Quality assurance refers to the systematic monitoring and evaluation of the various aspects of a project, service, or facility to ensure that high standards of quality are being met. A more direct and concise way of defining quality assurance and improvement is to simply say it is “tracking outcomes and adjusting care or practice.” It is essential that programs make rigorous efforts to analyze and improve practices for improved patient care as well as for cost efficiency and sustainability. It is important to recognize that while most organizations are trying to systematically improve value and quality, those that succeed have worked out the operational system and culture to do it.

Even though quality assurance and improvement concepts have been around for some time, many states, hospitals, and programs are not fully aware of what they do well and what they do not. Program evaluation is critical to improving effectiveness, cost efficiency, and overall sustainability of an Early Hearing Detection and Intervention (EHDI) program. Outcomes are used to determine and improve clinical care, cost effectiveness, and sustainability. Rigorous program evaluation goals include:

- Improving how we meet the needs of the families we serve.
- Measurement and improvement of performance.
- Developing evidence-based approach/strategies.

Program evaluation is critical to improving effectiveness, cost efficiency, and overall sustainability of an Early Hearing Detection and Intervention (EHDI) program. Outcomes are used to determine and improve clinical care, cost effectiveness, and sustainability. Rigorous program evaluation goals include:
Quality improvement and evaluation of EHDI programs should be applied at each level of the program.

All U.S. states and territories with Maternal and Child Health Bureau (MCHB) grants or Centers for Disease Control and Prevention (CDC) cooperative agreements are required to do systematic annual evaluations of their projects to implement, expand, and/or improve their EHDI program.

Quality improvement and evaluation of EHDI programs should be applied at each level of the program, including:

- The overall state EHDI program.
- Individual hospital and birthing center programs.
- Home births.
- Diagnostic and intervention programs (pediatric audiologists, amplification, cochlear implants).
- Tracking and surveillance programs.

State EHDI Program Evaluation

State program evaluation must focus on each of the key elements of an effective EHDI program. There are seven major key components and/or standards of a successful EHDI program described by MCHB, CDC, and the Joint Committee on Infant Hearing (JCIH). These components provide the minimum standard elements upon which evaluation of EHDI programs should focus (see Table 1).

As emphasized, the last key component specifically identifies evaluation for quality assurance and improvement. All state programs receiving MCHB EHDI grants must have a plan for program evaluation and must complete a comprehensive evaluation of their entire EHDI program.

A common approach to conducting a statewide EHDI evaluation includes collecting data from each of the

### Table 1

**Key Components and/or Standards of a Successful EHDI Program**

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>All newborns will be screened for hearing loss before 1 month of age.</td>
</tr>
<tr>
<td>2</td>
<td>All infants referred from screening will have diagnostic evaluations before 3 months of age.</td>
</tr>
<tr>
<td>3</td>
<td>All infants identified with hearing loss will receive appropriate medical, audiology, and educational intervention services before 6 months of age.</td>
</tr>
<tr>
<td>4</td>
<td>All infants with hearing loss will have a medical home.</td>
</tr>
<tr>
<td>5</td>
<td>Every state will have a complete EHDI Tracking and Surveillance System to minimize loss to follow-up.</td>
</tr>
<tr>
<td>6</td>
<td>All families will receive culturally competent family support.</td>
</tr>
<tr>
<td>7</td>
<td><em>Every state will do regular systematic monitoring and evaluation to improve the effectiveness of the EHDI program.</em></td>
</tr>
</tbody>
</table>
program stakeholders, using data from questionnaires, analysis of archival information, and onsite evaluations (see Tables 2 and 3). The overall goal is to collect information about how well hospitals and the state system are doing in achieving the seven objectives listed in Table 1.

Data from all of the sources listed in Table 3 are summarized by the evaluation team, analyzed according to the six goals previously described, and compiled into a report. The report can then be discussed and used to identify program improvement activities at all levels, such as staff from the state department of health, the state’s newborn hearing screening advisory committee, and staff from interested hospitals, etc. Typical reports include:

- Annual hospital report cards.
- Quarterly data reports to birth facilities and diagnostic centers with special emphasis on transferred infants.
- Verification of screening results for infants listed as passed and later identified with hearing loss.

It is important to compare program outcomes to other hospitals, programs, and states to learn what is working well and what can be improved. It is essential that success documented by outcome data be replicated (see Table 4).

Table 2
Examples of EHDI Data That Should Be Evaluated at a Minimum

<table>
<thead>
<tr>
<th>Screening Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Total number of live births.</td>
</tr>
<tr>
<td>- Number of babies screened.</td>
</tr>
<tr>
<td>- Missed screens, including homebirths and transferred infants.</td>
</tr>
<tr>
<td>- Number of babies not screened due to nonconsent.</td>
</tr>
<tr>
<td>- Number of babies passing screening or rescreening prior to discharge.</td>
</tr>
<tr>
<td>- Number of babies discharged not passing screening in one or both ears.</td>
</tr>
<tr>
<td>- Number of babies passing outpatient screening.</td>
</tr>
<tr>
<td>- Number of babies not passing outpatient screening in one or both ears.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Diagnostic Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Number of babies lost to follow-up (analyzed geographically).</td>
</tr>
<tr>
<td>- Number of infants diagnosed with hearing loss.</td>
</tr>
<tr>
<td>- Number of infants with confirmed hearing loss by type and degree.</td>
</tr>
<tr>
<td>- Number of infants diagnosed with late onset hearing loss through coordination with early childhood screening programs, such as Early Head Start.</td>
</tr>
<tr>
<td>- Number of babies with risk indicators (number and percentage).</td>
</tr>
<tr>
<td>- Median age at diagnosis.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Early Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Number of infants enrolled in early intervention.</td>
</tr>
<tr>
<td>- Number of infants lost to follow-up.</td>
</tr>
</tbody>
</table>
Each hospital in the state is asked to complete a questionnaire about their newborn hearing screening program. Questions are asked about:
- The hospital’s screening protocol.
- Equipment and practice.
- Follow-up.
- Referral for diagnosis.
- Satisfaction with the program.
- Obstacles that have been encountered.
- Areas in which assistance is needed.
- Satisfaction with previous assistance.
- Support provided by the state department of health.

Prior to distribution, drafts of the questionnaire should be reviewed by members of the state’s newborn hearing screening advisory committee for suggested revisions.

Hospitals in most states use an information management system (IMS) to submit data to the state department of health regarding:
- Number of babies born.
- Number of babies screened.
- Results of screening.
- Follow-up activities.
- Information about referral and diagnosis.

An external evaluation team analyzes this data to identify strengths and weaknesses of the program. The analysis of tracking data is useful in pinpointing areas where additional technical assistance and training are needed. For example, when inpatient refer rates are too high, it is frequently because too many people are screening babies, or one or two screeners are having difficulty. Although this data is available to hospitals, they often do not appreciate its value for program improvement. Thus, it is helpful to have an external evaluation team review the state data to identify areas where assistance is needed.

A random sample of parents whose babies were screened during a defined time period are sent a questionnaire regarding:
- Their perceptions about the screening program.
- What they saw as the strengths and weaknesses.
- Suggestions for improving the program.

The sample of parents should include those whose baby:
- Passed the inpatient screening.
- Did not pass the inpatient screening but passed an outpatient screening.
- Did not pass either the inpatient or outpatient screening.

Respondents are assured of anonymity, so they can be open about any concerns they may have, as well as identifying aspects of the program that are working well. The results of these questionnaires are used to determine whether appropriate information and support are being provided to parents.

A random sample of physicians listed in the IMS can also be surveyed. Physicians listed as the primary healthcare provider for babies who are screened are sent a questionnaire assessing their attitude and knowledge about the universal newborn hearing screening program. They are asked to identify strengths, weaknesses, and suggestions for program improvement.

A small sample of hospitals are selected for onsite visits by a team of evaluators who are experienced with newborn hearing screening programs. The site visit should include:
- Interviews with program staff (e.g., screeners, screening program manager, nursery coordinator, director of women’s services).
- Observation of screening activities.
- Review of records and program policies.
- Examination of materials for parents.
### Table 4

<table>
<thead>
<tr>
<th>Program Evaluation Tools</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Maternal and Child Health Bureau (MCHB) and Centers for Disease Control and Prevention (CDC)</strong></td>
</tr>
<tr>
<td>States receiving MCHB funding for their EHDI programs must have a formal plan for evaluation written into their grant. Funds can be used to pay an outside party to conduct an evaluation.</td>
</tr>
<tr>
<td>Federal grantees are also subject to a formal review process through the Office of Performance Review. This formal review process occurs over several months via conference calls with the grantee and key stakeholders. These calls focus on identification of success and challenges pertaining to the goals written into the federal grant and culminate with a 2-day site visit with the grantee and key stakeholders. A plan is formulated to address challenges. If necessary, expert support and assistance can be funded and provided to grantees.</td>
</tr>
<tr>
<td>The CDC has an excellent publication entitled, “Framework for Program Evaluation in Public Health,” which can be used to design, conduct, and report results of program quality assurance evaluations. The publication is available at <a href="http://www.cdc.gov/eval/framework.htm">www.cdc.gov/eval/framework.htm</a>. Along with other valuable information, it gives detailed suggestions about six iterative steps and four standards that govern effective program evaluation, as depicted below.</td>
</tr>
</tbody>
</table>

### Step 1. Engage program stakeholders.
This includes all those involved, affected, and all primary users. For example, in an EHDI program, this includes hospitals, pediatricians and primary care physicians, audiologists, parents, the state department of health, and EHDI program officials.

### Step 2. Describe the program.
Provide a detailed, in-depth description of the program, including the need, expected effects, activities, resources, stage, content, logic model, etc.

### Step 3. Focus the evaluation design.
Address the purpose of the evaluation, users, uses, questions, methods, and agreements.

### Step 4. Gather credible evidence.
Look at key indicators, sources, quality, quantity, and logistics.

### Step 5. Justify conclusions.
Look at standards, analysis and synthesis of data, interpretation, judgment, and recommendations.

### Step 6. Ensure use and share lessons learned.
Focus on feedback, follow-up, and dissemination of information.


Under this category, you will find:
- NCHAM statewide evaluation tools.
- Hospital surveys and evaluation tools.
- Audiologist/diagnostic center surveys.
- Early intervention program activities surveys.
- Parent and family reactions to EHDI program activities surveys.
- General EHDI surveys.
- Examples of evaluations already conducted by states.
- Downloadable copies of evaluation instruments.

Examples of questionnaires, surveys, and checklists that have been used by others can be found on the NCHAM website under Evaluation in the *EHDI Components* section. This information is available to any EHDI program at no charge. Programs are free to use the materials, tools, and samples and to adapt them to individual program needs and circumstances.

Four standards for effective evaluation are:

**Standard 1. Utility.**
Will the evaluation serve the information needs of the intended users?

**Standard 2. Feasibility.**
Is the evaluation realistic, prudent, diplomatic, and frugal?

**Standard 3. Propriety.**
Will the evaluators behave legally, ethically, and with due regard for the welfare of those involved and those affected?

**Standard 4. Accuracy.**
Will the evaluation reveal and convey technically accurate information?

An instructional video and workbook to assist in implementing a successful program evaluation is available at no cost from the CDC. The URL is http://www.cdc.gov/eval/framework.htm

Additional issues to consider regarding quality assurance and improvement:

- Should the EHDI program evaluation be contracted out to an independent external evaluator, or should an internal evaluation be done by someone from the department of health? Advantages of external evaluation include removal of internal biases and obtaining expertise in evaluation. Some resources for external evaluation may be found in other state programs that have developed expertise in EHDI program evaluation. Key personnel from those programs may be hired to complete an external evaluation. NCHAM also provides qualified experts to conduct evaluations of comprehensive programs.

- What resources and expertise are available for external evaluation? How much should a comprehensive evaluation of a state EHDI program cost? Obviously, hiring an outside expert to conduct an evaluation can be expensive. A legitimate question might be, “Doesn’t a comprehensive evaluation involve money that could be better spent for serving babies and families?” One response to this question is that an expert evaluation can enhance program sustainability. Documented outcomes and improved practices can prove a program’s value and result in continued and committed funding.
Online Resources and Links

- National Center for Hearing Assessment and Management, www.infanthearing.org

References

National Center for Hearing Assessment and Management. Program evaluation.
Utah State Department of Health. Utah’s Early Hearing Detection and Intervention program evaluation model.