SUMMARY OF AUGUST 2021 RESEARCH WORKGROUP MEETING

Tim Ferreira
Research Work Group Chair
Autism Society of North Carolina
Review of Workgroup Efforts and Research-Related Topics

I. Review: Legal Considerations, Objectives

II. NC HIEA Proposed Research Request Framework
   - Objectives
   - Elements
   - Workflow

III. Additional Topics
   - Academic Research
   - Commercialization of Data

IV. Implementation

V. Questions for Discussion
Research Subcommittee Recap: Legal Considerations

- **Statewide Health Information Exchange Act**
  - NC HIEA is to develop “[p]rotocols for data integrity, data sharing, data security, HIPAA compliance, and business intelligence as defined in G.S. 143B-1381. To the extent permitted by HIPAA, protocols for data sharing shall allow for the disclosure of data for academic research.”

- **Prohibition on Commercial Purposes**
  N.C. Gen. Stat. § 90-414.6

- **Participation Agreement**
  § 2.39 “Permitted Purposes”

- **Opt Out**
  N.C. Gen. Stat. § 90-414.6

- **HIPAA** Privacy and Security Rules

- **Information Blocking Regulations** New federal regulations
Proposed Research Request Review Framework: Overview

Considerations from internal review and Workgroup feedback

- Support expanded research activities within the NC HIEA’s existing means
- Consistent and efficient review process
- Evaluate research requests with input from multiple stakeholders / perspectives
- Data security and protection
- Engage Advisory Board at appropriate levels, leverage insights and priorities
- Scalable, flexible approach where researchers cover their costs
Proposed Research Request Review Framework: Objectives

• Develop a research request program that supports academic research with a clear patient purpose to improve care, diagnosis, or treatment

  - Proposed addition to NC HIEA Guiding Principles:
    - *The NC HIEA will support academic research that enhances patient-centered care that crosses organizational and geographic boundaries as well as academic research to improve outcomes and care that requires multi-site data that would otherwise be unavailable.*

• Establish an application period with clearly defined schedule, requirements for requests, and notification of “award status.”
  - Proposing twice yearly process initially; could accelerate as the HIE and program matures (see slide)
  - Create applications and forms tailored to research requests by leveraging state and federal examples
Proposed Research Request Review Framework: Objectives

- Designate a formal body to oversee the request process
  - Propose appointing the Use Case Work Group as the body that will formally review qualifying applications and provides NC HIEA with recommendations for (i) approval and/or (ii) priority requests
  - HIEA staff will “qualify” applications based on prerequisites in the application
    - Applicants who submit incomplete applications will have a brief, defined time period to cure applications so they can be considered for review.

- Require requestors to fund data requests (cost recovery)

- Advisory Board and/or Research Workgroup articulates research priorities to inform Use Case Work Group evaluations; receives reports on evaluation process and on completed research
Proposed Research Request Review Framework: Key Elements

Twice Annual Review Cycle

- Regular, established cadence for collecting, reviewing, and fulfilling approved research requests
- Dedicated resource (project officer) to support the application process and provide consultation to interested parties
- Written application provides a single “landing spot” for those seeking to access and use NC HIEA data for research purposes
  - Enhanced tracking
  - More efficient and uniform responses to requests
  - More effective budgeting, resource allocation
- NC HIEA Director reserves the right to address critical research and access requests outside of this framework
Draft Research Request Workflow

Research Project Team requests consult with HIEA Project Officer

- Is Project Team asking for a research request?
  - No: Moves to UCW Project request workflow
  - Yes: Project Team is sent application and will work with an HIEA Project Officer.

  - Does the application meet the initial screening requirements?
    - No: Project Team Proposal is sent to UCWG members for review
    - Yes: Does NC HealthConnex team recommend UCWG review?
      - No: Denial letter sent
      - Yes: UCWG makes recommendations about research requests using scoring rubric

  - Project Team works with the HIEA Project Officer addressing any questions or concerns from the UCWG

  - Advisory Board Comments
    - Yes: NC HealthConnex integrates project into development strategy
    - No: UCWG makes recommendations about research requests using scoring rubric

- UCWG makes recommendations about research requests using scoring rubric

*NOTE: UCW = Use-Case Workgroup

Bi-annual review process with defined time periods associated with the workflow.
Proposed Research Request Review Framework: Key Elements

Written Application (Must be a NCHealthConnex Participant or Affiliated with a Participant)

- Application to build on present Use Case Work Group materials should include:
  - Research Request Summary
  - Primary Investigator
  - Study Protocol
  - IRB Approval Letter
  - Data Management Plan
  - Data Use Agreement
  - Evidence of funding or acknowledgement that HIEA honoring request is contingent upon applicant securing funding
  - Specifications Document

- Additional considerations: prohibition against commercialization, security risks, data linking

- Application does not take the place of IRB review
Proposed Research Request Review Framework: Elements

Use Case Work Group

- Broader membership than HIEA Advisory Board
  - Leverage existing expertise
  - Add members for additional perspectives
  - Scalable structure

- UCWG advisory recommendations:
  - Informed by Advisory Board priorities and oversight
  - Advisory Board receive report on UCWG recommendations

- NC HIEA leadership utilize UCWG feedback when fulfilling requests
Proposed Research Request Review Framework: Elements

Use Case Work Group: Evaluation

- UCWG to apply a consistent review
  - Review materials vetted by NC HIEA staff before meeting
  - Formulate a rubric for evaluation - Rank recommendations and/or sort requests into multiple categories (e.g., priority recommendation; recommended, if resources available; do not recommend)

- Understand NC HIEA resources available to support research projects
  - Dedicated Program Officer (new hire)
  - Part-time legal support
  - Part-time HIEA analyst support
  - Technical support for delivery
Proposed Research Request Review Framework: Elements

Full Advisory Board, Research Workgroup
- Help set NC HIEA research agenda
  - Define research goals and objectives; identify priority use cases
  - Refine and approve research-related policies or protocols
  - Input into UCWG make-up, activities
  - Evaluate effectiveness of processes implemented (*request an annual convening of the Workgroup for evaluation of program*)

- Receive reports
  - UCWG recommendations and NC HIEA implementation
  - Completed studies by researchers

- Calibrate involvement with research requests over time
Additional Topics Reviewed (Pre-decisional)

Characteristics of Academic Research

- Requestor is affiliated/partnered with academic institution
- Request has been approved by an IRB
- Requestor agrees to publish finding, peer review
- Request has clear patient purpose to improve care, diagnosis or treatment

Defining Commercialization of Data

“Commercial Purposes” are defined as:
- Access, use, redisclosure, and storage of clinical and demographic data sent to or through NC HealthConnex (“HIE data”) beyond the purposes of supporting (i) treatment, payment, and health care operations as they are described in HIPAA.; (ii) population health; (iii) government programs; or (iv) academic research.
- Redisclosure or exchange of HIE Data with third-party organizations for the primary purposes of improving business operations, cost-cutting, or profit-seeking, without explicitly stated benefits to patients.
- Sale of HIE Data in exchange for money, other clinical or demographic data, services, or other items of value.
- NC HIEA and the Department of Information Technology reserve the right to conduct due diligence by examining data uses and proposed use cases in order to ensure legal compliance.
Proposed Research Request Review Framework: Implementation

- Advisory Board research agenda *(September AB meeting begin discussion)*

- Resource allocation / budget; fees *(HIEA team to provide update at next subcommittee meeting)*

- Governance: policy updates, formal documents, internal protocols

- Use Case Work Group
  - Membership, protocols

- Create operative documents
  - Data request application; application schedule; review rubric
  - Data use agreements
  - IRB and compliance review documents
LEGISLATIVE REPORT WORKGROUP UPDATE

Carolyn Spence
Legislative Reporting Work Group Chair
Alexander Youth Network
“On or before March 1, 2022, the NC HIE Advisory Board shall submit to the Joint Legislative Oversight Committee on Health and Human Services recommendations regarding appropriate features or actions to support enforcement of the Statewide Health Information Exchange Act contained in Article 29B of Chapter 90 of the General Statutes and the results of the outreach efforts in subsection (b) of this section.”

“The HIE Authority shall contact each entity or provider identified and ascertain the status of the entity’s or provider’s effort to connect to the HIE. The HIE Authority shall share information with each provider or entity about the Statewide Health Information Exchange Act and how to connect to the HIE Network.”
NCSL 2021-26 Workgroup Makeup

Carolyn Spence, Subcommittee Chair – Chief Information Officer, Alexander Youth Network  
Christie Burris – Executive Director, NC HIEA  
Dr. Bill Way – Chief Medical Officer, Wake Radiology  
Christy Revels, Subcommittee Lead HIEA Staff – Strategic Solutions, NC HIEA  
Leigh Jackson – Legislative Director, NC Department of Information Technology  
Eric Snider – Deputy General Counsel, NC Department of Information Technology and NC HIEA Legal Counsel  
Dr. Aaron Leininger – Network Medical Director, Triangle East, UNC Health  
Barry Hillman – Director of eSolutions, Blue Cross and Blue Shield of North Carolina  
Joe Bastante – Chief Technology Officer, Blue Cross and Blue Shield of North Carolina  
Chris Weathington – Director, NC Area Health Education Centers (NC AHEC) Practice Support  
Eric Myers – Principal Consultant and Lead HIE Strategic Consultant, SAS  
Michelle Ries – Associate Director, NC Institute of Medicine  
Gerald Belton – Business Intelligence Developer, State Health Plan  
Jennifer Braley – Manager, Projects, State Health Plan  
Kendall Bourdon – Assistant General Counsel, State Health Plan  
Melanie Bush – Chief Administration Officer, NC Medicaid  
Kelly Crosbie – Chief Quality Officer, NC Medicaid
Goals and Objectives of the NCSL 2021-26 Workgroup

• Identify and summarize current barriers to connection; examine available mitigation strategies

• Consider possible opportunities/consequences for providers/entities who fail to comply with the HIE Act, including how our organizations and others might facilitate/support their compliance

• Produce recommendations to the NC HIEA Advisory Board by January and a comprehensive report to the General Assembly by March 1, 2022, that details:
  • NC providers/entities to whom the mandate applies, and who remain unconnected to date, including high-level metrics by provider type
  • Targeted outreach conducted with all unconnected providers, and their engagement statuses
  • Considerations and recommendations for incentives, penalties and other consequences for failing to comply
  • Other recommendations to support provider/entity compliance with the HIE Act and boost HIE utility and usability
Proposed Timeline of Activities

9/15
Begin analytics

10/6
Subcommittee work session #1

11/12
Subcommittee work session #2

12/10
Subcommittee work session #3: recommendations

~Mid-Jan.
Draft report delivered to HIEA Advisory Board

3/1/2022
Final report delivered to General Assembly

8/17
Subcommittee kickoff

9/22
Initial briefing to HIEA Board

10/31
Interim analytics distributed

11/30
Final analytics distributed

~Early Jan.
Draft report distributed to subcommittee members for feedback; commence outreach to unconnected

~Early Feb.
Draft report submitted to state agencies for approval
Status of Analytics Project

- **Goal:** determine individual providers and entities mandated to connect who remain unconnected

- **Status:** contract with SAS approved last week; work has begun

- **Deliverables:**
  - **Interim (10/31):** scope to be determined based on feasibility
  - **Final (11/30):** report of all active Medicaid and State Health Plan providers, known organizational affiliations, contact information, and connection status (connected, voluntary, not connected); high-level summary statistics on the connected and unconnected by payer type, provider type, etc.
  - **January 2022:** Commence outreach to unconnected providers and entities
Barriers to Connection

• Per DHHS, HIEA and SAS survey data over the past 36 months, providers say barriers are largely financial and training-related (reduced time/bandwidth due to Covid hasn’t helped)

• Two-thirds of EHR vendors surveyed charge for one-time integration; one-third of EHR vendors charge ongoing maintenance fees for the HIE connection

• Additional challenges noted by AHEC include desire for bidirectional capability where it may not yet be available, and other improvements to ease of use and workflow integration

• Technical challenges and delays: currently 785 sites are in “on hold” status for various reasons

Note: provider survey and focus groups under consideration to add to findings.
Considerations to Resolve “The Mandate” to Connect

- **Lift the mandate for certain providers** for whom the burden to connect is too heavy, but provide access to the HIE and its services

- **Accelerate statewide universal broadband efforts**, and consider temporary waivers or “access only” HIE participation for providers where this barrier exists

- **Expand no-cost, hands-on HIEA training program** to include SHP providers

The “Mandate” appears at N.C.G.S. 90-414.4(b) (“as a condition of receiving State funds, including Medicaid funds” certain providers and entities must connect to the HIE network and submit data).
Considerations to Resolve “The Mandate” to Connect, Cont’d

• Further efforts to incentivize connection through:
  • **Grants or reimbursement programs** to neutralize connection and initial interface maintenance costs
  • **Enhanced payment arrangement with payers/managed care organizations** for participating with the HIE and/or in quality reporting initiatives
  • A proposed **tax credit for connected providers**

• If deemed necessary, revise the law so the State may reserve the legal right to impose annual penalties on providers without participation agreements or who fail to show a good faith effort to work toward connection

*Note*: additional extensions of time in the form of new “deadlines” for certain providers to connect are not under consideration
Considerations for Additional Recommendations

• Expand the current mandate to share all patient data, not just state-funded patients

• Adjust governance model to permit, and build out, portal use for other parties with a need (care management teams, managed care organizations, payers, program management, etc.)

• NC HealthConnex as a statewide “health data utility,” including as a public health gateway
  • Work toward total automation of state-level public health regulatory reporting (immunizations, communicable diseases, covid, cancer cases, etc.)
Considerations for Additional Recommendations, Cont’d

- Encourage creation of and interface with a **North Carolina All Payers Claims Database** (APCD) to complete the patient record and amplify reporting capabilities.

- Propose consideration of an **increase in Medicaid reimbursement rates**, especially for behavioral health providers, to retain them within the program and facilitate participation with HIE.

- Propose contracting with an outside research group to **study and document NC HealthConnex ROI**.

**What are we missing?**
NC HIEA UPDATE

Christie Burris
Executive Director
NC HIEA
Update – 3rd Quarter 2021 Activities

1. Operations Update
   • Closeout of HITECH; Transition to Medicaid Enterprise System Funding
   • DHHS Pandemic Response
   • Data Quality Program
   • Strategic Planning for Roadmap 2025
   • Policies/Participation Expansion
   • SHIEC

2. Metrics Update
Operations Update
HITECH to MES: Funding Progression Path – Next Steps

- Maximize the current funding from HITECH prior to its sunset.
- Shift implemented and operational HITECH-funded technology to Medicaid Enterprise System 75/25 enhanced funding in support of ongoing operations.
- Continue consulting with NC DHHS on developing new HIE functions to ensure their capabilities serve as an extension of the Medicaid Enterprise System.
- Finalize Outcomes-Based Certification (OBC) criteria for technology and activities eligible for enhanced federal funding.
- Work with NC DHHS to facilitate interactions with federal partners, including a demo and completing the Operational Readiness Review (ORR) and other documentation required by CMS.
Clinical Data Exchange within the Future MES

Clinical Data Exchange Goals for Future State MES
- Automated integration of claims/encounters, clinical and human services data to facilitate closer to real-time action and response.
- **North Carolina and Case Management programs** should receive clinical information only available through EHRs (i.e., blood pressure, weight, depression screening, prenatal care information) from the NC HIE.
- These information sources make predictive analytics, risk stratification, and modeling for care management programs stronger and more accurate.

“Increasing access to care for North Carolinians will help them live healthier, more productive lives.”
- Dr. Mandy Cohen, Secretary NC Department Health and Human Services
Integration of standards-based data that can be used to optimize member, provider, and consumer experiences across various work streams. Provides access to the right data at the right time, at the right access point.

Interoperability platform that facilitates timely and holistic views of business capabilities and integrated clinical and human services data – e.g., integrated care plan, integrated portals, etc.

Simplifies operational and clinical experiences for Medicaid business leaders, providers, beneficiaries, PHPs, caregivers, etc. at multiple touchpoints.

Provides business owners with direct and seamless access to data to support operational and business needs. Platforms and solutions interact with each other via the interoperability platform.
NC DHHS & NC HIEA Pandemic Response Efforts

CVMS – Covid Vaccine Management System
- Continue onboarding for vaccine administration
- Participating in design for integrated vaccine systems – CVMS & NCIR
- Continue patient matching services and enhancements

BIDP – Business Intelligence Data Platform
- Linking person records across DHHS systems for public health/pandemic analysis
- Focus on NC COVID, NCIR, NC Medicaid
Data Quality Update

2020
0.1

• Data Target finalized with data element-level expectations for HIE Participants.
• Review of Hospital Place of Service reporting completed.
• Data Quality integrated in onboard materials

2020/2021
V1

• Creation of the Data Quality Dashboard to easily view Participants’ data elements with % populated and export to provide report to Participants

2021
V2

• USCDI Webinars
• Creation of Jira Ticketing System
• 1:1 Calls with the Participants to review Data Quality Scorecard
• Iterative working sessions/emails with the Participants to improve Data Quality/PoS
NC HIEA Privacy and Security Policies: Proposed Revisions to Conform to S.L. 2021-26

September 22, 2021
Overview

- **April 2021:** Revisions to NC HIEA Privacy and Security Policies to address rules prohibiting Information Blocking; new policy addresses individual’s access to electronic health records

- **Session Law 2021-26:**

  SECTION 6. G.S. 90-414.6 reads as rewritten:

  "§ 90-414.6. State ownership of HIE Network data.
  Any data pertaining to services rendered to Medicaid and other State-funded health care program beneficiaries submitted through and stored by the HIE Network pursuant to G.S. 90-414.4 or any other provision of this Article shall be and will remain the sole property of the State. Any data or product derived from the aggregated, de-identified data submitted to and stored by the HIE Network pursuant to G.S. 90-414.4 or any other provision of this Article, shall be and will remain the sole property of the State. The Authority shall not allow data it receives pursuant to G.S. 90-414.4 or any other provision of this Article to be used or disclosed by or to any person or entity for commercial purposes or for any other purpose other than those set forth in G.S. 90-414.4(a) or G.S. 90-414.2. To the extent the Authority receives requests for electronic health information as the term is defined in 45 C.F.R. § 171.102, or other medical records from an individual, an individual's personal representative, or an individual or entity purporting to act on an individual's behalf, the Authority (i) shall not fulfill the request and (ii) shall make available to the requester and the public, via the Authority's website, educational materials about how to access such information from other sources."
Proposed Policy Revisions: Privacy & Security

New State Law at G.S. 90-414.6 does not implicate Information Blocking

§ 171.103 Information blocking.
   (a) Information blocking means a practice that—

   (1) Except as required by law or covered by an exception set forth in subpart B or subpart C of this part, is likely to interfere with access, exchange, or use of electronic health information; and

   (2) If conducted by a ... health information exchange, such ... exchange knows, or should know, that such practice is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information...

Revise Privacy & Security Policies to conform to State Law

- Section 15: Individuals’ Access to Electronic Health Information
  - Remove provisions concerning fulfillment of individual’s requests
  - Addition: HIEA to provide educational materials and redirect individuals to their providers

- Section 16: Requests to Access, Exchange, and Use Electronic Health Information; Prohibition Against Information Blocking; Safe Harbors
  - Conforming edits: deletions of provisions regarding individuals’ requests
  - Addition: Compliance with G.S. 90-414.6 does not constitute information blocking
Considerations for Expanding Participant Base with Limited Participation Agreements

• DHHS Divisions – i.e. vocational rehabilitation
• Value-Based Care; Care Coordination – i.e. ACOs, CINs
• Health Screening/Assessment for Clinical Trials
Annual Conference August 2021:
- Christie Burris and Eric Myers participated on a panel “Rapid Innovation and New Partnerships in the COVID-19 Pandemic”
- Announced formal affiliation with The Network for Regional Healthcare Improvement (NRHI) formed Civitas Networks for Health

Advocacy efforts/Submitted comment letters for:
- CMS Medicaid Cost Allocation
- CMS-1751-P: Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies;
- Cures 2.0
Key Metrics:

Data Connections:
• 356 year-to-date facility connections - January-March/84; April-June/224; July-August/48

NC*Notify:
• 153 live in production
• 36 enrolled
• 2.5 million alerts generated in August 2021

NCIR:
• 92 practices live

CVMS:
• 49 live in production
• 68 ready for production
• 35 enrolled

ELR-
• 16 full ELR feeds live; 7 COVID-only live

Trainings:
• 168 trainings conducted 2nd & 3rd quarter

Data Exchange- July 2021:
• 3.8 M CCDs
• 20.4 M ADTs
• Patient Search – 886,820
• Document Query – 756,588
• Document Retrieval – 920,317
• EHX Document Retrieval – 513,545
Questions?