

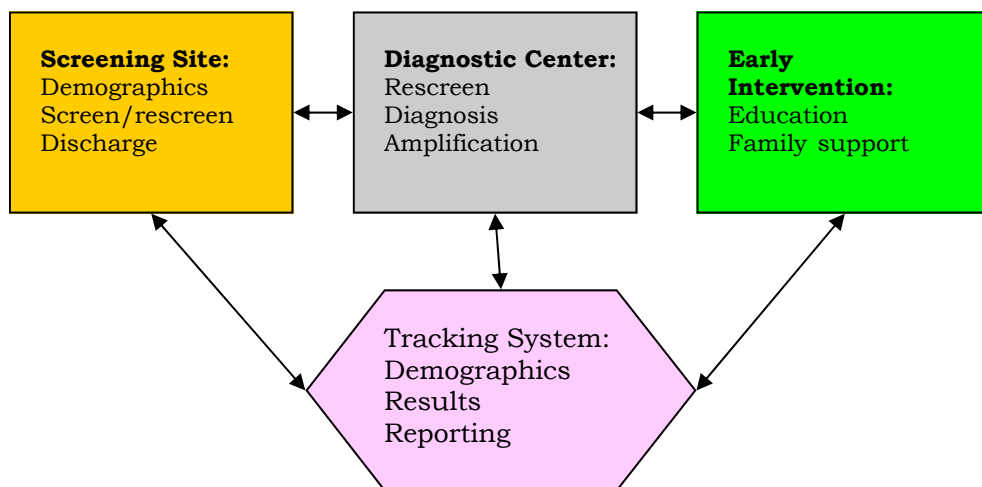
The User's Guide to Early Hearing Detection and Intervention Information Management Systems

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EHDI PROGRAM DESIGN

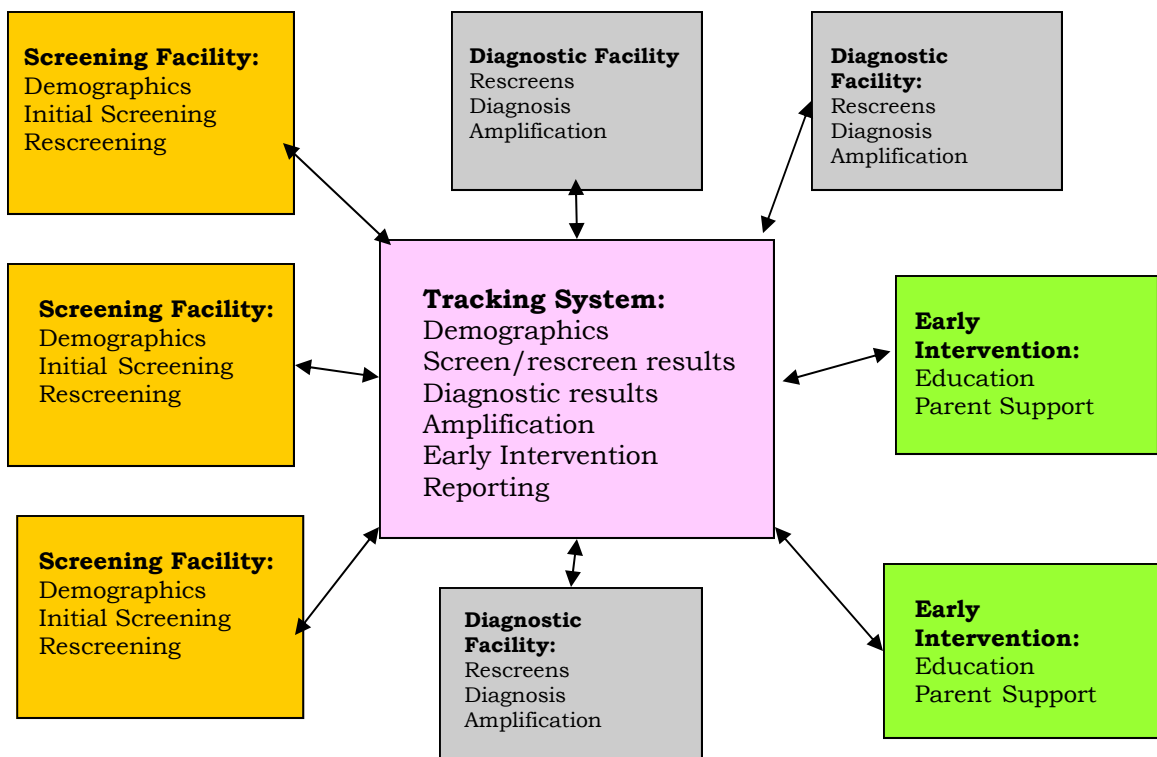
To the casual observer, Early Hearing Detection and Intervention (EHDI) programs are simple to design and operate. The basic requirements are to screen all babies, identify those who have a hearing loss by 3 months of age and enroll them in early intervention prior to 6 months of age. Since most babies are born in hospitals, screening programs have been developed to take advantage of this captive population and provide the first hearing screening prior to discharge from the newborn nursery. Other programs have been implemented to screen those born outside birthing hospitals as early as possible. The percentage of babies screened prior to discharge from the newborn nursery continues to increase each year and it appears very likely that newborn hearing screening will be truly universal in the not too distant future. Accomplishing the identification of hearing loss and enrollment into early intervention is not quite so simple nor well defined. Reports of more than 25% of babies being lost to follow-up following a non-pass or not screened result are far too frequent. EHDI requires the coordinated efforts of numerous professionals operating within a well designed and coordinated system.

EHDI program design varies considerably, depending on the requirements and resources of the population served. In its simplest form screening, diagnosis and early intervention are each provided by a single source or homogenous group of sources. Infants flow seamlessly from the initial screening process to a diagnostic center, receive amplification and enroll in the early intervention system within the requisite 6 months that most programs strive to achieve. In this type of program, an Information Management System need only track the progress of each infant through the system and report the results.



Single Source Program Design

More commonly, EHDI programs have multiple screening sites, several diagnostic facilities and more than one early intervention provider. Tracking infants through such a system, while challenging, is the only way to ensure that program goals are being met.



A Typical EHDI Program

One of the most challenging aspects of establishing an EHDI program is information management. If the only task were to count and report the total number of births, the number screened, the number who passed and the number of non-passes, program design would be very easy. When all the other information necessary to follow-up and track babies is added in, program design becomes much more complex. Even the simplest of programs generates an astounding amount of data which can quickly overwhelm the capacity of a poorly conceived management system.

The purpose of this booklet is to assist in the selection and design of an Information Management System (IMS) that best suits the requirements of your EHDI program.

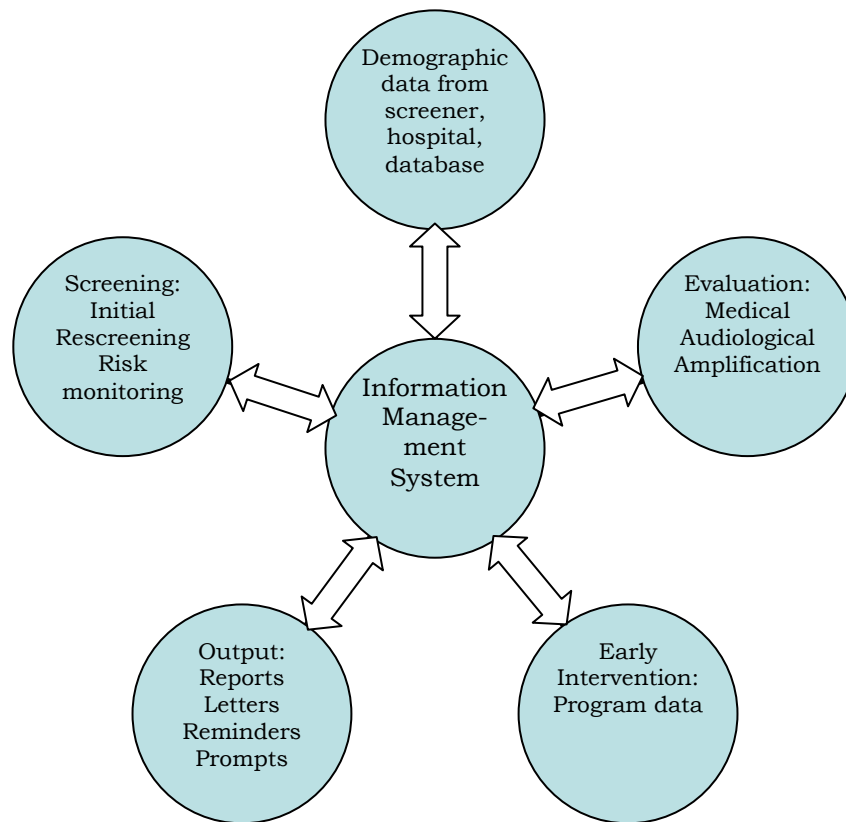
DATA TO BE MANAGED

A certain amount of data is basic to EHDI programs. Assuming you are interested in doing more than just simply counting numbers, your data will include items in the following areas:

- ◆ Demographics—Name, birth date, medical ID, sex, hospital name, nursery type, parent/contact name, address, telephone, name and address of PCP. Demographic data may also include insurance carrier information, language preference of the family, transfer hospital, etc.
- ◆ In-Patient Screening Results—Date, type of test, results for each ear, reasons if not screened, screener identification and unit identification.
- ◆ Out-patient Screening Results—Date, type of test, results for each ear, reasons if not screened, screener identification.
- ◆ Risk factors—information on any of the JCIH or locally determined risk factors present.
- ◆ Diagnostic Results—Date, type of test, results for each ear, additional test data, recommendations, diagnostician identification and demographic information.
- ◆ Amplification Information—Date, specifications, test results, recommendations, dispenser information.
- ◆ Early Intervention—Date of enrollment, program identification, service provider, recommendations.
- ◆ Tracking Data—Recommendations, schedules, changes, updates, reminders.

TYPES OF INFORMATION MANAGEMENT SYSTEMS

Information does, in some manner or other, get managed in every EHDI program. It is unrealistic to expect program personnel to monitor the movement of each baby through the system without adequate information from each stage of the process. Reporting results and quality assurance efforts require that information be regularly compiled and examined. As you can see from the following diagram, the Information Management System (IMS) is an integral and critical part of the operations of any EHDI program.



The Information Management System Is Central to EHDI Programs

The kinds of management systems are almost as diverse as the range of programs. Here are some of the types of information management systems commonly reported:

“Home Grown” management systems are characterized by simplicity and effectiveness for limited program requirements. Pencil and paper systems are an example of systems designed to meet specific needs and resources. Many programs, lacking the financial wherewithal to purchase or develop a computerized system, have started with pencil and paper reporting systems that adequately served their purpose. Paper and pencil systems are, by definition, very labor intensive—there must be adequate personnel to deal with the anticipated volume of paper forms received. Some have adapted software products, such as Microsoft Excel or Access databases to serve the purposes of their EHDI programs. A few EHDI programs have custom written software, taking in to account their own needs and capabilities. For small numbers of births and limited tracking needs, “Home Grown” systems are often initially quite adequate.



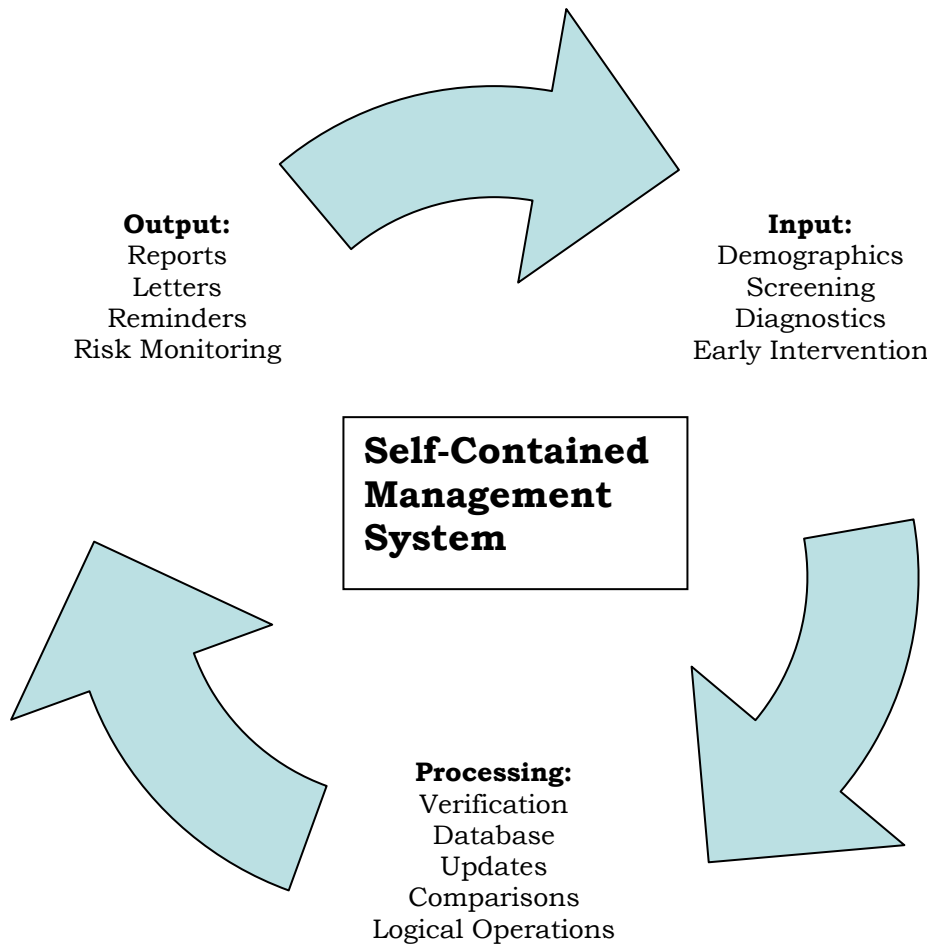
**EHDI information often outgrows the capacity of
Pencil & Paper systems**

The danger, of course, is making the “home grown” system too limited for expanding numbers of births and reporting requirements. Increasing the capacity and range of capability of such systems is often very difficult and labor intensive. Another danger of “home grown” systems is that they often become obsolete due to improvements in operating systems and programming languages. Programs written in DOS, those using unconventional languages or discontinued software may be faced with the prospect of depending on obsolete hardware to function. It is critical that any “home grown” system be designed with the future in mind, an often exceedingly difficult task for those without the proper background and experience.

Self-Contained Systems. These are single purpose systems developed with the needs of EHDI programs in mind. There are two types of self-contained systems—those developed by manufacturers for use only with their equipment and those developed for use by multiple pieces of equipment and in many different settings. Most of the software designed by manufacturers for use with a specific piece of equipment is adequate for screening in a single facility, but not designed for multiple location tracking and the follow-up needs of a full blown EHDI program.

There are at least two systems designed to work with multiple pieces of equipment and across multiple settings. Although they approach their

tasks differently, either can be the foundation for an effective EHDI information management system. Self-contained systems utilize modular software, some components of which are intended to be installed on screening equipment and others on equipment used for tracking and follow-up. Equipment used for both purposes can have multiple modules installed. Communication between the screening equipment and tracking software may be accomplished through transfer by disk, modem, or on a network. Networked software allows each computer in the system to share a common database.



Self-contained systems provide security settings so access to system functions and data can be controlled. Screeners, for example, may be able to add demographic data and screening results but not access reporting functions. Security settings may also prevent unauthorized use of any part of the system and ensure confidentiality of the data.

Web Based Systems. Currently, many EHDI programs are using, developing or looking at purchasing a web-based information management system. For EHDI programs with multiple participants, often in many geographic locations, web-based systems allow access to the IMS from any location with internet capability. The ability to enter, access, view and update information contained in the database from almost anywhere with little more than web-browser software can be a definite plus to encouraging EHDI program participation. There may be multiple levels of users for this type of system, each accessing modules specific to their functions within the total Information Management System.

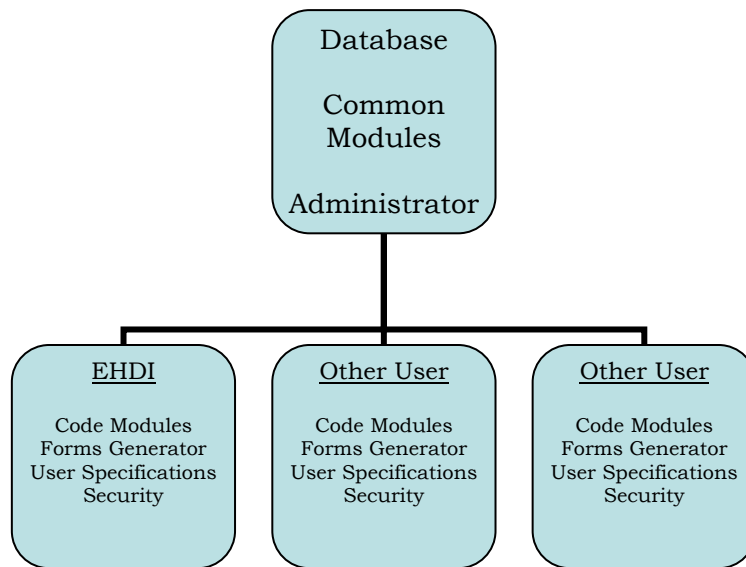
To the user, a web-based system looks like a single program that performs the functions for which it was designed. In practice, web-based systems usually consist of numerous modules, each designed to fulfill a specific purpose in the operation of the system. Acquiring screening data may be done by one module, report generation by another and logical operations on the database by yet another. Each user accesses the system through a user interface--a system module designed to identify, provide secure access and allow operations according to the level of permission granted by the system administrator.

Updating modular software is often an ongoing process, since specific aspects of program operation are constantly changing. Modifying the screening parameters or the types of equipment from which results will be obtained, for instance, may involve changes to only one module, allowing other users to continue their operations during the update process. If all the software is contained on the web server, the administrator has only one piece of software to update to make the changes available to all the system users.

To utilize this type of system, each user must have internet capability and access. The system is accessed by going to a specific website, signing in to the user interface and either entering information or generating reports according to the level of permission the user has within the system. Users of this type of system may be defined by the amount of software on their individual computer as THIN, SLIM or THICK clients. Thin clients have only internet access and all software is contained on the server, thick clients have complete software on their system and are accessing only the database on the web. Slim clients may have varying degrees of local software on their system. In web-based systems, the database as well as software modules and the user interface are hosted on a server accessed by all individual users via the internet. The amount of information each user may create, view, modify or report on depends on the level of permission set when the system is accessed.

Some web-based systems have been designed to accept data directly from hospital screening units, while others have proprietary methods of acquiring data from participants in the EHDI program. In all cases, the web server contains the database and amalgamates information from all the users into some form usable by those responsible for administration and monitoring of the program. There are several commercial web-based information management systems that have been developed specifically for EHDI applications.

Integrated Systems. Integrated systems may be self contained, networked or web-based. The primary differentiator is the use of a common database among several distinctively different, but related, applications. A few states are integrating electronic birth certificate, metabolic screening, hearing screening, diagnostic, early intervention and immunization information into a single database. In a recent self-survey, one state found they were maintaining 28 separate databases on children! The possibility of combining all those databases into one has certainly been the subject of much discussion and planning.



An Integrated Information Management System

The concept of integration into one database that can serve the purposes of many programs appears to be efficient and cost effective. The idea of being able to populate the database from, for example, the electronic birth registry and then have each participant add their specific information to the already existing record does eliminate a great deal of duplication of data input effort. In practice, meeting the needs of a multitude of users can be difficult for software designers and administrators. The considerable tracking and follow-up requirements of

an effective EHDI system are often foreign to designers of integrated systems, resulting in steep learning curves and lengthy delays in implementation. Several such systems are in use and being refined at this time.

Integrated systems share a common database, several common modules for features such as data input, report generation, updating records and other administrative tasks. Each user has specific code modules, forms generators, user specifications and levels of security. The level of data sharing in integrated systems depends on the administrative structure of the EHDI program and the legal constraints under which the program operates.

INFORMATION MANAGEMENT REQUIREMENTS OF YOUR PROGRAM

Here are some additional questions you must be prepared to address in specifying the information management requirements of your program:

- ◆ How will you populate the database?
- ◆ How will data be collected?
- ◆ Will the data be shared? With whom?
- ◆ What operations do you expect from the software?
- ◆ What logical conventions should be incorporated into the software?
- ◆ What provisions will be made for regular updating of the system?
- ◆ What types of reports will you require?
- ◆ What about technical support?
- ◆ How will using this system make your program more efficient and effective?

Let us address each of the preceding questions in more detail:

How will you populate the database? Obviously you need a record of each live birth. This information may be obtained from birth records and entered into your system manually, or may be transferred automatically from some other database (such as an electronic birth registry system.) Alternatively, demographic information about each birth may be entered by the screener prior to actually conducting the initial hearing screen. Your system must provide not only for babies actually tested, but those who refuse, are transferred, missed or not screened for some other reason. However the database is populated, it is important to be able to identify all live births and ensure their participation in your EHDI program.

How will data be collected? A common method of collecting data is on paper forms, information from which is manually entered into an EHDI

system. Many systems include provisions for data to be transferred directly from screening equipment or hospital databases. Others use local or web-based forms to collect data from various sources. It is important that your system provide for data to be collected in a variety of ways.

Will the data be shared? With whom? What provisions will be made for data sharing? How will you address concerns regarding privacy and security of records? Are there legal or practical limitations on data sharing? Information is the lifeblood of any EHDI program and it is vital that timely, accurate information reach those involved if the 1-3-6 month goals are to be achieved for every baby.

What operations do you expect from the IMS? Does your program desire only counting and statistical functions? Do you want to generate fairly elaborate reports, reminders and correspondence? How will the demands of your program grow over the next few years? Will the software be capable of handling your additional requirements without undue delay or expense?

What logical conventions should be incorporated into the IMS? One of the strengths of a computer based information management system is the ability to incorporate logical conventions that can assist program personnel in various ways. The simplest logic may be used to match children and results—since screening and follow-up information may be coming from multiple sources. The next logical step is determining the significance of data received and calculating such things as most conclusive results from several received, deciding which results should be given more priority, matching information on babies transferred to different facilities, which contact may be most appropriate, etc. Reports and reminders are examples of logical operations that must be part of any IMS. While predefined reports may be appropriate for many tasks, the ability to design your own report criteria using built-in logical operations greatly increases the versatility of your IMS.

What provisions are there for regular updating of the software? Can your system be readily updated to take advantage of new hardware capabilities? How will changing some of the parameters of your program affect the system? Will your present data be compatible with any updates? Are there provisions for protection of your database during any updating operations? While software must be expected to serve the needs of users in the short term, it must also establish a foundation that enables flexibility, extensibility and scalability for the future.

“It is quite apparent that the screening and information management portion of EHDI programs is at the crossroads

of two rapidly changing fields—(1) early hearing detection and intervention and (2) information technology. It is certain that changes in these two fields over the next few years will impact the way hearing screening is done, how data is recorded, and how information is used to provide better services to children and families.” (Dr. Karl White, Personal Correspondence, 2003)

What types of reports will you require? While you expect to be able to monitor the number of births, number screened, number passed and number of non-passes, few programs would be happy to receive only this limited amount of information. Quality assurance efforts dictate that you be able to monitor program efficiency and effectiveness by hospital and, in many cases, by individual screener. The Centers for Disease Control has identified a number of data elements that are collected from programs in the United States to help determine effectiveness of our EHDI efforts:

- ◆ The number of live births
- ◆ The number screened prior to discharge
- ◆ Number screened after discharge, but before one month of age
- ◆ Number referred for audiological evaluation
- ◆ Number who received audiologic evaluation by 3 months of age
- ◆ Number with Permanent Childhood Hearing Loss (PCHL), aged 0-7 years, by birth year
- ◆ Number with PCHL by classification
- ◆ Average/median age of diagnosis
- ◆ Number of infants enrolled in early intervention by 6 months of age

The CDC data elements are designed as a pre-defined report in many information management systems and help to serve as a good base for quality assurance efforts. As mentioned earlier, the ability to tailor reports to the requirements of your program greatly simplifies your follow-up and tracking efforts.

Assessing the effectiveness of an EHDI program may depend on results and reports collected over a long period of time, i.e., comparing hearing screening information from kindergarten testing to newborn hearing screening results to find hearing losses that may have been missed in the initial screening. Including capability to add and compare additional information to that already contained in the IMS may significantly increase the usefulness of your system.

What about technical support? This question always provokes a lively discussion between program suppliers and consumers. Anyone who has purchased computer software from one of the large, multi-national

companies can tell horror stories of trying to obtain meaningful technical support. A supplier who promises technical support during normal business hours may not be much comfort to a hospital screener faced with a problem that prevents her from doing her job at midnight. On the other hand, off-hour technical support is often prohibitively expensive, so the needs of your program must be balanced with the budget you have available for information management. Technical support is crucial if your system is to function as intended—it is not a matter of IF problems will occur, but only a matter of when. Careful training of staff can go a long way toward eliminating mundane problems, but technical support is essential when more complex problems appear. Screening and professional staff are rarely computer savvy enough to be able to solve complex IMS issues on their own, so your EHDl program will be heavily dependent on technical support availability and effectiveness.

When faced with whiz-bang demonstrations of the things an IMS will do, the question must be asked: **“How will using this system make our program more efficient and effective?”** Often, there are many flashy capabilities and extra options that have absolutely nothing to do with how your program is conducted. We have all seen the systems that will give us volumes of information, but have no provision to generate the follow-up letters that we need to send almost daily.

SELECTING (OR DESIGNING) AN EHDl INFORMATION MANAGEMENT SYSTEM

When considering an information management system, it is wise to start with broad functional requirements, then look at specifics that are necessary for your EHDl program. Whether you are considering a commercial package or designing your own system, looking at existing software may save you from “reinventing the wheel.” Often, programs developing a list of specifications find that some items are not essential and add substantially to the cost and complexity of program design. Adding non-essential items and features may not add much value or functionality to your overall system.

For hospital based screening programs, your information management system must have the following broad functional capabilities:

- ◆ Record user information (hospitals, screeners, screening equipment used)
- ◆ Record infant demographics and birth information
- ◆ Record parent, contact and provider information
- ◆ Identify the screening status of any child registered on the local system

- ◆ Capture/record newborn hearing screening and rescreening results from designated equipment
- ◆ Record information on babies not screened and the reason not screened
- ◆ Record scheduled appointments for screening or follow-up services
- ◆ Allow new patient related data to be defined, recorded and retrieved
- ◆ Document appointment and provider information related to referral for re-screening, diagnostic assessment, or early intervention services
- ◆ Document information related to scheduled follow-up dates for outpatient screening, assessment, diagnostic and intervention services
- ◆ Document information related to results of assessment and diagnostic services. The following minimum data should be available for each ear:
 - Air and bone conduction click threshold
 - Tone pip ABR (at least 4 frequencies)
 - SSEP thresholds (at least 4 frequencies)
 - Tympanometry—probe frequency and results
 - OAE results (TEOAE and/or DPOAE)
 - Behavioral hearing thresholds at multiple frequencies
 - Dates and types of tests carried out
 - Hearing aid fitting: left, right ear, type of aid, specifications
 - Hearing aid verification measures (DSL, etc)
 - Early intervention details: date enrolled, type of program
 - Comments
- ◆ Generate correspondence to parents and providers related to results, referrals, scheduled follow-up, failure to keep appointments, risk monitoring and other related activities
- ◆ Alert EHDI staff when information related to follow-up services has not been received and recorded
- ◆ Generate and archive routine and user-configured reports
- ◆ Archive and retrieve individual infant records and event information
- ◆ Support controlled levels of access for individual and groups of users
- ◆ Enable groups of users to have appropriate access to data and system functions
- ◆ Provide back-up and recovery functions to ensure that no infants information is lost or compromised
- ◆ All data must be validated on entry and users prompted to correct inappropriate data
- ◆ Provide for security and privacy of individual patient data

- ◆ Have an area assigned to free text entry for comments, progress notes and information not specified in other screens
- ◆ Include provisions for confidential transfer of data from all service sites to a central database
- ◆ Contain provisions to identify and suitably deal with duplicate records
- ◆ Support the use of context sensitive help facilities
- ◆ Have a consistent “look and feel” across all major functional areas
- ◆ Provide for software fixes, upgrades, new releases and enhancements on a regular basis
- ◆ Provide for data compatibility and integrity of the database for future releases and upgrades

In addition to the basic functional requirements as listed earlier, there are several attributes of systems and suppliers that you may wish to consider:

Technical specifications—your program design will drive the need for an information management system. Screening programs are typically one stage (screening is completed when baby is an inpatient) or two stage (initial screening is done as an inpatient and, for those who do not pass, screening is completed on an outpatient basis.) Within a one or two stage program, there may be several test protocols, i.e., OAE followed by AABR and diagnostic ABR for those who refer or OAE, AABR with diagnostic ABR after discharge, or several OAE’s with OAE-AABR after discharge, etc. If you are considering an “off the shelf” system, it is important to specify data elements and functions that best suit the design of your program. Your specifications must include provisions, however, for any unanticipated changes in the design of your program due to procedural or technical advances.

Choose a contractor with expertise and experience in EHDI. The implementation of an Information Management System is a complex undertaking that requires an unusual mixture of expertise and experience in health care delivery systems, implementation of newborn hearing screening and follow-up systems, and software development and support. Far too often, EHDI is added as an afterthought to some other information management system with little understanding of the unique requirements for tracking and follow-up an effective program requires. Implementation of Information Management must be a collaborative endeavor that responds effectively to the needs of stakeholders. Understanding the needs of all the program participants and responding to those needs makes system implementation a relatively smooth process. Often minor modifications of the Information Management

System can make significant differences in reducing the implementation timeline.

Comprehensive Implementation Plan. Implementing an effective Information Management System is much more than just purchasing a piece of software and distributing it to users. A systematic and comprehensive implementation plan is required. In addition to providing the actual software, the supplier (or designer) must be prepared to accommodate the needs of all the users for training and support. The user must be prepared to work with the supplier's project manager to ensure that implementation at each site is designed to meet their needs and functions exactly as specified. As part of the implementation plan, provisions must be made for maintenance and periodic upgrading of the software and hardware as necessary.

Initial and Ongoing User Support. Support to the end user must be readily available at the time it is needed. A local help desk or support specialist can be of considerable help to users, particularly during the initial implementation stages of any IMS. Suppliers are often willing to train local support staff as a routine part of system implementation. Most system suppliers have personnel available to provide help to local support specialists and end users, but the quality and availability of that support varies widely among suppliers. Placing several calls to gauge the adequacy of support services is always a wise practice prior to committing to final purchase of any system.

Software Attributes. The IMS should be easily expanded to accommodate more users and heavier processing demands. Performance with both light and heavy processing loads should be sufficient that no users are experiencing undue delays in their ability to use the system. It goes almost without saying that the software should provide sufficient redundancy so as to provide acceptable reliability. Security should be robust and flexible, most easily provided in multi-layered systems. Program managers must be able to access all areas of the system, while restricting users to only those portions for which they are responsible.

Allow for Future Growth and Expansion. Invariably, as an IMS serves the needs of an EHDI program, users think of ways to improve program effectiveness by refinements in either content or purpose of the system. If the IMS system is designed properly, additional growth and expansion can be accomplished by changing one or more layers of the system while preserving the integrity and safety of the database. One of the primary considerations in any growth and expansion plan is compatibility with present data. Since follow-up and tracking are ongoing processes, any disruption in the integrity of the data may have serious consequences.

Successful Track Record. Implementing an IMS for a regional or statewide EHDI program is a significant investment of both financial and personnel resources. For that reason, it is important to ensure that the IMS is being purchased from a supplier or designed by an organization that has a successful track record and will be available in the future to continue to support and improve the system. Obtain references from any potential supplier and take the time to check those references carefully. Information gained from present users of systems can be very helpful in making the very best decision for your IMS supplier or designer.

Whose Servers? Some IMS suppliers are now offering to host your database and software on their servers, usually at a location remote to your program. Users access the system via the internet and all operations are conducted at the remote site. In practice, where the servers are located matters little to the users. There are some advantages to this type of system:

- ◆ More elaborate servers may be provided
- ◆ Data processing professionals will be responsible for server operation, maintenance and updating
- ◆ Data should be regularly archived and stored securely off-site
- ◆ Software updates are easier for the supplier to implement

Potential disadvantages to remote hosting include:

- ◆ Your whole program is out of operation if the servers or the internet are not functioning
- ◆ You have no control over when backup and archiving are done for your data
- ◆ Security issues may be easier to resolve on a local level
- ◆ The number of users on the system at any time may significantly affect the speed of your operations
- ◆ Your program may not be assigned high priority for technical support or problem resolution
- ◆ Ownership issues regarding your data may surface if you decide to change systems or suppliers
- ◆ Bankruptcy, ownership changes or other business problems of the supplier may have an adverse effect on the continued operation of your IMS

Further information regarding EHDI Information Management Systems:

Helpful information, contact information for state EHDI and data management coordinators, and links to Information Management System suppliers may be found on the NCHAM website: www.infanthearing.org