Getting Research Data Sets from the USRDS

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American Society of Nephrology
Renal Week
Atlanta
November, 8, 2013
Approved USRDS requests for data and approved manuscripts: 2001 to 2013 (October)

<table>
<thead>
<tr>
<th>Year</th>
<th>Data Requests</th>
<th>Manuscripts</th>
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Approved USRDS requests for data and approved manuscripts: 2001 to 2013 (October)
Outline for research proposals using USRDS data

I. Research topic and submission date

II. Background information

III. Study design
   - Objectives
   - Hypothesis(es)
   - Analytical methods

IV. Data being requested
   a. List of Standard Analytical Files needed
   b. Description of data security: responsible party, computer access, etc
   c. Timeframe for the project
   d. Statement that data will be returned to the USRDS or destroyed at the end of the project.

V. Outline of estimated costs of requested data: source of funding

VI. IRB clearance (or waiver)

VII. Signed agreement for release of data (DUA)

VIII. Investigator information for principal investigator and co-authors, supply:
   - Name
   - Affiliation
   - Business address
   - Business phone number
   - Business fax number
   - Email address
Outline for research proposals using USRDS data linkages with other data sets

I Research topic and submission date
II Background information
III Study design
   Objectives
   Hypothesis(es)
   Description of data linkage – variables to be used in linkage
   Analytical methods
IV Privacy Issues
   a. Statement describing that patient consent allows such a merge or a statement why patient consent could not be obtained.
   b. IRB clearance (REQUIRED)
V Data being requested
   a. List of Standard Analytical Files needed
   b. Description of data security: responsible party, computer access, etc
   c. Timeframe for the project
   d. Statement that data will be returned to the USRDS or destroyed at the end of the project.
VI Outline of estimated costs of requested data: source of funding
VII Signed agreement for release of data (DUA)
VIII Investigator information for principal investigator and co-authors
Data Use Agreement (DUA)

- In concert with CMS policy (from which almost all USRDS data derive), we no longer have DUAs with individual investigators.

- The DUA is an agreement between the USRDS and the institution requesting the data. The DUA must be signed by the appropriate institutional authority responsible for IT and privacy security (as the requestor).

- It has to be co-signed by the investigator(s) as well to acknowledge their responsibility for privacy protection for this kind of individual patient data.
USRDS Available Data Sets

• Standard Analysis Files (SAF)
  – Core CD – Patient, treatment history, payer sequence, transplant, wait list, DMMS, medical evidence, facility
  – Transplant CD – follow-up data, immunosuppressives
  – Hospital CD – dates, diagnoses and procedures
  – Claims CDs – institutional and physician/supplier
  – “Backcasted” data (ages 67 +)

• Clinical Performance Measures (CPM) merged data (thru 2008)

• Case Mix Adequacy (1986-87), DMMS (1993, 1996)

• Comprehensive Dialysis Study (2005-08)

• Veterans Administration (VA) linked data? NO!
5 % Medicare sample

- 1992 through 2011 defined cohorts
- Follow-up data including
  - Hospitalization
  - Mortality
  - ESRD
  - Medicare expenditures
  - All billing data
Size of 5% Medicare sample for CKD patients
USRDS Available Data Sets
Part D – pharmaceutical data

1. Years 2006 through 2011
2. Enrollment data
   o part D, credible coverage, unknown
   o LIS
   o Gap coverage type
   o Monthly premium
3. Drug data
   o Service date
   o Quantity, days supply, dosage
   o Brand name, generic name, product service ID (NDC)
   o Benefit phase (gap, catastrophic, etc)
   o Total cost, beneficiary co-pay
NIDDK central repository components

• Biosample repository:
  – archival storage of biological specimens

• Database repository:
  – maintain archival datasets,
  – respond to queries about data and stored samples

• Genetics repository:
  – create immortalized cell lines, DNA extraction

- [https://www.niddkrepository.org/home/](https://www.niddkrepository.org/home/)
We have data and samples available for you!
The NIDDK Central Repository

What are the Benefits of the Repository?

- Many datasets and sample collections are available.
- Design your own study using the dataset and sample collection you select.
- Pay for only the samples you select to match your research criteria.
- The data is free and it is easy to apply for access.
- The samples are a worthwhile investment for your proposed research.
- Combine studies to increase the power of your results.
- Statistical consultation available (speak directly with Repository staff).

Take advantage of the Repository resources that are available to enhance your research!
Current kidney repository holdings

AASK (The African American Study of Kidney Disease and Hypertension Study)
ATN (Acute Renal Failure Trial Network)
CDS (Comprehensive Dialysis Study)
CRIC (The Chronic Renal Insufficiency Cohort Study)
CRISP (The Consortium for Radiological Imaging Studies of Polycystic Kidney Disease)
DAC - Fistula (The Clopidogrel Prevention of Early AV Fistula Thrombosis Study)
DAC - Graft (The Aggrenox Prevention of Access Stenosis Study)
FIND (Family Investigation of Nephropathy and Diabetes)
GoKinD (The Genetics of Kidneys in Diabetes)
HEMO (The Hemodialysis Study)
MDRD (The Modification of Diet in Renal Disease)
NANS (National Analgesic Nephropathy Study)
Approved data requests for research files from NIDDK Repository (to date)

<table>
<thead>
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<th>Total Data Requests</th>
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Thank you