

ISSUES IN SHARING DATA ACROSS TRIALS: LESSONS FROM THE NIMH COLLABORATIVE DATA SYNTHESIS ON ADOLESCENT DEPRESSION TRIALS STUDY



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Synthesis Across Multiple, Long-Term Outcomes of
Prevention Interventions among LGBT Youth**

Overview

Collaborative Data Synthesis on Adolescent Depression Trials Study's (CDSADT)

- Importance of data sharing and data synthesis
- Practical issues in implementing NIH policies on data sharing
- Addressing human subjects issues
- Problem-solving potential barriers to sharing research data
- A model for establishing collaborative data sharing and synthesis collaborations

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Importance of Data Sharing

- Demand for researchers to share data has increased dramatically in recent years (see Curran & Hussong, 2009; Nosek, Spies & Motyl, 2012; Savage & Vickers, 2009)
- Need to replicate and confirm scientific findings to bolster confidence across research areas, by increasing transparency in research (see November 2012 special section of *Perspectives in Psychological Science*)
- Data sharing also serves the critical function of enabling the synthesis of findings across trials.
- Innovative statistical methods have helped resolve barriers to data synthesis, answering research questions that cannot be answered by individual trials alone (see Curran & Hussong, 2009; Brown et al., 2011)

NIH & Data Sharing

- Both NIH and NSF have policies articulating expectations that funded researchers will share data gathered through grants (NSF, 2011; NIH, 2003)
- Through NIH's leadership, data sharing efforts are increasingly being established at the start of projects, making large datasets available to researchers for analyses and helping to accelerate science (National Cancer Institute, 2012), including data from:
 - Genome-wide association studies- GWAS (NIH, 2007)
 - Autism Spectrum Disorder research (National Database for Autism Research, 2011)

The Sharing of Existing Data

- Large-scale, prospectively planned and coordinated data sharing efforts are critical, but represent major time and financial commitments.
- Opportunities exist for sharing data from completed trials, yielding large, combined datasets cost-effectively.

The Sharing of Existing Data

- Savage and Vickers (2009):
 - Attempted to obtain data from 10 articles from *Public Library of Science Medicine* and *PLoS Clinical Trials* journals
 - These journals require authors to sign agreement to share data (rationale is to permit re-analysis to confirm the study findings)
 - 10% success rate obtaining these data
- Wicherts, Borsboom, Kats & Molenaar (2006):
 - Attempted to obtain data from 141 articles published by American Psychological Association journals
 - Also require authors to agree to share data for re-analysis
 - 26% success rate
- Limited positive incentives for investigators to share data
- Other approaches needed to encourage widespread data sharing and synthesis- collaborative approaches

Barriers to Data Sharing

Data Ownership and rights to the data- Investigators who conducted the trials, individual research participants, the public whose taxpayer dollars funded the research

Data Protection- protecting the privacy rights and welfare of study participants

Data Interpretation- gathering enough information to properly understand the trial and interpret findings

NIMH Collaborative Data Synthesis on Adolescent Depression Trials Study (CDSADT)

C. Hendricks Brown, PI; George Howe, Co-I

Ongoing collaborative data sharing and synthesis project developing partnerships among researchers who have interventions to prevent or treat adolescent depression, as well as stakeholders in the study results (e.g., community leaders, practitioners, and advocates.)

Project Goal:

Development and application of novel quantitative methods necessary to integrate findings across trials, with direct application to the growing set of trials on **preventing and treating depression in adolescence**, and their relevance for building and testing the next generation of comprehensive intervention strategies.

NIMH CDSADT Study

Brings together datasets from approximately 40 existing prevention and treatment trials in adolescent depression, as well as other researchers and data stakeholders, to answer questions about:

- 1) for whom do interventions work?
- 2) by what pathways do interventions have their effects?

Background: Adolescent Depression Interventions

- There are efficacious interventions to prevent and treat depression among youth (see Brent et al., 1997; Compas et al., 2009; Dishion, Kavanagh, Schneiger, Nelson, & Kaufman, 2002; Garber et al., 2009; Gillham et al., 2007; March et al., 2004; Stice, Shaw, Bohon, Marti, & Rohde, 2009; Wolchik et al., 2000)
- There is evidence that interventions do not work equally well for all youth, and that they may work through different mechanisms for different youth.

Differential Subgroup Response to Interventions

Penn Resilience Program –PRP (Cardemil, Reivich & Seligman, 2002)

- School-based prevention program that teaches youth cognitive and social problem-solving skills
- Examined efficacy of PRP in low income African American and Latino youth
- Findings: PRP had beneficial effects for the Latino children, but no differentially beneficial effects for the African American children.
- *Reasons for differential efficacy are unclear, so examining mechanisms or mediators is important.*

Differential Mechanisms by which Interventions Work

Bridges to Middle School Prevention Intervention (Gonzales et al., 2012)-
Family-based prevention program for Latino youth

- Acculturation differences on mediators of youth internalizing symptoms:
 - More acculturated families showed greater increases in **maternal monitoring**, which predicted fewer internalizing symptoms.
 - Less acculturated families showed greater decreases in **maternal harsh parenting**, which predicted fewer internalizing symptoms.
- “... youth and families may benefit in different ways through their participation in universal interventions depending on their unique cultural strengths and needs.”

Differential Subgroup Response to Interventions

Synthesis analyses across 3 trials of the *Familias Unidas Prevention Intervention*- total sample of 721 youth and parents (Perrino et al., under review in *Prevention Science*)

- Intervention more efficacious in reducing internalizing symptoms for youth with lower levels (more problematic) of parent-adolescent communication at baseline than those with higher levels (healthier).
- Effects on youth internalizing symptoms mediated by improvements in parent-adolescent communication, specifically for adolescents with poorer initial communication levels.
- Findings only evident when data from the 3 trials were combined and synthesis analyses were conducted.

Moving towards Scientific & Health Equity

Understanding which interventions work best for minority and vulnerable subgroups may help address health inequities

Intervention moderator and mediator research can:

- Highlight how interventions can be improved
 - Permit matching interventions to individuals likely to benefit from them
 - Improve the reach of interventions
-
- Yet, inclusion of minority and vulnerable subgroups in individual research studies is often too low to conduct meaningful analyses to answer these research questions (Brown et al., 2011)

Strategies for Building a Collaborative Data Synthesis Project

Manuscript describes experiences building collaborative partnerships with these investigators and gathering de-identified datasets, and has following objectives:

- 1) increase support for data sharing and synthesis collaborations among researchers to help advance scientific knowledge
- 2) provide a model for establishing these collaborations using the example of the ongoing NIMH CDSADT Study.

Identifies 5 Steps for building collaborative data sharing and synthesis project

Perrino, Howe, Sperling, Beardslee, Sandler, Shern, Pantin, Kaupert, Cano, Cruden, Bandiera, & C. Hendricks Brown. (in press). Advancing Science through Collaborative Data Sharing and Synthesis. Perspectives on Psychological Science

Strategies for Building a Collaborative Data Synthesis Project

1. Identifying a Research Question

- Specifying an important research question in the field that can be addressed through a data sharing and synthesis study

Strategies for Building a Collaborative Data Synthesis Project

2. Identifying Stakeholders

- Identifying individuals with a stake in the data (“data stakeholders”) or with a stake in the findings of the data synthesis study (“stakeholders in the synthesis findings”).
- In CDSADT, stakeholders have included the study’s facilitating team, individual study investigators, IRBs, community advocates, adolescent depression care providers, and adolescents at risk for depression and their families.

Strategies for Building a Collaborative Data Synthesis Project (continued)

3. Using a Community Based Participatory Research Framework

- Moved away from working independently to collect and analyze data
- Uses a participatory method for collaborative data synthesis
- Data stakeholders invited to participate actively in virtually all research aspects -- articulation of research questions, interpretation and publication of results, and dissemination of findings.
- Similar conceptually to community based participatory research, in which academic researchers join with community stakeholders to collaborate as active research partners (Israel, Eng, Schulz, Parker, & Satcher, 2005).

Strategies for Building a Collaborative Data Synthesis Project (continued)

4. Building and Maintaining Partnerships

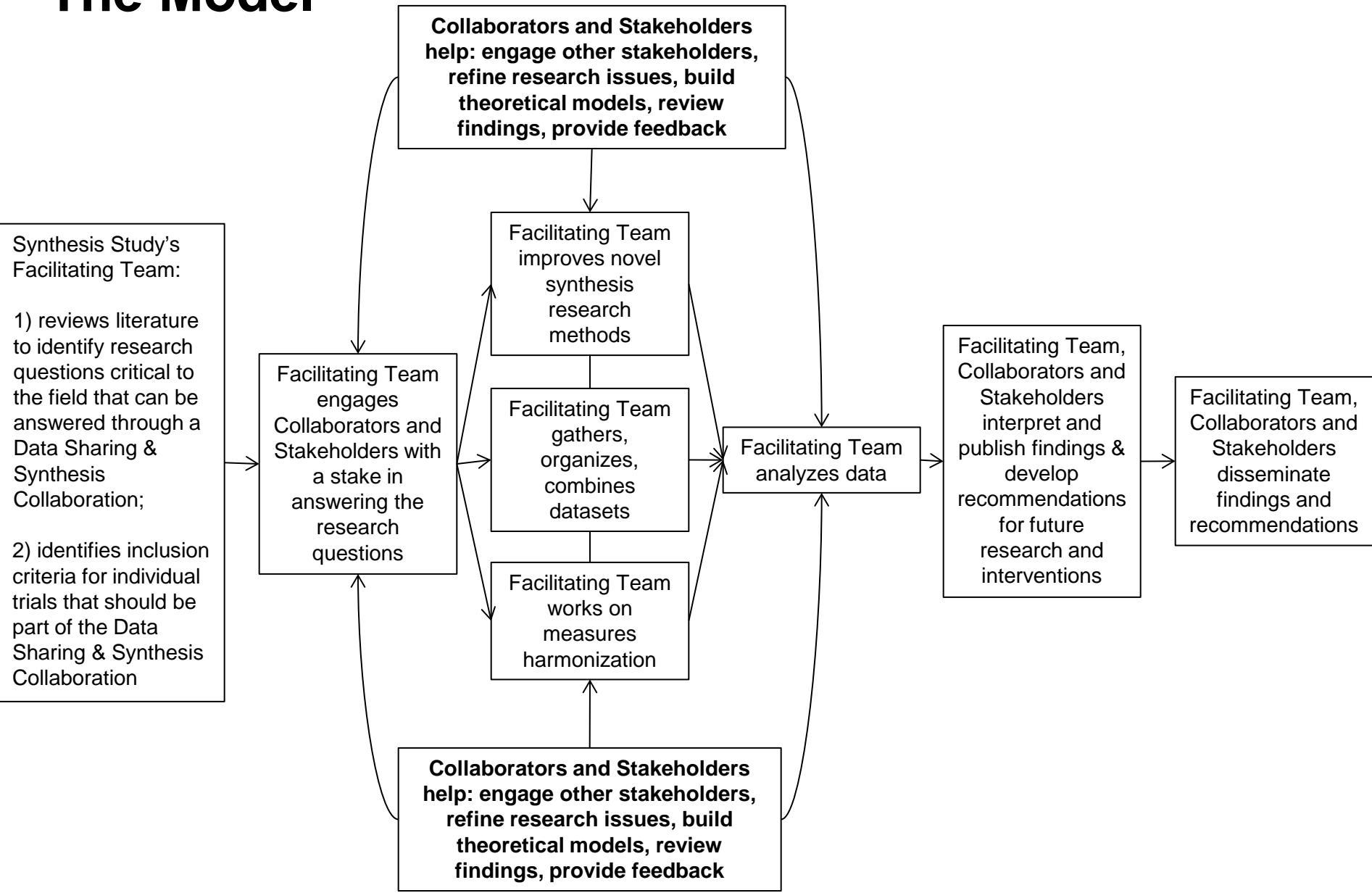
- Individual discussions with stakeholders to involve them in CDSADT by establishing shared goals for the overall project and stakeholders themselves.
- Regular meetings with stakeholders
- Common goals:
 - Development of quantitative methods to analyze aggregated data
 - Production and dissemination of new findings
 - Establishment of priority and best-practice recommendations for the field to guide next generation of studies and practice improvement
 - Answering of research questions that cannot be answered through individual efforts

Strategies for Building a Collaborative Data Synthesis Project (continued)

5. Securing Funding to Support Collaborative Data Synthesis

- All of the steps in the process of developing these research collaborations
- Funding provided by NIMH has been a critical resource allowing the facilitating team to: engage collaborators and stakeholders, address IRB issues, gather and manage data, develop and refine statistical methodologies, conduct analyses, etc.

The Model



Overcoming Challenges to Data Sharing

- **IRBs- Issues of Data privacy & confidentiality.**
 - Working closely with local IRBs and regulatory agencies, involving them as data stakeholders
 - Data is de-identified by original research teams prior to sharing
 - Study's standard operating procedures include strict data safeguarding and protection procedures

***There is a need to harmonize IRB regulations with regard to data sharing procedures.

Overcoming Challenges to Data Sharing

Individual investigators

- Concerns that CDSADT study would publish findings the individual study team was planning to publish
 - Development of data sharing agreements addressing issues of concern
 - Clearly differentiating the CDSADT study's research questions from the individual investigators' research questions
 - Publication of findings across trials rather than within trials
 - Inclusion of individual investigators as co-authors of synthesis manuscripts
- Concerns about CDSADT team misinterpreting data
 - Continued involvement of investigators in the synthesis study after data has been shared
 - Individual investigators have essential information and experience to guide and interpret the analyses, enriching the findings and laying the groundwork for disseminating results

Overcoming Challenges to Data Sharing

Practitioners, Community Advocates, and Community Members as Stakeholders in the Data Findings

- In CDSADT study, mental health practitioners, advocates and community members have a clear interest in collaborative efforts to share and synthesize data.
- Ultimately, findings must inform prevention and treatment practices in the community
- CDSADT has involved the leader of a mental health advocacy group and the director of a national non-profit organization that helps families identify, address, and cope with depressive disorders.

NIH Data Sharing Resources

U.S. Department of Health & Human Services

NIH National Institutes of Health
Office of Extramural Research

Search
Glossary & Acronyms

HOME ABOUT GRANTS FUNDING FORMS & DEADLINES **GRANTS POLICY** NEWS & EVENTS ABOUT OER NIH HOME

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Grants Policy

- Policy & Guidance**
- Compliance & Oversight
- Research Involving Human Subjects
- Office of Laboratory Animal Welfare (DLAW)
- Animals in Research
- Peer Review Policies & Practices
- Intellectual Property Policy
- Acknowledging NIH Funding
- Invention Reporting (iEdison)
- NIH Public Access
- Research Integrity

NIH Data Sharing Policy and Implementation Guidance

(Updated: March 5, 2003)

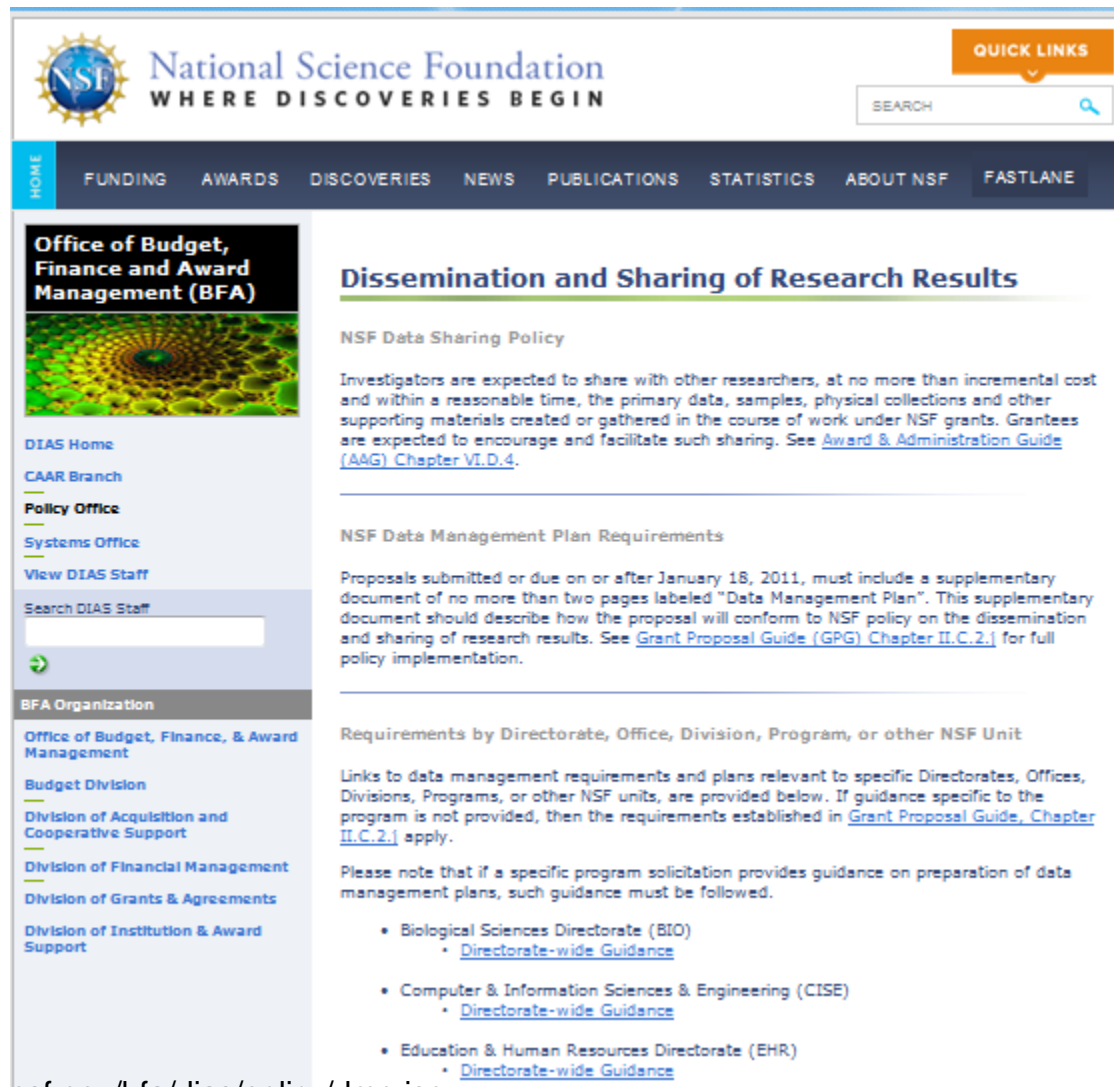
This guidance provides the National Institutes of Health (NIH) policy statement on data sharing and additional information on the implementation of this policy.

- **Goals of Data Sharing**
- **Applicability**
- **Implementation**
 - **Timeliness of Data Sharing**
 - **Human Subjects and Privacy Issues**
 - **Proprietary Data**
 - **Methods for Data Sharing**
 - **Data Documentation**
 - **Funds for Data Sharing**
 - **Review Considerations**
- **What to Include in an NIH Application**
- **Examples of Data Sharing Plans**
- **Definitions**
 - **Covered Entity**
 - **Data**
 - **Data Archive**
 - **Data Enclave**

Internet | D

http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm

NSF Data Sharing Resources



NSF National Science Foundation
WHERE DISCOVERIES BEGIN

QUICK LINKS

SEARCH

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Division of Financial Management
Division of Grants & Agreements
Division of Institution & Award Support

Dissemination and Sharing of Research Results

NSF Data Sharing Policy

Investigators are expected to share with other researchers, at no more than incremental cost and within a reasonable time, the primary data, samples, physical collections and other supporting materials created or gathered in the course of work under NSF grants. Grantees are expected to encourage and facilitate such sharing. See [Award & Administration Guide \(AAG\) Chapter VI.D.4.](#)

NSF Data Management Plan Requirements

Proposals submitted or due on or after January 18, 2011, must include a supplementary document of no more than two pages labeled "Data Management Plan". This supplementary document should describe how the proposal will conform to NSF policy on the dissemination and sharing of research results. See [Grant Proposal Guide \(GPG\) Chapter II.C.2.](#) for full policy implementation.

Requirements by Directorate, Office, Division, Program, or other NSF Unit

Links to data management requirements and plans relevant to specific Directorates, Offices, Divisions, Programs, or other NSF units, are provided below. If guidance specific to the program is not provided, then the requirements established in [Grant Proposal Guide, Chapter II.C.2.](#) apply.

Please note that if a specific program solicitation provides guidance on preparation of data management plans, such guidance must be followed.

- Biological Sciences Directorate (BIO)
 - [Directorate-wide Guidance](#)
- Computer & Information Sciences & Engineering (CISE)
 - [Directorate-wide Guidance](#)
- Education & Human Resources Directorate (EHR)
 - [Directorate-wide Guidance](#)

<http://www.nsf.gov/bfa/dias/policy/dmp.jsp>

Discussion

- Might a collaborative data sharing and synthesis model help address the research gaps in LGBT health?
- What data are available in existing studies that can help answer pressing research questions?
- Who are the stakeholders in the data and in the data findings?
- What are the specific challenges to establishing collaborative efforts?
- What are the common interests of the stakeholders that can build a collaborative effort?