Quality Control Measures

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ADC Data Core Leaders Meeting
October 2, 2004
Quality Control Defined

- Methods and procedures implemented to insure that data are collected, managed, and utilized with accuracy and precision

“Specific Aim 2 is to upgrade and enhance the functionality of the existing database in response to the needs of the Clinical and Neuropathology Cores, expand the MDS to the Uniform Data Set (UDS) created by the NIA Clinical Taskforce, maintain quality control and security, to create queries and reports as well as related databases in support of other ADC Cores (e.g. the new one to store and retrieve MRI data efficiently) and to develop additional workshops for training in the use of the database by local ADC personnel.” – UT SW ADC Grant, Statistics and Data Management Core
Five-Phase Approach to QC

- **Development**
  Control on protocol and forms development

- **Data Collection**
  Control implemented for data collection

- **Database**
  Control implemented within the structure of the database

- **Data Entry**
  Control of the data entry process

- **Post Entry**
  Control procedures after data have been entered
Development Controls
Control on protocol and forms development

- **Protocol Development**
  -- Developed by clinicians in consultation with database and statistics personnel
  -- Protocol: “what” we will receive “when” in terms of data

- **Forms Creation**
  -- Actual forms made by Statistics and Data Management Core personnel
  -- **Well defined** unambiguous items
  -- Standard measures selected to meet the needs of local center, NACC, and the ADC research community at large (e.g., MMSE)
  -- Include **exact** NACC items to increase reliability and reduce data transfer errors.

- **Pilot Testing New Forms**
  -- Is what we think we want to collect feasible to actually collect?
Note use of discrete item responses when possible. Well-defined and easy for data entry.
**Note inclusion of exact NACC item**

### Visit/Contact (Page 3 of 4 - End of Visit)

**NACC Diagnosis**

1. Did the subject meet clinical criteria for dementia (e.g., DSM IV or other) at the most recent evaluation for dementia?
   - [ ] Yes
   - [ ] No

   **IF No**
   - [ ] Not documented: control subject, no neurological disorder
   - [ ] Not documented: control subject, no neurological disorder
   - [ ] Questionable dementia (e.g., CDH 0.5) or cognitive impairment (NEI, AAMD)
   - [ ] Down Syndrome but not documented
   - [ ] Other
   - [ ] No diagnosis made

   **IF Yes**
   - [ ] Documented: subject met criteria for dementia, what was the primary diagnosis?

   **Alzheimer's Dementia**
   - [ ] Alzheimer's disease (e.g., NINCDS 'probable Alzheimer's disease' or DSM IV 'dementia of the Alzheimer type' (DAT))
   - [ ] Alzheimer's disease with other conditions or variants in course (e.g., NINCDS possible Alzheimer's disease, DEM IV multiple etiologies where Alzheimer's is the predominant cause)

   **Mixed AD/DE/-IB** if 1 or 2 checked for Alzheimer's Dementia. Few subjects also meet clinical criteria for dementia with Lewy bodies, Lowe body variant Alzheimer's disease, or diffuse Lewy body disease (DLB)
   - [ ] Yes
   - [ ] No
   - [ ] Unknown

   **Non-Alzheimer's Dementia (primary cause of dementia) not Alzheimer's**
   - [ ] Fronto-temporal dementia (e.g., Pick's, FTD)
   - [ ] Parkinson's disease dementia
   - [ ] Huntington's disease (HD)
   - [ ] Progressive supranuclear palsy (PSP)
   - [ ] Alzheim-related dementia
   - [ ] Cortical atrophy
   - [ ] Communicating, obstructive, or normal pressure hydrocephalus
   - [ ] Vascular dementia (e.g., dementia due to stroke)
   - [ ] Dementia with Lewy Bodies (not Parkinson's Dementia) (DLB)
   - [ ] Frontotemporal dementia (e.g., CTEF, FTDL)
   - [ ] Rasmussen's encephalitis
   - [ ] Primary progressive aphasia
   - [ ] Non-AD dementia
   - [ ] Dementia due to multiple non-Alzheimer's etiologies
   - [ ] Dementia due to other medical conditions
   - [ ] Other non-Alzheimer's dementia

### Visit/Contact (Page 4 of 4 - End of Visit)

2. Subject has signs and symptoms of psychosis
   - [ ] Yes
   - [ ] No

3. Subject had depression at the most recent evaluation
   - [ ] Yes
   - [ ] No

4. Subject had delirium at the most recent evaluation
   - [ ] Yes
   - [ ] No

5. UTSAW ADC Diagnostic Code (select one code presence of depression, delirium, or Parkinsonism):
   - [ ] Primary:
   - [ ] Secondary:
   - [ ] Secondary:

6. Status at end of this visit:
   - [ ] Active: further in-person visits expected
   - [ ] Active: further phone (or other) visits expected
   - [ ] Active: no further visits expected, autopsy expected or have autopsy consent
   - [ ] Inactive: no further data expected, no autopsy expected
   - [ ] Inactive: Do not contact further

   If status is 1 or 2

7. Date of next expected FU: __/__/____ (m/d/y)

8. Is subject available for research studies?
   - [ ] Yes
   - [ ] No
   
   Reason, if No: ____________________________
Data Collection Controls

Control implemented for data collection

• Manual of Operations
  -- Specific data collection specifications and procedures
  -- Should answer the “…and how do we fill this out?” question
  -- Insures a standard way to collect data

• Training in data collection
  -- Both protocol and forms training for clinical staff
  -- Protocol: Clinical staff must know **what** to collect **when**
  -- Forms: Clinical staff must know precisely **how** to collect the data

• Data Review
  -- Collected data reviewed by clinical staff for medical accuracy and completeness before sending to data management
Database Controls
Control implemented within the structure of the database

• **Field controls**
  -- Only valid values allowed
  -- Avoid use of allowing Null (blank) values.
  -- Require codes for missing data (e.g., -9=Missing)

• **Database Integrity**
  -- We have trouble if we have an MMSE entered for a subject that has not been defined in the database. This is controlled by implementing referential integrity at the database.

• **Validation within fields and between fields**
  -- Can the Date of Death be before the Date of Birth? Can control this type of validation at entry or with secondary checks post entry.

• **Data Dictionary**
  -- REQUIRED
  -- At analysis, statistical personnel should never have to do a frequency check within a field to know precisely what it contains. The data dictionary must completely define this for ALL fields.

• **Security**
  -- Used to control who can do what with data within the database.
Data Entry Controls
Control of the data entry process

• Pre-entry review by data management staff
  -- Note that this is the second data review before data entry, the first occurring at data collection by clinical personnel

• Use of standard double data entry procedure

• Distribution of responsibility
  -- Database Manager
    + Controls global data flow
    + Ability to add and delete records
  -- Data Entry Staff
    + Only responsible to enter data into pre-existing records
    + No ability to add or delete records
Post Entry Controls
Control procedures after data have been entered

• **Secondary Validation Checks**
  -- **Clinical Validation**: Does the data make clinical sense? (e.g., Has a normal control subject been given an Alzheimer’s diagnosis at their initial evaluation???)

  -- **ADC Site specific validations**: (e.g., at UT Southwestern, our subjects can move in and out of cohort modules. We must validate the control of this movement.)

  -- **Cross record checks**: Checks like Date of Death before Date of Birth can be done post entry.

• **Auditing**

  -- **Entered Data**: random sample of data selected and audited against entered data. Historically, a controlled double data entry procedure combined with solid database control leads to an extremely high degree of accuracy.

  -- **Missed Data**: Sample clinical patient data records against data entered into database if *copies* of data records are all that are sent for data entry.

• **Aggregate Reports**
  -- Used to spot data outliers in fields and overall trends in the data
Request For Copies

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