

A Prospective Birth Cohort Study Involving Environmental Uranium Exposure in the Navajo
Nation
Manual of Procedures (MOPs) for Developmental Screening

Overview

Navajo communities have been exposed to legacy waste of uranium mining for more than 50 years. Community members are concerned that the exposures have led to reproductive toxicity as well as impaired development in their children. Similar concerns have been raised in other communities where uranium exposures have occurred but no definitive studies have been conducted in humans. In the Navajo Birth Cohort study we will examine the reproductive outcomes in pregnant women, follow and assess their children from 2 months to 1 year of age, and set up a system to allow follow up through childhood age 6 years to evaluate the impacts of uranium exposure on biological and psychosocial endpoints. The research will be conducted by a team of research scientists, Navajo and federal agency representatives, clinicians, and Navajo culture and language experts using community-based techniques.

In response to community requests, this particular aspect of the Navajo Birth Cohort project will study the prenatal, perinatal, and early postnatal health effects of environmental exposures to uranium and associated mining wastes on Navajo mothers and their offspring. The project has multiple goals, but those relevant to this manual focus on establishing a birth cohort of 1,500 infants born to Navajo women who will be assessed and followed for birth, growth, and neurodevelopmental outcomes to 12 months of age.

Purpose of MOPs

The purpose of this manual is to institute procedures to ensure a consistent, streamlined, and efficient administration of two developmental measures: the Ages and Stages Questionnaire – Inventory (ASQ-I) and the Mullen Scales of Early Learning (MSEL). In order to maximize compliance and consistency with the administration of these measures at 4 time points, this manual will provide a detailed, step-by-step guide for the standardized administration of the ASQ-I and MSEL.

1.1 Participants

The participants for this aspect of the research study will be infants born to mothers who were enrolled in the study and followed during their pregnancy. Mothers of the infants will be asked to complete the ASQ-I about their child at 2, 6, 9, and 12 months of age. In order to directly assess the child's development, a trained examiner will administer the MSEL at 12 months of age. Both the ASQ-I and MSEL will be administered at 12 months of age to assess concurrent validity of the two measures.

1.2 Required Test Procedures

1.2.1 Test Administration Order

The ASQ-I is a parent report measure about child development and administered to the mother within one month of the specified time points (2, 6, 9, and 12 months of age) according to the protocol outlined in this manual. At 12 months of age, the child will be administered the MSEL by a trained professional.

1.2.2 The Testing Session

As part of the mother's participation in the study, a Community Health Representative (CHR) will meet with the mother to discuss the study and review the consent form. At the time of assessment, the CHR will clarify that the assessments are for research purposes; however limited interpretive information may be provided by the CHR to the infant's mother and family should there be an issue of clinical concern. A clinical concern is indicated when a child scores below the average range on either or both of the test measures administered. Specifics about this range is described below in the "Test Interpretation and Feedback to Parents" section below. When a clinical concern is identified, the CHR will bring the results to the attention of the parent, using the feedback form developed specifically for this study. This form will be provided to the family, appropriate community agency, and the child's primary care doctor.

Making the family feel comfortable with the questionnaires and testing situation is critical to obtaining accurate assessment results. These measures will be administered in a quiet and confidential location (i.e., not a clinic waiting room) to ensure that the family feels as comfortable as possible discussing private information about their child's development. In order to establish rapport, the CHR will spend a few minutes with the child and parent together before proceeding with the evaluation and briefly explain the purpose of the assessment. During the assessments at each time point, the goal is to create an atmosphere in which the mother or caretaker will feel safe to communicate openly without fear of being criticized or judged.

During the 12-month visit the ASQ-I is initially administered and then MSEL administered. As with the ASQ-I administrations before, the CHR will also allow the child time to become acquainted with the testing room before beginning. The CHR should use his/her discretion to determine when breaks or temporary suspensions of the testing are necessary due to factors that impact the infant's performance, such as fatigue, hunger, illness, or distress.

1.2.3 Test Administration

ASQ-I: The ASQ-I is a population screening measure that is completed on a paper form and used to assess a child's development between the ages of 1 month and 5 ½ years of age. The ASQ-I is an inventory of a child's functioning in a number of domains, including communication, gross & fine motor skills, problem solving and personal social skills.

The ASQ-I will be administered by one of the CHRs to the mother (or significant caretaker). The CHR will begin asking the mother (or significant caretaker) questions based upon the appropriate starting point for the child's chronological (or adjusted chronological age). For example, if the child is 5 weeks old, the CHR will begin asking questions at the starting point designated for a one month old child. Time burden for completion of the ASQ-I ranges from less than 5 minutes for children age 2 months to up to 20 minutes for children who are 12 months of age.

The current research study is assessing children at four time points: 2, 6, 9, and 12 months of age, thus possible ASQ-I manipulatives for the child's chronological age will need to be present. If a child's age at the time of their appointment does not fall at one of these exact ages, please refer to the chart on the front of the ASQ-I to determine the appropriate beginning question.

The CHR will ask the ASQ-I question exactly as written to the mother (or significant caretaker) and allow them to respond in one of three ways: Yes, Sometimes, and Not Yet. Starting with the child's chronological age (or adjusted chronological age), the CHR determines a basal age (four consecutive responses of "Yes") and proceeds to ask the questions until four responses of "Not Yet" have been recorded. If the CHR does not obtain a basal (i.e., four consecutive responses of "Yes") on the initial items asked, then the CHR should administer the previous items in reverse order until a basal is reached (i.e., four consecutive responses of "Yes"). After the basal is reached, the CHR can continue administering the remaining items after the basal until four consecutive responses of "Not Yet" have been recorded. *The CHR should be careful to not supplement the question with any additional information or explanation.*

MSEL: The Mullen Scales of Early Learning (MSEL) assesses early intellectual development and is used for children from birth to 5 years, 8 months old. The MSEL is comprised of five (5) scales: Gross Motor, Fine Motor, Visual Reception, Expressive Language, and Receptive Language. The Fine Motor, Visual Reception, Expressive Language, and Receptive Language scales combine to form an Early Learning Composite scores. As a result, only these four scales will be assessed for this study and the Gross Motor scale will not be administered. A 1-year-old can be assessed in approximately 15 minutes, with additional time allowed to establish rapport with the child and help them become comfortable with the testing environment. For each scale, a T-score and percentile is obtained based on the child's raw scores, resulting in five raw and five t-scores for each child (Fine Motor, Visual Reception, Expressive Language, and Receptive Language and Early Learning Composite). Age-equivalents based on the raw scores are also available to indicate the developmental age at which the child is functioning on that particular scale. The T-scores from each scale are combined to establish the Early Learning Composite score.

The MSEL is an individually administered measure of children's development that will be administered in a standardized manner according to the test manual by a CHR who has undergone extensive training in test administration and scoring by the study clinical psychologists. Ideally, the MSEL administration should occur at the beginning of the child's clinic visit prior to any procedures or shots to maximize compliance during the assessment. The CHR who is administering the assessment should take time to establish rapport with the mother (or significant caretaker) and child. This familiarity is established by first administering the 12 month ASQ-I, followed by the MSEL. The MSEL should be administered in 1 session. The CHR should use his/her discretion to determine when breaks or temporary suspensions of the testing are necessary due to disruption of the child's performance (e.g., the child is sick and noncompliant, the clinic appointment is during the child's naptime, or the child is fussy and noncompliant).

Calculating Chronological Age: In order to calculate a child's age, follow the example below:

	Year	Month	Day	
Today's date	1998	09	21	(today's date)
Birthdate	1997	06	03	(birthdate)

	1	03	18	chronological age – 15 months, 18 days

First, as you would for a subtraction or addition problem, start on the far right side. Subtract the days. In this example, 21 days – 3 days = 18 days. Next, subtract the months. In this example, 9 months – 6 months = 3 months. Next, subtract the years. In this example, 1998-1997 = 1 year. If any of the numbers in the birthday exceed the numbers for the current date, you must borrow, just as you would in a subtraction problem. Take the following example:

	Year	Month	Day	
Today's date	1998	06	3	(today's date)
Birthdate	1997	09	21	(birthdate)
	0	8	12	chronological age = 8 months, 12 days

Since you cannot subtract 21 from 3, you need to borrow from the next column, which is the Month column. You are borrowing one month, which is 30 days. As a result, add 30 days to the current 3 days that already exist in the Day column to equal 33 days. Since you borrowed those days, subtract one month from the Month column. Calculate the number of days for the child's chronological age by subtracting the two numbers in the Day column (i.e., 33 days – 21 days = 12 days). Your equation should look like this:

	Year	Month	Day	
Today's date	1998	05	33	(today's date)
Birthdate	1997	09	21	(birthdate)
	0	8	12	chronological age = 8 months, 12 days

Follow a similar example for the Month column. Since you cannot subtract 9 from 5, you will need to borrow 12 months from the Year column. Add 12 to the Month column to bring your total to 17 and subtract a year from 1998 for the 12 months you just borrowed. The equation should look like this:

	Year	Month	Day	
Today's date	1997	17	33	(today's date)
Birthdate	1997	09	21	(birthdate)
	0	8	12	chronological age = 8 months, 12 days

Adjusting for prematurity: If a child is premature (i.e., 37 weeks or less), you will need to adjust their chronological age for both the ASQ-I and MSEL. To make this adjustment, you will need to subtract the number of weeks that the child was premature from their chronological age determined by the method above before calculating the adjusted chronological age (per the method above). For example, if a child is currently 15 months (60 weeks) old, but was born 6 weeks early, then the adjusted age is 13 months, 2 weeks (54 weeks) old.

1.2.4 Test Interpretation and Feedback to Parents

Once the ASQ-I is administered and scored by the CHR, limited feedback will be provided to families about their child's performance. Parents will be informed whether their child passed or failed the screening instrument and provided with this information in written form immediately after screening procedures have been scored. No other interpretation is provided. Any child who fails the ASQ-I will be referred for an evaluation at the local Navajo early childhood intervention program associated with the clinic. The child's primary care physician will also be made aware of the referral and results of screening with the same written form provided to the mother (or significant caretaker).

Administration of the MSEL for this project is completed in the context of a research study and does not constitute a clinical examination, thus is not intended for clinical use. After administration and scoring of the MSEL according to guidelines outlined in the test manual, minimal feedback will be provided to families. Parents will be informed if their child scores within normal limits, above normal limits, or below normal limits. The four individual scales on the MSEL (Visual Reception, Fine Motor, Receptive Language, and Expressive Language) are scored using T-scores. A T-score within normal limits for the purposes of this research study is defined as any score between 35 and 65. T-scores above normal limits are defined as scores above 65. T-scores below normal limits are defined as scores below 35, and are therefore an area of clinical concern. The Early Learning Composite, which is comprised of the four individual scales, is scored using Standard Scores, rather than T-scores. For the purposes of this study, a Standard Score within normal limits is defined as any score between 80 and 120. A Standard Score above 120 is defined as a score that falls above normal limits. If a child's Standard Score falls below 80, then it is below normal limits and is of clinical concern. In the case where a child's scores fall below normal limits on any of the four individual scales or on the Early Learning Composite, the child will be referred to the local Navajo early childhood intervention program. The child's primary care physician will also be made aware of the referral and results of screening with the same written form provided to the mother (or significant caretaker).

1.3 Quality Control

All of the assessments in the developmental battery will be administered and scored by a CHR at the participating clinic. The CHR is responsible for the integrity of the data collected. Each site will also have a clinical psychologist who will conduct QA spot checks of the test administration and review all patient files for data scoring accuracy. To ensure that the CHR continues to administer the assessments in a standardized format, every tenth administration of both the ASQ-I and MSEL will be observed and coded separately. Following the administration of each instrument, the scores will be compared for reliability. Reliable scores are those that are 90% in agreement with the psychologist's scores. If the CHR is not reliable, additional training by the psychologist will be completed to ensure standardized and reliable administration of the instruments. Further, the psychologist will conduct spot checks of the scoring to ensure the data are accurate.

1.4 Data Security

Participant protocols from the ASQ-I and MSEL will be kept securely and data coded into the study database at a secure location.

The CHR will provide original ASQ-I data forms/protocols to the study center for purposes of data entry. The CHR may make a copy of the ASQ-I data form/protocol for a child being referred for early intervention services.

The MSEL paper protocol will be provided to the study center for data entry by the CHR who administered the measure.

A Prospective Birth Cohort Study Involving Environmental Uranium Exposure in the Navajo Nation

Child Name: _____
Child DOB: _____
Chronological Age: _____
Date of Study Examination: _____

To Whom It May Concern:

Today, _____ was seen for a developmental screening during his/her participation in research study titled, "A Prospective Birth Cohort Study Involving Environmental Uranium Exposure in the Navajo Nation." As part of this study examination, the following results were obtained:

Measures administered include:

Ages and Stages Questionnaire – Inventory (ASQ-I)	Yes	No
Mullen Scales of Early Learning (MSEL)	Yes	No

ASQ-I Results:	Pass	Concern
Communication	<input type="checkbox"/>	<input type="checkbox"/>
Gross motor skills	<input type="checkbox"/>	<input type="checkbox"/>
Fine motor skills	<input type="checkbox"/>	<input type="checkbox"/>
Problem Solving	<input type="checkbox"/>	<input type="checkbox"/>
Personal Social Skills	<input type="checkbox"/>	<input type="checkbox"/>

MSEL Results:	Pass	Concern
Fine Motor	<input type="checkbox"/>	<input type="checkbox"/>
Visual Reception	<input type="checkbox"/>	<input type="checkbox"/>
Expressive Language	<input type="checkbox"/>	<input type="checkbox"/>
Receptive Language	<input type="checkbox"/>	<input type="checkbox"/>
Early Learning Composite	<input type="checkbox"/>	<input type="checkbox"/>

Referral made? Yes No To whom? _____ Date ____/____/____

Comments:

If you have questions about these results, please feel free to contact one of us.

Sincerely,

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