Early Hearing Detection and Intervention
State Planning Meeting CDC
November 8-9, 2000
Decatur, Georgia

Wednesday, November 8

Welcome, Introductions and Overview

The meeting was called to order at 8:30 am, by Dr. June Holstrum, Center for Child Development, Disability and Health, CDC, who welcomed everyone and introduced Dr. Coleen Boyle, Center for Birth Defects, Child Development, Disability and Health, CDC.
Dr. Boyle said the Center was delighted to be working with Health Resources Services Administration (HRSA) and National Institute of Health (NIH) to provide appropriate services for children with hearing problems. She said early detection and intervention are vital in order to provide those services in a timely manner.

Grant Management Issues - Ms. Sonia Rowell, Procurement and Grants Specialist, CDC
(notebook section 2)

Ms. Rowell reviewed the following grant management issues: required information on correspondence; Grants Management Office (GMO) responsibilities; Program Office (PO) responsibilities; grantee responsibilities; reasons for award restrictions; removal of restrictions; no-no's for restricted items; removal of restrictions; and how to contact the GMO.

> All grants correspondence must contain the CDC-assigned award number, the signature of the Principal Investigator (PI) and that of a representative of the business office.
>
> The GMO ensures conformance with policies and regulations governing the award, its administration, and any changes to the award; ensures conformance to special terms and conditions placed on the award; and receives all correspondence from the grantee and provides official responses to the grantee.
>
> The PO responds to technical and programmatic questions or correspondence; provides direct consultation and assistance on program matters; evaluates the programmatic compliance; and assists the GMO by providing recommendations on requests requiring GMO approval.
>
> The grantee is responsible for carrying out the activities and objectives in the approved application; following the terms and conditions of the award; submitting all required reports; and informing CDC of any issues concerning the award.

Awards may be restricted for any of the following reasons: human subjects issues, extensive IRB review by CDC and the grantee are required; use of funds are not clearly identified; failure to comply with terms and conditions of the award; missing documentation, such as names of contractors and subcontractors, period of performance not stated, method of contractor selection not delineated, itemized budget and justification not included.

Restrictions can be removed when the grantee adheres to the requirements of the award. Restrictions are removed only upon the receipt of written approval from GMO, verbal approval is not given. Approval may be given for a single project, for IRB approval, or for the entire award. The removal of restrictions process takes approximately 30 days.

No-no's for restricted items include: conducting human subject research without SPA(s) or current IRB approval -- IRB approval is good for one year only; requests to release restrictions received by GMO after the end of the budget period; costs incurred for restricted items without written approval from GMO; acting from verbal approval from anyone at CDC; selecting key personnel positions prior to obtaining approval from the PO and the GMO.

How to contact the Grants Office

Ms. Lisa Garbarino
Grants Management Officer

Ms. Sonia Rowell
Grants Management Specialist

CDC/Procurement and Grants Office
2920 Brandywine Road, NE, Room 3000
Atlanta, Georgia 30341
770-488-2724, phone 770-488-2777, fax

Session I: Collaboration - Activities and Roles
Moderator: Dr. June Holstrum, CDC
(notebook section 3)

Dr. Holstrum said the purpose of Session I was to gain a common understanding of the direction Early Hearing Detection and Intervention programs will be taking during the next five years of the grant. The panelists for this session were influential in getting the EHDI program started.

Presenter: Ms. Pat Dewey, Directors of Speech and Hearing Programs in State Health and Welfare Agencies (DSHPSHWA)

DSHPSHWA was established in 1964 to: develop a better understanding of programming for communication disorders within the public health and welfare setting; develop more efficient programs for the diagnosis and treatment of communication disorders within the public health setting; encourage research of the services for communication disorders within the public health setting; and provide a means for continued professional growth relative to programming for communication disorders within the public health setting.

Initially, DPS, as the organization is now called, was attached to ASHA as a related professional organization. When DPS began, the 15-20 members were a new breed of professional, with responsibility for statewide speech and hearing programs. In the 1980s, states were beginning to establish newborn hearing screening programs, and the professional contact DPS provided was invaluable to the membership. Today DPS is composed of 66 members, including one each from Puerto Rico and Guam, and several members from Canada.

Dr. Aaron Favors is the Federal representative. As of 1999, nine states and the District of Columbia have no identified members. Nurses and physicians are now included in the membership. Members have been active in national maternal and child health issues, and over the past year the group has drafted five position papers on communication disorders.

Future areas of focus include medical home assurances for children with special health care needs, managed care issues and data collection.

Presenter: Dr. Karl White, National EHDI Technical Assistance Center

All babies should be screened for hearing loss before one month of age, diagnosed with hearing loss by three months, and receive intervention by six months. All babies should receive treatment that is culturally competent, and all children should have medical homes.

The number of hospitals in the US currently offering newborn hearing screening programs (NHSP), has grown from 30 in 1993, to 1400 in 2000, totaling 2 million babies per year. This increase is due to improved screening techniques and equipment that make identifying children with hearing problems faster and easier, and hand-held screening devices that make identification cheaper. Acceptance of NHSP by policy makers, the increased number of successful programs, and increased public awareness and demand have all contributed to more and better screening programs.

All states are doing some screening, and 13 states screen 90% of all newborns. Thirty-two states have legislation on newborn screening, but some states have not funded NHSP. Some 2,800 hospitals are not yet screening newborns for hearing problems, which means 2 million babies,

about half of all newborns, are not being screened. Also, tracking and follow-up are not yet in place as part of the public health milieu.

There are concerns about the screenings that are being done. The quality of the some of the audiologic reports indicate that some audiologists are not trained in newborn screening, and that others need retraining. Although appropriate early intervention for profoundly hearing impairment is good, the system is not designed to adequately handle mild, moderate and unilateral hearing losses.

Over the last decade there has been a good deal of Federal support, beginning with the Healthy People 2000 goals in 1990, the Maternal and Child Health grants and the CDC grants focusing on data integration have helped tremendously.

One of the eight Federal initiatives is the EHDI Technical Assistance System. The goal of the system is to work with states and hospitals; serve as a clearinghouse for materials and expertise to assist states in ensuring that every child with hearing loss is identified and enrolled in treatment; see that every family is provided culturally competent assistance; ensure that each child has a medical home, and help states develop tracking and follow-up systems that can link with other Public Health systems. The Center's technical assistance strategies to states include: an expanded website; bulletin board; state home pages; a toll-free technical assistance telephone line; production of EHDI monographs; hosting workshops and meetings; publication of a newsletter; maintain a National EHDI Assistance network of expert audiologists from 10 regions; and collaboration with other agencies and groups.

Presenter: Ms. Irene Forsman, HRSA

The Health Resources Services Administration (HRSA) is the agency that supports the grants program on newborn hearing screening. The focus of this program is on services, which parallels the CDC grant which focuses on tracking and screening data.

The HRSA grants program requires: screening prior to discharge from the newborn nursery; audiologic diagnosis by three months; enrollment in an early intervention program by six months; linkage to a medical home; and linkages to family-to-family support.

HRSA is a partner with CDC which provides: quality monitoring; data collection and management; outcomes evaluation; determination of causes and risk factors for congenital hearing loss; data sharing; and cost effectiveness studies.

HRSA has plans to share data with immunization registries and has a number of utilization projects. The genetics program is issuing an RFP for data sharing.

Another HRSA partner, the NIDCD, is charged with research and development on the efficacy of new techniques and technology including clinical studies of efficacy of intervention and related research.

In April 2000, HRSA awarded 22 states funds for Universal Newborn Hearing Screening and Intervention (UNHSI) programs, and funded one technical assistance center. In 2001 there will be authorizing legislation, but appropriations are still pending. An RFP has been issued for an additional $5 million for 31 state programs. The due date for proposals is December 8, 2000, with reviews occurring in February 2001, and awards made March 31, 2001. The RFP is posted on the MCHB website and will be published in the *Federal Register*.

Currently 22 states are funded. These states are well-spread-out over the country, with a natural mix of urban and rural states being represented. Less than 50% of kids with hearing loss are in early intervention programs, and that is not acceptable for funded states. There is no sense in screening, if kids do not get the help they need.

There is a meeting being planned in June on the genetics of deafness to develop guidelines for genetic testing and counseling.

Presenter: Dr. Terese Finitzo, Joint Committee on Infant Hearing (JCIH)

The JCIH has issued a 2001 statement on accountability, that recommends principles and guidelines for EHDI programs. These recommendations include quality indicators and benchmarks individual hospitals and practitioners can use to monitor progress toward the goal of improved language and literacy for children who are deaf and hard of hearing.

The JCIH goals for 2001 include: placing infants at center of family care; broad dissemination of 2000 Position Statement to states, medical and health care professionals and organizations, insurers, HEDIS, practitioners, and educators; promoting the use of principles in hospitals and state EHDIs; appointing a subcommittee to review and propose an EHDI legislative model; studying the issues around and roadblocks to implementation; developing detection algorithms; focusing on data collection and management; interaction with other organizations; examining the genetics of hearing loss; and reimbursement for screening, diagnosis and treatment.

An evidence gathering session to work on implementing these goals will take place February 26-27, 2001, at the ASHA headquarters in Rockville, Maryland. Families and other EHDI stakeholders will participate.

The JCIH position statement can be found on the ASHA, AAP, and AAA websites, and in the October issue of *Pediatrics*.

Presenter: Dr. Amy Donahue, NIDCD, National Institutes of Health (NIH)

The National Institute on Deafness and Communication Disorders (NIDCD) is part of the National Institutes of Health (NIH). The NIH supports research and has had an interest in hearing impairment since 1993. The research NIDCD supports should: form the basis for clinical practice; provide data for public health policy; and provide information for practice guidelines. NIDCD provides grants related to newborn hearing screening, hearing aids, issues concerning cochlear implants, and grants specifically for early identification and intervention.

Recent grants have funded four new studies, including intervention issues after identification, how to intervene, what to do, and outcome measurement.

In addition to research, NIDCD interacts with all communities involved in early identification and intervention. NIDCD convenes a working group to look at research questions, but, since the groups meet only three times per year, it has difficulty keeping up with changing issues. In September the working group took a holistic look at screening and intervention. (The minutes of that meeting are in notebook section 3).

Questions that need to be answered involve: auditory response recognition, how to know if a child is responding to hearing aids; the genetics of hearing loss, genotype and phenotype identification; genetic testing, ethical and legal issues; and over-referral consequences.

Presenter: Ms. Lisa Holden-Pitt, OSERS

The Office of Special Education Rehabilitation Services (OSERS) is within the Office of Special Education Programs.

OSERS priority begins with the referral to intervention of families of toddlers who have been identified as having a hearing loss. This jurisdiction comes from the 1997 Individuals with Disability Education Act (IDEA), Part III. With hearing screening becoming more routine, many more children will be identified with hearing loss in the early months of life rather than early years of life. OSEP recognizes the apparent advantage of early knowledge of hearing loss and intervention, but realizes that there is not necessarily an advantage to outcome if quality and timely services are not provided. Early intervention in communication skills development is essential, and for those desiring proficiency in auditory-oral communication earlier intervention with digital hearing aids or cochlear implants is preferred. Early identification and diagnosis in a newborn comes at a particularly fragile family time, and introducing these technologies can be difficult.

OSEP's partnership with agencies, such as CDC, allows OSEP to measure the state-level success in identifying and reaching these families with services. OSEP's most recent annual report shows that nearly 10% of those receiving services through early intervention are receiving otologic services.

OSEP funds several EHDI-related projects, (see list in notebook section 3).

Another critical element for early intervention is that medical professionals and parents must be familiar with the referral process. OSER is working with the Bureau of Maternal and Child Health to reach pediatricians to get earlier intervention across disabilities, trying to get away from the "wait and see" approach.

Other OSEP projects include: sharing data from the state monitoring and research division, to see what is and is not working in the states so that research initiatives can be better tuned. A primary OSEP objective is that all children with disabilities receive appropriate services to address individual needs. OSEP sees the need for broad, longitudinal study of children with hearing loss and their outcomes. Through collaborative efforts such a study can be accomplished.

Session II: Infrastructure and System Building
(notebook section 4)

The CDC Perspective
Presenter: Dr. Coleen Boyle, CDC

Dr. Boyle reviewed what CDC is asking of the grantees.

> The EHDI data tracking and surveillance system does not consist of just monitoring who is being screened for hearing loss, but should also include diagnoses and interventions. The EHDI is not a stand-alone tracking program, but an ongoing program that will reveal improvements and deficiencies. An integral component of the state-based EHDI is monitoring implementation and evaluation of the system. The data gathered will allow investigation of the genetic and environmental causes of hearing loss. The state data will allow CDC to compile national data to track progress re: national objectives, to identify population subgroups in need of special attention for tracking, and to examine the risk factors for hearing impairment.
>
> The EHDI will link with other state data systems for children with special health care needs, which will allow CDC to look at the services that are used by providers and to determine the services needed by children.
>
> Research priorities for Level II (those states with currently good surveillance and tracking programs) include cost effectiveness, causes and associated factors in hearing loss, benefits of early identification and intervention, and psychosocial and family issues. (Utah is the only Level II awardee, but if additional funding is available, CDC will add one or two Level II states.)

On October 17, 2000, President Clinton signed the Child Health Act of 2000, which, among other things, created the Center for Child Development, Disability and Health at CDC. The Center had formerly been a division of the National Center for Environmental Health. The conversion to a center must be implemented within 180 days, and all programs will remain untouched.

Interaction with States
Presenter: Dr. Vince Campbell, CDC

Interaction with the states through communication is the greatest concern over the life of the program, so that states are aware of the goals and objectives of the programs, and can implement their programs.

Interaction with the states is outlined in PA00076, Cooperative Agreement (notebook section 2). You will be referred to that announcement over the next five years as the blue print for your program. The PA will serve as the framework for your objectives and evaluation plan.

CDC role in the cooperative partnership is to provide technical assistance on design, program development, evaluation methods, approaches used for state-based EHDI tracking and surveillance, technical assistance on the development of research questions and analytic guidance, data analysis technical assistance, and facilitation of data compilation.

State projects will take part in committees concerning data sources, populating the database, reporting systems, evaluation plan, family issues and concerns, data items and definitions, and the executive committee. A further description is provided in notebook section 11.

Two CDC publications each project should have, which are available online, are the *CDC Framework for Program Evaluation in Public Health*, and the *1988 Guidelines for Evaluating Surveillance Programs*, for which an update is due next month.

Committees will be composed of a member from each state, and a CDC person. Committees will meet by conference call once per month. The Executive Committee will be chaired by Dr. Holstrum and will include the PI/Pm from each program, plus the chairs of the other committees. This committee will communicate monthly as well, to keep track of events across committees.

Barriers and Enhancers
Dr. Karl White - Introduction

The most serious barriers to successful Universal Newborn Hearing Screening (UNHS) are expense and reimbursement. Other issues include physician opposition, the unwillingness of hospitals to add a new procedure, the perception that too many babies do not pass the screen on the first test, and that the babies' stay in the hospital is too short for effective screening and follow-up. Another concern is that, even if babies are screened, there will be no services available

for them, so screening raises false hope in the parents. Parent opposition and lack of proved benefits of screening are not issues.

State Example: Maine - Ms. Ellie Mulcahy

Three years ago one hospital in Maine was offering UNHS. An audiologist drafted sample legislation requiring testing. Maine is a rural state, and in many areas people cannot get to an audiologist. The legislation asked for four health department staff persons to conduct the program, but only two positions were approved. Small hospitals are also unable to do screening because they have neither the personnel, nor the funds, to hire staff. There are 32 birth hospitals in the state, most of which are along the Route 95 corridor, which is the most populated. Medical services are available within 45 minutes to one hour's drive on either side of the corridor. The licensed audiologists are mainly in the same area, and they drive 60-90 minutes between hospitals.

Challenges and approaches

1) Attitudes - because of a lack of awareness, only 10 hospitals are conducting UNHS. To overcome this lack of awareness, the Department of Health (DOH), held a statewide workshop in which two panels participated. One panel was from the perspective of the hospitals and audiologists, and the second was from the parents' perspective.

2) Funding - most birthing hospitals are small, with only two having more than 1000 births per year. After surveying hospitals, perinatal nurse managers were referred to other people who had creative approaches to working with hospitals. Peer support and pressure worked to the advantage of screening, in that the perinatal nurses' group meets quarterly. Local groups such as the Lions, helped raise funds, as did bake sales and raffles.

3) Reimbursement - Medicaid uses "prospective reimbursement" for the inpatient setting. Hospitals cannot bill for services performed by nurses. The DOH will consult with Medicaid and insurers to gain reimbursement.

4) Access - although there are 52 audiologists in Maine, their distribution within the state is uneven, with only two being located in the north region. Also, it is unknown how many of the audiologists have experience or training in screening newborns. The DOH is developing a survey of audiologists to determine their training, experience and interest in mentoring. The DOH is also planning a conference in conjunction with a university for audiologists.

5) Distance - many families must drive up to three hours to receive a comprehensive audiologic evaluation. The DOH is supporting linkages between providers and agencies, and encouraging mentoring to increase skills with infants.

6) Poor linkages - between providers and agencies, hamper skills attainment and service provision. The state is developing a resource list for families, hospitals, providers and agencies.

7) Tracking and surveillance - limited staff are available to conduct the activities. The DOH is partnering with the University of Maine for database development and management. The state is also working to develop better relationships between audiologists and the early intervention staff. State legislation approved two new positions for the DOH.

State Example: Hawaii - Dr. Beppie Shapiro

Hawaii started newborn screening in 1988 without state funding. Although Hawaii was the first state to develop enabling legislation, the health department found there were no experts in the state, the screening process was unfamiliar, and there was no outcomes data for comparison. Everyone knew that children were identified too late, but neither doctors nor hospitals knew how to identify children earlier.

There was also opposition from some of the powerful physicians in the state who feared screening was unproven by research and might result in either over referrals, or overwhelming the system with legitimate referrals. Some audiologists were opposed to the screening protocol and equipment the state mandated. Other barriers to UNHS were the unknowns, such as: the resources that would be needed; how long screening would take; what the process would be; how diagnoses would be handled; how many audiologists were experienced working with newborns; how to treat hearing losses that were mild or moderate; the overestimation of the transferability of skills of pediatric audiologists and early intervention specialists to young infants with hearing loss/unilateral hearing loss; the effect of parents receiving bad news early in the baby's life; the lack of coordination of services. There were also communication problems between the hospital and audiologists who were unfamiliar with newborn hearing screening; between hospitals and medical specialists, e.g., ENTs; and between audiologists and central staff who were not used to having to pass information to other parties. Coordination of special cases, such as deaf/blind infants was also a problem.

Several things helped the program succeed, especially a strong leader, a strong commitment from the majority of hospital newborn hearing screening managers, 1990 legislation, funding support through and MCH grant from 1994-97, and, during a critical period, the UNHS coordinator was also a practicing audiologist.

Hawaii overcame the barriers to UNHS by persuading parents and professional leaders of the benefits of the program, importing experts to advise the program and help persuade leaders, and disarming the enemy with information. Hawaii also used the lack of mandating legislation as a plus by convincing hospitals and physicians to comply voluntarily, rather than because they had to comply.

There are some things, however, that Hawaii would have done differently, including: mandating data collection and sharing; mandating screening implementation; starting training of audiologists before identifying children; choosing performance outcomes and indicators before selecting a database. Even without these changes Hawaii went form screening 19% of newborns in 1992, to screening 99% of newborns in 1998. Home screening is also being offered. In 1987, identification of hearing loss occurred by 50 months of age, by 1998, identification occurred by six months.

The future for Hawaii includes data integration, working toward full participation, and improving early intervention services for children with hearing impairment and their families.

State Example: Arkansas - Dr. Laura Smith-Olinde

In 1993, Arkansas passed high-risk paper screen legislation. In 1999, universal physiologic screening was passed for hospitals with more than 50 births per year, which required hospitals to perform or arrange for a bilateral physiologic screen. Forty-seven of 54 affected birth facilities have UNHS programs in place, which will cover some 99% of births in the state.

Before 1995, Arkansas Department of Health (ADH) audiologists traveled to several Little Rock area hospitals to screen NICU infants' hearing. The Arkansas Children's Hospital Audiology Department began a universal screening program in one hospital outside the Little Rock area.

Hospitals were reluctant to take on the voluntary and unreimbursed responsibility of a continuing and expanding infant screening program. However, when hospitals were informed of the date ADH/ACH personnel would stop screening, hospital personnel were trained to perform the screening, with ADH/ACH providing technical support.

Legislation proposed by the Arkansas Hospital Association wanted screening to occur only at the hospitals with 500 or more births per year, but that would only reach some 75% of births, and many of those hospitals were already screening voluntarily. The legislation was changed from 500 births per year to 50 births per year. The ADH was also successful in getting Medicaid mandated to reimburse hospitals for screening in addition to the stated per diem.

Although the legislation is an unfunded mandate, many hospitals choose expensive equipment, and others opted to use a two-stage process using a cheaper screen initially and a more expensive screen for secondary confirmation.

The main Health Department clinic and two satellite clinics were closed in early 2000, making follow-up difficult. The screening legislation is vague, and says nothing about having to do anything after discharge. Hospitals are not held responsible for children they miss. In addition, the three audiology clinics, in which the first visit was free, have closed. So now there are 12 counties with no audiologists, and many people have no transportation to get to the few remaining audiologists. To assist families, ACH audiologists travel to clinics around the state, and a university-affiliated program travels to the Delta region monthly.

Reimbursement remains a problem since a new ARKids Program has replaced Medicaid. The new program does not cover audiologic testing or screening and no hearing aids are covered. There is no free screening in the state. Insurance companies will not be mandated to pay for screening.

There are two separate early intervention programs in the state for children with hearing loss, but neither program is housed in the ADH and each is in a separate agency. The CDC grant has encouraged people to collaborate across agencies, but turf issues have to be worked out.

There is a lack of awareness of hearing loss in the state. Hearing loss is often called the "invisible disorder". Arkansas was recently rated the unhealthiest state in the nation. The ADH is trying to raise awareness through a quarterly newsletter, by adding the Infant Hearing Program to the 1-800 telephone information line, by developing a website(s), and a media campaign.

The UNHS program is invisible within the department of health largely because it is a new program with a new director. The program is trying to raise its profile within the department by talking to ADH staff at Grand Rounds, and by making other programs stakeholders.

Discussion

The presenters were asked which data tracking systems they used. Maine replied that the University of Maine Speech Disorders Department has allotted funds for the tracking system which is being developed. Electronic birth certificates are cross matched with metabolic screening to capture border births, and a similar system will be used with hearing and home births. No information is received on births to residents that occur outside the state, and primary care physicians will be required to ascertain screening and facilitate follow-up. Hawaii uses the Hi-Track system. Hawaii captures some births through WIC and other programs. Arkansas uses a combination of paper and computer. Paper forms are received n each child, and the data is entered into a WANG mainframe. They are trying to convert to a PC system. Arkansas gets data from Tennessee on out-of-state births to residents, but not from others. Many out-of-state Arkansas births occur in Oklahoma, and many Mississippi parents give birth in Arkansas.

ARKids is a CHIP program. It was suggested that CDC and others present could impact CHIP at the national level for reimbursement. Ms. Forsman said CHIP at the Federal and local levels is willing to cooperate, but they are not at the table yet. HRSA has hired a contractor to work with them, as has ASHA.

Session III - Collecting Standardized Data for Evaluating EHDI Programs
Dr. June Holstrum - Introduction
(notebook section 5)

Dr. Holstrum referred to the materials in section 5 of the notebook. These materials provide a framework for selecting data items, and offer proposed definitions for the standardization of

EHDI tracking systems. Sample data collection forms are also included. The proposed core data will provide the basis of the national data set, but states will collection information that does not go to CDC, as well.

The Healthy People 2010 Hearing Goal 28-11, proposes to increase the population of newborns who are screened for hearing loss by age one month, have an audiologic evaluation by age three months, and are enrolled in appropriate intervention services by age six months. The potential data source to monitor this goal is the CDC state-based EHDI Program Network. National data set items will be finalized in the data items committee. At the basic level the data set will need to include the number of children screened by one month of age, diagnosed by three months of age and receiving services by six months of age.

Data collection items for the national data set are:

1) Number of live births
2) Number screened prior to discharge, before one month of age
3) Number referred for audiologic evaluation
4) Number who received audiologic evaluation by three months of age
5) Number of children with permanent congenital hearing loss aged 0-7
    - Laterality of hearing loss
    - Type of hearing loss
    - Degree of hearing loss
        - Mild hearing loss
        - Moderate hearing loss
        - Severe hearing loss
        - Profound hearing loss
6) Average/Median Age in months of diagnosis of hearing loss
7) Number of infants receiving intervention by six months of age

JCIH has developed quality indicators for the screening, confirmation of hearing loss, and intervention services components of the EHDI program, which are listed in section five of the notebook.

The JCIH also has developed risk indicators for hearing loss where UNHS is not yet available. Risk indicators for birth through 28 months of age include: an illness or condition requiring admission of 48 hours or greater of an NICU; stigmata or other symptoms associated with a syndrome known to include hearing loss; family history of permanent childhood hearing loss; craniofacial abnormalities of the pinna and ear canal; and in-utero infections.

Risk indicators for 29 days through two years of age in addition to the above include, but are not limited to: parental or caregiver concern; postnatal infections associated with hearing loss; neonatal indicators; syndromes associated with progressive hearing loss; neurodegenerative disorders; and/or persistent or recurrent otitis media.

Data collected for the EHDI tracking and surveillance systems should address the following items from the RFP: status of infants through the EHDI process; risk status of identified infants; types of hearing loss; types of intervention; identification of late onset and progressive hearing loss; unexpected clusters of children with hearing loss; false positive rates; loss to follow-up; parent concerns; professional concerns; and timeliness, completeness and success of project.

State Example: Utah - Mr. John Eichwald

Mr. Eichwald gave an historical overview of newborn screening efforts since 1953, beginning with the development of the Apgar scores in the 1950s, to current JCIH recommendations.

Utah began hearing screening in 1967, when 117 infants were screened in four Salt Lake City hospitals in a seven-day period. Utah began using a maternal questionnaire for hearing screening in 1976, but decided two years later that it was not effective. A question on hearing was added to the birth certificate, instead.

In 1987, *"The Ups and "Downs" of High Risk Hearing Screening: The Utah Statewide Program"* was published, which identified six weaknesses in high-risk hearing screening; high false positive rate, poor identification of risk from birth certificate data; high percentage of congenital hearing loss not found, high loss to follow-up, privacy and confidentiality.

In 1998 the Utah Department of Health (UDOH) began looking at the X-12 data standards as the Utah model. Those standards include name, date, demographic, address and alphanumeric identifier standards. CDC tends to be more on the HL-7 standard and various other Federal agencies use different standards, so finding one standard will be difficult.

Also in 1998, Utah amended the legislative mandate for metabolic screening to include hearing loss. Hospitals with more than 100 births were required to screen. The rate of screening has increased from 34.9% in 1995 when screening was voluntary, to 92% in 1999 following the legislative mandate.

Utah has received an MCHB grant that requires all states and jurisdictions to report data in a standardized format for use with their block grant applications. Of the 18 national core performance measures specified by MCHB, two relate to UNHS. Utah is trying to link its data from birth certificate data and the hospital Hi*Track system to assist in program monitoring, tracking, follow-up and reporting.

Utah is currently implementing the Child Health Advanced Record Management (CHARM) program to link hearing screening records, newborn metabolic screening records and vital records for the entire population of children born in Utah. The long-term goal calls for linking this data with immunization data and expanding to more child-health related databases. CHARM is pilot testing the use of a unique identifier. This identifier is added to the birth certificate and the Hi*Track. One thousand labels were created with the metabolic kit number and distributed to one

small rural hospital and one large urban hospital. In a three month period, 599 births certificates were recorded from the two hospitals, there were 596 records of metabolic heel sticks, and 589 were entered into the Hi*Track system. Future activities include further data analysis, following up with the hospital staff, identifying what worked and what did not, and determining the next steps.

Discussion

Participants were unsure that unique identifiers could be used, as the Family Records Privacy Act (FRPA) forbids data sharing using unique identifiers.

State Example: Minnesota - Ms. Pat Rice

In 1997, 8% of the newborns in Minnesota were screened for hearing loss, in 2000, to date, 58% of newborns have been screened, and it is projected that 76% will have been screened during the year once all data has been received.

There are 112 birthing hospitals in Minnesota. The smaller hospitals have willingly joined the hearing screening program, seeing it as a value-added service for its patients. However, the larger hospitals have been more reluctant to participate. Of the 112 hospitals, 58 have screening programs reaching 58% of newborns, 16 other hospitals have plans to screen, which should reach 18% more children.

Current data items collected include the number of births, the number of newborns screened, the number of birthing hospitals, and Federal Child Count Part C data, i.e., the number of children 0-3 years of who have received diagnoses of deaf or hard of hearing and are enrolled in early intervention centers. In 1999, 58 children in Minnesota were receiving Part C services.

Screening data elements at birth include: no screening program; the number of children who passed the screening; the number of children screened who were referred; the number discharged and transferred before screening; the number deceased; and the number of children whose status is unknown. Information needed includes the percentage of children who pass and fail the screening; the percentage screened before one month of age; the percentage of children identified before three months of age; the types of hearing loss, etc.

Minnesota EHDI has several options for populating its database, such as metabolic screening data, birth certificates, and the Follow Along Program (FAP). FAP hospitals refer at-risk children to community nursing programs. Minnesota has a public health nurse in every county. The Department of Health would like to send hearing data to the FAP for follow-up. In some counties, every baby gets a visit from the county health nurse, and many parents view the county nurse as a non-threatening.

Goals of the FAP are: to support families; exchange information between families and health care providers; ensure a medical home for each child; assure early identification and intervention of disabilities; provide data for local, regional, statewide and national planning; and enhance interagency collaboration.

Strengths of the Minnesota program include an interagency agreement among the departments of health, education, human services and economic security, the FAP, web-based data management programs in the health and education departments, and the voluntary nature of the EHDI program. Another asset is the MCHB UNHS Grant Program. Funding from this program has allowed the state to increase public awareness of UNHS, form an advisory committee, work with the University of Minnesota on an audiology and mutidisciplinary education curriculum, and form regional EHDI teams.

The challenges Minnesota faces are how to provide the data needed by the local, state, regional and national entities, how to handle individual data at the state level without a privacy rule, and how to obtain hospital "buy-in" to merge their data with the state's data systems?

Session IV - Populating the database
Mr. Brandt Culpepper - Introduction

Mr. Culpepper said since states were working with multiple levels of data, they need to be aware of what kind of data is needed at each level, and how the data is used, so that the process can be simplified and unnecessary data is not collected. Data is gathered for use at the hospital, local/community, regional, state and national levels. Data resources include public, Federal, established state systems and commercially available systems. States can show the UNHS works, if the data and indicators to look for are known.

Vital Statistics, EBC
Presenter: Ms. Mary Anne Freedman, CDC

Registration of vital records is decentralized in the US. It is a state responsibility that is governed by state law. There are 57 registration areas in the US, one in each of the 50 states, the District of Columbia, New York City, and five US territories. New York has separate laws governing New York City and the rest of the state. Births and deaths are registered by service providers, hospitals, doctors, medical examiners and funeral directors.

Birth certificates in the US have two purposes, one as a legal document offering proof of birth, and the other as a data source for demographic and health information. Legal information gathered includes name, place of birth, parents, and the name of the certifier of the birth. Data gathered includes medical and health status, demographic data, prenatal care information, risk data, and birth anomalies. There is also a place for states to add questions specific to that state.

For the past 50 years, 99% of all births have occurred in hospitals. Data is gathered from the mother's medical records, and a birth certificate is typed. The appropriate signatures are obtained and the certificate is sent to the registrar within 10 days of the birth. The local registrar accepts the record and forwards it to the state within one month. Electronic birth certificates (EBC) changes the process. The birth can be recorded immediately, electronic signatures can be obtained, and the document can be sent electronically to both the local and state registrars simultaneously. An EBC is a prima facia document.

The standard certificate revision, due in 2003, will change the way states record births. Every state will have to revamp its software, and the opportunity will be present for the EHDI to link with the electronic birth registry. EHDIs should get to know their state registrars to develop the partnerships they need.

Hi*Track
Presenter: Dr. Karl White, Utah

The purpose of the EHDI data system is to improve the rate of children being screened, diagnosed and treated for hearing loss. Quality assurance of data and research information depend on what each entity wants the system to do. Hospitals, local and state DOHs and national agencies all want different data. Therefore, core data must be identified that everyone will collect, and flexibility must be allowed for optional and research variables. Core data include basic information, such as numbers of children, the hospital doing the screening, screening results, referrals, etc.

Computers allow better tracking and follow-up, communication with stakeholders, aids reporting to funding agencies and administrators, improves program management and enhances quality assurance.

Statewide computer systems can assist in monitoring program status to identify inservice and technical assistance needs, act as a safety net for babies who fall through the cracks, assist with follow-up for diagnosis and enrollment in intervention programs, provide access to data for public health policy and administrative decisions, and can link to other public health data systems, such as immunization registries, WIC, vital statistics, early intervention, and birth defects registries. Other benefits of computerized systems include identifying children lost to follow-up, finding late onset hearing problems through birth defects registries, and making immunizations more easy to follow up.

Hospitals are more likely to voluntarily comply with data collection if they can see how data will be used locally, that data entry is quick and reduces other reporting requirements, and information is easy to transfer.

Three states use the DOS-based Hi*Track system. In Utah all but three hospitals use Hi*Track, with some sending data electronically and some sending in disks. In Iowa some hospitals send

data to the area education agency, then to the state, while others send data directly to the state. In Hawaii, all data are sent to the 0-3 project first, then the state and early intervention providers.

There are several options for developing EHDI systems. Each state can develop its own system, modify an existing system, integrate with the EBC, or purchase an existing system.
When looking at the options, each state needs to think through how people in the system will submit data, as it is not always easy to access web connections.

Hi*Track is used in 200 hospitals across the country. If hand held screening devices are used, a list of the babies who pass the screen and who are referred can be entered into the system. Information for each baby is entered along with the mother's information and hearing information. Follow-up letters can be generated in several languages, reports can be generated, and data from other equipment can be merged. Utah does not issue an EBC until after the baby is screened. Hospital records differ from EBC records, therefore, by merging all babies who can be identified for screening. Utah state law requires screening. The Utah system also allows access to much data not already in the Hi*Track, such as JCIH risk factors and mother's address. Merging data does create issues with overwrite rules, who has better information, and which information goes into the system. Duplicate matching is needed to determine whether a baby has been entered more than once.

OZ
Presenter: Mr. Ken Pool

OZ Systems move data from donors to recipients and from OZ system to OZ system. As a recipient OZ might be used to log nursery information in real time as each child is born, receive data from billing records or EBCs. As a donor OZ may send information to a screener, a registry, or another OZ system. Entering data once decreases costs and the chance of errors.

The OZ system receives data from systems other than OZ systems as ASCII import. Screener data is received as OZ-7. OZ uses an open standards interface with which all manufacturers can interface. EBC data is received as ASCII import in secure data packets. It donates data as ASCII export, to systems other than OZ systems.

ASCII is best used for local public data exchange because it is universal, however, it is not secure or confidential. OZ-7 is allows open data exchange that is secure.

Secure data packets are automated completely, can be sent over public methods, are encoded and encrypted, and cannot be opened or accessed by anyone other than the password holder. These packets are addressable and allow for multiple data source integration.

Neometrics
Presenter: Ms. Diana Laukaitis

(notebook section 7)

Twenty-four state health departments are long-term users of the Neometrics system for newborn hearing and metabolic screening. The system allows the DOHs to share information with their various constituencies, with a minimum of data input. Remote users access the system through the web, with the first security wall being the DOH. These users can enter demographic data and get additional information in return, as determined by the DOH.

Missouri is an example of a state using the Neometrics system. In Missouri, hospital nurseries, medical records offices, physicians' offices, follow-up centers, patients and health care providers are remote users who can access the system. After the hospital has screened and/or referred the newborn, that data is entered into the system either by the remote user via the web, or by a paper form mailed to the DOH. If the hospital enters data through the web, then a label is printed so that dual entry is not necessary. The hospital can see the results, can pull back data needed for additional statistical analysis, and can pull in medical records information. This data is added to the MOHSAIC data warehouse.

Neometrics is an Oracle database, but OCDB will work as well. Data can be sent to other applications also.

CMS features include: immediate notification of positive screens; audiologist and treatment center referrals by zip code, city or county; bi-directional communication and data transfers among local, state and regional facilities; and long-term care can be included for future program expansion.

CMS enhancements for the hearing program include: patient's family history related to hearing; referrals to audiologists; patient status and treatment records; patient care information for long-term follow-up; and state early intervention services reports.

Web-based features of CMS include: on-line access for health care providers to reports, results and patient status; reports available in HTML format suitable for publishing on the Internet; and statistical reports generated showing the number of infants screened, referred and repeating the test.

State Example - Iowa - Dr. Lenore Holte
(notebook section 6)

The University Hospital School, of the University of Iowa has a contract with the Iowa Department of Public Health (IDPH) to provide training and technical assistance to audiologists, and pediatric audiologists. The many partners involved in the program is a strength, but it is also a barrier to data sharing and transfer. UNBS is voluntary, and there is no EHDI legislation in the state. There are 94 birthing hospitals in Iowa, with 85 participating in screening, representing 97% of the births in the state. Screening personnel include audiologists, OB nurses, pediatric nurse

practitioners and part-time screeners. Screening methods include automated brain stem response and otacoustic emissions.

Data managers were very important in getting screening started in the state. Data managers include private audiologists, hospital audiologists and educational audiologists from Iowa's Area Education Agencies (AEA). The AEAs overlap with the Part C regions, so audiologists are sufficiently spread out to cover the state. The northwest section of the state has a dearth of services, but BoysTown in Nebraska provides services for Iowans as well.

AEA audiologist provide rescreens of babies who fail the birth admission screen. These rescreens are performed in the hospital or AEA offices, screener training and EHDI data management services.

Iowa EHDI funding comes from three sources. One is the cooperative agreement between the University Hospital School and IDPH funded by IDEA, Part C, a second is an MCHB Improvement Projects Grant, and the third is a CDC cooperative agreement with IDPH.

Iowa is currently operating many systems such as, SIMS, Hi*Track, and a paper system. Data flow from: 1) small and medium hospitals to AEAs to the IDPH database for timely follow-up, and 2) directly from large hospitals to IDPH.

In 1999, there were 36,000 births, 19,105 of which were in reporting hospitals. Of those reporting hospital births, 17,829 were screened, with 708 not passing the final birth admission screen, yielding a 4% referral rate. There are no data on diagnosis of hearing loss, entry into early intervention or progressive risk indicators. There are 94 babies annually with permanent hearing loss.

Once timeliness is assured, data will flow from the hospitals to IDPH with follow-up information sent to the AEAs. Data items will include those recommended by CDC, and
EHDI fields in the EBC will serve as a check on the accuracy of aggregate screening data. Some AEAs see EHDI data as part of their duties, others do not. AEAs are independent entities, and there is no consensus.

Barriers to EHDI implementation include a lack of agreement on the role of audiologists and AEAs, time constraints, consent, confidentiality, sharing data and inconsistent professional preparation.

Future plans call for linking the EHDI to the genetic and metabolic databases, the deaf/blind census and the birth defects registry. The EHDI also plans to link to the educational information management system (IMS), which draws intervention information from IEP and IFSP.

State Example: Massachusetts - Ms. Janet Farrell and Mr. Saul Franklin

(notebook section 7)

Massachusetts has a long history of record keeping, having the oldest continuing vital records in the US - since 1841. The legislative history ranges from the Premature Infant Reporting Law in the 1930s, to the Universal Newborn Hearing Screening Law in 1998.

State law mandates screening and insurers are required to pay for them. Hospitals are required to arrange for testing and screening. State law also provides for an Advisory Committee composed of consumers and providers.

The High Risk Infant Identification System (HRIIS) includes hearing loss. HRIIS was a paper system, parallel to the birth registry process. It resulted in too many delays and errors. Sometimes follow-up letters were sent to people who had lost babies. That system was scrapped.

The FIRSTLink was implemented with HRSA funds and includes a broader scope than the HRIIS. There is a consent process integrated with birth registration and records are downloaded daily from the Vital Statistics Registry. Data is also transmitted to community-based programs. Fifteen hospitals have over half the births in the state. Hospital data will be the initial means for populating the system, but birth defects information will be included later.

The UNHS program ensures hearing screening for all newborns, requires change to the EBC, and develops the Childhood Hearing Data System (CHDS) to support tracking and testing outcomes. To date, 53 out of 54 hospitals have submitted newborn hearing screening protocols.

Postnatal data collection will be a paper system to start, and informed consent is a stumbling block. Also, mismatches are a big problem. CHDS will link with the Early Intervention Information System (EIIS). There are concerns over the length of time it takes to enroll a child in EI, approximately 45 days, and with the date the diagnosis is entered. The EIIS has a field for the birth certificate number, which can be linked to check for kids who have moved into the state and are not receiving services.

There are proposed plans to identify older children, up to age seven, with hearing loss using DPH-approved audiologic centers, non-approved centers, the DPH School Health Unit and the Department of Education.

Data challenges include: early discharge (48 hours stay) versus the time-sensitive screening process; integrating with the birth certificate registry will improve data quality, but there is no way to assure all children are captured; decentralized versus centralized data collection; address changes for high-risk children, often within three weeks of birth; name changes for children; and home and out-of-state births.

There are 1,500 births to Massachusetts residents that occur out-of-state, most at Rhode Island Institute, and attempts to work an a Memorandum of Understanding (MOU) have been unsuccessful.

Future directions call for evolution to a web-based CHDS to make access easier for testing centers, possible links to primary care providers, and a plan that is consistent with those for the EBC system.

Thursday, November 9

The meeting was called to order at 8:30 by Dr. Holstrum.

Ms. Dewey provided some information on the Virginia program. Virginia developed its own web-based hospital reporting system. The system has proven beneficial in that it allows the Department of Health immediate access to records, and changes can be made quickly. Since the system is paid for by Federal funds, it may be available to other states for modifications.

Section V - Data integration
Mr. Ken Pool - Introduction

Mr. Pool provided an overview of data integration, discussing the steps, priorities and context necessary for integration to occur.

The steps include determining the why, what, where, how and who of data integration.

1) Why - reasons to integrate are optimization of quality and cost of care, and accountability;
2) What - the arenas of care include hearing and metabolic screening, registries, Child Find activities, etc.;
3) Where - bedside, regional clinics/offices, laboratory, Health Department;
4) How - approaches to data integration include a cascading flow of data, synchronized data sets, a single data set with multiple applications, or a single application with a single dataset;
5) Who- do it yourself, hire a consultant, use an integrated application, or outsource data integration to a service provider.

The first priority of data integration must be the quality of the data. It must be accurate, timely, obtainable, usable, and secure/confidential. Secondly, who can modify and access data must be determined.

Data integration is the basis for operational integration, and operational integration should define data integration strategies.

Blood Spot Screening

Presenter: Mr. Brad Therrell, NNSGRC

The National Newborn Screening and Genetic Resource Center (NNSGRC), in cooperation with HRSA, provides a forum for interaction concerning newborn screening and genetics programs, provides education and serves as a resource center. The UNS programs in 22 states are reviewed in depth, and a subcommittee has been added to look at newborn hearing screening.

Mr. Therrell encouraged EHDI programs to use newborn heelstick programs to populate their databases. Depending on the state, newborns are screened for three to 30 metabolic disorders. Newborn screening programs include screening, diagnosis, intervention, follow-up, management and evaluation. NSP provide practitioner's manuals, and require standardized minimum data collection. Since the heelstick information is already entered into a database, using the same system avoids duplication of effort, and reduces errors and multiple entries for a single child. Database sharing/warehousing can occur among hospital admissions offices, newborn and hearing screening programs, and birth, immunization and birth defects registries.
A general data warehouse can contain and combine data from all sources, and data can be shared with many programs.

The issues surrounding data sharing and warehousing include whose information will be included, parental consent to have and share information, how and with whom to share information, security and privacy concerns, and a universal identifier.

The benefits of data sharing include putting follow-up in the hands of public health, centralization of data on all newborns, and not needing separate data systems. The drawbacks to data sharing include the need for additional follow-up staff, gaining the cooperation of parents and physicians, additional data manipulation at birth, and needing an updated system.

In order to share data states must modify their systems, modify data collection forms, prepare parent letters, and develop protocols for hospitals and physicians.

Birth Defects Surveillance
Presenter: Ms. Cara Mai

In the US there are between 120,00-160,000 children born with major birth defects each year. These children account for 30% of hospital admissions, at a cost of $8 million annually. Birth defects are the leading cause of infant mortality.

New Jersey was the first state to begin birth defects surveillance, starting in 1926. CDC joined the effort in 1968, and currently only nine state have no surveillance program.

The purposes of birth defects registries (BDR) are to detect trends, quantify morbidity and mortality, stimulate research, register cases for analytic research, evaluate service needs, guide intervention, and direct education and advocacy.

BDRs provide data for comprehensive reviews and accurate diagnostic criteria and classification. The BDR is a large database containing timely information, personal identifiers and providing confidentiality.

Case ascertainment requires an examination of every baby born, a review of medical records, a legislative mandate for hospital and physician reporting, linkage of multiple datasets, and inclusion of vital statistics records.

Data sources for database population include vital records, hospital records, genetics screenings, perinatal clinics, Medicaid records, insurance records, HMO data, and hospital discharge information.

The National Birth Defects Prevention Network will meet January 29-31, 2001, in San Antonio. For more information log-on to www.nbdpn.org.

Immunizations Registries
Presenter: Dr. Rob Linkins, National Immunization Program(NIP), CDC
(notebook section 8)

The US currently has the highest immunization coverage and lowest disease rates in its history, so it could be argued that there is no need for immunization registries. But immunization registries do have benefits in that they assist parents and physicians in keeping up with the complex childhood immunization schedule, which is further complicated by a mobile society. Providers often overestimate the coverage of children in their practices, and when children change providers shots may be unnecessarily repeated, or missed entirely.
Immunization registries also consolidate records, produce recalls and reminders, and identify "pockets of need".

The Healthy People 2010 immunization goal is to increase to 95% the proportion of children 0-6 years of age enrolled in a fully functional population-based registry. All states are developing or implementing registries. With 22% of children in registries currently, the cost has been $181.3 million in Federal funds to date.

The challenges facing immunization registries are to ensure protections of privacy and confidentiality, participation of all providers and recipients, functioning of registries and sustainable funding.

Minimum confidentiality standards and specifications have been developed by the National Vaccine Advisory Committee (NVAC), and include confidentiality policies and agreements, notification and choice, explanation of data use, access to and disclosure of information, penalties for unauthorized disclosure, and data retention and disposal.

NIP will work with professional and parent organizations to demonstrate the usefulness of registries in order to ensure full participation. Currently, 74% of public providers and 42% of private providers use registries.

To ensure registries function well a core dataset has been developed which includes: patient name, birth date and sex; birth state/country; mother's name; and vaccine type, manufacturer, date and lot number. Immunization registries require use of H standards.

Immunization registries cost $5 per child per year, totaling $125 million per year to develop and operate. One sustainable funding source is Medicaid which can fund up to 90% of the financing to develop a registry. The Vaccines for Children Program may be an additional funding source.

For more information on immunization registries log-on to www.cdc.gov/nip/registry

All Kids Count
Presenter: Dr. David Ross, Director

All Kids Count (AKC) is a program of the Task Force for Child Survival and Development, and is funded by the Robert Wood Johnson Foundation. By the end of Phase I AKC knew that registry development was feasible and what a functional registry was, but there still were no functional registries, so, in 1998, Phase II was funded.

Managing immunization information is a challenge since there are 11,000 children born each day, who should receive 18-22 shots each, by the age of six. Of course, immunization registries face the same challenges and have many of the same goals and characteristics of other registries. By sharing data with newborn metabolic and hearing screening, lead screening, birth and infant death registries and EPSDT much duplication of effort can be saved, and resources can be maximized.

The AKC III Mission is to demonstrate that linking or integrating preventive child health information systems can: improve therapeutic and preventive decisions through consolidated information; ensure follow-up according to standards; eliminate redundant data entry and multiple systems management; and provide public health officials, payers and purchasers with population-based information.

AKC III tasks include: developing a shared vision among payers, providers, vendors and purchasers; demonstrating the value of integrated preventive health information; sponsoring innovative projects; addressing privacy and confidentiality concerns; identifying long-term financing options; and assuring flexibility through standards.

For more information log-on to **www.allkidscount.org, or www.dross@taskforce.org.**

Part C - Child Find
Presenter: Ms. Lisa Holden-Pitt, OSEP/OSERS

The State Monitoring Division of the OSEP is the Child Find contact. When developing the program regulations, local interpretations of Federal legislation was factored in. For information on how states use child find, log-on to www.ed.gov/offices/OSERS/OSEP/.

The main function of IDEA is to assess state and local efforts to provide early intervention and educational services to infants and toddlers with disabilities. OSEP conducts continuous improvement monitoring on five cluster areas, with Child Find being one of those areas.

Before 1986, intervention and educational services were offered by a number of agencies, and Congress recognized the need for coordination of services and to address diversity issues within communities. This was the catalyst for IDEA, Part C.

To be eligible for Part C services, a child must be developmentally delayed or have a condition that can lead to developmental delay over time. States are required to identify a lead agency to administer the program, develop a state definition of developmental delay, and identify children at-risk. Cross-state variation of definitions varies widely.

The lack of descriptive information on how states organize to offer services is significant, since the Federal goal is assist states to coordinate existing resources to provide services. Part C funds are centered around providing a safety net or filling gaps in state services.

Although IDEA is administered by the DOE on the national level, on the state level the DOE is the lead agency in only one third of the states. Federal regulations require that the lead agency, with the advisement of the state Interagency Coordinating Council, ensures compliance with state policies and procedures by all public and private entities participating.

Primary referral sources are required to provide materials for parents and professionals on the availability of early intervention services. Public awareness programs also are required, that address how to make referrals to service agencies. Lead agencies must have procedures to determine the extent of information dissemination.

Part C funding is determined by birth census data, and usually includes a variety of funding sources, including Federal funds in addition to Part C, state, Medicaid, private insurance, and, in some cases, direct payment by families.

States are required to identify the procedures by which data are compiled.

The OSEP monitoring staff developed a list of program components that make a good program, including having an early childhood tracking system for at-risk children, and actively searching for all children to provide screening.

Child Find systems that are not coordinated with all other agencies providing early intervention services are out of compliance.

OSEP found that delays are occurring in initial evaluation and assessment of children referred to early intervention, and not all services are being offered with the 45-day timeline. These delays are due to lack of personnel, difficulties in coordinating services and travel distances to receive services.

Relating to yesterday's question concerning FRPA restrictions on data sharing, some exemptions are made for longitudinal studies. It is important that we make people aware of the need for coordination of data, which meshes with the current efforts of many Federal agencies for synchronization of relational databases. We must change the minds of people who are making the decisions on what can and cannot be used.

Session VI: Portability, Integration and Confidentiality
Dr. Vince Campbell, Introduction

This session will discuss the policies, procedures, regulations and guidelines that allow data to travel across different settings.

HIPPA/HISSB
Presenter: Ms. Helen Regnery, Chief, Executive Secretariat, HISSB, CDC

HISSB/CDC is formulating enacting policy for public health surveillance systems. The long-term vision for data standards is to enhance the comparability, quality and integrity of health information through uniform data policies and standards. Successful data integration requires data standards. There are three essential elements for successful integration: 1) data standards; 2) communication infrastructure; and 3) policy-level agreements. For integration to occur, people need to be shown what it means to share data.

With the rise of the age of information technology, industry recognized the benefits of electronic data interchange (EDI), and many industries developed proprietary formats. Currently, there are 400 formats for electronic health claims. If information is to be shared, saving time and money and protecting patients, there will have to be legislation authorizing its integration and requiring development of standards.

A significant step in the development of health data standards was the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The purposes of HIPAA are to improve the efficiency and effectiveness of the health care system by standardizing the electronic data interchange of certain administrative and financial transactions, and to protect the security and privacy of transmitted information.

The Administrative Simplification Provision of the act requires HHS to adopt national standards that all health plans, clearinghouses and providers who conduct transactions electronically must implement.

Several entities are charged with implementing HIPAA. The DHHS Secretary is mandated to adopt transaction standards, and required to issue regulations to protect privacy of electronically transmitted information. The DHHS Data Council is in charge of implementing the Administrative Simplification Provision of HIPAA. The National Committee on Vital Health Statistics (NCVHS) is required to study issues and report to the Secretary recommendations and legislative proposals for uniform standards. The NCVHS is not a government committee, but is comprised of representatives from the private sector and universities. The Standards Development Organizations (SDOs) are the key to standards development.

The HHS Secretary published Privacy NPRM, November 3, 1999, as required by law. The Final Rule, issued in August 2000, established ASCX12N as the required standard for seven transactions and NCPDP as the standard for pharmacy transactions. The code sets that must be used are: ICD-9-CM; CPT-4; HCPCS; CDT-3; and NCD. This rule does away with local codes and moves to national HCPCS code system.

Other NPRMS are in progress including a national provider identification number, an employer identification number, a national plan identification number and a personal identification number. The personal number is on hold.

The CDC also is active in standards activities. The National Electronic Disease Surveillance System (NEDSS) is HIPAA compliant.

For additional information log-on to www.dcd.gov/od/hissb/.

IRB/OMB
Presenter: Mr. Mark Long, Human Subjects Manager, CDC

Human subjects research is a new area of specialization that arose after the Nazis experiments of WWII. It is easy to abuse the trust research subjects place in researchers, so researchers must ensure that participation is voluntary, that it is based on informed consent, and that, above all, no harm is done to the participants. Data must be used responsibly and participants must be informed that although every effort will be made to protect them, it is possible that data from the research can be used against them.

Resources are available for consultation on human subjects research including CDC POs, the Center for Environmental Health, Center for Birth Defects, and the OHR.

One of the questions asked of human subjects research is, "Is it research?", as the line between evaluation and research is often unclear. Another question to consider is, "Will harm occur if the

information is released?". If the risk is minimal, i.e., no greater than those faced in every day life, then the IRB chair can approve the research, However, if the risk is greater than minimal, a full IRB review is required. There are 3000 IRBs in the US.

Mr. Long reviewed several documents given to participants: "Developing a Protocol", the "Alphabetical & Annotated Index of Human Subjects Documents" and "Consent for CDC Research".

Mr. Long said informed consent can be waived in some settings, but the state IRB has to be contacted first. He also referred participants to the HHS document "Responsible Conduct of Research".

For more information log-on to www.cdc.gov/od/ads/hsr, or, as a last resort, contact Mr. Long at 404/639-4035.

Session VII: Data Integration - State Examples
Ms. Irene Forsman - Introduction
(notebook section 10)

State Example: Colorado - Ms. Vicki Thomson

Ms. Thomas said that other states would not want to use a paper data management system, nor would they want to copy Colorado's legislation.

Colorado has 63,000 births per year at 60 birthing hospitals. Fifty hospitals use EBCs. Only the Federal Army Hospital refuses to screen. Colorado passed legislation in 1997.

Colorado has ample research to back up the 1/3/6 months recommendations. The critical language development period is between 0-6 months, and data show that children who are identified and treated early have almost normal outcomes.

Colorado developed its Data Management System to look at how individual hospitals are doing with screening newborns. To bring EBC clerks on board the Department of Public Health and Environment (DPHE) held community forums around state.

The NHSP uses the EBC to populate the hearing and genetics databases. Final discharge screening results are given to the EBC clerk, and babies are coded to determine appropriate follow-up - M is missed, D is deceased, T is transferred, and R is refused. Results are sent to the DPHE within four days. Eventually, results will be sent to the medical home/PCP as well. Monthly reports are sent to all birthing hospitals and names of infants that failed the screen, missed or transferred remain in the report until follow-up has occurred. Hospitals resubmit updated monthly reports, and Audiology Regional Coordinators monitor hospital screening programs. One problem is that many small hospitals do not have Internet access, therefore much

of the system is a paper system. Audiologists submit follow-up reports on all infants referred from the NHSP. Results are sent to the medical home/PCP of each child. Colorado is gathering follow-up data to determine what needs to be funded.

The Colorado Resource Coordinator is funded by Part C funds. This program started over 20 years ago, and Colorado is one of the few states with a separate early intervention program. Most children needing intervention are hooked up to the Colorado Home Program. The referral rate is 2%.

Advantages of the Colorado Infant Hearing Data Management System include: utilization of a system already in place; decreased duplication of entering demographic data; efficiency; minimal cost; and provision of opportunities to integrate with other programs. Disadvantages of the system include: reliance on a manual system for updates; reliance on a manual voluntary system for the hearing coordinators; and requires FTE for inputting.

State Example: New Jersey - Ms. Pam Costa

New Jersey has the oldest Birth Defects Registry in the US, dating from 1928. The registry began with orthopedic conditions. Changes in Federal funding continues the state's integration of surveillance and case management. In 1964 metabolic screens were added to the registry, and in 1977 hearing impairment was added. The legislation is so broad that no changes were needed to add hearing screening. Almost 60% of the hospitals in the state are conducting hearing screening.

Building the system has required many components including Title V funding, broad legislation, MCH block funding, state, local and Federal funding, communication/partnerships, consumer input, and an evaluation component.

The Special Child Health Services Registry contains birth defects, biochemical, hearing case management, and EIS genetics data and information. Each county has a case manager who is independent, but still provides data. Families are sent information letters and brochures concerning their child's problem(s).

The Commissioner of Health can release data to other agencies as she sees fit. Services are provided for children from 0-21. Case management attempts to contact each family of a registered child. This is the entry point for Part C.

Each component includes quality assurance measures. Criteria are measurable, and the system encourages/provides means for self-evaluation for reporting agencies. Data are used to link to treatment services, surveillance, research, needs assessments, and collaborating projects.

New Jersey has more EPA Superfund sites than any other state. It also has the highest AIDS rate in women, and the fifth highest overall. The AIDS program wanted all pregnant women to receive antiretroviral therapy, without regard for birth defects.

The system provides many services, such as screening and treatment, letters to parents and PCPs, case management, and Part C services. Coordination includes local, state and Federal health and social service agencies.

The New Jersey system works for the following reasons: the broad authorizing law; funding from the MCH block grant; its location in the Division of Family Health Services; it is part of an integrated system beyond CSHCN; good communication among partners for the aid of children; data are part of the system; it is integrated with numerous agencies; there is buy-in from agencies and hospitals; it provides New Jersey with the ability to meet challenges; there was public involvement in rule readoption, members of the advisory panels review rules every five years.

The challenges still faced are confidentiality, staffing and access to out-of-state vital records.

The benefits of the system are: it helps children; it is cost effective; it provides timely identification of children and directs them to referral and case management/EIP evaluation; it promotes communication and builds partnerships among the agencies/departments involved in surveillance and services; and it provides data to answer public concerns.

State Example: Michigan - Ms. Elise Dimon

The Michigan Department of Community Health (MDCH) wanted a mandating law, but hospitals were already screening voluntarily, using the National Academy of Sciences Guidelines to Screening. Hearing screening was added to the metabolic screen. Eventually, only one form will be used and demographic data will be sent only once to the MDCH. Bar codes will allow linking of data that is received at different times. Of the 103 birth hospitals in Michigan, 101 will start screening for all babies. Quarterly reports are sent to the hospitals letting them know which children were not screened, so they can conduct follow-up with those children.

Newborn hearing screening is linked to the Newborn Screening database which is composed of seven blood specimen screens. The number of infants reported to that database is the denominator, and all newborns who have hearing slips sent to the MDCH comprise the numerator. Further analysis is available relative to reported hearing information. Currently the NSP has a manual entry. Infants and children with reported hearing loss are now being linked to the Birth Defects Registry. The BDR will be a focal point for linkage with other databases, such as CSHCS and Early On®Michigan database. Michigan will link the newborn hearing and metabolic screening to birth certificates as a true denominator.

The MDCH is currently upgrading its system for many functions including electronic reporting for demographics. Vital Statistics is also working on a five-year plan to upgrade for electronic reporting and data integration. Grant funds are allowing the state to upgrade the systems.

In 1997, reported follow-up rates were less than 5%. In 1998, with the development of forms and the use of a part-time consultant, follow-up rates improved to 25%. Additional part-time staff

were able to increase rates to 50% in 1999, and in 2000, follow-up rates are between 50-65%. Referral rate are about 3%.

At present, there is little tracking of hearing aid fitting and educational intervention with children identified by the NHSP. There is ongoing discussion with the EarlyOn® program to provide that data. Although there is no impact data available, anecdotally it is clear that infants who are entered into the system are getting help much quicker.

To expand services to children, the NHSP will use Medicaid volunteers, with WIC and HeadStart. An education grant will send nurses to visit all newborns to determine what services they need. This will be done on a county-by-county basis.

Several challenges still faced by the program include how to look at later on-set hearing loss and progressive hearing loss, and determine who will monitor their needs and progress.

The Michigan Hospital Association is now pushing third party payers to pay for hearing screening.

Session VIII - Next Steps
List Serves
Presenter: Dr. Roy Ing, CDC
(notebook section 11)

CDC has set up List Serves and a Web Board to facilitate peer-to-peer sharing of information and communication among committee members. A List Serve has been set up for each of the seven committees.

Data integration is a difficult, but exciting, subject. The second Internet revolution is underway and it will allow servers to connect to other servers to look for information. XML will be the new industry-wide language standard and new systems will need to be able to use that language.

Privacy and confidentiality will continue to be problems, but data has to be integrated.

The meeting was then adjourned