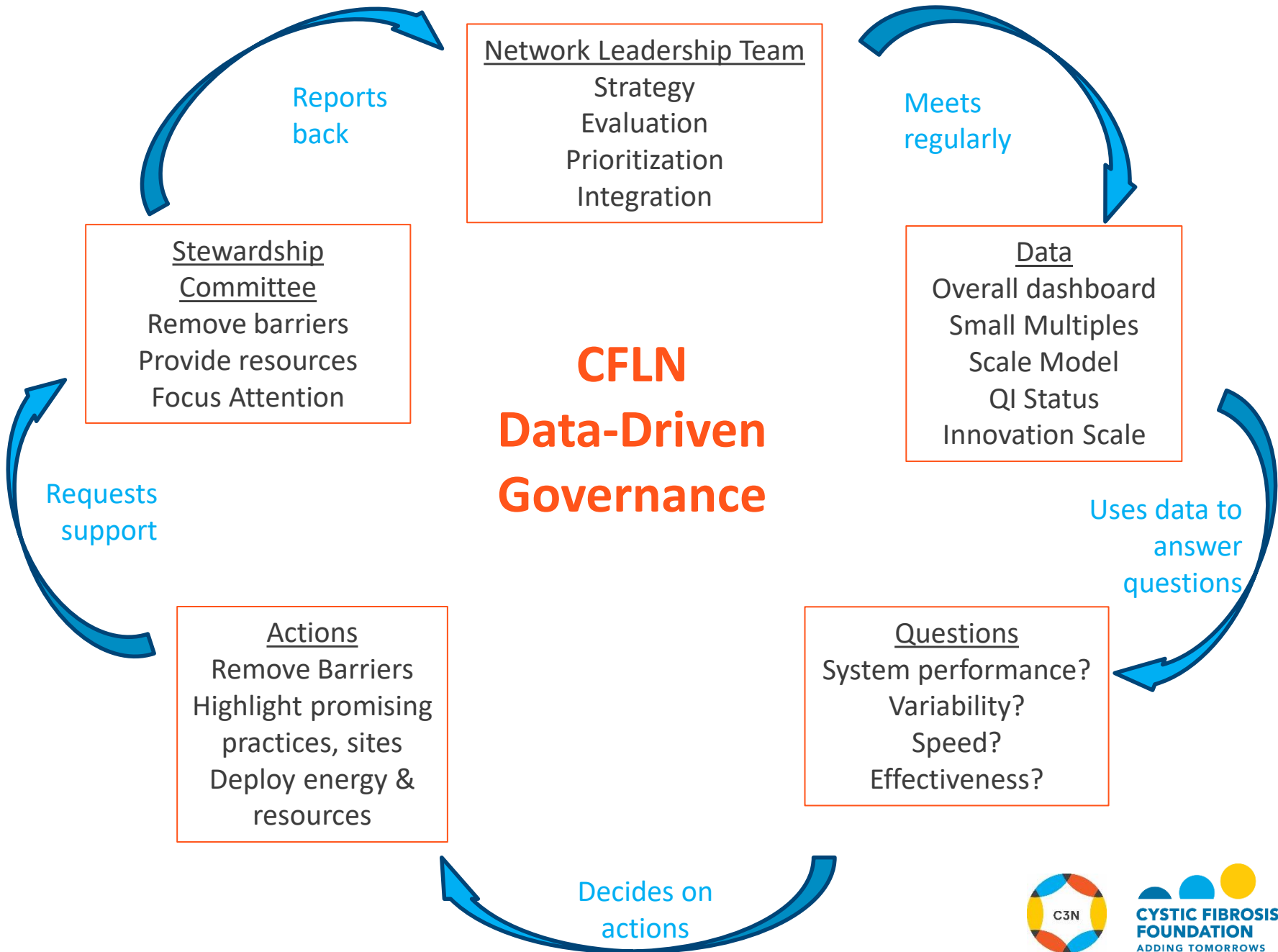


Cystic Fibrosis Learning Network

Implementation Phase

**Governance &
Organizational Structure**





Culture, Context, & Models Helping Us Frame Our Future



FIGURE S-2 Schematic of the health care system today.

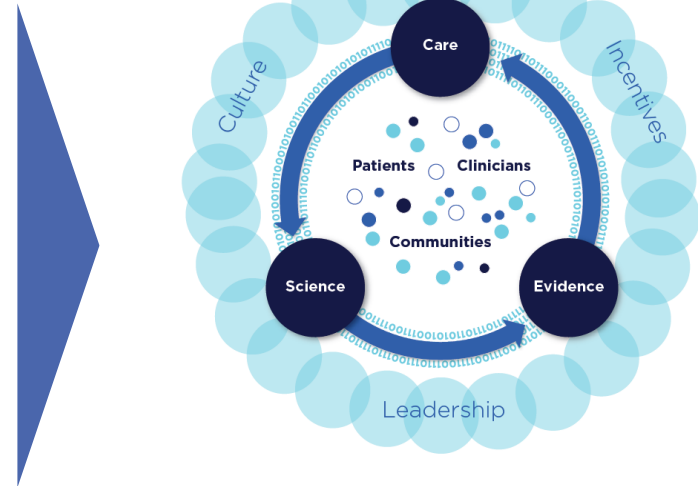
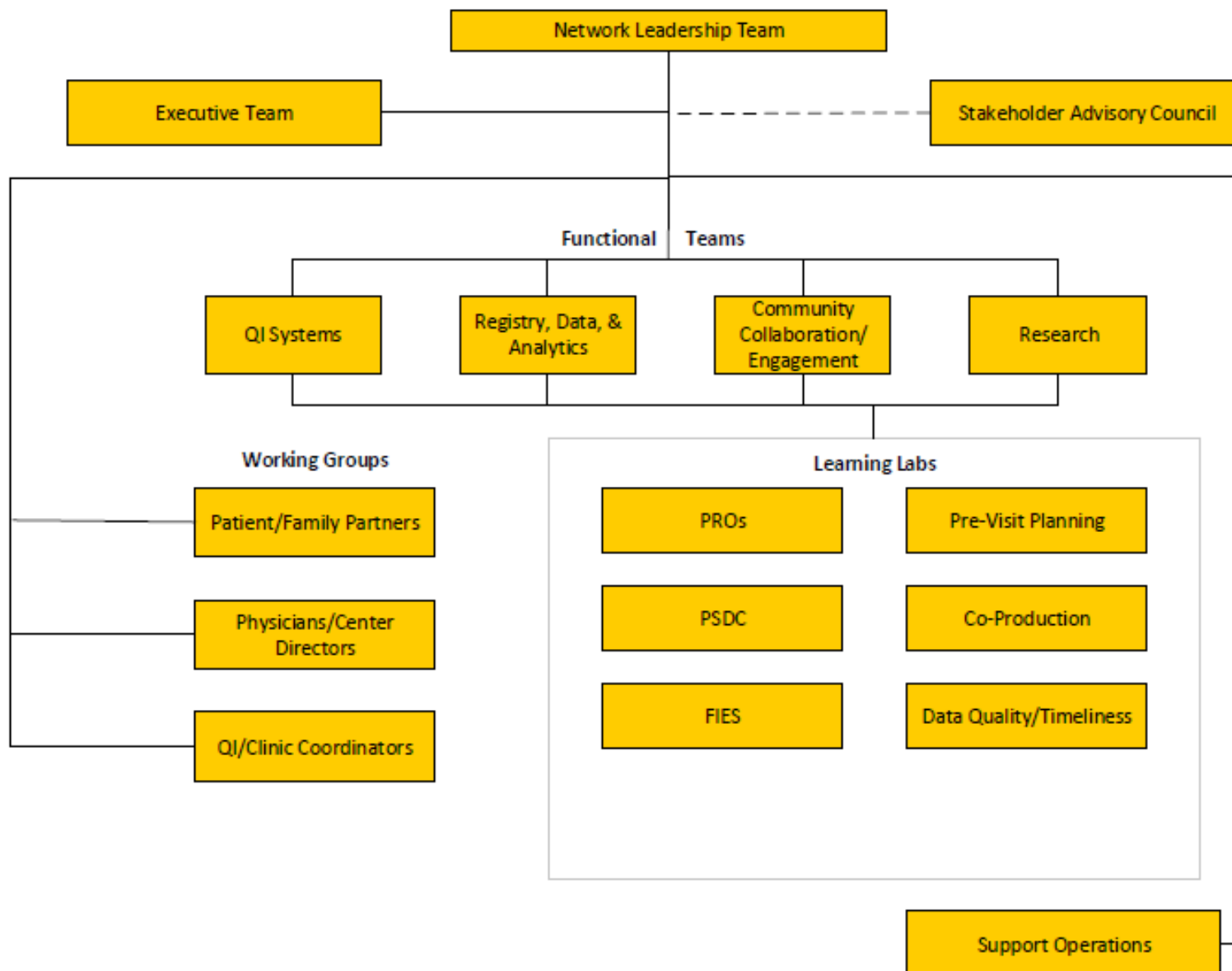


FIGURE S-3 Schematic of the continuously learning health care system.

Moving towards a continuously learning
health care system

DRAFT CF Learning Network Organizational Chart v3



Example of Distribution of Sponsors & Efforts

LEADERSHIP + GOVERNANCE

Network Leadership Team (NLT) - *Internal Advisory & Strategic*

Composition:

- Team Chair(s)
 - One physician & one Patient or Family Partner (PFP): [Name] & [Name]
- Members
 - Physicians, nurses, other CF clinicians (blend of pediatric & adult care): [Name] & [Name]
 - Two people with CF & two family caregivers: [Name] & [Name]
- CFLN Stewardship Committee
 - [Names]
- Other Attendees
 - QICs, CFFPR, CFLN Specialists: [Names]

Focus = Accountable for strategic planning, network results, integration, evaluation & prioritization

Meeting Frequency = Currently semi-monthly (recommend @ least monthly, 90-minutes)

Stewardship Committee – *Strategic & Operational*

Composition:

- Network Sponsor/Registry Leads: [Name] & [Name]
- Network PI + Science Lead: [Name]
- Network Medical + Research Director/Co-PI: [Name]
- Network Improvement Advisor: [Name]
- Network Manager: [Name]
- CFLN Lead QI Learner: [Name]
- NLT Co-Chairs: [Name] & [Name]

Focus = Accountable for financial + operational success of strategic plan set by Network Leadership Team, ensuring adequate support to subcommittees, working groups, program teams (including removing barriers), & stakeholder satisfaction

- Resources, policy development, strategic w/ respect to CFF & other organizations (e.g., The Dartmouth Institute)

Meeting Frequency = Currently semi-monthly (recommend @ least monthly, 90-minutes)

Stakeholder Advisory Committee (SAC) - *External Advisory*

Composition:

- SAC Members
 - [Names]
- Stewardship Committee
 - [Names]
- Network Leadership Team Chair(s):
 - [Name] & [Name]

Focus = Advising & providing feedback to executive branch/team on strategic alliances, network direction, & integration with related initiatives, ensuring the overall needs of the diverse collaborative participants & CF community

Meeting Frequency = 3x yearly

Stakeholder Advisory Committee (SAC) - *External Advisory*

Key Responsibilities:

- Contribute ideas to help the CFLN NLT address urgent & crucial questions
- Connect the CFLN NLT to external initiatives, organizations, & thought leaders to foster continuous learning
- Advise on sustainable growth of the CFLN to spread & scale innovations
- Present or facilitate portions of the SAC meeting

Pre-Work:

- Review CFLN measures & milestones (keystone, Patient & Family Partnerships, Patient & Family Experience of Care, 90-day goals, 180-challenge, network maturity model)
- Share relevant external work (reports, articles, presentations) for SAC members to review

FUNCTIONAL TEAMS

Functional Teams - Operations

Teams:

- QI Systems (see slide 14)
- Registry, Data, & Analytics (see slide 15)
- Community Collaboration + Engagement
- Research

Composition:

- Stewardship Committee (SC) sponsor, team leader, members, operational support staff

Focus = *Set strategic direction for specific subcommittee activities & structure; implements & oversees activities that support the direction of each of subcommittee*

Meeting Frequency = *Bi-weekly to Monthly*

SC Sponsors

Learning Lab Sponsors in Action	The Learning Lab Sponsor will...
Build Will	Advocate & promote engagement & activation from necessary individuals, teams, groups, & organizations; Clarify needs, promote understanding of causes & issues, connect the issues to our core mission, & help identify the best pathways to improvement
Advise on Improvement Strategy	Keep primary focus on improvement science; Advise on learning lab improvement strategies
Build Improvement Leaders	Advise & coach the learning lab leaders on quality improvement & change management; Grow the pipeline for future network leadership
Remove Barriers	Seek to understand learning lab issues that are interrupting improvement activities & help to resolve them; Escalate issues/decisions to the Executive Leadership Team; Recruit additional resources, use his or her network contacts to make connections for the team, or mediate parties to work to an agreement
Foster Integrations	Encourage & support cross learning lab collaborations; look for cross-team opportunities & promote synergies among the improvement teams.

Team Leaders

Learning Lab Leaders in Action	The Learning Lab Leader will ...
Build a Learning & Improving Community	Build a culture of all teach all learn in the learning lab community. Foster a healthy learning environment; Facilitate the Learning Labs including agendas & outcomes & developing content for Lab topics at learning sessions; Celebrate success & promote learning from failures.
Inform Improvement Strategy	Review evidence, define relevant measures, review aggregate & network team data & results to continually update improvement theory (key driver diagram) for the Learning Lab outcomes; Consider the design to reach full scale of successful changes, create change packages.
Drive Desired Outcomes	Set aspirational & annual goals, communicate those goals, & identify & spread successful interventions to meet goals; Work with the center teams/care teams to ensure mutually beneficial interventions are co-produced with families; Maintain responsibility for overall learning lab results; Set a culture for rapid learning that includes a quick pace of work, appropriate type & amount of testing, applying test rigor, & evidence of test efforts.

Functional Team: QI Systems - *Operations*

Composition:

- SC Sponsor: [Name]
- Team Leader: [Name]
- SMEs or other contributing members: [Name]
 - Potentially select LLC coaches as needed
- Operational Support Staff: [Name]

Focus =

Meeting Frequency = Monthly (TBA)

- CFLN QIC subgroup meets weekly

Functional Team: Data Systems - *Operations*

Composition:

- SC Sponsor: [Name]
- Team Leader: [Name]
- SMEs or other contributing members: [Names]
- Operational Support Staff: [Name] (network manager), [Name] (data systems operations)

Focus =

Meeting Frequency = Semi-monthly

- Measures Subgroup composition/focus to be revisited in first quarter of 2019

Functional Team: Community Collaboration + Engagement - *Operations*

Composition:

- SC Sponsor: [Name]
- Team Leader: TBD
- SMEs or other contributing members: [Name]
- Operational Support Staff: [Names]

Focus =

Meeting Frequency =

WORKING GROUPS

Working Groups - *Representative*

Example Teams:

- Patient + Family Partners + Leaders
- Physicians/Center Directors
- Quality Improvement Leaders (QILs)
- Additional as prioritized, e.g. other clinical disciplines, regional collaboratives, pediatric vs. adult care groups

Composition:

- SC or NLT sponsor, team leader, members, operational support staff
- As needed: QI consultant or analytics consultation

Focus = *Role-specific collaboration groups to support those in the network & growth of future leaders*

Meeting Frequency = *Bi-weekly to Monthly*

SC/NLT Sponsors

Learning Lab Sponsors in Action	The Learning Lab Sponsor will...
Build Will	Advocate & promote engagement & activation from necessary individuals, teams, groups, & organizations; Clarify needs, promote understanding of causes & issues, connect the issues to our core mission, & help identify the best pathways to improvement
Advise on Improvement Strategy	Keep primary focus on improvement science; Advise on learning lab improvement strategies
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Team Leaders

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Drive Desired Outcomes	Set aspirational & annual goals, communicate those goals, & identify & spread successful interventions to meet goals; Work with the center teams/care teams to ensure mutually beneficial interventions are co-produced with families; Maintain responsibility for overall learning lab results; Set a culture for rapid learning that includes a quick pace of work, appropriate type & amount of testing, applying test rigor, & evidence of test efforts.

Working Group: Patient/Family Partners (PFPs) + Leaders - Representative

Composition:

- ET/NLT Sponsor: [Name]
- Team Leaders: [Name]
 - *Can we have a parent co-lead/co-sponsor?*
- SMEs or other contributing members: *could list here the most active PFPs?*
 - Open to all PFPs members within the network
- Operational Support Staff: [Names]

Focus = *Provide patient, parent & family perspective for collaborative activities. Learn what makes a Patient & Family Partner & Clinical Care Team coproduce most successfully, improve PFPs abilities to coproduce with their clinical teams, support PFPs as they navigate the relationship with their clinical teams.*

Meeting Frequency = *Monthly*

Working Group: Patient/Family Partners (PFPs) + Leaders

- Representative

Key Responsibilities:

1. Represent the PFPs on a Network-wide level
2. Facilitating outreach & education to patients/families to increase involvement in improvement & care
3. Recommending priorities including but not limited to Community Conference topics reflecting the patient/family perspective
4. Developing a community of parents that advise & contribute meaningful action to the Network's success
5. Provide monthly data to the Network based on their experience as a PFP
6. Increase capacity of the care team to improve outcomes, value, & experience of PFPs by collaborating with care teams in designing & testing innovations to improve care & outcomes

Working Group: Physicians/Center Directors -

Representative

Composition:

- SC/NLT Sponsor: [Name]
- Team Leader:
- SMEs or other contributing members:
- Operational Support Staff:

Focus =

Meeting Frequency =

Working Group: Quality Improvement Leaders (QILs)-

Representative

Composition:

- NLT Sponsor: [Name]
- ET Sponsor: [Name]
- Team Co-Leaders: [Name] & [Name]
- SMEs or other contributing members: [Name]
 - Open to all QILs within the network
- Operational Support Staff: [Name]

Focus = *To offer support, provide quality improvement plus team building learning & exercises, as well as serve as a platform assisting in problem solving for Network teams & their QILs.*

Meeting Frequency = *Quarterly 60-minute meetings*

INNOVATION LABS

Innovation Labs - Operations

Examples:

- Implemented changes
 - e.g., components of the Chronic Care Model: PVP, co-production, data quality/timeliness
- 180 day challenge teams
 - PSDC, PROs
- New improvement initiatives
 - FIES, HRQOL, others as they emerge

Composition:

- NLT sponsor, team leader, CFLN QIC, SMEs, analytics support, operational support

Definition = A multi-center collaborative strategy to identify interventions of best practices for improving outcomes for which previously available knowledge was insufficient.

Focus = *Test innovations via distributed learning & stage/gate process, develop change packages, monitor reliability of changes at program level, compare intervention outcomes among cohorts*

Meeting Frequency = *Determined by the timeline & resources available*

What Is an Innovation Lab?

A multi-center, voluntary, collaborative strategy to identify interventions of best practices for improving outcomes for which previously available knowledge was insufficient.

Design & Plan

Team: 6-10 Experts

Deliverables:

- SMART AIMS
- Family of measures
- Data collection approach
- Improvement Theory
- KDD
- Determine center commitment for Innovation Lab

Opt – in Innovation Lab

Team: 5-10 Centers

Deliverables:

- Evidence of improvement
- Improvements in process measures
- Create, revise, & refine change package



Innovation Lab
starts here!

Network Wide Improvement

Team: Spread - All Centers

Deliverables:

- All centers adopt measures & improvement approaches at their local environment
- Network wide/aggregate improvement

Sustain Improvement

Team: All Centers

Deliverables:

- Review measures quarterly
- Convene experts if special cause

Initial Labs:

1. FIES – Summer 2019
2. HRQOL – Fall 2019

References: IHI, SPS, NPC, CNU, Anderson Center (LHS), Actor Orient Network

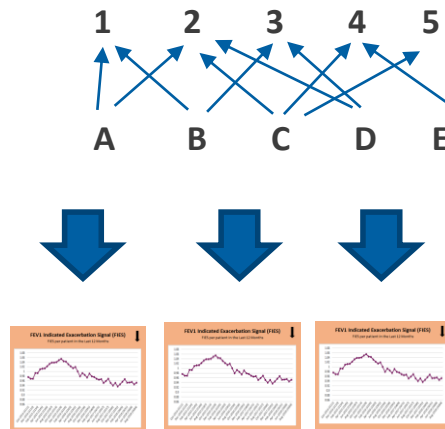
Distributed Learning Structure

- **FIES Innovation Lab** as case study – prospective testing
 - **Aim:** Decrease incidence of FIES from 1.0 to 0.5 by December 31, 2021
 - **Measure:** FIES in the last 12 months for CFLN patients
 - **Changes to be tested:** (Subject matter experts develop draft change package with list of change concepts/interventions to test)

Changes

Programs

Outcomes



- a) Distribute changes across programs
- b) Monitor reliability of changes at program level
- c) Group programs by interventions & compare outcomes for these cohorts

NLT Sponsors

Innovation Lab Sponsors in Action	The Innovation Lab Sponsor will...
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Innovation Lab: FIES

Composition:

- NLT Sponsor: [Name]
- Team Co-Leaders: [Name] & [Name]
- SMEs/content contributors
 - Faculty: [Names]
 - Nurse: [Names]
 - Respiratory Therapist: [Names]
 - RD: [Name]
 - Social Worker: [Name]
 - Data & Analytics: [Names]
 - Patient/Family Partners: [Names]
- CFLN Improvement Advisors/Consultants
 - [Names]
- Operational Support Staff
 - [Names]
- Additional Consultants (as needed)
 - [Names]

Focus/Aim = *Decrease incidence of FIES from 1.0 to 0.5 by December 31, 2021 (?)*

Meeting Frequency =

Innovation Lab: HRQOL

Composition:

- NLT Sponsor: [Name]
- Team Co-Leaders: [Name] & [Name]
- SMEs/content contributors
 - Faculty: [Names]
 - Nurse:
 - Social Worker/psychologist/mental health coordinator:
 - PFEC Survey: [Names]
 - Data & Analytics: [Names]
 - Patient/Family Partners: [Names]
- CFLN Improvement Advisors/Consultants
 - [Names]
- Operational Support Staff
 - [Names]
- Additional Consultants (as needed)

Focus/Aim =

Meeting Frequency =

PARTICIPATING PROGRAM QI TEAMS

Program QI Teams - Operations

Composition (minimal requirements):

- Physician Champion
- QI Coordinator
- Patient/Family Partner(s)
- Additional CF clinical care experts

Focus = *Test, share, & report improvement initiatives to the network while growing capacity for improvement & prioritizing projects at their institutions. Foster institutional/divisional support & financial backing of participation in the network. Ensure training + acclimating of program team members & PFPs in QI & the network's methodologies.*

Meeting Frequency = *Determined by the teams themselves; minimal requirement of monthly*

NETWORK OPERATIONS

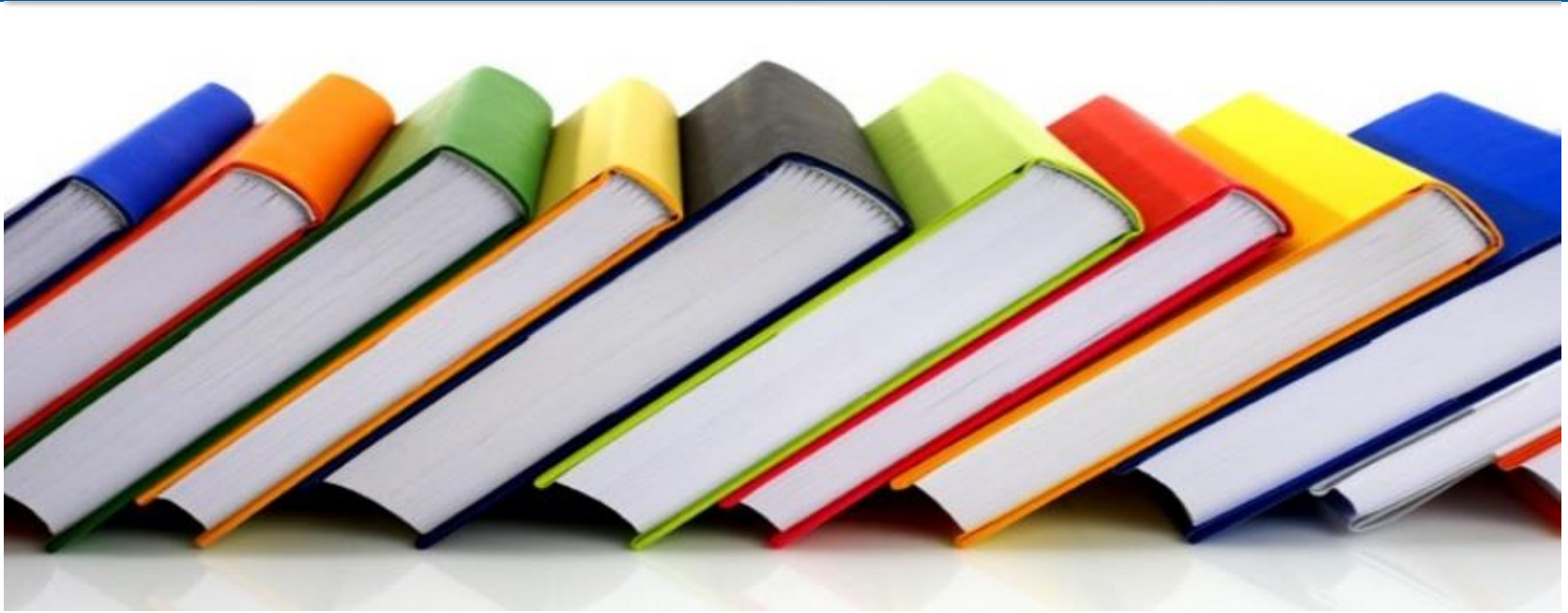
Support Operations - *Operations*

Composition:

- Project Manager: [Names]
- Specialist – Project Management: [Names]
- Project Coordinator: [Name]
- QICs: [Names]

Focus =

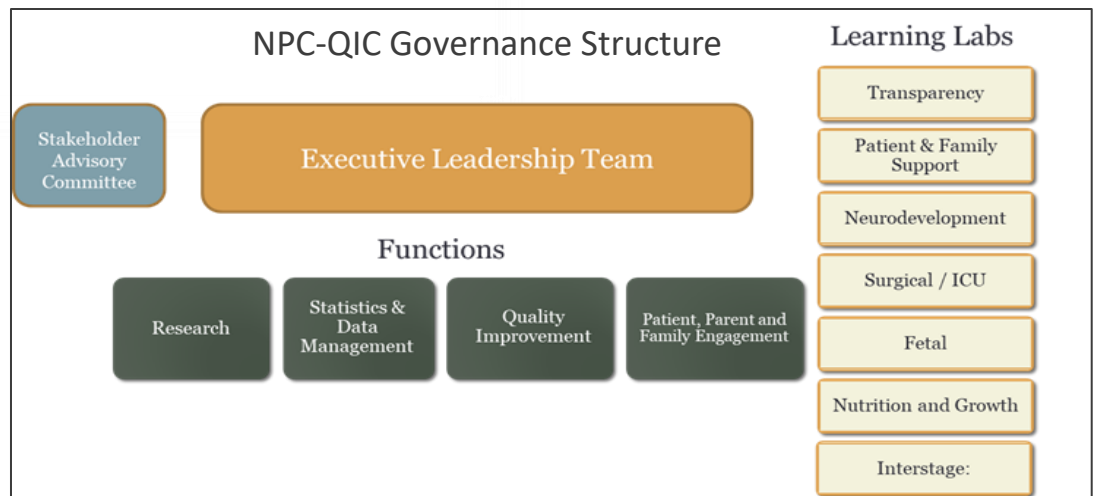
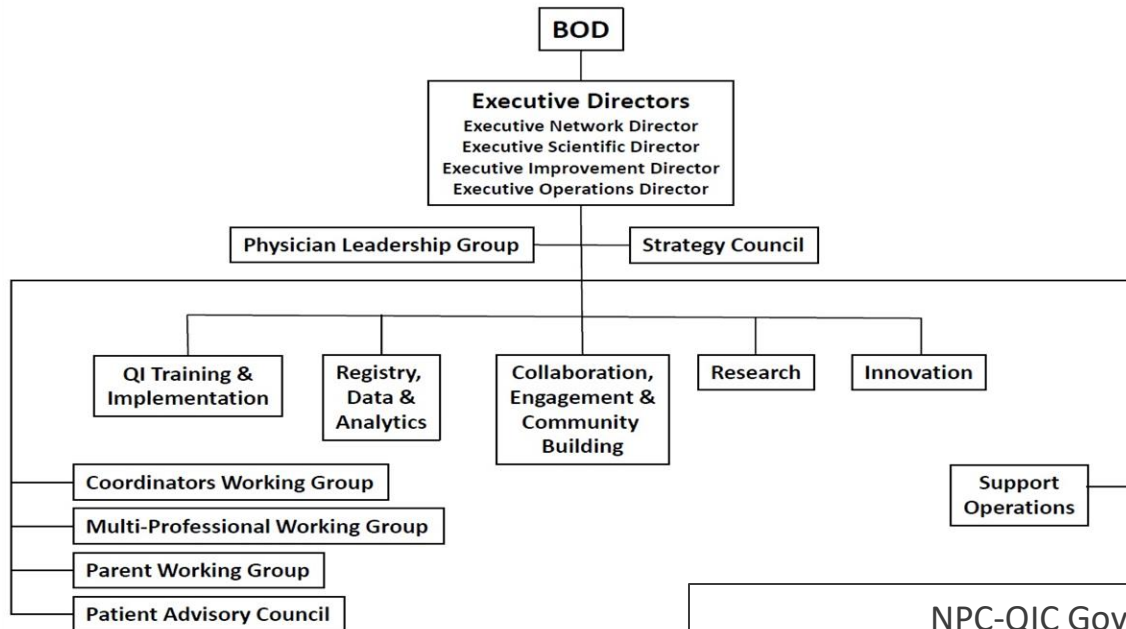
Meeting Frequency = *Weekly*



FOR REFERENCE

Established LN Organizational Charts

ImproveCareNow Organizational Chart



LN Governance Components:

- Stakeholders in Governance & Management
- Governance & Management Structures
- Network Policies
- Network Membership Policy
- Network Collaboration Policy
- Knowledge Sharing
- Attribution Policies & Procedures
- Data Policies & Procedures
- Institutional Review Board (IRB) Policies & Protocols
 - *Not applicable to CFLN*
- Financial Sustainability – Business Plan Development

LN Governance Manual –

Stakeholders in Governance & Management:

1. Strategic Leadership

(Board of Directors, Executive Directors, Physician Leadership Group, Strategy Council, or leadership team)

- Set the unifying vision/direction & global & specific aims of the network; & they engage in high-level planning & resource allocation in order to achieve those aims

2. Operations

- Network day to day operations & management + develop, implement, & track implementations of network's policies/SOPs & procedures

3. Representative

- Key point is to include stakeholder sub-groups that represent patients-families, clinicians & researchers, & not only at each care center but spanning the whole network

4. Advisory

- Stakeholders who are not formally part of the network but who are smart, wise, capable or otherwise willing & able to help from time to time

LN Governance Manual –

Stakeholders in Governance & Management contd.:

Strategic Leadership

- Clinical Leads
- Opinion Leaders
- Parent Leaders
- Operations Lead/**Business Manager/Legal/CEOs**

Operations

- Network Directors
- Project Managers
- QI Coaches
- **Communications & Engagement Specialists**
- **Data Analysts**
- **Informatics Specialists**

Representative

- **Clinical Steering Committees**
- **Research Committees**
- Parent Working Groups
- Patient Advisory Councils

Advisory

- Consultants
- **Mentors**
- Clinicians
- **Researchers**
- Patients/Families

LN Governance Manual –

Governance & Management Structures:

- **Person Center-Supported Learning Networks**
 - **Network Operations Director** (if applicable)
 - Project Manager
 - **Senior Specialist – Project Management**
 - Specialist – Project Management
 - Coordinator – Project Management
- **Network Management Infrastructure/Capacity**
 - Written management processes & operating procedures
 - Formal onboarding procedures for new network staff
 - **Formal process in progress & being tested**
 - Descriptions & prioritization of work flows & opportunities
 - **Not complete but have for most**
 - Network staffing model
 - Budgeting procedures
 - Dedicated administrative support
 - Dedicated time for network faculty & leaders
 - **Processes & schedules in place to review regularly all of the above**

LN Governance Manual - Policies:

- **Network Policies**

- Should be written up from very startup of the network, continually updated, & key decisions made note of
 - CFLN has some network policies drafted but could use more

- **Network Membership Policy**

- Includes the guidelines, rights & obligations of members of the learning network
 - 1st requires continual “buy-in”
 - Renewed agreement (usually annually); including spelled out “give & take”
 - Plan for dealing w/ member’s failure to uphold/meet expectations
 - Network managers should draft the membership policy in consultation with network leadership, & then maintain & implement the policy
 - CFLN network has charter but would be beneficial to have this piece called out separately

- **Network Collaboration Policy**

- Includes processes for engaging stakeholders & organizations external to the network, for example, sponsors, funders, professional organizations & industry
 - None of LNs have developed due to only recently started to develop

LN Governance Manual – Knowledge Sharing:

*Knowledge sharing is **essential** to achieving spread of successful interventions throughout a LN & sustaining them*

- **Virtual Community Commons**

- Should function as a repository to share existing assets & as stimulus for co-production.
- Platform to facilitate frequent, sophisticated & inclusive of all stakeholders sharing should develop apace
 - As amount of info/documents grows a commons will need to be developed that is searchable
 - As network becomes more inclusive of all stakeholders at all 4 governance levels, so too will the network become more democratic in how it creates, shares, & uses knowledge (i.e. Wikipedia)
- Governance policies should be developed around contribution, curation of contributions, sharing documents, & taking & modifying existing documents
 - Should also protect the intellectual property/authorship of contributors, ensure proper acknowledgments, & respect copyright-protected materials

LN Governance Manual –

Attribution Policies & Procedures:

- **Authorship/Publishing**

- LN leaders/mangers develop policies & structure for Research Committee to govern:
 - What research is approved & prioritized using network registry data, in alignment with network's aims
 - How manuscripts generated from proposals to answer research hypotheses are formatted, reviewed, edited & published
- Recommend following ICMJE & URM for authorship credit & acknowledgements

- **Intellectual Property**

- It should be made clear in the text of any manuscript
 - Produced with research data from the network that network dataset was used for analysis
 - Include description & limitations of network dataset

LN Governance Manual – Data Policies & Procedures:

- **Strategic Importance**

- LN leaders/managers should think about kind of data wish to collect; research, improvement, outcomes or process data + what reports are needed
- Consider what level of transparency network requires for each type of data, & what the network can feasibly achieve

- **Operational Components**

- Need to take into account network operations staff – managers, legal, regulatory, informatics, etc.

“Networks should take these issues very seriously & may need to consider outside, expert support in developing policies, procedures, & systems!”

- Data Sharing & Access
- Data Security
- Data Ownership
- Privacy & Security Considerations

LN Governance Manual – Financial Sustainability:

- **Financial Sustainability Meaning**

- Financial sustainability or self-sufficiency means different things to different networks
- Networks must have a general plan of what “viable” means for their specific network, with regards to funding streams such as membership fees, grants, industry partners, etc.
- Mature networks regularly review their financial position & even store up reserves to cover an extended period of operations in case of a funding shortfall

- **Developing Business Plan**

- Does not imply that networks ought to be run like a business; rather, a business plan is simply a widely used tool for responsible financial planning & stewardship
- **Basic Steps in Writing Include:**
 - Describing key leaders & organizational structure of network
 - Identifying network products, programs, & services
 - Identifying marketing opportunities & threats
 - Development of financial plan
 - Getting leadership approval & stakeholder buy-in

- **Ideal State**

- Network has established regular business planning cycles whose timing are in alignment with the development strategic & operational plans, which in turn have been developed with sponsor/governance oversight