Evaluating Innovations in Medicaid

OVERVIEW OF EVALUATION DESIGN FOR DIGITAL HEALTH COMPANIES

Developed by the Center for Community Health and Evaluation
in partnership with the California Health Care Foundation

CHCF INNOVATION FUND

Why evaluate as a digital health company?

- **Improve program design or implementation** by understanding what is working and what is not
- **Ensure accountability** to your investors and communities
- **Demonstrate impact** — prove your ability to deliver outcomes
- **Strengthen marketing materials** by including data to support your value proposition
- **Support fundraising, sales, and grant writing**
- **Inform the field** by contributing to research about what works to improve health care access and quality

Before starting, consider evaluation feasibility

- **How stable is the product?** Stability impacts the type of evaluation you might want to invest in.
- **Has the product been implemented and at what scale?** Scale impacts data availability.
- **Do you have sufficient reach and engagement?** This impacts your ability to answer evaluation questions.
- **Do you have the needed partnerships in place?** For example, do you have a health system partner?
- **Do you have the capacity to engage in evaluation?** Consider available funding, staffing, expertise.

What if it is not feasible to do a full evaluation?

Consider an exploratory study to get an early indication of how things are working and the types of outcomes you could expect.

Typically based on:

- Early implementation
- Convenience samples
- A small sample size
- Easily available data
- Lower resource expenditure

Establish a vision for evaluation

Which key partners and end users need to be engaged in making decisions about the evaluation?

Can you clearly describe your product or intervention? Could you articulate how your activities will lead to your desired outcomes?

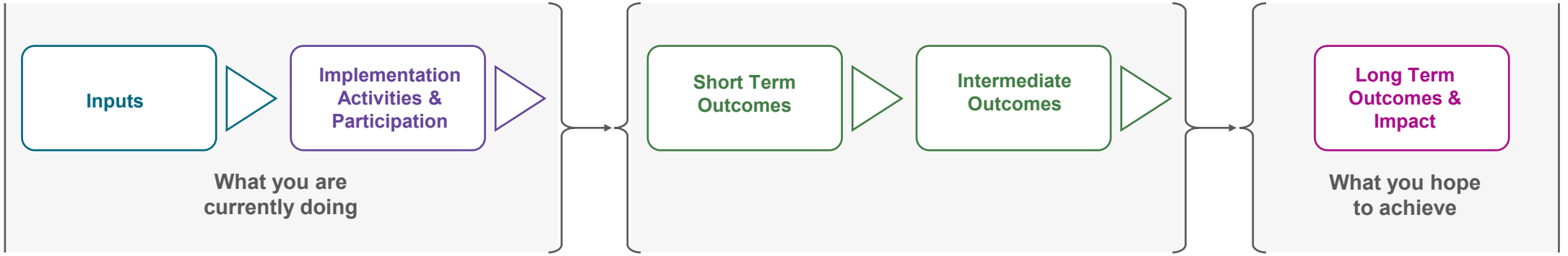
What do you need to know from the evaluation? What are your and your partners' key questions?

Most health system / tech partnerships want to understand **long-term outcomes:**

- Impact on patients (health outcomes)
- Cost-effectiveness, return on investment

Consider setting up an evaluation workgroup with representatives from key partner organizations to ensure alignment on vision and consistent engagement throughout the evaluation.

Use a theory of change to inform the evaluation



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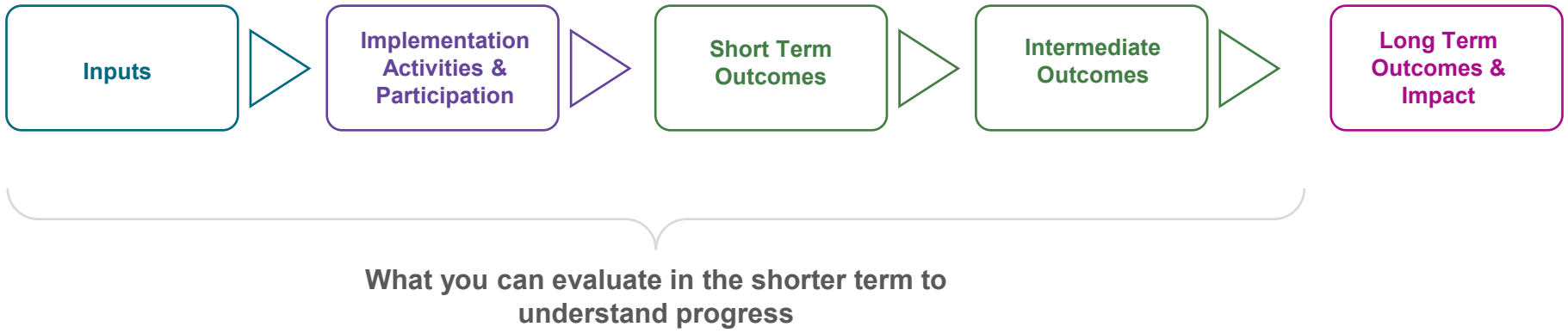

Throughout your evaluation, starting with developing the theory of change, consider how **cultural context and implicit bias** might be impacting your perceptions of how and why your product is or isn't working. Consider if there are any other important **contextual considerations** to pay attention to.

Example: Maternity Journey Text-Based Navigation Program

Inputs	Activities	Participation	Short-Term Outcomes	Intermediate Outcomes	Long-Term Outcomes
Tech company • Navigators • Texting platform **Hospital system** • Leadership buy-in • Financial support • Engagement from staff • Patient data **Patients** engaging with hospital system	**Predelivery** • Screen patients for risk factors and needs • Ensure health care access • Connect patients to community resources • Provide patient education • Listen to patient expectations and concerns • Escalate needs to hospital system **Postdelivery** • Assess maternal mental health • Support patients' lactation needs • Confirm pediatric and follow-up ob/midwifery appts. • Connect patients to community resources • Listen to patient expectations and concerns • Escalate needs to hospital system • Collect feedback	• All pregnant people seeking prenatal care, classes, center tours, delivering at participating hospitals • Focus on black birthing people	• Patients are engaged early in pregnancy • Patients have high utilization and engagement with navigation services • Patients have a positive experience with services, feel listened to, and are comfortable • Patients' short-term needs are met	**Patients have increased:** • Knowledge of resources and support • Access to resources and support • Self-efficacy (i.e., willingness to ask questions, raise concerns) • Engagement in care and confidence in the health care system	• Increased healthy behaviors, decreased risk factors • Reduced complications during pregnancy and delivery • Improved infant health outcomes • Reduced maternal mortality • Increased breast-feeding initiation **Impact** Reduced disparities and improved equity in birth outcomes, particularly for people of color

Next steps for evaluation planning

Use your theory of change to identify your research questions and measures you'll use to answer them.

1. What are your key evaluation questions?

Type	Goal	Examples
Process	Understand how the product is being implemented and opportunities for improvement	• What inputs were needed? • How is your product working? • Can end users access and use the product? • How are partnerships and collaborations working?
Outcome	Understand short- and long- term changes made because of your product	• Who have you engaged and how? • Are there changes in people's behaviors or health outcomes? • Were outcomes experienced equitably across patient populations?

2. How will you answer questions?

Can you identify measures for each evaluation question?

Are reach, engagement, and every outcome clearly defined and measurable?

For each measure, have you established a source, data collection method, and frequency?

Benefits of including process evaluation questions

Early in the intervention, process evaluation can help you:

- Understand what's working and what's not
- Inform program improvement and potential spread
- Improve the effectiveness of the partnership
- Articulate how your product or intervention contributes to long-term outcomes
- Shape expectations for what information you can provide in the short term

Process evaluation (continued)

Examples of process evaluation questions:

- **Reach of the intervention**
- **Demographics of participants**
- **Utilization, services provided**
- **Effectiveness of activities**
- **Tension points and challenges**
- **Data availability and information flow**
- **Staff and patient satisfaction**
- **Benefits and challenges of the partnership**

Consider who needs access to implementation data and when data are needed to inform decisions.

Including qualitative data to understand how and why

The strongest evaluations include mixed methods (both quantitative and qualitative).

Quantitative data can tell you if something worked, qualitative data tells you how it

Qualitative data benefits:

- Centers patient voice
- Engages staff
- Captures nuance
- Helps to tell a story with your data

Qualitative data examples:

- Patient interviews, focus groups, stories, testimonials
- Staff interviews or reflective conversations
- Community partner interviews
- Observation
- After action reviews
- Open-ended responses

Designing the outcome evaluation

Plan early for this stage of an evaluation, and wait to invest in analysis until you have the following:

- **Fully implemented product**
- **Sufficient scope and reach**
- **Access to needed data**

Determining outcome evaluation design

	Pre/Post (Nonexperimental)	Case/Control (Nonexperimental)	Pre/Post (Quasi-experimental)	Randomized Controlled Trial (Experimental)
Research question	Did outcomes change for participants before and after participation?	Looking back, did outcomes change for participants compared to a similar group of nonparticipants?	Looking over time, how does the intervention group compare with a control group?	Looking over time, how does the randomized intervention group compare with a control group?
Strengths: Why would you choose this design?	Engage only those who have agreed to use your product; often easier and less resource-intensive. Can compare high utilizers to low utilizers (or make other intracohort comparisons). Can discuss how the product contributed to outcomes.	Includes longitudinal data. Fairly rapid to complete because data are already collected and available. Can be implemented even if you are starting mid-intervention, since data are retrospective.	Can track participants and nonparticipants over time. Works well when you can't randomize who receives the intervention. A viable comparison/control group makes this design stronger.	You can ethically randomize your intervention and control groups. This study design gives the most confidence that demonstrated outcomes are attributable to your product.
Limitations: Why would you *not* choose this design?	Can't track a cohort over time. Can't confidently attribute outcomes to your product, because reasons patients engage likely confound outcomes (e.g., access, resources, motivation).	Requires sufficient retrospective data available in the format you need. Unable to follow patients over time prospectively; limited by already available data.	Can't confidently attribute outcomes to your product, as the control group is often self-selected.	Requires ethically randomizing participants and withholding the product from a subset.
			Requires a viable comparison group without too many confounders. Requires tracking data over time and investing time and resources.	

Determining evaluation design

	OBSERVATION OR CORRELATIONAL DESIGN (WITHOUT COMPARISON GROUP)		CONTOLLED OUTCOME DESIGN (WITH COMPARISON GROUP)		
	Implementation	**Pre-Post**	**Case-Control**	**Pre-Post**	**Randomized Controlled Trial**
Research Question	Is the program being implemented effectively and what factors influence successful delivery and execution?	Do participant outcomes change over time, before and after the intervention?	Looking back, what factors were different between people with and without the outcome, and could one of those factors have caused the outcome?	Do participant outcomes change over time, before and after the intervention, relative to changes in a comparison group?	Do participant outcomes change over time, before and after intervention, relative to changes in a comparison group, when group members are randomly assigned?
Best for	Understanding how a program works in practice and identifying barriers to successful implementation	Initial assessment of intervention's effects; generating hypotheses for further research	Investigating risk factors for a specific health outcome, especially a rare condition	Assessing intervention's effects, with consideration of the potential influence of external factors	Definitively testing intervention's effects and impact, apart from the potential influence of external factors
Strengths **Why would you choose this design?**	• Clarifies how program is being implemented in the real-world. • Identifies issues early so adjustments can be made. • Generates lessons to support replication and scale in other settings.	• Practical approach to assessing impact, while running normal operations. • Can compare high- and low-utilizers. • Early insights to inform follow-on studies.	• Quick and efficient way to generate hypotheses about cause-and-effect, given data have already been collected. • Especially effective when the outcome of interest is rare.	• Strong approach for establishing causal relationships, controlling for external factors that may bias results.	•Gold standard for establishing causal relationships, minimizing bias and maximizing reliability of results. •Empowers healthcare leaders to make important decisions about patient care and resource allocation.
Limitations **Why would you *not* choose this design?**	• Lessons on implementation process, not health outcomes. • Difficult to generalize findings to other contexts and/or isolate process elements of that are critical to success.	• Without comparison group, impossible to determine if intervention and outcomes are causally related.	• Limited by the type and amount of retrospective data available to researchers. • Impossible to determine if observed differences cause outcome.	• Without random assignment, systematic differences between intervention and control groups make it hard to determine cause-and-effect.	• Study design, recruiting participants, obtaining consent, and tracking long-term outcomes can take months. • Gathering high-quality data from multiple sources and running statistics require extra expertise and tech resources.

Consider how you will implement your evaluation plan

	Key Areas	Example Considerations
1	**Data collection**	• What data are needed, and are they accessible? • How will data be managed and shared? • Who is responsible for data collection? • How can various segments of the population be included equitably?
2	**Data analysis and reporting**	• What analysis is possible given the data? • How will partners and users engage in interpretation and reporting? • Who benefits from seeing the evaluation results? Is it for internal or external audiences? • How will the data be used for improvements or to inform decisions?
3	**Timeline**	• When will the product be fully implemented? When could outcomes become measurable? • How long of a study period is needed?
4	**Staffing**	• Does each partner have capacity internally to engage in evaluation, including planning, data collection and analysis, interpretation, and dissemination? • Is any external evaluation support needed?
5	**Agreements**	• What contracts are needed? • What data sharing and data use agreements are needed? • How will HIPAA compliance be assured?
6	**Budget**	• What resources are available to support the evaluation? Will they be sufficient?

Conducting the evaluation internally or externally

An external evaluator can:

Provide an independent perspective; more credible to some audiences

Bring additional capacity and expertise to inform and implement the evaluation

Provide feedback and data to inform decisions

Help facilitate conversations between implementation partners and support feedback loops

Support evaluation and data capacity building (e.g., setting up data fields, level of analysis)

An internal evaluator can:

Understand context

Have more seamless access to data

Have the potential to drive more program improvement due to integration with the organization

Be more sustainable for ongoing or long-term monitoring and evaluation

When selecting an external evaluation partner, consider:

- Your evaluation approach — focus on independence and maintaining distance or focus on quality improvement and integration
- Desire for supporting internal capacity building
- Subject or methods expertise needed
- Credibility and characteristics of the team
- How much you can trust and be candid with this partner
- Alignment in values and goals

For more information and resources

Access the open source toolkit online:

Interactive PDF toolkit

Two-page quick reference

Case study illustration

Workbook to help with planning

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CENTER FOR COMMUNITY HEALTH AND EVALUATION

Contact CCHE for more information:

Maggie Jones, MPH

maggie.e.jones@kp.org

cche.org

CENTER FOR COMMUNITY HEALTH AND EVALUATION

Evaluating Innovations in Medicaid

AN EVALUATION DESIGN TOOLKIT FOR TECH START UPS

Developed by the Center for Community Health and Evaluation
in partnership with the California Health Care Foundation

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