

Pediatric Assessments of
Neurological &
Neurocognitive Function for
Cardiovascular Devices
Workshop

Center for Devices & Radiological Health

FDA

March 25, 2010

Availability of Assessments: Economics, Risks, and Benefit

Janice Ware, PhD

Associate Director

Developmental Medicine Center

Children's Hospital Harvard Medical School

Cardiac Neurodevelopmental Program

- Establish systematic ND follow-up of CICU "graduates"
- Provide infrastructure for ND testing of children in clinical trials

Cardiac Neurodevelopmental Research Registry

The Registry serves as a source for future hypothesis-driven applications aimed at exploring risk factors for adverse neurodevelopmental outcome in children with congenital heart disease

Cardiac ND Protocol

- Inpatient pre-discharge ND eval
 - Standard of Care
 - Physician's Orders
- Standard neuropsychological battery
- Data Registry
- Aids Child overlap
 - Enrollment in multiple studies

Reimbursement

- Clinical services billed to patient insurance (medical and/or mental health benefits)
- Data not related to clinical care is not billed
- Patients who decline Registry but who wish to participate in a study seen separately (testing expenses through the research study)
- Non-registry patients are seen & billed for the same services by the same team in our Outpatient department

Impact of Clinical Billing

- Clinical research model affects staffing patterns and cost of service
- Test choices and assessment protocols are driven by clinical need
- Billing rates

What have we learned?

- “Universal” & persistent motor delays
- Link between early motor delays & later cognitive dysfunction
- Higher rates of autism than expected
- Undetected genetic disorders
- Significant feeding & growth problems
- Moderating effect of caregiving environment

Critical Data Points

- Medical co-morbidities (Autism, VCFS)
- Motor (strength, tone, postural reactions)
- Handedness determination
- Head circumference
- Attention (recruiting, shifting, releasing)
- Caregiving environment
- Emotional/psychiatric co-morbidities

Critical Data Points

- Cognition (IQ)
 - Brazelton Neonatal Scale (0-3 mos)
 - Bayley Scales (3-36 months)
 - Differential Ability Scales (4+ years)
- Neuropsychological processes (attention, memory, language, motor, executive functions)
 - Kaufman Assessment Battery for Children (4+ years)
 - NEPSY-II (3+ years)

Critical Data, cont.

- Daily living skills
 - Adaptive Behavior Assessment System
- Autism Spectrum Disorder
 - M-CHAT (screening questionnaire)
 - SCQ (screening questionnaire)
 - ADOS (diagnostic test)

Critical Data, cont.

- Attention & Behavior
 - *Behavior Assessment System for Children*
- Language
 - *MacArthur Communication Inventory (1-3 years)*
 - *CELF*
- School Readiness
 - *Bracken School Readiness Scale*

Data Registry

- CNP Program Staff obtain parent consent to participate in the Registry before child is discharged from initial inpatient stay
- Participating in the Registry means that CNP can use the information from their child's neurodevelopmental assessments for research purposes

Who is Eligible?

Child eligibility:

- Cardiac surgery at age < 1 year, or
- Participant in a clinical research study with neurodevelopmental endpoints, or
- Referred by a cardiologist or other clinician for neurodevelopmental assessment

Specifically, the Registry will:

- Maintain a central, anonymized computer repository of
 - Medical Information
 - Neurodevelopmental evaluations deriving from clinical assessments
- Provide neurodevelopmental data for specific research projects.