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CHAPTER 1. TOLSURF FOLLOW-UP OVERVIEW

1 Introduction

All surviving infants who participate in the TOLSURF Study will be followed with pulmonary breathing questionnaires throughout the first 18 months and neurodevelopmental follow-up at 12 ± 1 months, and 24 ± 2 months corrected gestational age.

1.1 Pulmonary follow-up

The Pulmonary Breathing Outcomes Questionnaires will be performed at discharge and again at 3, 6, 9, 12, and 24 months corrected age. Content of questionnaires will include:

	Discharge†	3 mos*	6 mos*	9 mos*	12 mos*	18 mos**
Contact information	X	X	X	X	X	X
Housing environment (number of rooms/people)	X				X	X
Diet (breast milk exposure)	X		X		X	Ask when weaned
Smoking exposure	X		X		X	X
Other environmental exposures	X					
Family history	X					X
Interval pulmonary history						
Cough		X	X	X	X	X
Wheeze by(MD/RN report)		X	X	X	X	X
ED/urgent visit		X	X	X	X	X
Hospitalization		X	X	X	X	X
Medications		X	X	X	X	X
Home oxygen		X	X	X	X	X
Patient allergy						X

† Interview to be conducted between 2 weeks prior and 4 weeks after discharge/transfer from study hospital

* Interview to be conducted at ± 1 month

** Assessment at 22-26 months

1.2. Neurodevelopmental Follow Up

Infants will receive a neurodevelopmental assessment which will include:

	12 Months*	24 Months**
Growth Parameters	√	√
Medical History	√	√
Developmental History	√	√
GMFCS Assessment of Motor Function	√	√
M-CHAT		√
Bayley Scales of Infant Development III		√

* ± 1 month

** ± 2 months

Individual centers are encouraged to schedule additional earlier follow-up assessments. The neonatal follow-up programs will remain masked to the treatment assignment of each infant.

1.3 TOLSURF Follow-up Objectives

1.3.1. Study Objectives- Pulmonary FU

The study objectives for the pulmonary follow-up program are the following:

1.3.1.1. To track and evaluate the interaction of risk factors of early disease, characteristics of early treatment, allergic, environmental and psychosocial factors on the development of subsequent respiratory dysfunction.

1.3.2. Study Objectives – Neurdevelopmental FU

The study objectives for the neurodevelopmental follow-up program are the following:

1.3.2.1. To track and successfully follow at 24 ± 2 months of age all surviving infants randomized into the TOLSURF study.

1.3.2.2. To characterize development of the study population by standardized methods in the areas of motor skills, cognitive skills, language and behavior.

1.3.2.3. To determine the 24 ± 2 month (corrected age) mortality and the prevalence of specific medical morbidities in infants.

1.3.2.4. To characterize growth outcome and its relationship to neurodevelopmental outcomes in this population at 24 ± 2 months.

1.3.2.5. To assess the utilization of special support services and other medical resources by this population.

1.3.2.6. To evaluate behavior and sensory sensitivities that may lead to functional impairment versus a perceived risk for autism spectrum disorder in this population.

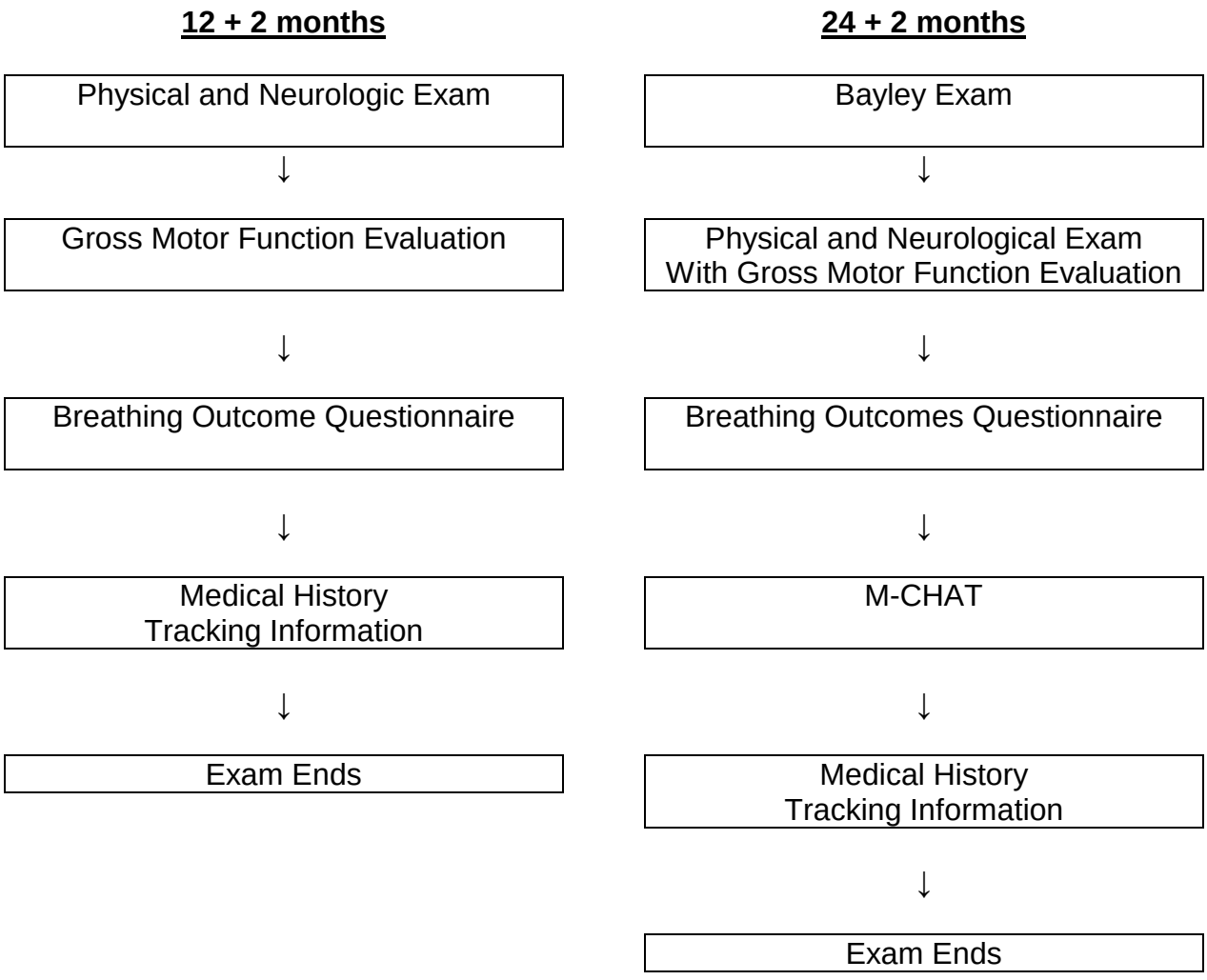
1.4. Order of Evaluation Administration

For the 12 and 24 month visits, a suggested order of procedures is given in Figure 1. Although the exact order of the procedures at the visit cannot be predetermined as it depends on the appropriate state of the child, the Bayley Scales of Infant Development III (BSID III) should be administered early in the clinic visit before medical procedures or interviews, if possible. Best performance is compromised if the child is tired, hungry, or upset. The caretaker should be present for this exam.

Following the BSID III exam, the physical and neurological exam can be conducted. The caretaker may be present for the exam. If she or he is present for the exam, then the following interviews can take place after the exam:

X Medical History Assessment.

Figure 1: overview of TOLSURF Follow up Visit



1. Phone calls
2. Certified letters or mailgrams
3. Reminder postcards (don't rely solely on this method)
4. Contacting mother's obstetrician, child's pediatrician or other physicians

If the phone number and/or address are unavailable, it may be possible to make contact through services the family may be linked to, such as the pediatrician, or early intervention clinics. Other sources include hospital admissions and county agencies. It may also be necessary to send people into the field to track down the family. The methods and the number of attempts made to contact each family should be documented.

2.3 Incentive for Recruitment, Follow-up, and Tracking

Any incentives given to families must be pre-approved by your site IRB. IRB's differ in what they will allow. Factors influencing compliance are the following:

2.3.1. Value

The patients perceive that they get some value for themselves or for their infants. Items that are perceived or described as valuable can be:

1. Information, which is useful now or later.
2. Perception that the people running the study truly care for them as well as their infant.
3. They see value in the project as helping themselves or future patients (few patients see value in being altruistic).
4. Healthcare/developmental assessments for their infant.

2.3.2. Removal of Barriers

Removal of barriers is important in recruiting and maintaining patients in the study. Major barriers are:

1. Transportation - this can be resolved by providing transportation, such as taxi service, if the distances are not too great, or reimbursement for transportation or parking expenses. Transportation is the major issue for people living in the city who do not have private means to keep health appointments.
2. Child care for siblings - this can be resolved by providing child care when patients come back for follow-up assessment. Need for childcare frequently arises while the infant is still in the ICN. Providing some childcare to supervise older siblings while the mother is visiting removes a barrier and is often perceived as a value and as a sign of caring.

2.3.3. Incentives

These should not be used to influence the voluntary nature of participation in the study. Incentives are sometime similar to perceived value based on parent/infant needs, i.e. free health care, developmental toys, or a monetary nature. Incentives can be given at the time of the visit and the parents can be told at the time of the enrollment what the incentive will be. Incentives can also be used to keep track of patients who are seen frequently as motivation to keep their address current with the study coordinator.

Some other ideas for incentives are:

1. Annual birthday cards can be incentives or perceived as a sign of value or care.
2. Taking photographs of the infants at each visit. For many people this is a value, again, especially for low income parents.
3. Developmental toys.
4. Gift certificates.

2.3.4. Perception of Care and Trust

This is more difficult to define; however, people who perceive that the Study Center cares for them and trust that it has more than only their scientific goal in mind are much more likely to continue in the study. Thus, it is important to establish a relationship with the parents while the baby is in the hospital and continue this relationship. Ongoing contact at specific intervals (approximately every 3 months), either by mail or by phone, will reinforce the concept of caring, while enabling the Study Center to track patients.

Prior to discharge, verification of addresses and phone numbers of the patients and other family members and neighbors needs to be done. It is important that patients are made aware that any information regarding address or phone number remains strictly confidential and will be used only for the sole purpose of making appointments for the babies= benefit.

A successful follow-up program needs to establish a caring, trustful relationship with the family while the baby is in the nursery and maintain this relationship with regular contacts. For this, a number of contact sources such as neighbors and/or friends should be identified and verified.

Providing care for an infant while simultaneously collecting research data is an extremely efficient way of maintaining patients in long-term follow-up. However, if the patient utilizes a local clinic or PMD, it is important to establish a good relationship with the primary care provider. Informing the primary care provider of the infant's enrollment helps to maintain patients in a longitudinal study; thus, keeping primary care providers informed about any information collected on the patient, especially if the information can be useful for patient care (for example, BSID III will be very useful as a means of support for study visits).

CHAPTER 3. Breathing Outcomes Interval Questionnaire (3, 6, 9, 12, and 18 months)

This form should be completed by the study coordinator, follow-up nurse, practitioner, or designee using the best information available. If the medical record is available, this information should be used along with history reported by the caretaker. The interview should be conducted in person if possible. If this is not possible, a telephone interview may be conducted. The assessment should include all illnesses, procedures, surgeries and follow-up needs following the initial discharge.

3.1. General instructions for Administration

3.1.1. Script:

The script for the discharge and interval follow up questionnaires follows. Spoken words will be in *italic script*. Instructions to the person administering the questionnaire will be in non-italic script.

3.1.2. Person to be interviewed:

Every attempt should be made to interview the **primary caretaker** and the same person at each time point. The caretaker needs to live with the child.

3.1.3. Timing of interviews:

Discharge questionnaire should be administered at discharge from study hospital ± 2 weeks. Interval questionnaires (3, 6, 9, 12 and 18 months corrected age) should be administered at specified time point ± 1 month. **22-26** month corrected age questionnaire should be administered during specified interval.

3.2. TOLSURF Breathing Outcomes Discharge Questionnaire Script

3.2.1. The Discharge Questionnaire Intro

This questionnaire should be administered at the time of discharge from the study hospital ± 2 weeks. Complete CRF form 16B with data collected from this interview and fax the form into DCC when completed.

Introduction: "Premature babies are more likely than full term babies to have breathing problems after discharge from the intensive care nursery. One of the purposes of this study is to see whether or not the treatment your baby received as part of the TOLSURF Study improves your baby's breathing in the 18-22 months following the baby's due date.

As part of this study, we will contact you every 3 months or so to ask you questions about your baby's breathing. The questions will be about your baby's breathing symptoms, such as wheezing and coughing, and about your baby's need for medical visits and treatments for breathing problems.

When we contact you, we'd like you to gather any notes, medications or other information about your baby's breathing. We will ask questions about how often your baby has

breathing difficulties, including wheezing or coughing, whether your baby visited a doctor's office, emergency room or was hospitalized for breathing problems, and whether your baby has needed breathing medicines or treatments.

Right now, we'd like to ask you a few questions about your home and about whether breathing problems run in the family in order to help us understand your baby's breathing and risk for breathing problems at home. We are also going to ask you about the information we need to continue to stay in contact with you while your child remains in the study, including your phone numbers and email addresses and contact information of relatives or friends that will know how to get in touch with you if your contact information changes. As with all information we collect, the answers to these questions will be kept confidential."

3.2.2. Discharge Questionnaire

Confirm child's name, birth date and sex.

DC Question 1: *"To confirm who I'm speaking with, what is your relationship to the baby?"*
Every effort should be made to interview the primary caretaker. The caretaker needs to live with the child.

DC Question 2*:* *"How many people normally live in your home including your baby? When counting the total number, include anyone who lives in your home at least six months of the year."*

DC Question 2a*:* *"Are they any other children younger than 5 (other than your baby) that live in the home with you? How many other children?"*

DC Question 3: *"Do you have any pets currently? For example, a dog, cat, birds, fish, or others? What are they?"*
Select all that apply. Write in additional animals concisely (*e.g.,* "reptiles" to describe snake + turtle).

DC Question 4: *"What type of milk does your child take? Breastmilk only, formula only, or a combination of both?"*
Select one. If infant is taking only breast milk that is either sometimes or consistently fortified with formula powder, record "Breastmilk only". If child is not taking enteral feeds (*e.g*., TPN-only), record "no enteral feeds". Note typographical error on CRF version 1, "no external feeds", which should be marked if no enteral feeds.

DC Question 5: *"Will your child receive any care outside the home in the next year*?"

DC Question 5a: If yes, *"Who will provide the care?"*
Select all that apply.

DC Question 5b: "*Are there other children that are not siblings present at the outside care site?"*

DC Question 6a: "Which of the following *statements best describes the situation regarding smoking in your child's home? Smoking is allowed in any room in the home, smoking is limited to part of the house where the child will rarely go, occasionally, there is smoking inside the house (visitor, family member), or there is no smoking inside the house at all"*

DC Question 6b: "*Does either parent of the child smoke?"*
If yes: "*Can you estimate the total number of cigarettes smoked per day by both parents?"*
Select one: < 5, 5-10, 10-20, > one pack per day, unknown. Prompt for best estimate. May prompt with options if unable to supply number.

DC Question 6c: "*Altogether, how many people who live in the house smoke?"*
Select one. Any smoker counts, whether they smoke in the home, outside the home or at some distant location.

DC Question 6d. "*Will your child travel at least once a week in a vehicle that someone smokes in, even if they only smoke in it when the child is not in the car?"*

DC Question 7: *"Please tell us what breathing and allergy problems run in your child's family."*

DC Question 7a: "*For the biological parents (mother and father): asthma/recurrent lung infections, allergies/hay fever, medication allergies, eczema*"
Select all that apply.

DC Question 7b: "*For the grandparents: asthma/recurrent lung infections, allergies/hay fever, medication allergies, eczema*"
Select all that apply.

DC Question 7c: "*For siblings: asthma/recurrent lung infections, allergies/hay fever, medication allergies, eczema*"
Select all that apply.

DC Question 8: *"Please tell us more about your baby's background."*

DC Question 8a: *"What is the mother's level of education?"*
Please note error in categories in CRF version 1. Use the following instructions for completing this question. Select one: ≤ 8th grade (record if high school not completed), high school (record if graduated from high school but not college), some college (do not record this option), college graduate (self-explanatory), advanced degree (record if any graduate study).

DC Question 8b: *"What is the father's level of education?"*
Please note error in categories in version 1. Use the following instructions for completing this question. Select one: ≤ 8th grade (record if high school not completed), high school (record if graduated from high school but not college), some college (do not record this option), college graduate (self-explanatory), advanced degree (record if any graduate

study).

DC Question 8c: *"How will your child's health care be paid for?"*
Select one: Private insurance, Medicaid/public insurance, No insurance (self pay)

3.2.3. Discharge Contact Information:

TOLSURF Contact Information Form is to be maintained at the study site, and not faxed into the DCC. Please ensure that all information remains at the study site in a locked cabinet.

"Will your child be known by a different name after discharge from the hospital?"
If yes, enter AKA for child.

"Please give us information so we can contact you (and the baby's father) to continue to collect information about your baby's breathing outcome and to arrange follow up visits."
Prompt for all information on both parents, if available: name, AKA, address, home, work and cell phone numbers, email address.

"Please give us the names and information for relatives or friends that will know how to get in touch with you in the next 2 years if your contact information should change."
Prompt for all information: name, address, home, work and cell phone numbers, email address.

"If you are willing, please give us your social security number and another form of identification (driver's license, identification card). We will use this information to contact you only if we are unable to locate you using the contact information from you and your family and friends. This information will be kept separately from all other information about your child, it will remain locked in the investigator's office and it will be destroyed at the completion of the study."

3.3. TOLSURF Breathing Outcomes Interval Questionnaire Script: 3, 6, 9, 12 and 18 months corrected age

This information is to be collected from parent/guardian at 3, 6, 9 and 12 months (± 1 month) corrected age, and at 18 months corrected age. Corrected age is the age after correcting the child's prematurity to 40 weeks, *i.e.*, at 40 weeks postmenstrual age, the infant will be 0 months.

Complete CRF form 23 for "Breathing Outcomes Interval Questionnaire" with data collected from this interview and fax form into DCC when completed.

The intervals collect different data items. The questions included in each interval are listed below:
3 and 9 months – Complete Questions 1-12
6 and 12 months – Complete Questions 1-18

18 months – Complete Questions 1-23

3.3.1. Contact information

Contact Information Form is to be maintained at the study site, and not faxed into the DCC. Please ensure that all information remains at the study site in a locked cabinet.

"First, we'd like to check whether any of your contact information has changed since we last talked. Do you have any new contact phone numbers or a new address or email account we should have on file for you?"
Write in any changes to address, home, work and cell numbers, or email address.

3.3.2. Form 23. Interval Questionnaires (3, 6, 9, 12, and 18 months)

Interval Pulmonary Questionnaires will be completed using TOLSURF Data Form 23.

These questions (23.1 thru 23.4) should be completed prior to the interview. The "History of last interview" will facilitate completion of the current questionnaire, since you will be able to help prompt the parent/guardian with the timing of most recent information given. Every attempt should be made to contact the parent/guardian and schedule the interview within the prescribed time frame. Initiate first contact just prior to eligible time period and schedule a time to speak with primary caregiver at the time of initial contact. If the family is unable to schedule an interview at that time, establish repeat contact to conduct interview until eligible time period has elapsed. If you are still unable to complete the interview despite these efforts, select the single best reason for this failure from the options in Question 4 (child died, unable to contact, family refused, other (write in reason).

FORM 23:

Question 23.1 Current Interview
Current Interview will be pre-populated with the appropriate timing of the interview (3, 6, 9, 12, or 18 months). Confirm child's name, birth date and sex.

Question 23.2. History of Last Interview
Record the date of the last interview the patient completed (Discharge, 3m, 6m, 9m, 12m).

Question 23.3. Indicate which interview was the last one completed
Fill-in the bubble indicating the last interview the patient completed (history of last interview information).

Question 23.4: Was an interview conducted for the current time period?
Was information collected during current period? Indicate Yes or No.

23.4.a. If yes, include date information was obtained. If no, indicate why interview was not done, then you are finished with this form (however, remember to put initials in banner on each page).

23.4.b. Choice of reasons why interview was not done include:

- O Child died
- O Unable to contact *(Check this if you attempted to contact family, but were unable to connect. Do not stop trying to contact family. Utilize your follow-up and any ancillary methods to make connection for next interview period.)*
- O Family refused contact. *(Check this if to connected with family and they refused to conduct interview. Do not stop trying to contact family. Utilize your follow-up and any ancillary methods (having site PI call to make connection for next interview period.)*
- O Consent withdrawn. No further follow-up. *(Check this if family has decided that they wish to withdraw from study participation. No further contact should be attempted.*
- O Other. Indicate if there was another reason why interview could not be done. *If the patient remains in the hospital for the current time period (date ± 1 month), check "Other" and indicate reason infant remained hospitalized. was for:*
  - *"Respiratory Reasons" (infant remains on respiratory support > NC of 2 lpm (any FIO2)), or*
  - *"Other Medical Reasons" (Infant requires NC< 2 lpm and/or remains hospitalized for feeding, surgical or other reasons).*

Script for families completing the interview:

"As you may remember, premature babies are more likely than full term babies to have breathing problems after discharge from the intensive care nursery. One of the purposes of this study is to see whether or not the treatment your baby received as part of the TOLSURF Study improves your baby's breathing in the 18-22 months following the baby's due date.

As part of this study, we had originally talked about contacting you every 3 months or so to ask you questions about your baby's breathing. Your baby is now 3 (6, 9, 12 or 18-22) months corrected age and we'd like to see how your baby has been doing since discharge (the last time we talked). If you have any notes, medications or other information about your baby's breathing, we'd like for you to collect them now."

Question 23.5: *"To confirm who I'm speaking with, what is your relationship to the baby?"*

Every effort should be made to interview the primary caretaker and the same person at each time point. The caretaker needs to live with the child.

Question 23.6: "*Since discharge (or the last time we spoke), has your child had a cough that was not associated with a cold (that is, a cough when he or she did not*

have a cold)?"
Indicate Yes or No. If yes, complete 6a-b.

Question 23.6.a: "*How often do you notice a cough that is not associated with a cold?"* Select one. May prompt for options:

O every day,
O not every day but more than once a week,
O once a week, or
O not every week.

Question 23.6.b: *"What time of day does your child have a cough that is not associated with a cold?* Select one. May prompt for options:

O more often during the day,
O the same amount whether it is day or night, or
O more often at night.

Question 23.7: "*Since discharge (or the last time we spoke), has a medical person such as a nurse or a doctor told you that he/she heard wheezing when listening to your child's chest?"* *Indicate Yes or No.*

Question 23.7.a: If yes, "*When has a medical person said they heard wheezing in your child's chest* (Select one):.

O only when your child has had a cold,
O only when your child does not have a cold, or
O both when your child does and does not have a cold?"

Question 23.8: "*Since discharge (or the last time we spoke), has your child been treated in the Emergency Department or by another doctor in the office or clinic because of a breathing problem or a change in his/her breathing?"* Select Yes or No.

Question 23.8.a: If yes, "*How many times was your child treated in the Emergency Department or clinic since discharge (or the last time we spoke)*?" Select one.

O ≤ 2
O 3-5
O 6-10
O > 10

Question 23.9: "*Since discharge (or the last time we spoke), has your child been admitted to the hospital overnight?"* Select Yes or No.

If yes, complete 9a-b.

Question 23.9.a: "*How many times was your child admitted to the hospital*

overnight?" Record total number.

Question 23.9.b: "*How many times was this because of a breathing problem or a change in his/her breathing?"* Record total number.

Question 23.10: "*Is your child currently on oxygen or a breathing machine (ventilator) at home?"* Indicate Yes or No.

If yes, complete 10a-b.

Question 23.10.a: "*Is your child on oxygen currently?"* Select Yes or No.

Question 23.10.b: "*Is your child on a ventilator currently?"* Select Yes or No.

If no, complete 10c-d.

Question 23.10.c: "*Was your child on oxygen at home since discharge (or the last time we spoke) but has come off oxygen since that time?"* Select Yes or No.

Question 23.10.d: "*Was your child on a ventilator at home since discharge (or the last time we spoke) but has come off the ventilator since that time?"* Select Yes or No

Question 23.11: *"Since discharge (or the last time we spoke), has your child been diagnosed with a respiratory syncytial virus (RSV) infection?"* Select Yes or No

RSV needs to be a lab diagnosis. Lots of things cause bronchiolitis, not just RSV. Other data shows that it is RSV that causes a more severe illness and has greater implications for later morbidity.

Question 23.12: "*I'm going to list several categories of medications and I'd like for you to tell me which of these medications, with the name of the medicines, if you recall, your child has taken, since discharge (or the last time we spoke).* *These can be either medicine's taken at home or in the hospital.*

Select all that apply for 12 and 12.1. Ask parent/guardian to list the names of medications. Don't prompt with specific examples, but do help them say/spell the medication name.

Drug categories:

A. Bronchodilators?
B. Inhaled steroids?
C. Diuretics
D. Steroids by mouth or by a shot or intravenous?
E. Pulmonary vasodilators or medications to treat pulmonary hypertension?
F. None of these?"

Medication List:

CHAPTER 4. MEDICAL and NEURODEVELOPMENTAL FOLLOW-UP AT 12 and 24 MONTHS…FORM 24

(FAMILY HISTORY, MEDICAL HISTORY AND EXAMINATIONS)

4.1. Overview

This form should be completed by the follow-up nurse, practitioner, or designee using the best information available. If the medical record is available, this information should be used along with history reported by the caretaker. The interview should be conducted in person if possible. If this is not possible, a telephone interview may be conducted. The assessment should include all illnesses, procedures, surgeries and follow-up needs following the initial discharge.

4.2. Contact Information

***Contact Information Form* is to be maintained at the study site, and not faxed into the DCC. Please ensure that all information remains at the study site in a locked cabinet.**

"First, we'd like to check whether any of your contact information has changed since we last talked. Do you have any new contact phone numbers or a new address or email account we should have on file for you?"

Write in any changes to address, home, work and cell numbers, or email address.

4.3. FORM 24 - Questionnaire at 12 and 24 Months

First, Record the infants' corrected age at the current visit (12 or 24 months). *This should be pre-filled on the 12/24 month forms*.

Question 24.1.a. Was the exam performed?

Check "yes" if exam was performed and move to 24.1.b.

*Note: If infant is *still in the hospital* at 12 or 24 months, you should complete the interview in person and/or over the phone (may need a combination). Please answer "yes" and continue to 24.1.b.

Check 'no" if exam was not performed and indicate reason in 24.1.a.i.

24.1.a.i. Indicate reason exam was not performed.

O Child died
O Unable to contact family
O Family refused this exam
O Consent withdrawn. No further follow-up
O Family moved out of area of follow-up clinic
O Other (describe reason)

Note: If exam/questionnaire were not done, do not complete any further questions on this form. Simply complete banner information on all pages and fax to DCC.

Question 24.1.b. Was the child evaluated in person in the clinic, as an inpatient if he/she remains in the hospital, or over the phone?

Check “At FollowUp Clinic” if child was brought to the neonatal follow-up clinic or evaluated in the child’s home.

Check “In hospital as in-patient” if the child is currently or has remained in the hospital for this interview.

Check “Other” if patient was evaluated at another place (not hospital, not clinic..eg: in the home). Specify where visit occurred.

Check “Over the telephone” if an in-person evaluation could not be performed.

24.1.b.i. Indicate the Reason interview had to be done over the phone (*choose one).*

O Moved out of the area of follow-up site *(if so, try to contact by phone and complete questionnaire by phone.)*

O Could not schedule clinic visit *(if so, try to contact by phone and complete questionnaire by phone.)*

Question 24.1.c. Date of Exam: ___/___/___ (Record date of exam or date you spoke with parents)

Question 24.2. *“What is the relationship of the person accompanying child to the clinic visit (or doing interview over the phone)… What is your relationship to the baby?”* Every effort should be made to interview the primary caretaker. The caretaker needs to live with the child. Record the relationship of person accompanying infant to clinic (mother, father, grandparent, foster parent, other).

Question 24.3. (Family and Social History at Time of Assessment)
“Please tell us more about your baby’s background.”

Question 24.3a*: “What s the living arrangement in your household??? Who is (are) the primary caretakers living with your baby (one parent, two parents, foster home, other)? If “Other”, specify who. If hospitalized, say “still in hospital”.*

Question 24.3b: *“What is the primary language spoken in your baby’s home*? If English is spoken as a second language, specify what is the1st language.

Question 24.3.c: *“What is the mother’s level of education?”*

Select one:
O Some education, high school not completed,
O High school graduate,
O Some college,
O College graduate ,
O Graduate study (record if any graduate study).
O Unknown/Unavailable

Question 24.3.d: *"What is the mother's employment?"*

Select one: O Employed as: Specify _____
O Full time homemaker
O Student
O Unemployed
O Unknown

24.4. Medical History at Time of Assessment

Question 24.4.a: *"Since initial hospitalization (or last visit at 12 months), has your child received any of the following diagnoses or surgeries?* Choose all that apply.

O Gastrostomy tube placement
O Ventriculoperitoneal shunt placement
O Seizure disorder requiring treatment
O Failure to thrive
O Tympanostomy tube placement
O Eye surgery
O PDA ligation or other closure of PDA
O No diagnoses or surgeries received since initial hospitalization or last follow-up exam.

Question 24.4.b: "*How many times has your child been hospitalized for non-respiratory illness or surgery (total hospitalizations since last visit, including those in 4a)?* Record reported number of hospitalizations ____, None, or Not Applicable (if patient has been continuously in hospital or is currently hospitalized).

Question 24.4.c: (ASKED AT 12 and 24 MONTHS) "*I'm going to list several categories of medications given for chronic medical conditions. I'd like for you to tell me which of these medications, with the name of the medicines, if you recall, your child has taken, since your 12 month interview (or the last time we spoke)? These can be either medicines taken at home or in the hospital.(see medications list on last page of Form 24).*

O Anti-reflux medications?
O Prokinetics?
O Anti-epileptics?
O Other: Specify _____
O Not taking any medications listed above

Medication List: Ask parent/guardian to list the names of medications. Don't prompt with specific examples, but do help them say/spell the medication name. Select a that apply.

Bronchodilators
albuterol (Ventolin),
levalbuterol (Xopenex),
ipratropium bromide (Atrovent) ,

Inhaled steroids
beclomethasone (Qvar),
budesonide (Pulmicort),

flunisolide (Aerobid),
fluticasone (Flovent),
triamcinolone (Azmacort)

Diuretics
furosemide (Lasix),
chlorothiazide (Diuril),
hydrochlorothiazide (Hydrodiuril),
aldactone

Systemic steroids
cortisone,
dexamethasone,
prednisone,
prednisolone,
methylprednisolone

Pulmonary vasodilators
sildenafil (Revatio),
tadafil (Adcirca),
bosentan (Tracleer),
ambrisentan (Myogen),
inhaled iloprost (Ventavis),
beraprost, trepoprostenol,
epoprostenol (Flolan),
inhaled nitric oxide

Vitamins or Vitamin Supplements
Polyvisol with/without iron,
Trivisol (with/without iron),
D-vison, Multivitamin drops,
Children's complete chewable vitamins or multivitamins (with or without iron and with/without calcium:
Cetrum,
Flinstones,
Bugs Bunny,
Pokeman,
ScoobyDoo,
Lil'Critters)

Anti-reflux medications
ranitidine (Zantac),
pantoprazole (Protonix)
lansoprozole (Prevacid),

ProKinetics
metoclopromide (Reglan),
erythromycin

Anti-epileptics
phenobarbitol,
levetiracetam (Keppra),
Valproate (Depakote),
phentoin (Dilantin)

Other (specify)
_____

_____

None

Question 24.4.d: Answer these questions at 24 months:

Question 24.d.i: Medications "*I'm going to list several categories of medications and I'd like for you to tell me which of these medications, with the name of the medicines, if you recall, your child has taken, since your 12 month interview (or the last time we spoke)? These can be either medicines taken at home or in the hospital. (see medications list on last page of Form 24).*
A. O Inhaled Bronchodilators?
B. O Inhaled steroids?
C. O Diuretics?

D. O Steroids by mouth or by a shot or intravenous?
E. O Pulmonary Vasodilators?
F. O Vitamins/supplements containing Vit D?
G. O None of the Above

Question 24.d.ii: Hayfever *(Asked at 24 Months)* "*Has your child ever had hay fever or another condition that makes his/her nose or eyes runny, stuffy, or itchy not associated with a cold (that is, without a cold)?"* Select Yes or No.

Question 24.d.iii: Food Allergy *(Asked at 24 Months)* "*Has your child ever been allergic to any food? An allergy includes reactions that include rash and swelling, not vomiting or diarrhea."* Select Yes or No.

Question 24.d.iv: Medication Allergy *(Asked at 24 Months) Has your child ever been allergic to any medication? An allergy includes reactions that include rash and swelling, not vomiting or diarrhea." Select Yes or No.*

Question 24.d.v: Eczema *(Asked at 24 Months)* "*Has your child ever had eczema diagnosed by a doctor (allergic skin rash)?"* Select Yes or No.

Question 24.d.vi: Asthma *(Asked at 24 Months)* "*Has your child been diagnosed with asthma by a doctor?"* Select Yes or No.

Question 24.4.e. Milestones

Question 24.4.e.i.: Is your child able to sit alone without support?
Answer: O Yes or O No

Question 24.4.e.i.a.: If Yes, ask *"How old was your child when your child sat alone without support?" (Record in months, corrected gestational age. Round down to the nearest month corrected age).*

Question 24.4.e.ii.: Is your child able to walk independently?
Answer: O Yes or O No

Question 24.4.e.ii.a.: If Yes, ask *"How old was your child when your child walked independently (in months, corrected gestational age)?"*

Question 24.5: Growth Parameters

Question 24.5a: Weight.
Child should be weighed without clothing or diapers. Record weight to the nearest hundredth of a kilogram.

24.10.2. Was the Bayley test administered in English? O Yes O No
Code Yes if Bayley Exam was conducted in English, or No if it was conducted in any other language.

24.10.2.a. If not, was an interpreter used? O Yes O No
Code Yes if an interpreter was required or the caretaker served as the translator.
Code No, if a certified Bayley examiner conducted the exam in another language.

24.10.3. Indicate the date test was done (mm/dd/yyyy) ___/___/_____

24.10.4. Bayley Scoring:

24.10.4.a. Cognitive Composite score: ___ ___ ___

24.10.4.b. Language Composite score: ___ ___ ___

24.10.4.b.i. Receptive Language scaled score. ___ ___

24.10.4.b.ii. Expressive Language scaled score. ___ ___

24.10.4.c. Motor Composite score: ___ ___ ___

24.10.4.c.i. Gross Motor scaled score. ___ ___

24.10.4.c.ii. Fine Motor scaled score. ___ ___

24.10.5. BSID III Examiner signature: _____

24.10.5.a. Is this page signed? O Yes O No Date Signed (mm/dd/yy): ___/___/___

Question 24.11: Modified Checklist for Autism in Toddlers (M-CHAT)
For instructions on administering the M-CHAT see Chapter 7.

If the parent is unable to complete at the Clinic Follow-Up visit, for one reason or another, please schedule a time to complete by telephone.

24.11.1. If applicable, record date the M-CHAT was completed at the Clinic Follow-Up Visit (mm/dd/yyyy).
Record "Not Done", if not completed at visit.

24.11.1.a. If applicable, record date the M-CHAT was completed over the phone.
Record "Not Done", if not completed over the phone.

The following questions should be answered about how the child "usually" is. Encourage parent to try and answer every question. If the behavior has only been seen once or twice, answer "No" as I the child has not done it.

24.11.2. Does your child enjoy being swung, bounced on your knee, etc.? Yes / No / No ans

24.11.3. Does your child take an interest in other children? Yes / No / No ans

24.11.4. Does your child like climbing on things, such as up stairs? Yes / No / No ans

24.11.5. Does your child enjoy playing peek-a-boo/hide-and-seek? Yes / No / No ans

24.11.6. Does your child ever pretend, for example, to talk on the phone or take care of a doll or pretend other things? Yes / No / No ans

24.11.7. Does your child ever use his/her index finger to point, to ask for something? Yes / No / No ans

24.11.8. Does your child ever use his/her index finger to point, to indicate interest in something? Yes / No / No ans

24.11.9. Can your child play properly with small toys (e.g. cars or blocks) without just mouthing,fiddling, or dropping them? Yes / No / No ans

24.11.10. Does your child ever bring objects over to you (parent) to show you something? Yes / No / No ans

24.11.11. Does your child look you in the eye for more than a second or two? Yes / No / No ans

24.11.12. Does your child ever seem oversensitive to noise? (e.g., plugging ears) Yes / No / No ans

24.11.13. Does your child smile in response to your face or your smile? Yes / No / No ans

24.11.14. Does your child imitate you? (e.g., you make a face-will your child imitate it?) Yes / No / No ans

24.11.15. Does your child respond to his/her name when you call? Yes / No / No ans

24.11.16. If you point at a toy across the room, does your child look at it? Yes / No / No ans

24.11.17. Does your child walk? Yes / No / No ans

24.11.18. Does your child look at things you are looking at? Yes / No / No ans

24.11.19. Does your child make unusual finger movements near his/her face? Yes / No / No ans

24.11.20. Does your child try to attract your attention to his/her own activity? Yes / No / No ans

24.11.21. Have you ever wondered if your child is deaf? Yes / No / No ans

24.11.22. Does your child understand what people say? Yes / No / No ans

24.11.23. Does your child sometimes stare at nothing or wander with no purpose? Yes / No / No ans

24.11.24. Does your child look at your face to check your reaction when faced with something unfamiliar? Yes / No / No ans

CHAPTER 5. Gross Motor Function Classification System (GMFCS)

5.1. GMFCS - Completed at both 12 and 24 month visits.

This exam is fully described by Palisano et al; Dev Med Child Neurology 1997; 39:214-23. It is being used to estimate gross motor dysfunction in this population rather than to attempt to diagnose cerebral palsy due to the difficulties standardizing assessments and diagnoses of CP.

5.1.1. Description of Current Gross Motor Function

The Gross Motor Function Classification developed by Palisano et al. focuses on children's functional achievements rather than on their limitations. The emphasis is on the child's ordinary performance (not best capacity) in the home or community setting, and should not include judgments about prognosis. Thus, as a general principle, an attempt should be made to determine what level best represents the child's present abilities and limitations in gross motor function.

The descriptions of the 5 levels of function are broad and it may not be possible to describe the exact function of every child within each level. For example, an infant with hemiplegia, who is unable to crawl on hands and knees, but otherwise fits the description of level I (e.g., can sit with both hands free, can creep (commando crawl) or bottom shuffle and pull to stand), would be classified accordingly as being in level I. In contrast, another child with hemisyndrome who can sit but needs to use hand to maintain floor sitting, and can creep and pull to stand would be classified as level II. The distinction between these two examples is the ability of the former child to sit with both hands free. The scale is ordinal, with no intent that the distance between levels be considered equal. The functional abilities and limitations for each age interval are intended to serve as guideline, and are no comprehensive and are not norms. Distinctions between levels of gross motor function are based on functional limitations, the need for assistive technology including mobility devices (such as walkers and wheeled mobility), and to a much lesser extent the quality of movements. Level I represents the continuum of children with neuromotor impairments whose functional limitations are less than what is typically associated with cerebral palsy, or who have CP of minimal severity (such as children with hemisyndromes). The distinctions between levels I and II, therefore, are not as pronounced as the distinctions between other levels, particularly for infants who are 1 to 2 years of age. Assistive mobility devices which may be considered in distinguishing between levels II and III in older children are generally not used in children who are under 2 years of age.

A summary of the descriptions of each level for ages 1 to 2 years is as follows:

Level I

Infants move in and out of sitting and floor sit with both hands free to manipulate objects. Infants creep or crawl on hands and knees, pull to stand and take steps holding onto furniture. Some may creep or bottom shuffle, but are able to travel independently. Infants walk between 18 months and 2 years of age without holding on.

Level II

Infants maintain floor sitting but may need to use their hands for support to maintain balance. Infants creep on their stomach or crawl on hands and knees. Infants may pull to stand and take steps holding onto furniture.

Level III

Infants maintain floor sitting when the low back is supported. Infants roll and creep forward on their stomachs.

Level IV

Infants have head control but trunk support is required for floor sitting. Infants can roll to supine and may roll to prone.

Level V

Physical impairments limit voluntary control of movements. Infants are unable to maintain antigravity head and trunk postures in prone and sitting. Infants require adult assistance to roll.

For the purpose of the TOLSURF trial, there is no need to determine the actual GMFCS for the child, but rather to respond to questions about their gross motor function. The algorithm on the data collection form will lead investigators through gross motor functions requiring only yes or no answers.

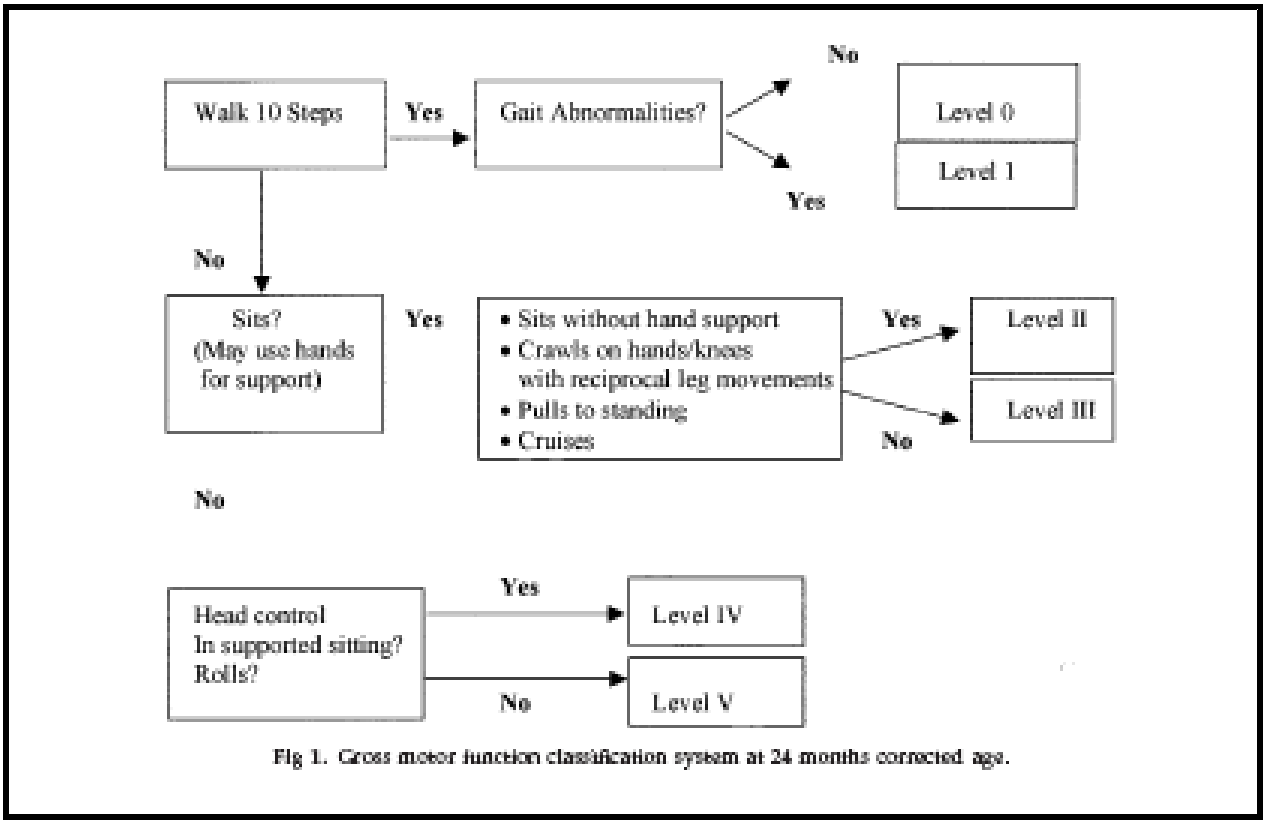


Fig 1. Gross motor function classification system at 24 months corrected age.

(*Palisano et al, Med Child Neurol, 1997; 39:214-233. Algorithm adapted by Rosenbaum P and Saigal S for TIPP Trial, and utilized in the NICHD Neonatal Research Network under the direction of Betty Vohr).

CHAPTER 6. BAYLEY SCALES OF INFANT DEVELOPMENT (BSID III)

The Bayley Scales of Infant Development III (BSID-III) will be undertaken at the 24 ± 2 month visit. The BSID-III consists of three major components: cognitive, language, and motor. The social-emotional and adaptive behavioral subtests of the BSID III will not be used. Estimated time to administer the BSID-II for this age level is 60-75 minutes. The Psychological Corporation undertook the revision and re-standardization of the original BSID and BSID II. They are responsible for technical support and distribution of the test materials and forms.

6.1 Reliability and Certification

Examiners must be certified. To be certified a Bayley examiner, one must successfully complete the following: 1) Review (with scores) a supplied videotape of a Bayley exam performed by a gold standard examiner, and 2) Supply one videotape of the examiner with an accurate performance and scoring of BSID III on a 22-26 month old child. Gold standard reviewers project will comment on the tapes and certify at least one psychometrist at each site. This certified psychometrist will be responsible for all other examiners at the site in order to ensure reliability.

6.2 Procedural Guidelines

The following is a list of procedural and scoring guidelines. The references made in 1 to 13 below refer to the BSID manual.

6.2.1. Primary Caretaker

The primary caretaker should accompany the child during the administration of the BSID-III. If the primary caretaker is not present, the adult who brought the infant to the clinic should stay with the child.

6.2.2. Masking of Examiners

Examiners must be masked to the birthweight of the child or to clinically significant family and developmental history.

6.2.3. Spanish

The examiner should ask the caretaker about the child's language experience. Use the child's preferred language during administration of the BSID-III. The examiner must be fluent in Spanish and in the dialect most familiar to the child in order to interpret the child's names for objects and pictures, and spontaneous language.

6.2.4. Priority of the BSID-III during the Clinic Visit

Priority of the BSID-III should be administered early in the clinic visit before medical procedures or interviews if at all possible. Best performance is compromised if the child is tired, hungry, or upset.

6.2.5. Encouragement

Refer to the BSID-III manual for information about the amount and style of encouragement offered by the examiner. The examiner should encourage effort in order to secure best performance but not comment on performance.

6.2.6. Order of Administration

A flexible order of administration is best. It is not necessary to follow cue sheets unless the examiner finds this helpful.

6.2.7. Administration and Scoring

Administer the mental and motor scales adhering to the basal and ceiling rules (p. 43). Use the full range of scoring for no credit (e.g. failure, refusal, omissions, reports by the caretaker).

6.2.8. To Calculate the composite and scaled scores

Transform the raw scores for the items to their respective composite scores (cognitive, language, and motor) and scaled subscores (receptive and expressive language, fine and gross motor) per BSID III instructions. Be sure to use the appropriate table for the child's adjusted age. Do not complete the confidence interval information or classification or copy data from the other forms.

6.2.9. Interruption of Administration (p.36)

If the examiner must stop the test and resume later on during the visit or at another session (preferably within two weeks), complete the test score in the usual way. You should not repeat items that the child failed in the first administration. However, if the child did not attend or attempt an item, you may repeat it. Leave that item blank to indicate that it can be repeated. **The entire test can be repeated, if it is determined that the child was not making his/her best effort at the first visit, such as in the case where the child was too ill.** The entire test should be repeated if it has been greater than two weeks since the last testing unless there are certain items that the examiner knows cannot be attempted again. If at the time of the second testing the child enters into another age category for testing, administer the Bayley Exam for the older age category. If the test is repeated, it should be administered within the visit window (22-26 months corrected age).

6.2.10. Incomplete Exams

The three language, cognitive, and motor composite scores are independent; thus missing data on one scale does not affect the other. If the examiner omits an item by mistake, the item is given >no credit=. If more than 2 items are omitted, the exam is invalid. If the baseline and ceiling are not achieved, the exam is invalid. Invalid data should be discarded.

6.2.11. Data Entry

The summary scores for adjusted age will be entered onto the Bayley Score summary Sheet.

6.2.12. If Data Collection Begins Before Certification is Achieved

Until the examiner is certified on the BSID-III, videotape the administration and score as usual. A certified examiner will score from the videotape. Position the camera behind the examiner slightly off to the side focusing on the child and its workspace. For the motor items, the camera operator must adjust the camera's position with the child's activity.

6.3. Additional Guidelines

1. Use the Bayley stairs.

2. Use exact language or scripts from the manual for instructions. Avoid paraphrasing.

3. Record your scoring direction on the testing form rather than making notes on cue sheets and transferring to score sheet after exam.

4. Reference the manual as needed during administration, but the examiner should know the items well enough not to break the flow of the exam.

5. Use a watch for timed items.

6. Use the child's *corrected age* to select the initial item set.

7. Use enclosed scripts to control caretaker input into the assessment.

8. Encourage the child without over-repetition of instructions restricted by the manual (e.g. A Good job&, AOK), rather than comments linked to success.

9. Organize test materials to be nearby but out of sight of the child. A bucket near the flint is suggested for reusable objects.

10. Keep the test materials and stop watch off the table to avoid distracting the child.

11. Examiner will be given the date the child reaches 24 months corrected age. The age at the time of the exam is determined by adding or subtracting the relevant amount of days.

12. Based on observations of cognitive delay, the examiner uses her clinical judgement in selecting the initial item set. Good indicators for cognitive delay are: delayed language or gross motor skills, parental report, how the child handles the blocks or a crayon, performance on the form board.

13. Non-English speaking families require that the examiner arranges translation.

14. The primary caretaker stays with the child during the exam. The child sits on the caretaker's lap or in a youth/high chair with the caretaker nearby.

15. The examiner does not review the subject's chart prior to the exam in order to stay masked to the neonatal history of the child and the results of previous developmental tests. Observation made at the assessment that the child has had particular medical conditions or knowledge that the child had been referred at a previous clinic visit do not count as unmasking.

16. All assessments must take place in the clinic to ensure a standardized environment.

17. Data Entry: Only the composite language, cognitive, and motor scores, as well as receptive and expressive language scaled scores and fine and gross motor scaled scores are entered into the database along with the identification information and age at the exam. Additional variables include: whether the exam was conducted in English and it not, whether an interpreter was used.

18. Videotape all subjects prior to full certification.

19. Only two items can be inadvertently omitted by the examiner. If more than 2 omitted items, the exam is unscorable.

6.4. Scripts

Scripts to be used with parents before testing starts:

Thanks for coming in today. I want to explain what I will be doing with _____ (child's name). I am going to show him different toys and see how he responds to them. I will be giving him items at this age level and above, so I don't expect him to know how to do every item today.

I have to present the items in a certain way, with certain instructions, so I will ask that you not repeat the instructions or show him what to do. Just make him comfortable on your lap. It's O.K. to encourage him by saying "Go ahead, you do it". Also, all the toys are washed and are a safe size (except the red beads) so it's O.K. if things go to the mouth.

Note to examiners: It also helps to give reminders to parents before bringing out certain items.

* For picture book items and toys that you want the child to label say, *I don't want to say the name of these.*

* For crayon and pencil items, "*I don't want to tell him what to do with these – let's see what he does"* or "*Please don't hold the paper for him."*

Give gentle reminders as necessary to an over-involved parent.

6.5. Section F. BSID III Summary Sheet

The BSID summary score sheet should be completed by the Bayley examiner.

Complete TOLSURF Study Data Form 24.10.

24.10.1. Was this child able to be tested?
Answer: O Yes or O No.
|
If No, indicate the reason:
O Visual Impairment
O Hearing Impairment
O Parent Refused

O Severe Behavior Disorder
O Child did not Cooperate with several exam attempts
O Severe behavior disorder
O Severe developmental delay
O Exam done over the phone
O Other Specify: _____
If No, now skip to question 24.11.

24.10.2. Was the test administered in English? O Yes O No
Code Yes if Bayley Exam was conducted in English, or No if it was conducted in any other language.

24.10.2.a. If not, was an interpreter used? O Yes O No
Code Yes if an interpreter was required or the caretaker served as the translator.
Code No, if a certified Bayley examiner conducted the exam in another language.

24.10.3. Indicate the date test was done (mm/dd/yyyy) ___/___/_____

24.10.4. Bayley Scoring:

24.10.4.a. Cognitive Composite score: ___ ___ ___

24.10.4.b. Language Composite score: ___ ___ ___

24.10.4.b.i. Receptive Language scaled score. ___ ___

24.10.4.b.ii. Expressive Language scaled score. ___ ___

24.10.4.c. Motor Composite score: ___ ___ ___

24.10.4.c.i. Gross Motor scaled score. ___ ___

24.10.4.c.ii. Fine Motor scaled score. ___ ___

24.10.5. BSID III Examiner signature: _____

24.10.5.a. Is this page signed? O Yes O No Date Signed (mm/dd/yy): ___/___/___

CHAPTER 7. Modified Checklist for Autism in Toddlers (M-CHAT) at 24 months

7.1. M-CHAT Background

There has been a recent suggestion in the literature regarding premature infants being at a higher risk for autism than the general pediatric population. Many providers of long term care for former premature infants find that the children do not exhibit the classic features of ASD including social and communication disorders, but rather sensory processing disturbances. The M-CHAT is the most broadly used screening instrument for ASD. By collecting individual item endorsement, we hope to gain more insight into why former preterm infants screen positive on the tool.

It is important that the tool be completed in full and we encourage centers to have their parents complete each item rather than skip any individual item. If, however, a parent has skipped an item, we do offer a space on the data collection form for "no answer provided," which we hope will be minimally used.

7.2. Instructions and Permissions for Use of the M-CHAT

The Modified Checklist for Autism in Toddlers (M-CHAT; Robins, Fein, & Barton, 1999) is available for free download for clinical, research, and educational purposes. There are two authorized websites: the MCHAT and supplemental materials can be downloaded from www.firstsigns.org or from Dr. Robins' website, at http://www2.gsu.edu/~wwwpsy/faculty/robins.htm.

Users should be aware that the M-CHAT continues to be studied, and may be revised in the future. Any revisions will be posted to the two websites noted above.
Furthermore, the M-CHAT is a copyrighted instrument, and use of the M-CHAT must follow these guidelines:

(1) Reprints/reproductions of the M-CHAT must include the copyright at the bottom ([illegible] Fein, & Barton). No modifications can be made to items or instructions without permission from the authors.
(2) The M-CHAT must be used in its entirety. There is no evidence that using a subset of items will be valid.
(3) Parties interested in reproducing the M-CHAT in print (e.g., a book or journal article) or electronically (e.g., as part of digital medical records or software packages) must contact Diana Robins to request permission (drobins@gsu.edu).

7.3. Instructions for Use

The M-CHAT is validated for screening toddlers between 16 and 30 months of age, to assess risk for autism spectrum disorders (ASD). The M-CHAT can be administered and scored as part of a well-child check-up, and also can be used by specialists or other professionals to assess risk for ASD. The primary goal of the M-CHAT was to maximize sensitivity, meaning to detect as many cases of ASD as possible.

Therefore, there is a high false positive rate, meaning that not all children who score at risk for ASD will be diagnosed with ASD. To address this, we have developed a structured follow-up interview for use in conjunction with the M-CHAT; it is available at the two websites listed above. Users should be aware that even with the follow-up questions, a significant number of the children who fail the M-CHAT will not be
diagnosed with an ASD; however, these children are at risk for other developmental disorders or delays, and therefore, evaluation is warranted for any child who fails the screening.

The M-CHAT can be scored in less than two minutes. Scoring instructions can be downloaded from http://www2.gsu.edu/~wwwpsy/faculty/robins.htm **or www.firstsigns.org**. We also have developed a scoring template, which is available on these websites; when printed on an overhead transparency and laid over the completed M-CHAT, it facilitates scoring. Please note that minor differences in printers may
cause your scoring template not to line up exactly with the printed M-CHAT.

Children who fail more than 3 items total or 2 critical items (particularly if these scores remain elevated after the follow-up interview) should be referred for diagnostic evaluation by a specialist trained to evaluate ASD in very young children. In addition, children for whom there are physician, parent, or other professional's concerns about ASD should be referred for evaluation, given that it is unlikely for any screening instrument to have 100% sensitivity.

7.4. M-CHAT

Instruct the parent to please fill out the following about how their child usually is. Please try to answer every question. If the behavior is rare (e.g., you've seen it once or twice), please answer as if the child does not do it.

1. Does your child enjoy being swung, bounced on your knee, etc.? Yes No

2. Does your child take an interest in other children? Yes No

3. Does your child like climbing on things, such as up stairs? Yes No

4. Does your child enjoy playing peek-a-boo/hide-and-seek? Yes No

5. Does your child ever pretend, for example, to talk on the phone or take care of a doll or pretend other things? Yes No

6. Does your child ever use his/her index finger to point, to ask for something? Yes No

7. Does your child ever use his/her index finger to point, to indicate interest in something? Yes No

8. Can your child play properly with small toys (e.g. cars or blocks) without just mouthing, fiddling, or dropping them? Yes No

9. Does your child ever bring objects over to you (parent) to show you something? Yes No

10. Does your child look you in the eye for more than a second or two? Yes No

11. Does your child ever seem oversensitive to noise? (e.g., plugging ears) Yes No

12. Does your child smile in response to your face or your smile? Yes No

13. Does your child imitate you? (e.g., you make a face-will your child imitate it?) Yes No

14. Does your child respond to his/her name when you call? Yes No

15. If you point at a toy across the room, does your child look at it? Yes No

16. Does your child walk? Yes No

17. Does your child look at things you are looking at? Yes No

18. Does your child make unusual finger movements near his/her face? Yes No

19. Does your child try to attract your attention to his/her own activity? Yes No

20. Have you ever wondered if your child is deaf? Yes No

21. Does your child understand what people say? Yes No

22. Does your child sometimes stare at nothing or wander with no purpose? Yes No

23. Does your child look at your face to check your reaction when faced with something unfamiliar? Yes No