AcademyHealth

State-University Partnership Learning Network (SUPLN) Distributed Research Network (DRN) Feasibility Report

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Patient-Centered Outcomes Research (PCOR) and the State-University Partnership Learning Network (SUPLN)

With support from a Patient-Centered Outcomes Research (PCOR) Engagement Award, AcademyHealth is working to transform the State-University Partnership Learning Network (SUPLN) into a sustainable collaborative that can enhance state capacity to produce, disseminate, and use patient-centered outcomes research. Over the past two years, the SUPLN engagement has become more robust with additional partnerships joining the Network, sharing best practices on creating data warehouses and other data-related issues, optimizing federal Medicaid matching funds, and conducting timely and relevant evaluations. In addition, an unforeseen value of the SUPLN is that various partnerships are collaborating with each other independent of formal SUPLN engagement activities. With this continued growth, AcademyHealth has undertaken this feasibility assessment to measure the SUPLN’s capacity and desirability to develop their own distributed research network (DRN).

What Is A Distributed Research Network?

A distributed research network (DRN) is a network of data partners that retain and analyze their own data, forgoing the need for a central repository, allowing for greater accumulation of data without the concerns for data security.

For the purposes of large data analyses relying on these multiple data partners, the core data are standardized using a common data model (CDM), which is a set of tables that serve to “standardize the format and content of data” required for the analyses. The CDM improves comparability of distributed analyses and study validity and, once implemented, allows for more efficient execution of cross-state analyses.

Once the CDM is constructed it can be continually updated by the DRN for use in future research projects. The standardized programming code using the structure and variable names and formats of the CDM is then “distributed” to each partner for local execution. Aggregate results are reported to the Coordinating Center where the Principal Lead conducting the research will synthesize the aggregate findings.

The DRN relies on a Coordinating Center, which provides two critical roles:
- The Administrative Coordinating Center provides key management functions, including the convening of calls/meetings, support for the governance structures and overall oversight of the DRN, and communication with DRN members. This team provides the same support and oversight for all projects.
- The Principal Lead manages and coordinates the research project’s data analytic functions for specific projects, including suggesting modifications to the CDM, and providing programming code based on the CDM to each partner along with guidance on implementation. Note: The Principal Lead will vary/rotate based on the research project. If there are multiple research projects, there could be multiple Principal Leads that will contribute Coordinating Center functions for their own specific projects using the DRN’s CDM.

The DRN also relies on individual state “data holders” which refers to the researchers who provide the data analysis and research function for the individual or “local” partner.

SUPLN partnerships have a substantial interest in being able to support and participate in a Medicaid DRN. They have discussed during conference calls and in-person convenings the difficulties related to the quality and timeliness of Medicaid data currently available. Specifically, there is no up-to-date national source of state-level Medicaid data (i.e., available MAX data is not very current and does not capture much of the states’ experience following the implementation of the Affordable Care Act). Additionally, it appears that the T-MSIS datasets will not be available soon, and federal and state policymakers are increasingly asking for cross-state analyses. Therefore, a SUPLN DRN provides a great resource —i.e., readily available claims-level Medicaid data, the expertise of university-based researchers experienced in working with Medicaid data, and state agency partners willing to make the data available to the researchers. As such, SUPLN partners are overwhelmingly in support of exploring the feasibility of developing a DRN. This report details the approach taken, information gathered, and recommendations derived from the feasibility evaluation.

**Background**
The SUPLN is a learning community of 26 state government agency and state university research partners in 23 states that promote the use evidence-based health policy research to inform state policy and agency practice, with a focus on transforming Medicaid-based healthcare (See Appendix A for list of SUPLN state partnerships). This learning network has grown into a robust community with the capacity to conduct valuable, policy-relevant cross-state Medicaid analyses to inform state Medicaid programs and advance the health and wellbeing of the beneficiaries they serve. To understand the capacities of these partnerships, we explored their capabilities in two phases.

The following section describes the structured approach AcademyHealth employed to explore the desirability and capacity of state-university partnerships to participate in a DRN. AcademyHealth conducted the assessment in two phases: an Environmental Scan and a DRN Feasibility Assessment, as described below.

**Methodology: Feasibility Assessment Approach**

**Phase I: Environmental Scan**
To obtain a detailed understanding of each state-university partnership’s formal relationships and capabilities, we conducted an environmental scan in spring 2017 consisting of a survey of the 23 state-university partnerships participating in the SUPLN at that time. To develop the survey, AcademyHealth formed a SUPLN DRN Environmental Scan Workgroup (the “Workgroup”) of 16 volunteer SUPLN participants (See Appendix B for a list of Workgroup members). The environmental scan was informed by a comprehensive SUPLN Distributed Research Network Feasibility Survey fielded to assess the university partners’ access to their state databases, their data linkage and integration capabilities, data request processes, and analytic capacity. Issues related to analytic capacity included several related areas such as understanding the roles of the university in Medicaid policy development, the types of analyses performed for Medicaid agencies, and the publishing rights of the university partners.

Consistent with the active engagement of the SUPLN membership, survey results indicated all 19 partnership respondents were interested in exploring a DRN — underscoring the critical role the university partners play in their state’s Medicaid policy analysis. This survey confirmed their collective capacity to provide Medicaid policy and data analysis within and across state Medicaid programs and assisted in identifying the data integration capabilities, analytic capacities, and resources that can
contribute to the feasibility of creating and sustaining a DRN. Based on the environmental scan, we collected a wealth of information and identified multiple partnerships with robust, sustainable relationships, enabling us to proceed with a DRN feasibility assessment.

**Phase II: Feasibility Assessment**

We reconstituted the original **SUPLN DRN Environmental Scan Workgroup** as the **DRN Feasibility Workgroup** (the “DRN Workgroup”) to conduct the feasibility assessment (*See Appendix B*). The charge of the workgroup was to examine the components essential to building and functioning as a DRN and viewed as critical to accelerating the pace of collaboration among the states and ensuring sustainability over time. Where possible, the DRN Workgroup recommended approaches that would align with the capacity of their own partnerships as they know it, with consideration for the likely abilities of their SUPLN colleagues. It is important to note however that any formal DRN development would involve the full SUPLN in developing and adopting foundational governance principles and structures, as described below under **Section I: Governance**.

This feasibility assessment first required AcademyHealth SUPLN staff to review existing literature on distributed data and research networks, and hold interviews with key experts in building and managing DRNs (*See Appendix C*). This review helped us to understand the role of governance principles, data-sharing and data security policies, quality assurance procedures, and operating policies in accelerating the pace of state collaboration to allow cross-state analyses. The information gathering resulted in the identification of four key DRN development categories (i.e., governance, sustainability, operations, and technical-buildout) deemed essential to build and operate a DRN.

The initial kick-off call addressed DRN Workgroup key objectives and obtained consensus on workgroup meeting structure and timeline. Through a series of structured conference calls, we explored each of the four components and discussed potential challenges. In some cases, where feasible, the DRN Workgroup agreed upon solutions for the purposes of building the initial DRN foundation. We also identified critical parameters for the DRN to ensure we were assessing capacity accurately. For example, the DRN Workgroup agreed that the partnerships would work with the Medicaid claims data as the primary dataset for this DRN based on accessibility to those data. The DRN Workgroup noted that the DRN should leverage any knowledge that SUPLN members can share, effectively building off existing processes and procedures as well as templates (e.g., for data use agreements, data sharing, privacy and security assurances, etc.). In addition, they underscored that it is critical to address data sharing, privacy and data security issues, lack of data standards, and workforce capacity issues, among other potential challenges from the onset to ensure the DRN is indeed functional.

Of note, the DRN Workgroup immediately introduced two challenges and proposed solutions.

- **Challenge: Obtaining Prior Approval from the State Partner to Access the Data.**
  DRN Workgroup members acknowledged that obtaining prior approval for data access might be difficult due to the varying scope and structure of contracts partnerships may have between the university and Medicaid agency. For example, while a few university partners have on-going real-time access to Medicaid data, others are required to request access on a project-by-project basis. The Workgroup noted that the request and approval process often can take a substantial amount of time. The DRN Workgroup acknowledged that while prior-authorization would be beneficial, it was unlikely that all their state partners could comply.
Potential Solutions: DRN Workgroup members suggested possible solutions, with some providing examples of how states are tackling the issue, including:

- The DRN could develop an overarching agreement for SUPLN that could cover analyses related to a particular dataset and topic/project focus if demonstrated it would be helpful/interest to Medicaid agencies. As an example, the Multi-state Medicaid Opioid Use Disorder (OUD) project (the ‘Pilot Project’ - See Box 1) led by the University of Pittsburgh, the SUPLN university partner from Pennsylvania, created a Memorandum of Understanding (MOU) for all participating states. This template could meet this criterion. The project utilizes Medicaid claims data, focuses on a common set of 15 access and treatment measures, and meets the objective of addressing a shared concern by Medicaid state policymakers as it affects their beneficiaries.

- The DRN could leverage the existing CMS state data entity agreement (ResDAC has on-site), which provides some latitude for state agencies to manage data.

- The DRN could build a standard business case document to use when the university partners request data use agreements with their state agency colleagues. That document could address the following questions: What qualifies the university researchers to receive pre-approval from the state agency? What is the scope of the work? What will be done with the data? What are the questions around releasing the data?

The business case document can underscore how SUPLN analyses could provide more timely review of Medicaid data, especially given that comparative analysis with T-MSIS is not possible currently. As part of this business case and to incentivize support from the state partners, the Workgroup suggested exploring whether DRN analyses by the university would be eligible for Medicaid claiming.

Challenge: Obtaining Prior Approval from the State Partner to Disseminate Analysis Results. DRN Workgroup members noted that the ability to share data analysis results also varies by partnership, so they need to consider the approval process for purposes of sharing analyses and publishing.

Potential Solutions: A DRN Workgroup member noted that many partnerships have established review processes for publishing that could be leveraged for this DRN. The SUPLN could adopt this process as a standard approach across the DRN’s participating partnerships when building the full-scale DRN.
**Box 1: Multi-state Medicaid Opioid Use Disorder Project**

*Background:* As AcademyHealth staff was finalizing the Environmental Scan and beginning its subsequent work on the DRN Feasibility Study, we were approached by the leadership of our University of Pittsburgh colleagues—the academic partner for Pennsylvania’s SUPLN partnership, about the possibility of engaging with them on a project to conduct multi-state analyses on issues related to opioid use disorder. Such a multi-state project also could act as a pilot for developing and testing a small-scale DRN. This pilot project was initially launched with each participating state providing internal and in-kind resources in order to participate in such an important endeavor while external funding sources are being pursued.

This project involves critical state Medicaid clinical leaders and university researchers, from the SUPLN and the Medicaid Medical Directors Network, also let by AcademyHealth. The MMDN provides a forum for knowledge exchange among the physicians who advise state Medicaid Directors on clinical policy and practice. It promotes the sharing of ideas and best practices, focusing on the use of evidence-based care and services, assessment of healthcare quality, and the redesign of delivery systems. A number of MMDN states had previously collaborated on three multi-state analyses of Medicaid data. Together, these networks are uniquely positioned to provide timely, multi-state analyses of Medicaid data to inform policy related to treatment of OUD.

*Project Focus:* Medicaid plays a significant role in addressing the epidemic of opioid addiction and overdose in the US. In 2015, non-elderly adult Medicaid enrollees accounted for 12% of the adult population but 25% of those with an opioid use disorder (OUD). Recognizing many components of evidence-based treatment for addiction are considered optional benefits under federal law, Medicaid programs vary significantly in their coverage of specific approaches such as screening, intervention and referral, methadone, and peer support. State Medicaid programs also vary in how they are implementing major delivery system and provider payment reforms, many of which seek to expand the continuum of services available and to integrate behavioral health and general medical care.

States have identified an urgent need for timely measures of access to and quality of OUD treatment across state Medicaid programs acutely impacted by the opioid crisis to: 1) inform state capacity-building efforts aimed at mitigating this public health crisis; 2) provide a benchmark for federal and state evaluations of substance use disorder policy changes; and 3) facilitate comparisons between states that differ in coverage and regulation of addiction treatment in order to inform policymakers.

As such, working with the University of Pittsburgh as the Principal Lead, we recruited a subset of nine regionally-located state-university partnerships (KY, MD, MI, NC, OH, PA, WI, WV and VA) with which to collaborate to conduct a multi-state study on access to, and quality of, treatment for OUD in Medicaid in states heavily affected by the opioid crisis. Drawing on existing measures of access to and quality of substance use disorders from National Committee for Quality Assurance (NCQA), National Quality Forum, and Pharmacy Quality Alliance, as well as other sources, this multi-state study will:
• Examine state-level trends and between-state differences in several measures of access to and quality of OUD care in Medicaid including quality of opioid prescribing, rates of initiation and engagement in addiction treatment, quality of treatment including medication-assisted treatment, and the intensity of acute care related to substance use disorders.

• Examine within-state differences in these quality measures across demographic groups, eligibility categories, and counties or regions within Medicaid programs.

_Pilot Project Framework and Data Protection:_ To maintain confidentiality of health information and avoid complications caused by multiple data use agreements between states, the OUD Pilot Project chose to build a DRN framework that leverages the common strengths shared across state data partners and keep the structure simple for the purposes of a pilot. First, to avoid data sharing challenges, it was determined that each state data partner would maintain control of their own state Medicaid claims data and conduct their own analyses as participating data holders. Second, each participating data holder would provide aggregated non-identifiable results, not raw data, to the Principal Lead for synthesis; in the OUD Pilot Project, the Principal Lead provided the data coordinating function. This decentralized structure is a cornerstone of a DRN and enabled each participating partnership to readily agree to participate based on its data privacy and security framework. These summarized results are shared only after each data holder’s state agency reviews per the terms of their individual agreement with their university. The Principal Lead intended for the OUD Pilot Project to provide guidance for the development of a Medicaid common data model (CDM) to serve a full-fledged SUPLN DRN in the future. During the course of the project, it became clear that it was more efficient to develop an actual CDM from the onset. While requiring additional upfront time and resources, the effort to create a CDM and ask each partner to transform their data to a common structure and format would be time-saving over the course of the pilot. This upfront investment will result in a sustainable CDM structure that can be used and built upon for future projects that address expansive or even different Medicaid data needs.
Section I: Governance

In order to consider the development of a DRN, it is critical to first discuss the development of a blueprint for governance. Governance includes a model for an organizational structure that comprises representative membership of the SUPLN at-large as well as SUPLN leadership, and the principles needed to support decision-making and guide DRN functionality. Specifically, we noted that to create the framework within which a SUPLN DRN would operate, we would need to identify guiding principles, propose a governance model, and suggest governance board composition.

Guiding Principles

The DRN Workgroup referred to the guiding principles that PCORnet developed for its DRN\(^1\), identifying those that appeared applicable to a proposed research network scope for SUPLN. The Workgroup suggested that the principles be organized by functional role (See Appendix D for Examples of DRN Guiding Principles). Yet, once reorganized it was then suggested that it would be better served to be organized by governance component, such as principles related to decision-making processes or principles associated with the handling of data. The process of examining Guiding Principles was time-intensive and proved difficult to complete – largely due to having the conversation about the DRN at a conceptual level where roles and responsibilities are hypothesized but not tested. In the full process of establishing a DRN, developing and finalizing guiding principles will be a critical task that will require an iterative process and a comprehensive understanding of the roles involved and their functionalities.

Governance Model

The DRN Workgroup referred to governance examples from the Health Care Systems Research Network (HCSRN)\(^2\) and agreed on the responsibilities and composition of the Steering Committee, including developing policies and procedures, having one representative from each DRN SUPLN participating data holder, and establishing a consensus-based governance structure (See Appendix E for information about HCSRN). The Workgroup acknowledged that identifying and determining selection criteria and term limits of leadership roles would be an important task when building the full-scale DRN.

Governance Board

The DRN Workgroup recommended the establishment of a Steering Committee to serve as the outward facing governing body, with the responsibility to establish DRN policies, budget strategies and activities to sustain the research network. In addition, they recommended creating an Executive Committee, comprised of a small number of Steering Committee members to guide the Steering Committee in the management of their own governing policies and initiatives.

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\(^1\) PCORnet DRN and CDM Guiding Principles from DSSNI TF – CDRN Member Call, December 1, 2014.

Similar to the approach discussed with the DRN Workgroup, the University of Pittsburgh Principal Lead team proposed a governance model that organized leadership into three groups with overlapping membership:

- **Steering Committee**: Comprised of AcademyHealth, Principal Lead, SUPLN university researcher partners and their Medicaid agency partners from each state. The project Steering Committee meets monthly to provide guidance for the nine university partners (“data holders”) on project scope and study questions. The Steering Committee also reviews and interprets study findings. State agency partners on the steering committee will facilitate dissemination of the findings to state, local and federal stakeholders.

- **Coordination Center**: Led by AcademyHealth and Principal Lead*, both serving key distinct roles.
  - AcademyHealth provides the key administrative functions, including the convening of calls/meetings, support for the governance structures and overall oversight of the DRN, and communication with DRN members.
  - The Principal Lead provides the data coordination functions, including facilitating the methods/data core meetings, developing and refining the Common Data Model, collecting measure specifications, developing programming code to distribute for local execution by university data holders, as well as synthesizing aggregate results from data holders.

*Note: The Principal Lead will vary/rotate based on the research project. If there are multiple research projects, there could be multiple Principal Leads that will serve as the data coordinator for their own specific projects using the DRN’s Common Data Model and adapting it for their specific project needs. AcademyHealth would serve as the DRN administrator across all projects.

- **Methods/Data Core Group**: Composed of faculty and staff from the nine data holders to facilitate a standardized approach to:
  1. Define cohorts of Medicaid members with opioid use or OUD;
  2. Develop and document key analytic measures available using Medicaid claims data; and
  3. Draft statistical software code and empirical approaches for statistical analyses of the OUD access and quality measures.

The Methods/Data Core Group meets biweekly to develop and refine analysis plans to ensure comparability of analyses across states.

- **Writing and Dissemination Group**: This group will be represented by the data holders’ faculty and staff and will be responsible for compiling aggregate reports from each state, and drafting interim and final reports for state partners. Each data holder’s representative on the writing group will take responsibility for soliciting state-specific feedback both from the data holder’s university colleagues and state agency partners. The Writing and Dissemination Group, with
oversight from the Steering Committee, will also establish a process for facilitating peer-reviewed publications and develop other dissemination strategies.

In addition, the Principal Lead, Julie Donohue, Ph.D., consulted thoroughly with the University of Pittsburgh’s legal department to review the most practical form of agreement among the data holders in order to: 1) encourage and enable participation by the broadest array of SUPLN members; 2) ensure/acknowledge adherence to existing agreements between the universities and their state agency partners; and 3) ensure compliance with other regulatory requirements (e.g., IRB approval).

Due to the fact that the Pilot Project will involve the sharing of results and not data between partnerships it was determined that a Memorandum of Understanding (MOU), as opposed to a Data Use Agreement (DUA), would be the most appropriate form of agreement. As designed, the MOU’s purpose is “to memorialize the parties’ intent to develop a consortium of members for the purposes of completing the Pilot Project. A draft of the MOU was circulated to each university data holder for comment and each university’s legal authority has approved it. The key components of the MOU included:

- A description of the purpose and scope of the OUD Pilot Project;
- A list of the universities participating, including a provision allowing for the inclusion of additional partners in future;
- Pilot project member commitments including responsibilities for analyzing data, sharing of results (not data) with the University of Pittsburgh (Principal Lead), participating in the project Steering Committee, Methods/Data Core Group, and Writing and Dissemination Committee, devoting resources to launching the project, procuring all required regulatory approvals (e.g., IRB approval), and obtaining state partner buy-in/approval in writing; and
- A description of the collaborative engagement process including provisions for updating the terms of the MOU throughout the course of the project.

Partnerships participating in the Pilot Project have approved the MOU language thus ensuring ease of replicability for future projects.

Lessons Learned

The Pilot Project has provided a number of valuable insights for a SUPLN DRN:

- There is substantial interest among university and state partners in multi-state projects as evidenced by the initial commitment of three states, which quickly expanded to nine, despite the significant time investment required.

- The Methods/Data Core Group deliberations revealed substantial variation across states in how measures are defined for access to and the quality of OUD treatment. This variation points to the value of a DRN for the development of standardized approaches to measurement definitions to facilitate multi-state comparisons.

- While each of the states had conducted previous analyses of the prevalence of OUD, no single state-university partnership had conducted a comprehensive assessment of access to and the quality of treatment. The creation of a governance structure (Steering Committee, Methods/Data Core Group) has permitted the sharing of data sources across states to advance quality measurement more efficiently than would have been feasible with any one state working in isolation.
- The variation across states in underlying data structures and variable formats necessitated the development of a CDM for the Pilot Project. The CDM, developed by the University of Pittsburgh, can be modified for future DRN projects. While requiring some upfront investment once the CDM is developed and participating states have adopted it, the Principal Lead can produce SAS code for OUD measures that can be used by all participating data holders, producing comparable measures across the participating states.
**Section II: Sustainability**

When building a DRN, the discussion of governance and sustainability often intertwine. In fact, when addressing foundational governance components, the discussion often considers how such structures, decision-making approach, leadership, etc. will lend to the growth and sustainable nature of the DRN. Addressing sustainability is paramount when considering future funding.

Referencing Holve’s “Four Pillars of Sustainability” article,\(^3\) the DRN Workgroup reviewed the recommended four foundational elements necessary for building a successful sustainable DRN structure and evaluated the SUPLN’s current capacity to meet these. These elements include:

- trust;
- strong governance structure;
- an identified model for managing the DRN; and
- financial and administrative support.

**Trust**

First, a sustainable DRN relies on *trusted relationships between participating partners* (e.g., data holders, Principal Lead, and Coordinating Center). This trust ensures that partners are equal contributors to the DRN, abide by data security and sharing principles, and are reliable in their participation in research efforts.

The DRN Workgroup discussed the question about whether trust is a precondition for DRN development. They acknowledged that the existing trust that the SUPLN has developed and facilitated among SUPLN members provides a valuable foundation for this DRN. The SUPLN DRN distinguishes itself from other DRNs based on the common purpose the university researchers share in serving their state agencies and maintaining their long-term relationships. The Workgroup did note that trust is just as essential between the university researchers and their own state agency partners although the Workgroup recognized that levels of trust could differ within various partnerships. Thus, the Workgroup concluded that a successful DRN requires the ability for the DRN to develop a value proposition for state agency staff in order to secure initial buy-in and ensure continued support.

**Governance**

Secondly, *a strong governance structure*, as outlined above, contributes largely to and supports this trust. Specifically, a transparent governance infrastructure that addresses such issues as privacy and security; data access and use; the roles and responsibilities of data holders; and legal issues and requirements among others, can build and ensure continued trust and allow for scalability of the DRN over time.

**Management Model**

Third, *a robust model for overall management* is needed to support the goals of the DRN. Time allocated for project management administration must meet the aims of the network, but also be realistic given the amount of funding and resources. This model should consider management responsibilities for the various roles, including the Coordinating Center, as well as each research project’s Principal Lead,

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and the identified project manager for each participating data holder. Project management estimates must consider the time needed to build trusting partnerships, identifying roles and responsibilities, and obtaining data use agreements. It must also delineate time required for various stages of individual project development, including time for start-up, management of project, developing/modifying and testing measures, modifying the CDM, synthesizing data results, and dissemination efforts.

The DRN Workgroup suggested a matrix could be a useful tool to outline the roles and responsibilities of key DRN participants so that SUPLN members could begin to consider the needs of each role across the phases of a project. They also underscored the need for operational support at the data holder level, recognizing that they should establish some infrastructure to be “at the ready” for multi-state research requests. A matrix could help document those key functions for data holders, the Principal Lead, and the Coordinating Center.

**Strong Financial Foundation**

Fourth, a sustainable DRN necessitates reliable financial and administrative support to maintain core management staff that can respond to research requests as well as support development efforts to identify and pursue self-initiated research projects. A DRN can rely on in-kind support from participating DRN data holders in the form of shared personnel and expertise, core technical needs, and database maintenance. Some DRNs like the Health Care Systems Research Network (HCSRN) rely on membership dues to provide a core level of management support.

A DRN can also seek targeted financial support to cover technology and personnel needs – maybe for one designated person (at a percent of FTE) within each participating university. Sources for this support could be in the form of membership dues, user fees, or funded through a designated grant or research contract.4

The issue of on-going financial support generated substantial discussion. The DRN Workgroup inquired if it is possible to track the current costs for the start-up and implementation phases of the Pilot Project. One member inquired if a formal cost-center approach exists that estimates the actual dollar value of in-kind contributions provided by the participating university data holders. The Workgroup noted that this investment information is critical for individual participating states when pursuing federal match for supporting such research efforts with the goal of informing their own state Medicaid policies. One Workgroup member posited that for those state partners who are not interested in funding their own staff or do not have staffing resources to conduct the research, funding their university partners as the data holder to participate in a DRN could provide a valuable option for conducting analyses in near real-time. Workgroup members acknowledged this interest could vary by state.

The DRN Workgroup invited Sarah Greene, the Director of the HCSRN, to discuss her experience with the development and management of research networks including HCSRN5 and PCORnet.6 Ms. Greene defined sustainability based on her experience and outlined what key touchstones are critical to address to ensure a DRN’s viability. To address the concern regarding upfront investment costs, she recommended that the university data holders leverage any existing analytic efforts and learnings thereof from participating in PCORnet, the National Patient-Centered Clinical Research Network designed by

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4 Holve, p. 3.
5 http://www.hcsrn.org/en/
6 http://www.pcornet.org/
PCORI. PCORnet actually serves as a network of networks, harnessing large amounts of health data and patient partnerships. University data holders that are members of PCORnet can consult with those peers that may have experience also using Medicaid claims data to gauge the time and effort required to acquire, clean, and harmonize the data.

Ms. Greene emphasized that considering sustainability is as important as developing a governance structure during the initial phases of establishing the network. Specifically, she recommended that SUPLN partners consider key touchstones as they plan to evaluate their capacity (See Box on Key Touchstones for DRN Sustainability).

**Key Touchstones for DRN Sustainability**

**Demonstrate Value-add.** Can you articulate the value a SUPLN DRN offers state agency and university partners? In other words, how would it differentiate from other networks? Recognize the value proposition may differ for each stakeholder.

The DRN Workgroup felt confident that the SUPLN offers a unique value-add with respect to the central role that university partnership members play as analysts of Medicaid claims data. One DRN Workgroup member also noted that there is a value proposition for state agency partners as many of them are increasingly thinking regionally and believe cross-border interests are valuable to understand. Since limited resources are being invested, states are even more concerned with trying to benchmark themselves and, therefore, wish to ensure that they are getting a more sustainable model for research analysis.

**Build Trust.** Does your network already have trusted relationships? Or will the network have to build this into their foundation? Consider the socio-cultural components that ensure member participation and commitment.

The DRN Workgroup confidently acknowledged that the trust and mechanics of collaboration are well-established among university academic partners. There is one question as to whether the trust is as established on the state agency side, however DRN Workgroup members noted that the state trust may not present a significant issue if each data holder maintains control of their own data and they are not shared across the DRN.

**Estimate Administrative Time and Labor Needs.** Can you approximate the operational needs of both the central coordinating center as well as the individual data holders to ensure the DRN functions properly? For example, HCSRN participants are asked to commit a data manager (at about 20-50% full time equivalent), with the primary role to map the data to the CDM. Ms. Greene noted that, even as the Executive Director of the Network, she is not clear about how each participant funds their own data manager, acknowledging that there is no “one-size fits all” model for every partner. This is likely to be true for SUPLN partnerships participating in a DRN as well.

The DRN Workgroup posed the question of how the project lead and coordinating center staff can adequately estimate their administrative time needs upfront. Ms. Greene acknowledged this as a persistent challenge when starting up networks as well as individual projects. For information on how to adequately estimate their administrative time and workforce needs upfront, she suggested we consult with additional experts, such as Lesley Curtis, who serves as the Lead of the Distributed Research Network Operations Center for PCORnet, and Harvard
Pilgrim, as the lead of the FDA Sentinel Initiative. Contacting key experts such as these would be one of the first steps the SUPLN would make when initially developing a DRN.

**Ensure Financial Resources.** Do you have a plan or various plans for financial sustainability? Utilize existing on-line tools and resources, such as, the Community Toolbox, which provides matrices for partnership formation and collaboration, as well as, outlines 18 modules on how to achieve financial sustainability.

The DRN Workgroup acknowledged that assuring sustainable funding sources, including necessary start-up resources, is of paramount interest and challenge. Without the demonstrated value of a pilot project, it is difficult to compete for grant or membership-based funding. However, without the funding, it is difficult to test a project of scale. As a result, the DRN Workgroup is interested to learn from the Pilot Project, both in terms of expended labor and projected costs, hoping it will be useful when estimating the establishment of a Coordinating Center and cost and labor needs of future projects.

**Ensure Security of Information.** Can you ensure that each state/academic partner’s proprietary information (and review process) is secure and protected? In addition, can you establish a communications and dissemination process that ensure results are shared appropriately and each data holder’s review process is respected?

The DRN Workgroup reviewed and agreed to establish a DRN framework similar to that which was adopted by the Pilot Project. Specifically, the Workgroup agreed with the standard MOU agreement, which outlines that only aggregate data are shared with the Principal Lead while the data holders each retain their individual raw data. Additionally, a core governance component is the establishment of a Dissemination Advisory Committee, like that of the Pilot Project’s Writing and Dissemination Workgroup that communicates and disseminates research findings, including peer-reviewed publications.
In developing the framework for conducting the Pilot Project, the Principal Lead and team were very thoughtful in developing the structure of the Pilot Project to form a foundation upon which the SUPLN DRN can grow and evolve.

The Pilot Project has established trust. It first relies on a group of committed state agency and university partners that have equal buy-in and participation as well as established trust – both within their own state-academic partnership and across the partnerships. This trust has facilitated the sharing of materials and methods across partnerships. That, combined with each partnership’s willingness to be flexible, has allowed for the development of standardized measure definitions and a preliminary CDM.

The Pilot Project also has a core governance structure, as outlined above under Section I: Governance, to ensure equal participation and representation from the state agency and academic partners. In fact, the participating states recommended early on to have each state’s Medicaid Medical Director participate on the Steering Committee, which has ensured communication and commitment among state agency decision-makers. The active engagement by the Medicaid Medical Directors also increases the likelihood that the Pilot Project’s work product will be useful to state agency partners because they have had the opportunity to provide detailed input on the project scope.

The Pilot Project has provided the DRN Workgroup with a sense of the operational capacity and needs required for a limited engagement. While it is complicated to extrapolate key lessons from that information to estimate the needs for future projects or building a full-scale DRN, this Pilot Project confirms the need for sustainable funding resources to help develop and maintain the infrastructure as well as financing additional projects. (See Pilot Project: Operations Approach under Section III: Operations for further description.)
Section III: Operations
When considering the functionality of the DRN, it is essential to understand the full operational needs of managing the DRN, including workforce, financial, and communications resources.

**Estimating Staffing Needs**
First, developing a robust operations plan requires an estimate of designated staffing needs across the various roles, including the Principal Lead (and staff), the Coordinating Center, and the individual data holders including both the state agencies and universities. Producing those estimates can prove challenging for the initial DRN formation. As a result, where particular data holders may have participated in another DRN, like PCORnet, those estimates could be useful as starting points. Without adequate estimates upon which to build committed support, the ability to initiate a DRN will be in jeopardy. The need to understand specific workforce needs and estimated resources to support them generated many questions by the DRN Workgroup; lessons from the Pilot Project can serve to inform future estimates.

**Estimating Start-Up and Ongoing Operating Costs**
 Paramount to this issue is the need for start-up funds and ongoing resources to support central roles within the DRN. In order to understand and approximate these needs, we consulted with various experts. Overall, it was noted that the upfront costs will largely be greater than on-going maintenance costs. Overall, it was noted that the upfront costs will largely be greater than on-going maintenance costs. Once certain fixed or foundational structures and processes are in place, time requirements are less intensive for some roles and activities. For example, HCSRN supports the central coordinating center, which includes its Executive Director and staff, through membership dues. Individual HCSRN participants are asked to commit a data manager at about 20-50% full time equivalent (FTE) to ensure adequate resources to map the data to the CDM, but the sources of those funds are different for each data holder as there is no “one-size fits all” model for every partner. This variation is likely to be true for SUPLN partnerships participating in a DRN as well.

**Developing a Strong Communications and Dissemination Strategy**
In discussion with key experts, the DRN Workgroup underscored that communications was a key element of operations, ensuring consistent, singular information shared across the DRN. Through a strong communication and marketing plan, the DRN itself as well as the individual research studies could be promoted more effectively. Additionally, with this dissemination, the DRN itself could gain additional visibility, partners, and financing. The DRN Workgroup noted that a key component of this communication strategy is the development of a set of talking points for academic partners to use when approaching their state agency partners about participating in the DRN.

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**Box 4: Pilot Project: Operations Approach and Lessons Learned**

To better understand the potential upfront administrative time required of a Principal Lead, we consulted with Julie Donohue, Ph.D., from the University of Pittsburgh, to glean her experience managing the OUD Pilot Project. In assessing workforce needs from the Pilot Project data holders, Dr. Donohue reflected that the programming/data analyst needs are more extensive for each of the data holders on the front end to implement the CDM but then decrease once the CDM is in place. The time investment by the Principal Lead team are relatively constant throughout the life of the project.
Specifically, based on the Pilot Project management, Dr. Donohue estimated 20% of her time is devoted to providing management as the Principal Lead of this Pilot Project. In addition, she shared that the project has required 10% effort from two additional faculty members, 50% of a full-time equivalent data analyst, and 20% of a project coordinator’s time. Faculty effort has been devoted to reviewing the literature in support of candidate OUD measures, presenting those measures to the project Steering Committee, assembling specifications and coding methodologies for discussion by the Methods/Data Core Group, and participating in monthly and biweekly calls. Data analyst time has contributed to development of the CDM, cross-walking the Pennsylvania Medicaid data to the CDM, instructing other data holders how to implement the CDM, creation of data analysis plans and SAS code for execution of each measure, and compilation of aggregate results. Project coordinator time has been required for scheduling of meetings, literature reviews, note-taking, IRB submission, MOU development, and other administrative support for the project.

Consulting with a subset of data holders, it is estimated that each state, which includes the state Medicaid representative as well as university research partner (i.e., data holder) has contributed 10% effort of one to two faculty members to participate in Steering Committee and Methods/Data Core Group calls, prepare measures for discussion by the Steering Committee (each state data holder took responsibility for presenting one to three measures for discussion), gather materials (e.g., coding methodologies) to share with the group, and supervise the data analyst. Each state has contributed roughly 30 to 40% data analyst time in the first few months of the project to implement the CDM, and will contribute about 25% data analyst time over the remainder of the project for executing SAS code and analysis plans developed by the Principal Lead. It was also noted by one data holder that there are additional expenses related to the data infrastructure to house the data, about 10% for data center administration.
Section IV: Technical Build-Out

Once the DRN Workgroup considered the DRN organizational structure, including decision-making approach, fundamental roles and responsibilities, workforce needs and sources of funding, the Workgroup considered the technical construction or “build-out” of the data sharing and analytic infrastructure. While the final DRN Workgroup meeting focused on this fundamental topic, the technical build-out received attention throughout the DRN Workgroups discussions - especially when assessing the core operations and additional workforce needs for data holders. As a result, to assess the infrastructure needs and capacity, and not replicate prior discussions, the DRN Workgroup hosted a presentation from the Pilot Project’s Principal Lead, Julie Donohue, Ph.D., where she detailed the Pilot Project’s structure, as it compared to the DRN Workgroup’s discussion, and reflected on lessons learned.

Box 5: Pilot Project: Technical Build-Out and Lessons Learned

As outlined above under Section I: Governance, the build-out of the Pilot Project drew upon information about existing distributed research and data networks, particularly PCORnet and the FDA’s Sentinel Initiative. It first relied on ensuring multi-state participation and establishing the appropriate governance structure.

- First, the decision to use an MOU between the data holders prevented any start-up delays, and had the benefit, through an added provision, of allowing additional data holder participants to join at any time if interested.

- Secondly, the governance structure and consensus-based decision-making approach provided a smooth process, ensuring engagement of both state and university partners and providing a structured process. As discussed under Section I: Governance, the Pilot Project’s governance structure consisted of four foundational workgroups: a Steering Committee that oversees the project organization, serves as a decision-making entity; a Methods/Data Core Group that focuses on the data analytic elements; a Writing/Dissemination Committee that interprets and disseminates the findings; and a Coordinating Center, led by the Principal Lead and AcademyHealth.

As addressed above under Section III: Operations, the Pilot Project’s DRN shares the same core technical characteristics/functions as identified by the DRN Workgroup for the SUPLN DRN structure. The data holders keep and analyze their own data, standardizing the data using a Common Data Model. They provide results, not data, to the coordinating center. The Principal Lead/Coordinating Center distributes SAS code to partners for local execution, reviews results, and compiles findings. All activities are audited and secure.

Of note, the Pilot Project’s Coordinating Center identified additional roles and responsibilities than first considered by the DRN Workgroup, which focused on the functions that the AcademyHealth SUPLN staff could help fulfill. Drawing from the PCORnet DRN’s Coordinating Center structure, she envisioned the SUPLN DRN Coordinating Center would provide static management functions (e.g., convene partners, facilitate the overall governance structures and management of the DRN, field requests from SUPLN members to use the DRN), as provided by AcademyHealth, in addition to the key
data coordination functions required of each research projects. This data coordination role would be provided by the specific project’s Principal Lead research university that specializes in the particular research question. A DRN Workgroup member asked if there is a deep learning curve to serve in the Data Coordinating Center capacity when presenting a research question to the DRN and, thus, serving at the Principal Lead. Dr. Donohue explained that the role requires a team of faculty and staff that possesses a deep knowledge/familiarity in Medicaid claims.

Lastly, with respect to the technical build-out, the Pilot Project team initially considered not using a CDM imagining that there would be significant upfront labor required to implement it. However, it was determined quickly that the underlying data structures varied greatly across the participating states. Additionally, the standardization of the data by using a CDM would improve comparability of analyses and the validity of the research studies. The Principal Lead team, referring to the Sentinel CDM, drafted a limited CDM that included a core set of demographic measures and the 15 OUD measures being analyzed.
Conclusion
Overall, the DRN Feasibility Workgroup assessed that a DRN developed under the auspices of the SUPLN is feasible, identifying the following criteria as critical to building a sustainable network:

- **Trusted Partnerships**: The DRN Workgroup proposed a governance structure, including a Coordinating Center, Steering Committee and Executive Committee and Dissemination Advisory Committee, whose success is predicated on the trusted relationships within participating SUPLN partnerships. This inherent trust both across partnerships and with each state’s partnership is fundamental to developing a DRN that shares common interests in serving the Medicaid agencies. This, in turn, ensures sustainability.

- **Existing Infrastructure**: The DRN can leverage existing data sharing agreements and review processes already in place across partnerships – streamlining the research project start-up process and avoiding inefficiencies on a project’s backend.

- **Identified Operational Support**: The DRN Workgroup identified key roles and responsibilities, delineating the operational support required within the administrative and data management roles of the Coordinating Center, data holder partners and Steering Committee and Executive Committee governing bodies. AcademyHealth is well-positioned to fulfill the Coordinating Center’s management role, facilitating convenings, guiding governing bodies, fielding partnerships inquiries to use the DRN for research and disseminate key communications. The university data holder partners as well as the Principal Lead can leverage their existing relationships with AcademyHealth and their state partners to gauge their support needs.

- **Defined Core Infrastructure**: The DRN Workgroup has access to a core Common Data Model (CDM), developed under the Multi-State OUD Pilot Project. This initial CDM can readily serve as a foundational structure upon which additional analytical efforts can be based, enabling opportunities for future cross-state analyses.

The SUPLN, by its very nature, possesses the factors that lend themselves to building a successful infrastructure:

- Established trust between states and their university partners and among cross-state partnerships;
- Existing data sharing agreements and review processes in place with state partners;
- Strong analytic capacity; and
- An immense value-add to offer state colleagues and others who are interested in supporting multi-state collaborations and analyses.
APPENDICES

A. SUPLN State Partnerships

- Arkansas
- California*
- Delaware
- Georgia
- Iowa
- Kentucky*
- Louisiana
- Maine
- Maryland
- Massachusetts
- Michigan*
- Minnesota
- New Hampshire
- New Jersey
- North Carolina
- Ohio
- Oregon
- Pennsylvania
- South Carolina
- Texas
- Virginia
- West Virginia
- Wisconsin

*Denotes multiple partnerships
B. DRN Feasibility Workgroup Members

- **Dr. Marguerite Burns**, Population Health Institute, University of Wisconsin School of Medicine & Public Health
- **Dr. Joel Cantor**, Center for State Health Policy, Rutgers University
- **Dr. Evan Cole**, University of Pittsburgh Medicaid Research Center, Department of Health Policy and Management and Health Policy Institute
- **Ms. Amy Costello**, Institute for Health Policy and Practice, University of New Hampshire
- **Dr. Jay Himmelstein**, Center for Health Policy and Research, University of Massachusetts Medical School
- **Dr. Gilbert Liu**, Child and Adolescent Health Research Design and Support (CAHRDS), University of Louisville, Louisville, KY
- **Dr. Noel Mazade**, Jordan Institute at the University of North Carolina-Chapel Hill School of Social Work
- **Ms. Mary Joan McDuffie**, Center for Community Research and Service, University of Delaware
- **Dr. Steven W. Peuquet**, Center for Community Research and Service, University of Delaware
- **Dr. Jo Porter**, Institute for Health Policy and Practice, University of New Hampshire
- **Dr. Naderah Pourat**, Center for Health Policy Research, University of California, Los Angeles
- **Mr. Tim Sahr**, Ohio Colleges of Medicine Government Resource Center, Ohio State University
- **Dr. Angela Snyder**, Georgia Health Policy Center, Georgia State University
- **Ms. Laura Spicer**, Hilltop Institute, University of Maryland, Baltimore County
- **Ms. Cynthia Woodcock**, Hilltop Institute, University of Maryland, Baltimore County
C. Literature Reviewed


D. Examples of DRN Guiding Principles

Core Guiding Principles of Distributed Data Networks

- Data holder sites maintain control over their data.
- Data holder sites standardize their data to a common data model (CDM).
- Data holder sites’ ongoing involvement is needed in order to interpret data and findings; they are the most familiar with the data and are therefore the partners in the network.
- Programming code is securely distributed to data holders for them to execute locally and in a manner that makes it easy for them to execute.
- Following execution of programming code, data holders return results that were produced by the executed code to the requestor. Typically, data returned are aggregated rather than patient-level data.

Guiding Principles for PCORnet DRN

- The PCORnet DRN will follow the policies and procedures adopted by the Steering Committee.
- Clinical Data Research Networks (CDRNs) and Patient-Powered Research Networks (PPRNs) will control how their data are used as allowed by internal governance policies. Data resources developed for PCORnet will stay within the CDRNs and PPRNs and under their control.
- CDRNs and PPRNs understand their data better than any other potential user of the data. They know how, when, where, and from whom the data were collected, and the best ways to interpret findings based on their data.
- The CDRNs and PPRNs are expected to document key considerations and limitations of their data sets, and provide assistance to partners as to the proper interpretation of their data in the context of specific questions.
- To achieve the goal of a national patient-centered clinical research network, PCORnet will emphasize pursuit of a pragmatic approach to building a flexible yet standards-centric data infrastructure. Thus, the PCORnet DRN will be built in phases, each phase designed to establish specific incremental capabilities and to accommodate iterative learning and evolution of strategies and processes.
- The PCORnet DRN strategies and processes will adapt to meet future needs while remaining responsive to realities of the current ecosystem of healthcare practices and technologies.
- All PCORnet participants will protect the confidentiality of shared data in accordance with PCORnet policies and procedures. The Coordinating Center will work with researchers to define the minimum data necessary to fulfill each distributed research query. Data shared within the network will be held in confidence and only made available to authorized individuals and entities.
- Data and results shared or transmitted across PCORnet will be securely managed in accordance with guidelines established by the PCORnet Steering Committee and only made available to authorized individuals and entities.

7 Distributed Data Networks: A Blueprint for Big Data Sharing and Healthcare Analytics
8 PCORnet DRN and CDM Guiding Principles
- Highly functional research networks exist outside of PCORnet. PCORnet will draw from the diverse experience of other network efforts, and to the extent possible, will re-use and adapt existing tools, infrastructure, and approaches that are well aligned with PCORnet DRN aims.
- PCORnet member networks will develop a model for a physical or logical data set that will be implemented by each CDRN and PPRN. This common data model (CDM) will harmonize names, values, and definitions for data elements of general interest to PCORnet.
- It is not expected that all CDRNs and PPRNs will be able to populate all parts of the PCORnet CDM. It is the responsibility of the CDRNs and PPRNs to communicate availability of each data domain and element.
- The DSSNI Task Force, with guidance from other Task Forces as needed, will be responsible for development and maintenance of the PCORnet CDM. Each PPRN and CDRN will be expected to participate so that the CDM reflects local input.
- The PCORnet CDM will be developed in a modular, incremental, and extensible fashion. New types of data will be needed, or newly available, during the life of PCORnet. Data domains and data elements will be added, revised, and deprecated throughout an iterative CDM lifecycle. Personnel from the CDRNs and PPRNs will work with the DSSNI Task Force (and other Task Forces as appropriate) to assist in these efforts.
- Documentation will be clear and transparent so that its contents are understandable to all contributors. The CDM will be intuitive and easy for analysts and investigators to use. Investigators and analysts with prior experience using research data will not need additional skills or knowledge to use the CDM.
- Other common data element and common data model initiatives exist. PCORnet will draw from the experience of others within and outside of PCORI, leveraging existing successful approaches and data model definitions wherever possible.
- The CDM will reflect variables and values found in the local data. If some data are coded in a way that is unique to a site, mapping the data to a standardized format will be necessary. Values in the source data before mapping will also be included in the CDM. Derived variables should be avoided.
- CDRNs and PPRNs may include additional domains and data elements in localized versions of the PCORnet CDM.
E. HCRSN Governance Model and Board

The Health Care Systems Research Network (HCRSN), formerly known as the HMO Research Network, brings together research centers embedded within some of the U.S.’s best and most innovative healthcare systems. Collectively, the HCRSN represents over 1,900 scientists and research staff with methodological and content expertise from an array of disciplines. The HCRSN is a virtual organization: A group of independent organizations sharing resources to achieve a common set of goals.

Membership:
- Members are public-domain research departments embedded in healthcare systems
- Membership dues support a small, distributed staff and a shared infrastructure
- Dedicated research staff conduct non-proprietary research
- Collectively, a community of embedded researchers with unique “delivery system science” expertise
- Affiliate status for new members until key HCSRN integration milestones are met

Governance:
- Formal bylaws document governance processes
- One representative per site serves on volunteer Governing Board
- Consensus-driven governance model
  (1 vote/member)
- Elected Chair and Vice Chair lead the Governing Board and Executive Committee (2-year terms)

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**HCRSN Organizational Chart**

![HCRSN Organizational Chart](image)

**Key Committees At-A-Glance**

<table>
<thead>
<tr>
<th>Committee</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Governing Board</td>
<td>Outward facing, network positioning, set policy, budget and strategic direction.</td>
</tr>
<tr>
<td>Executive Committee</td>
<td>Increase Board efficiency and agility, manage Board policies and initiatives.</td>
</tr>
<tr>
<td>Asset Stewardship</td>
<td>Inward facing, cross-project coordination, create and maintain shared infrastructure.</td>
</tr>
<tr>
<td>IRB Coordination</td>
<td>Develop and implement Network-wide ceding processes.</td>
</tr>
<tr>
<td>Virtual Data Warehouse (VDW) Operations</td>
<td>Coordinate, support and oversee VDW development and management across sites.</td>
</tr>
<tr>
<td>Research Administrators</td>
<td>Share best practices, develop and implement HCRSN-wide administrative efficiencies.</td>
</tr>
</tbody>
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