CHCS Center for Health Care Strategies, Inc.

Complex Care Program Development:
A New Framework for Design and Evaluation

By David Labby, MD, PhD [*]

IN BRIEF

While medical-technological interventions undergo robust research and design protocol to "come to market," there is no formal development "process" for care management programs serving complex populations. Absent a formalized development process, providers and policymakers are often called on to answer the fundamental question: *Does this complex care program work?* In this brief, author David Labby, MD, PhD, former chief medical officer for Health Share of Oregon and a long-time innovator of care improvements for vulnerable populations, describes a proposed framework to help guide the development and refinement of programs targeting this population.

> *Clinicians really like our program. We seem to be getting good results. But we can't really prove its effectiveness with strong data and hope no one asks.*
>
> *They wanted us to come up with a proven effective program in 12 months. Completely unrealistic.*
>
> *We created a comparison group from claims. It made our program look good, but there are major non-claims differences between the groups and we don't believe it is really accurate.*
>
> *We tried to do a randomized controlled trial, but we kept changing the program so it is hard to know what we were testing.*

These statements likely ring familiar to anyone seeking to prove the value of complex care programs. While most medical-technological interventions (e.g., drugs or devices) go through a well-described series of rigorous developmental steps over an average of eight to 12 years — including initial research and design (R&D), testing on non-human subjects, and phased human safety and effectiveness trials — there is no formal development process for "care management" interventions. Most successful complex care programs, like medical-technological interventions, use some type of iterative development process to determine what "works best" in engaging and delivering services to their target population. However, there is often little formal recognition of the critical role that this process plays in their life cycle.

This brief, a product of the *Complex Care Innovation Lab* made possible by Kaiser Permanente Community Benefit, is part of a series exploring opportunities to improve evaluation of complex care programs.

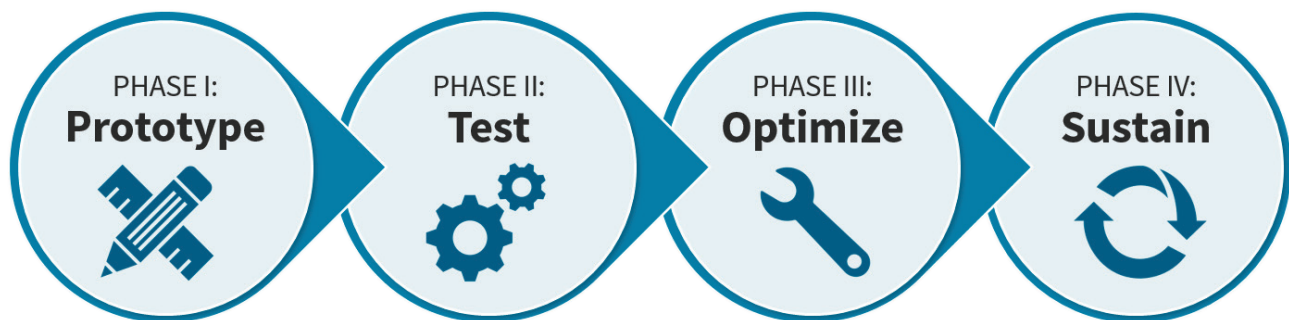## complex care
INNOVATION LAB

Absent a more formalized development process, health system organizations and policymakers legitimately want to answer the fundamental question: *Does this complex care program work?* Organizational leaders need to decide whether to continue supporting a program in development or commit resources elsewhere. Time lines are usually short given performance and budget pressures. As a result, many complex care programs are subjected to full summative evaluation or litmus tests before they have been fully implemented and tested. Such premature evaluation risks inaccurate conclusions and potentially wasting initial investments.

While complex care programs are spreading, most would argue that this is an emerging field of clinical practice with much left to learn and only the beginnings of a rigorous evidence base. A common understanding of and framework for evaluating the overall complex care program development process would allow both organizational leaders and clinical innovators to ensure that an initiative is "on track," by both focusing on the most salient developmental tasks and questions, and showing progress through meaningful metrics. Given the level of experience that now exists due to the increasing spread of complex care programs, it is time to start defining that process.

Conceptual Model for Complex Care Program Development

Following is a proposed "phased" framework for complex care program development. It starts by suggesting common tasks that complex care interventions must undertake as they move from concept to implementation to full-scale deployment. It then outlines considerations relevant for each phase, as well as proposed criteria for assessing success. It attempts to build on what is familiar as well as suggest areas for further exploration. Much of what is proposed in Phases 1, 2 and 4, *Prototype Development*, *Initial Testing*, and *Sustainability*, follows the kinds of questions articulated in quality improvement or program development literature. Phase 3, *Program Optimization*, however, is a more novel approach that is most likely to need further discussion and experimentation.

Exhibit: Complex Care Program Development Framework

Phase I: Prototype Development

This initial phase is used to identify what innovative approaches are possible to help solve systemic challenges. Key questions explored in this phase include:

- ***What innovative approaches are possible to help solve key organizational or system-level challenges?***

- ***How can we use the resources we have and that are potentially available to us in new ways to achieve system goals?***

To address these questions, the following considerations should be explored:

1. **Problem Analysis and Concept Development:** *What problem are we trying to solve based on health system goals and available data?*

   - What are the major drivers that produce the problem we wish to solve?

   - What potential "mechanisms" are available to achieve better outcomes?

   - What are the specific program objectives based on known, achievable benchmarks or expert opinion?

   - What level of investment would be required and what potential return on investment is anticipated?

   > *Success criteria*: Organizational leadership buy-in for program concept based on alignment with organizational priorities, leading to deployment of resources to support model design.

2. **Model Design:** *What changes are needed to achieve which improved outcomes?*

   - Who is the target population?

   - What are the major drivers of sub-optimal outcomes for the target population?

   - What skills and staff are needed to produce the desired outcomes?

   - What is the theory of action? Why should this intervention work?

   - Where should the program be located in the within the health care system, e.g., primary care, emergency department, health plan, pharmacy, etc.?

   - What are the projected program costs and funding needs?

   > *Success criteria*: Organizational and local delivery system leadership buy-in to program model design based on feasibility and on meeting system, provider and patient goals. Ultimately, securing commitment to partner in prototype development.

3. **Specification Development:** *Who are the local champions and "knowledge holders" whose buy-in and input is needed to guide optimal program design?*

- What are the specific program workflows, training, and supervision processes?

- What is the project plan, including timeline and measureable process and outcome performance targets?

- What is the best reporting and oversight relationship to assure continued alignment with organizational strategic and fiscal needs?

- What evidence-based practices can be included and/or adapted?

Success criteria: Completion of the initial program description and project plan reflecting the above elements, with signoff from local leadership champions and active support for formation of a team to test the new model.

Phase II: Proof of Concept Testing (initial launch and full testing in local context)

This developmental phase focuses on identifying whether the program is operationally feasible and acceptable to patients, providers, and program staff. Considerations to address during this phase include:

- What are the key tasks associated with launching (e.g., initial hiring and training, contracting with new partners) and implementing workflows (e.g., creating referral pathways)? What are the measureable and reportable milestones for each to keep implementation "on track"?

- How do we know the program is being implemented as designed? What data tell us the prototype design is working as expected or, if not, needs to be changed? What metrics do we have or need to create?

- How can the prototype team be engaged in "process improvement" adjustments to optimize success? What training do staff need to be able to make improvement part of their daily work?

- How can staff and patient feedback be used to establish program "value?"

- What needs to be communicated to stakeholders about the program's early successes, learnings, challenges, and potential in order to ensure ongoing support?

- What is sufficient time for full prototype implementation, fine-tuning, and adequate initial testing? When will sufficient "proof of concept" of the assumptions behind the program be obtained, even if it is not yet meeting all expectations? What are the metrics and qualitative findings that will establish this?

Success criteria: Ability to meet established process targets; positive qualitative feedback from staff and patients on program value; recognition of value of program by leadership and resources to continue or expand the program as key organizational strategic initiative.

Phase III: Program Optimization

In the program optimization phase, organizations are looking to understand whether program resources are being used in the most efficient way and generating the highest impact possible. Organizations should also consider improving how programmatic and community resources are being used in this stage. Programs should address the following considerations during this phase:

- Compared to overall results, what groups of patients have the best outcomes? The worst outcomes? How do we characterize or identify these subgroups to learn whether and how to refocus efforts? What are the key characteristics of the optimal target patient population?

- What kinds of interventions are most effective? Which staff are most successful in providing them? What data are available to make and support these decisions?

- What clinical or community settings provide the most opportunities for which interventions?

- What is the program's unique contribution versus what others in the provider system or community can do?

- Does the program produce unexpected outcomes, whether positive or negative? Is there evidence of harm?

- What other kinds of data and evaluation processes are needed to understand program's effectiveness?

Success criteria: Ability to describe what has been learned from the program and refocus effort as necessary to produce the highest value to stakeholders; confirmed alignment of program outcomes, as they are now understood, with organizational objectives; commitment to continued support for program implementation.

Phase IV: Program Sustainability

This final phase of program development examines whether the program is meeting organizational needs and priorities, and whether it is producing an adequate "return on investment" for stakeholders. The below considerations provide a guide for assessing program sustainability:

- What "returns" does the organization now expect from its investment in the program?

- Beyond lowered costs, what does the organization value from the program?

- How will the organization know program results are better than what would happen without it?

  » How rigorous an evaluation does the organization require to demonstrate positive program outcomes?

  » If a comparison group is required to demonstrate program effect, can the program describe the key characteristics of its target population with sufficient accuracy to identify a truly matched comparison group?

Success criteria: Ability to demonstrate adequate return on investment to stakeholders for program sustainability and continued development.

Next Steps for Enhancing Complex Care Program Development

Clinical complex care programs face multiple ongoing challenges. They must be:

■ Valued by system leadership in the face of competing demands;

■ Perceived as valuable by both patients and point of service providers;

■ Able to make a measurable impact despite not being able to control or simplify the multiple variables that produce outcomes; and

■ Able to adapt to evolving internal and external environments and stakeholder demands.

While there is broad support for focusing on the small group of high-need complex patients who use the largest portion of health care resources, given these challenges both innovators and system leaders would benefit from an improved understanding of the overall developmental process through which such programs are built. System leaders' decision-making could be informed with more accurate expectations, and at the same time, clinical innovation could be informed by knowledge of common steps taken in creating effective complex care programs.

There is almost certainly more than one detailed roadmap by which complex care programs are built: Health systems are very different with diverse goals, cultures, and resources, as are communities, insured populations, and the experience of those served. Regardless, it is likely that enough has been learned about complex care programs to begin to articulate how such programs are built and therefore appropriately evaluated.

CHCS WELCOMES YOUR FEEDBACK

CHCS extends an invitation for readers to share ideas to build on this proposed approach to program development; please submit feedback to Rachel Davis, associate director for program innovation, at **rdavis@chcs.org**.

ABOUT THE CENTER FOR HEALTH CARE STRATEGIES

The Center for Health Care Strategies (CHCS) is a nonprofit policy center dedicated to improving the health of low-income Americans. It works with state and federal agencies, health plans, providers, and consumer groups to develop innovative programs that better serve people with complex and high-cost health care needs. For more information, visit **www.chcs.org**.

This brief is a product of the *Complex Care Innovation Lab,* a national initiative made possible by Kaiser Permanente Community Benefit that brings together leading innovators in improving care for low-income individuals with complex medical and social needs. For more information, visit **www.chcs.org/innovation-lab/**.

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