BROWN
School of Public Health

NIH Collaboratory Steering Committee Meeting

Data Governance / Data Sharing

May 9, 2016 from 11:00 a.m. – 12:00 p.m.

PROVEN

PRagmatic Trial of Video Education in Nursing Homes

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Q1 - What is your current data sharing plan, and do you foresee any obstacles?

- At a minimum, we will share an aggregate data set at the (de-identified) provider level.

FAC ID	% Pts Post Acute	Target Group	Pt. Count	Inter-vention	Women	>85	ADRD	CHF/ COPD	Saw Video	Hospi-talized	Hospice Use
1	30%	Yes	#	Yes/no	#	#	#	#	#	#	#
1	30%	No									
2	50%	Yes									
2	50%	Yes									

Q1 - What is your current data sharing plan, and do you foresee any obstacles? (continued)

- Contingent on obtaining permission from CMS, we are investigating the possibility of creating an anonymous person-level outcomes analytic file (to allow replication of PROVEN outcomes analyses), which would contain:
  - Dummy dates
  - Fake provider IDs
  - No geographic information

Q1 - What is your current data sharing plan, and do you foresee any obstacles? (continued)

- Main obstacle: CMS is the custodian of the outcomes data under our approved Data Use Agreement (DUA).
  - Will be challenging to obtain CMS permission
  - As a matter of precedent, it has not been done to our knowledge

Q2 - What information did the IRB require in order to waive informed consent about how the data would be shared beyond the study?

- We committed to share information about study results with our partners who are free to share with their staff and patients.

Q3 - How will you put the policy from the data sharing work group into practice in your study?

- We will adhere to existing *NIH Data Sharing Policy and Implementation Guidance,* which is required for all NIH Collaboratory pragmatic trials:
  - The privacy of participants will be safeguarded.
  - Data will be made as widely and freely available as possible given privacy concerns and data restrictions under our government Data Use Agreement.
  - Data will be shared no later than the acceptance for publication of the main study findings.

Q3 - How will you put the policy from the data sharing work group into practice in your study? (continued)

- Item 1: Collaboratory investigators will each share, at a minimum, a final research data set upon which the accepted primary pragmatic trial publication is based.
- Item 2: The Collaboratory Steering Committee recognizes that sharing data derived from clinical care in studies performed in partnership with health care systems may, under some situations, require precautions in addition to those regarding patient confidentiality, to protect specific interests of collaborating health care systems, facilities or providers. Precautions such as allowing data sharing in more supervised or restricted settings, such as access to researchers who agree to limited pre-approved research goals, may be appropriate to address these needs in implementing this data sharing policy.
  - Let's address these together…

Q3 - How will you put the policy from the data sharing work group into practice in your study? (continued)

- Four options for sharing our data:

1. Create aggregate data set at (de-identified) provider level.
2. Create an anonymous person-level file containing actual people but no real dates, provider IDs, or geographic information; if approved by CMS, give file to NIH.
3. Same as #2 above, but give file to a restricted-access enclave which will manage the DUAs and delegate access.
4. Create multiply imputed synthetic data sets -- essentially simulations that contain no real people. The final synthetic data set (huge multiple replicate), would allow replication of our findings and additional analyses. If approved by CMS, give files to NIH.

Q3 - How will you put the policy from the data sharing work group into practice in your study? (continued)

- We might be able to share a restricted file. In some instances, CMS allows NIH-funded investigators to set up procedures that allow individual investigators access to restricted data.

- CMS has extensive data use agreement procedures with which we are familiar and others' access to individual level data are always restricted.

Q3 - How will you put the policy from the data sharing work group into practice in your study? (continued)

- Item 3: Consistent with NIH policy and guidance, Collaboratory investigators will choose the least restrictive method for sharing of research data that provides appropriate protection for participant privacy, health system privacy, and scientific integrity.
  - Facility level aggregate counts of individuals separated by "target group"
    - Allows for summary analysis at a more detailed level than meta-analysis
    - Allows for some stratification by facility type

Q3 - How will you put the policy from the data sharing work group into practice in your study? (continued)

- Item 4: Collaboratory investigators will work with NIH to implement this data sharing policy, to ensure the appropriate administrative processes and technical infra-structure are in place to support timely data sharing for the Collaboratory.
  - A formal request for creation of an individual-level, de-identified data set will be prepared and submitted to the CMS privacy board
  - An aggregated data set will be created and quarterly updates of the data will be done when detailed reports are made to the DSMB

Q4 - What data are you planning to share from your project (individual-level data, group-level data, specific variables/outcomes, etc.)?

- Variables of interest in an aggregate data set at the (de-identified) provider level:
  - Counts by case and type:
    - Patient risk group: advanced dementia, CHF or COPD
    - Long-stay vs. short-stay
    - Hospitalized
    - Age strata
    - Gender
    - Dual Eligible or not
    - Study arm (experimental, control)
    - # of patients in group exposed to ACP video (experimental arm only)

Q4 - What data are you planning to share from your project (individual-level data, group-level data, specific variables/outcomes, etc.)? (continued)

- An anonymous person-level outcome analytic file, **if approved by CMS**, would include these same variables of interest but with dummy dates, fake provider IDs, and no geographic information:
  - Patient risk group: advanced dementia, CHF or COPD
  - Long-stay vs. short-stay
  - Hospitalizations
  - Survival in days
  - Age strata
  - Gender
  - Dual Eligible
  - Study arm (experimental, control)
  - Number of exposures to ACP video (experimental arm only)