



Cochlear implants and meningitis

In July 2002, the U.S. Food and Drug Administration (FDA) issued a public health note that *there might be an association between cochlear implants and the occurrence of bacterial meningitis*. In other words, people who have cochlear implants **might** be more likely than people without cochlear implants to get bacterial meningitis. Up-to-date information about this topic is available at <http://www.fda.gov/cdrh/safety/cochlear.html>. The site also contains information about how to reduce the risk of meningitis for recipients of cochlear implants.

Just how big is the risk? Thus far, 53 cases of meningitis have been reported among approximately 25,000 people in the United States who have received cochlear implants. Unless many more cases of meningitis among cochlear implant recipients are reported, this means about 2 of every 1,000 people who receive an implant will contract bacterial meningitis. Although this is higher than the incidence of bacterial meningitis in the general population, it is still a very low risk.

There might be an association between cochlear implants and the occurrence of bacterial meningitis.

What is a cochlear implant?

A cochlear implant is a surgically inserted device that delivers electrical stimulation to the inner ear and eighth cranial nerve and has both internal and external components. Approximately 60,000 adults and children worldwide have received cochlear implants. Almost all people who get a cochlear implant have a profound or severe hearing loss in each ear. Often they have tried hearing aids but still cannot understand speech. Not everyone is a candidate for an implant. Individuals with a hearing loss due to lesions of the acoustic nerve or central auditory pathway—or absence of developed cochlear—would not be candidates. The FDA approved the implant for adults in 1985 and for children over the age of 18 months. In 1990, the FDA approved the use of some cochlear implants in children as young as 12 months of age, although these children must first use hearing aids for 3 to 6 months and demonstrate little or no benefit from traditional amplification.

What is meningitis?

Meningitis is an infection of the lining of the surface of the brain and may be either viral or bacterial. Early symptoms of meningitis in infants and young children include fever, irritability, lethargy, and loss of appetite. Older children and adults may also manifest headache, stiff neck, nausea and vomiting, and confusion or alteration in consciousness. Physicians are encouraged to consider a diagnosis of meningitis in cochlear implant patients when such symptoms exist and begin appropriate diagnostic testing and treatment as soon as possible.

The FDA reports that there have been 91 cases of meningitis worldwide, and 17 of those have died. Three manufacturers make FDA-approved cochlear implants used in the United States: Advanced Bionics Corporation, Cochlear Corporation, and MED-EL Corporation, and cases have been reported for each type of device. Of the 53 cases reported in the United States:

- Most were younger than 7 years of age, although some adults with cochlear implants also became ill with meningitis.
- Symptoms of the meningitis began within 24 hours to more than 6 years after the implant surgery.

continued, page 5

IN THIS ISSUE

Cochlear implants and meningitis	1
Around the world: Universal neonatal hearing screening in Croatia	2
The Web	2
American Academy of Pediatrics EHDI program information	3
2003 National Early Hearing Detection and Intervention Conference	3
Techniques and tidbits	3
Beyond newborn hearing screening: Who will do the diagnostic follow-up?	4
In the news	4
Upcoming events	6

Around the world: Universal neonatal hearing screening in Croatia

Editor's Note: For those of you who are struggling to make your statewide EHDI program a reality, we thought you would be inspired by the account sent to us from Dr. B. Marn at the Children's University Hospital in Zagreb Croatia. In spite of the difficulties caused by years of war and a shattered economy, Dr. Marn has managed to implement a nationwide EHDI program in a little more than 1 year. Very impressive!!!

Until 12 months ago, there were no maternity wards in Croatia with Universal Hearing Screening (UNHS). Hearing screening in Croatia is still usually performed by pediatricians using behavioral methods on primary-care- or tertiary-care-level infants at the age of 3 months and older, and much of this screening is limited to babies with neurological problems. As is true in other countries where there is no organized hearing screening program, the average age at which hearing loss is identified is approximately 2 years of age. If the incidence of about 3 per 1,000 is assumed to be true in Croatia as it is in other countries, there are about 105 infants with hearing loss born every year.

In November 2001, Dr. B. Marn, who has been an advocate of UNHS in Croatia for more than 20 years, initiated the purchase of one OAE screener with support of a local radio station. A few weeks later, the State Institute for Family, Maternity, and Youth Protection, in conjunction with Children's University Hospital Zagreb,

developed a pilot project for UNHS at a maternity ward in Zagreb with an annual birth rate of approximately 3,000 newborns and the ENT department of Children's University Hospital Zagreb. UNHS began in Croatia in February 2002 after the initiative was successfully completed. A two-staged model is used. The first stage is in the maternity unit, and the second stage is in the tertiary-care university hospital. In the first stage, nurses trained to use automated OAE equipment conduct the screening. Infants who do not pass are then referred for a second-stage OAE screening and an ENT examination. A letter is sent to parents whose babies do not pass the screenings to encourage them to return for follow-up testing.

In 4 months, 912 newborns were tested before discharge: 96% passed the hearing screen, 3.5% referred on one ear, and 0.5% referred on both ears. Up to now, about 75% of the referrals have come back for follow-up. One child with a congenital bilateral hearing impairment was confirmed at the age of 17 days.

Initial results show that UNHS is possible in our maternity wards without significant organization problems, that our nurses are capable of managing numerous hearing screenings even after a short period of education and training, and that parents take an active role in the health service and care of their baby's hearing.

continued, page 5

THE WEB www.infanthearing.org

State Early Hearing Detection and Intervention (EHDI) Web sites

Twenty-four states have developed Web sites describing their state's Early Hearing Detection and Intervention (EHDI) programs. Many of these sites contain a wealth of information to help parents and health-care professionals make sure infants and toddlers with hearing loss receive the best possible services. You can check out the Web site for your state at <http://www.cdc.gov/ncbddd/ehdi/protocol3.htm>. If your state doesn't have a Web site, you may want to contact your EHDI coordinator and encourage him/her to develop one. If your state already has a Web site, consider additional information you would like to see posted there and ways it could be improved. Most state coordinators are very open to such suggestions.



SOUND IDEAS, November 2002, Vol. 4, No. 1. *Sound Ideas* is a quarterly publication of the National Center for Hearing Assessment and Management (NCHAM). Its goal is to provide information to hospital staff, health-care providers, early interventionists, families, and public health officials to help in the establishment and expansion of successful newborn hearing screening and intervention programs.

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The newsletter is also available at our Web site, <http://www.infanthearing.org>. Send us your e-mail address at nchamhelp@coe.usu.edu, and we will e-mail you each time the newsletter is published. If you would like to submit an article, contact the editor, Karen Ditty, at DittyKM@aol.com.

American Academy of Pediatrics EHDI program information

In 2001, the American Academy of Pediatrics (AAP) implemented a program, *Improving the Effectiveness of Newborn Hearing Screening, Diagnosis, and Intervention Through the Medical Home*. This program focused on increasing involvement of primary care pediatricians and other child health-care providers in EHDI activities by linking follow-up services more closely to the newborn's medical home. Housed in the AAP Department of State Government and Chapter Affairs, the program is a partnership between the AAP national office, state AAP chapters, and the National Center for Hearing Assessment and Management (NCHAM) at Utah State University. It is funded by an educational grant from the Maternal and Child Health Bureau and the Centers for Disease Control and Prevention.

As part of this program, nearly every AAP chapter has appointed an Early Hearing Detection and Intervention (EHDI) Chapter Champion to serve as the point person on this issue at the state and local level. The majority of the Chapter Champions participated in the February 11-13, 2002, National EHDI conference in Vienna, VA and will participate in the 2nd National EHDI Conference in Atlanta in 2003. Chapter Champions are working to coordinate efforts among physicians who care for young children, health-care professionals, state health departments, hospitals, and others in an effort to implement and enhance state EHDI programs and to ensure that this issue is prioritized at the state level. Chapter Champions have also begun to collaborate with state EHDI coordinators to provide pediatric expertise to state-level programs and educational offerings. To obtain the name of the Chapter Champion in your state, visit the AAP Web site at <http://www.medicalhome.info.org/screening/hearing.html> (the Chapter Champion listing is downloadable in a PDF format). Chapter Champions are often available to speak at meetings, work with state advisory groups, or assist in drafting policies and guidelines.

2003 National Early Hearing Detection & Intervention Conference

The 2nd Annual National Early Hearing Detection and Intervention (EHDI) Conference is scheduled for February 24-26, 2003, in Atlanta, Georgia.

Registration information and materials are now available at <http://www.infanthearing.org/meeting/ehdi2003/index.html>.

Conference speakers will disseminate current knowledge regarding EHDI and promote sharing ideas and information for the implementation and enhancement of EHDI programs among states, private industry, advocacy and partner groups, and education organizations.

The 2nd Annual National Early Hearing Detection and Intervention Conference will:

- Provide a framework for enhancing the implementation of comprehensive, state-based EHDI systems and programs.
- Improve the awareness of EHDI-related issues among the key stakeholders.
- Facilitate opportunities for collaborations, partnership building, and the sharing of successful strategies to address the issues of children with hearing loss and their families.

Keynote speakers include: Jay Hall, Martin Hyde, and Patrick Brookhouser. There will also be plenary panels on "Transitions: Screening to Diagnostics to Early Intervention to School," "EHDI Research Updates and Opportunities," "EHDI Tracking and Reporting," "Parent Perspectives on EHDI and Communication Options,"

continued, page 5

TECHNIQUES AND TIDBITS

Every baby screened before going home

How can you be sure every baby is screened before they go home from the hospital?

- 1 Work with your information systems department and develop a printout of every baby born at your facility and track that information daily. (Some data-management systems download information directly from your admissions department.)
- 2 Include the hearing screening as part of your standard of care at the hospital.
- 3 Routinely screen all infants that are at least 6-12 hours old.
- 4 Screen babies at designated times during the day to establish a routine for the hospital staff.
- 5 Develop a system of notification when an unscreened baby is discharged from the NICU to the well-baby nursery so that screening may take place.
- 6 Inform parents in their prenatal classes about the screening so they understand the importance of the test being performed prior to the infant's discharge from the hospital.

Even when a baby is inadvertently discharged without a hearing screening, be sure that the infant's parents and primary care physician are notified of the need for a follow-up hearing screen and that the appropriate records are documented.

Beyond newborn hearing screening: Who will do the diagnostic follow-up?

A question we all know the answer to but many are not prepared to handle! In the ideal world, we need to obtain a diagnostic audiological evaluation, fit the infant with hearing aids, and make sure he or she is enrolled in early intervention before 6 months of age. Although many audiologists work daily with children, few are comfortable performing diagnostics and interpreting those results for newborns. "Pediatric audiologists" are often found in "children's" hospitals and not in the standard private audiological practice or ENT office setting. In some states, parents have to travel many miles to obtain a definitive audiological test. Many states have created guidelines for what constitutes appropriate audiological evaluation and management of infants and children with hearing loss. Unfortunately, even though they have the guidelines, it is very difficult to find enough qualified "pediatric audiologists" to implement these guidelines.

The shortage of qualified pediatric audiologists has led many people to call for inservice training workshops. Various organizations have responded by holding workshops to help audiologists become better informed and prepared for the

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hearing care of infants. Most of these workshops are 1 or 2 days, with participants receiving information in the traditional formats of lecture and handouts. Although useful and up-to-date

information is presented, participating audiologists often do not have enough time to integrate the information.

A great deal has also been published, and books are now available, about audiologic diagnosis for infants. Recently, the *Hearing Journal* [November 2002, Vol. 55(11)] released a special issue on "Beyond Infant Screening: What Comes Next?"

Workshops and literature are good vehicles for disseminating information and protocols to audiologists. However, without hands-on experience and actual practice in a clinical setting, many audiologists find it difficult to apply the new material in their own practices with infants. An alternative to such short-term, largely lecture-based training is distance education and "telemedicine." Combined with an intensive face-to-face workshop and follow-up practicum, this approach offers a valuable alternative for developing the competency audiologists need for providing services to infants and toddlers.

The National Center for Hearing Assessment and Management (NCHAM) supported by the Maternal & Child Health Bureau (MCHB) has initiated a series of three-part workshops which use distance education technology to do

training in diagnostic audiology. Each workshop consists of an (a) online tutorial, (b) face-to-face workshop, and (c) supervised practicum.

The "Infant Hearing Diagnostic Workshops" are being held across the United States over the next 2-1/2 years. Part 1 is an online tutorial of basic knowledge needed for pediatric audiological evaluations. Over a 6-week period, participants read articles and interact weekly with experts on a Web-based chat room and electronic whiteboard and demonstrate their mastery of this material using an online learning test at the end of the 6-week period. Part 2 has participants attend a 2-day, face-to-face workshop where the various equipment and assessment techniques used for infants and young children are demonstrated

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and then performed. This workshop is led by a nationally known presenter in the field of audiology and staffed by expert audiologists drawn from NCHAM's nationwide network of over 20 audiologists who are experienced pediatric audiologists. Part 3 requires participants to complete a practicum with three-five infants and toddlers. Confidential reports for each child are reviewed by the faculty members. Chat rooms are used to review and discuss the practicum results.

This approach allows audiologists to acquire the information and clinical experience they need without interfering with their ability to conduct their daily professional responsibilities. Thus far, three workshops have been conducted and five more are scheduled for 2003. Participant evaluations of the workshops have been very positive.

With greater numbers of audiologists trained in appropriate diagnostic and amplification procedures for infants and toddlers, we will not only know "what to do next," but we will also be able to identify *who* can do it! For information about future workshops, visit NCHAM's Web site at www.infanthearing.org/workshop/index.html.

IN THE NEWS

The American Academy of Audiology is presenting an interactive Web seminar, *Update on Meningitis and Cochlear Implants*. It will be presented by Jon Shallop, Ph.D, and Colin Driscoll, MD, of Mayo Clinic on Friday, December 6, 2002, from 11:00 a.m. - 1:00 p.m. (Eastern Time). This seminar is designed to give audiologists and other hearing professionals information regarding the timely diagnosis and treatment of meningitis in patients with cochlear implants, as well as updates on recommended protocols for cochlear implant candidacy. For more information and to register for this seminar, log onto www.audiology.org/professional/seminars.

Cochlear implants and meningitis

from page 1

- Over 50% of the people developed meningitis within the first year after the implant surgery.

People reportedly at a greater risk of developing meningitis are:

- People whose inner ear is not formed normally.
- People who had meningitis in the past.
- Young children (especially younger than 5 years of age).
- People who have ear infections.
- People who have trouble fighting infections because of immune deficiencies.
- People who have had previous surgery to the inner ear or head.

What is being done to learn more about the possible association between cochlear implants and meningitis?

The FDA and CDC are gathering information to help determine why the incidence of meningitis appears to be so much higher among people who have received cochlear implants than the general population. The FDA and CDC are working to:

- Identify all cases of bacterial meningitis that occurred in children who received cochlear implants.
- Discover factors that may put children with cochlear implants at greater risk for meningitis.
- Identify the types of bacteria that caused the meningitis in each of the cases.

Although most states require the reporting of meningitis cases, state health departments often do not identify whether these cases involved a cochlear implant recipient. The FDA wants to know about any child or adult with a cochlear implant who had meningitis after getting the implant and are requesting that the FDA's MedWatch program be notified in one of four ways:

1. Online at <http://www.accessdata.fda.gov/scripts/medwatch/>
2. By telephone at 1.800.FDA.1088
3. By fax at 1.800.FDA.0178
4. By mail: MedWatch, Food and Drug Administration, HF-2, 5600 Fishers Lane, Rockville, MD 20857

According to CDC, people with cochlear implants should be sure they have a current vaccination against Streptococcus pneumoniae bacterium. To learn more about these vaccines and the recommendations for people with cochlear implants, go to: <http://www.cdc.gov/nip/issues/cochlear/cochlear-gen.htm>.

Around the world . . .

from page 2

In December 2001, the media-supported project in Croatia was started by the Ministry of War Veterans under the name of "Let Them Hear." Their idea was to collect money for cochlear implants and early intervention programs for 86 hearing-impaired children. Dr. Marn was able to widen the objective to include the purchase of hearing screening equipment for a nationwide UNHS program. In spite of the difficult economic situation, especially because of war in Croatia in recent years, the people of Croatia (less than 5 million people) donated approximately \$2 million to fund this initiative.

In September 2002, a national UNHS program was begun. Two-stage screening is being done in hospitals, and those who do not pass are referred for AABR in one of seven Audiology departments across the country. With a complete diagnostic evaluation in the first few months of the baby's life, it is expected that an intervention program will be started before the age of 6 months. In addition, the "Croatian Association for Early Hearing Diagnostics" was founded to bring together professionals from different specialties.

In summary, Croatia is well on its way to having a nationwide newborn hearing screening, diagnosis, and intervention program. The program has grown from nothing to a nationwide program in less than one year, thanks to the initiative of Dr. B. Marn (with the assistance of Dr. F. Grandori, Italy; and Dr. K. White, USA) and the wonderful support of the media!

2003 National EHDI Conference . . .

from page 3

and a seminar on "Evaluation of Public Health Programs." Many small-group workshops and roundtable discussions are planned, as are state displays of EHDI materials and exhibits by manufacturers and related nonprofit organizations. A copy of the tentative agenda is available at <http://www.infantheating.org/>. Continuing education credits (CEUs) will be offered for audiologists, physicians, nurses, and others.

WE'RE ELECTRONIC!!!

Future editions of this newsletter will primarily be distributed electronically at www.infanthearing.org.

To have a printed copy sent, register at www.infanthearing.org. HEAR's to early hearing screening for all babies!

UPCOMING EVENTS

December 6, 2002, 11:00 a.m. - 1:00 p.m. (Eastern Time) • Update on Meningitis and Cochlear Implants. Virtual Seminar. **Registration online:** www.audiology.org/professional/seminars.

January 7, 2003, 2:00 p.m. (Eastern Time) • CDC Ad Hoc Teleconference. Information about topic and agenda available at www.cdc.gov/ncdbbb/ehdi/ddtele.htm.

February 24-26, 2003 • 2nd Annual National Early Hearing Detection and Intervention (EHDI) Conference, Atlanta Georgia, USA. **Registration and materials online:** <http://www.desainc.com/ConfEHDI.htm>.

April 2-3, 2003 • American Academy of Audiology 15th Annual Convention and Exposition, San Antonio, Texas, USA. **Contact:** American Academy of Audiology, 8201 Greensboro Drive, Suite 300, McLean, VA 22102, USA, 703.610.9022, Fax: 703.610.9005.

April 24-26, 2003 • Ninth Symposium Cochlear Implants in Children, Transforming the World of Sound, The Ronald Reagan International Trade Center, Washington, DC. *Sponsored by* Listening Center at Johns Hopkins and the River School. **Contact:** <http://www.ci2003.com>.