Evaluating Innovations in Medicaid

AN EVALUATION DESIGN TOOLKIT FOR DIGITAL HEALTH COMPANIES

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

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About the Author

This toolkit was developed by Elena "Noon" Kuo, PhD, Senior Evaluation and Learning Consultant, and Maggie Jones, MPH, Director, at the Center for Community Health and Evaluation (CCHE), with support from Grant Clark, Communications Specialist, and Melissa Trapp Petty, Evaluation Division Manager. CCHE designs and evaluates health-related programs and initiatives across the United States. This toolkit content is adapted from CCHE's Measuring What Matters: A Practical Approach to Evaluation curriculum. CCHE is based in Seattle and is part of Kaiser Permanente Washington Health Research Institute.

Overview of the Toolkit

This toolkit is designed for founders of digital health companies whose product is aimed at improving health or health equity. The examples throughout the toolkit are focused specifically on start-ups serving patients enrolled in Medicaid, but most content is applicable to many populations.

This toolkit is intended to be used as either a self-directed resource, a one-on-one coaching tool, or a collaborative learning tool to support formal evaluation design. The navigation allows one to jump to specific content; the toolkit is not meant to be read sequentially in one sitting.

Equitable evaluation principles are purposely embedded throughout the toolkit rather than given their own separate section. The authors believe that equity is a critical component of all aspects of evaluation and should be consistently considered throughout the design process.

The toolkit is organized into five sections:

1. 1. Assess Readiness to Evaluate
2. 2. Establish an Evaluation Vision
3. 3. Determine the Evaluation Design
4. 4. Prepare for Launch and Implementation
5. 5. Resources & About CCHE

Other resources:

The toolkit includes links to templates and other resources throughout for those who want to go deeper on certain topics.

This icon indicates worksheets are available to help support your evaluation planning; they can be found in the evaluation planning workbook (Word).

This icon indicates a case study example, which is also compiled into one case study example document.

An evaluation checklist is available for quick reference.

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ASSESS READINESS TO EVALUATE

1. Assess Readiness to Evaluate

This section is intended to help you determine whether the time is right to evaluate your product or service. Before planning your approach, it is critical to consider what you hope to learn through evaluation, your product's current stage of development, and whether it is feasible to gather the information you need to meet your evaluation goals.

This section includes:

a. Confirm Value of Evaluation

b. Determine if Product is Sufficiently Established

c. Assess Feasibility of Evaluation at This Time

1a. Confirm Value of Evaluation

Evaluation can contribute to your digital health company's work in many ways, including these:

Improve program design or implementation.
Give your team a better sense of what's working and not working to improve your product and implementation efforts.

Ensure accountability.
Be accountable to investors and the communities you serve by reporting on impact and what's driving results.

Demonstrate impact.
Prove your ability to deliver outcomes and move the needle on improving health.

Strengthen marketing materials.
Improve your marketing materials with data that clarify your value proposition.

Support fundraising, sales, and grant writing.
Drive revenue (volume and price) by proving the effectiveness of your product and showing your commitment to quality.

Inform the field.
Contribute to research that helps improve healthcare access and quality by making findings, both positive and negative, available to others.

1a. Confirm Value of Evaluation (continued)

Case Study: Text-Based Navigation Program or click here for the full case study example (Word)

A digital health company developed a text-based navigation program to help connect birthing people to appropriate care and other resources during and after their pregnancy.

- The program had been piloted and was growing.
- The digital health company was interested in conducting an evaluation to demonstrate the impact of the program, understand which subgroups were benefiting, and identify any gaps or disparities in reach and impact.
- The company also wanted to make the case that its health system customer should continue to invest in the program beyond the initial pilot and implementation phase.

Bottom Line

Evaluation could help ensure the sustainability of the program by demonstrating its impact on patients' health.

1b. Determine if Product is Sufficiently Established

The stage of product development and scale determines what you can learn through evaluation and the types of evaluations that are appropriate. Some questions to consider include these:

How "stable" is the product?

- Are you engaged in significant ongoing iteration and prototyping, or do you have a stable and consistent product?
- Will the product be "off the shelf," or will you customize it for the specific needs of your clients?
- Is your company currently experiencing significant growth?

Has the product been implemented, and at what scale?

- Are you working on an initial launch?
- How long have users had access to the product? Has it been weeks, months, or years?
- How widely is the product available? Is it available across multiple settings, geographies, and population types?
- How many people are using the product, overall and by important sub-segments (e.g., demographic groups)? Are important groups not participating?
- Have enough customers used the product for enough time for sufficient data to exist to answer your evaluation questions?

1b. Determine if Product is Sufficiently Established (continued)

Case Study: Text-Based Navigation Program or click here for the full case study example (Word)

The product's stage of development impacts what kind of evaluation is most appropriate.

In this case, the digital health company had piloted a text-based navigation program in two clinics and had conducted an internal quality improvement study to refine product features and workflows.

The company was preparing to expand into additional clinics. They were interested in evaluating expansion efforts and monitoring implementation and impact in different settings.

Bottom Line

Evaluation would be useful for the company to ensure effective implementation and measure impact in different settings.

1c. Assess Feasibility of Evaluation at This Time

Before you begin, it's important to consider whether conducting a meaningful evaluation is feasible at this time. Some factors to consider include these:

Funding

- Is sufficient funding available to support an evaluation?
- Are your partner(s) interested in contributing to the effort?

Staffing

- Do you have the staff, in numbers and expertise, to support each phase of the work, including evaluation design, data collection and analysis, and dissemination of findings?
- Are your partners willing and able to make their own staff available as necessary?

Reach and engagement

- Has your product achieved reach, engagement, and scale so that enough data exists to answer the evaluation questions you care about most?

Timeline

- What are your key evaluation questions (Section 2c) and what study design makes sense (Section 3)? How much time is required to plan and implement that work (Section 4)?
- The minimum time to results is typically 12 to 18 months and that may not be sufficient to measure long-term impacts. Do you need findings by a specific date? Can you complete a study in time?
- Have there been significant leadership changes in your company or among partners, or important changes in the competitive landscape or regulatory environment, that could prolong decision-making or stall implementation?
- Shorter timelines generally require more funding and staff. Do you have incremental resources available?

1c. Assess Feasibility of an Evaluation at This Time (continued)

Case Study: Text-Based Navigation Program or click here for the full case study example (Word)

Funding

A health foundation was ready to grant fund an evaluation to understand the navigation program's impact on disparities in birth outcomes and inform the field.

Staffing

The digital health company did not have sufficient capacity to lead the evaluation in-house and was interested in engaging an external evaluator for support and to provide an independent perspective.

Reach and engagement

The product had been piloted in two clinics and was due to launch in several others, significantly increasing reach and engagement.

Bottom line

It felt feasible and important to move forward with an evaluation at this point.

Timeline

The digital health company and its health system partner wanted to have evaluation results within 12 months to inform the renewal of their contract.

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ESTABLISH AN EVALUATION VISION

2. Establish an Evaluation Vision

Conducting an evaluation is complex and requires thoughtful engagement of your critical partners. During evaluation design, you need to confirm these partners clearly understand the activities that drive your product's intended outcomes and agree on the important evaluation questions that need to be answered.

This section includes:

a. Prioritize Equity in Your Evaluation

b. Engage Your Partners

c. Create a Logic Model

d. Prioritize Evaluation Questions

2a. Prioritize Equity in Your Evaluation

Many factors directly and indirectly impact the evaluation questions you choose to ask, your approach to implementation and analysis, and how you tell the story of your program, including:

- Unconscious biases regarding impacted populations, expected outcomes, and your own belief that the product is effective
- Cultural contexts assumed in product design and/or implementation
- Power dynamics in decision making processes between and among you and your evaluation partners
- Norms around data privacy, patient protections, and transparency
- Potential variation in how the evaluation is implemented across sites and/or populations

Bottom Line

Consider these factors throughout planning and implementation to help you make choices intentionally and increase the odds your approach is culturally responsive.

2a. Prioritize Equity in Your Evaluation (continued)

Case Study: Text-Based Navigation Program or click here for the full case study example (Word)

The text-based navigation program was being implemented in a complex ecosystem, with multiple provider organizations, among racially and socioeconomically diverse users. There were significant opportunities for miscommunication.

Establishing a multistakeholder planning and implementation workgroup was critical to ensuring all partners started and remained on the same page.

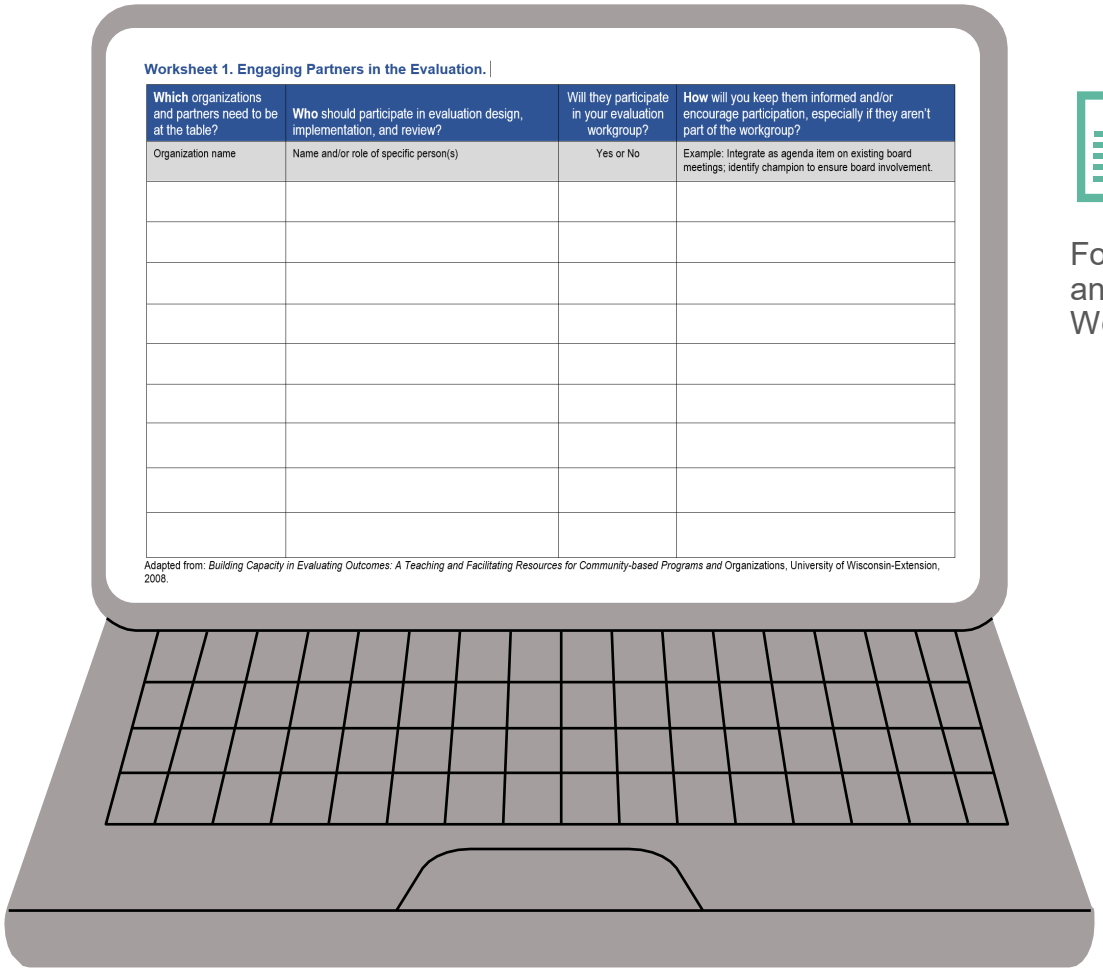
Early discussions daylighted the need to create a logic model to ensure that all partners understood and agreed on program implementation. There were also different data-sharing assumptions and norms between the digital health start-up and health system. Regular workgroup meetings supported ongoing coordination and collective visibility into these and many other details.

Bottom Line

Ongoing discussions within a multistakeholder workgroup was needed to ensure equitable buy-in and decision-making among partners.

2b. Engage Your Partners

Ensuring you have partnerships in place to evaluate your product is a necessary first step for design and implementation. Please refer to Worksheet 1 (Word) to brainstorm which partners need to be engaged and how you will communicate with them over time.



Worksheet 1. Engaging Partners in the Evaluation.

Which organizations and partners need to be at the table?	**Who** should participate in evaluation design, implementation, and review?	Will they participate in your evaluation workgroup?	**How** will you keep them informed and/or encourage participation, especially if they aren't part of the workgroup?
Organization name	Name and/or role of specific person(s)	Yes or No	Example: Integrate as agenda item on existing board meetings; identify champion to ensure board involvement.

Adapted from: *Building Capacity in Evaluating Outcomes: A Teaching and Facilitating Resources for Community-based Programs and* Organizations, University of Wisconsin-Extension, 2008.

For more information about identifying your key partners and forming an evaluation workgroup, see slides 17 and 18. You may download a Word version of the Engaging Partners in the Evaluation worksheet.

2b. Engage Your Partners (continued)

Ensuring you have partnerships in place to support evaluation is a necessary first step in design and implementation.

Identify one or more health plan or provider partner.

Implementation partners are needed to help you: (1) reach sufficient people in your target population and (2) access data on health status and outcomes for the people using your product and a potential comparison group.

Form an evaluation workgroup.

A workgroup can facilitate efficient and effective decision making and buy-in across all phases of evaluation, including planning and design, data collection and analysis, and dissemination of research findings.

Establish buy-in and commitment.

While it takes significant time, negotiating a formal memorandum of understanding (MOU) provides a solid reference point to help mitigate any issues that surface during the evaluation the road. Discussions should include:

- **Vision.** Create a shared vision and set expectations about evaluation design and implementation (e.g., whether the purpose is program improvement, marketing, business development, or demonstrating return on investment).
- **Partner engagement.** Agree on how partners will engage and what resources they are expected to contribute, including time, funding, and staffing (see Section 1c).
- **Data sharing.** Understand partners' willingness to share quantitative and qualitative data, identified or deidentified, in a timely way.
- **Distribution of findings.** Agree on whether evaluative findings will be shared publicly, or if they are intended for internal use only. See Section 4d for dissemination considerations.
- **Decisionmaking.** Determine how partners will communicate and make decisions, how competing priorities will be managed, and how equity issues will be addressed over the course of the project.

2b. Engage Your Partners (continued)

Case Study: Text-Based Navigation Program or click here for the full case study example (Word)

The digital health company had a contract with a national health care system to spread its program to five more facilities. The health care system's strategic goal was to address disparities in birth outcomes, which aligned with the company's capabilities and goals. A supportive foundation hired an external evaluator, with input from both organizations.

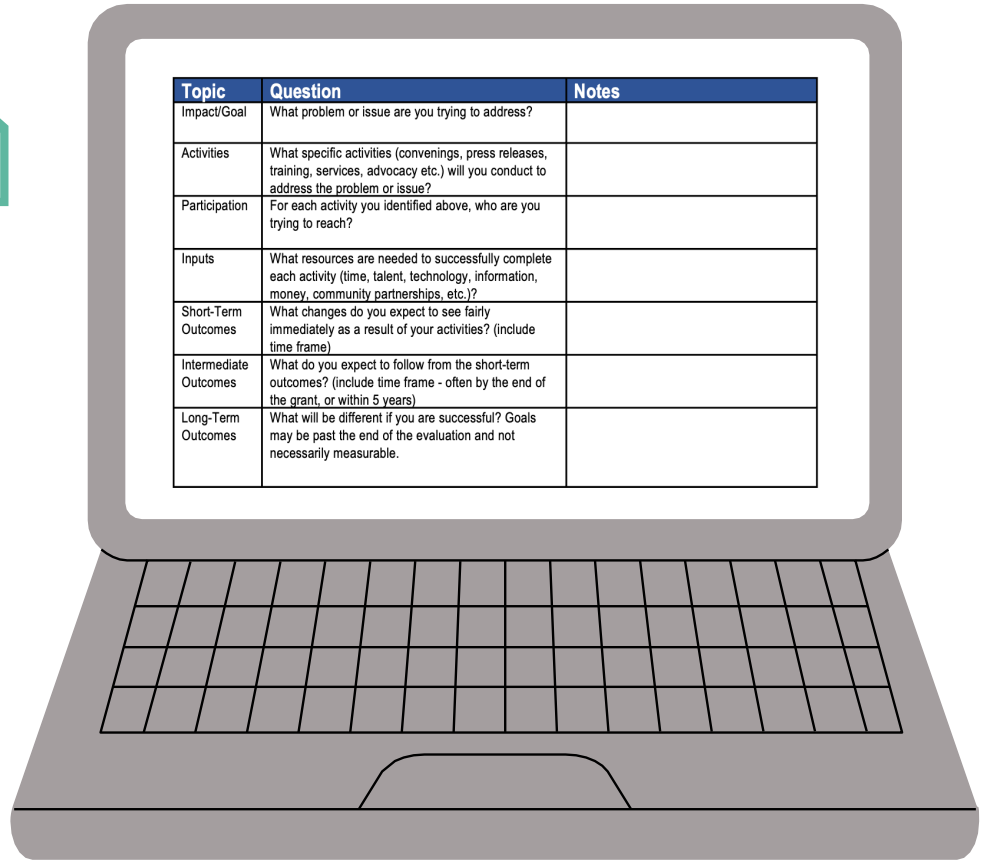
The external evaluator formed a workgroup which met regularly to design and implement the evaluation. Although the external evaluator facilitated this process, there was substantial engagement from the health system, digital health company, and the foundation.

Workgroup representatives included:

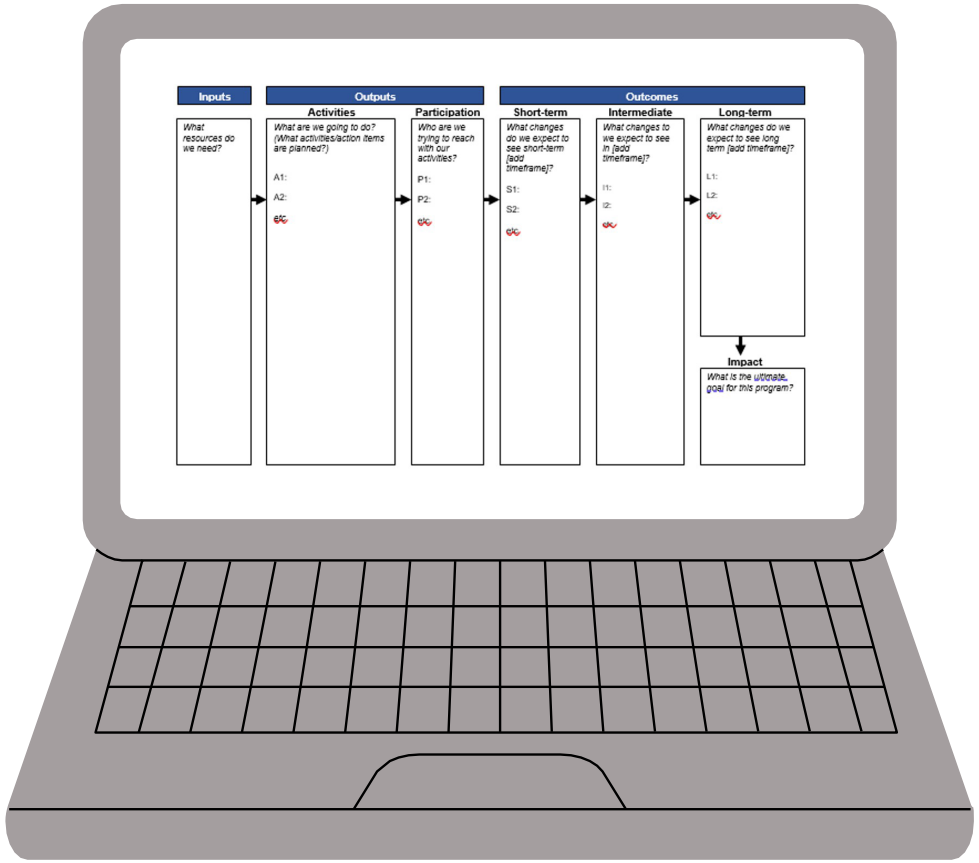
- External evaluation team
- Implementation lead from the health system
- Data analyst from the health system
- Implementation leads from the tech company
- Data analyst from the tech company
- Program officer from the foundation

2c. Create a Logic Model

The next step is to develop a logic model or theory of change that helps to describe your product or intervention so all parties understand and agree on the components required for successful product implementation. This will help to guide the evaluation. Please refer to Worksheet 2a and Worksheet 2b to help you develop your logic model.



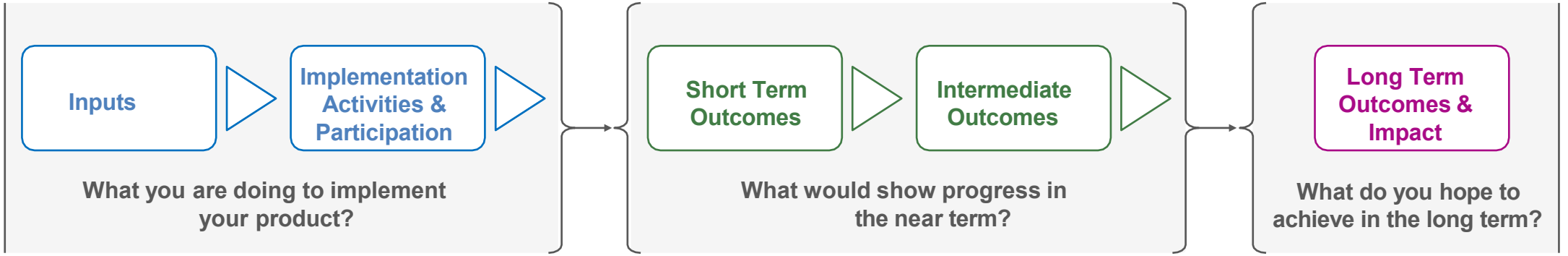
Topic	Question	Notes
Impact/Goal	What problem or issue are you trying to address?	
Activities	What specific activities (convenings, press releases, training, services, advocacy etc.) will you conduct to address the problem or issue?	
Participation	For each activity you identified above, who are you trying to reach?	
Inputs	What resources are needed to successfully complete each activity (time, talent, technology, information, money, community partnerships, etc.)?	
Short-Term Outcomes	What changes do you expect to see fairly immediately as a result of your activities? (include time frame)	
Intermediate Outcomes	What do you expect to follow from the short-term outcomes? (include time frame - often by the end of the grant, or within 5 years)	
Long-Term Outcomes	What will be different if you are successful? Goals may be past the end of the evaluation and not necessarily measurable.	



2c. Create a Logic Model (continued)

Theories of change or logic models are visual descriptions of how your investments and implementation activities result in your intended outcomes. *

Creating a logic model provides a strong scaffold from which to build your evaluation plan so you can track implementation progress and know whether you are on course to achieve your long-term outcomes. These tools help to ensure all partners have a shared understanding of what you are doing and what you are trying to achieve.



For more information, see CCHE's *Measuring What Matters:* *Creating a Logic Model* (PDF).

* For the purposes of this toolkit, we use a logic model framework. While it flows from left to right, people often start by considering the long-term outcomes and impact and work their way backward.

2c. Create a Logic Model (continued)

COMPONENT	DESCRIPTION
Inputs	In your logic model, the inputs include resources needed to support the product implementation. These may include organizational, staff, and monetary resources. Inputs are important to articulate for planning purposes. They are also important for implementation to understand if there are critical resources missing that may impact the product's effectiveness. Identifying these inputs early allows for pivoting and troubleshooting in real time.
Activities & Participation	The activities and participation aspects of the logic model identify what your product does and what activities need to happen to deliver the product to users and support their use. Articulating the activities for a program helps to ensure that all partners have a common understanding of what the product and intervention entail. This can be particularly helpful in ensuring your partners know what will be expected of them. For an evaluation, understanding whether the activities happened as planned can help to explain why outcomes may or may not have been achieved.
Outcomes	Outcomes articulate what you will achieve. Often people think of short-term outcomes as changes that happen in less than one year, intermediate as two to five years, and long-term as more than five years. However, your time frame may vary depending on the intervention. The most important thing in developing outcomes is that they build on the activities and each other in a stepwise manner. While long-term outcomes may be unrealistic to measure for a while (or ever), measuring short-term and intermediate outcomes enables you to demonstrate progress toward your goals and make course corrections as needed.

Note: If you have a long-term outcome related to improved equity or reduced disparities, consider how inputs and activities help you to achieve that goal and whether there are additional activities that will contribute to achieving your equity goals.

2c. Create a Logic Model (continued)

Case Study: Text-Based Navigation Program or click here for the full case study example (Word)

The evaluation workgroup developed a logic model for the text-based navigation program to ensure every participant understood the inputs and activities required to drive the program's success.

The group discussed the inputs and activities necessary to implement the program, and how these led to long-term outcomes.

They reviewed the shorter-term outcomes that would indicate progress and whether the program was on track, and longer-term ones focused on improved health outcomes and fewer disparities across groups.

The workgroup considered whether it as realistic to expect these longer-term outcomes within the study's timeline. Participants agreed it was believable that the program could impact birth outcomes within a 12-month period, except for infant mortality, which is relatively infrequent in the overall population.

2c. Create a Logic Model (continued)

Case Study: Text-Based Navigation Program Logic Model or click here for the full case study example (Word)

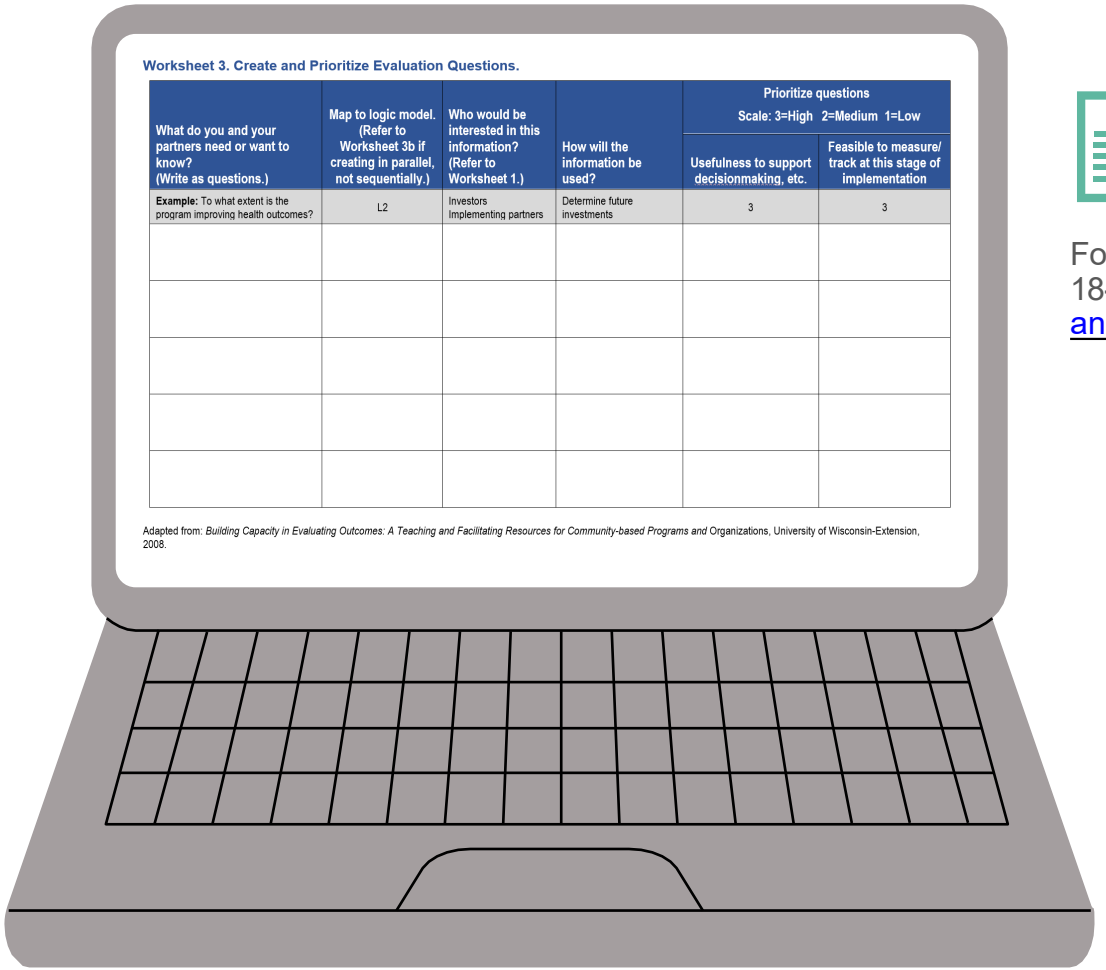
INPUTS	ACTIVITIES	PARTICIPANTS	SHORT-TERM OUTCOMES	INTERMEDIATE OUTCOMES	LONG-TERM OUTCOMES
Tech company • Navigators • Texting platform **Hospital system** • Leader buy-in • Financial support • Engagement from clinical and outreach staff • Patient data **Patients** engaging with hospital System	**Predelivery** • Screen patients for risk factors and social needs • Ensure healthcare access • Connect to community resources • Provide patient education (e.g., car seat education) • Listen to patient expectations and concerns • Escalate to hospital system, if needed **Postdelivery** • Assess maternal mental health • Support patients' lactation needs • Confirm pediatric and OB/ midwifery appts • Connect to community resources • Listen to patient expectations and concerns • Escalate to hospital system, if needed • Collect feedback	All pregnant people seeking prenatal care, prenatal classes, birthing center tours, and those delivering at participating hospitals Specific 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 comfortable • Patients' short-term needs are met	• Patients have increased knowledge of resources and support • Patients have increased access to resources and support • Patients have increased self-efficacy (i.e., willingness to ask questions, raise concerns) • Patients have increased 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 initiation of breastfeeding **IMPACT** Reduced disparities and improved equity in birth outcomes, particularly for people of color

Bottom Line

Having a logic model for reference helped ensure all partners were on the same page.

2d. Prioritize Evaluation Questions

Evaluation questions should specify what's most important for you and your partners to learn. Worksheet 3 can help you to brainstorm and prioritize your questions.



Worksheet 3. Create and Prioritize Evaluation Questions.

What do you and your partners need or want to know? (Write as questions.)	Map to logic model. (Refer to Worksheet 3b if creating in parallel, not sequentially.)	Who would be interested in this information? (Refer to Worksheet 1.)	How will the information be used?	Prioritize questions Scale: 3=High 2=Medium 1=Low	
				Usefulness to support decisionmaking, etc.	Feasible to measure/ track at this stage of implementation
Example: To what extent is the program improving health outcomes?	L2	Investors Implementing partners	Determine future investments	3	3

Adapted from: *Building Capacity in Evaluating Outcomes: A Teaching and Facilitating Resources for Community-based Programs and* Organizations, University of Wisconsin-Extension, 2008.

For more information about prioritizing evaluation questions, see slides 18-20. You may download a Word version of Worksheet 3: Create and prioritize evaluation questions.

2d. Prioritize Evaluation Questions (continued)

Evaluation questions may focus on whether the program is being implemented as intended, if it delivers positive health outcomes, or both.

Implementation (or Process) Questions

These questions ask about the inputs, activities, and participation columns in your logic model, and help you understand whether the program is being implemented according to plan and what factors may be standing in the way of success.

- What services have been provided?
- How effective are the activities?
- What tensions and challenges exist related to implementation?
- What are the benefits and challenges of the customer partnership?
- What is the reach of the intervention

Outcome Questions

These questions ask whether your product has had its intended impact, and map to the short-term, intermediate, and long-term outcomes in your logic model.

- Who have you engaged and to what extent?
- Have there been changes in people's behaviors or health status?
- Have these outcomes been achieved evenly across the patient population or are some populations benefiting more than others?

Engage your partners in prioritizing your questions.

Reaching agreement will help ensure partners are aligned on the purpose and goals of the work.

Consider equity in selecting and framing the list.

- Do the evaluation questions help us understand the program's effects on health inequities?
- How might the intervention and evaluation benefit or harm the program and the community?
- Might the intervention and evaluation have differential impacts on people and drivers of systemic inequity?
- Are any assumptions or biases influencing our questions? (See Section 2a.)

2d. Prioritize Evaluation Questions (continued)

Case Study: Text-Based Navigation Program or click here for the full case study example (Word)

The workgroup discussed what partners wanted to learn from the evaluation.

The digital health company's initial quality study showed improvements in user engagement and birth outcomes. Given the intervention was part of the health system's strategic goal to reduce disparities in birth outcomes, both organizations wanted to understand if the navigation program improved outcomes specifically in underserved patient populations.

They prioritized the following outcomes questions:

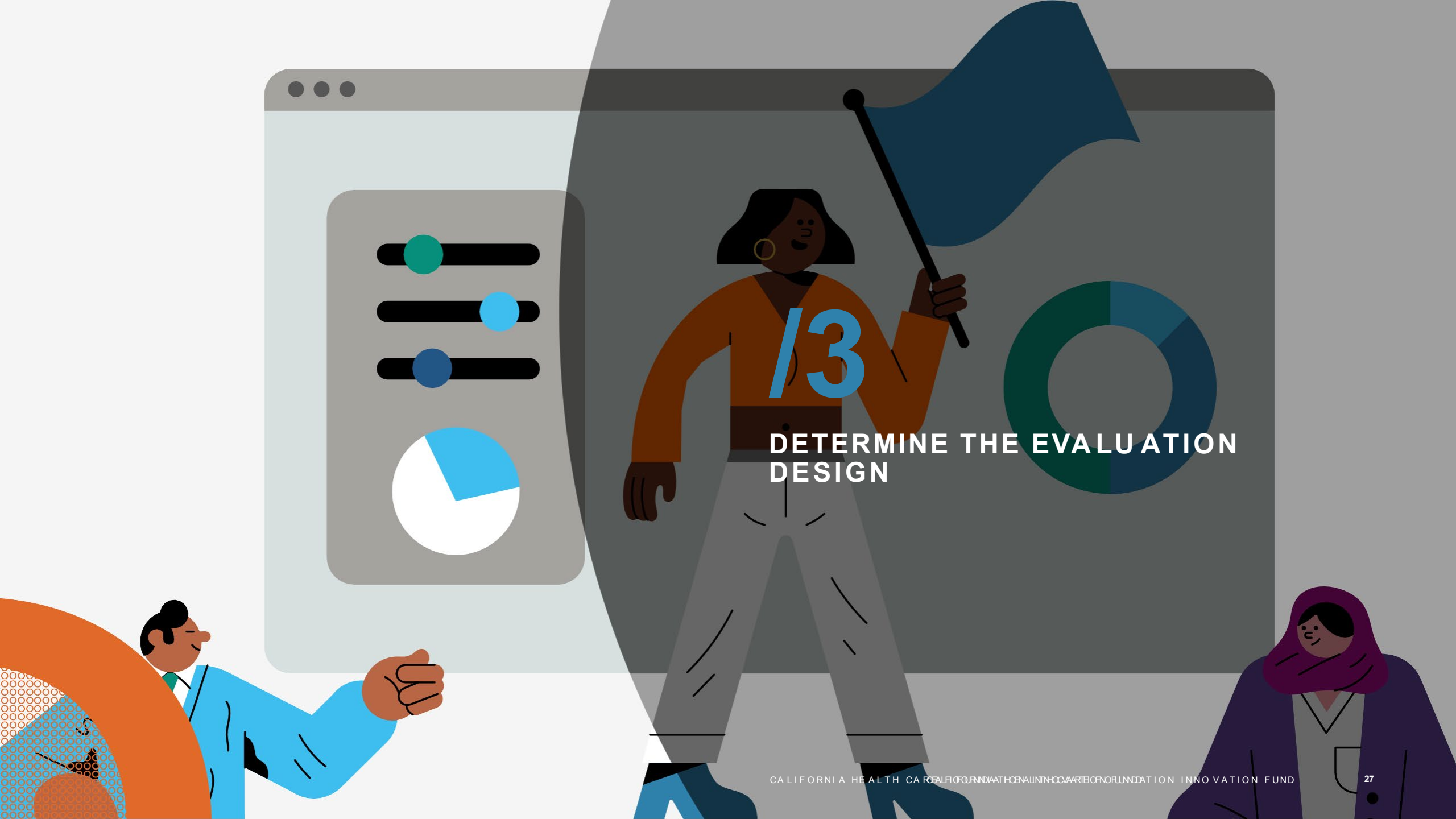
- What is the program's impact on health outcomes for birthing people and babies?
- Are there differences in engagement, experience, or outcomes by race/ethnicity or other demographic variables?
- What is the experience of patients who participate in the program?

Due to implementation challenges at new clinics, they included process questions as well:

- How was the program implemented? How did implementation vary across facilities?
- What was the experience of the health system staff, providers, and navigators?
- Who was reached by the program? What services/resources were provided/utilized?
- What are potential areas for program improvement needed to achieve optimal outcomes?

Bottom Line

The process of creating and refining evaluation questions helped partners agree on goals and understand components needed for an evaluation.



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DETERMINE THE EVALUATION DESIGN

3. Determine the Evaluation Design

This section will walk through the key steps in determining your evaluation design. With your partners' support, you will need to select specific measures for your evaluation questions, data sources and collection methods, and your approach to controlling for confounding variables that could bias your findings.

This section includes:

a. Select Measures for the Evaluation Questions

b. Identify Data Sources and Collection Methods

c. Establish Approach to Comparisons and Controls

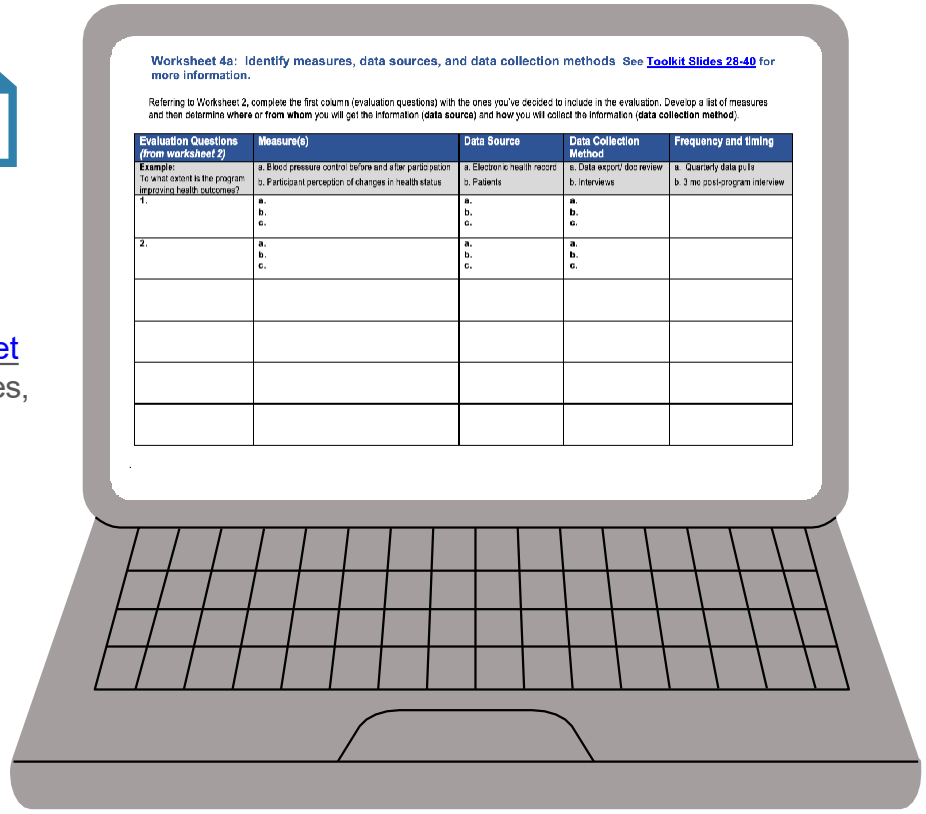
d. Create Guidelines for Data Sharing and Management

e. Plan for Analysis and Interpretation

3a. Select Measures for the Evaluation Questions

With your evaluation questions in hand, next you determine what specific information or "measures" answer those questions. This section walks through how to identify the measures that will ground your evaluation. Below is a screenshot of Worksheet 4a we will be referencing.

For more information about identifying measures, see slides 28–40. You may download a Word version of Worksheet 4a on identifying measures, data sources, and data collection methods.



Worksheet 4a: Identify measures, data sources, and data collection methods See Toolkit Slides 28-40 for more information.

Referring to Worksheet 2, complete the first column (evaluation questions) with the ones you've decided to include in the evaluation. Develop a list of measures and then determine **where** or **from whom** you will get the information (**data source**) and **how** you will collect the information (**data collection method**).

Evaluation Questions *(from worksheet 2)*	Measure(s)	Data Source	Data Collection Method	Frequency and timing
Example: To what extent is the program improving health outcomes?	a. Blood pressure control before and after participation b. Participant perception of changes in health status	a. Electronic health record b. Patients	a. Data export/ doc review b. Interviews	a. Quarterly data pulls b. 3 mo post-program interview
1.	a. b. c.	a. b. c.	a. b. c.	
2.	a. b. c.	a. b. c.	a. b. c.	

3a. Select Measures for the Evaluation Questions (continued)

An evaluation "measure" answers the question, "If the outcome is achieved, how will we know?"

Measures are information that indicate progress against a stated goal. They are typically numerical values that can be calculated, aggregated, or broken out by one or more dimensions. Here are some examples:

- A measure of academic achievement is high school graduation rate
- A measure of a residential area's walkability is the proportion of streets that have sidewalks
- A measure of adult health is the percentage of those who have their blood pressure under control

Bottom Line

Selecting measures associated with your critical evaluation questions, and then identifying sources of that information, are important first steps in evaluation design.

3a. Select Measures for the Evaluation Questions (continued)

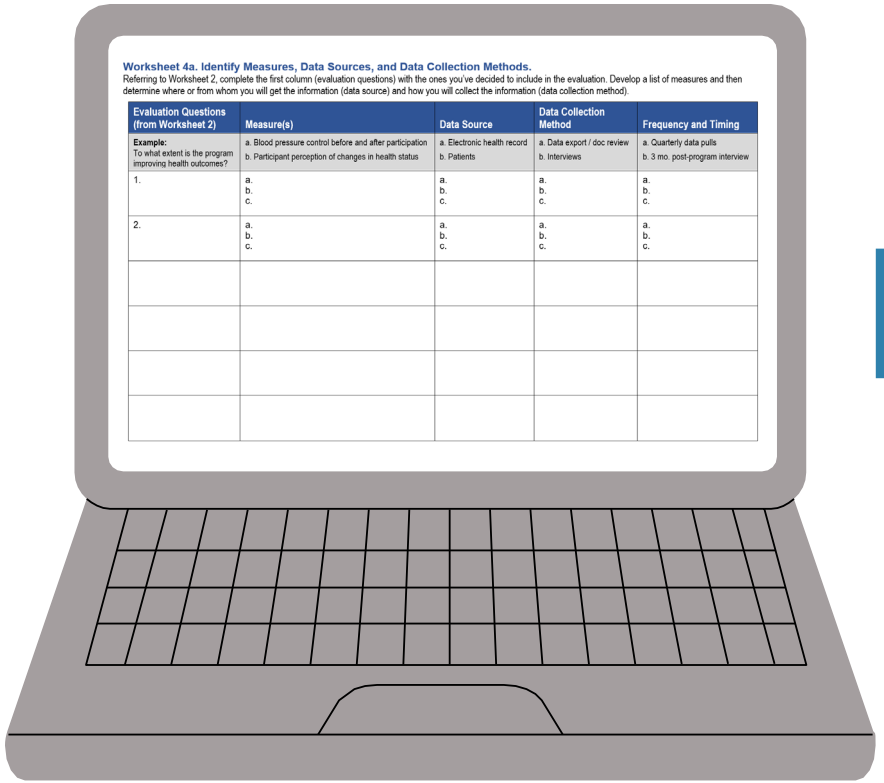
Case Study: Text-Based Navigation Program or click here for the full case study example (Word)

The workgroup identified measures for each of their evaluation questions. Below is a snapshot; the full list can be accessed in the case study example.

Evaluation Question	Measures Related to Outcomes	Measures Related to Implementation
Were there differences in engagement, experience, or outcomes by demographic variables?	• Birth complications, infant health, increased breastfeeding initiation, by race/ethnicity and other demographics	• Access to care, engagement, utilization, satisfaction, by race/ethnicity and other demographics
What is the experience of patients who participate in the navigation program?	• Patient trust and confidence in the program and their health care provider • At the end of the program, whether they recommend it to others, felt it added value • Reduced disparities and improved equity for patients of color	• Patient-reported satisfaction (e.g., needs were met, felt listened to) • Patient engagement in care • Patient knowledge of available resources • Net promoter score

3b. Identify Data Sources and Collection Methods

With your evaluation questions and measures in hand, next determine the sources of the data your need to answer your evaluation questions and the methods you will use to collect that data. See Worksheet 4a for reference.



Worksheet 4a. Identify Measures, Data Sources, and Data Collection Methods.

Referring to Worksheet 2, complete the first column (evaluation questions) with the ones you've decided to include in the evaluation. Develop a list of measures and then determine where or from whom you will get the information (data source) and how you will collect the information (data collection method).

Evaluation Questions (from Worksheet 2)	Measure(s)	Data Source	Data Collection Method	Frequency and Timing
Example: To what extent is the program improving health outcomes?	a. Blood pressure control before and after participation b. Participant perception of changes in health status	a. Electronic health record b. Patients	a. Data export / doc review b. Interviews	a. Quarterly data pulls b. 3 mo. post-program interview
1.	a. b. c.	a. b. c.	a. b. c.	a. b. c.
2.	a. b. c.	a. b. c.	a. b. c.	a. b. c.

You may download a Word version of Worksheet 4a on identifying measures, data sources, and data collection methods.

3b. Identify Data Sources and Collection Methods (continued)

Strong evaluations incorporate data from multiple sources, collected in several ways, to provide the most accurate and comprehensive picture of a study's findings. The specific mix of these depends on the program's nature, evaluation questions, and available resources.

In thinking through the sources of important data, you should consider:

- Is there more than one source for the data?
- Which source is likely to provide the best information?
- How easy or difficult will it be to access and collect the needed information from a particular source?
- Is a particular source more or less likely to be bias in how or where the information is generated?
- What variables and/or sources of data will best inform the researchers about the intervention's impact on populations that experience inequities?

3b. Identify Data Sources and Collection Methods (continued)

Data sources typically include a mix of primary and second data and qualitative and quantitative information.

Evaluators can gather program and participant data directly and/or through third-parties.

- **Primary data** is new information collected by the evaluator directly from participants and other stakeholders.
- **Secondary data** is information that already exists and was collected by third-parties, such as health plan claims data, and that may be helpful to answering the evaluation questions.

Data sources can be "qualitative" and/or "quantitative" information.

- **Quantitative data** is numerical information, gathered by measuring and counting, and analyzed using statistical analysis. It may include reach, participant characteristics, services provided, and measures of patient health outcomes.
- **Qualitative data** is descriptive, conceptual, and interpretive information, gathered by interviewing and observing, and analyzed by grouping it in terms of meaningful categories or themes. It can be useful to understand, for example, why staff diverted from the original implementation plan or what motivated specific patients to stick with the program over time.

3b. Identify Data Sources and Collection Methods (continued)

There are many different approaches to collecting the data you need, including the methods below:

COLLECTION METHOD	DESCRIPTION
Surveys & Questionnaires	Quantitative and qualitative information reported directly from individual participants and other stakeholders.
Interviews & Focus Groups	Detailed qualitative insights reflecting diverse perspectives and shared experiences.
Process Mapping	Visual representations of program workflows that can help identify implementation bottlenecks and inefficiencies.
Direct Observation & Checklists	Firsthand validation of adherence to program designs and/or standardized protocols.
Quantitative Data Transfer from Digital Health Tools	Real-time quantitative information on participants' adoption and use of mobile apps or web-based platforms.
Quantitative Data Transfer from Administrative & Clinical Partners	Quantitative information from healthcare payers, providers, and other social service organizations on health status and/or utilization.

Note on Health Equity

It's crucial that data collection methods are culturally sensitive and accessible to diverse populations, including those with limited English proficiency or low health literacy.

3b. Identify Data Sources and Collection Methods (continued)

Examples of primary data, information collected by the evaluator from participants and stakeholders, are provided, with links to additional resources on data collection methods.

PRIMARY DATA	COLLECTION METHODS	DATA TYPES	RESOURCES
Individual Feedback From participants, leadership, staff, implementers, community partners	• Surveys & Questionnaires • Interviews • Testimonials • Journals	• Knowledge, attitudes, beliefs, self-efficacy • Self-reported change in behaviors and other outcomes • Feedback on implementation	Overview of collecting data (PDF) Conducting interviews (PDF) with quantitative rating questions and open-ended discussion questions Conducting surveys (PDF) with both quantitative and open-ended text responses
Group Feedback From patients, participants, staff, trainees, community partners	• Small group discussions • Focus groups	• Perceptions regarding needs, wants, program implementation, changes, outcomes	Conducting focus groups (PDF)
Observations Of participants recorded in evaluator notes, checklists	• Documenting by trained observers	• Observations of environment, work flows, patient interactions, performance, etc.	Conducting direct observations (PDF)

3b. Identify Data Sources and Collection Methods (continued)

Examples of secondary data, information collected by stakeholders who are not the evaluator, are provided below, with examples of collection methods and data types.

SECONDARY DATA	COLLECTION METHODS	DATA TYPES
Engagement Data from Digital Health Company Real-time quantitative data on participant adoption and use of digital tool(s).	Data transfers from systems within mobile devise app, web-based platform, wearable device, or remote monitoring system	• Overall uptake and engagement (e.g., #, %, trends) • Demographics of users and non-users • In-app behavior, activities, duration • Patient-reported information
Clinical Data From Healthcare Providers Quantitative information from providers that deliver individuals' primary, specialty, emergency, and/or hospital care.	Data transfers from: • Electronic Health Record • Patient Portals or registries • Care coordination systems	• Diagnoses • Laboratory tests and results • Procedures and results • Vital signs over time
Administrative Data from Health Plans Quantitative information from commercial or public payors that manage benefits and process claims and payments.	Data transfers from: • Claims databases • Case management platforms • Population health management systems	• Medical utilization, costs • Prescriptions and medication adherence • Health Effectiveness Data and Information Sets (HEDIS) data • Patient reported experience
Social needs and/or public health information from community-based or government organizations.	Data transfers from: • Case management systems • Administrative and reporting systems	• Social service needs and utilization (e.g., housing, food, foster care) • Referrals made and completed • Public health registries

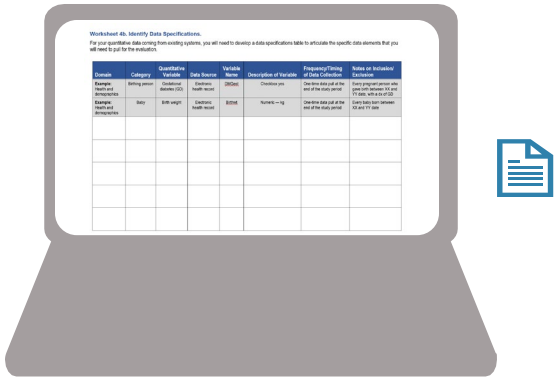
3b. Identify Data Sources and Collection Methods (continued)

Understanding the nature of your partners' quantitative data is an important step in designing the evaluation and planning for implementation. Creating strong data specifications (aka data "specs") and requesting "test" data sets from your partners early on will make data sharing more efficient and effective on the backend. See Worksheet 4b for reference.

The evaluation team should consider factors such as:

- For each measure, what type of data is available and in what format?
- How complete is each field? Is there a pattern to the types of missing data?
- Which identifier(s) will be used to merge independent data sets?
- Do existing data allow you to answer the evaluation questions, or do you need to pivot your approach?
- Do the data seem accurate and believable?
- Is there a sharable data dictionary that defines each variable and includes how specifications have changed over time?
- Are there any concerns about protected health information, particularly for open text fields? How might those data be removed?

You may download a Word version of Worksheet 4b on identifying data specifications.



Assessing availability and merging and cleaning the data can take multiple iterations and several weeks depending on the complexity and current state of the data and staff capacity to work through data considerations.

Data sharing agreements must be in place early in the evaluation design phase, before implementation, to share data with an external evaluator, and meet HIPAA requirements. If you can't share data with evaluators early, share shell tables so they can get a sense of what will be available. More on types of agreements are in Section 4a.

3b. Identify Data Sources and Collection Methods (continued)

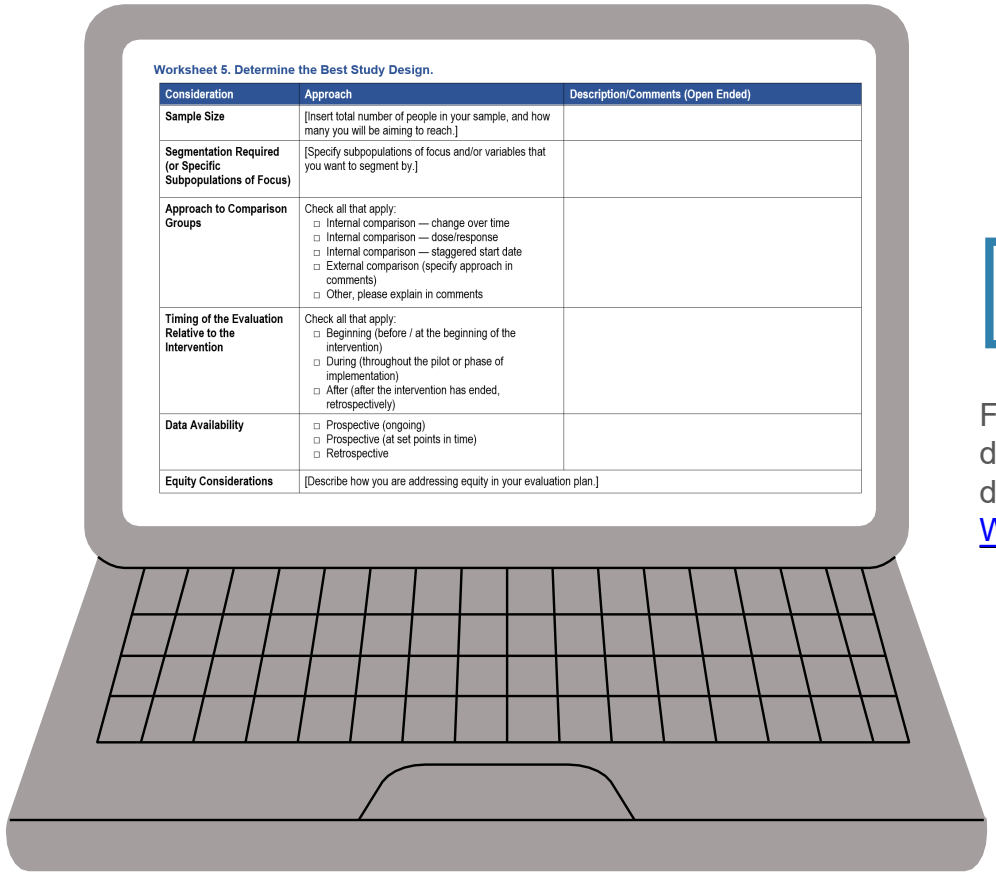
Spotlight on Health Plan Data and Data Sharing

Many digital health companies rely on health plan partners to access data about health outcomes, utilization, and cost. If you will be partnering with health plans, there are some considerations to keep in mind:

- **Allow sufficient time to access health plan data**. You will need to implement a business associate agreement (BAA, see Section 4d), and consider how you're using and who will see personal health information (PHI).
- **The process to complete contracting and data agreements can take three to six months to resolve.** Once you have the necessary agreements in place, there may be additional delays getting the requested data due to limited health plan staff capacity and competing priorities.
- **Understand early which data the health plan has and is willing to share**. Some health plan data (e.g., cost data) is considered proprietary. Other data (e.g., data on race and ethnicity) can be unreliable or incomplete. If you're working with multiple health plans, the data is likely to vary across them, so you'll need to discuss how to best utilize and compare data from multiple sources.
- **Expect high churn to impact your ability to track members consistently over time.** Health plans have current data only for currently covered members. For a longitudinal study, it can be difficult to maintain consistency within data sets if your study spans enrollment periods or if members are deemed ineligible and dropped from coverage. An evaluation plan should consider implications of losing members and gaining newly eligible members during the study period.

3c. Determine Approach to Comparison and Controls

Once you have identified your data sources and collection methods, you will be ready to consider the best research design for your evaluation, including your approach to comparison and control . Please refer to Worksheet 5 (Word) to help think through your study design.



Worksheet 5. Determine the Best Study Design.

Consideration	Approach	Description/Comments (Open Ended)
Sample Size	[Insert total number of people in your sample, and how many you will be aiming to reach.]	
Segmentation Required (or Specific Subpopulations of Focus)	[Specify subpopulations of focus and/or variables that you want to segment by.]	
Approach to Comparison Groups	Check all that apply: □ Internal comparison — change over time □ Internal comparison — dose/response □ Internal comparison — staggered start date □ External comparison (specify approach in comments) □ Other, please explain in comments	
Timing of the Evaluation Relative to the Intervention	Check all that apply: □ Beginning (before / at the beginning of the intervention) □ During (throughout the pilot or phase of implementation) □ After (after the intervention has ended, retrospectively)	
Data Availability	□ Prospective (ongoing) □ Prospective (at set points in time) □ Retrospective	
Equity Considerations	[Describe how you are addressing equity in your evaluation plan.]	

For more information about study design, see slides 41-45. You may download a Word version of Worksheet 5.

3c. Determine Approach to Comparisons and Controls (continued)

Comparison and Control groups are used to determine a cause-and-effect relationship between the intervention and the outcomes. Ideally, research designs hold all variables, apart from the intervention, constant to correctly measure the entire effect of the treatment without interference from any "confounding" variables.

Researchers compare people who do and don't participate in the intervention to establish cause-and-effect.

"External" comparison groups draw from similar people outside the participant population to compare to the intervention group. Ideally, these people are eligible for the program but aren't participating for an unrelated reason.

"Internal" comparison groups draw from similar people inside the participant population and assess if outcomes are different based on HOW or HOW MUCH members engage in the program.

- **Dose-Response studies** vary the intensity of engagement and assess the impact on health outcomes.
- **Staggered-Start-Date studies** vary the timing of when the intervention takes place, which can help clarify the affect of major changes in program design or events in the macroenvironment.

In research, you say: "Correlation doesn't imply causation."

Correlation means that when one variable changes, so does the other. There is a statistical association between the two variables. But covariation does not necessarily establish a direct or indirect causal relationship.

Causation means that a change in one variable causes a change in another variable; there is a cause-and-effect relationship between the two.

Randomization, or random assignment of participants to the intervention and control groups, is another way to ensures groups are initially similar and mitigate for "selection bias" that could skew the evaluation findings.

3c. Determine Approach to Comparisons and Controls (continued)

There is not a "right" or "best" type of research design. Each one serves a different purpose and might be best depending on needs, resources, and timing. Here are some basic types of research designs with different approaches to comparison and controls:

Descriptive or Correlational Studies are designed without a comparison group.

They focus on developing a clear picture of a process or group's characteristics, statistics, trends, and/or internal/external relationships as they exist in the real world.

- **An implementation study** describes how well a program or service is being administered. Process measures— access, adoption, feasibility, fidelity, implementation cost, coverage, and sustainability—can serve as indicators of implementation progress or status relative to what is intended.
- **A pre-post outcomes study, without a comparison group,** is a longitudinal study that measures how an outcome of interest in a group of participants changes from before an intervention begins and afterwards. The pre- and post-intervention data are compared to assess changes. This study design cannot rule out that something other than the intervention may have caused a change.

Controlled Outcomes Studies include a comparison group.

They focus on establishing a cause-and-effect relationship between an intervention and outcome.

- **A case-control observational study** compares two groups of people, cases and controls, to identify factors that may cause a specific health outcome. Researchers analyze information collected from/on two groups in the past - cases who have the outcome of interest and controls who do not - and compares group members' experiences and characteristics.
- **A controlled pre-post study (also called "Quasi-Experimental" design)** analyzes participant outcomes of an intervention and non-intervention group, where participants' group association pre-exist naturally rather than being assigned by researchers after systematic randomization.
- **Randomly Controlled Trial (RCT) (also called an "Experimental" Design)** is a comparative study that examines outcomes of intervention and non-intervention groups, where participants were recruited, randomized, and assigned to groups.

3c. Determine Approach to Comparisons and Controls (continued)

The "sample size" you use in your evaluation is another way to control for the influence of external factors with potential to distort your findings. Sample size, or the number of participants (e.g., individuals, hospitals, communities) in the study, directly impacts the validity, reliability, and generalizability of your findings.

Larger sample sizes minimize the effects of outliers in your population and strengthen the evaluation:

- **Statistical power and precision.** Ability to detect a true effect, if one exists, and estimate impact within a narrow range.
- **Generalizability.** Ability to deliver findings that are broadly applicable to populations or settings beyond the study.
- **Subgroup Analyses.** Ability to determine how the intervention affects different groups differently (e.g., ethnic groups, age categories).

Larger samples also require more resources, time, and attention.

Evaluators need to balance the value of robust evidence verses the efficient use of limited resources and burdens placed on research participants.

What specific sample size is required to detect a statistically relevant change in your outcome of interest? Evaluators determine the appropriate sample size through "power calculations." You can read more about calculations for determining sample size here.

Note on Health Equity

Where patient populations are very diverse, it's particularly important to ensure adequate representation of different demographic groups and geographic regions.

3c. Determine Approach to Comparisons and Controls (continued)

	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	• 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	• 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.
Resources	$$$	$	$$	$$$	$$$$
Sample	Varies	#	##	###	####
Duration	@	@@	@	@@@	@@@

3c. Determine Approach to Comparisons and Controls (continued)

Case Study: Text-Based Navigation Program or click here for the full case study example (Word)

Workgroup members decided that a pre-post evaluation design, without a control group, would be the best choice for their needs.

They left room to compare various levels of patient engagement and health outcomes (i.e., the "dose-response" effects), depending on how and how many patients joined the program. They included a strong qualitative component in the evaluation design to hear directly from staff and participants about their experiences and feelings on the program's implementation and results.

Bottom Line

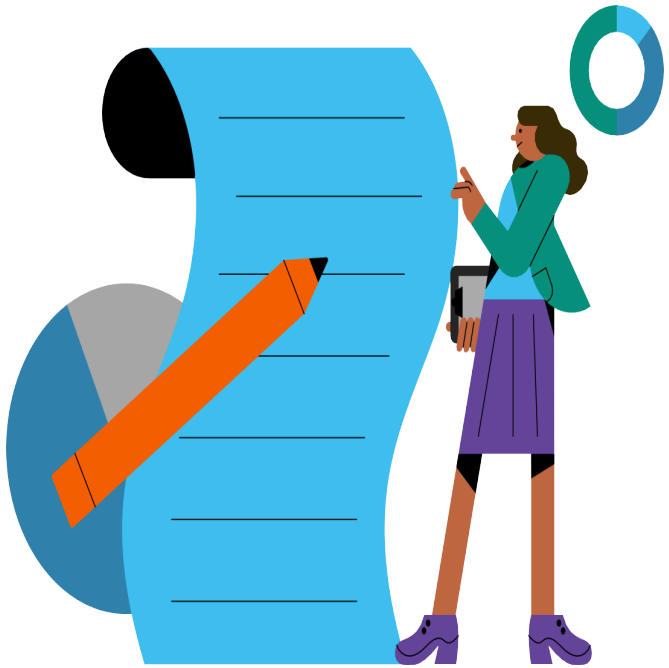
Robust and collaborative conversation, grounded by a clear logic model describing how the navigation program was intended to work, enabled partners to land on a cohesive evaluation design that met everyone's needs.

3d. Create Guidelines for Data Sharing and Management

Take the time up front to establish the systems and protocols for how qualitative and quantitative information will be shared and managed between evaluation partners, including the digital health company, health plan, healthcare provider, and/or external evaluator.

Establish roles and responsibilities for each step of data collection and management, including who will be responsible for collecting, sharing, storing, merging, cleaning, and analyzing the data. If data comes from multiple sources, expect ongoing engagement and iteration between partners.

Define approaches to data sharing including processes, frequency, and formats. Secure file transfer systems (SFT), or another system that uses secure protocols and encryption to safeguard data in transit, is needed to keep protected health information (PHI) and other data private. In general, data files are too large for email and having one central method for sharing data securely is best practice.



Create a management system:

- **How data will be stored** - e.g., the folder structure and how data will be "secured"
- **How data will be tracked** - e.g., a tracking sheet that identifies type of data, when it will be received, what source, where stored, and how/when it's cleaned and manipulated.
- **How participants will be identified and tracked** - consider creating a "study ID number" for each participant. Avoid relying on a person's name, birthdate, and address.
- **How changes in data will be flagged** — changes in data metrics and formats are common, so systems that track and accommodate these changes are critical.

3d. Create Guidelines for Data Sharing and Management (continued)

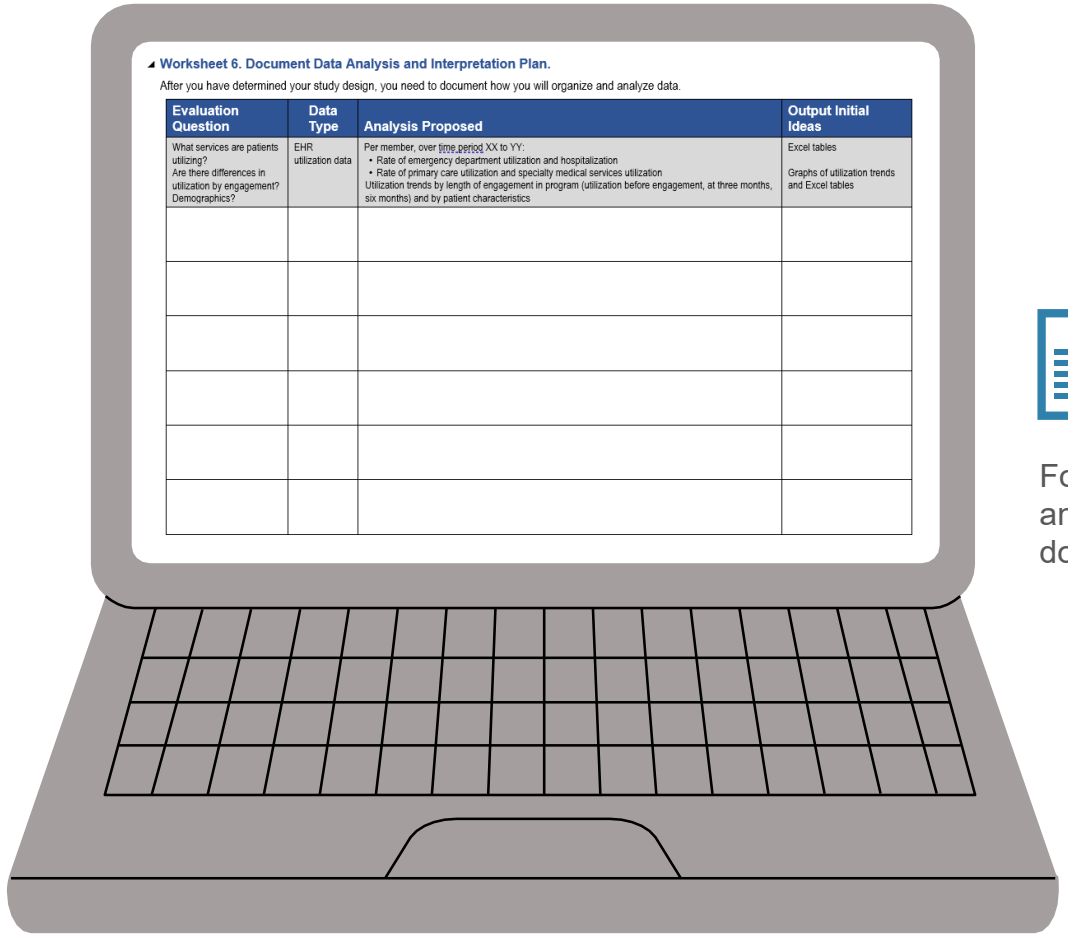
Case Study: Text-Based Navigation Program or click here for the full case study example (Word)

The evaluation workgroup completed the table below that includes the timing and frequency of select data collection activities.

EVALUATION QUESTION	MEASURES	DATA SOURCE	DATA COLLECTION FREQUENCY/TIMING
Were there differences in engagement, experience, or outcomes by demographic variables?	• Race/ethnicity of patients engaging with program • Analysis of utilization, satisfaction, and outcome data by race/ethnicity	• Health system data • Navigation program data	• Data pull at the midpoint and end of the study period
What is the experience of patients who participate in the navigation program?	• Patient reported satisfaction (e.g., needs were met, felt listened to, engagement) • Patient engagement in care & trust of health care system • Patient knowledge of available resources • Net promoter score	• Patient interviews • Navigation program data	• Rolling interviews at three months postpartum • Data pull at midpoint and end of the study period

3e. Plan for Analysis and Interpretation

Once you have outlined the research design, you will prepare for the statistical analysis and interpretation phase of your work, which should include your evaluation partners for their perspectives and insights. Please refer to Worksheet 6 (Word) to document your initial plans.



Worksheet 6. Document Data Analysis and Interpretation Plan.

After you have determined your study design, you need to document how you will organize and analyze data.

Evaluation Question	Data Type	Analysis Proposed	Output Initial Ideas
What services are patients utilizing? Are there differences in utilization by engagement? Demographics?	EHR utilization data	Per member, over time period XX to YY: • Rate of emergency department utilization and hospitalization • Rate of primary care utilization and specialty medical services utilization Utilization trends by length of engagement in program (utilization before engagement, at three months, six months) and by patient characteristics	Excel tables Graphs of utilization trends and Excel tables

For more information about planning for data analysis and interpretation, see slide 49. You may download a Word version of Worksheet 6.

3e. Plan for Analysis and Interpretation (continued)

Once you have outlined the research design, you can prepare for the statistical analysis and interpretation phase of your work, which should include your partners for their perspectives and insights. Consider the following questions as you do:

Preparing for Analysis

- What specific statistical analyses do you plan to run? Will those analyses provide precise answers to the critical evaluation questions?
- Do you have the software tools you need to, for example, randomize participants, match disparate data sets, de-identify personal health information, run analyses, and produce intuitive data tables and reports?
- Thinking ahead, what data tables will you need to complete and share for your partners so they understand the analyzes and can help interpret the results?
- What will you do if/when you face significant data quality or access issues that prevent you from proceeding as planned? (For example, if you have missing data about patient demographics and cannot segment by race/ethnicity.)

Preparing for Interpretation

- How will you leverage your partners to interpret initial findings and motivate them to share their perspectives actively and openly?
- What structures and processes can you use to check potential biases and ensure you and your partners ask “Why?” whenever you see trends in the data?
- Check for errors. If a finding is contrary to expectations or disparate data sources are at odds, check for potential errors in data entry or cleaning (e.g., a scale inverted, wrong units)
- Think about stratifications. Look for patterns in subgroups and individuals that do not follow the overall trends and ask why. Qualitative data can be useful to explain differential patterns in the quantitative data.
- Don’t overstate results. Don’t draw causality if the study design doesn’t justify it. Be wary of “one-liners” that can be misinterpreted, for example, stating that “XX people used the product, resulting in YY referrals that saved ZZ dollars.”
- Document limitations. Being transparent about the limitations of your data and your analysis will strengthen people’s trust in the research overall.

/4

PREPARE FOR LAUNCH AND IMPLEMENTATION

4a
4b
4c
4d

4. Prepare for Launch and Implement

Once you and your partners have agreed on evaluation purpose and design, you need to plan for implementing the work in advance of the formal start. This section describes the important plans and agreements and offers some best practices.

This section includes:

a. Establish Agreements Necessary to Protect Participants

b. Develop Staffing Plans

c. Craft Budget and Timelines

d. Plan Approach to Disseminate Findings and Pivot If Necessary

4a. Establish Agreements Necessary to Protect Participants

Once evaluation design is complete, you and your partners will need to select, negotiate, and sign agreements and contracts that protect your organizations and their constituents.

What agreements are necessary and appropriate will depend on the type of data being shared, your intended final products, and the policies of your evaluation partners.

It may be tempting to move ahead without some or all the necessary documentation or to comply by "checking the box" without careful consideration. Such decisions could put your company at legal risk, compromise your ability to use and disseminate the findings, and/or undermine protections that exist for the people using your products.

Types of agreements that may be necessary for your evaluation appear on the following slide.

4a. Establish Agreements Necessary to Protect Participants (continued)

AGREEMENT TYPES	PURPOSE	RESOURCES
Memorandum of Understanding (MOU)	Sometimes legally binding, sometimes not, agreement between parties that outlines topics such as the purpose and scope of work, roles and responsibilities, decision-making rights, and financial expectations.. It is often a precursor to a legally binding contract.	Sample template from CDC (Word)
Financial Contract(s)	Legally binding document between parties that defines and governs the parties' rights and responsibilities regarding funding. It often also includes language around data sharing and how funds can be used to support the work.	Each entity's contracting department will have unique needs.
Business Associate Agreement (BAA)	Necessary if parties intend to share identified data or protected health information (PHI). The BAA commits both entities to safeguarding PHI according to HIPAA regulations, and outlines who owns data, how data can be used (e.g., internally, externally, for sales, in publications), and what permissions are needed to access and disseminate data and findings.	Sample template from HHS (PDF)
Data Sharing Agreements / Data Use Agreements (DSAs/DUAs)	Necessary for transmitting or receiving a limited data set that has been stripped of direct patient identifiers specified in the HIPAA Privacy Rule (e.g., name, contact information, social security number, medical record number, etc.). Like a BAA, outlines who owns data, how the data can be used, and what permissions are needed to access and disseminate data and findings.	Sample template from CDC (Word)
Institutional Review Board (IRB) Review and Approval	Required for studies that involve human subjects to assure their protection and welfare. IRB is a formally constituted group with authority to approve, require modifications to, or disapprove research protocols and materials.	Typically, the health system will have an established IRB board or committee.
File Transfer Program or Secure File Transfer Program (FTP/SFT)	A data sharing system that uses secure protocols and encryption to safeguard data in transit. All users are vetted and given access to individual folders to pass protected health data between institutions.	Typically, these systems are already in place for each of your partners.
HIPAA Certification	Some organizations may require some form of recognition that their partner organizations' staff who will have access to PHI have the same level of HIPAA knowledge required by their own policies and procedures.	CITI Program provides HIPAA training and certification aligned with HIPAA legislation (1996) .

4a. Establish Agreements Necessary to Protect Participants (continued)

Case Study: Text-Based Navigation Program or click here for the full case study example (Word)

A data sharing agreement (DSA) between the health system and external evaluator enabled health system staff to de-identify data sets and provide them to the external evaluator to be merged and analyzed.

A business associate agreement (BAA) between the health system and digital health company was also required for data sharing and matching of patient-identified information. Due to contracting issues, limited specialized staff, and lengthy legal review, it took six months to establish the BAA and for data collection to begin, which significantly delayed the evaluation timeline.

Institution review board (IRB) approvals were necessary for both the external evaluator and health system. The process smoothly and quickly, although this step can often cause delays. Both IRBs determined the evaluation work was "not research" given the primary purpose was internal quality improvement.

Bottom Line

It can take months to determine what agreements are needed and to get them in place, so project plans should allow sufficient time upfront and include contingencies in case approvals take longer than expected.

4b. Develop Staffing Plans

Optimal staffing will depend on the nature of the evaluation, number of unique partners, scale and duration of the work. You should think through staffing by each stage of the evaluation.

Staffing to establish vision and design requires representatives from every organization and area of expertise to develop an effective evaluation design and meaningful commitment, including leaders from senior management, product design and implementation, data systems and IT, quality and evaluation, and legal.

Staffing to implement data collection and analyses requires a smaller number of specialized experts for:

- Interviews, focus groups, surveys, and data pulls from IT systems
- Quantitative data sharing, cleaning, and integration
- Statistical analyses, ideally with robust controls and comparison groups

Staffing to interpret findings requires:

- A small team to structure presentations, facilitate insightful conversations, and synthesize agreed-on conclusions
- A wide range of functional and organizational representatives to participate in feedback sessions and signal support for conclusions

Staffing to dissemination findings requires a small team with communications expertise to:

- Revisit and confirm initial communications plans
- Prepare final reports and communications materials
- Disseminate findings, narrowly to internal stakeholders or broadly through media, convenings, or peer-reviewed journals

Bottom Line

Robust evaluations typically require representatives from across participating organizations, organizational roles, and areas of expertise – and a person or team charged with project management and facilitation. Organizations often hire an external evaluation firm to support the work.

4b. Develop Staffing Plans (continued)

Consider hiring an external person or team that specializes in evaluation design and implementation. There are advantages to either approach:

Advantages of External Evaluation Team

- Additional capacity and expertise related to data collection, data management, statistical analyses, complex project management, and/or publishing in peer-reviewed journals
- An independent perspective and credibility from an outsider's perspective, if the research is conducted at arms-length

Advantages of Internal Evaluation Team

- Intuitive understanding of the work's context and purpose
- More seamless access to critical data and resources
- Ability to drive real-time continuous improvements
- More sustainable integrated support for very long projects

If you decide on an external evaluator, consider these factors in selecting one:

- Approach to evaluation (e.g., focus on maintaining independence, focus on iterative quality improvement)
- Specific areas of technical or subject matter expertise you lack internally
- Ability and willingness to supporting basic internal capacity
- The team's credibility, trust-worthiness, and/or collaborative spirit
- Alignment in values and goals for the work

4b. Develop Staffing Plans (continued)

Establish and maintain an evaluation workgroup with standing meetings to address questions and challenges as they arise.

Workgroup participants from each participating organization should include:

- **An engaged leader and decisionmaker.** This person will help to set expectations for an evaluation, ensure participation and access to information, determine what can be improved/modified based on evaluation results, make connections between an evaluation and business goals, and inform dissemination decisions.
- **A data lead.** This person will be responsible for providing data to the evaluator and working with the evaluator to understand, manipulate, and refine the data as needed.

Some topics for workgroup discussions include:

- **Timeline and scope of work.** Changes to the evaluation workplan and/or agreed-upon activities, responsibilities, timelines, and key decision points.
- **Data collection tools.** Review and feedback on data collection tools, including survey instruments, interview questions, and shell data tables to ensure parties align on what information is being gathered as part of an evaluation.
- **Budget.** Changes in timeline or scope of work that have budget implications and how any additional expenses will be accounted for and/or shared.
- **Pivots.** Adjustments necessary to the evaluation plan or underlying product design or implementation. These kinds of pivots are discussed more in Section 4d.

4c. Create Budgets and Timelines

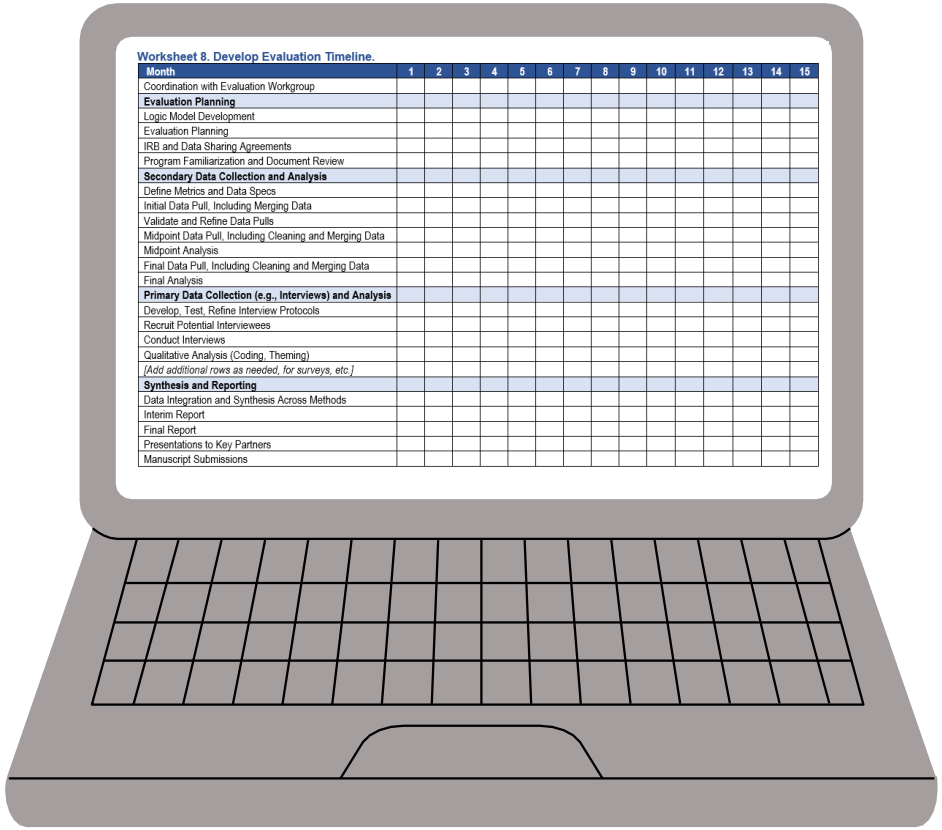
To determine a project timeline, consider how long it takes to deliver the intervention, note when you need evaluation results, and work backward from there.

Robust evaluation will take at least 12 months:

- At least three months to plan research and negotiate data sharing agreements, with more required for more partners, participants, and complex agreements (see Section 4c.)
- At least six months for data collection and analyses. If using retrospective data, this full period may be shorter.
- At least three months for generate findings, get buy-in from partners, and develop reports.

Beyond these general guidelines, consider:

- How much time is needed between the intervention and intended health outcomes (refer to your logic model)?
- Do you already have access to longitudinal data? If not, how long do you need to track participants to see results?
- Do you want or need to follow up with participants after the intervention to understand if results were sustained?



Worksheet 8. Develop Evaluation Timeline.

Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Coordination with Evaluation Workgroup															
Evaluation Planning															
Logic Model Development															
Evaluation Planning															
IRB and Data Sharing Agreements															
Program Familiarization and Document Review															
Secondary Data Collection and Analysis															
Define Metrics and Data Specs															
Initial Data Pull, Including Merging Data															
Validate and Refine Data Pulls															
Midpoint Data Pull, Including Cleaning and Merging Data															
Midpoint Analysis															
Final Data Pull, Including Cleaning and Merging Data															
Final Analysis															
Primary Data Collection (e.g., Interviews) and Analysis															
Develop, Test, Refine Interview Protocols															
Recruit Potential Interviewees															
Conduct Interviews															
Qualitative Analysis (Coding, Theming)															
[Add additional rows as needed, for surveys, etc.]															
Synthesis and Reporting															
Data Integration and Synthesis Across Methods															
Interim Report															
Final Report															
Presentations to Key Partners															
Manuscript Submissions															

You may download a Word version of Worksheet 8 on developing an evaluation timeline.

4c. Create Budgets and Timelines (continued)

Case Study: Text-Based Navigation Program Preparing to Operationalize or click here for the full case study example (Word)

Once evaluation planning and design were complete, the workgroup turned to logistical considerations:

- **Capacity.** Agreed the external evaluator would handle data management and analysis, a core group of representatives would join regular meetings, and a meaningful set of measures would be shared between the digital health company and health system.
- **Data access.** Started work on the IRB, BAA, and DSA agreements, which eventually ran long by three months.
- **Budget.** Reviewed a comprehensive budget including resources required from each partner.
- **Timeline. Agreed** on a comprehensive timeline and workplan (see next slide), which were reviewed and adjusted at each workgroup meeting. For example, when finalizing the DSA took three months longer, the timing of clinical data collection and patient interviews was pushed out.

Bottom Line

The workgroup determined it was feasible to implement the evaluation as designed but continually revisited the budget and timeline as changes came up over the evaluation period.

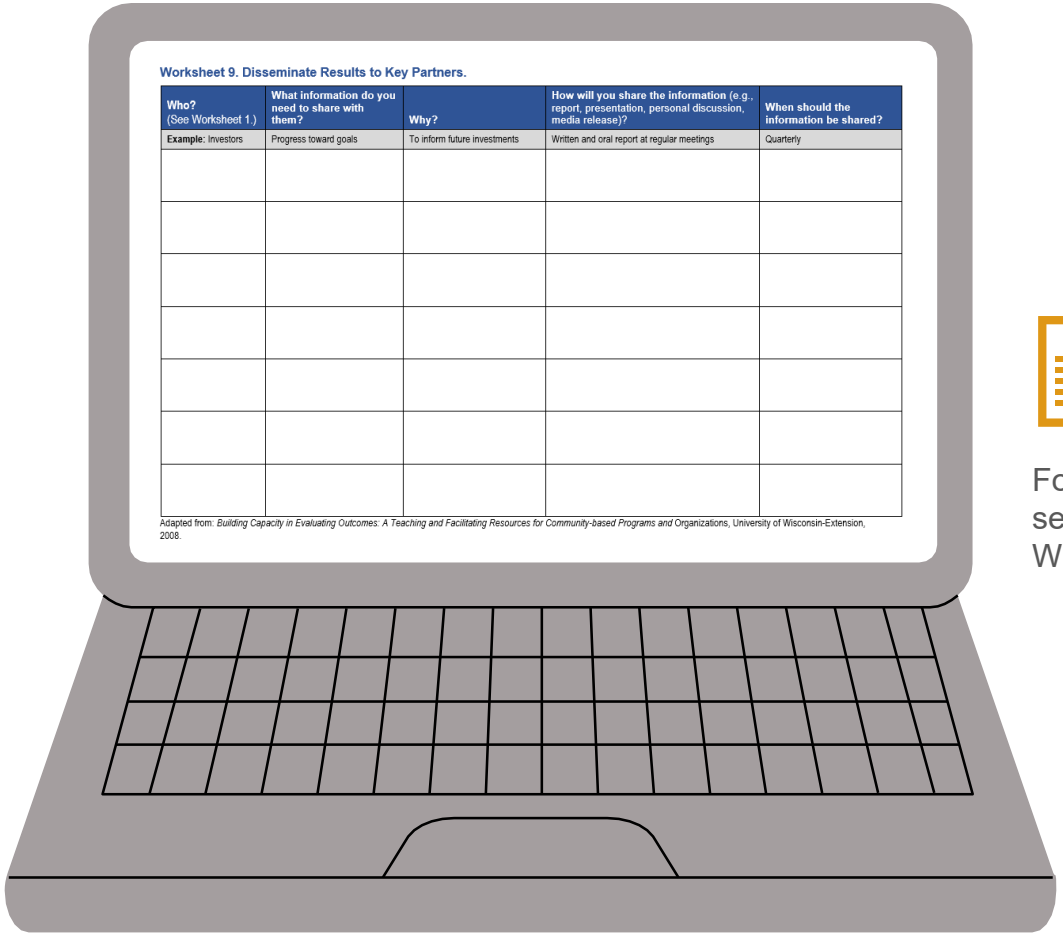
4c. Create Budgets and Timelines (continued)

Case Study: Text-Based Navigation Program Workplan or click here for the full case study example (Word)

MONTH	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D
Coordination with evaluation workgroup	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Evaluation planning															
Logic model development	X														
Evaluation plan		X	X												
IRB & data sharing agreements	X	X	X												
Program familiarization & document review	X	X	X												
Clinical data collection															
Define metrics & data specs	X	X	X												
Validate & refine data pulls				X											
Initial data analysis					X										
Midpoint data pull								X							
Final data pull												X			
Final analysis												X	X	X	
Interviews (primary data collection)															
Develop, test, refine staff & patient interview protocols			X	X											
Staff interviews				X	X						X	X			
Patient interviews							X	X	X						
Qualitative analysis						X				X	X	X	X	X	
Reporting															
Internal learning session						X									
Interim report									X						
Final report														X	X

4d. Plan Approach to Disseminating Results and Potential Pivots

After you've analyzed and interpreted your data, you will need to determine how information will be shared. It is helpful to have these conversations early to ensure key partners are aligned, and it is also necessary to revisit these decisions once results are final.



Worksheet 9. Disseminate Results to Key Partners.

Who? (See Worksheet 1.)	What information do you need to share with them?	Why?	How will you share the information (e.g., report, presentation, personal discussion, media release)?	When should the information be shared?
Example: Investors	Progress toward goals	To inform future investments	Written and oral report at regular meetings	Quarterly

Adapted from: *Building Capacity in Evaluating Outcomes: A Teaching and Facilitating Resources for Community-based Programs and* Organizations, University of Wisconsin-Extension, 2008.

For more information about dissemination, see slides 63 and 63 You may download a Word version of Worksheet 9.

4d. Plan Approach to Disseminating Results and Potential Pivots (continued)

After you've analyzed and interpreted your data, you will need to revisit how findings will be shared. Partners may feel different about dissemination opportunities depending on the results of the evaluation. Consider:

Who needs access to the results, and by when? Ideally, an evaluation will be used to inform decisions and next steps. The timing of dissemination should consider key decision points so that data are available to inform those decisions. Ideally, you would have this mapped out in an evaluation timeline.

What findings, if any, will be disseminated to participants? From an equity and engagement perspective, it is always best practice to share data with people who participate. This does not need to be a full report on all the data but a summary of what was learned and how it's being used. This can help participants feel like their voices were heard and the time they spent engaging in an evaluation was worthwhile.

What methods, resources, and findings can become publicly available? To inform the field and benefit others doing similar work, it is helpful to share evaluation resources and results in the public domain. This might include unique methods or tools you used, survey instruments developed, or the results of an evaluation itself.

Who makes decisions about what is disseminated? You will need to engage with your key partners about what aspects of the project are proprietary and what can be shared or published through peer-reviewed publications or other mechanisms. The decision to share findings can be contentious, especially if the results are not positive and partners want to "protect" their product or brand.

How will you communicate your findings? If a written report, what's the high-level outline and length? If a presentation, what data tables will be critical to summarize raw data, characterize control and intervention groups, and present results?

Who needs to vet the reports and presentations before they are shared? Different organizations have different policies and procedures around sharing information internally and externally. It is important to understand what, if any, review process is required before disseminating results. An external evaluator may have their own dissemination goals that will need to be considered.

4d. Plan Approach to Disseminating Results and Potential Pivots (continued)

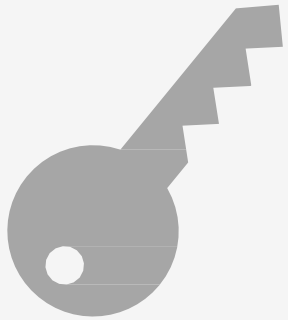
It is useful to think proactively about internal and external factors that could impact the evaluation, who needs to be involved in deciding to pivot, and how changes should be managed.

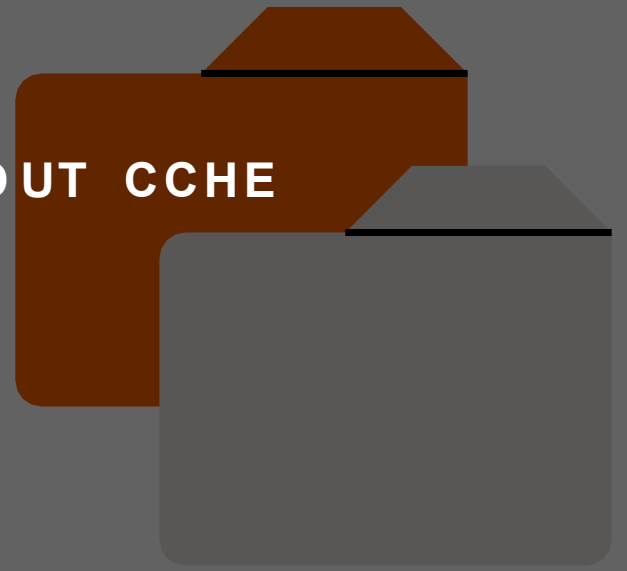
Most interventions occur in a complex, constantly shifting environment. Internal and external changes in funding, resources, priorities, policies, and practices can all impact an evaluation. Several factors could necessitate major or minor adjustments to the evaluation:

- **Interim results, either positive or negative.** For example, randomized controlled trials in clinical settings include specific triggers for discontinuing research when it's unethical to continue.
- **Unanticipated redesign of the program or intervention.** Your partners should notify you proactively if circumstances necessitate the evaluation to be restructured or metrics for gauging impact to be adjusted.
- **Evolution in the policy, regulatory, or competitive landscape.** Big-picture dynamics could alter how participants engage or your partners' interest in marketing the program.
- **New partners or partner priorities.** Changes in the composition or needs of your leadership group could require you to revisit the evaluation questions, metrics, data sources, or timelines. Ongoing workgroup meetings help identify these factors early and keep partners aligned.

/5

RESOURCES & ABOUT CCHE





5. Additional Resources

Abundant resources and tools are available to support your effort to plan and implement evaluation projects, especially those focus to improving health access and quality of care in Medicaid.

This section includes:

a. Additional Resources

b. Center for Community Health and Evaluation (CCHE)

5a. Additional Resources

This checklist (PDF) gives a quick summary of key questions and considerations when considering evaluation.

This case study example (Word) was referenced throughout the toolkit. We have combined the sections into one document to illustrate how the toolkit steps might play out in the real world.

This workbook (Word) was referenced throughout the toolkit and has been combined into one document for your own evaluation planning.

Measuring What Matters is CCHE's evaluation design toolkit that walks the user through several stages of an evaluation process, from creating a logic model to implementing different kinds of evaluation activities.

This equity evaluation discussion guide and these equitable design checklists are useful to support creating an equitable evaluation.

5b. Center for Community Health and Evaluation

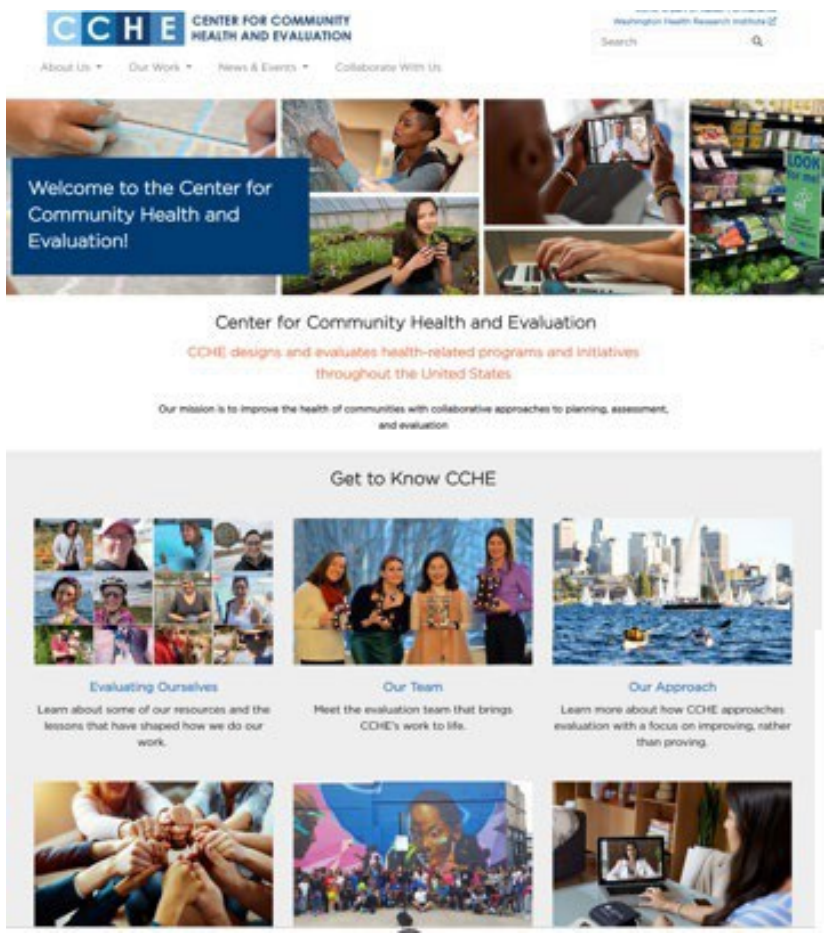
CCHE designs and evaluates health-related programs and initiatives throughout the United States.

Our mission is to improve the health of communities with collaborative approaches to planning, assessment, and evaluation.

As an evaluation partner, CCHE uses a participatory approach that values diverse perspectives and centers equity.

www.cche.org

cche@kp.org



PARTNERSHIP

RESULTS

INSIGHTS

Evaluating Innovations in Medicaid

AN EVALUATION DESIGN TOOLKIT FOR DIGITAL HEALTH COMPANIES

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

CHCF INNOVATION FUND