MODULE 2

GOVERNANCE AND MANAGEMENT

THE LEARNING NETWORKS GUIDE: BUILDING A LEARNING HEALTHCARE SYSTEM NETWORK

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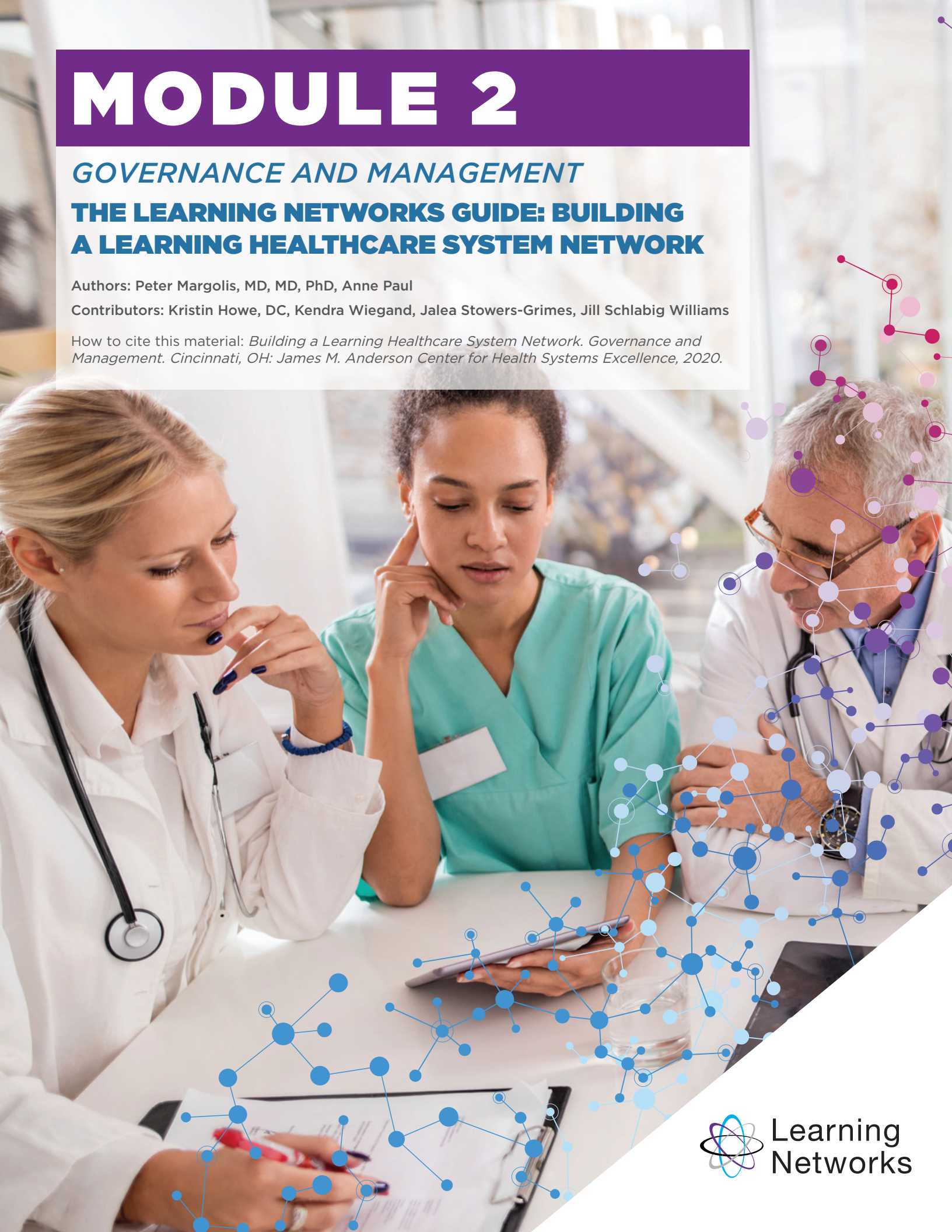

Learning Networks

TABLE OF CONTENTS

TABLE OF CONTENTS

INTRODUCTION

Network management becomes the hub where all activities of design, implementation, and ongoing yearly cycles of growth and improvement inside a learning network meet. Effective coordination and organization of these activities have the power to help the network go farther, faster. While an enabler of network success, this area is also the most diverse in terms of processes and skillsets required.

This module first provides an overview of several of the key theories underlying the development and operation of successful learning health systems. It then describes initial requirements and a set of strategies that can be used as the network grows to monitor the capability of the infrastructure to absorb new members and deliver on its promises. This module is a required reading for anyone establishing or managing daily operations in a learning network.

KEY ELEMENTS

Since 2006, groups of researchers, clinicians, and families, with support from Cincinnati Children's Hospital Medical Center and leadership from the American Board of Pediatrics, have been successful in establishing learning health systems that we call learning networks. (Britto et al., 2018) A common framework and methods support the transformation of the healthcare system towards a learning health system.

Everyone in a learning health system network shares a commitment to enabling patients, families, clinicians, researchers, health system leaders, and institutions to work together to improve the health and healthcare of patients and families by generating new knowledge, spawning innovation, and improving healthcare systems (better outcomes, better experience, and lower cost). Network participants foster the trust and cooperation necessary to protect, steward, and preserve the knowledge and assets that all participants contribute to helping people lead healthier lives. The network exists to nurture the capabilities of participants so that impact is accelerated and grows. (Snow et al., 2011)

PHASE 1:
DESIGN & DEVELOPMENT

This section describes initial requirements for establishing a new learning network and a set of strategies that can be used as the network grows to monitor the capability of the infrastructure to absorb new members and deliver on its promises.

PHASE 1

Since learning networks operate under the principle of Common Pool Assets (see the Introduction for further details), the Anderson Center and its network teams have tested the governance principles described under Key Elements, and have designed governance models that, even if different in their structure, still follow the below guiding principles:

1. **Patients, families and clinicians first.** We maintain an unrelenting focus on what matters most to patients and families and those who provide care. (Britto et al., 2018) Our commitment aligns healthcare services and research to produce and apply knowledge faster and better to improve the health of patients and families.

2. **We share.** We achieve more together than is possible alone. We get better together by sharing expertise, data, tools and knowledge to create the common resources for a learning healthcare system. Pooled assets create new value. (Stabell and Fjeldstad, 1998) Shared assets become available to enable each participant and participating organization to do its work better. We avoid unnecessary duplication by developing standardized policies and processes.

3. **We all have a say in the design and governance of our shared assets.** Collective efforts require fairness. (Ostrom, 2009) We share responsibility to develop, maintain, and participate in community governance. We have an equitable say in oversight and decisions regarding pooled resources including policies and standards, membership criteria, definitions of contributions, effort and costs, as well as the distribution of benefits and re-investment decisions. We commit to negotiating a system in which benefits are proportional to contribution, effort and costs.

4. **Transparency.** A high degree of transparency promotes trust by allowing each of us to monitor what is contributed and what is withdrawn.

5. **Autonomy and self-determination.** The community provides flexibility about how members participate. Participation in value-producing activities (e.g., research or improvement) will be up to each participant and participating organization (i.e., each participant or organization can decide if it wants to participate in a particular project, study or network).

6. **Clear boundaries, fair and low-cost dispute resolution, and rules for sanctioning members.** The network community develops clear boundaries around what is shared, and graduated dispute resolution mechanisms that take place within the network.

7. **Commitment to improving the system.** Participants recognize that they are part of a dynamic and evolving system and are committed to improving it over time as the system grows and matures and learning takes place.

Plan for the Design Process

Identify Leadership Team and Distinct Roles

Learning Networks can be established with various types of leadership structures, which may then evolve over time. At the start, the leadership can be one individual, though many times it is a small group. It is important to clarify the roles and responsibilities of the leader(s).

Identify a Network Management Team

The principal investigator (PI), who will act as the chair of the future network, is responsible for identifying the team that will provide day-to-day support during the design phase. The management team should be led by a project manager (PM) with experience managing multi-site projects involving complex matters such as regulatory, legal, contracting, budgeting, and staffing. The project manager should have solid written and oral communication skills and experience managing geographically remote stakeholders. Depending on the network capacity, the project manager can oversee a team of project management specialists skilled in project planning, managing milestones/deliverables, and meeting facilitation. Operational support staff should also be available to complete activities such as administration, communications, and event planning. For details about roles and responsibilities within management and operations teams, refer to the below resource. To estimate level of effort for staff, refer to the section "Determine the Level of Effort."

Resources

- Job description of Network Management team: Roles in a Learning Network (Appendix 2.1). This was adapted from roles in a Breakthrough Series Collaborative.

Identify a Quality Improvement Team

The principal investigator should also identify the quality improvement (QI) team that will provide QI support during the design phase. For a description of the QI roles and responsibilities, see Appendix 2.1. To learn more about QI activities, see Module 2: Quality Improvement.

Identify the Design and Early Network Leaders

The principal investigator is primarily responsible for identifying a group of peer leaders to provide feedback and content expertise during the design phase. As these design leaders are identified, the management team develops and socializes their roles and responsibilities and the descriptions of the workgroups they will lead in order to complete the design milestones listed in the design charter (refer to the section "Create a Design Charter").

At a minimum, the following workgroups should be represented during the design phase. Each workgroup requires a designated lead. Some combination of these workgroups is possible and co-leadership is possible if the roles are clearly divided:

- Leadership Workgroup (can be combined with Quality Improvement workgroup)
- Community Engagement Workgroup (recommended that parents and patients participate in each of the workgroups in addition to having their own workgroup)
- Quality Improvement Workgroup
- Data and Analytics Workgroup (can be combined with registry workgroup)
- Registry Workgroup

The leaders of the above workgroups during the design phase may not be the same individuals as the ongoing network leadership team. The design phase requires the ability to think outside of the box in order to rethink the way care is delivered. As a result, it is often best to include creative minds in this process, individuals who are not afraid to speak up and address challenging issues in group settings. However, as the design phase ends and the implementation phase launches, it becomes critical to expand the group. With such expansion, a different profile of leaders may emerge. Those network leaders need to be comfortable diving into the more routine day-to-day activities of network operations while still energizing the forward-thinking early adopters and engaging with a diverse set of stakeholders.

If the design phase includes an ethnography study (refer to the section "Conduct an Ethnography Study"), a dedicated workgroup and leader could be identified to manage the ethnography study and disseminate its learnings.

Resources

- Example workgroup descriptions (Appendix 2.2)

The network PI, the design leaders, the QI team, and the management team constitute the "design team."

Create a Design Charter

A design charter is a fundamental first step in the design phase. The definition of a design charter and examples of design charters are provided in Module 1: Systems of Leadership. Development of the charter is primarily the responsibility of the QI Specialist (QIS). However, the management team is responsible for adding the key milestones timeline and a preliminary organizational chart with a description of each workgroup and their tasks to the charter. System level measures, and a list of high-level system requirements, are also part of the charter and should be developed in close collaboration with the Data and Analytics and QI workgroups.

System-level measures correspond to the system-level aims that the network wishes to reach within a given time. An explanation of system-level measures and examples are provided in Module 4: Quality Improvement.

System requirements are high-level features that the design team recognizes as critical for the new healthcare system to be considered optimal by all users of the system. An example of system requirements is provided below; also see Module 6: Data and Analytics.

Because of the nature of a design charter, its creation is intended to be an iterative and collaborative process, involving as many stakeholders as possible.

Resources

- System level requirements example (Appendix 2.3)
- Design charter examples in Module 1: Systems of Leadership, Appendix 1.12.
- System-level measures examples in Module 4: Quality Improvement, Section “Measures Development Overview”

Determine the Level of Effort

The principal investigator and management team will use a work breakdown structure (WBS) to evaluate the hours required to complete tasks and assess the total allocation per role.

Resources

- Work breakdown structure template (contact the Learning Networks Program Project Management Group for the latest template, LearningNetworks@cchmc.org)

Develop a Design Workplan

The management team is responsible for developing a workplan that covers the entire design phase. A lighter version of the workplan is needed in the charter and can look like a list of milestones with a timeline of high-level activities (refer to the section "Create a Design Charter"). However, the management team will develop and maintain a detailed workplan that tracks the completion of the many tasks and activities that cut across the design cores: community engagement, quality improvement, data and analytics (measures), registry, and operations. Workplans can be in any format (e.g., Excel, Microsoft Project, Word). However, they should all share the same features: description of the activity, when it is due, who is completing it, activity status (complete/in progress/not complete or % complete) and dependencies (in other words, if the activity does not get implemented by the due date, what are the implications?). The management team should update the workplan regularly (e.g., weekly) by attending the various meetings, workgroups, and events. The workplan should be the driver of the internal team meeting (refer to the section "Set Up Meetings"), a meeting where the internal team (management, leadership, community engagement, QI, data and analytics leads) comes together to update each other on progress, risks, and issues. Because detailed workplans can be overwhelming to present in a meeting, it might be best to identify the areas of concern in the workplan and bring them to the attention of the group as agenda items. See resource below for an example of a design workplan.

Resources

- PCORnet design workplan (see Module 1: Systems of Leadership Appendix 1.13)

Kick Off the Project with the Leaders

Once the design charter and workplan are drafted and resources are identified, the management team works alongside the QI team to set up the kick-off meeting (KOM).

The meeting should last 1-2 hours and gather design leaders, workgroup leads, the operations team, improvement specialists, improvement advisors, and other relevant partners, such as a sponsor. This group should be a mix of clinicians, researchers, parents, patients, management staff, donors, and grantors.

The management and operations teams are responsible for scheduling the meeting, inviting the right attendees, and developing the roles and responsibilities of each workgroup and their leaders. The management team is also responsible for developing the timeline and list of deliverables for which each workgroup is accountable. This information should be available in a management plan. Extracts of the management plan should be converted into PowerPoint slides for the purpose of the kick-off meeting.

The principal investigator will lead the meeting with the support of the QI and management team.

At the end of that meeting, each participant should have a clear idea of their role in the design phase, the workgroup they belong to, the expectations and deliverables for that workgroup, and the overall timeline for the project with key milestones for all to reach as a team.

Resources

- Management plan template (contact the Learning Networks Program Project Management Group for the latest template, LearningNetworks@cchmc.org)
- KOM slide template (contact the Learning Networks Program Project Management Group for the latest template, LearningNetworks@cchmc.org)

Set Up Meetings

The management team will work with the operations support team to follow up with each workgroup lead (refer to the section "Kick off the Project with the Leaders") to provide assistance with identifying workgroup members and setting up regular meetings for the workgroup.

The operations team is also responsible for setting up the meeting in which the leads of data and analytics, registry, QI, project management, and community engagement come together to update each other on progress, risks, and issues. For more details about what is discussed during such team meetings, see resources below.

Resources

- Internal Team Meeting Agenda Components – typical components included in an agenda template:
    - Meeting name, date, time, and call-in/web platform details
    - Attendance (list of invitees and indication of attendance (e.g., checkbox, bold, or highlight attendees)
    - Key topics/agenda item – include objective, facilitator of the topic, and time allotted to discuss. Topics should focus on:
        - Items that need a decision
        - Items that require action
        - Items that need discussion to come to a decision
        - Potential risks or issues
    - Next steps/action items
    - Key Decisions (optional – may be included to avoid revisiting discussions)
    - Closed action items (optional – may be included for awareness)
    - Parking lot (optional – items to be discussed later, but still pertinent)
    - Announcements (optional – e.g., upcoming out of office)

Choose a Document Sharing Platform

The management team is responsible for identifying a platform that will allow the design team to edit and share materials, manage version control, and keep each other abreast of progress on deliverables. Various platforms are available; the best one to choose will depend on the likes and habits of the leadership team and the institutional firewall in place. Examples of platforms include Dropbox, SharePoint, Google Docs, Slack, Smartsheet, etc.

Streamline the Communication

Design involves extensive communication across multiple parties with numerous activities to be coordinated. Because of the connectivity of the activities, team members need to be aware of what occurs during the design phase. Management teams are responsible for identifying how to best streamline communication between key players. Which method to use will vary based on the preferences of the contributors in the design phase. Many network management teams opt for a weekly digest or email recap with a list of to-dos for the leaders to complete in preparation for upcoming meetings. Another option can be to put together an actual newsletter using Constant Contact or another platform. For an example of email digests and/or newsletters see Resources below.

Resources

- Constant Contact Newsletter: PCORnet LHS Pilot News (Appendix 2.4)

Generate New Ideas

After the kick-off meeting, the design team and its workgroups are encouraged to generate new ideas that will lead to a fundamental redesign of the healthcare system surrounding the condition of focus. Understanding the needs of all users of the system is the critical starting point. Observation is the primary method used to gain a deeper understanding of the needs of patients, family members, and providers in the care system. Ideas are then generated to address the unmet needs identified. What are their likes and dislikes? What are their latent needs not addressed by the current healthcare system? Such observations, obtained by "walking in the shoes" (refer to the section "Conduct an Ethnography Study") of the patient/family member, require an approach that integrates "doing, thinking, feeling, and being" by the observer. This combination reduces the chasm between the observer and the patient/family member, leading to the experience of the observer being closer to the reality of the patient/family member. This approach facilitates neutrality of observations. Innovations emerge from the inferences drawn from these observations. The management team works alongside the QI team and the leadership team to support the following activities:

Conduct Environmental Scans

One way to generate new ideas is to conduct an environmental scan of the current system. An environmental scan is an assessment of the care system as it exists today ("as is"). An environmental scan should be conducted in the areas of QI, data and analytics, project management, research, community engagement, and operations management. Environmental scans may include surveying prospective centers/clinics/partnering agencies with questions that help evaluate what does and does not work in the current system of care. Environmental scans often include a literature review to identify new ideas that have proven to work in various fields and could be applied to address the problems in the clinical field being re-designed or gaps in existing knowledge or care delivery that need to be closed. Workgroups can use various tools to share their ideas, including Google Drive, Dropbox, SurveyMonkey and others. The management team is responsible for monitoring progress of each workgroup, assisting with identifying the right platform to share ideas, and assisting with literature review as needed.

Resources

- Example of platforms to share environmental scan ideas:
  Cystic Fibrosis Learning Network (CFLN) example (Appendix 2.5)

Complete an IT Assessment of Available Registries

Design teams may want to research the technology platforms ("registries") available in the market to assist their future quality improvement work. The technical requirements of quality improvement registries often differ from traditional research registries. It will be important to conduct a gap analysis comparing ideal features to the ones available in existing registries. For more information about a registry's typical QI functionalities and examples of IT gap assessments, see Module 6: Data and Analytics. The management team may assist with identifying the right players to discuss registry features, set up meetings, and follow up with the appropriate stakeholders to ensure progress is made with both registry design and registry integration with external sources of data.

Complete a QI Capability Assessment

If a group of care centers are participating in the design phase with the prospect of joining the network after it launches, it may be possible to complete a QI capability assessment during the design phase. If centers have not been recruited yet, this activity should take place in the implementation phase. For details about what a QI capability assessment is, how to roll it out to sites, and how to interpret the results, see Module 4: Quality Improvement. The management team may help with deploying the QI assessment tools to the centers (via SurveyMonkey, Smartsheet, Google Forms etc.), reviewing results, and presenting the results in a way that helps the leadership make critical decisions around QI training needs and level of QI offerings in the network.

Resources

- Visuals of QI assessment
    - QI assessment MUSIQ survey (Appendix 2.6)
    - QI assessment ACIC survey

Monitor Progress

The management team is responsible for monitoring the progress made by the various workgroups in completing their environmental scans. The lead of each workgroup reports out on their own key findings and hears ideas generated by the other workgroups. The key findings shared by all workgroups help the leadership team, with the support of the QI and data teams, to start drafting a network charter, high-level priority measures, and a preliminary theory of change (or key driver diagram). For more details on a network charter, measures, and key driver diagrams, see Module 4: Quality Improvement.

Conduct Design Meeting(s)

The design team should plan for at least one design meeting during the design phase. The agenda of the design meeting will vary depending on how many are held during the design phase. They are often 1-2 full days in length.

If two design meetings are scheduled, the first design meeting should be an opportunity to bring everyone together to participate in hands-on exercises to describe the current system and visualize an idealized future one. Such in-person meetings help address regulatory, technical, social and clinical gaps, frustrations, opportunities, and barriers. It also continues the brainstorming phase started with the environmental scan exercise and engages all participants in hands-on activities to generate new ideas in designing the system. Teams can use poster sessions to showcase social or technology-driven innovations shown to successfully support patients with various chronic conditions (for example, a newly developed app, an innovative grass roots method to engage patients, etc.). The second meeting usually takes place 5-6 months later. During that time, the attendees review interventions that have been fleshed out since the first design meeting and rank them in a priority order. At the end of the meeting, the attendees have a full roadmap of what interventions they will focus on in the next 12 months and how they will get started.

If one design meeting is planned, it should be scheduled 3-4 months into the design phase of network development and focus on finalizing the network charter, system-level measures, and key driver diagrams. These are the foundational elements of the design phase without which no further progress can be made. Everyone involved must agree on the vision and mission (or aims) of the network, what success will look like (outcomes and process measures at the system level and clinic level) and what changes the network will test in clinics to assess improvement (interventions).

For an example of a design meeting agenda, see Module 4: Quality Improvement and the resources listed below.

The management and operations teams (includes an event planner, depending on team composition) are responsible for the logistics involved in setting up and executing the design meeting. This includes finding a venue, ensuring that meals and beverages are provided as needed, negotiating the contract, reserving a hotel and travel if necessary, advertising/monitoring the registration, printing materials, addressing participants' questions, etc.

Resources

- Improving Renal Outcomes Collaborative (IROC) example of design meeting agenda (see Module 4: Quality Improvement Appendix 4.1)
- Work plan for PCORnet design Meeting (Appendix 2.7) – detailed view of the tasks involved in setting up and executing a design meeting

Conduct an Ethnography Study

If funding allows, an ethnography study can be a great way to gather inputs from all participants in a healthcare system. An ethnography study involves interviews and focus groups with patients, caregivers, providers, researchers, and hospital administrators to understand their needs and frustrations with the current system. Themes are identified and grouped around personas. Personas are fictional individuals that incarnate the traits of a group of interviewees sharing similar experiences and responses. Personas can help a design team be more targeted in defining interventions to change the healthcare system.

For instance, if a persona emerges that represents teenagers with low self-esteem and a tendency to quit treatment plans, the design team can think of concrete interventions that would help this persona address his/her ongoing struggles.

The management team should help establish a contract with the ethnography consultants, including developing a scope of work and monitoring progress and completion.

If funding is not available, another way to collect these types of insights is to conduct a "Walk a Mile" session. "Walk a Mile" is an exercise that involves a deck of cards with questions pertaining to situations that participants in the healthcare system face. As people pick a card, they need to think about their answer to the challenging situation and engage the group in bringing different perspectives to the discussion. The management and operations teams assist the QI team in documenting the feedback during the session and providing direction to the group regarding the subsequent ranking exercise.

These suggested approaches and others eliciting the same type of feedback may be combined.

Resources

- Walk a Miles Cards

Prioritize Interventions

The ideas generated during the design session(s) become the basis for interventions the network will test in order to achieve their pre-determined objectives. The design team is responsible for cataloguing and prioritizing proposed interventions, whatever the method used to generate them.

The prioritization exercise can be a structured process or a more organic one depending on the ideas generated. Larger and more complex teams and/or studies generating detailed and complex interventions may require a more structured prioritization exercise. For examples of structured or organic ways to prioritize interventions, refer to the resources below.

In both cases, the management and operations teams assist the leadership and QI teams in completing the prioritization exercise, including testing any web platform that might be used to complete the ranking, collecting the prioritization sheets from the attendees, tabulating the results, and drafting a visualization of the results.

Resources

- T1D Excel Ranking Exercise methodology (Appendix 2.8)
- Complex / structured prioritization exercise, including on-line ranking and auto-generation of ranking charts (contact the Learning Networks Program Project Management Group for the latest template, LearningNetworks@cchmc.org)

Monitor Completion of Registry and Data Milestones

It is the responsibility of the management team to ensure that the registry and data workgroups complete their deliverables due at the end of design and to assist with mitigation plans as needed. For more details on what these deliverables are, see Module 6: Data and Analytics. The management and operations teams may be asked to schedule the data and registry workgroup meetings, take notes, produce the agenda in collaboration with the workgroup lead, and follow up on action items with the participants. The management team should also be able to connect the information across the workgroups, including the implications of data collection on legal agreements and IRB protocols. For more details about IRB and legal issues, see the next section.

Establish IRB Protocol and Legal Agreements

The management team is responsible for coordinating the activities around Institutional Review Board (IRB) and legal agreements. Learning networks collect data that is used for both QI and research purposes. As such, it comes with standard IRB and legal requirements. Management staff can access templates for IRB protocols, consent and assent forms, and customize the language to meet network needs.

It is recommended that learning networks use a central IRB model to standardize regulatory matters across multiple centers. As networks grow, it becomes challenging to operate under a local IRB review model. In the local IRB model, each participating center is responsible for getting local IRB approval of the protocol and amendments. Because of the variation in IRB reviews, this model often leads to differences in languages across protocols and increases the risk of errors and possible data breach. For that reason, and in full alignment with the recommendations from the National Institutes of Health (NIH), multi-site studies are strongly encouraged to choose one IRB of record that will serve as the main IRB for the entire study. The management team is responsible for assisting the principal investigator in locating an academic or commercial IRB willing to play such role. Once that IRB is identified, it is recommended that a regulatory specialist be involved in managing the relationship with that IRB and handle the communication with the participating network sites regarding their possible reliance on a single IRB of record. For information about the central IRB model, see SMART IRB website.

Depending on the type of data that the design team agrees will be entered into the registry, the network may require legal agreements such as a data use agreement for a limited data set or for full protected health information (PHI) and/or a business associate agreement. The institution that will host the registry will likely determine the terms of the data use agreement and business associate agreement for the reasons explained above. If each institution were to impose their own legal terms, it would be challenging to cohesively manage the flow of data across the network. Hence, the same data use agreement and business associate agreement templates should be shared with each of the participating centers. The institution hosting the registry will likely determine the terms of the relationship.

To understand how to roll out the legal documents and IRB to prospective centers, refer to the section "On-board Sites."

Resources

- IRB template (Appendix 2.9)

Complete a Sustainability Plan

The management team will assist the leadership team in the creation of a sustainability plan that addresses the critical sources of revenue and expenses for the network. Understanding the gaps between the two will help generate productive dialogue around diversifying fundraising activities and starting early conversation with prospective donors.

It is recommended that the costs of day-to-day network operations be covered under participating center fees and that grant funding be used to develop specific projects. Site fees are annual membership payments made by participating centers to the network in exchange for access to the network infrastructure.

The management team often plays an important role in helping the leadership consider the revenue streams and cost elements of running a learning network over a period of three to five years. The management team may be directly involved in identifying the cost elements affecting a network and coming up with assumptions for cost and revenue estimates. As part of this exercise, the management team will need to have access to some salary information in order to provide a realistic pro forma, or financial projections for a specific time period in a specified format, to which the leadership team can react.

Resources

- Module 3: Financial Sustainability (includes pro forma template in Appendix 3.3)

Develop a Recruitment Plan and Membership Policy

If the pro forma indicates the need to rely on site fees, it is critical that the network develop a recruitment plan including a solid, value-based proposal to attract participating centers. A recruitment plan should include documents that convey not only the concept and the vision of the network, but also clearly articulate the value gained by participating.

The value of participating in a network will vary by individual participating center. Some centers will value dollar savings above all, while others prefer guarantees that participation in a network will open increased access to grants and publications. For others, access to QI training and coaching, best practices, and demonstrated improvement of patients' outcomes and team's performance over time will be key.

A role of the management team is to support recruitment efforts led by the leaders of the network. The latter are involved in relationship building with leaders of institutions as well as with leaders in the field to support their efforts to build capacity and resources. Examples of this include both providing talking points and value statements for network leaders to discuss with their institutional leadership as well as conveying the value and evidence directly to institutional leadership. In addition, it involves establishing connections between institutions.

The management team can provide valuable support to the network leadership team in articulating the "return on investment" to hospital administrators and incorporating the information into support materials (recruitment slides, pitch, brochures, etc.).

Once network leadership has determined how best to frame the value of participation to its prospective members, the management and operations teams are responsible for drafting recruitment slides, developing brochures that provide key points about the benefits of joining the network, and drafting letters that will be emailed to the prospective sites with a description of the expectations from each party in the network.

Resources

- Pediatric Rheumatology Care & Outcomes Improvement Network (PR-COIN) brochure (Appendix 2.10)
- IROC Value for Administrators (see Module 1: Systems of Leadership Appendix 1.11)
- Letters of Commitment and Expectations (contact the Learning Networks Program Project Management Group for the latest template, LearningNetworks@cchmc.org)

Develop a Communication Plan

The operations team is responsible for developing a communication plan that identifies strategies for reaching diverse stakeholder groups and the various means by which new developments and targeted messaging will be shared. The network should also think about developing its brand (including logo), and a social media presence. See Module 5: Engagement and Community Building for examples.

Conclude the Design Phase

Several deliverables should be finalized and made available to the entire team at the conclusion of the design phase. The management team is responsible for housing and making available a final version of the items below as well as archiving draft versions.

1. Network Charter (see also Module 4: Quality Improvement)
2. Management Plan
3. Workplan
4. Key Driver Diagram (see also Module 4: Quality Improvement)
5. Prioritized list of change concepts (see also Module 4: Quality Improvement)
6. Registry Roadmap/Plan (see Module 6: Data and Analytics)
7. Operational Definition of the Measures (see also Module 6: Data and Analytics)
8. Case Report Forms (see Module 6: Data and Analytics)
9. Sustainability Plan (see Module 3: Financial Sustainability)
10. Communication Plan (see also Module 5: Engagement and Community Building)
11. Recruitment Plan

PHASE 2:
IMPLEMENTATION & YEARLY CYCLES

Phase 2 officially starts when the above 11 deliverables are finalized, and the learning network is ready to start operationalizing the plans developed during the design phase. The first priority is to grow the network by attracting participating centers and on-boarding them to the QI and registry infrastructure. This phase requires the implementation of many operational activities, which this section describes.

PHASE 2

Recruit Sites

The network leaders are responsible for identifying new prospective sites and pitching the network concept and benefits of joining. The management team can support them in their efforts by coordinating with the operations team to arrange one-on-one conference calls, set up webinars where multiple prospective sites are invited to learn about the network and what it has to offer, or organize a meet and greet at a professional conference to introduce the network to the audience. The management team also plays a key role in creating the recruitment materials, including slides, brochures, and other materials (refer to the sections "Develop a Recruitment Plan and Membership Policy" and "On-Board Sites").

Resources

- OPQC Join the Progesterone Project virtual invitation webpage
- Recruitment materials templates (contact the Learning Networks Program Project Management Group for the latest template, LearningNetworks@cchmc.org)

On-board Sites

On-boarding sites refers to the process involved from the moment a center expresses an interest in joining a network all the way to the center fully participating in the QI and data collection activities of the learning network.

Set up On-boarding Meeting

Network leaders are often responsible for recruiting centers. As they identify prospects, the management team is responsible for disseminating the recruitment materials developed in the design phase for the prospective centers to review and sign. Signature acts as a commitment on the part of the centers to fulfill the roles and responsibilities that come with participating in a network. Once the signed recruitment materials are received, the management team sets up an on-boarding meeting to orient the newly committed centers.

On-boarding meetings serve three purposes: 1) welcome the clinical team to the network and give a general overview of the network; 2) orient the team to IRB and legal matters required to participate in data submission; 3) introduce teams to QI activities, key webinars, communication platforms, and important events. The management team and the QIS should plan and co-facilitate this conversation. Network PIs are not mandatory.

During the on-boarding meeting, the management team explains the IRB and legal documents of the network and ensures the prospective sites have a clear understanding of next steps for obtaining appropriate signatures at their institutions. To help centers process the information, the management team may want to create support materials to help sites circulate the documents internally for approval and facilitate prompt review after the on-boarding meeting is over.

The management team may be involved throughout the review and signing process to address sites' questions about any of the IRB or legal documents. A tracker indicating the status of the IRB and legal documents with each prospective site should be created to track the turnaround time. This approach will help identify ways to accelerate the review process. The management team should escalate to the PI any issues with signature or approval of the legal and IRB materials.

During that on-boarding meeting (or in a separate meeting), the centers should also be oriented to the network, its organizational structure, the many opportunities to participate in the workgroups that compose it, and the QI activities they will be implementing at their sites. Refer to the section "Set up QI Infrastructure" for a description of the QI infrastructure that should be explained to the sites during the on-boarding call, so they know what to expect in terms of meetings and events.

Resources

- PR-COIN on-boarding meeting presentation (Appendix 2.11)
- Example of legal packet for centers to share with local legal team
    - Cover letter to LHS PI Organization - Legal email to Epilepsy Foundation (Appendix 2.12)
    - Legal FAQ for clinics (Appendix 2.14)
- Example of IRB packet for centers to share with local IRB - PR-COIN onboarding IRB Legal (Appendix 2.13)
- Ohio Perinatal Quality Collaborative (OPQC) participation agreement tracker (Appendix 2.15)

Create an On-boarding Packet

Following the on-boarding meeting, the management team works with the center to complete an on-boarding packet. In that packet, the center team indicates who is locally responsible for completing certain activities, who should receive what type of communication, and who is interested in joining what workgroup. The method to be used for completing the packet may vary. The packet can be emailed and include electronic check boxes. SurveyMonkey can also be used to collect the on-boarding packet information.

The center should complete the on-boarding packet and send it back to the management team responsible for tracking the information. The management staff should use the on-boarding packet information to update the workgroup meeting calendars to include new participants and to update calendar invitations to key network calls, QI training, and other upcoming events. The management team is accountable for developing the trackers and other tools to keep the on-boarding packet information saved and updated over time.

Resources

- ICN Welcome Packet Informational Brochure (see Appendix 5.9 in Module 5: Engagement and Community Building)
- OPQC tracker (Appendix 2.16)

Set Up QI Infrastructure

Establish Action Period Calls

Action Period calls (AP calls) are monthly webinars that gather the network leadership, management and QI teams together with the participating clinical sites for the purpose of sharing updates, giving guidance or direction, and discussing progress made over the past month. These calls play a vital role in keeping the community informed and connected regardless of geographic location. They are also the primary platform for centers to learn what other sites are working on, while sharing successes and challenges to accelerate their own center's learning curve. The management team is responsible for setting up and managing the logistics of AP calls, while the QIS is responsible for creating the content and facilitating the calls. For more details about AP calls content development, see Module 4: Quality Improvement.

The management and operations teams are involved in setting up the calls, communicating with the centers and presenters before the call (reminders, etc.), executing the call at the scheduled day and time, and following up after the call (action items, reminders etc.). As the network grows, it is recommended to offer two call options each month, where the same content is repeated during both calls. Clinical staff need only participate in one of the two calls offered, thus allowing for greater overall participation, depending on individual availability. This is especially helpful when sites are located in different time zones. The best approach to accomplish this task is to first identify time slots that work for the leadership team (PI, Co-I, QIS, data lead, etc.). The time slots can then be shared in a Doodle poll with participating sites to identify overlaps. It is recommended to identify time slots with a regular frequency (for instance: 1st Monday of the month from 12pm to 1pm ET and 4th Thursday of the month from 3pm to 4pm ET). Regular patterns help create a habit and expectation with network care centers. This regular cadence also provides the network leadership and management teams with consistent time secured to prepare for the call and gather assignments from the sites between calls.

Resources

- OPQC AP call roles and responsibilities (Appendix 2.17)
- AP call RACI (Responsible, Accountable, Consult, Inform) Matrix (Appendix 2.18)

Monitor Plan-Do-Study-Act Ramp Cycles

Key to quality improvement methodology, a plan-do-study-act (PDSA) ramp cycle is a set of related, repeated cycles focused first on testing and refining and then implementing and sustaining a common change strategy. Between AP calls, it is customary to track progress made by the participating centers in testing new changes in their clinics.

The management team is usually responsible for creating monthly reports for the QIS to review. Such reports can take many forms. They are usually generated out of a series of questions for centers to answer on a regular basis (i.e. monthly). SurveyMonkey or REDCap can be used to collect the feedback. The answers to these questions are compiled and shared with the QIS for review.

Monthly reports provide valuable information to the QIS that will help them give targeted coaching as well as meaningful feedback during the AP calls. For details about how monthly reports help QISs in their coaching and training efforts, see Module 4: Quality Improvement.

Establish Learning Sessions

Learning sessions (also called Community conferences) are one- to two-day in-person conferences during which participating centers come together to review past activities, identify key learnings and successful change strategies, and finalize change packages. It also serves as a milestone at which to launch a new initiative, introduce a draft change package or kick off a new breakthrough series cycle during which centers will focus on a brand-new set of activities. It is recommended to host at least two learning sessions a year, typically six months apart. To learn more about learning sessions, their standard agendas, and how they are used to propel the work of the network, see Module 4: Quality Improvement.

The management and operations teams play a critical role in planning and executing the learning session. The QIS is responsible for the creation of the agenda, the identification of the presenters, and the development of any pre-work packet for centers to complete before the conference. The management and operations teams (may include an event planner, depending on team composition) teams are traditionally responsible for logistics and coordination of the event, including venue, contract, catering, AV equipment, folders, printouts, badges, registration promotion, etc., and communicating about the event with centers, parents, and patients.

While most learning sessions are in-person, larger or more established networks might also be interested in virtual learning sessions. Including virtual attendees to an in-person learning session is also an option, especially in circumstances where travelling is not recommended for patients and patient families.

Pharmaceutical groups may be interested in sponsoring a learning session by hosting a booth or an event at the learning session. If the learning session will provide continuing medical education (CME) to the attendees, the management team should disclose the collaboration with pharmaceutical groups to the institution that will be crediting the CME and proper processes should be followed to ensure compliance with CME requirements.

Resources

- Workplan for Learning Session (contact the Learning Networks Program Event Planning Center of Excellence for the latest template, LearningNetworks@cchmc.org)
- Workplan for Virtual Learning Session (contact the Learning Networks Program Event Planning Center of Excellence for the latest template, LearningNetworks@cchmc.org)

Initiate CME Credit

Continuing medical education (CME) credit can be claimed for learning sessions. Offering CME credits can be a powerful recruitment and retention tool for certain centers. A planning conversation with the relevant CME office should take place at least four to five months before the learning sessions. The management team is responsible for initiating this conversation.

During the meeting with the CME office, the CME team will share with the management team a timeline by which they will need certain deliverables completed, including objectives of the learning session, gaps in learning, rationale as to how the learning session will address such gaps, etc. The agenda and list of speakers as well as a preliminary budget will need to be reviewed and approved by the CME group. Speakers will need to attest their talk is independent from any outside influence, such as industry funding. If using a CME group within an academic institution, it is likely that the management team will be prompted to complete all deliverables online. Any financial support from commercial entities will need to be disclosed and a contract between the CME group and the commercial entity itself will likely need to be signed. The contract will help clarify what the commercial entity is allowed to display at the learning session based on the nature of the financial support. For more details about CME, contact the CME group you will be engaging with.

Provide QI Training/Coaching

Between AP calls, the QIS touches base with participating centers to review their PDSAs and address any challenges. The operations team plays an important role in setting up these QI training/coaching calls. It is recommended to organize group coaching as much as possible to allow centers to keep learning from each other instead of relying exclusively on the knowledge and expertise of the coach. Learning labs are one model used in learning networks to organize such group coaching (see Module 4: Quality Improvement for details). The operations team can help with identifying common time slots and scheduling these coaching calls on an as-needed basis.

Additionally, some QISs like to on-board all new centers to the quality improvement methodology used in the network through a full-fledged training program. Such QI training can be generic, or custom made. In the latter case, the QIS will develop a QI training program specific to the network. QI training can be a great way to bring centers together and demonstrate value to a network by teaching teams the basics of QI. It is also a mechanism that allows the QIS to collect important information from the centers through the pre-work assignments. Indeed, as part of pre-work to complete before training sessions, the QIS may request centers submit data. This data can be used to create run charts and control charts to visualize the quality improvement effort that is going on at each center and allow for comparison of performance if possible. As centers submit their pre-work, the QIS can assess progress and identify top performers that will present at the next AP calls. Again, the management team can help schedule the QI training, aiming for opportunities to host group trainings as much as possible. For more details about QI training, see Module 4: Quality Improvement.

Resources

- IHI Open School course catalog

Initiate Maintenance of Certification

Maintenance of Certification (MOC) is another added value for centers to participate in learning networks. Physicians have to complete at least 25 points worth of QI activity to receive MOC Part IV credit through the American Board of Pediatrics (ABP). MOC Part II can also be offered. MOC is also available in adult care through medical specialty boards. The management team should check with the American boards serving the medical specialty in question if MOC can be offered.

Learning networks can be set up to authorize centers to use their ongoing QI activities in the network as the basis for claiming their MOC. The management team is responsible for working with the MOC organization and completing the required paperwork to have the network recognized as a vehicle for Part IV and II MOC. To see examples of typical questions asked by MOC entities to start the process of adding a learning network to the ABP Part IV MOC portfolio, contact the MOC Office for the latest application.

Set up the Community Engagement Infrastructure

The management team is often directly involved in supporting the nascent parent and/or patient group. For information about why having a Community Engagement Group is important, see Module 5: Engagement and Community Building. It takes only one parent or patient lead to get started with structuring the engagement work in a network.

The management team is responsible for helping the network lead parent/patient with setting up community engagement workgroup meetings, providing assistance with identifying group members, inviting members to the meetings, and following up with members after the call. The management team plays the role of a liaison, making sure to escalate questions raised during the call for which leadership or QI input is needed. The management team can also be helpful to a parent group in providing tools and templates to create engagement policies, workgroup structure, and processes. The engagement group may also lead some network-level projects for which support from the management team is required. A project may require consent to be collected, or non-disclosure agreements to be signed, or special AV equipment to be secured.

Manage Invoices and Review Expenses

With oversight from the management team, the operations team should work with the business office or accounts payable team to produce invoices, including the ones used to collect the site fees, if the latter is used as a source of revenue. Depending on the role that the accounting team will play, the management team may need to develop a tracker to document the expenses and revenues throughout the year. Any over- or undercharge should be addressed promptly and escalated to the leadership team as needed. Copies of invoices should be saved in a secured file and used as support documentation during monthly expense review.

Execute the Communication Plan

The operations team is responsible for executing the communication plan developed at the end of the design phase. Once a network brand has been developed, template slides, letterheads and other communication vehicles should carry the network logo. Social media accounts should be created under the name of the network and have a dedicated person assigned to promoting online engagement (e.g., ICN twitter, PR-COIN Facebook).

The operations team is responsible for developing the network's newsletter. The newsletter should inform the participating centers about any important network-wide activities, reminders of upcoming events or due dates for assignments, and spotlight any learning from the PDSA ramping cycles. Constant Contact is a familiar platform used for building sleek newsletters. Other activities may also be included in the communication plan, such as a patient-facing blog, media relations program, webinar series, etc.

Additionally, the operations team needs to make sure the network has a platform to share documents and document its learnings. Such a platform might be different from what the network relied on during the design phase. During implementation, networks need a platform through which participating centers can easily access and locate what they need. All tools, change packages, workgroup information, and upcoming events/calendars should be stored there. It is recommended that such a platform be password protected and only accessible by committed centers. The operations team should work with the vendor that will provide the platform to determine the user access rights and administrative rights. The operation team will be responsible for granting the access and updating the content on the platform.

The operations team is also responsible for developing the network contact list, especially the names and contact information of the clinical team members, and other relevant contacts, using basic systems such as Excel or Access to more complex ones like Salesforce.

Execute the Project Plan

All activities described above should be tracked using a project or workplan. Annual network workplans will look different from the design workplan described in the section "Develop a Design Workplan" but will be important to ensure all the nascent operational pieces of the network are executed on time and in a coordinated fashion.

Complete Phase 2 and Move on to Phase 3

By the time Year 1 of Phase 2 ends, the management team should ensure the following deliverables have been finalized and made available to the entire team:

1. Recruitment: Webinars, recruitment materials, on-boarding packet and process, contact list of members, tracker of IRB and legal approval.
2. QI Infrastructure: Calendar of AP calls and QI training, workplans for learning sessions, MOC and CME applications, tracking process of PDSAs.
3. Program Management: Sustainability plan, project plan, communication plan.

During the subsequent years, the management team needs to monitor the operations of the new network, modify processes as new teams join, and ensure needs are met with adequate staffing and resources. As the network grows in size and maturity, the management team needs to assist the leadership team in sustaining the network.

PHASE 3:
SUSTAINING THE NETWORK

PHASE 3

Growth and Spread

As the network grows in size, participants must assess its capability to spread its learnings. A network that knows how to raise awareness of its successes is a network that will likely attract prospective centers. More centers, however, mean more pressure on the infrastructure. The role of the management team is to monitor the capability of the infrastructure to absorb new members and deliver on its promises.

Different management models have emerged for networks of various sizes. When a network includes more than 30 centers, it may make sense to organize the centers into subgroups characterized by common characteristics. These subgroups may require their own infrastructure, with their own set of webinars, monthly reports, QI training and coaching. For example, as the network grows, Learning Labs can begin to replace Action Period calls, where the sites group themselves by outcome or intervention. This structure allows for a larger group of centers to still maintain the benefits of a smaller group discussion and shared learning around a similar outcome or intervention. A step approach can be designed, where completing the interventions in one learning lab gives sites the tools needed to succeed in the next learning lab. This structure allows for both newer participating centers and established participating centers to continue to learn and benefit from the network. This model is prevalent in large learning networks with more than 100 clinical sites, where a single monthly call for instance is no longer feasible. For more details about Learning Labs, please read Module 4: Quality Improvement.

Along the same lines, the planning of a learning session gains in complexity as more centers join. Though still within a similar 1-3-day timeframe, learning sessions can branch out with break-out sessions and content tracks, to ensure that each site is benefiting from the event, regardless of how new or advanced they are in the network. Similarly, various communication and management platforms have been used, as a knowledge management platform used to support 20 centers may not be adequate if the network grows to 35 or even more.

The management team is responsible for working alongside the QI, data, and leadership teams to assess the infrastructure needs as the network grows. More specifically, the management team should revisit the pro forma financial projections every year and the required staffing structure and hardware/software needs of the network. For more information about how to estimate future needs of the network and corresponding staffing composition, see Module 3: Financial Sustainability.

Growth often comes with additional patients and caregivers joining a network, who may find themselves overwhelmed with the myriad of workgroups and opportunities to participate at the network and local levels. Platforms such as NationBuilder can help structure the community in a way so that subgroups receive appropriate communication pieces relevant to their needs and can quickly engage on what matters to them. The operations team is responsible for managing such platforms and coordinating the external communication to the community. For more information about NationBuilder and how to engage network communities, see Module 5: Engagement and Community Building.

Capture and Develop New Knowledge

As the network expands, innovation and ideas are generated in multiple places across the network sites, making it more challenging to identify, document and spread them. Developing solid processes for reporting back new generated knowledge is critical. The knowledge generated from the QI work should be captured through the monthly reports and the performance charts described in the sections "Set Up QI Infrastructure: Monitor Plan-Do-Study-Act Ramp Cycles" and "Set Up QI Infrastructure: Establish Action Period Calls." The learnings should be summarized in the AP calls, vetted by the leadership team, documented in change packages, presented at learning sessions, stored on a common knowledge platform, and used in on-boarding materials to bring new centers into the networks. All learnings should be taught to the new centers and become part of a "bundle" of evidence-based processes that have proven to lead to improved outcomes (also called a Play Book). The QIS plays a central role in capturing the learnings, and the management team plays an important role in ensuring the learnings are curated, shared appropriately, and available to all.

In learning networks, knowledge is also generated from more traditional research, with data used to answer research questions. The management team is responsible for co-facilitating the network research workgroup and developing the procedures the network will follow when pursuing research interests. Data sharing policies, processes, and expectations, and authorship policies are standards that the management team can develop and present to the network for approval. As research studies get approved and supported by the network, the management team is responsible for tracking their implementation and outputs, including publications.

Resources

- Authorship policy, data sharing expectations, and data sharing policy (contact the Learning Networks Program Project Management Group for the latest template, LearningNetworks@cchmc.org)

Best Practices and Standard Operating Procedures

As a network grows, it becomes imperative to document the processes that teams follow when rolling out their work. In the early stages of a network, the familiarity of the team members with each other tends to delay the creation of standard operating procedures. Teams are comfortable with each other, and the first new sites have a greater tolerance to mistakes because they appreciate the uniqueness of the work being launched. However, as the network matures, greater expectations are placed on network leadership and operations teams to act as experts in their domains. Greater expectations create the need to document processes so the infrastructure can operate independently of a specific person (e.g., the project manager). The standard operating procedures (SOP) should include details such as what activities to implement and how to implement them. What role is responsible for executing the task should also be identified.

Resources

- Standard Operating Procedure template (contact the Learning Networks Program Project Management Group for the latest template, LearningNetworks@cchmc.org)

Adapt Governance Structure

As a network grows, the operations change, and with that the governance model changes as well. Organizational structures that worked at the design stage or during the first couple of years of existence may not be adequate when the network reaches a certain size or maturity. New committees may need to be created, new leaders may emerge, and new expectations may appear around decision making.

As an example, growing networks may decide to create several leadership roles that include Clinical Director/Leader, Executive Director/Leader, and Scientific Director/Principal Investigator. The role of the directors/leaders address such topics as shaping the strategy and vision of the network, recruiting and retaining participating centers, fundraising efforts, financial oversight, and content expertise. While in Phase 1 and the beginning of Phase 2, all leaders in the network may have worked together to fulfill these roles, it is likely that in Phase 3, they will differentiate the roles.

In addition to network leaders, a Board of Directors would act as a governing body to develop policies, provide oversight, and establish long term strategies. Members of the board should be diverse and include internal and external members of the community.

Resources

- ICN leadership role descriptions
    - o ImproveCareNow Clinical Director
    - o ImproveCareNow Executive Director

Research/data coordinators at every center may choose to meet regularly to share best practices around data collection and data entry, or operationalization of a new intervention.

A network may decide to open its doors to prospective centers and have them participate for a limited time in the life of the networks as if they were members, so they can make an informed decision about joining. What type of benefits these prospects will enjoy during the trial period and what level of data will be shared with them are all relevant governance questions for networks to address. Integrating parents and patients in the leadership decisions of a network is another big step in the life of a network that changes the governance model.

Parents who may be grouped as a committee and participate on selected interventions, may now be asked to act as leaders and make decisions on the future of the network alongside the network leadership.

The ability of the network to adapt its governance in a way that ensures all voices are heard is critical to its survival and growth. Finding ways to represent all stakeholders in the decision-making process is the ultimate goal.

Deliverables Due in Phase 3

During Phase 3, the management team should ensure the following deliverables have been finalized and made available to the entire team.

1. Business plan (see Module 3: Financial Sustainability Appendix 3.1)

2. Organizational structure (Appendix 2.19)

3. Clear governance policies

4. SOPs for every activity handled by the network

YOUR IMPROVEMENT SUGGESTIONS

We strive to provide the best guide and resources for you. How did we do?

Your feedback helps us continuously improve. Please share your feedback with us: https://www.surveymonkey.com/r/ZHGJF88. Thank you!

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