causality for the combination has been established. The safety of using methylphenidate in combination with clonidine or other centrally acting alpha-2 agonists has not been systematically evaluated.

Carcinogenesis, Mutagenesis, and Impairment of Fertility: In a lifetime carcinogenicity study carried out in B6C3F1 mice, methylphenidate caused an increase in hepatocellular adenomas and, in males only, an increase in hepatoblastomas at a daily dose of approximately 60 mg/kg/day. This dose is approximately 30 times and 4 times the maximum recommended human dose of CONCERTA® on a mg/kg and mg/m² basis, respectively. Hepatoblastoma is a relatively rare rodent malignant tumor type. There was no increase in total malignant hepatic tumors. The mouse strain used is sensitive to the development of hepatic tumors, and the significance of these results to humans is unknown. Methylphenidate did not cause any increases in tumors in a lifetime carcinogenicity study carried out in F344 rats; the highest dose used was approximately 45 mg/kg/day, which is approximately 22 times and 5 times the maximum recommended human dose of CONCERTA® on a mg/kg and mg/m² basis, respectively. In a 24-week carcinogenicity study in the transgenic mouse strain p53^{+/+}, which is sensitive to genotoxic carcinogens, there was no evidence of carcinogenicity. Male and female mice were fed diets containing the same concentration of methylphenidate as in the lifetime carcinogenicity study; the high-dose groups were exposed to 60 to 74 mg/kg/day of methylphenidate. Methylphenidate was not mutagenic in the *in vitro* Ames reverse mutation assay or the *in vitro* mouse lymphoma cell forward mutation assay. Sister chromatid exchanges and chromosome aberrations were increased, indicative of a weak clastogenic response, in an *in vitro* assay in cultured Chinese Hamster Ovary cells. Methylphenidate was negative *in vivo* in males and females in the mouse bone marrow micronucleus assay. Methylphenidate did not impair fertility in male or female mice that were fed diets containing the drug in an 18-week Continuous Breeding study. The study was conducted at doses up to 160 mg/kg/day, approximately 80-fold and 8-fold the highest recommended human dose of CONCERTA® on a mg/kg and mg/m² basis, respectively.

Pregnancy: Teratogenic Effects: Pregnancy Category C: Methylphenidate has been shown to have teratogenic effects in rabbits when given in doses of 200 mg/kg/day, which is approximately 100 times and 40 times the maximum recommended human dose on a mg/kg and mg/m² basis, respectively. A reproduction study in rats revealed no evidence of harm to the fetus at oral doses up to 30 mg/kg/day, approximately 15-fold and 3-fold the maximum recommended human dose of CONCERTA® on a mg/kg and mg/m² basis, respectively. The approximate plasma exposure to methylphenidate plus its main metabolite PPA in pregnant rats was 2 times that seen in trials in volunteers and patients with the maximum recommended dose of CONCERTA® based on the AUC. The safety of methylphenidate for use during human pregnancy has not been established. There are no adequate and well-controlled studies in pregnant women. CONCERTA® should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: It is not known whether methylphenidate is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised if CONCERTA® is administered to a nursing woman.

Pediatric Use: The safety and efficacy of CONCERTA® in children under 6 years old have not been established. Long-term effects of methylphenidate in children have not been well established (see WARNINGS).

ADVERSE REACTIONS

The premarketing development program for CONCERTA® included exposures in a total of 755 participants in clinical trials (469 patients, 286 healthy adult subjects). These participants received CONCERTA® 18, 36, and/or 54 mg/day. The 469 patients (ages 6 to 13) were evaluated in three controlled clinical studies (Studies 1, 2, and 3), two uncontrolled clinical studies (including a long-term safety study), and one clinical pharmacology study in children with ADHD. Of the 469 patients in this program, 68 CONCERTA®-treated patients in one uncontrolled dose-initiation study were naive to any pharmacologic therapy for their ADHD. Safety data on all patients are included in the discussion that follows. Adverse reactions were assessed by collecting adverse events, results of physical examinations, vital signs, weights, laboratory analyses, and ECGs. Adverse events during exposure were obtained primarily by general inquiry and recorded by clinical investigators using terminology of their own choosing. Consequently, it is not possible to provide a meaningful estimate of the proportion of individuals experiencing adverse events without first grouping similar types of events into a smaller number of standardized event categories. In the table and listings that follow, COSTART terminology has been used to classify reported adverse events. The stated frequencies of adverse events represent the proportion of individuals who experienced, at least once, a treatment-emergent adverse event of the type listed. An event was considered treatment emergent if it occurred for the first time or worsened while receiving therapy following baseline evaluation.

Adverse Findings in Clinical Trials with CONCERTA®: Adverse Events Associated with Discontinuation of Treatment: In the 4-week placebo-controlled, parallel-group trial one CONCERTA®-treated patient (0.9%; 1/106) and one placebo-treated patient (1.0%; 1/99) discontinued due to an adverse event (sadness and increase in tics, respectively). In uncontrolled studies up to 12 months with CONCERTA®, 6.6% (29/441) patients discontinued for adverse events. Those events associated with discontinuation of CONCERTA® in more than one patient included the following: twitching (tics, 1.8%); anorexia (loss of appetite, 0.9%); aggravation reaction (0.7%); hostility (0.7%); insomnia (0.7%); and somnolence (0.5%).

Adverse Events Occurring at an Incidence of 1% or more Among CONCERTA®-Treated Patients: Table 1 enumerates, for a 4-week placebo-controlled, parallel-group trial in children with ADHD at CONCERTA® doses of 18, 36, or 54 mg/day, the incidence of treatment-emergent adverse events. The table includes only those events that occurred in 1% or more of patients treated with CONCERTA® where the incidence in patients treated with CONCERTA® was greater than the incidence in placebo-treated patients. The prescriber should be aware that these figures cannot be used to predict the incidence of adverse events in the course of usual medical practice where patient characteristics and other factors differ from those which prevailed in the clinical trials. Similarly, the cited frequencies cannot be compared with figures obtained from other clinical investigations involving different treatments, uses, and investigators. The cited figures, however, do provide the prescribing physician with some basis for estimating the relative contribution of drug and non-drug factors to the adverse event incidence rate in the population studied.

Table 1
Incidence of Treatment-Emergent Events* in a 4-Week Placebo-Controlled Clinical Trial of CONCERTA®

Body System	Preferred Term	CONCERTA® (n=106)	Placebo (n= 99)
General	Headache	14 %	10 %
	Abdominal pain (stomachache)	7 %	1 %
Digestive	Vomiting	4 %	3 %
	Anorexia (loss of appetite)	4 %	0 %
	Dizziness	2 %	0 %
Nervous	Insomnia	4 %	1 %
	Upper Respiratory Tract Infection	8 %	5 %
Respiratory	Cough Increased	4 %	2 %
	Pharyngitis	4 %	3 %
	Sinusitis	3 %	0 %

* Events, regardless of causality, for which the incidence for patients treated with CONCERTA® was at least 1% and greater than the incidence among placebo-treated patients. Incidence greater than 1% has been rounded to the nearest whole number.

Tics: In a long-term uncontrolled study (n=407 children), the cumulative incidence of new onset of tics was 8% after 10 months of treatment with CONCERTA®.

Post-Marketing Experience with CONCERTA®: Additional very rare undesirable effects were noted during the marketing experience: difficulties in visual accommodation, blurred vision, abnormal liver function tests (eg, transaminase elevation), palpitations, arrhythmia, leukopenia, and thrombocytopenia.

Adverse Events with Other Methylphenidate HCl Products: Nervousness and insomnia are the most common adverse reactions reported with other methylphenidate products. Other reactions include hypersensitivity (including skin rash, urticaria, fever, arthralgia, exfoliative dermatitis, erythema multiforme with histopathological findings of necrotizing vasculitis, and thrombocytopenic purpura); anorexia; nausea; dizziness; palpitations; headache; dyskinesia; drowsiness; blood pressure and pulse changes, both up and down; tachycardia; angina; abdominal pain; weight loss during prolonged therapy. There have been rare reports of Tourette's syndrome. Toxic psychosis has been reported. Although a definite causal relationship has not been established, the following have been reported in patients taking this drug: hepatic coma; isolated cases of cerebral arteritis and/or occlusion; anemia; transient depressed mood; a few instances of scalp hair loss. Very rare reports of neuroleptic malignant syndrome (NMS) have been received, and, in most of these, patients were concurrently receiving therapies associated with NMS. In a single report, a ten year old boy who had been taking methylphenidate for approximately 18 months experienced an NMS-like event within 45 minutes of ingesting his first dose of venlafaxine. It is uncertain whether this case represented a drug-drug interaction, a response to either drug alone, or some other cause. In children, loss of appetite, abdominal pain, weight loss during prolonged therapy, insomnia, and tachycardia may occur more frequently; however, any of the other adverse reactions listed above may also occur.

DRUG ABUSE AND DEPENDENCE

Controlled Substance Class: CONCERTA®, like other methylphenidate products, is classified as a Schedule II controlled substance by federal regulation.

Abuse, Dependence, and Tolerance: See WARNINGS for boxed warning containing drug abuse and dependence information.

OVERDOSAGE

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

Recommended Treatment: Treatment consists of appropriate supportive measures. The patient must be protected against self-injury and against external stimuli that would aggravate overstimulation already present. Gastric contents may be evacuated by gastric lavage as indicated. Before performing gastric lavage, control agitation and seizures if present and protect the airway. Other measures to detoxify the gut include administration of activated charcoal and a cathartic. Intensive care must be provided to maintain adequate circulation and respiratory exchange; external cooling procedures may be required for hyperpyrexia. Efficacy of peritoneal dialysis or extracorporeal hemodialysis for CONCERTA® overdose has not been established. The prolonged release of methylphenidate from CONCERTA® should be considered when treating patients with overdose.

Poison Control Center: As with the management of all overdose, the possibility of multiple drug ingestion should be considered. The physician may wish to consider contacting a poison control center for up-to-date information on the management of overdose with methylphenidate.

Rx Only.

For more information call 1-888-440-7903 or visit www.concerta.net

Manufactured by ALZA Corporation, Mountain View, CA 94043. Distributed and marketed by McNeil Consumer & Specialty Pharmaceuticals, Fort Washington, PA 19034.



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An Introduction to the Acute Otitis Media Guideline

After 2½ years of work, the AAP and AAFP released the Clinical Practice Guideline, Diagnosis and Management of Acute Otitis Media (AOM). AOM is the most common infection for which antibacterial agents are prescribed in the United States and has a significant impact on children's health, cost of pediatric care, and the

rate diagnosis be made. While this appears to be self-evident, there has been no widely accepted definition of AOM in the literature, and clinicians' accuracy in diagnosing middle ear effusion ranges from 50-70%. The short definition used in the AHRQ report and adopted in the guideline is: A diagnosis of acute otitis media requires 1) a history of acute onset of signs and symptoms, 2) the presence of middle-ear effusion, and 3) signs and symptoms of middle-ear inflammation. A longer definition clarifying each point can also be found in the guideline. In order to make an accurate diagnosis of AOM, the clinician must become skilled in the use of pneumatic otoscopy and may need to use tympanometry or acoustic reflectometry to maximize the likelihood of a correct diagnosis. The guideline acknowledges that even with the

older with a definite diagnosis and non-severe illness (fever < 102.6 F and mild otalgia), or with an uncertain diagnosis, and in children between 6 months and 2 years with an uncertain diagnosis and non-severe illness. All other children should be started on antibiotics at the time of diagnosis. The risk of observation in appropriately selected children is minimal. While children who are observed may have approximately 1 more day of pain and fever, proper use of symptomatic treatment will alleviate these symptoms.

Considering the enormous amount of antibiotics prescribed for otitis media, the decrease that would result from improved diagnosis and the use of observation will have a huge influence on the selective pressure we place on bacteria to develop resistance.

If an antibiotic is prescribed either initially or if the child persists with symptoms at 48-72 hours while being observed, the guideline recommends the use of amoxicillin at a dose of 80-90 mg/kg/day. This higher dose will treat most *S. pneumoniae* including those with intermediate resistance to penicillin. Additional recommendations are made for antibiotic selection for children who are allergic to penicillin, are believed to have a higher risk of illness from *H. influenzae* and *M. catarrhalis*, or who fail initial therapy.

Finally the guideline addresses preventive measures including immunization with pneumococcal conjugate vaccine and influenza vaccine, breastfeeding, not propping bottles, not exposing the child to second-hand smoke, decreasing pacifier use, and considerations related to day care. No recommendations are

In order to make an accurate diagnosis of AOM, the clinician must become skilled in the use of pneumatic otoscopy.

use of antibiotics. While the usual practice in the US is to prescribe antibiotics whenever a diagnosis of otitis media is made, often including children who actually have otitis media externa (OME) or in whom the diagnosis of AOM is uncertain, the practice in many countries in Europe is to observe children with AOM and only prescribe antibiotics if the child remains sick 48-72 hours after diagnosis. At least partly due to this practice, the rate of antibiotic resistance of the bacteria commonly associated with AOM, especially *S. pneumoniae*, is much lower in these countries than in the US. There is no apparent increase in morbidity from AOM in such countries as the Netherlands than here. The reason the AAP and AAFP chose to sponsor this guideline was concern over our rising antibiotic resistance rate and the successful experience with observation in Europe.

The first step in writing the guideline was an evidence-based report by the Agency for Healthcare Research and Quality (AHRQ). The guideline committee, composed of general pediatricians, family physicians, otolaryngologists, infectious disease experts, epidemiologists, and an expert in evidence-based medicine was then formed to write the guideline. In addition to the AHRQ report, additional literature published through September 2003 was intensively reviewed to form the evidence base for writing the guideline. Finally, the guideline was reviewed by numerous clinicians and experts in the field. Recommendations were ranked based on quality of evidence used and relative benefit and risk using standards established by the AAP.

The first recommendation is that an accu-

rate diagnosis be made. While this appears to be self-evident, there has been no widely accepted definition of AOM in the literature, and clinicians' accuracy in diagnosing middle ear effusion ranges from 50-70%. The short definition used in the AHRQ report and adopted in the guideline is: A diagnosis of acute otitis media requires 1) a history of acute onset of signs and symptoms, 2) the presence of middle-ear effusion, and 3) signs and symptoms of middle-ear inflammation. A longer definition clarifying each point can also be found in the guideline. In order to make an accurate diagnosis of AOM, the clinician must become skilled in the use of pneumatic otoscopy and may need to use tympanometry or acoustic reflectometry to maximize the likelihood of a correct diagnosis. The guideline acknowledges that even with the

best equipment and diagnostic skills there will be times when the diagnosis is uncertain and addresses these situations. Before thinking about subsequent management, it is important to relieve the pain of AOM. The committee felt that making the child comfortable is so important that we made pain management the second and strongest recommendation. While many modalities of pain management have been tried, none have

Before thinking about subsequent management, it is important to relieve the pain of AOM.

been shown to be safer and more effective than acetaminophen or ibuprofen.

Clearly the most controversial part of the guideline is the observation option. First it must be emphasized that this is an option and not a recommendation. This means that the literature on both sides of the issue is relatively weak and that there is a relative balance of benefit and risk in the individual child. As an option clinicians should not feel obligated to use observation but should consider it in their decision-making.

The observation option refers to deferring antibacterial treatment of selected children for 48 to 72 hours and limiting initial management to symptomatic relief. The decision to observe is based on the child's age, diagnostic certainty and severity of illness. Candidates for observation are children 2 years of age and

made regarding complementary and alternative medicine as the literature is inadequate to draw conclusions.

Guidelines are not intended to be a "cookbook" for medical care. The intent is to elucidate the published evidence and help the clinician to make intelligent decisions. In all cases, care must be based on what is best for the individual patient.

The complete AOM guideline can be found in the May, 2004 issue of Pediatrics and at www.aap.org.

Dr. Leibenthal is co-chair of the AAP Subcommittee on the Diagnosis and Management of Acute Otitis Media.

Early Intervention and Caries Risk Assessment Are the Keys to Controlling Dental Disease in Children

Oariona Lowe, M.A., D.D.S. and
Carla Lidner, D.D.S., M.S.

Dental caries is the most prevalent childhood disease identified today and is known to be a transmissible bacterial infection that occurs early in life and progresses throughout adulthood. The bacterial origin of the decay process has been recognized since the late 1800s, but the transmissible nature was not confirmed until 1975. In recent decades, strategies utilized within the United States to reduce the prevalence of decay were mostly related to introduction of fluoride into the drinking water and introduction of topical fluoride applica-

tions. Surveys of California children have revealed that they have on average twice the national level of untreated tooth decay. We must now encourage more aggressive ways of dealing with dental disease just as we would for any other bacterially transmitted disease. New recommendations and guidelines have been developed to assist health care providers, individuals, and communities in improving basic oral health. These recommendations and guidelines are designed for use with children as well as with adults.

Dental caries is simply "tooth decay." Specific bacteria (*Streptococcus mutans*, *Streptococcus sobrinus*, and *Lactobacillus*) on the tooth surface feed on fermentable carbohydrates such as sucrose, glucose, fructose, and cornstarch and then secrete acids as waste products. These acids travel into the tooth and dissolve the minerals of the tooth. Demineralization or loss of mineralization from the tooth or dental enamel occurs and if this process is not arrested or reversed, a cavity (or decayed area) is formed. If fluoride is present in water sources, it is deposited between the mineral crystals of the tooth and inhibits the loss of those minerals. Fluoride, if present in the oral environment, may also provide an actual opportunity for a tooth to remineralize itself by linking the phosphate and calcium crystals into a veneer-like overlay on the tooth. Fluoride is even known to inhibit the bacteria of

plaque that form on the surfaces of the teeth at the beginning of the decay process. Fluoride works through topical action and it can enter the oral environment from water, foods, beverages, or other specific products.

Current recommendations on caries management include early detection and caries prevention programs. Preventing dental disease is less invasive and therefore less expensive than treating its effects. Assessing the caries risk of the individual is an approach to managing caries and has become a popular evaluative tool in caries treatment modalities.

This article focuses on the prevention of dental caries through early intervention and it seeks to provide a how-to-approach to successful caries risk assessment and caries management using antibacterial agents. The suggested strategies provide a cross-disciplinary approach that can be utilized by medicine, dentistry, nursing, and other providers who together can affect changes and help to prevent decay in children.

Early Dental Visits Aid in the Prevention of Dental Caries

Recent reports by dentists and researchers suggest that the management of dental caries (cavities) lies in the prevention of the disease through an understanding of the decay process. Stewart and Hale stated in a current article that the medical strategy for preventing dental

Table 1 AAPD Caries-risk Assessment Tool (CAT)

Caries risk indicators		
Low risk	Moderate risk	High Risk
Clinical Conditions		
No carious teeth in past 24 months	Carious teeth in 24 months	Carious teeth in the past 12 months
No enamel demineralization (enamel caries "white-spot lesions")	One area of enamel demineralization (enamel caries "white-spot lesions")	More than one area of enamel demineralization (enamel caries "white-spot lesions")
No visible plaque; no gingivitis	Gingivitis	Gingivitis
		Visible plaque on anterior (front) teeth
		Radiographic enamel caries
		High titers of <i>Streptococcus mutans</i>
		Wearing dental or orthodontic appliances
		Enamel hypoplasia
Environmental characteristics		
Optimal systemic and topical fluoride exposure	Suboptimal systemic fluoride exposure with optimal topical exposure	Suboptimal topical fluoride exposure
Consumption of simple sugars or foods strongly associated with caries initiation primarily at mealtime	Occasional between meal exposures to simple sugars or foods strongly associated with caries	Frequent (i.e. three or more) between meal exposures to simple sugars or foods strongly associated with caries
High caregiver socioeconomic status	Midlevel caregiver socioeconomic status (i.e. eligible for school lunch program or SCHIP)	Low level caregiver socioeconomic status (i.e. eligible for Medicaid)
Regular use of dental care in an established dental home	Irregular use of dental services	No usual source of dental care
		Active caries present in the mother
General health conditions		
		Children with special needs
		Conditions impairing saliva composition/flow

From AAPD Reference Manual, Vol. 24, 2002-2003

decay consists of a systematic approach incorporating assessment of the caries risk of the primary caregiver, completing an infant oral examination and delaying or reducing bacterial colonization of the infant by lowering levels of cariogenic or acidogenic bacteria from the mother or caregiver as well as from the infant. It is recommended that providers of health care for infants and children be able to complete a caries risk assessment.

A framework for classifying caries risk in infants, children, and adolescents has been researched and outlined. This tool is based on a set of physical, environmental and general health factors. The American Academy of Pediatric Dentists intends for this guide to be revised periodically. It has been designed to help clinicians to adequately visualize children's teeth and mouth, have access to a reliable source for information and assess the components of caries risk.

Many observations show that the infant's health depends on the mother's knowledge of health-related issues. These observations emphasize the need to educate the mother and the caregiver in the prevention of dental decay. It is also documented that children receive more medical coverage than dental coverage and have greater access to medical care than dental care, thereby stressing the need for medical personnel to become more involved in oral health care. Primary care physicians, physician assistants, and nurses need to become more engaged in identifying children at risk and promoting positive health behaviors in medicine and dentistry. Health care delivery systems that address the total health needs of children using medical resources, resources from the community and schools, from private and public providers of care can help in eliminating disparities in dental care. Improving children's oral health is everyone's responsibility and eliminating preventable oral disease is a goal that the community and society should undertake.

Good oral health is essential to a child's overall health. It is necessary for optimal nutrition, function, speech and communication, sensory capacity, and appearance. Promotion of good oral health includes maximizing prevention and treating active disease. Disease prevention and health promotion are best cared for in childhood, as the risks of disease increase when preventive strategies are not undertaken at that time. Early onset of dental caries emphasizes the importance of early intervention especially when the caries process progresses to cavitation.

It is important that the infant's gums and oral cavity be cleaned prior to the eruption of the first tooth. The gum pads and mouth can be wiped down with a soft cloth or gauze pad. The gum pads in the child's mouth are covered with the same tissue that covers newly erupted teeth. The bacterial colonies found on the gum pads are the same as those found on the erupting teeth. Keeping the gum pads clean removes food residues and reduces the number

of oral bacteria found in the mouth. Plaque is an invisible film consisting of oral bacteria that adhere to the tooth surfaces and gums. Cleaning the gum tissues reduces the presence of oral bacteria and acid in the mouth. Lower bacterial counts can help decrease teething pain. After the teeth erupt the child's teeth should be cleaned at least twice daily with a toothbrush. Mothers will usually hesitate to do this because they are unfamiliar with the inside of their babies' mouths. Parents should be responsible for maintaining their children's oral hygiene especially before the age of six. Abundant educational materials are available for distribution in the offices of healthcare providers on the subject of nursing caries and any staff or provider time spent on reviewing these educational materials with the infant's mother or caregiver is time well spent. The potential for early childhood caries exists for the breastfed child as well as the bottle-fed and is related to extended and repetitive feeding times. Physician reminders to the caregivers about the risk is also very helpful.

First dental visits are generally for educational purposes, the first visit is a "well baby check for the teeth." The recommendation from the American Academy of Pediatric Dentistry and the American Dental Association is for the first dental visit to take place before age one. Many parents bring their children to the dentist after the third year, which is too late! At the first office visit the dentist examines the soft tissue and developing structures, diet and nutrition are reviewed, good oral hygiene is emphasized, oral habits are discussed, the use and benefits of fluorides is explained, and the important role of primary teeth is summarized.

When the child's mouth is checked, it is examined for possible soft tissue conditions. Occasionally, little white spots are observed on the roof of the mouth or palate. These are called Epstein's Pearl and are keratinized structures consisting of tough fibrous protein and require no treatment. Some babies are born with teeth in their mouths called natal teeth. These teeth may be observed immediately or may take 1 to 2 days to appear. Teeth that erupt prematurely are usually the first primary teeth and not extra teeth. Another condition identified in the mouth is the presence of "eruption cysts." These teeth cysts may develop on the gum pads and usually surround a developing tooth. They tend to disappear after a few days. "Tongue-tie" is a condition that may also be observed. A small membrane that "ties" the tongue to the mandibular ridge helps to position the tongue for nursing. This membrane usually disappears a few days after birth and the child is able to stretch the tongue forward. However, in some instances the membrane does not disappear but develops into heavy tissue causing the tip of the tongue to lock into position and, as a result, the tongue cannot be extruded properly. Depending on the severity of the tongue-tie, it should be evaluated for possible intervention by the primary care provider.

A review of dietary habits and nutrition is discussed as part of the initial exam. Diet and nutrition are important to the whole body but the most important effect of food on the teeth occurs when the food is in actual contact with the teeth. What a child eats or puts into its mouth is one of the easiest "caries culprits" to change. Limiting the amount of refined carbohydrates and the intake of sugar in any form is emphasized. A mouth that invites caries formation is one that is exposed to excessive amounts of soft, high carbohydrate, sugar-filled foods that remain in the mouth for long periods of time. Poor oral hygiene invites unfavorable bacterial counts to stabilize and colonize and foods containing sugar trigger acid formation. Enamel destroying acid is active for at least 20 minutes before it is buffered or dispersed by the flow of saliva. Limited use of the baby bottle and attention to what is placed in the bottle are reviewed along with the effects of prolonged breastfeeding. The importance of good oral hygiene is again emphasized. Supervising the child's brushing of teeth until age six or seven is recommended.

Oral habits and the detrimental effects they may have on the developing oral cavity should be discussed. These include thumb sucking, nail biting, teeth grinding, mouth breathing, and self-injurious habits. The importance of the primary teeth and why they might require restorative procedures should also be reviewed with the parent. The primary teeth serve as the foundation of the oral cavity. Early neglect or loss can result in developmental problems. The primary teeth are responsible for maintaining proper spaces for the permanent teeth. They 1) serve to guide the permanent teeth into position, 2) help in the development of the face and jaws; influencing the growth, height and shape of the face, which contribute to one's overall appearance and self-esteem, 3) help in the digestion of food especially as the infant's diet changes to more solid foods, and 4) are the foundation teeth. Early neglect or early loss can cause substantial problems with the newly developing permanent teeth. Injuries to the primary teeth can cause disturbances in the permanent dentition. If a primary tooth becomes infected and abscessed at the root, the infection may damage the succeeding tooth. When the child is about six years old, the first permanent molar erupts. This molar acts as an anchor for the dental arch and holds the remaining teeth in their proper positions. A checklist for the initial dental examination is provided in Table II.

Finally, as part of the initial examination, the benefits of fluoride use are reviewed. It is well documented that fluoride has reduced the rate of dental caries substantially and that fluoride supplements, fluoridated water, and fluoride preparations such as toothpastes, gels, rinses, and varnishes are readily available. But with the persistently high rates of dental decay, we must always ask the question, "Is there not more that we could do?" What about the bacterial transmissibility of caries? Should we

Table II. Initial Dental Examination Checklist

- First dental visit scheduled between six months and one year of age.
- The causes and prevention of dental disease discussed
- Soft tissue examination
- Dietary habits and nutrition reviewed
- Review of oral hygiene
- Discussion of oral habits and their effects
- The benefits of fluorides
- The importance of primary teeth
- Caries risk assessment

not try to treat the bacterial challenge directly? The answer to these questions leads us to the discussion of antibacterial agents that aid in the prevention of caries.

Caries Intervention Using Antibacterial Agents

The same bacteria that feed on carbohydrates and cause the deleterious effects in the caregiver host teeth are also transmissible to the child's host teeth. High bacterial challenge cannot be overcome by fluoride alone. Placing "fillings" has little effect on cariogenic bacterial loading in the mouth. The infectious process needs to be directly interrupted.

The effects of bacterially transmitted caries in children are startling. Children are known to be infected by mothers and caregivers through saliva transfer. Babies and infants are most susceptible from birth to about four years of age. Children infected early are known to have more cavities later in life. Children are also known to infect other children. Adults are known to infect other adults. The question remains: How can we prevent bacterial transmission of caries?

Antibacterial agents that are naturally present in saliva present the first line of defense against bacterial transmission. Almost all of the components of saliva are helpful, either by buffering acids or fortifying the tooth structure against attack. Saliva is also protective simply by providing a source of flow for clearance purposes. Antibacterial substances that are naturally found in saliva, such as lysozyme, lactoferrin and immunoglobulins, begin the fight to help keep the bacterial pathogens under control.

Extrinsic antibacterial agents provide a second line of defense. Manufactured antibacterial agents may be used in the case of high caries risk individuals. In the United States, 0.12 % chlorhexidine gluconate is available as a mouth rinse and is effective against *Streptococcus mutans*, but not as effective against *Lactobacillus*. For the mother or caregiver Chlorhexidine is prescribed as a mouth rinse: 10 ml once daily for a two-week period every two to three months. This broad-spectrum antibiotic works by opening up the cell membrane of the bacteria. Recent data indicates using the antibiotic for one week every month is similarly effective. In highly bacteria-challenged

individuals, this therapy will need to be continued for approximately one year and monitored by bacterial assessment. Problems associated with this compound are that it must be administered by the individual or home caregiver, that it affects taste and that compliance is often poor. Iodine (sold as 10 % povidine iodine, which is equivalent to 1 % iodine) may also prove to be a useful alternative to Chlorhexidine for children, especially since Chlorhexidine has not been recommended for children. It has been shown to reduce the incidence of early childhood caries in

high-risk children when applied once every two months but its effectiveness has not been proven thoroughly and clinical trials are still ongoing. The iodine therapy has the advantage that it can be applied in a dental office or by a health care provider simply by swabbing the teeth and is effective in reducing levels of *Lactobacillus* as well as *Streptococcus mutans*. Relatively new to the United States is Xylitol, a sweetener that looks and tastes like sucrose but is not fermented by cariogenic bacteria. Xylitol also inhibits attachment and transmission of the bacteria and can be delivered through chewing gum or lozenges as an effective anti-caries therapeutic measure. Xylitol gum chewed by mothers during the first two years of their children's lives has been shown to lead to much lower levels of caries in the children. Sodium bicarbonate (baking soda) has antibacterial properties and neutralizes acids produced by bacterial metabolism. It can be delivered via toothpaste or in solution. Future antibacterial agents that are more effective and easier to use will be of considerable benefit when they are available.

Other extrinsic agents, although not antibacterial, that help to stabilize the oral environment and protect against the rampage of bacterial destruction, are calcium and phosphate derived from dietary sources. Cheese, for example, is known to build strength and resistance of the tooth structure against bacterial destruction.

As mentioned earlier, fluoride provides inhibition of demineralization and enhances remineralization. If caries levels are low, then remineralization may be enough to halt the decay. In the case of caries-active individuals (and/or high bacterial levels), antibacterial therapy will be needed in conjunction with fluoride therapy and good dietary sources.

Summary

A caries risk assessment needs to be included in a child's general health assessment. Oral health is negatively affected by environmental factors, poor nutrition, lack of oral health education, diminished access to care, and inadequate resources. Success in improving children's oral health can only succeed when combined interdisciplinary efforts are under-

taken by all involved health care providers.

Dental decay and its manifestations are among the most prevalent health problems facing infants, children, and adolescents. Early intervention, first year dental examinations, fluoride use and antibacterial therapeutics are approaches used to aid in the reduction and eradication of dental decay.

Our special acknowledgement to Dr. John D. Featherstone (Chairman, Department of Preventive and Restorative Dentistry, UCSF School of Dentistry) to whom we owe much of our current understanding of the bacterial transmissibility of caries. His ongoing research is being noted throughout the world in dental education and dental public health efforts.

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CMA House of Delegates 2004 Report

Paul Y. Qaundah, M.D.

This year, the 133rd CMA House of Delegates (HOD) met in Sacramento from March 12 through March 15. Your pediatric representatives were: Alan Burckin, M.D., Stuart Cohen, M.D., and Paul Qaundah, M.D. In addition, our Executive Director, Kris Calvin, who is most knowledgeable about our issues, also attended the meetings.

The HOD set policy on pressing issues for all physicians in California. As your representatives, we took part in this annual session, debated and influenced pediatric issues. The five resolutions that we submitted were advanced and passed to our satisfaction. In addition, we debated and positively influenced resolutions pertaining to pediatrics and submitted by other physicians.

The following are priority pediatric resolutions that the House adopted as policy:

- Creation of task force on childhood obesity
Resolved: That CMA support the ongoing CMA Foundation efforts on childhood obesity in order that qualified physicians and scientists representing various disciplines can collectively produce rational and cohesive strategies for assisting children and their families with developing healthy living habits that will result in long-term weight control. (After the CMA Foundation contacted us to collaborate with their Task Force on obesity and Type II Diabetes, this resolution was amended to focus on appropriate collaboration.)
- Transcutaneous bilirubinometry
Resolved: That CMA support fair reimbursement for transcutaneous bilirubinometry from all third party payors; and be it further **RESOLVED:** That this matter be referred for national action.
- Transitioning special needs patients to adult care
Resolved: That CMA actively work with appropriate specialty societies to support programs that facilitate the transition of adults who were children with special health care needs to adult health care providers; and be it further **Resolved:** That CMA encourage the education of adult and pediatric healthcare providers in the transitional needs and appropriate care of pediatric patients with special health care needs when those patients reach adult-

hood.

- Deductibility of medical student loans
Resolved: That 100% of medical student loan interest be tax deductible on federal and state income tax returns; and be it further **Resolved:** That this be referred for national action.
- Stable funding for California poison control system
Resolved: That the California Legislature and Governor find the means to assure and institutionalize the stable and adequate funding of the California Poison Control System.
(This resolution was submitted by Lucy Crain, MD, our immediate Past District Chair.)
- Universal immunization for children
Resolved: That CMA support the concept

"We physicians are the heart and soul of our profession and are the advocates of medical ethics, professional standards, quality care, and strong patients-physician relationship."

of adequately funded universal immunization for all children in the United States; and be it further **Resolved:** That insurers be required to reimburse for all childhood immunizations recommended by the ACIP and AAP, without asking for the usual deductible; and be it further **Resolved:** That this matter be referred for national action.

- Support for the measles initiative
Resolved: That CMA take reasonable measures to make physicians aware of the global initiative to bring measles deaths to zero in Africa by 2005 by vaccinating 200,000,000 children and encourage them to support it; and be it further **Resolved:** That this matter be referred for national action.
- Support of asthma inhalers in schools
Resolved: That CMA support legislative efforts to authorize the possession and self administration of inhaled asthma medications in all public schools by children with asthma, provided there is written authorization from the child's parent or guardian and a written authorization from the health care provider documenting that the child has demonstrated the skills necessary to self-administer the medication.
- Protection of breast feeding
Resolved: That CMA discourage hospitals and health care professionals from distributing formula and bottles to women

who have stated a preference to breast feed; and be it further **Resolved:** That CMA recognize the inherent conflict of interest in infant formula manufacturers providing financial support for research or professional meetings regarding infant and child feeding; and be it further **Resolved:** That this issue be referred for national action.

- Residential swimming pool fencing
Resolved: That CMA consider supporting legislation that improves pool barrier safety standards and to have standards apply to property transfers as well as new residential swimming pools; and be it further **Resolved:** That CMA support and collaborate with various stakeholder organizations promoting pool safety, including measures requiring four-sided isolation fencing for residential swimming pools; and be it further **Resolved:** That this issue

be referred for national action.

Jack Lewin, MD, CEO of CMA, said in his speech to the House, "This Association has the power to positively influence the future of healthcare" and he is right. We are committed to preserve this profession. Lewin added, "We physicians are the heart and soul of our profession and are the advocates of medical ethics, professional standards, quality care, and strong patients-physician relationship." Medicine never changed. What changed is the interference of the businessman and others that led to lower reimbursement and higher malpractice insurance to the point that many physicians are closing their shop and many young people are discouraged from seeking medicine as a profession.

Playing alone, we all lose, but standing together, there is nothing we cannot accomplish.

Pediatrics benefits from our combined power when you join your medical society and CMA. If you are not a CMA member, please consider joining and lending your support to the above efforts.

Effects of Childcare on Children's Social and Emotional Development

Renee C. Wachtel M.D., FAAP and
Karen Sokal-Gutierrez M.D., MPH, FAAP

Over the past generation in the United States, there has been a dramatic increase in families' use of childcare for their young children. As of 2001, 51% of mothers with infants under one year of age were in the workforce, nearly double the rate of 27% in 1970.¹ The majority of working parents place their children in childcare before six months of age. With a large proportion of our children cared for in childcare—from a young age and for a significant amount of time—it is important to understand the potential impact of childcare



experiences on children's development.

Several well-respected random-assign-

ment, controlled intervention studies—the High/Scope Perry Preschool Project, the Abecedarian Study, and the Chicago Child-Parent Centers—have followed the short-term and long-term developmental outcomes for young children in childcare.^{2,3,4} Overall, these studies found that young children in high-quality childcare experienced significant advantages in socio-emotional and cognitive development, with the greatest benefits for disadvantaged children from families with lower income and lower educational backgrounds. However, other studies have raised concerns about behavioral problems associated with childcare.⁵

The July/August 2003 issue of the journal *Child Development* featured a series of articles addressing children's socio-emotional development in childcare. The lead article was entitled, "Does Amount of Time Spent in Child Care Predict Socioemotional Adjustment During the Transition to Kindergarten?"⁶ This article reported findings of the National Institute for Child Health and Human Development Early Child Care Research Network.

Study Design

This was a ten-site study following 1058 children from birth to kindergarten. It was designed as a longitudinal cohort study, following children in childcare arrangements chosen by their families, not an experimental, randomized, controlled trial.

The study population was diverse: Participating mothers had on average 14.4 years of education (with 27% having no more than a high school education), the average family income was 3.7 times the poverty level (but 25% had incomes no greater than twice the poverty level), 15% were single parents, and 20% were ethnic minorities.

Childcare arrangements were designated as either maternal care or "non-maternal childcare" defined as regular care by anyone other than the mother, including fathers, other relatives, centers, family day care providers, and nannies. Almost half of the children experienced non-maternal childcare for at least 10 hours/week by three months of age, and three out of four children were in non-maternal childcare by one year. Children received an average of 21 hours/week of non-maternal childcare between 3 and 6 month of age, increasing to 33 hours/week from 3 to 4½ years of age.

The study assessed the following variables:

- *Childcare characteristics:* The study documented the cumulative number of hours in non-maternal care, the types



of childcare, and changes in childcare arrangements over the study period. They also assessed the quality of the childcare by standardized observations of the caregiver-child interaction and stimulation (Observational Record of Caregiving Environment) at 6, 15, 24, 36 and 54 months of age.

- *Maternal, child and family characteristics:* The study controlled for maternal education, family income, partner status, sex of the child, and ethnicity. Maternal questionnaires were used to assess infant temperament at 6 months (Infant Temperament Questionnaire) and maternal depression (CES Depression Scale). Maternal sensitivity interacting with their child was assessed by standardized observations at 6, 15, 24, 36, and 54 months.

The key outcome—child adjustment at 4½ years of age and kindergarten entry—was assessed by the following measures:

- *Social competence* at 54 months of age and kindergarten: by mother, caregiver, and teacher reports (Social Skills Rating System, and California Preschool Social Competency Scale)
- *Behavioral problems* at 54 months of age and kindergarten: by mother, caregiver, and teacher reports (Child Behavior Checklist)
- *Adult-child conflict* in kindergarten: by teacher report (Student-Teacher Relationship Scale)
- *Play with other children* at 54 months: by observations during structured play with a peer; and play with other children in the childcare setting

Study Results

The study found that "overall, mothers, caregivers and teachers rated the sample well within the normal range on all standardized measures." However, a major finding of this study was the following: Children who experienced a greater cumulative quantity of non-

CONTINUED ON PAGE 28

Enzyme Replacement Therapy for Lysosomal Storage Disorders: A Case Study and Clues for Diagnosis

Shoji Yano, M.D., Ph.D.

For many years, lysosomal storage disorders (LSDs) were only mentioned in passing as part of basic genetics and biochemistry courses in medical school and in the corresponding textbooks. However, new enzyme replacement therapies have recently been approved which may halt or even reverse the progressive organ damage caused by these disorders. Early diagnosis and initiation of treatment may now allow pediatricians to reduce the morbidity and premature mortality in some of the LSDs. With these important advances in treatment, LSDs now deserve a more prominent place on our bookshelves and in our practice of pediatrics.

Lysosomes are organelles within the cytoplasm of all cells, responsible for the metabolism and recycling of macromolecules, including proteins, amino acids, complex carbohydrates, and lipids. Lysosomal storage disorders are a group of more than 40 inherited diseases, which are caused by a deficiency in one of the many lysosomal enzymes due to underlying genetic mutations. As a result, the specific substrates of these enzymes progressively accumulate within the lysosomes and eventually causes multi-system organ damage or dysfunction.

The most common LSDs, with an estimated prevalence of 1 in 60,000-120,000¹ are Gaucher disease (glucocerebrosidase deficiency), Fabry disease (α galactosidase deficiency) and the group of mucopolysaccharidoses (MPSs) of which MPS I (α L-iduronidase deficiency) is the prototype. While individually rare, LSDs have an overall combined incidence of about 1 in 7,000 to 8,000 births, making it likely that many pediatricians will encounter one or more patients with a LSD in

their career.

Recognition and diagnosis matters more now than ever because several LSDs now have treatment. Over the last twelve years, recombinant enzyme replacement therapies for Gaucher disease, Fabry disease, and MPS I have been developed and approved by the Food and Drug Administration (FDA). Additional enzyme replacement therapies are in the process of development for other LSDs.

A Case Study: Zachary's Story

Many LSDs present early in life to pediatricians, including MPS I. Some symptoms of MPS I may be present as early as 3 months (although the mean age of diagnosis is 9 months)². In a survey of MPS I patients and parents, 72% initially sought their first opinion from their pediatrician. Pediatricians play a key role in recognizing and referring these patients to geneticists and metabolic specialists for a definitive diagnosis and the initiation of treatment.

The story of Zachary is typical. Zachary presented at birth with an umbilical hernia and bilateral inguinal hernia, requiring surgery at age 2 months. During his first months of life, he was frequently seen by his pediatrician for

during sleep. At age 6 months, he was seen by an orthopedic surgeon for a lump on his back, and his parents were told that this kyphosis was postural and would improve with the child's growth. At that time, a pediatric resident also noted coarse facial features and an enlarged tongue in Zachary's medical record. Hepatomegaly was later noted and joint stiffness started to cause Zachary difficulty during play. These symptoms worsened over time. At age 12 months, Zachary was referred to a geneticist who made the diagnosis of MPS I. The clues to his diagnosis, while individually common, were revealed over time. As a cluster of signs and symptoms, these clues could be recognized as MPS and confirmed by a diagnostic enzyme assay to be MPS I.

Zachary had the classical features of the severe form of MPS I, also called Hurler's syndrome. The deficiency of the lysosomal enzyme α L-iduronidase leads to accumulation of the enzyme substrate, glycosaminoglycans, previously known as mucopolysaccharides. This substance is particularly disruptive during stages of rapid growth and development. It is during this time when nerves and growth plate tissues undergo extensive re-modeling. Given the widespread distribution in tissues,

it is not surprising that MPS I is associated with pathology in many organs and results in a wide range of clinical involvement (Table 1). The mortality of MPS I is principally due to the cardiac complications (mitral and aortic valvular diseases) and the obstructive airway disease. In the severe form, loss of motor skills and a halt in cognitive development becomes obvious around 2 years of age. For reasons that are not clear, the growth of these children may be accelerated for the first two years before slowing down and becoming delayed. The life expectancy for the most severe cases is less than 10 years of age, while milder patients may have significant disease morbidity but still may have a normal life span.

At an early stage of the disease some patients with the most severe forms of MPS I may be candidates for bone marrow transplantation, a reconstitution of the hematopoietic system with normal stem cells that are able to produce the missing enzyme. In April 2003, the FDA approved the first enzyme replacement therapy for moderate to severe MPS I, Aldurazyme®, a recombinant form of α L-iduronidase which can be administered intravenously to children with MPS I, like Zachary.

MPS I DISEASE SPECTRUM		
Symptom Presentation	Severe Patients	Attenuated Patients
Stiffened Joints	+++	++
Skeletal Abnormalities	+++	++
Carpal Tunnel Syndrome	+++	++
Cardiac (Valvular) Disease	+++	++
Recurrent Upper Airway Infections	+++	+
Obstructive Airway Disease /Sleep Apnea	+++	+
Corneal Clouding	+++	+
Spinal Cord Compression	+++	+
Hepatomegaly/Splenomegaly	+++	+
Inguinal or Umbilical Hernia	+++	+
Hearing Loss	+++	+
Mental Retardation	+++	-
Coarse Facial Features	+++	-
Communicating Hydrocephalus	+++	-
Abnormally Shaped Teeth	+++	-

Table 1. Spectrum of severity of MPS I and associated major clinical manifestations

recurrent otitis media. His parents also noticed a noisy breathing pattern including snoring

Clues to Diagnosis

Often, acute and early presentations are readily diagnosed, but more attenuated phenotypes with later onset can evade detection for many months and years until disease pathology is advanced. When should a pediatrician suspect a lysosomal storage disorder and refer a patient for diagnostic testing? Several obvious physical abnormalities may warrant further investigation — nonimmune fetal hydrops, organomegaly (Fig. 3), skeletal abnormalities (Fig. 4), unexplained joint stiffness, and “coarse” facial features (Fig. 5), especially when progressive. Anything that suggests a progressive, degenerative process deserves evaluation, such as loss of developmental skills, increasing behavioral abnormalities, or signs of muscular or neurological degeneration. Corneal and retinal changes may also be typically associated to some of the LSDs (Fig. 2). Unexplained pain in children — especially burning neuropathic pain in the extremities or bone pain — can also be due to a lysosomal storage disorder (Fabry or Gaucher disease, respectively). Note that many of the possible

indicators of lysosomal storage disease are subtle and are not uncommon in childhood, such as recurrent otitis media, behavioral problems, or gastrointestinal disturbances. Early diagnosis often requires the pediatrician to note suggestive symptoms that occur in concert, or a symptom or finding that seems unusual for a particular child — for example, facial features that differ subtly from other family members.

Summary

Some lysosomal storage disorders are now treatable with enzyme replacement therapy, including MPS I, Gaucher disease, and Fabry disease. These important advances raise the level of seriousness in making an early diagnosis, so that treatment can be initiated appropriately. While these individual lysosomal storage disorders are rare, as a group, these disorders are more common than most physicians appreciate. An awareness of the common presenting symptom clusters of LSDs can help pediatricians to know when they should make a referral to a geneticist for further management. Early diagnosis and initiation of treat-

ment is dependent on the pediatricians because the current Newborn Screening program does not detect LSDs. Expanded Newborn screening covering LSDs will hopefully become available soon. With the development of enzyme replacement therapy for a growing number of LSDs, those dusty old biochemistry and genetics textbooks have a new relevance to the practice of pediatrics, and in the lives of children like Zachary.

Dr. Yano's research is supported in part by Genzyme Corporation.

References

- 1 Estimation on the Australian population – prevalence and ratio may vary from country to country - Meikle et al. JAMA 281:249-254 (1999)
- 2 M.A. Cleary et al. The presenting features of mucopolysaccharidosis, Acta paediatr 84:337-9 (1995).



Figure 1: Mild coarse facial features in a 6-year-old child.



Figure 2: Corneal clouding

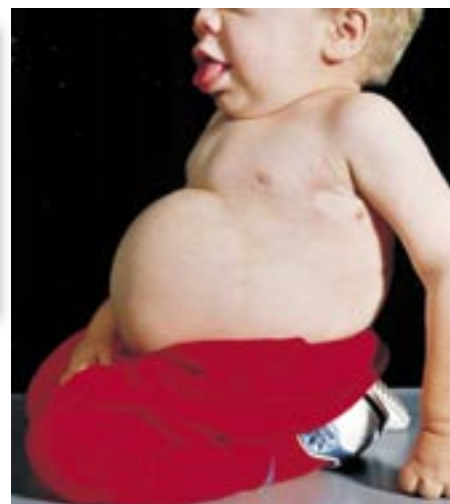


Figure 3: Organomegaly and macroglossia.



Figure 4: Pointed appearance of metacarpal bones



Figure 5: Coarse facial features in a 4-year-old child (before treatment).



Figure 6: The same child at 6 years of age after 8 months of the enzyme replacement therapy. Note coarse facial feature is improved.

A New Treatment for Children with Early Scoliosis or Thoracic Deformity

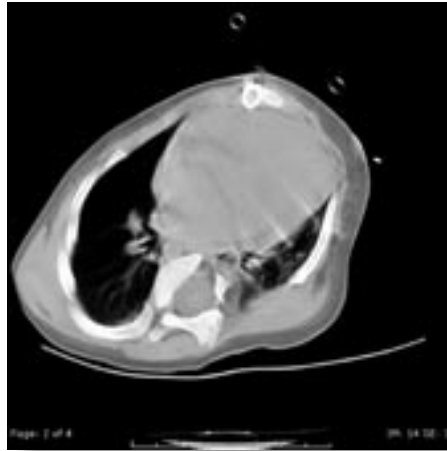
Christie N. Rice, M.S. and David L. Skaggs, M.D.

Scoliosis or chest wall deformity in young children can be life-threatening as the restricted chest wall ultimately limits the size of the child's lungs. This can be lethal if severe, and depending on the degree, can limit participation in normal activities. Traditional scoliosis surgery involving spine fusion may straighten the spine, but prevents normal growth of the spine and thorax. Sadly, up until now, little could be done to help these children.

A novel approach in pediatric spine and chest surgery is the titanium rib prosthesis developed by Dr. Robert Campbell in San Antonio, Texas. The titanium rib device is the centerpiece of an FDA investigational program, which consists of eight approved sites in the United States. Childrens Hospital Los Angeles (CHLA) is the only approved site



in California and one of two sites on the west coast. Members of The CHLA Early Scoliosis and Chest Wall Deformity Program include *Titanium rib prosthesis developed by Dr. Robert Campbell*



Traditional treatment ultimately prohibits further increases in the size of the thoracic cavity,

Dr. David Skaggs and Christie Rice, Orthopaedic Surgery, Dr. James Stein, Pediatric Surgery, Dr. Cheryl Lew and Dr. Tom Keens, Pulmonary Medicine, Dr. Christopher Newth, Critical Care Medicine and Dr. Joseph Farlo, Anesthesiology.

This new approach is based upon the premise that creating space to permit normal pulmonary development is of primary importance, and straightening the spine is secondary. Surgery involves surgically expanding the concave hemi-thorax, which not only straightens the spine, but more importantly, opens the chest and increases the thoracic volume to potentially allow normal lung growth. One or more vertical expandable prosthetic titanium rib devices are then placed to hold open the enlarged thorax. Use of this device is still under a research protocol, and studies are underway at CHLA to determine if the expanded thoracic size leads to improved pulmonary function and development.

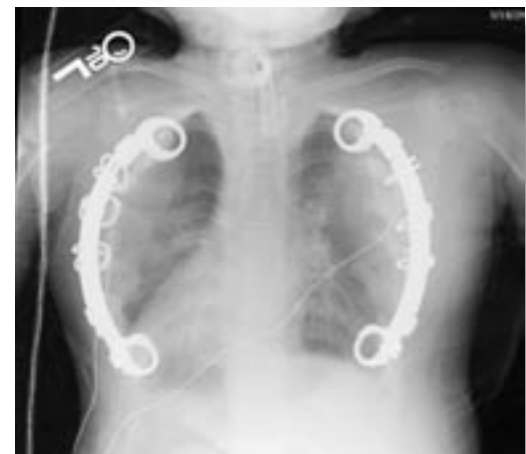
The traditional way of treating young children with scoliosis has been fusing the spine into a position that straightens it, however, this prohibits further spinal growth. Additionally, this ultimately prohibits further increases in the size of the thoracic cavity, which will lead to decreases in pulmonary function over time. One unique aspect of the titanium rib is the capability to further expand this device at regular intervals, to promote growth of the spine, increase thoracic space, and hopefully permit further lung growth as well. Approximately every 4-6 months lengthenings are carried out through a small, few centimeter incisions, usually on an outpatient basis. Most otherwise healthy children continue participating in their daily activities and sports.

This treatment is primarily indicated for children who still have potential for lung growth, which most believe continues at least up until age eight. In contrast, children who develop scoliosis during adolescence, which is much more common, are not at risk for hindered pulmonary development and may be treated by traditional means of spinal instru-

mentation and fusion.

One of the most exciting advances with the titanium rib prosthesis has been the treatment of Jeunes syndrome or other conditions with congenitally small chests. Children with these types of problems suffer from a progressive inability of their lungs to support normal growth and development due to a small thoracic cavity. Mechanical ventilation and early death have unfortunately been inevitable for most of these children. Treatment with the titanium rib prosthesis consists of expanding the chest laterally to greatly improve thoracic volume and pulmonary function.

An 18-month-old boy was transferred to Childrens Hospital Los Angeles from a NICU in California. The parents were told that their son would eventually die from suffocation even with the use of mechanical ventilation. After undergoing the surgical procedure in which his chest was expanded, his pulmonary function improved rapidly. Eight months after surgery, he was off mechanical ventilation, the tracheostomy was removed and he was able to



Treatment with the titanium rib prosthesis consists of expanding the chest laterally to greatly improve thoracic volume and pulmonary function.

run and play.

While the titanium rib prosthesis is not indicated for all young children with scoliosis, there are other cutting edge treatments available such as growing spinal instrumentation, which will also help obviate the need for fusion at a young age. The CHLA Early Scoliosis and Chest Wall Deformity Program utilizes a multidisciplinary approach in evaluating and treating these children. Evaluation includes pulmonary function tests, nutritional assessment and complete imaging studies of the chest and spine. For information, please contact Christie Rice, Research Coordinator Childrens Orthopaedic Center, Early Scoliosis and Chest Wall Deformity Program, Childrens Hospital Los Angeles.



Pre-op



Post-op

American Academy of Pediatrics 2004 Joint Meeting California District IX and New York District II



Above: At the Annual Joint District Meeting Awards dinner, on February 7, 2004, AAP-CA Chairperson Burton Willis, M.D. presented The Martin Gershman, M.D., Child Advocacy Award to Sylvia Micik, M.D. from AAP-CA Chapter 3 and Peter Michael Miller, M.D. from AAP-CA Chapter 1. The award was in recognition of their outstanding contributions to the health and lives of California's children.

Right: During the awards dinner, Dr. Willis also recognized Jeffrey Pensio, M.D. in appreciation for his many years of hard work and dedication to the California Pediatrician, the District and the children of California.



Dr. Cady, Chairman of the AMA Foundation, Dr. Bangasser, President California Medical Association, Dr. Kieu receiving the "Pride of the Profession" award from Dr. Palmisano, AMA President, Dr. Mike Magee representing Pfizer Medical Humanities Initiative.

On March 28th 2004, Quynh Kieu M.D., past president AAP CA Chapter 4, was honored with the "Pride in the Profession" award of the American Medical Association in Washington DC at the National Advocacy Conference. Since 2001, the award has recognized physicians who have contributed to the medical profession by "promoting the art and science of medicine and the betterment of public health." Among the four physicians recognized was fellow pediatrician Jack McConnell, who founded Volunteers in Medicine Clinic, which provides free care for uninsured in Hilton Head, South Carolina. Dr. Kieu was nominated by the California Medical Association and recommended by AAP District IX, as she has been a longtime legislative advocate and currently serves as co-chairperson of State Government Affairs.

This was the second award Dr. Kieu received, following the "Woman of the Year 2004" recognition by the California Legislature. She was nominated by Assemblyman Lou Correa and received the award in a ceremony on the floor of the Assembly on March 15, 2004.

Diversity in California: Appreciating Diverse Cultural Traditions and Celebrations

Myles B. Abbott, M.D., Edward R. Chu, M.D., and Jennifer A. Miller, M.D.

California has a highly diverse population. The latest U.S. Census Bureau "Profile of General Demographic Characteristics: 2000 Data Set" shows that 47% of the current population of California is white. The next largest groups are Hispanic/Latinos (32.4%), Asians (10.9%), and African-Americans (6.7%). The Census Bureau projects that by 2025 Hispanic/Latinos will be the largest group in California, surpassing the white population (42% v 33%). Today, Mexicans comprise the largest group of Hispanic/Latinos (77%), and the largest group of Asians is Chinese (26.5%).

Health care professionals can serve pediatric patients better if they appreciate the various cultural celebrations and customs that affect children. This article describes a few of these cultural events in three of the largest racial and ethnic groups in California: Mexican, Chinese, and African-American.

Mexican-American: Quinceañera

Quinceañera (KEEN-say-ahn-YAY-rah), honoring a girl's fifteenth birthday, is the most well-known and popular Mexican life cycle event. It celebrates a young Latina woman's transition from childhood to adulthood. This tradition traces its origins to both Aztec civilization and the Catholic religious values brought to Mexico by the Spanish in the early sixteenth century.

Previously, quinceañera marked a decision point for a young woman: she had to choose between devoting her life to the service of God or marrying and having a family. While still grounded in religion, young women today are not expected to make such a choice. Instead, there is a celebration that involves the whole community and includes a religious ceremony and a fiesta, or party.

The religious ceremony takes place in a church. The girl's family participates along with her "Court of Honor," which consists of the girl's best friends, both boys and girls. The fiesta follows the church ceremony and typically includes large quantities of homemade

foods (often made by members of the community), dancing, and gifts. The dancing begins with a waltz, led off by the girl and her Court of Honor. The tradition of the waltz dates back to the days of the Austrian Emperor Maximilian, who introduced it to Mexico while he ruled that country in the 1860s. The customary gift given to the girl is the muñeca (moo-NYAY-kah), an elegantly dressed doll. The doll symbolizes the childhood the girl is leaving behind, while the fancy dress represents the grownup world she is entering.

There is no equivalent life cycle event for Mexican boys. In addition to Mexico, quinceañera is also celebrated in Cuba, Puerto Rico and other countries in Latin America.

Chinese-American Newborns: The Red Egg and Ginger Party

The birth of a newborn child in Chinese-American culture is marked by a number of rituals and celebrations. One of the most well-known events is the one-month celebration known as the red egg and ginger party. This holiday has been a Chinese tradition for centuries. Infant mortality in ancient China was very high. If a baby reached one month of age, the child was likely to survive, so the event was celebrated. Today, it is an occasion to welcome the child into the community and announce the baby's name publicly.

The celebration is symbolic on many levels. The color red symbolizes good fortune and happiness. The egg represents the cycle of life and a new beginning. Even the shape of the egg is important, for its roundness symbolizes a harmonious life. The family sends out

child's parents give red-dyed eggs as gifts to their guests. Guests traditionally give the baby lucky money in red envelopes (for boys) and jewelry (for girls).

Ginger is prominently served as part of the meal at the party. Ginger also plays an important role in the mother's health. Mothers in Chinese culture try to preserve their chi, or the life energy source, to maintain balance, harmony, and moderation during the first month after giving birth. Chinese-American mothers may be cautioned to stay in bed for the first month and avoid exposure to "cold" elements, such as cold temperatures or cold water. Some mothers may even skip visits to the doctor in the baby's first month of life because of these beliefs, sending someone else to the office with the baby. In Chinese culture, ginger is considered yang (warm), which balances the yin (cold), adding warmth to the nutritional needs of the new mother. Food with ginger is served to keep the mother warm, improve her circulation, and help her immune system.

African-Americans: Black History Month, Kwanzaa, Juneteenth

African-Americans are not a homogeneous group. They are a combination of different peoples with origins in many countries and cultures. Unlike the other racial and ethnic groups discussed here, African-Americans differ because their pervasive culture is American. While people from other nations immigrated willingly to America, African Americans were brought here by force, as slaves. They could no longer celebrate their holidays or worship their gods, and their native cultures and traditions



colorful red invitations announcing the baby's birth and inviting relatives and friends to a party welcoming the newborn. At the party, the *Invitation to a Red Egg and Ginger Party*

were lost.

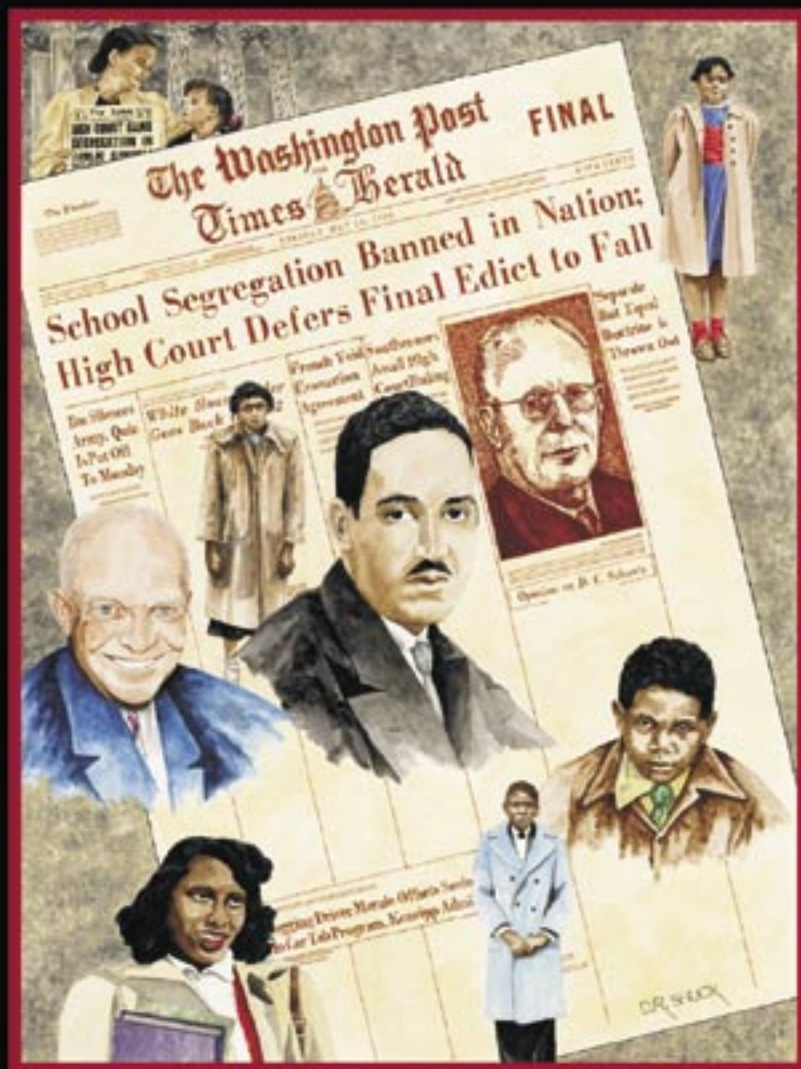
Once African-Americans were freed from slavery, they celebrated the same holidays

white Americans celebrated. Yet as a testament to their strength and fortitude, African-Americans have tried to maintain ties with their mother countries and cultures. They have created holidays that embrace the richness of those cultures and highlight their survival and achievements. Three noteworthy celebrations are Black History Month, Kwanzaa and Juneteenth.

A celebration of Black history was first created in 1926 by Carter G. Woodson. At that time, he proposed a one-week celebration to bring to light the many varied achievements of Africans and African-Americans. He chose February, because it was the birth month of two very important figures in black history at the time: Abraham Lincoln and Frederick Douglass. In 1976, Black History Month was expanded to include the entire month of February. Today, the month is filled with parades, celebrations, conferences, symposiums, and barbecues. Children are reminded that their culture is a rich one of which they can be proud. Radio stations give homage to African-American artists' contributions, and television stations play commercials honoring the contributions of African-Americans.

Kwanzaa (kwan-za), a holiday created by Dr. Maulana Karenga in 1966, is another way in which African-Americans celebrate their ties to Africa. The name Kwanzaa means "first fruits of the harvest," in Swahili, and is modeled after ceremonies that have been occurring in Africa for many years. This holiday deepens connections to African culture, strengthens communal ties, and reinforces the Nguza Saba, or seven principles. It was also seen as a way to galvanize and empower African-Americans. Kwanzaa runs from December 26 to January 1, and each day of Kwanzaa celebrates another principle. The principles are: umoja (unity), kujichagulia (self-determination), ujima (collective work and responsibility), ujamaa (cooperative economics), nia (purpose), kumba (creativity) and imani (faith). One candle in the kinara, or candleholder, is lit each day, in honor of these principles. Kwanzaa culminates with the Karamu, or great feast, on December 31; the following day, educational and cultural gifts are given to children. Kwanzaa is a wholly original creation. It is African-Americans' way of remembering where they came from and celebrating who they are now.

Most Americans believe that slavery ended with the Emancipation Proclamation on January 1, 1863. Juneteenth is a holiday commemorating the true end of slavery on June 19, 1865, when Union troops landed in Galveston, Texas and brought news that the war had ended and that the Emancipation Proclamation had set all slaves free. Until that time, more than 800,000 African men and women remained enslaved despite the fact that slavery had ended in the rest of the country 2 ½ years earlier. Juneteenth date became an official holiday in Texas in 1980, and many people throughout the country celebrate this day with food, fun



Black History Month
Brown v. Board of Education (50th Anniversary)
February

A Black History Month Poster; obtained from The Diversity Store www.diversitystore.com (800) 200-5964.

and educational enrichment. Many states have fairs and street festivals commemorating this date in history.

Putting this Information to Use

Pediatricians can communicate and relate more effectively with patients and their families when they understand the cultural events and traditions that their patients experience. One of California's greatest assets is its rich diversity of cultures. Pediatricians come into contact daily with these cultures, and it is to our benefit as well as our patients' to learn more about this diversity. We encourage our readers to add to what we have presented here and to describe the life events and traditions of these and other cultures in future issues of *California Pediatrician*.

Vitamin K for Newborn Babies: A Lesson in Advocacy

Quynh Kieu, M.D., FAAP

Thanh Hoa General Hospital, November 1999: the pediatrician from Orange County stared at the three-weeks old distressed infant, tachypneic, and jaundiced, covered with petechiae. Her mind considered differential diagnoses, none of them completely satisfactory. She looked at her Vietnamese colleague for infor-

mation, and Dr. Tran cheerfully responded, “the baby was admitted early today, and has vitamin K deficiency. We have already given her an injection of vitamin K.” To Dr. Nguyen’s amazement, the pediatric ward had three more babies with similar problems, and before the end of the week, four more babies were to join them with various degrees of hemorrhage. Apparently this “hemorrhagic disease of the newborn” was well known and had a high prevalence. Vietnamese physicians treated the infants with supportive care, and no, there was no preventive treatment. Within the medical mission group, the topic became an emotional issue: Project Vietnam, international program of California Chapter 4 had traveled to several provinces in central and north Vietnam since 1996, and had met with previous cases, but nowhere as many as in Thanh Hoa province. As the coordinator of the group, I believed the problem existed mainly in the rural

areas, but Ray Clarke, a retired chief of pediatrics at Kaiser-North California, who spent months in HochiMinh city and Hanoi, clarified, “There is no prophylactic vitamin K anywhere, despite the fact that the National Institute of Pediatrics in Hanoi sees 7-10 babies every week with the problem.” When our medical team returned to Hanoi after a most productive workweek offering surgical corrections to children with eye defects and orofacial deformities (mostly cleft lips and palates), pediatric leaders in Hanoi confirmed the prevalence of the hemorrhage, adding that



This mother has been ventilating her baby 24/7 for three weeks.

Vietnamese babies seemed to experience more commonly cerebral hemorrhage as a late form of the disease. Previous request for a national program of vitamin K prophylaxis had met with the often-heard answer “there is no funding.” Indeed, funding is scarce in Vietnam for healthcare, which receives less than 1% of Gross Development Product or less than \$3/capita annually in a country where people have an average income of less than \$1/day. Despite a population 80% rural, depending almost exclusively on the national network of commune health clinics, only 5% of the budget and 23% of all healthcare personnel support these 10,000 basic units of healthcare for the poor.

At our reception in Hanoi, the official representative of the Ministry of Health was strategically surrounded at the table by National Institute of Pediatrics leadership and our pediat-



Three newborn babies admitted on the same day with brain hemorrhage from vitamin K deficiency.



Four-month-old patient with hydrocephalus from IVH, a common complication of bleeding in the brain.



Another vitamin K deficiency victim in vegetative state

tricians who witnessed the unfortunate cases of vitamin K deficiency. With the multiple strong testimonies, we obtained his agreement to actively research the situation. Before we left, I worked out with the director of the Institute of Pediatrics a data collection from hospitals in Hanoi to document the casualties, focusing on the most extreme finding of cerebral hemorrhage, which is easiest to survey. The financing from Project Vietnam provided for the travel and some compensation for the labor-intensive manual record review at each of the pediatric units in Hanoi.

On November 6, 2000 at the 17th congress of the Vietnam Pediatric Association the findings were presented to an audience of over 400 pediatricians and officials, and they were overwhelming, painting a picture of preventable disaster. The five studies by Drs. Nguyen Van Thang and Nguyen Cong Khanh showed intracranial hemorrhage as the most common presentation of vitamin K deficiency in Vietnamese newborn:

- From 1991-98, about 1,400 cases were hospitalized in Hanoi, 34% of them residents of Ha Tay province.
- 88.5% of the patients were babies 1-2 months, generally breastfed healthy term newborn, and male infants were affected 3:1
- Mortality was 17.2% with 62.1% showing neurological damages mostly from hydrocephalus.
- The incidence of 1.25/1000 would place it as the highest in the world for cerebral hemorrhage, 20 times higher than in developed countries and four times more than neighboring Thailand.

Besides the Hanoi survey, reports from Central and South Vietnam corroborated the incidence of late cerebral hemorrhage, raising the concern of many sudden infant deaths at home, therefore undiagnosed and unreported, in rural areas. The hospitalized infants may represent the tip of the iceberg.

As a tragic reminder, during the conference, three babies were admitted on the same day at the National Institute of Pediatrics, coming from different provinces, with the same clinical picture of sudden seizure and evidence of blood loss. They showed extensive hemorrhage on brain imaging.

Upon my request, the Vietnam Pediatric Association unanimously endorsed a recommendation for vitamin K prophylaxis after birth, although the pediatrician-leaders reminded the audience that the request had been presented in the past to no avail.

Within the landscape of a developing country with many competing priorities, economic survival invariably rises at the top, even in the face of severe burden on the healthcare system and society. Since Vietnam cannot

manufacture vitamin K1 used for prophylaxis, the imported injectable drug costs 50cents or almost 15% of the annual per capita health expenditure.

Intense advocacy was needed and working with the National Institute of Pediatrics, we decided on a pilot project in the most affected region, to demonstrate the effectiveness of prevention. Healthcare authorities of the province of Ha Tay, home to the highest prevalence of cerebral hemorrhage, readily agreed since they had to treat many children with permanent sequelae of vitamin K deficiency. A joint proposal was submitted to the Ministry of Health requesting a one-year pilot to deliver vitamin K as an injection after birth to 40,000 newborn, the annual birth cohort in Ha Tay, with the National Institute of Pediatrics as respon-

Across the oceans, we are all the same at heart, professionals who have chosen to be "dedicated to the health of all children."

sible agency, and Project Vietnam sponsoring the medicine and training costs. However, our participation was contingent on the expressed condition that national policy would result if the pilot proved successful. Without any warranty of outside funding, it took 18 months to get approval.

I granted newspaper interviews in Vietnam to publicize the cause, and enlisted US congressman Ed Royce to visit Hanoi Institute of Pediatrics and urge prompt action. Meantime, we created a vitamin K fund and obtained assistance from individual supporters and friendly Vietnamese-American organizations such as ICAN, Lua Viet and the Vietnamese Pharmacists Association, and obtained a large gift of Abbott vitamin K thanks to Americares, an international relief agency. Overall, a total of 120,000 doses of vitamin K were provided for the project. In December 2001, healthcare providers in Ha Tay province received training regarding vitamin K administration, and the drug was uniformly distributed to reach every commune and village. Officially started in June 2002 after a limited trial period, the first six months tabulation showed no reported cases of hemorrhage province-wide. I continued to urge the Ministry of Health towards prompt national implementation, since every day would bring new cases in untreated areas of the country. My persistence received increasingly favorable reception. By December 2002, 20,000 babies had successfully benefited from prevention with vitamin K. On January 2, 2003 the Ministry of Health issued an official decree to institute vitamin K as a national policy: 1.6 million newborn would be protected every year!

Was this the happy ending? Not so, because no budget had been allocated for vitamin K. The cities and provinces which had the means, purchased the vitamin K, insured families were covered, however the poorest areas with most needs could not afford it.

Since Project Vietnam had advocated for the practice in five provinces where we worked, we saw many creative initiatives: Ninh Binh hospital gave .5mg (half dose) to save on the drug with good results (Vietnamese newborn average 5 lbs therefore this would be sufficient dose), a commune in Quang Binh province created a loan program: poor families would receive the shot and repay monthly. The commune health center director stated there was no default, and parents would religiously pay 5-10 cents every month. In the

meanwhile, communications with pharmaceutical manufacturers resulted in lower pricing. The Vietnamese Pharmacists Association had donated 10,000 doses of vitamin K2 produced in Vietnam, which seemed to show comparative efficacy. Last month, I discussed with the director of the vitamin K project about a new study using vitamin K2 and K3 both locally synthesized to compare with the vitamin K1 of international standard. Should it bear equivalent results, this would represent a giant leap in affordability and allow true penetration nationwide. Having the right policy is the first step, reaching universal implementation is the second, more difficult one. We continue to look for diverse avenues to speed the process, as no baby is safe until true national use.

In late March 2004, at Lang Son general hospital in the North highlands near the China border, one of the provinces with highest infant mortality, we saw a lone infant in the pediatric critical care room. He was jaundiced and breathed rapidly; he was covered with bruises and had vitamin K deficiency cerebral hemorrhage. The director of health services had previously denied a problem with vitamin K, the chief of pediatrics told her, "This is our second case this month." The baby came from a remote village where most of the mothers deliver at home.

As we return time after time to Vietnam, we are confronted with requests for high technology and expensive equipment we cannot provide. Our team members at times feel powerless without the ancillary services

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Lyme Disease: What California Pediatricians Should Know

Joel D. Klein M.D., FAAP

Lyme disease (LD) is the most common vector-borne disease in the U.S. While the majority of cases occur in the Northeast from Maine to Maryland, in the upper Midwest, Wisconsin and Minnesota, cases have also been reported in northern California and Oregon. Although the incidence of LD is 400 times less in California than in Connecticut, it remains an important disease, since failure to diagnose it may lead to significant clinical consequences.

Epidemiology

In the US, the bacterium that causes LD is a spirochete, *Borrelia burgdorferi*. In most areas of the US, the vector which transmits the bacterium is *Ixodes scapularis*, the deer tick. This tick undergoes a two-year life cycle, during which it acquires the organism by feeding on the white-footed mouse, which serves as the major reservoir for the organism. Transmission to humans occurs when the tick has a prolonged (24-48 hour) attachment to the skin.

In California, the Western black-legged tick, *Ixodes pacificus*, transmits the *B burgdorferi* to humans, resulting in LD. These ticks have three life stages. The larvae and nymphs are found in low moist vegetation such as leaf litter. Adults are more commonly found on tips of grasses and shrubs. These ticks are most generally found in the coastal regions and along the western slope of the Sierra Nevada range. Immature ticks feed on rodents, lizards and birds; adult ticks feed on larger animals such as deer. Both nymphs and adult females can transmit LD to humans although nymphs pose a greater risk because of their tiny size (about the size of a poppy seed).

Clinical Manifestations

Following inoculation of the spirochete into the skin, the characteristic lesion of LD, erythema migrans (EM) appears at the site of tick attachment. This lesion often appears as an annular, erythematous rash, non-painful, not pruritic, which may enlarge over several days. The most characteristic and diagnostic form of EM is the so-called bulls-eye. (Fig 1) However, EM may also appear as a cellulitis or as an expanding circular rash without a discernible center papule. For case finding purposes, the CDC requires the rash to be at least 5 cm in diameter.

If the spirochete disseminates from the original site of inoculation, infection may result in various clinical findings including multiple EM, CNS infection (meningitis, facial palsy), cardiac involvement, such as heart block, and arthralgias. Untreated infec-

tion can result in late manifestations of LD, including arthritis (usually monarticular of the knee). (Fig 2). Occasionally, the pediatrician may be faced with a mother who had LD during her pregnancy and is concerned about the possibility of congenital LD. The literature suggests that there is little evidence supporting the concept of congenital LD and that if it occurs, it is very rare.

Clinical manifestations of LD are summarized in Table 1.

Several of the physical findings seen in LD infection in children can be very suggestive or diagnostic of the disease. Facial palsy, an unusual finding in children in general, should lead the pediatrician to strongly consider a diagnosis of LD. Occasionally, infection will result in bilateral facial palsy. Likewise monarticular arthritis of the knee, (usually only mildly painful, not erythematous) should always suggest the possible diagnosis of LD. LD arthritis of the knee can result in a remarkably large effusion which can limit full extension of the knee. Other joints may less often develop arthritis. The presence of EM is diagnostic of LD and is the one manifestation with which pediatricians should be most familiar. Other clinical findings, which should lead the pediatrician to consider the diagnosis of LD, include 1) Second or third degree heart block and 2) aseptic meningitis. LD associated meningitis may be difficult to differentiate from aseptic meningitis secondary to enterovirus.



FIG 1: Typical EM rash of LD on the leg of a child. Note the bulls eye appearance.



FIG 2: Monarticular knee arthritis of LD. Minimal erythema and mild flexion contracture.

Diagnosis

Diagnosis of LD in children depends primarily on classical clinical manifestations, a strong index of suspicion, supplemented by appropriate serological laboratory tests.

Most laboratories perform an enzyme-linked immunosorbent assay (ELISA) to detect serum antibodies to *B burgdorferi*. Because of the excellent sensitivity, but relatively poor specificity of this test, laboratories will frequently confirm a positive ELISA with the Western Blot. This test will detect individual antibodies, to multiple antigens located on the organism, using electrophoresis. This increases the specificity of LD serology. Laboratories generally provide information for the interpretation of these tests.

Serologic testing may be negative in early infection or in children pretreated with antibiotics. On the other hand, serology may be falsely positive in children with EBV mononucleosis or various rheumatologic diseases. Finally, Lyme serology may remain positive for several years after appropriate treatment. Repeat serology is not generally recommended and cannot be used as a "test of cure".

Treatment

Appropriate treatment for LD depends on the stage at which it is diagnosed. Table 2 summarizes the current recommendations.

It is worth noting that facial palsy due to LD may persist for several months after recommended treatment, but usually completely resolves. Also, LD meningitis is occasionally accompanied by papilledema, which may persist for weeks. Finally, LD associated monoarticular arthritis may take up to 3-4 months to resolve after appropriate treatment

Take Home Facts for the Californian Pediatrician:

1. Although rare in California, LD has significant clinical consequences if untreated.
2. Think Lyme in children with facial palsy, monoarticular arthritis and aseptic meningitis (especially if CSF enteroviral PCR is negative or papilledema is present).
3. Learn to recognize EM and ask parents to take a picture of their child's rash if there is a concern for possible LD. EM may disappear before you are able to examine the child in your office.
4. Understand the difficulties associated with LD serology and order it when there is a genuine clinical suspicion.
5. Remember you may see children who have recently moved or are visiting from a Lyme endemic area.

Additional Reading

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Table 1. The main clinical manifestations of Lyme disease

Disease Stage	Timing after tick bite	Clinical manifestations
Early localized	3 -30 days	EM (single) Variable constitutional symptoms (myalgia, arthralgia, fever, headache, fatigue) Regional lymphadenopathy
Early disseminated	3 - 12 weeks	EM (single or multiple) Constitutional symptoms Neck pain Meningitis Cranial neuritis, e.g. facial palsy Radiculoneuritis Carditis (variable heart block) Ocular involvement
Late Disease	>2months	Arthritis

Table 2 Antibacterials useful for treating LD, based on clinical situation

Clinical manifestation	Usual treatment	Length of treatment	Dosage
Early localized LD			
	Doxycycline PO ^a	2 - 4 weeks	Doxycycline: 100mg bid (pediatric: 2-4 mg/kg/day divided bid)
	Amoxicillin	2 -4 weeks	Amoxicillin: 500mg tid (pediatric: 50mg/kg/day divided tid)
	Cefuroxime axetil	2-4 weeks	Cefuroxime axetil 500mg bid (pediatric: 20-30mg/kg/day divided bid)
Early disseminated LD			
No CNS involvement, no more than first-degree heart block	Doxycycline PO ^a Amoxicillin Cefuroxime axetil	4 weeks	Doxycycline: as above Amoxicillin: as above Cefuroxime axetil: as above
With CNS involvement, symptomatic carditis, PR interval >0.3 seconds, or second -or third-degree heart block	Ceftriaxone IV	2 weeks	Ceftriaxone: 2g OD (pediatric 100mg/kg/day)
Late LD			
Arthritis	Doxycycline PO ^a Amoxicillin	4 weeks 4 weeks	Doxycycline as above Amoxicillin: as above
^a Over 8 years of age			

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maternal childcare over the first 4 years of life exhibited slightly less social competence and slightly more adult-child conflict and externalizing behavioral problems at 4½ years of age and kindergarten, as assessed by parents, caregivers and kindergarten teachers. For example, 12-16% of children averaging 30-45 hours/week of childcare vs. 8-9% of children averaging less than 10 hours/week of childcare were considered “at risk” for externalizing behavior problems—i.e., they scored greater than 1 SD above the mean, although two SD is considered the level of clinical behavior problems. These behaviors include “assertiveness” (e.g., bragging, arguing a lot), “disobedience” (e.g., failing to carry out assigned tasks, disrupting school discipline), and “aggression” (e.g., getting into many fights, hitting others, destroying own things). The risk for behavioral problems was found to increase with increasing cumulative hours in childcare. Associations between the outcomes and the timing of entry into childcare were inconclusive.

The authors stated, “data seem consistent with Belsky’s (1999, 2001) conclusion that it is early, extensive, and continuous care—and thus cumulative quantity of care—that is most likely to be predictive of lower levels of socio-emotional adjustment,” and “Results such as these suggest that the first 6 months of life is not a sensitive period per se, but rather that the effects of earlier experiences...are contingent on later experiences.”

Although these findings raise concern, other findings may moderate the concern. The authors state, “the overwhelming majority did not score in the at-risk range, even when considering those experiencing the most child care.” Even among the children scoring “at-risk,” most were within the normal range and few scored within the range of clinical behavioral problems. In all, the effect sizes for childcare quantity on child behavior were low to moderate. In fact, several other factors were found to be important predictors of behavior. The authors noted, “The most consistent and

strongest predictor of all developmental outcomes...was maternal sensitivity. When mothers provided more sensitive care, their children evinced greater social competence, fewer problem behaviors, and less conflict with adults both at 54 months and in kindergarten.” In addition, higher quality care, higher maternal education, greater income, lower maternal depression, less childcare center attendance, and being a girl were all associated with a lower risk of behavior problems and greater social competence.

Study Limitations

Since this is not a randomized study, the results may be biased by any underlying differences between the maternal- and non-maternal childcare cohorts. Other than rating infant temperament at 6 months of age, the study did not fully explore the interaction between children’s individual temperament and childcare characteristics; and it is possible that a certain subset of children are temperamentally more sensitive to the effects of child care. Also, this study classified care by fathers in the same category as other childcare providers; but as more mothers and fathers share key parenting and childcare roles, perhaps it would be more appropriate to consider the effects of parental (maternal and paternal care) vs. non-parental child care.

Summary

This study raises important issues about the effects of childcare factors (quantity, quality, and type of childcare) and family characteristics (maternal sensitivity, maternal depression, maternal education, and family income) on children’s socio-emotional development. Based on the research, pediatricians can take some key steps to support families and childcare programs to promote children’s socio-emotional development:

- Provide guidance and support for families in their child rearing, emphasizing the importance of being sensitive and responsive to their children’s cues.
- Advise parents what to look for in child care: the type of childcare (either home-based, family childcare or center) that fits their child’s age, temperament and special needs; and good quality childcare with small group sizes and adequate adult-child ratios, nurturing and responsive caregivers, developmentally appropriate activities, and a safe and healthy environment. Refer them to their local Child Care Resource and Referral agency⁷ for information

on choosing childcare and local options.

- At each well-child visit:
 - Ask whether there are any changes in childcare, how the child is adjusting to childcare, and if they have any questions or concerns.
 - Screen for maternal depression. If a mother appears depressed, refer her to her primary care provider or mental health provider.
- If a child appears to have developmental or behavioral problems, make sure the child gets a full assessment. Work closely with the parent and the childcare provider to gather information about the child’s development and behavior, and develop a plan of action to implement consistently at home and childcare.
- Contact a local childcare program to offer a workshop on child development and behavior.
- Advocate for longer parental leave from work, greater financial assistance for low-income families, and greater funding and training for quality childcare.

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7. Call California Child Care Resource and Referral Network (800) 543-7793 or visit www.rnnetwork.org to find your local agency.



Dollars and Sense: Working Towards a Statewide Immunization Registry

Dean A. Blumberg, M.D., FAAP and
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California, like most other states, has made great strides in increasing the number of children who are immunized against debilitating and deadly diseases, but we have a good ways to go before we reach our goals to give children and communities maximum protection. Reaching the current target of 90% up-to-date immunization rate will require much effort from many people and organizations at the state and local levels in California. Extensive record keeping, follow-up, and coordination between healthcare providers, schools, and parents are needed to keep children from falling through the cracks.

C3I

The California Coalition for Childhood Immunization (also known as C3I) provides a statewide setting that brings together people from children's advocacy, healthcare provider associations (including District IX of the American Academy of Pediatrics), health plans, public health, state and federal agencies, academia, research settings, pharmaceutical companies, service organizations, and local immunization coalitions to strategize and advocate for immunization of all California's children and youth. C3I is a non-profit organization consisting of a public/private partnership of representatives from the organizations mentioned above. These leaders are working to improve childhood immunization rates by providing immunization education, supporting local immunization coalitions, and advocating for childhood immunization at a policy level as well as with the media.

Immunization Registries

One of the top goals of AAP District IX and C3I is to facilitate the development of a statewide immunization registry. An immunization registry is a confidential, computerized database that captures and consolidates children's immunization information in one central place. Shot records are entered into the registry at the healthcare provider's office or clinic. These records can be retrieved from the registry database if a child moves, changes healthcare providers, or if a parent loses the

California Regional Immunization Registries FY 2003-04 (Provisional)



printed immunization record card. The registry also forecasts due dates for upcoming immunization appointments, and generates reminder notices to help healthcare providers keep their patients on schedule.

How Will This Impact My Practice?

Pediatricians have enthusiastically embraced registries. The integration of immunization registries into the private sector has been facilitated with the assistance of local public health expertise as well as immunization coalitions. In the office, there is reduced paperwork for medical staff and less "calling around" to look for previous immunization records because rapid access to immunization records is available. Direct costs to healthcare providers are minimal, less than \$1 per child per year. And these costs are more than offset by the significant staff resource savings and more efficient record keeping. Registries increase employee

productivity by 20%.

Up-to-date immunizations are required by law for children to go to school (unless the parent signs an exemption), and licensed childcare centers must keep immunization records on each child by law. Schools and childcare centers can use the registry to make sure that students' immunizations are up-to-date when they register at school or childcare. By and large, parents are grateful for the help that registries provide in maintaining their child's current and complete records.

Security

State-of-the-art technology, California law, and implementation procedures protect registry information, including patients' privacy and physicians' records. Federal HIPAA guidelines permit provider practices and health plans to

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Retirement Options

Joan Hodgman, M.D.

The following two articles discuss life after retirement by two pediatricians who have retired from their busy private practices. One chose to stay in medicine and the other to leave medicine entirely. Their stories serve an interesting contrast to the retirement paths available.

...DULL OR BORING?

Doris A. Graves, MD

In the Spring 2003 edition of *California Pediatrician*, Joan E. Hodgman, M.D. stated, "Retirement should not be dull or boring." I agree. When I decided to "retire" from the private practice of pediatrics I was not planning to be bored. I was not expecting to travel around the world or to sit by the pool and watch the ripples in the water. My plans included extending my volunteer hours as attending physician at the Los Angeles County + University of Southern California Medical Center, continuing as a volunteer medical director at Camp Conrad/Chinnock and giving more hours of service to my church.

I have continued as a volunteer attending physician at the Pediatric Diabetic Clinic at LAC+USC where I started working 40 years ago ...

Did this happen? More than I expected. I ended up being the Nursery-Preschool Coordinator at my church ("since I knew so much about children" said the Minister of Family Life.) This has involved getting volunteer teachers for the children from birth through kindergarten, working with the teachers to get supplies for their lessons, and substituting when a teacher or helper did not show up. I now realize that working in the office one-on-one with a child is a lot different than "herding cats." That is how I describe working with the 2- and 3-year-olds in groups of 3 to 12 children. Don't get me wrong; it is fun, but three hours with these children is more exhausting than an 8-10 hour day in the office.

Another unexpected and interesting job developed when I was asked to temporarily join the Endocrine Department at Childrens Hospital of Los Angeles to see "pediatric" patients while they were short staffed. I spent a half-day a week for 16 months there (with pay) working up patients that needed primary care evaluation but were referred to CHLA for "endocrine" evaluation. Many of these patients had thyroid problems, but the bulk (not meant to be a pun) were referred for obesity. I will never forget the 16 year old who weighed 220 kg (not pounds). He ate enough for breakfast to feed an entire family of six.

Yes, I have continued as a volunteer attending physician at the Pediatric Diabetic Clinic at LAC+USC where I started working 40 years ago at the end of my residency. This half day each week has been a priority in my life not understood by many of my peers. I found to my surprise that some of them assumed I was getting paid for this time. I am, but not with money, only with the satisfaction of following the patients and working with the residents every week. After "retirement" I asked if I might be of use in the Endocrine Clinic. I was welcomed with opened arms. Since I am not an endocrinologist I am comfortable working with the "thyroid" patients, but I work up the rest of the patients like a resident and present them to the chief attending. I am enjoying this learning situation and am trying to bring my

knowledge up-to-date. Nothing boring about this! Pediatric ward attending one month a year is another undertaking I have continued since completing my residency. One must always remember that you do NOT tell the residents about "how hard it was when I was a resident." We have all heard that from our predecessors and didn't believe it.

I have just completed my 31st year as a volunteer medical director at Camp Conrad/Chinnock which serves more than 400 children with diabetes each summer. I am also on the board of directors for Diabetic Youth Services, Inc., the sponsoring agency of the camp.

As a member of the board of directors of the Diabetic Camping Association, I meet twice a year with representatives of numerous camps from the United States, Canada, and several other countries. We have an international conference about every 18 months. This year it was held in Nova Scotia. Did I say I wasn't planning world travel? My husband and I spent an additional time after the meeting and toured the Maritime Provinces of Canada.

Since I have "so much spare time" I continue to serve on the Board of Governors of the Occidental College Alumni Association and on the Communications Committee of that organization.

Have I left out anything? Yes. Keeping up

with our four children and their spouses and five grandchildren keeps us hopping from Simi Valley, California to as far as Louisville, Colorado to attend school functions, graduations, and other special events. Frequent babysitting of the youngest grandchild since he was five weeks old to his current age of four has been more the job of my husband since I am away part of most week days. We both marvel at the little things involved in the growth and development process that we didn't enjoy as much with our own children.

Is life after retirement dull or boring? No! I was told by my mother that a missionary friend of hers stated that "retirement means taking off the old tires, putting on new ones and continuing to roll along."

Advice to pediatricians contemplating retirement...

As you contemplate retirement, I have several comments and questions.

Be sure you want to retire. For many of us are in small private practices where there is no part-time. It is full time or nothing. In larger groups, a part-time option might be available. Do you have specific plans? Are you planning to continue in some kind of medical work or are you leaving medicine behind?

If you plan to volunteer or work part-time in a medical capacity, will you be provided malpractice insurance? Volunteering at a University Medical Center or school district will likely provide malpractice coverage while you are on-site. Outside volunteer groups usually cannot afford the insurance and probably neither can you. Medical mission trips outside of our country may be quite fulfilling and generally you won't need malpractice coverage.

If you are leaving medicine altogether, what plans do you have – hobbies, travel, writing, or...? Do you have the finances and physical stamina to accomplish your goals and dreams? Physicians are not used to being bored. Doing nothing for a few weeks or months is about all you will be able to take, so make some specific plans. Your club, church, schools, senior center, etc. would probably be happy to have you volunteer to help whether it is clerical, gardening, baby sitting, or odd jobs. Just ask!

If the time is here, GO FOR IT.

Doris A. Graves, M.D.

MY RETIREMENT

J. Richard Settlemayer, M.D.

A brief personal history: Started pediatric residency in 1956 at Los Angeles County+University of Southern California Medical Center. Married in 1957 and subsequently had seven children and one neonatal death. Spent two years after residency at Camp Pendleton taking care of Marine kids. Then to Whittier, California to practice pediatrics with Drs. John Mac Donald and Sherrod Swift.

I no longer have any desire to practice pediatrics nor to get back to the telephone race.

We developed a very large general Pediatric practice. I began daily teaching rounds for one month yearly in the LAC+USC nursery in 1961 and continued until 1985. I saw neonatology develop into a speciality and was director of a Level 2 Neonatal unit from 1975 to 1990. I was Chief of Staff of my hospital 1976-77. My wife died in June of 1992 after 35 years of happy and successful marriage.

During the 1970s, when I was very active in neonatology, my wife pointed out to me that I was becoming more impatient than usual. It was suggested that I take up woodworking. I went to parochial schools, which did not offer any shop courses, so I enrolled in a woodworking class at our local high school. I could cuss at that wood, spit at that wood, kick that wood, and could usually repair my damage and at the same time was able to really enjoy the diverse things I could do with it.

Perhaps a bit of medical history is appropriate now. My father died at age 57 of a coronary. In December 1985, at age 56, I had a coronary and angioplasty with no further symptoms. In the fall of 1999, I had a mild stroke with little residual. In July of 1994, I had back surgery and in 2000, a knee replacement.

With our children scattered over California, we had decided that when we retired we would be close in proximity to the children but would not live that close to any of them. We felt we all needed our independence, but if family was needed we would be close enough to be there. Between Los Angeles and San Diego, the Murrieta/Temecula area seemed good. In 1993, I purchased my new abode. Of course I

named it "Paradise." I was 65 miles from my office and would require a commuting time of 2½ to 3 hrs per day, four days a week, for a couple of years. I moved in July 1, 1994.

We had a number of Indian reservations in Temecula and I thought I would like to donate to their medical care. I interviewed at one of the clinics and was told they would welcome me on a voluntary basis. I did not want to be tied down to a rigid schedule as I had decided that I really wanted to see the world while I could get around on my own. I volunteered with the Bureau of Indian Affairs in January

1996 but was told they had a budget that was required to be spent and that I could be hired as a regular employee only. I continued to work three days a week, Tuesday, Wednesday, and Thursday in my pediatric practice, however it was a different kind of pediatrics than I was used to. If I were to have a case of bronchitis, pneumonia, or otitis media I rarely was able to see its follow up. It was like emergency medicine. That was not how I had practiced pediatrics for 40 years and I wanted to travel. I must admit I relished the idea of NO TELEPHONE CALLS. I had grown to hate that telephone and my beeper! I no longer had to spell out PEDIALYTE at 2 A.M.

In 1996, I completely left pediatrics (except for 15 grandchildren) and went on a four week tour of Germany and Spain with friends. During the trip, I met a nurse who was a widow from upper state New York. We had very much in common and were married in 1997. We have traveled extensively to all the continents so far but Antarctica. There is just so much to see and so little time to see it all.

When I'm at home I still do a lot of woodworking. I have a complete wood working shop in my third garage with a central vacuum, table saw, band saw, cut off saw, joiner/planer etc. I've made sanctuary furniture for a local church, furniture for my kids, rocking horses for my grandchildren and now am making a dollhouse for each family (working on number four). I am a Eucharistic Minister at our church and visit one of our hospitals once a month, bringing communion to an assisted living and Alzheimer unit and also to the dying for our local parish.

I entered a new community, which was a challenge. I was no longer Dr. Settlemayer where most people were familiar with my name but now it was Mr. Settlemayer, an ego change. Admittedly, sooner or later it comes out that I am a doctor. It is really not difficult to make new friends, just get involved and try not to be the leader. I am amazed at the number of patients and friends I had in the Whittier area who have subsequently migrated to the Temecula Valley. I'm also amazed when I see a graying lady or gentleman come up to me and say that I was his or her pediatrician. I usually say that it was "probably my father," as I'm sure I'm too young to have been there in their time!

I really loved pediatrics and it was very good to me. I am very grateful for the wonderful experiences I have had and to all the physicians who have given me these opportunities. I no longer have any desire to practice pediatrics nor to get back to the telephone race (or now feel naked without a cell phone!) It would take too much of my time to attempt to keep up with all of the new technology and stay proficient in the care of medical emergencies and general care of children. There's just so much to see and do that for me would leave too little time to devote to medicine the way I would want to do it. I am very content with my new partner in life and hope we will be able to continue to spend our time traveling and seeing the world, making new friends and renewing acquaintances. For me, life has been wonderful and full.

Advice to pediatricians contemplating retirement...

How did I make a decision of when and how to retire from pediatrics? I first had to have a purpose to retire into. Faith, that I could be fulfilled in doing something other than pediatrics. To be able to feel that the remaining time I had could be as full as I desired. I will always be grateful for the many wonderful experiences pediatrics has given me and my retirement days will also give me many things to be grateful for. Lastly, I planned on activities that others in my age group have found time to do. I would belong to a group which has paid its dues and now desires to do things which please me, things I can do when I want and have a feeling of contentment and satisfaction that my time is really my own. I love retirement!!!

J. Richard Settlemayer, M.D.

participate in immunization registries. In addition, parents must be informed before having their child's record included in the database, and retain the right to participate or not.

Immunization Registries Make A Difference

In California, there are nine regional immunization registries (including one in the planning phase) coordinated by the Statewide Immunization Information System (see figure on page 29). The regions work with local County Public Health Departments and clinics, and partner with private sector health plans, doctors' offices, and hospitals to ensure all relevant health care settings can use the registry. At the present time, 20% of children in California have been enrolled in this system. Regions participating in the registry have shown dramatic increases in the percentage of 2-year old children who have become fully immunized: an increase of 42% in San Luis Obispo County, 30% increase in San Diego

care providers, health plans and the California Department of Health Services. Savings from manually calculating immunizations, manually completing official patient immunization record cards, HEDIS reports, manual chart reviews in public health clinics, and costs for the National Immunization Survey add up to \$4.6 million annually. Finally, reduced disease and decreased overimmunization of children with incomplete immunization histories would save \$3.7 million annually.

Add it all up: spending \$12 million would save the state \$15.2 million per year. Looking at this another way, the lack of a statewide immunization registry is costing the state over \$3 million annually.

Note that the above cost analysis applies only to the state budget. Of course, the private sector will also be able to take advantage of the registry with an estimated additional savings of \$16.8 million annually.

Widespread Support

In addition to California AAP and C3I, the development of a statewide registry is endorsed

State-of-the-art technology, California law, and implementation procedures protect registry information, including patients' privacy and physicians' records.

County, and 15-24% increases in San Bernardino and Riverside Counties.

However, these regional registries each stand alone. Ideally, the regional registries would be linked via a state hub. Registries used by major health plans (e.g., Kaiser) would also be linked. The hub would function to unify the system, and to store, transmit, and analyze immunization data at the state level. The state registry would be more useful for children moving from one region to another in California. Once state registries are up and running, the ultimate goal is complete linkage to create a nationwide immunization registry.

Other states have recognized the benefits attainable from a statewide immunization registry. For example, Arizona documented a 35% increase in immunization coverage, and Oregon had a 7% increase after only one year.

So How Much Is This Going to Cost?

It is estimated that funding of a state hub would cost \$12 million annually. Given the current budget crisis in California, it may seem audacious to contemplate additional spending. However, consider the benefits to the State of California of a statewide immunization registry. First, verifying immunizations records is more efficient with a registry in place. Schools and WIC would realize \$6.9 million in savings every year due to reduced workload. Secondly, there is a vast amount of paperwork related to immunizations required for health

by the California Medical Association, California Academy of Family Physicians, California School Nurses Organization, California State Association of Counties, and the California State PTA.

Moving California Forward

California's size and diverse health care provider environment create challenges delivering needed immunizations in a timely manner. We should join other states in achieving higher immunization rates, and reducing preventable illnesses and deaths among California children.

SB 1764: Your Support Is Needed

California District IX AAP is working with C3I to encourage the funding of the state registry hub. We applaud Senator Jackie Speier for introducing a bill (SB 1764) to this end. A statewide immunization registry will benefit California children, their parents, schools and childcare, pediatricians and other healthcare providers, and the state itself.

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Diversity in California: Appreciating Diverse Cultural Traditions and Celebrations

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Lyme Disease: What California Pediatricians Should Know

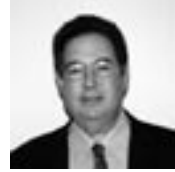
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CMA House of Delegates 2004 Report



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Effects of Childcare on Children's Social and Emotional Development

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District Report



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for diagnosis and treatment. Yet the developing world stands to benefit the most from simple interventions, and the burden of disease has shifted in Vietnam from infectious diseases to injuries and chronic diseases thanks to UNICEF programs teaching an integrated approach to disease management. Project Vietnam and its members sometimes get criticism from the Vietnamese-American community for working in North Vietnam and with the government. Yet our medical mission group grows larger every year, now an international team spanning four continents, our training team is in demand to present at medical schools and lead institutions as well as provinces, and we have ongoing projects at the National Institute of Pediatrics dealing with newborn hearing loss, infection control, neonatal respiratory distress, pediatric emergency services, child development evaluation, asthma survey, and we actively foster the development of pediatric specialties and comprehensive preventive child health services. Our chief engineer has volunteered in Vietnam for 18 months and has developed a basic respiratory device, a CPAP manufactured locally, which improved neonatal mortality within the first 24 hours by 20%. It will be licensed later this year as the first medical equipment produced in Vietnam. Every single project has the potential of becoming national guideline, now that the pediatric leadership has discovered the pathway to initiate healthcare policy. Often we lend our voice to recommend crucial health protocols, potentially costly to a system straining for resources. We will continue to work in provinces of most needs to improve one life at a time, but every survey done and intervention piloted in rural areas can find its way to create lasting improvements for everyone. Moreover, pediatricians have been empowered to advocate tirelessly for children. Across the oceans, we are all the same at heart, professionals who have chosen to be "dedicated to the health of all children.

SARS CONTINUED FROM PAGE 3

been exposed before the problem was recognized. Most facilities today, unfortunately, do not have the capacity to handle large numbers of patients who require respiratory isolation.

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VIGAMOX™

(moxifloxacin hydrochloride ophthalmic solution) 0.5% as base

DESCRIPTION: VIGAMOX™ (moxifloxacin HCl ophthalmic solution) 0.5% is a sterile ophthalmic solution. It is an 8-methoxy fluoroquinolone anti-infective for topical ophthalmic use.

Clinical Studies: In two randomized, double-masked, multicenter, controlled clinical trials in which patients were dosed 3 times a day for 4 days, VIGAMOX™ solution produced clinical cures on day 5-6 in 66% to 69% of patients treated for bacterial conjunctivitis. Microbiological success rates for the eradication of the baseline pathogens ranged from 84% to 94%. Please note that microbiologic eradication does not always correlate with clinical outcome in anti-infective trials.

INDICATIONS AND USAGE: VIGAMOX™ solution is indicated for the treatment of bacterial conjunctivitis caused by susceptible strains of the following organisms:

Aerobic Gram-positive microorganisms:

*Corynebacterium species**, *Micrococcus luteus**, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Staphylococcus haemolyticus*, *Staphylococcus hominis*, *Staphylococcus warneri**, *Streptococcus pneumoniae*, *Streptococcus viridans* group

Aerobic Gram-negative microorganisms:

*Acinetobacter lwoffii**, *Haemophilus influenzae*, *Haemophilus parainfluenzae**

Other microorganisms:

Chlamydia trachomatis

*Efficacy for this organism was studied in fewer than 10 infections.

CONTRAINDICATIONS: VIGAMOX™ (moxifloxacin HCl ophthalmic solution) is contraindicated in patients with a history of hypersensitivity to moxifloxacin, to other quinolones, or to any of the components in this medication.

WARNINGS: NOT FOR INJECTION.

VIGAMOX™ solution should not be injected subconjunctivally, nor should it be introduced directly into the anterior chamber of the eye.

In patients receiving systemically administered quinolones, including moxifloxacin, serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported, some following the first dose. Some reactions were accompanied by cardiovascular collapse, loss of consciousness, angioedema (including laryngeal, pharyngeal or facial edema), airway obstruction, dyspnea, urticaria, and itching. If an allergic reaction to moxifloxacin occurs, discontinue use of the drug. Serious acute hypersensitivity reactions may require immediate emergency treatment. Oxygen and airway management should be administered as clinically indicated.

PRECAUTIONS: General: As with other anti-infectives, prolonged use may result in overgrowth of non-susceptible organisms, including fungi. If superinfection occurs, discontinue use and institute alternative therapy. Whenever clinical judgment dictates, the patient should be examined with the aid of magnification, such as slit-lamp biomicroscopy, and, where appropriate, fluorescein staining. Patients should be advised not to wear contact lenses if they have signs and symptoms of bacterial conjunctivitis.

Information for Patients: Avoid contaminating the applicator tip with material from the eye, fingers or other source.

Systemically administered quinolones including moxifloxacin have been associated with hypersensitivity reactions, even following a single dose. Discontinue use immediately and contact your physician at the first sign of a rash or allergic reaction.

Drug Interactions: Drug-drug interaction studies have not been conducted with VIGAMOX™ solution. *In vitro* studies indicate that moxifloxacin does not inhibit CYP3A4, CYP2D6, CYP2C9, CYP2C19, or CYP1A2 indicating that moxifloxacin is unlikely to alter the pharmacokinetics of drugs metabolized by these cytochrome P450 isozymes.

Carcinogenesis, Mutagenesis, Impairment of Fertility:

Long-term studies in animals to determine the carcinogenic potential of moxifloxacin have not been performed. However, in an accelerated study with initiators and promoters, moxifloxacin was not carcinogenic in rats following up to 38 weeks of oral dosing at 500 mg/kg/day (approximately 21,700 times the highest recommended total daily human ophthalmic dose for a 50 kg person, on a mg/kg basis). Moxifloxacin was not mutagenic in four bacterial strains used in the Ames *Salmonella* reversion assay. As with other quinolones, the positive response observed with moxifloxacin in strain TA 102 using the same assay may be due to the inhibition of DNA gyrase. Moxifloxacin was not mutagenic in the CHO/HGPRT mammalian cell gene mutation assay. An equivocal result was obtained in the same assay when v79 cells were used. Moxifloxacin was clastogenic in the v79 chromosome aberration assay, but it did not induce unscheduled DNA synthesis in cultured rat hepatocytes. There was no evidence of genotoxicity *in vivo* in a micronucleus test or a dominant lethal test in mice.

Moxifloxacin had no effect on fertility in male and female rats at oral doses as high as 500 mg/kg/day, approximately 21,700 times the highest recommended total daily human ophthalmic dose. At 500 mg/kg orally there were slight effects on sperm morphology (head-tail separation) in male rats and on the estrous cycle in female rats.

Pregnancy: Teratogenic Effects. Pregnancy Category C: Moxifloxacin was not teratogenic when administered to pregnant rats during organogenesis at oral doses as high as 500 mg/kg/day (approximately 21,700 times the highest recommended total daily human ophthalmic dose); however, decreased fetal body weights and slightly delayed fetal skeletal development were observed. There was no evidence of teratogenicity when pregnant Cynomolgus monkeys were given oral doses as high as 100 mg/kg/day (approximately 4,300 times the highest recommended total daily human ophthalmic dose). An increased incidence of smaller fetuses was observed at 100 mg/kg/day. Since there are no adequate and well-controlled studies in pregnant women, VIGAMOX™ solution should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: Moxifloxacin has not been measured in human milk, although it can be presumed to be excreted in human milk. Caution should be exercised when VIGAMOX™ solution is administered to a nursing mother.

Pediatric Use: The safety and effectiveness of VIGAMOX™ solution in infants below 1 year of age have not been established.

There is no evidence that the ophthalmic administration of VIGAMOX™ has any effect on weight bearing joints, even though oral administration of some quinolones has been shown to cause arthropathy in immature animals.

Geriatric Use: No overall differences in safety and effectiveness have been observed between elderly and younger patients.

ADVERSE REACTIONS: The most frequently reported ocular adverse events were conjunctivitis, decreased visual acuity, dry eye, keratitis, ocular discomfort, ocular hyperemia, ocular pain, ocular pruritus, subconjunctival hemorrhage, and tearing. These events occurred in approximately 1-6% of patients. Nonocular adverse events reported at a rate of 1-4% were fever, increased cough, infection, otitis media, pharyngitis, rash, and rhinitis.

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