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EDITOR’S NOTE: WHY “THE SECOND SENSE”?

In his article “A sociology of smell,” Canadian anthropologist Anthony Synnott recounts Aristotle’s hierarchy of the senses, in which sight had primacy, followed secondarily by the sense of hearing, “whose beauty and music.”

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changes in the field. We have seen tremendous private practice for 39 years as a pediatrician in the process we often have at least one middleman (insurance companies) and sometimes some other administrative group; both get a cut of the pie. For centuries, we were referred to as physicians or doctors. Now we are addressed by the demeaning title, “providers” (we received our degrees in medicine, not “providology”). 

Finally, we have seen many of our services being performed in big chain pharmacies (eg, CVS) by a “doc in the box.” Who knows what you get there! It is time that we as pediatricians step up and stop being a bunch of wusses. We share much of the blame for allowing this sad state of affairs to happen. I do not believe that our organizations such as the AAP (and certainly not the AMA) represent the average pediatrician in practice. If we do not help ourselves, who will? If we want our best and brightest to choose careers in medicine, and pediatrics in particular, we must do something lest we see a further demise of our profession.

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Vaccinating moms to protect babies

The US Food and Drug Administration (FDA) is struggling to know how to set guidelines for research to bring about more maternal vaccination as a means of protecting the infant.

"Scientific advances and increasing recognition of unmet potential have led to a recent surge in activity and interest in maternal immunization," the agency said in a background paper for a hearing in November 2015.

There are currently no vaccines licensed specifically for use during pregnancy for the purpose of protecting the infant or the woman. However, there are some vaccines that are recommended for use in pregnancy.

The Centers for Disease Control and Prevention Advisory Committee on Immunization Practices (ACIP) has recommended that seasonal influenza vaccine be given to pregnant women and that Tdap be given in the third trimester. In addition, the ACIP recommends that hepatitis A and B, meningococcal, and pneumococcal vaccines be given only when the potential risks outweigh the potential benefits.

Vaccines being considered for development and for use in pregnancy to protect the infant include those for group B Streptococcus and respiratory syncytial virus.

However, the ethical and logistical issues around doing the research are difficult, speakers at the hearing told the agency.

Among the complexities is the fact that when there is a low disease incidence, clinical trials with disease endpoints may not be feasible in this country, said Marion F. Gruber, PhD, director of the FDA's Office of Vaccines Research and Review.

For the inactivated influenza vaccines and Tdap that are licensed and already recommended for use in pregnancy, doing trials that are placebo controlled or controlled with an unrelated vaccine could be considered unethical or logistically challenging. There may be a need, Gruber said, for using endpoints in studies other than clinical disease and using study designs other than randomly controlled trials.

Over a number of years, a division at the National Institute of Allergy and Infectious Diseases has taken vaccines for maternal immunization for 6 pathogens to Phase I or Phase II clinical trials. Those are group B Streptococcus, Haemophilus influenzae type b, Streptococcus pneumoniae, pertussis and respiratory syncytial virus, and influenza.

Richard Gorman, MD, associate director of the Division of Microbiology and Infectious Diseases, National Institutes of Health, said vaccines to be studied in pregnant women ideally should have had preclinical studies done on them and reproductive toxicology testing should show no fetal toxicity. In addition, he said, the vaccine should have had Phase I and II clinical trials done in nonpregnant healthy adults, providing guidance on dosage, safety and immunogenicity.

The FDA pointed out that another complication is that with some vaccines immunizing the pregnant woman may interfere with the baby's mounting an optimal response to the same vaccine or another vaccine.

After the committee had discussed other factors surrounding maternal vaccination, Vicky Pebsworth, PhD, RN, director of patient safety at the National Vaccine Information Center, said she had never seen a more complex topic in her years on the committee, indicating the day was a tsunami of ethically complex and terrifying questions.

Bruce Gellin, MD, director of the National Vaccine Program Office in the US Department of Health and Human Services, said the goal is to have seamless protection of the infant. This work may even allow researchers to reevaluate and possibly "decompress" the vaccine schedule for infants, he said.
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Our system of care provides the most comprehensive pediatric services in the Southwest today, from general pediatrics to specialty care. And we’re pioneering exploration and discovery in genomics and personalized medicine in the region with the new Phoenix Children’s Research Institute, envisioned to be the nation’s hub for translating medical discovery into the lifesaving treatments of tomorrow.
Obese kids visit the ED more often

A study that followed more than 19,500 children aged from 2 to 18 years for about 8 years found that those who were overweight or obese made more hospital emergency department (ED) and outpatient clinic visits than children of normal weight.

Investigators obtained electronic height, weight, and utilization data for participants—all residents of a single county in Minnesota—and calculated baseline body mass index (BMI). They categorized BMIs as underweight/healthy (<85th percentile), overweight (85th to <95th percentile), and obese (≥95th percentile). At baseline, 14.5% of children were overweight and 11.7% were obese. The retrospective analysis of participants’ medical records adjusted for potential confounding factors: age, sex, race, chronic medical conditions, and socioeconomic status. More than 5% of participants had chronic medical conditions, including upper respiratory disorders, skin disorders, osteoarthritis and joint conditions, anxiety/depression/bipolar, attention-deficit/behavior disorders, asthma, chronic neurologic problems, developmental disorders, headaches/migraines, back problems, diabetes, or dyslipidemia. The percentage of children with 3 or more chronic medical conditions rose with increasing BMI category.

Compared with children whose BMI was below the 85th percentile, those who were overweight and obese had more ED visits, even after adjustment for confounding factors. Of the total study population, 62% had at least 1 ED visit during the study period, with 4 indications accounting for 68% of all ED visits: accident/injury (34.2%), acute respiratory disease (16.8%), acute gastrointestinal (10.4%), and psychiatric/substance abuse (6.4%). As obesity status increased, so did frequency of ED visits for the 2 most common indications, accidents/injuries and acute respiratory problems. A higher BMI also was associated with moderately increased risk of outpatient clinic visits, but baseline BMI category did not affect the risk of hospitalizations (Lynch BA, et al. Acad Pediatr. 2015;15[6]:644-650).

Hospitals vary widely in rate of computed tomography scanning

Tertiary pediatric institutions differ greatly in how often they use computed tomography (CT) imaging, whether for emergency department (ED), inpatient, or observation encounters, and regardless of body region. Overall use of CT imaging is decreasing, however. These were the major findings of an analysis of 2009 to 2013 data extracted from the Pediatric Health Information System (PHIS) and encompassing more than 12.5 million patient encounters and 701,644 CT scans in 30 hospitals.

Overall, a mean of 56 scans were performed per 1000 encounters, with hospital-specific rates ranging from 26 to 108 scans per 1000 encounters. Body regions most often
imaged were head (60.1%), abdomen/pelvis (19.9%), neck (8.4%), and chest (7.7%). Imaging of the abdomen/pelvis, neck, and chest were most likely in inpatient/observation encounters and head scans in ED treat-and-release situations.

Unadjusted rates of CT scanning varied nearly 4-fold between hospitals with the lowest and highest scanning rates. Case mix—All Patient Refined Diagnosis Related Group and severity—accounted for 49% of the variability and hospital volume accounted for an additional 15%, with higher volume hospitals scanning at lower rates. This leaves 36% of the variability in use of CT imaging unexplained. The authors suggest that this variability may be attributable to differences in institutional or clinician practices (Lodwick DL, et al. Pediatrics. 2015;136[5]:e1212-e1219).

**Journal club**

**E-cigarette use likely leads to future cigarette use**

Adolescents and young adults who reported using electronic cigarettes (e-cigarettes) in a national survey were more likely to have progressed to smoking cigarettes 1 year later than their peers who did not use e-cigarettes. The survey was conducted in 694 individuals aged from 16 to 26 years who had never smoked cigarettes and were not susceptible to doing so in the future, as ascertained with several survey questions.

Only 16 of total participants (2.3%) used e-cigarettes at baseline. Whereas 31.3% of these e-cigarette users at baseline progressed to “susceptible” status, only 9.3% of those who did not use e-cigarettes at baseline made this progression. Similarly, 37.5% of individuals who used e-cigarettes at baseline progressed to cigarette smoking compared with 9.6% of those who did not use e-cigarettes. These findings held even after adjustment for multiple variables (Primack BA, et al. JAMA Pediatr. 2015;169[11]:1018-1023).

**Also of note**

Adjunctive laser acupuncture reduces the need for morphine therapy in neonatal abstinence syndrome (NAS). In a randomized trial in neonates with NAS, 28 infants received either laser acupuncture combined with pharmacologic therapy (morphine and phenobarbital) or pharmacologic therapy alone. Compared with those in the pharmacologic therapy alone group, infants who also received laser acupuncture required morphine therapy for a shorter period and had a significantly reduced hospital stay (Raith W, et al. Pediatrics. 2015;136[5]:876-884).
Hearing loss & the pediatrician

PAT F BASS III, MD, MS, MPH

Pediatric hearing loss is a very treatable problem. The pediatrician needs to be aware not only of always screening in the newborn, but also of indications for referral and workup as children get older.

With newborn hearing screening mandated in all states, the pediatrician has seen a profound reduction in the age when hearing loss is identified, and advances in treatment now allow treatment at very early ages. Pediatricians who have been in practice for some time will remember not detecting hearing loss until there was a failure to develop language at age 2 to 3 years in patients with severe hearing loss. In patients with milder forms of hearing loss, the age often was much later.

Newborn hearing screening is very good, but it is not perfect and will miss a number of cases. The pediatrician needs to be aware not only of always screening in the newborn, but also of indications for referral and workup as children get older. This article focuses on screening for hearing loss, risk factors for hearing loss, the physical exam, and workup of hearing loss as well as a brief discussion of treatment.

Early hearing detection and intervention

The American Academy of Pediatrics (AAP) recommends pediatricians follow the early hearing detection and intervention (EHDI) 1-3-6 plan that outlines what hearing assessments and referrals need to be completed before age 6 months. In brief, the EHDI 1-3-6 plan...
recommend currently mandated hospital-based screening and identification of a medical home for each infant. Infants who pass hospital-based screening will go into routine developmental and hearing-based screening in the pediatrician’s office.\textsuperscript{1,2}

In terms of ongoing care for all infants, the pediatrician should:
- Provide parents with information on hearing, speech, and language milestones, with instruction to notify the pediatrician with any concerns.
- Identify and treat any middle-ear disease.
- Provide appropriate vision, hearing, and developmental screening.
- Refer for audiologic evaluation for any parental concern related to speech, hearing, or language development.
- Refer any high-risk child for audiologic evaluation at least once before age 30 months:
  - Family history of hearing loss
  - ICU (neonatal intensive care unit) stay of more than 5 days
  - TORCH (toxoplasmosis, other infections [syphilis, varicella-zoster, parvovirus B19], rubella, cytomegalovirus [CMV], herpesvirus) infections
  - Infections associated with hearing loss such as bacterial or viral meningitis
  - Craniofacial anomalies
  - Suggestion of a syndrome associated with hearing loss (eg, Alport syndrome)
  - Neurodegenerative disorders (eg, Hunter syndrome) or sensory motor neuropathies (eg, Friedreich ataxia)
  - Head trauma
  - Chemotherapy

Any patient who failed screening, had an incomplete screening, or needs rescreening should be referred for otoacoustic emission (OAE) or auditory brainstem response (ABR) testing by age 1 month. Passing would place the infant into normal developmental screening.

If the infant fails at the 1-month screening, referral for a diagnostic evaluation should be made to a center capable of performing pediatric audiologic assessment with OAE, ABR, frequency-specific tone bursts, air/bone conduction, and the ability to sedate an infant in some cases. This assessment should be completed by age 3 months, and referral for intervention services should be made before age 6 months. Referral should include an otolaryngologist at a minimum and strong consideration for referral to an ophthalmologist because ophthalmologic abnormalities are increased among children with hearing loss.\textsuperscript{3} Additional referrals to a geneticist, developmental pediatrics, and other subspecialists (eg, cardiologist, nephrologist) as appropriate should be considered.

**Screening for hearing loss in older children**
The pediatrician will need to be able to screen for hearing loss beyond the newborn period to identify acquired hearing loss (eg, meningitis, noise exposure), progressive or delayed hearing loss (eg, neurodegenerative syndromes, intrauterine infections), or hearing loss not identified on newborn screens. With addition to the monitoring of children with the previously mentioned risk factors, use of digital music players is another risk factor that should be considered.\textsuperscript{4}

Older children and adolescents who may need a formal hearing screen may be identified by asking screening questions. Anyone with a positive response to any of the following questions adapted from the National Institute on Deafness and Other Communication Disorders (www.nidcd.nih.gov/health/hearing/pages/10ways.aspx) should trigger a more formal hearing evaluation:
- I hear but don’t always understand what others are saying.
- I have trouble hearing when others speak softly.
- I have trouble understanding someone if they are speaking in a different room.
- I have trouble hearing others when I am at a restaurant.
- I have trouble hearing others speak when they are not facing me.
- People tell me to turn down the TV.
- I find it hard to hear when I am in a group setting.
- I have difficulty catching most of the words when I go see a play or movie.
- I have trouble hearing on the
telephone.

I have trouble making out the words in songs.

One note of caution: A 2014 study utilizing the 10 hearing screening questions from the AAP’s Bright Futures program failed to identify adolescents at risk for hearing loss. The subjective assessment seemed to miss students with higher-frequency hearing loss, and the authors concluded that an objective screening measure may be preferred over the Bright Futures subjective assessment for routine preventive care.5

Office-based screening
A complete discussion of audiology screening is beyond the scope of this article. Screening older children in the office, however, can be done with any of these tools: OAE, in-office audiology, and otoscope audiograms. Any patient with an abnormal result should be referred for formal audiologic evaluation.6

Risk factors for hearing loss
Perinatal history. TORCH infections are the classic diseases leading to hearing loss attributed to prenatal exposure. Only CMV, however, remains a substantial cause of hearing loss today.7 Prematurity is another important risk factor with particular attention to the infant’s course noting hypoxia, sepsis, hyperbilirubinemia, and exposure to potentially ototoxic antibiotics or diuretics.8

Family history. A family history of hearing loss at a young age raises suspicions for a genetic cause. Because many genetic causes are autosomal recessive in nature, many present in families in whom no other child is impacted.8

Delays in milestones. Delays in motor milestones can be seen with cochleovestibular anomalies, vestibular disorders, some syndromic causes of hearing loss, and some acquired infectious causes of hearing loss such as meningitis.8

Infections and immunizations. It is important to remember that not all cases of meningitis are diagnosed. The pediatrician should be careful to look for hospitalizations in which antibiotics were administered. Review of immunizations is also important because unimmunized children remain at increased risk of acute otitis media that can be complicated by meningitis.8

Noise exposure. Assessing high-risk activities is important in the older child or adolescent presenting for hearing loss. Particular attention should be paid to the child’s use of earphones and MP3 players because this risk is commonly underappreciated by parents.8

Physical examination
Physical examination of the child with hearing loss should include developmental assessment, measurement of growth parameters, and a general assessment focused on manifestations of syndromic hearing loss such as the examples listed in the Table.8 Particular focus on the head and neck exam is important. In a retrospective study of 114 children with hearing loss referred to a tertiary care center, head and neck abnormalities helped to establish the etiology of hearing loss in more than 40%—primarily craniofacial anomalies.9 Other abnormal physical findings of the head and neck to look for in patients with hearing loss include heterochromia of the irises; malformation of the auricle or ear canal; dimpling or skin tags around the auricle, cleft lip or palate; asymmetry or hypoplasia of the facial structures; and microcephaly.8

The preauricular area and outer ear should be examined for pits or sinuses, size and shape of the pinna, and patency of the external auditory canal. Significant cerumen should be removed because it also can lead to hearing loss. The tympanic
membrane should be examined and pneumatic otoscopy performed. The tympanic membrane needs to be examined for perforation, scarring, and middle-ear fluid. Otitis media with effusion is a leading cause of acquired hearing loss, and acute otitis media may lead to short-term hearing loss.6-8

In older children and adolescents, hearing status can be assessed in the office using 256-Hz and 512-Hz tuning forks. These tools can also be used to perform the Weber and Rinne tests to help determine a conductive versus a sensorineural hearing loss (SNHL) etiology.8

**Workup**

Routine evaluation in a patient with unexplained SNHL has been questioned, citing low diagnostic yield.10 Laboratory testing, based on history, physical, and results of hearing testing is a reasonable approach.

A urinalysis and electrocardiogram (ECG) on initial diagnosis of a new SNHL can detect several rare conditions. Proteinuria suggests a diagnosis of Alport syndrome, whereas an ECG may demonstrate a prolonged QT syndrome that might otherwise manifest with syncope or sudden cardiac death that is preventable with beta blocker therapy.11

Testing for congenital CMV infection and targeted genetic testing can identify the cause for hearing loss in many newborns.12

Imaging is another consideration in patients with SNHL. Abnormalities on computed tomography and magnetic resonance imaging are reported in up to 40% of children with SNHL or mixed hearing loss, according to 1 series.10 Abnormalities help identify a cause of the hearing loss and help guide treatment. In some practices, ordering of imaging is deferred to the otolaryngologist because the most appropriate test depends on the particular situation and is in debate in the otolaryngology community.13,16

**Treatment**

Treatment of hearing loss depends on etiology. Pressure equalization tubes for the tympanic membrane may improve hearing for children with middle-ear effusion, Eustachian tube dysfunction, or recurrent acute otitis media. Tumors and cholesteatoma require surgical excision or mastoidectomy. Some conditions that cause conductive hearing loss also can be treated with either surgery such as atresia or stenosis of the external auditory canal.

Hearing amplification is the next step in the treatment of hearing impairment. Although establishing an etiology is desirable, amplification before age 6 months is associated with improved outcomes and should not be delayed if an etiology is not yet established.17,18

Hearing aids will be recommended after an audiologic evaluation and based on child age, type of hearing loss, and patient family preference.19 Some patients who will not benefit from a standard hearing aid may benefit from a device that transmits sound through bone. These are available as an external device as well as a bone-anchored implantable hearing aid system. There also are systems now available that directly vibrate the ossicles in the middle ear.20,21

Cochlear implants are recommended for severe-to-profound bilateral SNHL in cases in which hearing aids have not been beneficial.22,23 Bilateral cochlear implants have been advocated to improve functional hearing and performance in settings with a lot of background noise and to increase ability to localize sound.24,25

Hearing loss today is a very treatable problem. The pediatrician needs to understand the importance of newborn hearing screening and how to manage abnormal results, as well as understand when and why referral may be needed, how to work up a complaint of hearing loss, and the importance of referral. ■

For references, go to ContemporaryPediatrics.com/pediatric-hearing-loss
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WEB SITES

Managing Allergic Reactions: Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of the vaccine.

Incidence of Intussusception: No safety or efficacy data are available from clinical trials regarding the administration of RotaTeq® to infants who are potentially immunocompromised including: Infants with blood dyscrasias; infants with known or suspected primary immunodeficiency; infants with symptomatic HIV/AIDS; infants with solid organ or hematopoietic stem cell transplantation; or infants with congenital or acquired immunodeficiency.

Gastrointestinal Illness: No safety or efficacy data are available for administration of RotaTeq® to infants in whom the diagnosis could not be made with confidence. In a post-marketing observational study in the US cases of intussusception were observed in temporal association within 27 days following the first dose of RotaTeq®, with a median of 6 days.

In worldwide post-marketing surveillance, cases of intussusception have been reported in temporal association with RotaTeq®.

Fertile Illness: Fertile ill babies may be in danger of delaying use of RotaTeq® except when, in the opinion of the physician, withholding the vaccine would entail a greater risk. Lower-risk (=<100°F [38°C]) fever and mild upper respiratory symptoms and diarrhea are not considered to be a contraindication to the use of RotaTeq®.

Shedding and Transmission: Shedding of vaccine virus was evaluated among a subset of subjects in REST within 4 to 6 days after each dose and among all subjects who submitted a stool antigen rotavirus positive sample at any time. RotaTeq® shedding of rotavirus-specific antigen was detected in 2 of 38 (5.3%) RotaTeq® vaccine recipients and 1 of 38 (2.6%) placebo recipients after dose 1; 1 of 40 (2.5%), 1 (2.5%), and 1 (2.5%) vaccine recipients tested after dose 2 and in 1 of 38 (2.6%), 1 (2.6%), and 1 (2.6%) placebo recipients after dose 3. All rotavirus virus shedding was observed as early as 2 days after vaccination and as late as 15 days after a dose. Transmission of vaccine virus was not evaluated in phase 3 studies. Transmission of live vaccine virus was not observed to non-vaccinated contacts in post-marketing studies.

The potential risk of transmission of vaccine virus should be weighed against the risk of acquiring and transmitting natural virus. Caution is warranted when administering RotaTeq® to infants with immunodeficiency close contacts such as: Individuals with malignancies or who are otherwise immunocompromised; individuals with primary immunodeficiency; or individuals receiving immunosuppressive therapy.

Incomplete Registry: The clinical studies were not designed to assess the level of protection provided by one or more doses of RotaTeq®.

Limitations of Vaccine Effectiveness: RotaTeq® may not protect all recipients against rotavirus infection.

Post-Exposure Prophylaxis: No clinical data are available for RotaTeq® when administered after exposure to rotavirus.

ADVERSE REACTIONS

Clinical Studies Experience: 7,775 infants were evaluated in 3 placebo-controlled clinical trials including 3,818 in the RotaTeq® and 3,957 in the placebo groups. Parent/guardians were contacted on days 1, 7, 14, and 21 after each dose regarding intussusception and any other serious adverse events. The racial distribution was as follows: White (65%), American Indian (13%) and other races (22%); Black (8%) in both groups; Multiracial (5% in both groups); Asian (2% in both groups). Native American (2% in both groups). The gender distribution was 52% male and 48% female in both vaccination groups. Because clinical trials are conducted under conditions that may differ from normal clinical practice, adverse reaction rates reported below may not be reflective of those observed in clinical practice.

Severe Intussusception: Serious adverse events occurred in 0.4% of recipients of RotaTeq® when compared to 0.2% of placebo recipients within 42 days after the first dose in the clinical studies of RotaTeq®. The median age for the first serious adverse event was 2 months and the vaccine related serious adverse event was intussusception (RotaTeq vs. 0.7% Placebo), gastroenteritis (0.2% RotaTeq vs. 0.3% Placebo), pneumonia (0.2% RotaTeq vs. 0.2% Placebo), fever (18.1% RotaTeq vs. 0.1% Placebo), and primary intussusception (0.1% RotaTeq vs. 0.1% Placebo).Diarrhea was the most frequently reported serious adverse event for RotaTeq compared to placebo.

Intussusception: In REST, 34,077 vaccine recipients and 34,748 placebo recipients were monitored by active surveillance for signs of intussusception or any GI symptoms of intussusception at 3, 7, and 42 days after each dose, and every 4 weeks thereafter for 1 year after the first dose. For the primary safety outcome, cases of intussusception occurring within 42 days of any dose, there were 6 cases among vaccine recipients and 5 cases among placebo recipients (N=115 and N=115 respectively). Relative risk (95% CI)† 1.6 (0.4, 6.4)

Day Range

Relative risk

Placebo

Rota Teq

1

2

5

1.6 (0.4, 6.4)

All of the children who developed intussusception recovered without sequelae with the exception of a 9-month-old male who developed intussusception 98 days after dose 3 and died of post-operative sepsis. There was a single case of intussusception among 2,470 recipients of RotaTeq® in a 7-month-old male in the phase 1 and 2 studies (7/1,388 placebo).

Hematocrits/Hemoglobin: Hematocrits were reported as an adverse experience occurred in 0.5% (281/5,935) of vaccine and 0.6% (357/5,930) of placebo recipients within 42 days of any dose. Hematocrits reported as a serious adverse event occurred in 0.2% (9/4,350) of vaccine and 0.1% (4/4,350) of placebo recipients within 42 days of any dose.

RotaTeq® Efficacy and Safety Trial.

n (%) n (%)

Diarrhea

Vomiting

咽炎

Table 4: Solicited adverse experiences within the first week after doses 1, 2, and 3 (Detailed Safety Cohort)
Unusual abdominal pain in an 8-year-old boy

KUMARA V NIBHANIPUDI, MD, FAAP, FAAEM; RANIA HABAL, MD; DEEPALI JAIN, MD

THE CASE

A previously healthy 8-year-old Hispanic boy presented to the emergency department (ED) with a 2-day history of abdominal pain and 2 episodes of nonprojectile vomiting in the last 24 hours. There were no other accompanying symptoms. Past medical history and review of symptoms was unremarkable. Initially, the child and mother denied any use of medications. The family history was noncontributory.

Physical examination
Physical examination revealed a well-developed, well-nourished obese child in no acute distress. Vital signs were normal. Head, eyes, ears, nose, and throat examination was normal, and lungs were clear with good air entry. Cardiovascular examination was normal. Abdominal examination showed no abdominal distention, bruises, or lacerations.

There was moderate tenderness in the epigastric area and right upper quadrant. Bowel sounds were normal. Rectal examination was normal, and stool guaiac was negative. Neurologic examination revealed normal sensorium.

No obvious cranial nerve deficits and no motor and sensory deficits were noted. Deep tendon reflexes were symmetric, with downgoing toes bilaterally. Clinical suspicion of acute appendicitis, hepatitis, and acute cholecystitis prompted laboratory analysis and computed tomography (CT) scan of the abdomen.

Laboratory results revealed metabolic acidosis; elevated serum ammonia 270 mcg/dL (normal 15-45 mcg/dL); and marked elevation of liver enzymes, aspartate transaminase (AST) 1764 U/L (normal: 5-37 U/L), alanine transaminase (ALT) 2608 U/L (normal: 30-65 U/L), with a normal bilirubin level. The CT scan of the abdomen was deferred because preliminary laboratory tests suggested acute hepatic necrosis. Detailed inquiry regarding medication use suggested aspirin ingestion (2 tablets, strength unknown) 3 days prior to the patient presenting to the ED. Intravenous fluids were started; urine was sent for drug toxicology; and blood samples were drawn to determine prothrombin time and partial thromboplastin time.

Diagnosis
While waiting for the laboratory results, the child became more combative and disoriented. This change

TURN TO PAGE 29 FOR DIAGNOSIS.▶
Unidentified children who are deaf or hard of hearing may have delayed speech and language development that can interfere with daily functioning. Unidentified hearing loss also places a cost burden on families and the healthcare system, with the lifetime educational cost of hearing loss estimated in 2007 at $115,600 per child.1

As such, early screening for hearing loss is now mandated by 41 states, the District of Columbia, and Guam, all of which have passed statutes or regulatory guidance on ways to identify infants with hearing loss.1 In addition, The US Preventive Services Task Force, the Recommended Uniform Screening Panel (US Department of Health and Human Services Secretary’s Advisory Committee on Heritable Disorders in Newborns and Children), and the Joint Committee on Infant Hearing (JCIH) have recommended hearing loss screening in all newborns.

To help ensure that infants receive early screening, Early Hearing Detection and Intervention (EHDI) programs are now established in all jurisdictions within the United States. Based on evidence-based public health approaches, EHDI programs...
focus on both early screening of newborns as well as continual follow-up through tracking and surveillance with the coordinated help from public health agencies, clinical service providers, and families.\(^1\)

The importance of follow-up is highlighted by the prevalence of hearing loss throughout childhood because of, for example, late onset hearing loss or acquired hearing loss. In light of this, the American Academy of Pediatrics (AAP), along with the JCIH, recommends that newborns and children be monitored for hearing loss and additional hearing screening during early childhood within a medical home.\(^1\)

In 2002, the AAP published a policy statement to help clarify the concept and operational definition of the medical home.\(^2\)

In 2006, with support from the AAP, the National Center for Hearing Assessment and Management (NCHAM), and the Center for Childhood Deafness at Boys Town National Research Hospital in Nebraska conducted a national survey of primary care physicians to examine their knowledge, skills, and practices in participating in an EHDI program within a medical home.\(^3\) Results of the survey showed important gaps in knowledge among the physicians surveyed, including knowing when and where to refer infants for follow-up procedures; implementing surveillance for late-onset hearing loss; understanding the role of genetics in hearing loss; and familiarity with cochlear implants and criteria for candidacy.

In 2012-2013, a second survey was undertaken to gauge the progress made in improving physician understanding and skill since the 2006 survey.\(^4\) Rachel St. John, MD, director of the Family-Focused Center for Deaf and Hard of Hearing Children, Children’s Medical Center/University of Texas Southwestern Medical Center, Dallas, presented the latest results of this survey at the recent AAP National Conference and Exhibition in Washington, DC.

This article provides a summary of St. John's presentation, highlighting the gaps in knowledge that persist despite ongoing programs and efforts to ensure that hearing loss is correctly identified and treated in all infants and children. Key components of an effective EHDI program in the medical home setting will be described and resources provided to facilitate a clear and, hopefully, easy way for primary care physicians, pediatricians, and others to implement hearing loss screening within a continuum of care.

### Gaps in screening for hearing loss in children

In the 2012-2013 updated survey,
primary care providers across 24 states were surveyed about their understanding and attitudes regarding newborn hearing screening and follow-up. The survey included questions regarding knowledge of the current standards of practice recommended by the AAP known as the EHDI “1-3-6” timeline (Table 1) and the role of the medical home in hearing loss screening (Table 2).

Of the 2172 (11.5%) responders, 53.8% were pediatricians followed by 27.4% family practice physicians, 7.2% otolaryngologists, 3.1% neonatologists, and 0.6% obstetrician/gynecologists. Most responders practice in a metro area (56.5%) and were in private practice or community clinic (81.8%). Table 3 lists key gaps in knowledge that remain since the 2006 survey.

The survey also found that 29% of providers reported performing newborn hearing screening in their office, although few of those (only about 23%) used objective screening methods such as otoacoustic emissions. Importantly, most of these 29% of providers who do rescreening in their office rarely or never report results to their state EHDI coordinator, which goes against recommended policy, according to St. John.

These results highlight one of the key gaps found in the study, namely, a lack of knowledge of methods recommended for follow-up of in-office newborn hearing screening. Table 4 provides a detailed list of recommendations for providers who perform in-office newborn hearing screening. Note, although it is not prohibited to conduct the initial hearing screening in the office

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### GUIDELINES FOR RESCREENING IN THE MEDICAL HOME

For infants who do not pass their initial hospital-based hearing screening:

<table>
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<tr>
<th>Reporting</th>
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<tr>
<td>○ Report all normal and abnormal screening results to the state EHDI system (see <a href="http://www.infanthearing.org/status/cnhs.html">www.infanthearing.org/status/cnhs.html</a> to locate EHDI state coordinator).</td>
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<th>Equipment</th>
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<tr>
<td>○ Use a physiologic measurement, such as OAE technology, to rescreen hearing in infants (not a behavioral response to sounds or noises).³</td>
</tr>
<tr>
<td>○ Equipment used must be calibrated by the manufacturer so that the device is documented as capable of separating “pass” from “not-pass” at a level capable of detecting hearing loss of at least 30 dB.</td>
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<tr>
<td>○ Equipment must be maintained and recalibrated on a regular basis and at least annually.</td>
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<tr>
<th>Proper screening technique</th>
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<tr>
<td>○ Conduct the test in a quiet environment to minimize the risk of ambient noise.</td>
</tr>
<tr>
<td>○ Rescreen the infant only once at a single office visit to prevent delay in identifying a hearing loss. Infants who do not pass the rescreening should be referred to a qualified audiologist.</td>
</tr>
<tr>
<td>○ No more than 3 tests of each ear with the OAE probe should be used for rescreening. Refer the infant to a qualified infant audiologist if he/she fails to pass 3 probe tests.</td>
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<tr>
<td>○ Test both ears when rescreening, even if only 1 ear failed to pass the initial screening test.</td>
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<th>Communication of results</th>
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<tr>
<td>○ Convey results of rescreening to families in a culturally competent and sensitive manner to ensure understanding.</td>
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<tr>
<td>○ Tell families that screening does not provide a definitive diagnosis and strongly encourage them to take the next appropriate step for diagnostic testing. Convey this message in a way that does not provoke undue anxiety.</td>
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<th>Delayed-onset hearing loss</th>
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<tr>
<td>○ Delayed-onset hearing loss may be diagnosed at a later time after an infant initially passes a screening test.</td>
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<tr>
<td>○ If a caregiver expresses concern about the infant’s hearing or a delay in language development, or if the infant has risk factors for hearing loss, referral should be made for a pediatric audiology evaluation.</td>
</tr>
</tbody>
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³Normal hearing is not ensured in all infants who pass an OAE on rescreening. Those who did not pass an AABR at initial hospital screening should be rescreened with an AABR. If the infant does not pass an OAE on rescreening, then a hearing loss is likely. An AABR should always be used to initially screen infants hospitalized in the neonatal intensive care unit, and any rescreening should be done by an audiologist with experience of infants.

Abbreviations: AABR, automated auditory brainstem response; dB, decibel; EHDI, early hearing detection and intervention; OAE, otoacoustic emission.

From: American Academy of Pediatrics Task Force on Improving Newborn Hearing Screening, Diagnosis, and Intervention.⁵
setting, the AAP always encourages initial screening in the hospital.

**Resources to better adhere to EHDI**

A number of resources are easily available to pediatricians and other healthcare providers to better adhere to EHDI:

- **Familiarity with the “1-3-6” model:** St. John highlighted this resource as the most critical for providers to understand and implement (Table 1). The survey showed that physicians are not uniformly familiar with these recommendations, she said, and that familiarity with the recommendations will help providers address a delay in the development of hearing loss; understand the etiology of the hearing loss and need for further follow-up assistance by referral to specialists; and awareness of the risk of late-onset hearing loss.

- **AAP EHDI Tools:** St. John encouraged providers to take advantage of tools on the AAP EHDI website to help in clinical decision making. (See bit.ly/hearing-screening-EHDI-tools.) Table 5 lists several tools for pediatric primary care physicians.

- **Connect with state EHDI Coordinators:** St. John emphasized that providers who do newborn screening need to report results to the state. (See a list of state EHDI coordinators at www.infanthearing.org/status/cnhs.php.)

St. John ended her talk by encouraging pediatricians and physicians to spread the word about EHDI to residents (eg, through such venues as noon lectures, grand rounds, specialty rotations) and other staff physicians (eg, through grand rounds, state and national conferences).

**REFERENCES**


OME: Autoinflation study yields mixed reviews

JOHN JESITUS, MA

A new study that examined the use of autoinflation with a nasal balloon for otitis media with effusion (OME) has drawn criticism for the findings.

A recent randomized, controlled trial showing the utility of balloon autoinflation for otitis media with effusion (OME) in general practice perhaps raises more questions than it answers, experts tell Contemporary Pediatrics.

Drawing from 43 family practices in the United Kingdom, researchers randomized 320 children to receive either usual care or usual care plus balloon autoinflation (Otovent, Abigo Medical, Askim, Sweden; various manufacturers) performed 3 times daily for 1 to 3 months. The device requires children to inflate a balloon through a nozzle inserted into 1 nostril, then the other.

To satisfy inclusion criteria, children aged 4 to 11 years had to have objective otoscopic and tympanometric confirmation of OME in 1 or both ears (ie, at least 1 flat or type B tympanogram) at the time of randomization. Children also had to have a history of hearing loss or other relevant ear-related problems in the previous 3 months. Investigators excluded children with signs of acute otitis media, such as fever, ear pain, or otoscopic features of acute inflammation.

At the 1-month follow-up, investigators advised children who still had a flat tympanogram in either ear to continue with autoinflation for another 2 months. At each follow-up visit, children treated with autoinflation were more likely to have achieved tympanometric resolution than those who did not: 1-month adjusted relative risk (RR), 1.36, 95% confidence interval (CI), 0.99 to 1.88; 3-month adjusted RR, 1.37, 95% CI, 1.03 to 1.83. Analyses for individual ears, adjusted for subjects’ interear correlation, showed that tympanometric resolution was significantly
more likely with autoinflation at 1 month (adjusted RR, 1.38) and 3 months (adjusted RR, 1.41).

“Methodological issues”
The study has drawn criticism, however. Arlen D. Meyers, MD, MBA, says that the publication “adds some data, but because of methodological issues, we can’t say whether autoinflation works or doesn’t for OME.” He is an emeritus professor of otolaryngology at the University of Colorado School of Medicine, Aurora, and editor-in-chief of the Medscape reference, Otolaryngology—Facial Plastic Surgery.

Likewise, a separate group including Fiona McClenaghan, MRCS, Matthew Rollin, FRCS, and Antony Narula, FRCS, wrote a letter to the editors of the Canadian Medical Association Journal, which published the autoinflation study. The letter highlights methodological missteps involving researchers’ diagnosis of OME and the study’s apparently high compliance rate.2

“Our main concern about this investigation was that the authors didn’t diagnose OME,” Rollin says. He is a consultant ears-nose-throat surgeon at Imperial College Healthcare in London. The cardinal symptom of OME is hearing loss, he says, “and the authors apparently didn’t investigate, measure, or report this.” The study protocol mentioned hearing tests, he says, but investigators chose tests that did not meet the International Organization for Standardization (ISO) quality standard. Using ISO-standard hearing tests would have allowed researchers to accurately gauge hearing loss severity and distinguish whether the loss stems from failure of sound transmission or inner-ear or nerve problems, he says.

“Without measuring a child’s hearing loss, it is impossible to diagnose OME, because any hearing difficulty may be [attributed] apparently didn’t investigate, measure, or report this.” The study protocol mentioned hearing tests, he says, but investigators chose tests that did not meet the International Organization for Standardization (ISO) quality standard. Using ISO-standard hearing tests would have allowed researchers to accurately gauge hearing loss severity and distinguish whether the loss stems from failure of sound transmission or inner-ear or nerve problems, he says.

“Without measuring a child’s hearing loss, it is impossible to diagnose OME, because any hearing difficulty may be [attributed] to something else entirely. Even if a child has OME, its severity is graded on the basis of severity of hearing loss, and therefore a proper hearing test is necessary to decide whether intervention should be recommended or not,” Rollin says.

Rather than testing children with parental reports of hearing loss, which have been shown to be poor reflectors of OME, he says, the authors “simply offered screening with tympanometry to all comers, then claimed to have diagnosed OME in some of them.”

Diagnosing OME also requires expert examination of the eardrum, he says. In this regard, he and his co-authors write, “Simple otoscopy

The study seemed to indicate that children who autoinflated had somewhat better reported quality of life than those who did not.

... was performed by a practice-based nurse with unknown experience. Otoscopic findings consistent with OME are neither discussed nor defined.”

For diagnosing OME, says Meyers, tympanometry is reliable but not 100% predictive. Accordingly, “We don’t know, did the fluid clear at 1 month or 3?”

The study seemed to indicate that children who autoinflated had somewhat better reported quality of life than those who did not, notes Meyers. Specifically, Otitis Media Questionnaire (OMQ)-14 scores fell by 0.69 in the treatment group, versus 0.33 in the control group, at 3 months. Additionally, diaries kept by parents showed that children in the autoinflation cohort experienced fewer days with any OME-related symptom or problem than control-group children at 1 and 3 months.

“But the real issue, which was not addressed, is the impact of the intervention on patients’ hearing loss. The study authors really didn’t measure hearing—they measured it with tympanometry, which measures middle ear pressure, as an indicator or surrogate for OME. So it is possible that the kids felt better—they had less pressure or pain in their ears, but they still had hearing loss. So what have you accomplished? It doesn’t matter if a kid has a hearing loss once for 2 weeks or 3 months. How recurrent OME and hearing loss contribute to possible speech and language delay or developmental delay is another whole topic. We’re talking about an acute episode,” Meyers says.

In a letter replying to the concerns of Rollin’s group, study authors write that theirs was “not a population
simply defined by tympanometry” because patients had OME symptoms—a median of 7 in the treatment group and 6 among controls.3

The study authors’ letter continues, “Otoscopy was used primarily to exclude other ear pathology, since the specificity of otoscopy for OME is poor, [and] pneumatic otoscopy is not used reliably in primary care, and is also associated with concealment bias. Tympanometry was performed by trained nurses who used the modified Jerger criteria.”4

Questioning compliance

Rollin and colleagues also question the designation “all or most of the time” used to record families’ compliance with treatment. This ambiguity may explain the 1-month compliance rate of 89%, which, their letter says, “runs contrary to previously reported experience, including our own.”5,6

Meyers adds that 89% compliance is “just not believable.” Investigators chose the 4-to-11-year-old age bracket because they considered this group likely to be capable of complying with autoinflation. However, Meyers says that if one told a 4-year-old to use the device 3 times daily for 3 months while one was at work and unable to supervise, it would not happen. “I’m not saying the authors are lying,” but he questions the validity of the parents’ reporting. Reported compliance at 3 months was 80%.

Study authors contend in their letter that Rollin and co-authors’ references to experiences of poor compliance date back more than 20 years, “so either different explanations/techniques were used, or perhaps perceptions of parents and children have changed. Our pragmatic approach was very acceptable in present-day primary care. If self-report overestimated compliance, we will have underestimated the benefit of autoinflation.”5,6

Still, says Meyers, the balloon device is very technique dependent—its nozzle is designed for insertion while the user is drinking water. “When you swallow, it activates the muscles around the eustachian tube opening, that open the eustachian tube. That’s why sometimes when you swallow, you feel your ears pop—air rushes into the middle ear to equalize the negative pressure.” Based on the study, “I don’t know whether there’s a difference between the autoinsufflation of the eustachian tube passively, or with swallowing. They are different techniques. I don’t know how technique-sensitive autoinsufflation needs to be for it to work, and in whom. All these are minor technical details,” but they confound the study’s conclusions.

Other confounding variables include eustachian tube structure and function, says Meyers. In study patients, “We must assume no craniofacial abnormalities that impact the eustachian tube.” In 5% to 10% of children, he estimates, persistent malformation of the eustachian tubes prevents them from opening, and blowing into the autoinflation device will not help. Such abnormalities occur most frequently in children with cleft palate, cleft lip, or Down syndrome, all of whom have a higher incidence of OME, he says.

The study device is 1 of several ways to manage eustachian tube problems, Meyers adds. The Valsalva maneuver “pops” the ears as occurs during an airplane ride. The Politzer maneuver causes retrograde inflation of the middle ear by forcing air through the eustachian tube, somewhat like the balloon technique does. Eustachian tube catheters work somewhat similarly, he says, but this technique is no longer taught even in otolaryngology, much less primary care. These devices were more uncomfortable than the balloon method, and nearly impossible for young children to master, he explains.

“The bottom line is, the article supports the use of autoinflation—I agree. I don’t think it’s harmful, and in most instances, it has a relatively small complication rate,” he says.

The possible benefits in reducing symptoms and potentially hearing loss probably justifiy use of autoinflation, Meyers says, “although we can’t say 100%. However, we take a lot of medications that aren’t better than watchful waiting. So autoinflation is no different from many other things we do.”

For references, go to ContemporaryPediatrics.com/OME-balloon-autoinflation
in mental status prompted a diagnosis of hepatic encephalopathy, or Reye syndrome (Table). Appropriate management was begun. The patient was started on dextrose 10% in half normal saline solution, given at two-thirds maintenance. An urgent neurologic consultation was obtained. On initial neurologic evaluation, the child appeared somewhat sleepy but was arousable to verbal commands. The cranial nerve examination was normal with no papilledema. Motor examination showed no focal deficits. An urgent noncontrast head CT scan was normal, with no evidence of intracranial edema. Because of concerns about the potential increases in the intracranial pressure and cerebral herniation leading to mortality associated with Reye syndrome, the patient was transferred to a neurosurgical pediatric intensive care unit.

After transfer, the patient’s mental status continued to deteriorate and the child became comatose. A repeat CT scan of the head again revealed no evidence of increased intracranial pressure. An electroencephalogram (EEG) showed severe bilateral hemispheric slowing (2-3 Hz delta activity) with triphasic wave discharges. The clinical presentation and abnormal EEG findings were consistent with a diagnosis of hepatic encephalopathy.

**Epidemiology**

The incidence of Reye syndrome has significantly decreased over the last decade. Reye syndrome most commonly manifests between the ages of 4 and 12 years in children residing...
in rural and suburban communities. This patient, however, was an 8-year-old boy from an inner-city neighborhood. Children aged younger than 5 years have a significantly higher case fatality rate than children aged older than 5 years. From December 1980 to November 1997, 1207 cases were reported to the Centers for Disease Control and Prevention, with a peak of 555 cases in 1980. From 1987 through 1993, 36 cases were reported each year, and from 1994 through 1997 no more than 2 cases were reported each year. This declining incidence is attributed to increased awareness of the association of Reye syndrome with the use of aspirin and other aspirin-containing medications in children with flu-like illnesses (ie, varicella).

No statistical survey has been available since 1997. The majority of the cases have been reported in Caucasians (92.6%), as compared with other races. The patient, however, was a Hispanic child. Most cases occur in the months of December through April.

As mentioned previously, Reye syndrome is usually associated with viral infections, especially influenza B and varicella, when these are treated with salicylates. The case fatality rate is also increased by the presence of diarrhea during the antecedent illness.

Pathophysiology

Pathophysiology in Reye syndrome involves severe, generalized suppression of mitochondrial function, resulting in disturbances in fatty acid metabolism and carnitine function. The reasons for mitochondrial dysfunction are unknown.

The activity of hepatic enzymes including ornithine transcarbamylase (OTC), carbamoyl phosphate synthetase (CPS), and pyruvate dehydrogenase are severely reduced. Hyperammonemia occurs because of acquired deficiency in the activity of OTC and CPS. The major pathologic lesion is microvesicular fatty accumulation in the liver. Electron microscopy shows characteristic changes in mitochondrial morphology. Similar pathologic changes are seen in the brain, with marked edema.

Discussion

Reye syndrome exhibits a stereotypical biphasic course and usually occurs in a previously healthy child. Again, there is an etiologic link between Reye syndrome and the use of aspirin and viral infections. An upper respiratory tract infection or chicken pox is followed by an interval in which the child has seemingly recovered. Then, sudden onset of vomiting starts within 5 to 7 days of the viral illness. Delirium, followed by combative behavior, rapidly progresses to seizures, coma, and death.

Usually there are associated abnormalities of liver function with slight-to-moderate liver enlargement. Jaundice is not present at onset. Focal neurologic signs are usually absent. Cerebrospinal fluid pressure, however, is elevated. Although this case patient presented with mild abdominal complaints, he was found to have right-upper-quadrant abdominal tenderness on clinical evaluation. Assessment of liver function revealed marked elevation of liver enzymes, prompting the diagnosis of Reye syndrome. A review of the literature shows that abdominal pain, as seen in this case, is an uncommon presenting symptom of Reye syndrome. In atypical cases such as this patient, early diagnosis can be aided by a high level of clinical suspicion and assessment of liver function.

Disease progression is usually graded according to severity. Grades 1 through 3 represent mild-to-moderate illness. Grades 4 and 5 represent severe illness. The activity of mitochondrial enzyme glutamate dehydrogenase is greatly increased, and there is 3-fold or higher elevation in serum ammonia levels. Some patients have hypoprothrombinemia, which is refractory to vitamin K therapy. Hypoglycemia is characteristically seen in younger patients, although this patient did not have hypoglycemia.

In recent years, several inherited mitochondrial hepatopathies have been identified that produce an illness similar to Reye syndrome. In children aged younger than 5 years, other metabolic diseases such as organic aciduria and defects in fatty acid oxidation are often identified.
Acid oxidation metabolism such as acyl-CoA dehydrogenase deficiency need to be investigated.

**Treatment and outcome**

Management of Reye syndrome varies with severity of illness. All cases are hospitalized for observation and management. Aggressive therapies are needed in patients with rapid progression and neurologic deterioration. All patients should receive 10% to 15% glucose initially. In patients with cerebral edema, fluids should be restricted to two-thirds maintenance. In more severely ill patients, aggressive management of raised intracranial pressure is needed with intracranial pressure monitoring.

Despite aggressive management, the patient’s liver function deteriorated and his neurologic status worsened. He was electively intubated and transferred to a pediatric liver transplant center.

Dr Nibhanipudi is professor of clinical emergency medicine, New York Medical College, Valhalla, New York. Dr Habal is assistant clinical professor of emergency medicine, New York Medical College. Dr Jain is attending physician-NICU at Kings County Hospital Center, Brooklyn, New York. The authors have nothing to disclose in regard to affiliations with or financial interests in any organizations that may have an interest in any part of this article.

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We’ve made yours “to go”
In his final installment of the series “Pearls from the trenches,” Dr. Farber encourages pediatricians to think outside the box, to trust their “sixth sense” when it comes to treating patients, and always to look at what they are doing from the parents’ and child’s point of view.

This is my final installment of pearls. The articles have been a collection of practical tips gleaned mostly from in-office experience rather than textbooks. As such, any pediatrician can generate his or her own. There are several tricks for doing this. First and foremost is to keep an open mind and question imparted wisdom, even if ultimately accepted. I have heard it said that half of what we practice now will be out-of-date in 10 years, but the trick is to know which half. It is also important to analyze your own clinical approaches from time to time (eg, is it necessary to check deep tendon reflexes at an annual checkup?), and avoid treating children by rote, especially when your “sixth sense” suggests something atypical is going on. Try to think outside the box; it will make your job more fun. Lastly, always put yourself in the parents’ and child’s shoes, and look at what you are doing from their perspective. It will make you a much better pediatrician.
PARENT TIPS AND CONCERNS

1. After a febrile seizure, parents often have their child sleep with them, but they will not volunteer this information to you. I tell parents that only prolonged seizures are dangerous, and if the child sleeps through a short febrile seizure, that is unimportant. If their child is going to have a long seizure, they will hear strange noises from the room, and it will wake them (eg, if they have a monitor). Then they can deal with it.

2. If parents are frustrated by a baby with colic, they should take a break and go somewhere to decompress. The baby is going to cry anyway, and an upset and exhausted parent is not an effective one.

3. Family members often use specific terms as generics, and you need to be careful about this when taking a family history. Migraines mean headaches; bronchitis means a cough or asthma; croup often refers to a wet cough; and wheeze can mean stridor.

4. Fever is not 99°F.

5. If the fever began late Saturday night and it is now Monday morning, the parents will tell you, correctly, that it has been 3 days. It is more accurate to think in terms of hours (36 hours in this case).

6. Acts of commission are worse psychologically than acts of omission. If a child is given a rotavirus vaccine and he or she is one of the rare children who get intussusception from it, parents will feel that they have done a terrible thing, but if they don’t give the vaccine and their child is one of the large number that wind up hospitalized, they can console themselves that it was just meant to be. This is why it is necessary to convince some parents to try to look at risks objectively. A vaccine is not 100% safe, but it is safer than the alternative.

7. Parents (and others) have unusual views of risk/benefit. They will drive to the office even if they live within 3 miles and have an easy 1-hour walk. Although the drive is clearly more dangerous and they think nothing of it, they can shirk from vaccines with a much better risk/benefit ratio. (Having said this, I am comfortable with them driving, as long as they minimize the risks with car seats, not speeding, etc. Sometimes one must be practical.)

8. Nosebleeds come from the septum. That is where you need to pinch to stop bleeding, not below the nose or at the top of the bridge, as I have heard families do. It is sometimes necessary to reassure families that a child will not bleed to death from a nosebleed during sleep.

9. Predicting roseola in the office, when the child still has a fever, can save the family a trip back when the rash arrives.

10. Cool compresses can help nausea.

11. Show parents what their newborn can do (eg, grabbing with toes and fingers, placing/stepping/Galant reflexes). It gives them an early feeling of pride in their child.

12. “Blood” in the urine of a newborn is urate crystals. When parents come in with that as a chief complaint, tell them before you look at it that the diaper will be pink, not red. (Exception: Sometimes there can be a mini-period in girls.)

CONTINUED ON PAGE 35

LANGUAGE PEEVES

Now that an acceptable meaning for the word “literally” is “figuratively” (my head literally exploded when I read that), these are probably just the rantings of a curmudgeon, but they rankle nevertheless.

1. When presenting a case, do not describe a patient as a “7-year-old male boy.” Because “male” can be a noun, he can be just a “7-year-old male,” and I can infer he is a child from his age.

2. “Its” is the possessive form, while “it’s” means “it is.” If you are not sure which to use, substitute the phrase “it is” where you think it may go, and see if that fits.

3. A “septic workup” indicates that you introduced potentially fatal microbes while performing it. Please wash your hands, use sterile technique, and perform a “workup for sepsis” instead (I am willing to bend and accept a “sepsis workup”).

4. If a child is “nauseous,” it means he induces nausea in others. Very few children have this quality; the term you seek is probably “nauseated.”

5. When an inexperienced walker goes up stairs, the child usually puts 1 foot on the first step, then the other foot on the same step.
1 Numbers are useful, but they are not the be-all and end-all. Numbers may add gravitas, but they do not make a factoid a fact.

2 Don’t admit a complete blood count (CBC) or a pulse ox (within reason) to a hospital; admit because the child warrants it, not the lab work.

3 Stimulants are performance-enhancing drugs. Trying someone on one is not the way to make a diagnosis of attention-deficit/hyperactivity disorder (ADHD). The whole question of whether to give someone a stimulant if he or she is doing poorly in school, but does not have clear-cut ADHD, is a major ethical problem in pediatrics.

4 Do not order a test for your own piece of mind just to make sure, but only because you have a legitimate clinical reason for so doing. Any test not worth doing is worth doing twice. For example, if you order a CBC and it is unexpectedly abnormal, you will now want to get a second one to confirm that the first was misleading. Not ordering unnecessary tests will also avoid Ulysses syndrome, a long and pointless voyage (eg, after false positive findings) that never should have begun in the first place.

5 Calling it a sinus infection so you can use an antibiotic still does not justify the antibiotic.

6 If the “levo” or “dex” portion of a medicine were inactive, why would there be fewer adverse effects from a product such as levalbuterol or dexmethylphenidate, as the manufacturers claimed when the products were first unveiled?

7 Clarithromycin is taken more often per day, for a longer period of time, and causes more nausea, but apart from that, what other advantages does it have over azithromycin? (I know the latter has a black-box warning, but I have to expect one to show up on clarithromycin soon as well.)

8 Celebrities harm children by advocating against vaccines. Jenny McCarthy accuses vaccines of causing autism in her child, a disproven concept. This is from someone who actively promotes the use of tobacco. If she wants to spout an unproven theory and blame a foreign substance, I think silicone exposure would be a more likely candidate. Dr. Oz personally uses an alternative vaccine schedule, but he does recommend the American Academy of Pediatrics vaccine schedule. However, if you watch the clips from his show (available at www.doctoroz.com/videos/what-causes-autism-pt-4), the reason is (although he states it more diplomatically) because he feels most people aren’t smart enough to do what he has done.

9 In Virginia, one is required by law to tell patients that a negative Lyme test is not necessarily accurate (the law is quiet on the more likely false positive), so that now a negative test will not reassure a needlessly worried parent.

10 In Florida, at the present time, the law forbidding physicians from asking about guns in the home is still upheld. This should raise the hackles of any pediatrician, regardless of where one stands on the second amendment. Fortunately, it is not illegal to give advice about the potential dangers of guns (eg, to the parents of a depressed teenager).

11 In the past, the drug companies used to provide lunch for the office in exchange for a local ophthalmologist presenting a canned lecture on Vigamox. This talk included a statement that, given the nature of the product, the development of bacterial resistance was very unlikely. The speaker was not a microbiologist, but someone who just rehashed the company line. I am not a microbiologist, either, but it struck me at the time (and still does, years later), that that statement just couldn’t be true. The eventual development of resistance is the rule, not the exception.

12 Expert opinion in the past has included sepsis workups and hospitalization for antibiotics on all children aged younger than 2 months with fever; lumbar puncture and daily phenobarbital treatment for febrile seizures; lactose-free diets for diarrhea; and so on. Expert opinion has its place and may be informed, but it is not grounded in hard data and is only opinion. Always remember this, including in reference to anything you may have read in these articles.

REFERENCE

WORDS TO LIVE BY

1. Don’t send someone to an otolaryngologist to consider tubes unless you have already decided the patient could benefit from them.

2. Anticonvulsants interfere with the metabolism of many different medicine families including antibiotics, thyroid hormones, and psychopharmacologic agents.

3. Mood changes are not uncommon with stimulants.

4. Nasal aspirators are not needed unless there is mucus seen. Blindly aspirating will usually just irritate the nose in a child with a cold.

5. There is nothing wrong with a pediatrician changing a soiled diaper in the nursery. It is not necessary to close it back up surreptitiously and pretend it was clean.

6. Acne medicines prevent lesions, rather than treating preexisting ones. This is why acne medicines do not work right away, and why one has to treat areas with acne and not just individual pimples. Patients must understand this for them to comply with treatment.

7. A child who asks for a pull-up is toilet trained. The task, then, is just to phase in sitting on the toilet. For example, the child can be told that he can only have his diaper in the bathroom, then while standing next to the toilet, then while sitting on the toilet, etc.

8. It’s a problem if it’s a problem; otherwise it is just an observation. For example, sensory-integration dysfunction manifested by disliking tags on the back of shirts is treated by removing the tags, not by occupational therapy.

9. Do not make a diagnosis if you do not know what is going on. Know what you don’t know. It is fine to tell a parent you are not sure what something is, but will look into it. I have recently seen a child with wrist pain and no mass diagnosed with a ganglion. I have seen a young child with isolated thelarche, and the mother was told her daughter was going to have a period any day.

10. After 10 minutes, if not sooner, a breast is mostly empty. Having a child feed for 20 to 30 minutes at the first breast will exhaust both the mother and the child (and can lead to very sore nipples). Particularly for newborns, I recommend 10 minutes at the first breast, switching breasts for another 10, and then “topping off” for another 5 to 10 minutes at each breast if the baby is still hungry.

11. I am often given subpoenas to testify in custody battles. It would be most unusual for me to have an opinion as to whether or not 1 parent was bad or inferior. The lawyer usually has not bothered to talk to me first, to find what I might say. I am being called not as a factual witness (eg, what was the weight and height of the child), but as an expert witness (eg, is the child properly nourished; is the parent a good parent). As such, I can charge for my time, and, unless I clearly feel 1 parent is “right” and that I have something to contribute, I explain to the lawyer what my retainer and hourly fees are for testifying as such. On hearing this, the subpoena is invariably withdrawn, and I have not been to court for years.

REFERENCE


CONTINUED FROM LANGUAGE PEEVES

This is often described as “alternating feet.” However, everybody I know alternates feet when going up stairs. I have never seen someone go right foot, right foot, left foot, left foot. I have been unable to come up with an accurate 2-word phrase to describe this approach to stairs, but I can accept “marking time.” “Alternating steps” is acceptable for the more adult method of handling stairs.

6. The verb “affect” means to influence, while “effect” means to bring about. The noun “affect” refers to emotion, whereas the noun “effect” refers to a result. When I am reviewing a paper with multiple authors and see these words misused, I assume that the co-authors have not really read the paper.

Dr Schuman lays out his plan for a more meaningful way to document medical encounters and eliminate “note bloat,” thereby ensuring that physicians are appropriately compensated by government and insurance companies.

When the editors at Contemporary Pediatrics invited me to launch this section in 2012, I had no idea how much fun I would have writing it, and that our readers would actually find the topics interesting. Like most of you, I work in a clinic. I enjoy treating my patients, and there is not a day that goes by that I need to navigate obstacles imposed by insurance companies, government reforms, and my electronic health record (EHR). If there were to be a theme for this year’s Peds v2.0, it would be “taking back the practice of pediatrics” for ourselves and our patients. Yes, there will be lots of tech articles this year because this leopard will never change his digital spots. However, let’s begin our recovery of medical practice by discussing alternative ways of documenting office visits.

When I conducted my last tech workshop at the American Academy of Pediatrics National Conference and Exhibition in October last year (see “Best tech for pediatrics 2015,” Contemporary Pediatrics, December 2015), pediatricians told me that their EHRs were too hard to use, with the majority of attendees reporting that they are unable to complete their office notes during their regular hours. Many, if not most, were frequently taking at least an hour’s work home with them. This is no way to care for patients or ensure a quality life for medical providers!

**Our current documentation system**

...is designed to justify the level of coding for insurance company reimbursement rather than facilitating documentation of the office visit. The purpose of the office note should be to convey our clinical impression of the patient’s medical problems and communicate our plan for treatment and further evaluation to those who will read our note. The EHR note ensures continuity of care for our patients.

If you read the Peds v2.0 article “Level 4 office-visit coding” from February 2013, you know that coding office visits is based on the “medical decision making” involved, the nature of the presenting problem, and the number of problems addressed at the visit. Unless you assign a time designation with your note, to justify a 99214 visit you must include numerous elements in your note to ensure payment as a level 4 visit. Thus, a level 4 history includes at least 4 history of present illness (HPI) elements; at least 1 item from the past medical history (a medication list or allergy list qualifies), social history, or family history; and at least a 2-system review of systems (ROS). The level 4 physical exam requires examination of 5 to 7 systems, including the patient’s vital signs.

As every provider knows, when a note is reviewed we glance at the...
previous HPI, but our focus is on the assessment and plan for ongoing medical problems. To begin “taking back the practice of medicine,” we need to accomplish 2 goals. First, we need to convince insurance companies and the government that there are better, alternative ways to compensate physicians. Second, we need a more meaningful way to document medical encounters.

Rethinking physician compensation
Compensation of primary physicians is currently based on the notes associated with the office visit we generate when we care for patients. For procedure-based visits, insurance companies pay providers according to a fixed schedule for the procedure performed. In contrast, primary care visit payment is based on either the time spent at the visit and the amount of time counseling the patient or the medical decision making involved and the requisite number of elements needed to justify the level billed (addressed above). At the present time, “time stamping” our visits is the only way to avoid writing lengthy notes in our EHRs. In the interest of patient care and preserving the sanity of medical providers, we should avoid level 4 coding based on medical decision making. It just preserves an unnecessary “kitchen-sink” approach to medical documentation. Time stamping our notes just works (given our present system), and it encourages the generation of more practical, concise office notes that ensure continuity of patient care.

I would welcome alternative ways to compensate physicians that would be based on complexity of diagnosis (pneumonia should warrant a higher compensation versus upper respiratory infection [URI]), number of diagnoses, and perhaps the amount of follow-up that needs to be performed to complete the evaluation of a patient’s condition. For example, if we order labs or x-rays, we will need to contact a patient with the results, which can lead to further testing or referrals. Visits associated with the ordering of tests should trigger a higher reimbursement than a visit just for conjunctivitis or URI.

Another method to consider is to pay by the click. Using software “click counters,” I have determined that by the end of the day I have clicked anywhere from 1500 to 2000 buttons. If I click more buttons, I would like to be paid more. This method may accelerate the evolution of EHRs to the point where they are intuitive and user friendly, and can expedite production of quality notes.

Our current documentation system is designed to justify the level of coding for insurance company reimbursement.

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Better medical documentation
Our current system of medical documentation is based on the Problem-Oriented Medical Record developed and promoted by Lawrence Weed, MD, in the late 1960s. It is a systematic way of documenting a patient visit that has traditionally been associated with the SOAP note system: S stands for subjective and includes the chief complaint, history of present illness, family and social history, and ROS. Objective includes the vital signs and results of the examination. Assessment includes your clinical impression and Plan includes your recommendations for treatment and further workup (Table 1).

The SOAP system is straightforward and has proved its utility over decades of use. However, EHRs are template driven, and, as discussed above, to safeguard our salaries most primary care notes are easily many times as long as they need to be. If you stick with time-stamped notes, you can shorten your history elements to only the pertinent elements; likewise the ROS, which can be 1 line versus 10 lines (ie, 10-system ROS significant for nonproductive cough for 3 days). Similarly, only the pertinent physical findings can be listed in the Objective section. The most valuable part of the note is the assessment and plan. We should strive to generate office notes that can be viewed on a computer screen without scrolling!

APSO: The upside-down medical note
Most physicians consider the SOAP note’s assessment and plan to be the most important part of a medical note. Several physicians associated with the University of Colorado launched a quality improvement initiative a few years ago, whose goal was to convert clinics associated
with the medical center to APSO format, in which the Assessment and Plan appear at the beginning of a chart note, followed by the Subjective and Objective (Table 2). Surveys were conducted after conversion to the new format. Eighty-one percent of respondents reported that finding clinically relevant data was easier with APSO versus SOAP format, and 83% reported much faster browsing through EHR notes with APSO versus SOAP. Additionally, 75% preferred reading notes with the APSO format. I personally do not like the APSO format, and suggest that we consider highlighting the assessment/plan section of our notes in red to draw the reader’s attention to the most important area. Significant physical finds also can be similarly highlighted.

Other ways to expedite medical documentation

Prudent use of abbreviations leads to abbreviated notes. The Joint Commission has a short list of medical abbreviations that should not be used because they can lead to medical errors. However, most organizations have a list of commonly used abbreviations that are approved for use by their medical providers. These include acronyms such as: “hx” for “history,” “dx” for “diagnosis,” “fx” for “fracture,” “tx” for “treatment,” “rx” for “prescription,” and so on. In practice, we tend to use many abbreviations that are easily understood in the context of the note, considering the specialty of the author. For general pediatricians, ASD usually means “autism spectrum disorder,” whereas for the pediatric cardiologist, ASD usually

### Table 1: Time-stamped Level 4 SOAP Note with Abbreviations

<table>
<thead>
<tr>
<th>Allergen</th>
<th>Reactions</th>
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<tbody>
<tr>
<td>Penicillins</td>
<td>Hives</td>
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<tr>
<td>Cephalosporins</td>
<td>Rash</td>
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</table>

ROS: 10 systems were reviewed, including Eyes, Ears, Nose, Throat, Neck, Resp, Cor, GI, Ortho, and Neuro. All negative unless specified in HPI.

Temp (SRC): 36.7°C (98°F) (Temporal). Wt: 36.089 kg (79 lb 9 oz)

PE:
Gen: Awake and alert, interactive, NAD

Rapid strep negative

A/P:
1) Pharyngitis: Viral, symptomatic tx with prn f/u
2) BOM: Consider Streptococcus pneumoniae, nontypeable Haemophilus influenzae, Moraxella catarrhalis, and group A Streptococcus in addition to viruses as causative organisms. PT w/ drug allergies. Will tx with azithromycin. F/u 1 week if not improved.

Total of 25 minutes spent with patient with 13 minutes spent providing counseling. Issues discussed included medications, medication adverse effects, and future plans.

( ) Parent and/or ( ) patient expressed understanding and agrees with plan.

Author’s note: Physical finds and assessment plan (A/P) are highlighted in red to draw the reader’s attention to these sections.

Abbreviation: SOAP, subjective, objective, assessment, plan.
Abbreviations: The following may be included in the note below: 

w/ = with; w/o = without; f/u = follow-up; moc = mother of child;

foc = father of child; ST = sore throat; WOB = work of breathing;

PT = patient; NC = noncontributory; TM = tympanic membrane

CC: Sore throat and ear pain

A/P:
1) Pharyngitis: Viral, symptomatic tx with prn f/u
2) BOM: Consider *Streptococcus pneumoniae*, nontypeable *Haemophilus influenzae*, *Moraxella catarrhalis*, and group A *Streptococcus* in addition to viruses as causative organisms. PT w/ drug allergies. Will tx with azithromycin. F/u 1 week if not improved.

HPI: PT w/ 2-day hx of congestion, occasional tactile fever, w/o wheeze or labored breathing. PT with ear pain on R w/o drainage or change in hearing acuity. Appetite good, voiding and stooling well. PT also with ST, moderate in intensity and worsening over past 12 hours. No exposure to ill persons.

PMH/FH/SH: NC

Allergies

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Temp (SRC): 36.7°C (98°F) (Temporal). Wt: 36.089 kg (79 lb 9 oz)

PE:
Gen: Awake and alert, interactive, NAD
Head: NC/AT. Eyes: PERRLA, sclera without injection, no discharge. Ears: TMs inflamed bilaterally. Nose: No d/c noted. Throat: MMM, pharynx injected w/o exudate. Neck: No masses, no adenopathy. CV: RRR, S1S2 normal, no murmur, no heaves or rubs. Lungs: NI air entry bilat, no rhonchi or rales, no wheezes, no increased WOB. Abd: Soft, nt, nd, no organomegaly. Skin: No rashes, good turgor. Neuro: Grossly intact

Rapid strep negative

<table>
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Author’s note: Physical finds and assessment plan (A/P) are highlighted in red to draw the reader’s attention to these sections.

Abbreviation: APSO, assessment, plan, subjective, objective.

Problem list-oriented notes
If the purpose of concise notes is to ensure continuity of care, consider including the patient’s existing problem list in your note (Table 3). This serves as a reminder to update the problem list at every patient encounter. It also encourages physicians to ask about conditions that may not be related to the visit at hand. Patients
Abbreviations: The following may be included in the note below: w/ = with; w/o = without; f/u = follow-up; moc = mother of child; foc = father of child; ST = sore throat; WOB = work of breathing; PT = patient; NC = noncontributory; TM = tympanic membrane

CC: Sore throat and ear pain

HPI: PT w/ 2-day hx of congestion, occasional tactile fever, w/o wheeze or labored breathing. PT with ear pain on R w/o drainage or change in hearing acuity. Appetite good, voiding and stooling well. PT also with ST, moderate in intensity and worsening over past 12 hours. No exposure to ill persons.

The following are included in the patient’s current problem list w/ status updated as indicated:

1) Mild intermittent asthma: On Flovent 44 mcq bid during winter months, albuterol by mdi, 2 puff q 4 hours prn - No change, needs Flovent refill today, received influenza vaccine 1 month ago.

2) ADHD: Doing well in school on Focalin XR 20 mg q AM - Weight stable, wants to continue current regimen; has med check in 3 months.

3) Health maintenance: Due for well visit next month - Indicated that he will receive Tdap vaccine at visit.

PMH/FH/SH: NC

Allergies

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3) Asthma: See note. Flovent refilled today.
4) ADHD: To continue current regimen w/ f/u 3 months
5) Health maintenance: Moc to make appointment. Tdap handout provided.

Total of 25 minutes spent with patient with 13 minutes spent providing counseling. Issues discussed included medications, medication adverse effects, and future plans.

( x ) Parent and/or (    ) patient expressed understanding and agrees with plan.

Author’s note: Physical finds and assessment plan (A/P) are highlighted in red to draw the reader’s attention to these sections. Abbreviation: ADHD, attention-deficit/hyperactivity disorder.

Conclusion
I hope this article will encourage you to rethink how you generate your office notes. I believe it is our responsibility to reform medical practice, and there are ways to accomplish this that are more obvious than others. Please write to me at andrew.schuman@ymail.com to share your thoughts.
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“Yuma Regional Medical Center Pediatric Hospitalists’ seeks both full-time and part-time BC/BE Pediatricians for our dynamic Peds Hospitalist program, in place for the past 3 years and extremely supported by our community physicians.

“This excellent opportunity includes a strong hospital salary, full benefits package, a generous relocation allowance and a flexible schedule”

Yuma Regional Medical Center (YMRC), a 406 bed top-in-technology facility, includes a 22-bed pediatric unit and a 15-bed level IIIEQ Neonatal ICU to help care for the pediatric patients within our community of 265k residents.

This position will provide limited coverage for healthy newborns and will require no delivery attendance. Sub-specialty support is available through a combination of local physicians, as well as through affiliated tertiary care centers.

Yuma, Arizona is located just over 2 ½ hours drive- either direction- from both San Diego, California and Phoenix, Arizona and offers family-friendly, year around recreational opportunities in one of the sunniest cities across the US.

I welcome all inquiries into this exciting position!

Pam Orendorff
Director- Physician Relations & Physician Recruitment
Yuma Regional Medical Center
928-336-3032 • porendorff@yumaregional.org

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Aplasia cutis congenita (ACC) is a congenital malformation typically associated with single or multiple ulcers, crusts, and/or scars in the newborn, with or without other cutaneous and extracutaneous findings. The patient presented with the most common variant, in which an isolated hypertrophic scar is noted on or near the vertex of the scalp. In the newborn, the depth may vary with some cases involving epidermis and superficial dermis, although lesions may extend to deeper soft tissue and rarely through bone revealing exposed brain. The defect is usually 1 cm to 3 cm in diameter and may be rounded, elliptical, or stellate. This variant of ACC must be distinguished from a hair collar sign, in which a smooth, hairless, slightly elevated nodule containing a neuoronevus or meningeal cells is surrounded by a dense ring of long hair.

The causes are variable, including genetic, environmental, teratogenic, and vascular factors. A number of familial cases, most commonly the localized vertex lesions, have been reported.

The classification system for ACC is based on the number and location of the lesions and the presence or absence of associated malformations (Table).

**Management**

All patients require a careful medical evaluation to exclude associated findings. Imaging studies may be indicated when deeper soft tissue or bony defects are suspected. Surgical repair is important when the meninges and dural sinuses are involved.

<table>
<thead>
<tr>
<th>GROUP</th>
<th>MALFORMATIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1</td>
<td>Scalp lesions, without multiple anomalies</td>
</tr>
<tr>
<td>Group 2</td>
<td>Scalp lesions with limb anomalies (ie, Adams-Oliver syndrome, distal limb reduction anomalies)</td>
</tr>
<tr>
<td>Group 3</td>
<td>Scalp lesions with epidermal and sebaceous nevi; may be associated with ophthalmic and neurologic findings (ie, SCALP syndrome [nevus sebaceus, central nervous system malformations, aplasia cutis congenita, limbal dermoid, pigmented nevus])</td>
</tr>
<tr>
<td>Group 4</td>
<td>Hair collar overlying deeper embryologic malformations, such as meningomyelocele</td>
</tr>
<tr>
<td>Group 5</td>
<td>ACC associated with fetus papyraceus (death of twin fetus) or placental infarct</td>
</tr>
<tr>
<td>Group 6</td>
<td>ACC with epidermolysis bullosa</td>
</tr>
<tr>
<td>Group 7</td>
<td>ACC localized to extremities without epidermolysis bullosa</td>
</tr>
<tr>
<td>Group 8</td>
<td>ACC due to teratogens or intrauterine infection with HSV or VZV</td>
</tr>
<tr>
<td>Group 9</td>
<td>Associated with malformation syndromes (eg, trisomy 13, 4p deletion)</td>
</tr>
</tbody>
</table>

Abbreviations: ACC, aplasia cutis congenita; HSV, herpes simplex virus; VZV, varicella zoster virus.

Localised superficial ulcers usually heal within 2 to 4 weeks with conservative wound care (eg, silver sulfadiazine).

**Outcome**

The patient’s scar was present at birth, suggesting that the defect healed in utero. Her growth and development were normal; a review of systems was negative; and the physical exam was otherwise normal. Her parents were reassured accordingly.

Dr Sami is a pediatrician at Metropolitan Pediatrics, Arlington, Virginia. Dr Cohen, section editor for Dermcase, is professor of pediatrics and dermatology, Johns Hopkins University School of Medicine, Baltimore, Maryland. The author and section editor have nothing to disclose in regard to affiliations with or financial interests in any organizations that may have an interest in any part of this article. Vignettes are based on real cases that have been modified to focus on key teaching points. Images also may be edited or substituted for teaching purposes.

**REFERENCES**

Bald area on back of a girl’s scalp

AZADEH SAMI, DO, MSPH

THE CASE

The parents of a 4-year-old girl are worried about a bald area on the back of her scalp that has been present since birth. For more on this case, turn to page 43.
patients with suspected bacterial conjunctivitis who received Besivance bilaterally three times a day (16 doses total). Following the first and last dose, the maximum plasma besifloxacin concentration in each patient was less than 1.3 ng/mL. The mean besifloxacin Cmax was 0.37 ng/mL on day 1 and 0.43 ng/mL on day 6. The average elimination half-life of Besifloxacin in plasma following multiple dosing was estimated to be 7 hours.

12. Microbiology
Besifloxacin is an 8-chloro fluoroquinolone with a N-1 cyclopropyl group. The compound has activity against Gram-positive and Gram-negative bacteria due to the inhibition of both bacterial DNA gyrase and topoisomerase IV. DNA gyrase is an essential enzyme required for replication, transcription and repair of bacterial DNA. Topoisomerase IV is an essential enzyme required for partitioning of the chromosomal DNA during bacterial cell division. Besifloxacin is bactericidal with minimum bactericidal concentrations (MBCs) generally within one dilution of the minimum inhibitory concentrations (MICs). The mechanism of action of fluoroquinolones, including besifloxacin, is different from that of aminoglycoside, macrolide, and β-lactam antibiotics. Therefore, besifloxacin may be active against pathogens that are resistant to these antibiotics and these antibiotics may be active against pathogens that are resistant to besifloxacin. In vivo cross-resistance between besifloxacin and some fluoroquinolones.

In vitro resistance to besifloxacin develops via multiple-step mutations and occurs at a general frequency of < 3.3 x 10^-7 for Staphylococcus aureus and < 1 x 10^-10 for Staphylococcus pneumoniae.

Besifloxacin has been shown to be active against most isolates of the following bacteria both in vitro and in conjunctival infections treated in clinical trials as described in the INDICATIONS AND USAGE section: Aerococcus viridans, Corynebacterium pseudodiphteriticum, C. striatum, Haemophilus influenzae, Moraxella catarrhalis, Moraxella lacunata, Pseudomonas aeruginosa, Staphylococcus epidermidis, Staphylococcus hominis, Staphylococcus lugdunensis, Streptococcus mitis group, Streptococcus oralis, Streptococcus pneumoniae, Streptococcus salivarius.

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

2 DOSAGE AND ADMINISTRATION
Invert closed bottle and shake once before use. Instill one drop in the affected eye(s) 3 times a day, four to twelve hours apart for 7 days.

4 CONTRAINDICATIONS
None

5 WARNINGS AND PRECAUTIONS

5.1 Topical Ophthalmic Use Only NOT FOR INJECTION INTO THE EYE. Besivance is for topical ophthalmic use only, and should not be injected subconjunctivally, nor should it be introduced directly into the anterior chamber of the eye.

5.2 Growth of Resistant Organisms with Prolonged Use As with other anti-infective, prolonged use of Besivance (besifloxacin ophthalmic suspension) 0.6% may result in overgrowth of non-susceptible organisms, including fungi. If super-infection 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.

5.3 Avoidance of Contact Lenses Patients should not wear contact lenses if they have signs or symptoms of bacterial conjunctivitis or during the course of therapy with Besivance.

6 ADVERSE REACTIONS
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in one clinical trial of a drug cannot be directly compared with the rates observed in another clinical trial, and adverse reaction rates observed in one clinical trial of a drug and may not reflect the rates observed in clinical practice.

The data described below reflect exposure to Besivance in approximately 1,000 patients between 1 and 98 years old with clinical signs and symptoms of bacterial conjunctivitis. The most frequently reported ocular adverse reaction was conjunctival redness, reported in approximately 2% of patients.

Other adverse reactions reported in patients receiving Besivance occurring in approximately 1-2% of patients included: blurred vision, eye pain, eye irritation, eye pruritus and headache.

8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy Pregnancy Category C. Oral doses of besifloxacin up to 1000 mg/kg/day were not associated with visceral or skeletal malformations in rat pups in a study of embryo-fetal development, although this dose was associated with maternal toxicity including body weight gain and food consumption. In- creased postimplantation loss, decreased fetal body weights, and decreased fetal ossifi- cation were also observed. At this dose, the mean Cmax in the rat dams was approximately 20 mcg/mL, ~45,000 times the mean plasma concentrations measured in humans.

The reference Acceptable Effect Level (NOAEL) for this embryo-fetal development study was 100 mg/kg/day (Cmax ~5 mcg/mL, ~11,000 times the mean plasma concentrations measured in humans).

In a perinatal and postnatal development study in rats, the NOAELs for both fetal and maternal toxicity were also 100 mg/kg/day. At 1000 mg/kg/day, the pups weighed significantly less than controls and had a reduced neonatal survival rate. Attainment of developmental landmarks and sexual maturation were delayed, although surviving pups from this dose group that were reared to maturity did not demonstrate deficits in behavior, including activity, learning and memory, and their reproductive capacity appeared normal. From this dose group that were reared to maturity did not demonstrate deficits in behavior, including activity, learning and memory, and their reproductive capacity appeared normal.

13.2 Carcinogenesis, Mutagenesis, Impairment of Fertility Lethal and sublethal studies demonstrated no evidence of impaired fertility in male or female rats at oral doses of up to 1000 mg/kg/day. Besifloxacin did not impair fertility or the development of the offspring when administered to rats given the test compound up to 2,000 mg/kg by the oral route. In a fertility and early embryonic development study in rats, besifloxacin did not impair the fertility of male or female rats at oral doses of up to 500 mg/kg/day. This is over 10,000 times higher than the recommended total daily human ophthalmic dose.

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility These studies included: (1) absence of neoplasms in rats and mice treated for 100 weeks and given besifloxacin up to a dose of 500 mg/kg/day, and (2) increased incidence of hemangioendotheliomas in male F344 rats given doses of up to 500 mg/kg/day. Besifloxacin did not decrease the number of offspring for male rats. Besifloxacin did not affect fertility in female rats. Besifloxacin did not increase the rate of either spontaneous or chemically induced tumors in mice and rats.

13.1.1 Carcinogenesis Besifloxacin was negative in the following assays: in vivo studies demonstrated that Besifloxacin did not impair the fertility of male or female rats at oral doses of up to 500 mg/kg/day. This is over 10,000 times higher than the recommended total daily human ophthalmic dose.
For bacterial conjunctivitis in children as young as 12 months –

Unleash power against pathogens of concern.

• The first and only topical ophthalmic chlorofluoroquinolone
• Visible formulation designed to adhere to the ocular surface
• Flexible dosing that allows for up to 12 hours between doses

1 drop
3x a day
4 to 12 hours apart
For 7 days

Indication
BESIVANCE® (besifloxacin ophthalmic suspension) 0.6% is a quinolone antimicrobial indicated for the treatment of bacterial conjunctivitis caused by susceptible isolates of the following bacteria: Aerococcus viridans*, CDC coryneform group G, Corynebacterium pseudodiphtheriticum*, Corynebacterium striatum*, Haemophilus influenzae, Moraxella catarrhalis*, Moraxella lacunata*, Pseudomonas aeruginosa*, Staphylococcus aureus, Staphylococcus epidermidis, Staphylococcus hominis*, Staphylococcus lugdunensis*, Staphylococcus warneri*, Streptococcus mitis group, Streptococcus oralis, Streptococcus pneumoniae, Streptococcus salivarius*

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

Important Safety Information about BESIVANCE®
• BESIVANCE® is for topical ophthalmic use only, and should not be injected subconjunctivally, nor should it be introduced directly into the anterior chamber of the eye.
• As with other anti-infectives, prolonged use of BESIVANCE® may result in overgrowth of non-susceptible organisms, including fungi. If super-infection occurs, discontinue use and institute alternative therapy.
• Patients should not wear contact lenses if they have signs or symptoms of bacterial conjunctivitis or during the course of therapy with BESIVANCE®.
• The most common adverse event reported in 2% of patients treated with BESIVANCE® was conjunctival redness. Other adverse events reported in patients receiving BESIVANCE® occurring in approximately 1-2% of patients included: blurred vision, eye pain, eye irritation, eye pruritus and headache.
• BESIVANCE® is not intended to be administered systemically. Quinolones administered systemically have been associated with hypersensitivity reactions, even following a single dose. Patients should be advised to discontinue use immediately and contact their physician at the first sign of a rash or allergic reaction.
• Safety and effectiveness in infants below one year of age have not been established.

Please see brief summary of Prescribing Information on adjacent page.


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