UT SOUTHWESTERN MEDICAL CENTER

Quality Control Measures

Joan Reisch, Ph.D.

Director, Statistics and Data Management Core

Joe Webster

Center for Biostatistics and Clinical Science

U.T. Southwestern Medical Center at Dallas

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." – UTSW 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.

Alzheimer's Disease Center

SOUTHWESTERN THE UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER AT DALLAS

NIH P30-AG12300

Visit/Contact (Page 1 of 4)

Patient Name (L, F, M)	ADC ID	Examiner	Date of Exam/Contact
			month / day / year

1. **Currently Assigned Module** (check only one)

Always check the cohort this patient is currently assigned to. A patient can be in only one cohort at a time (denoted by an Initial visit, follow-up visits, and Exit visit). A visit can be either or both an ADC cohort visit and/or a research study visit, as indicated in items 2 and 3 below. (Research protocols will also have initial, follow-up and exit visits.)

- ☐ 1 Mild Cognitive Impairment Cohort
- ☐ 2 Early AD Cohort
- ☐ 3 Early AD with Psychotic Symptoms Cohort
- ☐ 4 FTD Cohort
- ☐ 5 Control Cohort
- ☐ 6 Control Autopsy Cohort
- ☐ 7 Minorities Cohort
- ☐ 8 Research Only Cohort
- ☐ 9 Other (includes patients prior to 01/2004)

2. **ADC cohort visit?** ☐ 1 Yes ☐ 0 No If yes, ADC cohort visit type
- ☐ 1 Initial visit
- ☐ 2 Follow-up visit
- ☐ 3 Exit visit

3. **Research study visit?** ☐ 1 Yes ☐ 0 No If yes, research study visit type
- ☐ 1 Initial visit
- ☐ 2 Follow-up visit
- ☐ 3 Exit visit

Study (1) _____ Phase _____

Study (2) _____ Phase _____

4. Visit made
- ☐ 1 In person
- ☐ 2 By phone

5. Med check?
- ☐ 1 Yes
- ☐ 0 No

6. Site of visit
- ☐ 1 UTSW
- ☐ 2 Native American Satellite
- ☐ 3 Other _____

7. Marital Status
- ☐ 1 Married
- ☐ 2 Widowed
- ☐ 3 Divorced
- ☐ 4 Separated
- ☐ 5 Never married
- ☐ 6 Other (e.g., not married but cohabitating)
- ☐ 9 Unknown

8. Current living situation
- ☐ 1 Private Residence
- ☐ 2 Retirement Community
- ☐ 3 Assisted Living
- ☐ 4 Nursing Home
- ☐ 5 Other
- ☐ 9 Unknown

If no longer in private residence, date when moved out: ___/___/_____ (m/d/y)

Form #1.300
Revised 09/02/2004

Visit/Contact (Page 2 of 4)

Patient Name (L, F, M)	ADC ID	Examiner	Date of Exam/Contact
			month / day / year

Concurrent Medications Log

Instructions: List all medications (prescription and over-the-counter, including vitamins) taken within the past three months. Enter "UNK" if day and month unknown. For multivitamin preparations, list the brand name of the preparation. Patient should bring in bottle, and list content of each pill for folic acid, vitamin B12, and vitamin B6. Use additional sheets if necessary.

☐ **No medications 3 months prior to this visit.**

Medication	Dose/ Route/ Freq	Start Date	End Date	Indications/Comments

Form #1.300
Revised 09/02/2004

Note inclusion of exact NACC item

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

Patient Name (L, F, M) | ADC ID | Examiner | Date of Exam/Contact (month, day, year)

NACC Diagnosis

1. Did the subject meet clinical criteria for dementia (e.g., DSM IV or other) at the most recent evaluation for dementia? ☐ 1 Yes ☐ 0 No

If No

Not demented — If subject did not meet criteria for dementia, what was the diagnosis?

- ☐ 1 Not demented control subject, no neurological disorder
- ☐ 2 Not demented, but has other neurological disorder (Parkinson's, MS, etc.)
- ☐ 3 Questionable dementia (e.g., CDR 0.5) or cognitive impairment (MCI, AAMI)
- ☐ 4 Down Syndrome but not demented
- ☐ 5 Other _____
- ☐ 6 No diagnosis made

If Yes

Demented — If subject met criteria for dementia, what was the primary diagnosis?

Alzheimer's Dementias

- ☐ 1 Alzheimer's disease (e.g. NINCDS **'probable Alzheimer's disease'** or DSM IV 'dementia of the Alzheimer's type') **(PR)**
- ☐ 2 Alzheimer's disease with other conditions or variations in course (e.g. NINCDS **'possible Alzheimer's disease'**, DSM IV multiple etiologies where Alzheimer's is the predominate cause) **(PO)**

Mixed AD/LDB If 1 or 2 checked for Alzheimer's Dementias, does subject also meet clinical criteria for dementia with Lewy bodies, Lewy body variant Alzheimer's disease, or diffuse Lewy body disease? **(AL)**

☐ 1 Yes ☐ 0 No ☐ 9 Unknown

Non –Alzheimer's Dementias (primary cause of dementia not Alzheimer's)

- ☐ 1 **Frontal lobe dementias (e.g. Pick's, FTD)**
- ☐ 2 Parkinson's disease dementia
- ☐ 3 Huntington's disease (HD)
- ☐ 4 Progressive supranuclear palsy (PSP)
- ☐ 5 Alcohol related dementias
- ☐ 6 Corticobasal degeneration
- ☐ 7 Communicating, obstructive, or normal pressure hydrocephalus
- ☐ 8 Vascular dementia (e.g. dementia due to stroke)
- ☐ 9 **Dementia with Lewy Bodies (not Parkinson's dementia) (DL)**
- ☐ 10 Prion-associated dementia (e.g. Creutzfeldt-Jakob)
- ☐ 11 Human immunodeficiency virus (HIV) encephalopathy
- ☐ 12 Primary progressive aphasia
- ☐ 13 Posterior cortical dysfunction
- ☐ 14 Down syndrome
- ☐ 16 Dementia due to multiple non-Alzheimer's etiologies
- ☐ 17 Dementia due to other general medical conditions
- ☐ 18 **Other non-Alzheimer's dementia**

Form #1.300
Revised 09/02/2004

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

Patient Name (L, F, M) | ADC ID | Examiner | Date of Exam/Contact (month, day, year)

2. Subject has signs and symptoms of psychosis ☐ 1 Yes ☐ 0 No
3. Subject had depression at the most recent evaluation ☐ 1 Yes ☐ 0 No
4. Subject had delirium at the most recent evaluation ☐ 1 Yes ☐ 0 No

5. UTSW ADC Diagnosis Codes (Make sure to code presence of depression, delirium, or Parkinsonism):

Primary: ☐ _____
Secondary: ☐ _____
Secondary: ☐ _____
Secondary: ☐ _____

6. **Status** at end of this visit:

- ☐ 1 Active: further in-person visits expected
- ☐ 2 Active: further phone (or other) visits expected
- ☐ 3 Active: no further visits expected, autopsy expected or have autopsy consent
- ☐ 4 Inactive: no further data expected, no autopsy expected
- ☐ 5 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? ☐ 1 Yes ☐ 0 No
Reason, if No: _____

Form #1.300
Revised 09/02/2004

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

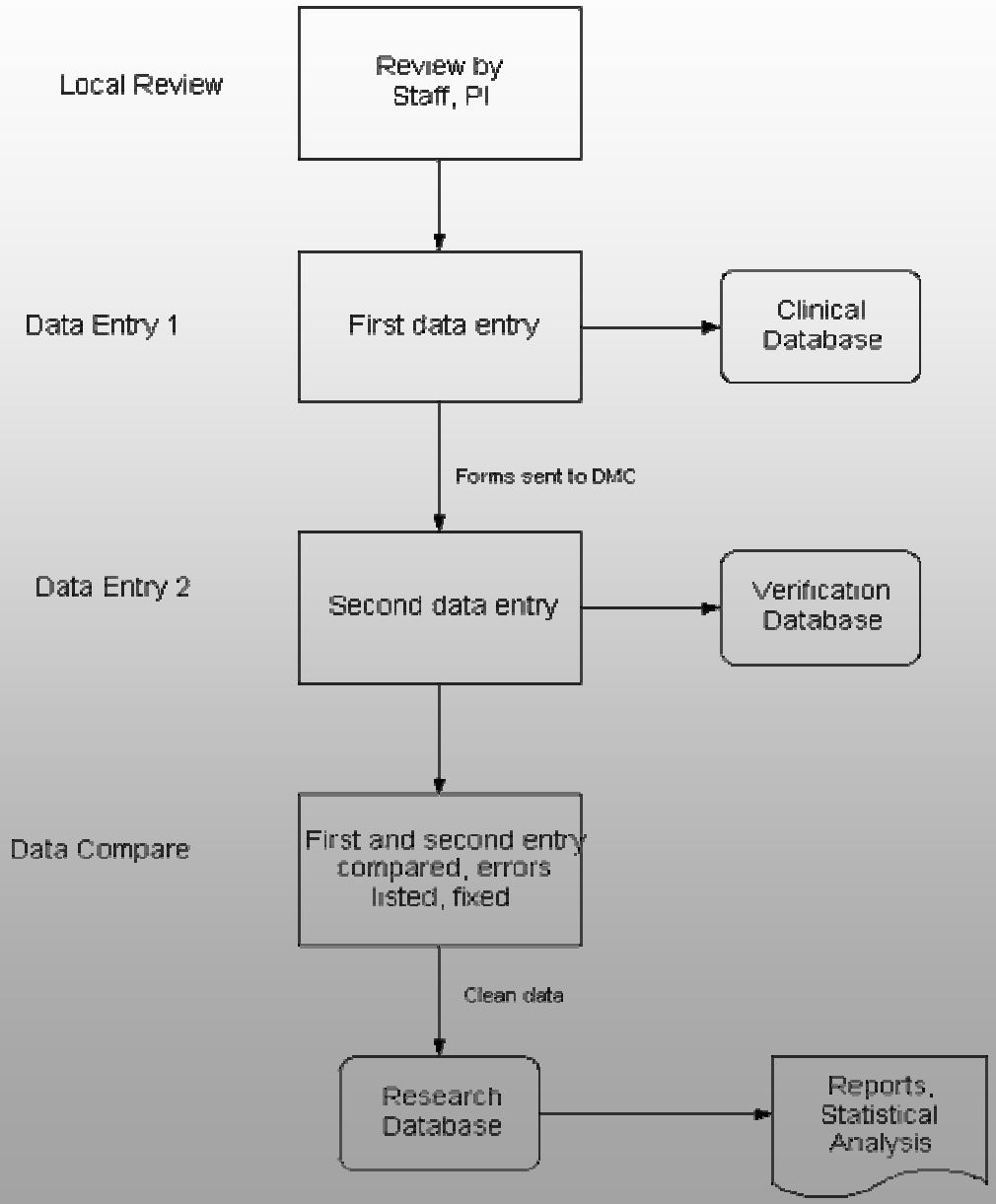
Control implemented within the structure of the database

- **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


Local Review
Review by Staff, PI
Data Entry 1
First data entry
Clinical Database
Forms sent to DMC
Data Entry 2
Second data entry
Verification Database
Data Compare
First and second entry compared, errors listed, fixed
Clean data
Research Database
Reports, Statistical Analysis

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

Joe Webster

Programming Applications Supervisor

Center for Biostatistics and Clinical Science

UT Southwestern Medical Center at Dallas

Phone: 214-648-3156

Fax: 214-648-7673

eMail: joe.webster@utsouthwestern.edu