Questions to Consider When Determining Equipment for a Universal Newborn Hearing Screening Program

Minnesota Newborn Screening Program



Population Characteristics

- · Where are the babies located?
- How many babies do you plan to screen annually?
- When would screening occur?

Staffing

- Who is available to perform this screening?
- · How many different people will be doing the screening?
- How much training will they need to perform these tasks?

Equipment

- How many other programs use this equipment in the same way as I plan to?
 - What are their results?
- Performance
 - What are the rates of false positives and negatives? (Refer rate)
 - Is the sensitivity & specificity data backed up by published research?
 - How does the performance vary by age of baby and type of screening personnel?
- How complicated is the equipment to use?
- How much training is required initially?
 - How much practice is required to maintain proficiency?
- How much time does each test take? (Include prep time, time to settle the newborn if needed, and clean up)
- Does the equipment provide a hard copy of results for charting and follow-up?
 - Is a seperate printer needed?
- Is a quiet room required?
- Is the equipment portable?
- How much does the equipment cost?
- What is the disposable supply cost?
- Is there additional costs for printing?
- Is equipment/supply sanitation required?
 - What is required?
 - What is involved?
 - Where and when is it done?
- How durable are the hardware and accessories?
- What is the accessory replacement cost?
- · How long does it take to replace accessories?

- What is the total cost per test?
 - Include: supplies, equipment depreciation, personnel time to prepare baby, perform test, and document results.
- Does the equipment require batteries or can it be operated from a wall socket?
- Does the equipment have FDA clearance specifically as automated screening equipment for newborn hearing screening?
- What is the charge for an extended warranty?
 - For calibration?
 - For basic service?
 - How often is this needed?
- Additional costs? For example, portable case, back-up battery?

Vendor

- Will the vendor conduct on-site training and retraining when needed?
 - What does this include?
 - What materials are avaliable?
 - Is there additional cost or is it included with equipment purchase?
- Does the vendor offer educational seminars and CME presentations for the medical staff?
 - Additional cost or included?
- Can the vendor provide a list of satisfied customers nationally and in my state that I may contact?
- Does the vendor have an 800 phone number?
- What kind of customer service is available?
 - To place orders?
 - To ask technical questions?
 - What hours are they accessible?
- What kind of background and training do the customer servuce personnel have?
- How quickly can the vendor send supplies?
- If the unit needs repair, how quickly can this be done?
 - Are loaner units available?
 - Is there a fee for the loaner unit?
- Is there a return policy?
- Does the vendor offer any screening database software?

Logistics

- Who will write and/or maintain the Policy & Procedure?
 - Is the Policy & Procedure current and reflect best practices in my state?
- How will the results be reported in the chart, to the parents, to the primary physician, to the state?
- What happens with the babies who did not pass the screening or who missed their screening?
- How will we keep track of the babies screened and their results?

