EXPERIENCE REPORT

Building responsive governance for learning networks

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Abstract

Introduction: This article describes a strategic governance review of Improve Care Now (ICN), a learning health network focused on improving clinical outcomes for adolescents with Crohn’s disease and ulcerative colitis (IBD). ICN is organized around an “enhanced” patient registry and collaborative community of patients, parents, clinicians, and researchers.

Methods: The engagement included a review of ICN’s governing documents, interviews and facilitated sessions with ICN stakeholders, and desk review to identify governance best practices that applied to ICN.

Results: The review made recommendations to establish a plan to transition ICN’s governance to its community, build pipelines for future network leaders, escalate uncommon data-sharing decisions, and design safe online spaces for community members.

Conclusions: Governance can provide the scaffolding to help networks grow: organizing structures that support consistent, well-documented, and inclusive decision-making.

KEYWORDS
community management, data collaborations, data sharing, governance, learning health networks

1 | INTRODUCTION

Learning health networks—collaborative communities of patients, clinicians, and researchers—are built on trust to maintain institutional membership, to promote cooperation over competition, and to encourage patient co-creation and engagement.1 Maintaining that trust beyond an initial founding community requires good governance organized processes for collective decision-making.

At ImproveCareNow (ICN), the network’s operations had begun to outgrow its governance. This paper reflects on a strategic governance review conducted for the ICN Network in the fall and winter of 2019.2 The review’s core goal was to help the Network correct this misalignment and resolve persistent ambiguities in its governance.

2 | BACKGROUND

Founded in 2007, the ICN Network is a learning health network focused on improving clinical outcomes for children and adolescents with Crohn’s disease and ulcerative colitis (IBD; see, e.g., Seid et al3 and Marsolo et al4).

The term “learning network” refers to a collaborative learning health system that is organized as an actor-oriented network.5 Actor-oriented networks emphasize distributed decision-making and self-organized problem solving among large groups.5 Britto et al. write that actor-oriented networks have three components: “(1) aligning participants around a common goal; (2) standards, processes, policies and infrastructure to enable multi-actor collaboration; and (3) a commons where information, knowledge, resources and know-how to achieve that goal are created and shared.”5

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Here, the ICN Network is organized around a collaborative patient registry used to drive quality improvement and research initiated by network member centers. Along with its registry, ICN maintains a multi-stakeholder community of patients, families, clinicians, researchers, and other professionals that are committed to collaborative problem-solving and peer-produced resource production. The ICN Network community holds regular conferences, hosts a resource library of community contribution, and maintains private community forums, along with a social media presence.

As of this writing, the ICN Network has 106 member centers, all but nine of which are in the United States (seven in Belgium, 1 in the United Kingdom, and one in Qatar). The bulk of ICN Network's funding comes from member dues.

At the time of the engagement, responsibility for the ICN Network was largely split between Cincinnati Children's Hospital Medical Center (CCHMC) and ICN Inc., a Vermont-based nonprofit organization. ICN Inc. collected dues from member networks, had a board of directors, and was a party to the Network's participation agreements. However, ICN Inc. had no staff, and operational responsibilities for the ICN Network were subcontracted to CCHMC, including hosting the registry, community platforms, and institutional review board (IRB). (ICN Inc. has since hired an executive director).

(Note: In this paper, the author uses “ICN” or the “ICN Network” to refer to the broader learning network: the community of member institutions, clinicians, researchers, patients, and parents. The author uses “ICN Inc.” to refer to the nonprofit corporation involved in the ICN Network’s management).

The engagement’s final report, which ICN Inc. published in summer 2020, offers 27 recommendations that touch on nearly every aspect of ICN’s operations. Here, I focus on four issues that are relevant to learning health networks and others engaged in similar health data collaborations: (a) achieving operational clarity and continuity; (b) building representative governance; (c) settling data ownership questions; and (d) designing community platforms.

### 2.1 Achieving operational clarity

Although a network’s activities are intended to be self-organizing, a network’s policies require central coordination. A network depends on leadership to help set its mission and scope, define processes and policies, organize decision-making, and maintain common pool resources. This is often critical at a network’s inception, where a small number of parent organizations might invest in a network’s startup phase until it can build a community large enough to sustain itself. This transition from incubation to independence may take years, and there are not always clear indicators that a collaboration is ready for the move. Much like an organizational spinning off a subsidiary, transitioning a network to operational independence often requires a deliberate disentangling between a network and its parent organization.

Here, from a basic organizational governance perspective, the ICN Network was in limbo. While its activities resembled a distributed network architecture, its operations were still effectively controlled by a single entity—CCHMC. The operational, contractual, and governance relationship between the ICN Inc., CCHMC, and the ICN Network was ambiguous. Policies that governed the network’s operations were out of date or under documented. Resolving that ambiguity would be key to the network’s continued growth.

### 2.2 Building representative governance

Empirical studies of multi-stakeholder collaborations suggest that fairness (along with inclusiveness, clarity, and conflict resolution) is one key to effective governance. That is, a sense that what an individual gets out of an initiative is proportional to what they put into it. A related analytical frame for determining who ought to be represented in a multi-stakeholder collaboration is based on influence: the more a stakeholder’s power to influence a collaboration, the more essential it is to involve them in the collaboration’s governance. Conversely, the more a collaboration’s power to influence a stakeholder, the more essential it is to involve that stakeholder in the collaboration’s governance.

Applied to networks built around health data, these heuristics show cracks. While proportionality may drive a sense of fairness for a network’s practitioners, a network that delivers proportional benefit to patients who participate in its governance (besides compensation for time) risk favoring patients who can afford to participate, furthering health inequities. Moreover, past a certain stage of growth, a network’s influence is likely to reach patients beyond its immediate community—via new research and protocols. While patients may benefit from a network’s activities, they may also be exposed to risks from the network’s use of or sharing of data, or miss the opportunity to influence the network’s allocation of resources. Together, this suggests that networks have a heightened obligation to involve patients in their governance and ensure that patient involvement does not further cement health inequities.

Here, ICN’s commitment to stakeholder representation was genuine, but informal. While parents and patients were involved in the network’s governance, they enjoyed few formal guarantees or protections. ICN did not term-limit board members, leaving it vulnerable as several members were poised to retire or depart.

### 2.3 Data ownership

ICN’s member centers contribute data to an enhanced patient registry. Patients of ICN member centers sign a broad consent form authorizing participation in the registry and accompanying study. ICN has a mature process and CCHMC-managed IRB for handling routine study requests from internal researchers and minimizing or eliminating PHI in registry reports. Machine learning advances enable new data partnerships with external parties, and the productization of analytic and predictive models. These products and partnerships could create persistent risk and inequity for patients that traditional human subject review may struggle to fully account for. They could also generate value and revenue that is difficult to predict in advance or reallocate after the fact.
Regardless of the relatively permissive regulatory environment in the United States, uncommon or unexpected data partnerships could threaten the trust bonds that hold a network (or other data collaboration) together, whether among members or between patients and the network. Networks need processes for assessing and handling non-routine data requests and ensuring that the network does not bear the burden of a partnership’s uncertainty.

Here, ICN’s processes for handling external data requests were unsettled, in contrast to a mature process for managing internal requests. In addition, a lack of clarity within ICN’s internal governing agreements contributed to disagreements about who “owned” the registry data: that is, who could permit use of the data, who holds rights over data derivatives, and who would be entitled to receive value from the data’s use.

2.4 | Designing community platforms

Building a healthy online community is a nontrivial task. The ubiquity of social media makes it difficult for alternative platforms to break through, but Facebook’s targeted advertising model can put patients at risk (see, e.g., Lecher12). Profile or group data could be used to identify patients and parents, target them with advertising, or make inferences about a person’s health.

While networks may choose to rely on social media for outreach, they are not good choices for private interactions and discussions among community members. While these interactions may not rise to the level of PHI, they are still potentially sensitive, and patients and parents may have expectations of privacy.

At the time of the engagement, ICN was in the early stages of preparing new private community discussion platforms. While ICN used Facebook and public social media to notify members of events, detailed recommendations on social media use were beyond the scope of our work.

3 | METHODOLOGY

The engagement had three primary components:

1. A review of the ICN Network’s key governing and operational documents. While not a compliance and regulatory review, this process aimed to reconstruct how the ICN Network was structured on paper, based on its implemented agreements and written policies.

2. Interviews and facilitated sessions with ICN staff and stakeholders. These interactions helped illustrate the ICN Network’s day-to-day activities, and where those activities may differ from written standard operating procedures. Workshops with a broad mix of ICN stakeholders helped shape drafts of the report, and prioritize the report’s recommendations for ICN leadership.

3. Finally, a desk review of best practices in multi-stakeholder and data governance was conducted. While not a comprehensive literature review, this research helped guide and evidence the report’s recommendations, and provided illustrative examples for the Network leadership as they implemented the recommendations.

Ultimately, this engagement was designed to be facilitative, rather than directive. That is, rather than directly writing new policies and contracts for the network, the report’s recommendations identified deficiencies and reframed possible solutions, while leaving the actual implementation to ICN.

Why? Governance is more than a network's policies; it is the continuous process for making policies and decisions, and determining whose input is needed before a decision can be made. The process of implementing new policies can itself strengthen the trust bonds that hold a collaboration together and ensure that all members share a common understanding of how the collaboration operates.

4 | RESULTS

4.1 | Achieving operational clarity: Deliberate transition planning

Learning networks and other data-driven collaborations sometimes begin as projects within individual organizations. As a network’s community grows, it sometimes makes sense for the network to reorganize as a discrete legal entity and begin to transition control from the network’s parent to the community, who eventually assume control of the independent entity. Networks without an independent entity—usually a nonprofit or a trust—are likely to be dominated by their parent organization, even unintentionally.

Although the ICN Network had incorporated an independent entity (ICN Inc.) at the time of the engagement, ICN Inc. and Cincinnati Children’s respective operational roles in the ICN Network were poorly defined, and there was no plan for ICN Inc. to gradually assume responsibility over the network. One consequence of this was that some of ICN’s policies had begun to fall out of date with the network’s actual practices.

Figure 1 illustrates one model for transitioning a network to independent governance (Adapted from Goldstein13). A network may start as a project within a parent organization. Over time, operational, financial, and legal responsibilities can be transitioned to a newly formed independent entity. The parent organization retains a gradually diminishing governance presence, such as via a board seat (or seats) that only the parent organization can remove. As with any spin-off, the goal is to allow a child entity to become self-sufficient, while providing backstop capabilities of a larger parent organization for as long as necessary.

Here, the report encouraged ICN Inc. and CCHMC to begin a gradual, formal transition process for ICN Inc. to assume operational control over the ICN Network. This included adjusting core data-sharing agreements to include ICN Inc. in the data chain of custody, identifying operational responsibilities within the network and plans for transferring them, and building a board of directors who was deliberatively representative of the Network community. CCHMC retained a formal role in the network’s governance during the transition.
A true spin-off may take years to execute, and may not be suitable for all networks. The ICN Network benefits from a substantial, dues-paying membership. Not all learning networks will be able—or should—follow ICN’s path: they may be too small, or too tightly integrated with a parent institution. But networks that do should incorporate transitions to independence into their long-term planning, with operational milestones to ensure stable financial and operational footing.

4.2 | Building representative governance:
Establishing leadership pipelines

Community-led learning networks benefit from a deliberate approach to representation, via written policies and bylaws. To support equity long term, networks must build pipelines to raise future leaders through the network, commit resources to supporting patient involvement, and incentivize research that closes health equity gaps.

Regardless of the stakeholders involved in a network’s governance, networks can be vulnerable when the founding leadership or board moves on or retires. Mitigating this vulnerability requires not only succession planning, but also mandated rotations in key governance roles. Board members should be termed and term-limited, and networks should focus on building pipelines of diverse stakeholders who can assume future leadership roles.

Here, ICN was facing both a lack of formal commitment to representative governance and a lack of formal succession pipelines. Adopting best practices from nonprofit governance, the report recommended a long-term board structure that meets the network’s stakeholder representation and expertise needs. To ensure that representation carried to meetings, the report recommended establishing quorum requirements and other stakeholder protections for parents and patients. A common complaint of parents and patients was that committee and council meetings took place during the workday, when they were unable to attend because of professional or school obligations.

However, this only establishes a leadership structure for the current moment. Well-governed community-driven organizations must invest in future generations of network leaders: by creating opportunities for incremental involvement in the network, and investing to support and subsidize that involvement. To begin the process of establishing leadership pipelines, the report recommended adopting the role of ICN’s semi-formal committees and councils to help the Network identify and train future leaders and provide opportunities for board members to stay involved after their term limits are up. In addition, the Network needs to invest in training and capacity building for all members of the ICN community, to help them better understand how the network operates and the potential benefits and risks that data may yield.

Much headway has been made on establishing best practices for involving patients in research collaborations. Learning networks like ICN, which are built around a decentralized, actor-oriented communities, must ensure that their inclusiveness continually matches their influence. And like any organization, they must build infrastructure that supports leadership successions by making capacity building and training widely available to network stakeholders.

4.3 | Data ownership: Accounting for uncertainty

As learning networks accumulate more data, and as computing capabilities for analyzing data continue to advance, networks may find themselves vetting complex requests for data, beyond routine research requests from in-network researchers, which are already well-covered by the network’s institutional agreements and consent forms. Data requests that are uncommon or not well covered by a network’s policies create the possibility of disputes. Member sites may disagree about the terms of external partnerships, even if they pass regulatory muster.

Here, as the network grew, ICN faced the potential for data sharing and ownership disputes. In addition to adopting data use agreements that limit secondary uses and derivatives, the report recommended an escalation framework for evaluating data requests. While routine requests from in-network researchers can be delegated to network staff, data exports and requests from third parties require approval from network leadership, the board, or the broader network membership.
Other networks or collaborations can adopt this approach, which is adapted from organizational governance. Staff can handle an organization's routine, low-risk decisions, while routine high-risk decisions are escalated to leadership. For decisions that are both uncommon and high risk, an organization's board (or a company's shareholders) may step in. In addition, an organization may require approval from stakeholders who are likely to be affected by a decision, especially negatively. This decision-making structure is especially useful when applied to potential data-sharing partnerships, which may not be easily predictable in advance.

Over time, networks or other multi-stakeholder data collaborations may face disputes about commercializing data, and how to allocate value within a multi-member network. While a deep review of options was beyond the scope of this engagement, a well-governed independent network may be the most appropriate neutral arbiter of value distribution.

### 4.4 Designing community platforms: Creating trusted space

An emphasis on networked community building distinguishes learning networks from generic data-sharing collaborations. For practitioners, community connections can spark new research and collaboration opportunities. For patients and parents, peer support can have a positive effect on outcomes and mental health. In addition to event programming, learning networks like ICN use online platforms to build connections between community members. A network may use privately hosted community forums to promote discussion and deeper engagement, while maintaining a presence on public media to promote events and improve the network's discoverability.

At the time of the engagement, ICN was preparing new private community platforms. As a result, the report focused on general design principles for building-trusted community spaces for patients, with a particular focus on who can access community spaces. In particular, the report recommended that ICN creates reserved spaces for patients and parents, and prohibit scraping or any data collection of content posted to ICN's private platforms. While this activity may be legally permissible, parents and patients may be reluctant to use the community space if they suspect their activity could be monitored or repurposed. The report recommended building separate sub-forums for third parties to interact with and connect to patients. In part because the community platforms were unbuilt, detailed content moderation and enforcement recommendations were beyond the scope of the engagement. As a start, the report recommended that ICN implement a code of conduct that covers all of its community spaces, online and offline. While a network's code of conduct can—and should—be adapted from existing sources, each network will need to set their own expectations about enforcement in conjunction with community members.

While ICN used Facebook and public social media to notify members of events, detailed recommendations on social media policies were beyond the scope of our work. And even once a safe community has been established, an enduring challenge for learning networks will be growing that community without relying on large social media platforms. Doing so successfully will require networks to reimagine invitations to patients and their families—for example, a boilerplate study consent form could be repurposed into a plain-language, friendly invitation to join a network's online community.

### 5 DISCUSSION—GOVERNANCE AS A HABIT

This review was focused on a single-learning network, itself an uncommon form of data-sharing collaboration. While the recommendations were grounded in best practices for governance, they were ultimately driven by ICN's needs and idiosyncrasies.

A running theme throughout the engagement was a need for the network to build habits from previously static policies. ICN's data-sharing procedures were professionally written, but outdated. ICN Inc. had a board that was representative of the network, but no plan for drawing successors from the community ranks. Parents and patients were included in meetings, but not always formally accommodated. To prevent policies from growing stagnant, ICN and other learning networks may need to adopt a quality improvement approach to managing the network's governance and written policies.

This suggests an opportunity for future research: qualitative descriptions and quantitative measures of a learning network (or other data collaboration's) organization and governance. More work is needed for networks to describe their operations, evaluate them, and tie governance to clinical and research goals, especially as their communities grow.

### 6 CONCLUSION

As networks grow, the personal ties that bind small communities together become strained. Governance can provide the scaffolding to help networks grow: organizing structures that support consistent, well documented, and inclusive decision-making. But networks ultimately succeed not just when they have well-crafted policies, but when they use those policies to be more responsive to changing technology, to uncertain decisions, and to the evolving needs of their community members.

### CONFLICT OF INTEREST

Cincinnati Children's Hospital Medical Center and ImproveCareNow paid the author to carry out the review described in this article. After the review was completed and separate from the review arrangements, the author has provided consulting work to Hive Networks, a company that builds software for managing learning networks.

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