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CASE STUDY: GENERALIZABILTY FRAMEWORK

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This resource was developed from a workshop, "Will It Work Here? A Generalizability Framework for Applying Evidence From Impact Evaluations in New Contexts," presented at the Camden Coalition's National Center for Complex Health and Social Needs conference *Putting Care at the Center* 2018. Learn more about the National Center at www.nationalcomplex.care.

GETTING STARTED

Start by reading The Generalizability Puzzle[1] to learn a practical approach for combining different kinds of evidence to assess whether a given policy will likely work in a new context. The article provides concrete examples of how evidence from prior evaluations can guide decisions about implementation in different contexts.

GENERALIZABILITY FRAMEWORK: BACKGROUND

The generalizability framework provides a practical approach for using evidence to assess whether a given program can be replicated or adapted to work in a new setting.

How exactly can evidence from randomized controlled trials (RCTs) and other rigorous evaluations inform the design of programs? There may be strong evidence showing that certain effects (e.g., improvements in health outcomes) were caused by a program. But if providers replicated this evidence-backed approach in a new context, could they expect the impact to be similar? Leaders, practitioners, and policymakers who develop, implement, and/or fund social programs often face this generalizability puzzle—whether the results of a specific program will generalize, or apply, to other contexts.

The steps in this framework guide users to assess the conditions and mechanisms underlying a previous program, consider the relevant local conditions in their own context, and ask questions to determine whether the implementation of a similar program in their own context might be effective and feasible.

[1] This resource and introductory text draw from Mary Ann Bates and Rachel Glennerster's, "The Generalizability Puzzle," 2017, Stanford Social Innovation Review. https://ssir.org/articles/entry/the_generalizability_puzzle.

GENERALIZABILITY FRAMEWORK OVERVIEW

The four steps of the generalizability framework provide a structure for assessing whether an evidence-based intervention will be effective in a new context.

Step 1: Theory of Change. Write down the theory of change for the original program and articulate the key assumptions for why it worked. For example, you could follow this format:

Step 2: Local Conditions. Find descriptive data to better understand if the underlying issue from the original context is also at play in your community. Answer the following questions:

- Does the issue or challenge that the original program aimed to solve exist in your community? To what extent?
- Is there evidence that the underlying cause is the same or similar?
- Are the same conditions that were important for the intervention to be implemented in the original context also true in your case?

Step 3: Generalized Lessons on Behavior. Assess the strength of the evidence for the mechanisms that made the program effective in the original context(s), and whether the key assumptions are likely to hold in your context. Answer the following questions:

- What evidence exists that the theory of change for the original program is valid?
  What is the quality of the evidence?
- What are the underlying reasons for why this theory is generally effective?
- What assumptions are required and do they hold in the new context?

Step 4: Local Implementation. Assess whether you or another organization can successfully implement the intervention with fidelity to the original model. Answer the following questions:

- What are the critical implementation assumptions that must be met for the program to be implemented with fidelity?
- In this new context, who would implement the program and do they have the capacity? What are potentially enabling/hindering factors?

CASE STUDY: APPLYING THE GENERALIZABILITY FRAMEWORK TO A PATIENT-CENTERED COMMUNITY HEALTH WORKER (CHW) INTERVENTION TO IMPROVE POSTHOSPITAL OUTCOMES

Study referenced: Kangovi, Shreya, Nandita Mitra, Lindsey Norton, Rory Harte, Xinyi Zhao, Tamala Carter, David Grande, and Judith A. Long. "Effect of Community Health Worker Support on Clinical Outcomes of Low-Income Patients Across Primary Care Facilities: A Randomized Clinical Trial." *JAMA Internal Medicine.* 178(12) (2018): 1635–1643. doi:10.1001/jamainternmed.2018.4630

Disclaimer: J-PAL North America was not involved in the above-referenced study, which is part of a larger body of research. We are using the study, which describes a randomized controlled trial (RCT) evaluating a community health worker-led intervention (IMPaCT), as an illustrative example to share how one could use the generalizability framework to assess whether an evaluation might apply to one's own context. For more comprehensive information about the IMPaCT model, see the Penn Center for Community Health Workers' webpage (chw.upenn.edu/about/). The Penn Center also engages with stakeholders from partner organizations (clinicians, patient representatives and health system leaders) to plan their CHW programs (see details at chw.upenn.edu/services/).

CASE STUDY INTRODUCTION

This case study walks through a hypothetical scenario of how you might use a generalizability framework to apply evidence from an evaluation to a new context. While this example refers to a community health worker (CHW) intervention, this framework can be used for many topic areas.

The scenario and steps below are simplified in order to give readers a general introduction. This case study provides an approximate overview of how you might approach the question of generalizability.

SCENARIO: OUTPATIENT PRIMARY CARE CENTER, RURAL INDIANA

For this case study, imagine that you are a staff member working at a health care center as described below. You are interested in starting a program with CHWs at your outpatient primary care center in rural Indiana.

Your analytics team has shown you that chronic disease control outcomes have been getting worse and that more patients are being readmitted to area hospitals. You think that hiring CHWs to work with patients might turn this trend around.

You start by doing some research and come across a randomized controlled trial (RCT) of a CHW program that looks promising. However, you're not exactly sure if the program will adapt well to your context.

PREVIOUS STUDY: IMPACT INTERVENTION IN THE PHILADELPHIA AREA

Here is what you learn about the previous randomized controlled trial (RCT) of a CHW program in a different context:

Study Setting: This study took place at three locations in the Philadelphia area: a VA (Veterans Affairs) primary care practice, a federally qualified health center, and an academic family practice clinic.

Study Eligibility: Patients in the study met the following criteria:

1. adult patients (aged 18 years or older) with an appointment in the previous year
2. residents of eight high-poverty ZIP codes in the Philadelphia, Pennsylvania area
3. uninsured or publicly insured, including all veterans
4. received a diagnosis for two or more targeted chronic diseases

INTERVENTION COMPONENTS

The intervention, known as IMPaCT (Individualized Management for Patient-Centered Targets), occurs in three stages. The Penn Center for Community Health Workers has more information on the IMPaCT model.

Stage 1: Goal setting. CHWs assess relevant socioeconomic determinants of health and collaborate with the patient to create individualized goals that feed into tailored action plans.

Stage 2: Tailored support. CHWs provide six months of hands-on, tailored support, communicating with patients at least once per week, including monthly in-person contact.

Stage 3: Connection with long-term support. CHWs help identify long-term supports such as neighbors or family members who can support the patients after the intervention is completed.

SUMMARY OF IMPACT STUDY RESULTS (PHILADELPHIA AREA)

Primary outcome: Self-rated physical health

Participants in both the treatment group (those that received the IMPaCT intervention) and control group (those that received services as usual) had similar improvements in self-rated physical health.

Secondary outcomes: Self-rated mental health, chronic disease control, patient activation, patient-reported quality of primary care, and all-cause hospitalization

Participants in the treatment group were more likely to report the highest quality of care, had spent fewer total days in the hospital over sixth months, and had lower odds of repeat hospitalizations, including 30-day readmissions.

APPLY THE GENERALIZABILITY FRAMEWORK

This generalizability framework will help you assess how a previously studied program might inform the development and implementation of a similar program in your context. Following the steps below can help you make informed decisions when implementing and/or adapting programs that have been evaluated previously (e.g., in this scenario, whether and how to implement the IMPaCT intervention in the rural Indiana setting).

STEP 1: MAP A THEORY OF CHANGE FOR THE PREVIOUS STUDY

A theory of change describes a strategy for achieving a long-term goal. Mapping a theory of change involves identifying the preconditions, pathways, and interventions necessary for success and clarifying the causal links between the intervention and the final outcome.

Using this worksheet, refer to the previous IMPaCT study and write down the theory of change for the original program. Write descriptions and indicators (also known as metrics) for each stage of the program and note key assumptions for why the program was effective.

	NEEDS	INPUTS: THE INTERVENTION AS PLANNED	OUTPUTS: DELIVERY OF THE INTERVENTION	INTERMEDIATE OUTCOMES: BEHAVIOR CHANGE	FINAL OUTCOMES: IMPACT
	What is the challenge this intervention seeks to address?	What is the intervention?	Is the intervention delivered?	What are the program's short-term goals?	What are the program's long-term goals?
COMPREHENSIVE DESCRIPTION OF STEP					
UNDERLYING ASSUMPTIONS					
INDICATORS OR METRICS FOR MEASUREMENT					

To illustrate a possible result of this mapping process, an example of a Theory of Change for the IMPaCT study is below.

THEORY OF CHANGE OF THE PREVIOUS IMPACT STUDY (PHILADELPHIA AREA)

	NEEDS	INPUTS: THE INTERVENTION AS PLANNED	OUTPUTS: DELIVERY OF THE INTERVENTION	INTERMEDIATE OUTCOMES: BEHAVIOR CHANGE	FINAL OUTCOMES: IMPACT
	What is the challenge this intervention seeks to address?	**What is the intervention?**	**Is the intervention delivered?**	**What are the program's short-term goals?**	**What are the program's long-term goals?**
COMPREHENSIVE DESCRIPTION OF STEP	Uninsured and publicly insured patients living in high-poverty areas have a high burden of chronic illness Patients with chronic illness contribute to high hospital usage, including readmissions Current hospital personnel lack time, skills, and/or linkages to address social determinants of health/social needs	CHWs (Community Health Workers): 1. Set goals and create action plans with patients 2. Support patients (via calls, texts, and visits) during/ post admission 3. Help patients identify long-term supports	CHWs meet with patients, set personalized goals, and create tailored action plans CHWs provide 6 months of hands-on tailored support, communicating with patients at least once per week, including face-to-face contact	CHW social support, navigation and advocacy enables patients to achieve goals set out in their action plans (e.g., if goal was to quit smoking, patient began attending smoking cessation classes)	Patients have improved self-rated health, chronic disease control, patient activation, quality of primary care, and lower all-cause hospitalization
UNDERLYING ASSUMPTIONS	Patients from underserved backgrounds mistrust current personnel	Socioeconomic and behavioral risk factors influence chronic disease outcomes and utilization	During meetings, CHWs have a clear sense of the procedures for setting goals and plans	Patients accurately report their progress on their goals	The listed outcomes have been validated and are accurately captured in existing data systems
INDICATORS OR METRICS FOR MEASUREMENT	Hospital usage by patients with chronic illness Hospitalizations Other indicators	CHWs have initial meetings with patients	Frequency of CHWs meeting with patients as planned over 6 months	Frequency of patients achieving their goals	Self-rated health Hospital usage Hospitalizations Other indicators of health and quality of care

STEP 2: ASSESS LOCAL CONDITIONS IN YOUR CONTEXT (RURAL INDIANA)

Search for descriptive data to better understand if the underlying issues and conditions from the original context are similar to those in your community. Checking the following sources may help you begin the search for relevant descriptive data:

- Records from your clinic (e.g. electronic medical records)
- Claims data
- Publicly available data from your community
- J-PAL North America's Catalog of Administrative Data Sets: To assist implementers and researchers in screening potential data sources, J-PAL North America has cataloged a number of key US data sets. The catalog documents procedures on how to access data based on information provided by the originating agencies.

Using the data you have found, answer the following questions:

- Does the issue or challenge that the original program aimed to solve exist in your community? To what extent?
  - In other words, does your program serve many uninsured and publicly insured patients living in high-poverty areas?
  - Is there a high burden of chronic illness that is modifiable through lifestyle and behavior changes (e.g., hypertension, diabetes)?
  - **Where to look for descriptive data:** You can draw from publicly available data in your community as well as claims or medical record data to find this information.

- Is there evidence that the underlying cause is the same or similar? That is, are there high levels of socioeconomic and behavioral risk factors among the population you serve?
  - **Where to look for descriptive data:** You could look at quantitative (e.g., claims, medical records) and qualitative data (e.g., survey results, medical chart notes) that your hospital collects to help you answer this.

- Are the same conditions that were important for the intervention to be implemented in the original context also true in your context in Indiana? One important difference to consider is that the study took place in a largely urban setting. This may make the face-to-face component of the intervention more difficult to implement if patients live very far away from your clinic.
  - **Where to look for descriptive data:** Again, you can draw from publicly available data in your community as well as claims or medical record data to find this information. For example, to assess ease of access to care in your rural setting versus the more urban settings of the IMPaCT study, estimate the average distance and/or time that it takes patients to travel to your clinic.

Answering these questions will allow you to assess how much your own context does or does not match the "Needs" column of the Theory of Change for the IMPaCT study.

STEP 3: ASSESS STRENGTH OF EVIDENCE ON BEHAVIORAL MECHANISMS AND ASK IF KEY ASSUMPTIONS HOLD

The next step is to assess the strength of existing evidence for the behavioral mechanisms that made the program effective in the original contexts, and whether the key assumptions are likely to hold in your context. Answer the following question:

- What evidence supports the theory of change for the original program?

Start by taking a look at peer-reviewed academic literature to confirm (or to call into question) the generalized lessons on behavior that are key underlying assumptions of the original program. Consider looking for previous research that could help answer the following questions:

- How does a patient's socioeconomic status affect their health?
- What else do we know about CHW program effectiveness?
- Is there evidence that personalized coaching to target behavior change can be effective?
- Why might each intervention component be effective?

Sources for evidence in the field of complex care include:

- Databases such as Medline and the Cumulative Index to Nursing and Allied Health Literature (CINAHL) Database
- Quick Reference Guide to Promising Care Models for Patients with Complex Needs. This resource summarizes the target populations, key features, and evidence for 28 care models for adults with complex needs.
- Search results from the Agency for Healthcare Research & Quality (AHRQ) website

Sources for evidence about potentially relevant social programs outside of the specific field of complex care include:

- J-PAL Evaluations Database
- J-PAL North America Evidence Portal (including a section on Health)
- What Works Clearinghouse (primarily focused on education)
- CrimeSolutions.gov (focused on criminal justice)
- Journal articles and literature reviews

What is the quality of the evidence you find? Are there rigorous studies that suggest the Theory of Change is likely to hold?

- As you assess the strength of research, it may be helpful to refer to J-PAL North America's two-page resource on impact evaluation methods. Different methods of impact evaluation require different assumptions to hold in order for them to offer reliable evidence.

STEP 4: ASSESS POSSIBILITIES FOR LOCAL IMPLEMENTATION: IMPLEMENT THE IMPACT MODEL AT YOUR CENTER IN INDIANA?

Finally, assess whether you could successfully implement the IMPaCT intervention in your own context (an outpatient care center in rural Indiana) with fidelity to the original model (as implemented in the Philadelphia area). Answer the following question:

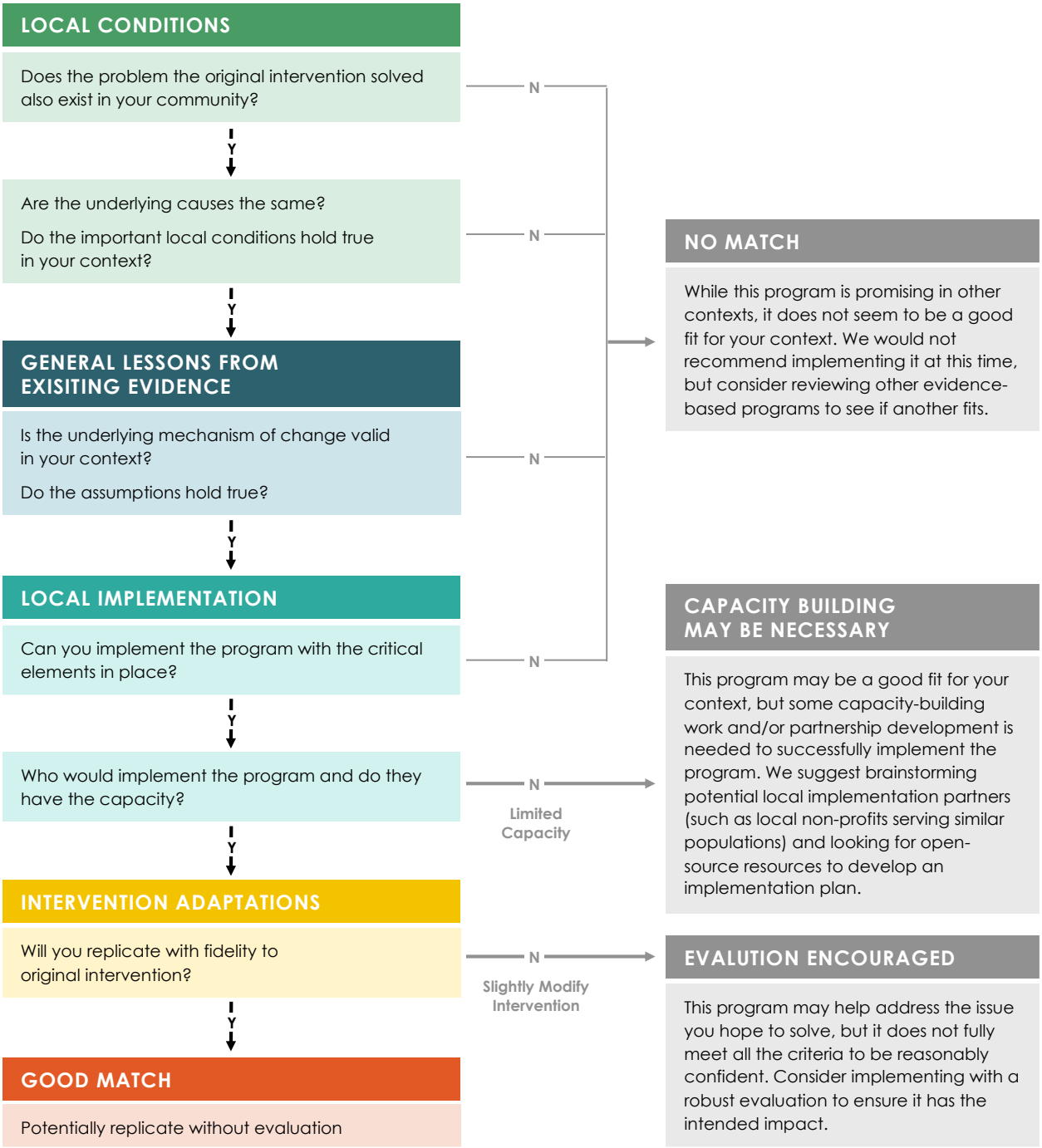
- What are the critical implementation assumptions that must be met for the program to be implemented with fidelity? Ensure that you understand all of the components of the intervention that was evaluated.

In this case, what implementation considerations would you have when deciding whether or not to implement IMPaCT in your clinic in Indiana? Consider:

- Who would implement the program and do they have the capacity to do so with fidelity? In addition to the CHWs, would you need to hire other personnel to support implementation? Is there a budget to implement the program with fidelity?
- CHWs support patients for a period of six months over the phone and in person. Is this feasible in your context? How might you need to adapt the program to fit in your setting?

PUTTING IT ALL TOGETHER: DECISION TREE

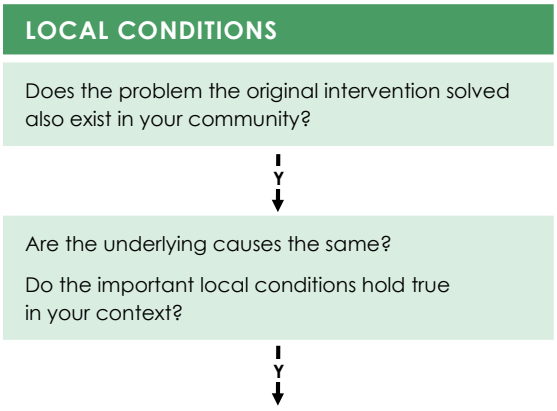
Finally, once you have completed the steps of the generalizability framework, you can use the following decision tree to help you interpret your analysis:



Here are the three key questions that the decision tree can help you answer:

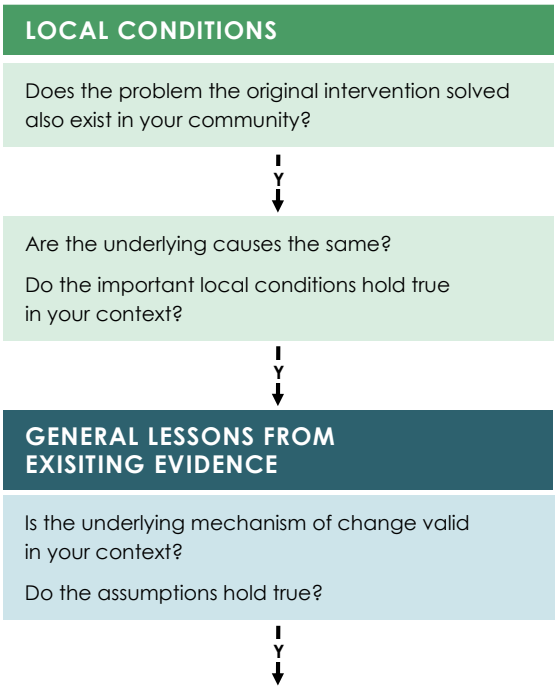
- Should you implement a version of the IMPaCT model in Indiana?
- Would it be feasible to implement the IMPaCT model as it is, or would the model need to be adapted?
- Would it be valuable to evaluate an adaptation of the IMPaCT model in your setting?

In reality, each decision point below would depend on the specifics of your context and would most likely involve research and deliberations with others at your organization. Here are some simplified conclusions you might reach about the IMPaCT scenario:

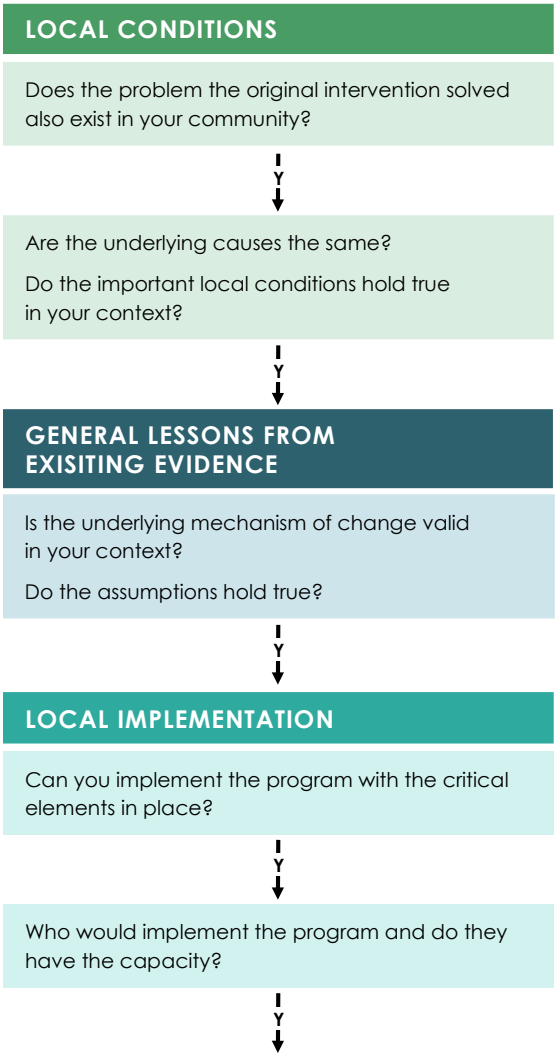


At the decision points in this "Local Conditions" step, you might determine that based on characteristics of the patients you serve and the current conditions at your primary care center in Indiana, the underlying causes do seem to be the same (answering "Yes" to each of the questions posed in the two green boxes).

After considering the next question and conducting further research you also determine that the underlying mechanism of change and assumptions hold true (answering "Yes" to the "General Lessons from Existing Evidence" questions in the blue box shown in the below diagram).

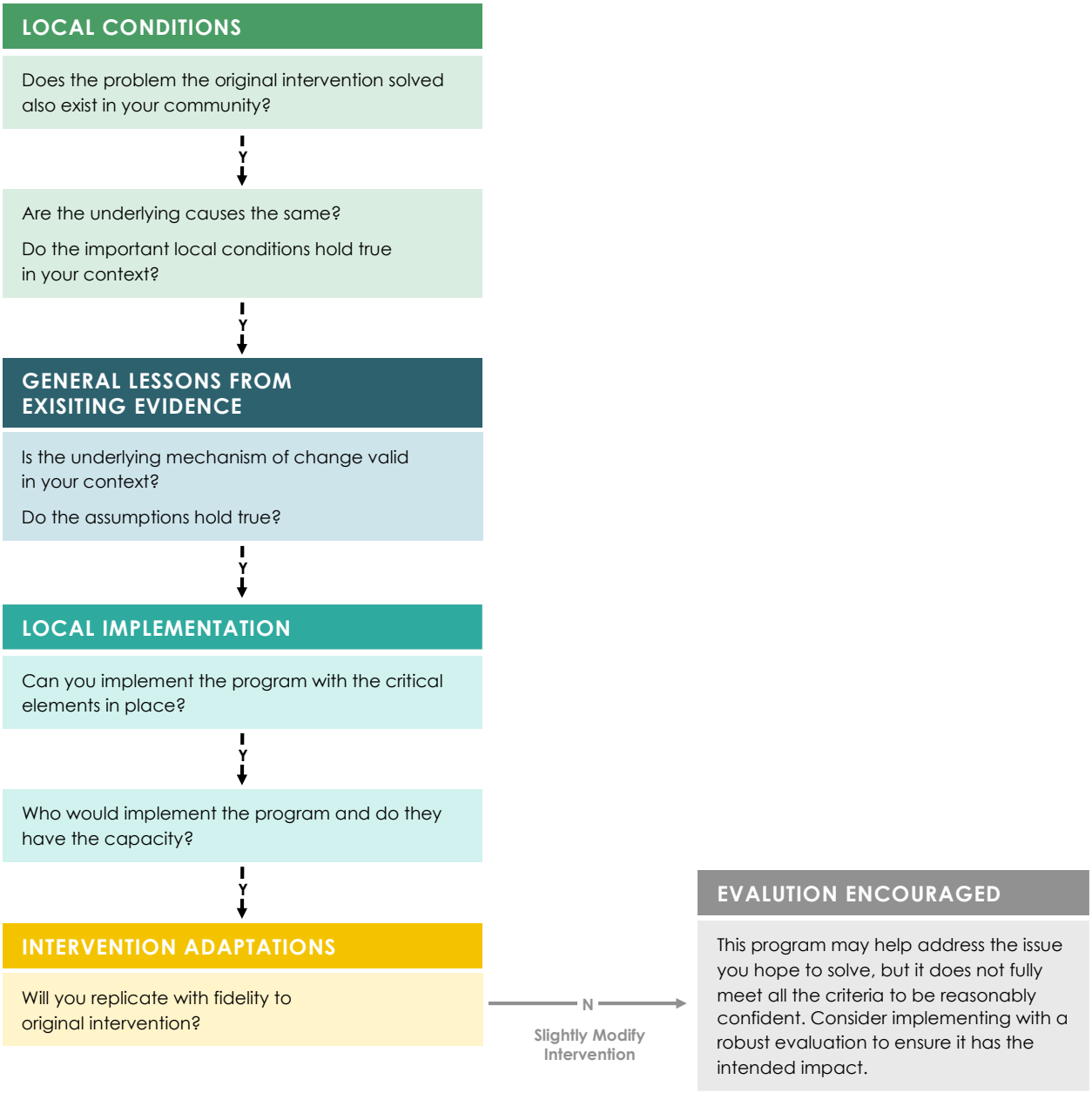


You then speak with key stakeholders at your clinic, who help you determine that your clinic would be able to implement the program with critical elements in place and that existing staff have the capacity and skill to implement the program (answering "Yes to the "Local Implementation" questions in the teal boxes shown in the below diagram).

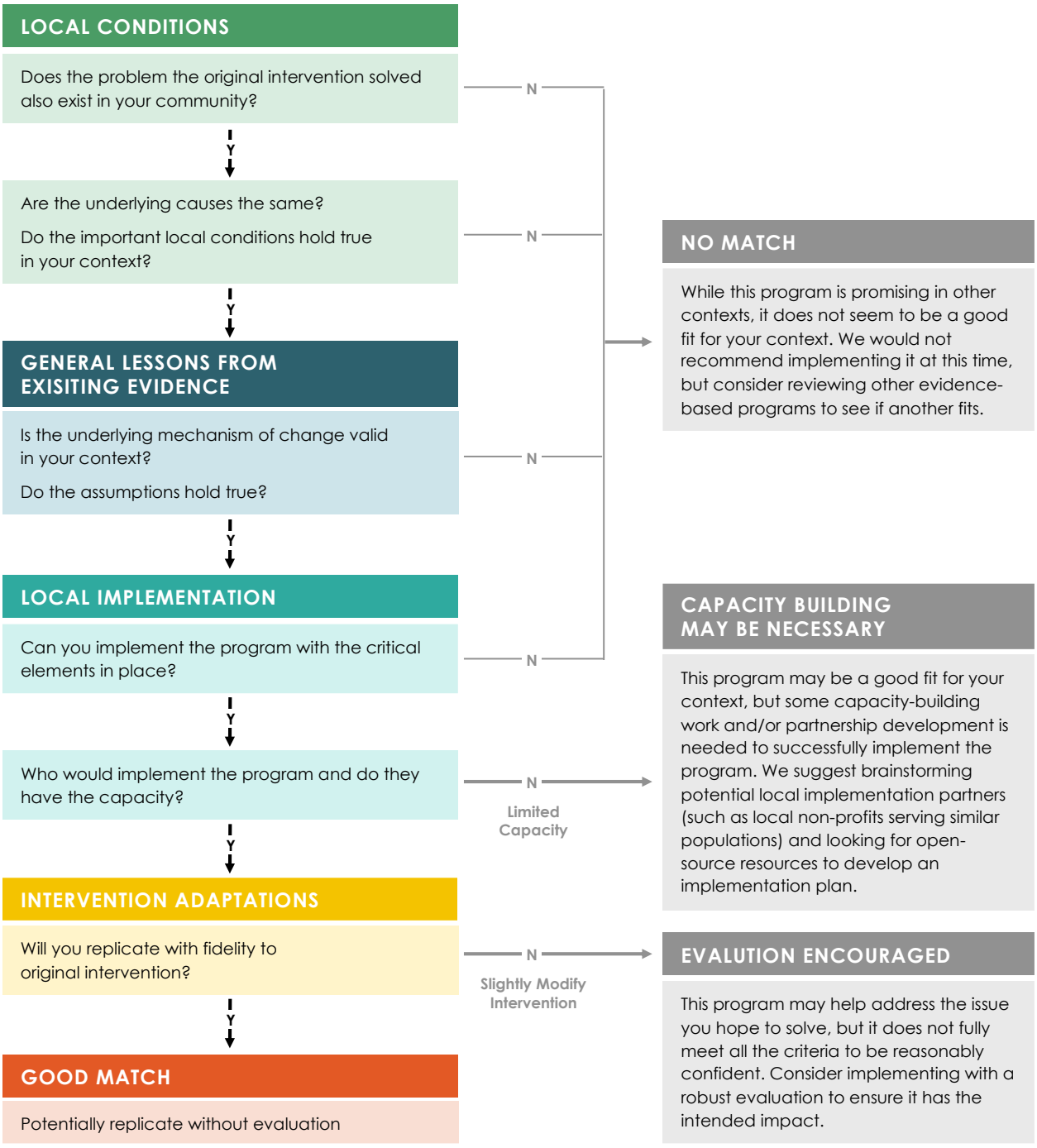


You then consider whether the intervention should be adapted or modified for your clinic in rural Indiana. You are not sure that regular in-person touchpoints will be feasible for your more rural clinic population, so you would like to adapt the program to include more telephonic access to CHWs.

After going through these steps and the decision tree, it seems like this intervention might be a good fit for your context in rural Indiana, with some adaptations (answering "No: Slightly modify intervention" to the "Intervention Adaptations" question in the yellow box). In the scenario of this case study, because you were basing decisions primarily on only one previous randomized evaluation, it may be valuable to you and to others to conduct an evaluation: you might implement a slightly adapted program with a robust evaluation plan to test whether and how the program would be effective in your different context. An additional evaluation would assess whether the adapted program achieves its intended impact and would contribute to the evidence base for CHW interventions.



As you undertake the steps of the generalizability framework and decision tree, your answers might be different—a program may not be a good match for your setting, or your organization may lack the capacity to implement the program's key components. Remember, there are many possible decision tree pathways:



CONCLUSION:

We hope this case study provides a helpful approach to addressing the generalizability puzzle: whether a program that worked in one setting is a good fit to scale or adapt to another setting. This generalizability framework demonstrates that evidence from prior evaluations can shed light on how a program works and provide guidance about how to design and implement an evidence-backed program in one's own context.

MORE INFORMATION

- Examples in the Applying Research Insights section of J-PAL's Evidence to Policy page provide additional context and describe how people have successfully applied generalizable research insights to design new programs.
- To find out more about generalizability, read "The Generalizability Puzzle" by Mary Ann Bates and Rachel Glennerster, written with policymakers in mind.

ABOUT US

J-PAL North America is a research center at MIT that works to improve the effectiveness of social programs through three core activities: research, policy outreach, and capacity-building. J-PAL North America's U.S. Health Care Delivery Initiative (HCDI) supports randomized evaluations of strategies that aim to make health care delivery in the United States more efficient, effective, and equitable.

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FURTHER QUESTIONS?

Please feel free to email Kalila Jackson-Spieker (kalilajs@povertyactionlab.org) if you have any questions about this resource.