DECISION GUIDE

DESIGNING A "FOOD IS MEDICINE" PROGRAM TO PILOT IN MICHIGAN'S UPPER PENINSULA

What. This guide is intended to help food assistance and health care organizations collaboratively design a Food Is Medicine (FIM) program. FIM programs are rooted in the understanding that the food we put into our bodies influences our health. FIM programs seek to improve health or treat disease or illness by influencing dietary behaviors. We focus on three intervention models:

- *Medically-Tailored meals (MTM)*. Meals provided to patients as part of a treatment program for a health condition, such as a diet-related disease. Food is selected by a Registered Dietician Nutritionist (RDN) or equivalent.
- *Nutritionally-Tailored Food Packages* (Also known as medically-tailored food packages). Bulk food or grocery packages provided to patients as part of a treatment program for a health condition or prevention of a diet-related disease. Food is selected by an RDN or equivalent.
- *Nutritious Food Referrals or Packages*. Referral or "prescription" for healthy food provided to a patient from a health care provider. The healthy food prescription is filled by the patients receiving a package of bulk food (e.g., CSA box) or by selecting healthy food at a retail location such as a grocery store or farmers' market. Food is healthy and nutrient dense, but not tailored to a specific treatment program.

How. We recommend using the document in the order presented. Use the *Model Comparison* and *Supporting Information* (highlights from research and input from the field) to understand opportunities. Use the *Objectives* and *Questions for Consideration* as prompts for discussion, negotiation, and decisions.

Who. This guide is intended for use by potential partners across the health care sector (e.g., physician's office, outpatient clinic, hospital, etc.) and emergency food sector (e.g., food banks, pantries, etc.).

When. Use this guide at a pre-partnership stage; i.e., when a food bank/pantry and a health care setting have identified a need and/or desire to work together to develop a Food Is Medicine intervention, but before an intervention has been designed.

Why. There are many successful food intervention models, but there is no proven, turn-key, FIM solution that exists for extremely rural areas. Programs have been piloted with some success, but evidence of outcomes is limited and much is not generalizable to other locations and environments. For a program to be successful, it requires some level of tailoring specific to the location in which it is implemented.

Action Steps

This guide was developed in response to a request from food banks to help them develop a FIM model to be implemented in a health care setting. The action steps are organized as follows:

- Establish Your Goals and Desired Impact
- Determine Your Target Population
- Consider Logistics, Procurement, Costs, and Resources
- Design the Intervention
- Other Considerations

The guide will walk organizations through key action steps that are intended to culminate in the identification of model parameters, that make sense for their specific setting *(Design the Intervention*). However, there is more work to be done prior to launching any intervention. The final section, *Other Considerations*, provides guidance for continuing the work beyond this document, with a list of critical areas for developing, implementing, and assessing FIM programs.

ESTABLISH YOUR GOALS AND DESIRED IMPACT

Objectives

- Identify where there are shared goals across organizations, and any areas where your goals may be at odds.
- Consider the goals around improving health outcomes, health care utilization, health care costs, food security, food sovereignty, access to healthy food, dietary and health behaviors, diet quality, and health equity.
- Understand the relevancy of each FIM model in light of your shared goals.

Model Comparison

	Medically-Tailored Meals	Nutritionally-Tailored Food Packages	Nutritious Food Referrals or Packages
Impact	Have shown an impact on: • Health outcomes (glycemic control,[1] heart failure symptoms)[2] • Health care cost[3,4, 5,6] • Admissions and readmission rates (nursing home, inpatient)[7,8,9 10] and length of stay[11] • Health care utilization (Emergency department visits and transport use)[12] • Food security[13] • Diet quality[14] • Quality of life (mental health related)[15]	Have shown impact on[16]: • Health outcomes (glycemic control), • Fruit and vegetable intake, • Health behavior (medication adherence)[17] • Food security and stability[18]	Have shown impact on: • Routine or preventative health behavior[19] • Diet quality[20] • Health outcomes (decreased HBA1c and BMI)[21] Recipients have perceived an improvement in food insecurity and food access[22]
Level of Evidence	**Evidence Based.** There are several scientifically rigorous evaluations that show promising results.	**Emerging.** There are a limited number of studies that show mixed results on health outcomes and behaviors	**Promising.** There are several studies that show promising results but few are rigorous. Studies on health outcomes (e.g., BMI) have shown mixed results.

Questions to Consider

- What are the goals and drivers of your organization and partner organizations? Where do your goals align (i.e., shared goals) and where do they differ?
- What challenges do you hope to address with an FIM intervention? What change(s) do you want to see as the result of the program?
- What are the desired impacts of the organizations involved?
- How important is it to show measurable results of the program? What level of impact needs to be demonstrated by your efforts (e.g., individual, community, systems level)?

- What level of evidence is deemed sufficient for your organization to invest in a program direction?
- What resources do you have or will you secure to evaluate your program? Are there constraints related to the timeline of length of the project and related evaluation?

Supporting Information

There is a strong and substantial body of evidence on the impact of diet and food insecurity on health outcomes and cost. However, our level of certainty of the benefits of FIM interventions varies by model.

- There is a stronger, more conclusive, body of evidence on the benefits of MTM interventions. MTM is a more established intervention that has been operating in the U.S. since at least 1990. MTM programs have been rigorously evaluated and show strong evidence of benefits, particularly in health care cost savings and readmission rates. More recent research (however, only a few studies) show support for the conclusion that MTM interventions also impact dietary quality and food insecurity of patients.
- There are few studies of nutritionally-tailored food packages. There are mixed results on the impact of health outcomes and health behaviors with a rigorous study showing no impact.
- There are several studies that show promising results of nutritious food referrals or packages, but few are scientifically rigorous. Studies of health outcomes show mixed results. To our knowledge, there are no studies on health care cost or utilization (outside of preventative services). Evidence of benefits is stronger for intermediate outcomes, such as changes to dietary intake, than health outcomes.
- One study that evaluated a variation—a non-tailored meal option in their FIM program, found that patients that received non-tailored meals had fewer emergency department visits and lower health care and lower medical spending than matched nonparticipants.[23] Non-tailored meal programs, while common, generally do not have a health care focus. Examples include the home-delivered meal program, Meals-On-Wheels, and congregate meal programs such as school meals or those provided at community settings such as senior centers.

Food Security. Evidence of benefits of FIM interventions on food security is promising for all three categories but limited because it has been less often addressed in studies. Therefore, it is unclear whether changes in food insecurity status or some other mechanism influence health, cost, utilization, and other outcomes.

Rural Intervention. Little is known about how any of the FIM intervention models play out in rural settings. One high rigor randomized controlled trial (RCT) study of a nutritious food package (CSA) intervention found statistically significant improvements in diet quality and food insecurity compared to the control group.[24]

DETERMINE YOUR TARGET POPULATION

Objectives

- Identify where there may be a common customer (client/patient) across organizations, and the extent to which these are shared priority populations.
- Consider what difficulties the population might have for accessing food or meals.
- Understand the relevancy of each FIM model for priority populations or common customers.

Model Comparison

	Medically Tailored Meals	Nutritionally-Tailored Food Packages	Nutritious Food Referrals or Packages
Target Population	• Diagnosed disease • At risk for inadequate nutrition • Usually not intended to address food insecurity • Sicker population • Difficulty shopping or preparing food in the home, e.g. persons that are elderly, disabled, or recently discharged from the hospital	• Diagnosed with or at risk of diet-related disease, and • Inadequate nutrition or food insecurity • Able to prepare food in the home	• Diagnosed with or at risk of diet-related disease, or • Inadequate nutrition or food insecurity • Relative health or illness is not a criteria • Able to prepare, and possibly shop for, food in the home
Treatment or Prevention	Part of a treatment program for a health condition	Part of a treatment program for a health condition or prevention of a diet-related disease	Healthy food is not tailored to a specific treatment program. Appropriate for broad prevention efforts of diet-related diseases.

Questions to Consider

- Who are the priority populations that you, your partners, or your funders are committed to serving? What populations are priorities according to community health needs assessments or organizational assessments?
- Of those that receive your services, who would most benefit from a FIM intervention? Consider health conditions and food access.
- What diet-related diseases or health conditions:
  - Have the highest prevalence in your community?
  - Are most costly to the health care organization?
  - Are most treatable/ avoidable through change in diet?
  - Have the largest disparities in prevalence or outcomes?
  - Who is at highest risk for food insecurity in your community?
  - Who has difficulty shopping for or preparing meals?

- Are there structural barriers to food access in your community? 25
- Who is most affected?

Supporting Information

- *Prevention Versus Treatment*. FIM programs fall on a spectrum from aiming to prevent to treat severe illness or chronic disease. FIM programs intended to "treat" are more intensive, on the account that they must meet more specific needs of people with more severe illness. Where as a prevention-focused program may provide foods that are generally considered healthy (e.g., fruits and vegetables), a treatment-focused program would further tailor food; for example, providing fruits and vegetables (and other foods) that are low in potassium for people with chronic kidney disease.[26]

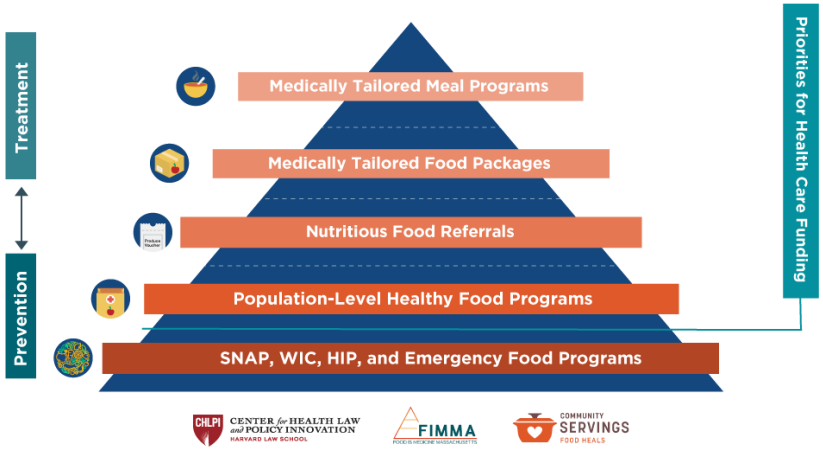

Figure 1. Food Is Medicine Pyramid[27]

- *Likeliness of Results*. More intensive treatments for people who are ill may be more likely to show larger measurable results in the short- to medium- term. The authors of a 2019 study of MTMs noted that, "It is unlikely that similar results would be seen were the intervention applied to a healthier population, as the risk of admission or high health care costs, even in the absence of intervention, would be substantially lower."[28] The authors also attribute their findings to having a patient population that is likely to benefit more substantially from the intervention due the "clinical, nutritional, and social risk factors that interacted to produce a high short-term risk of clinical deterioration if they did not receive nutritional intervention." They caution against generalizing or expecting the same findings for populations that do not have the same combination of social risk factors of the patients targeted by this intervention.
- *Evaluation Considerations*. In the absence of "high short-term risk" (as discussed above), health outcomes may take a longer time to be realized than intermediate outcomes (e.g., improved dietary behavior). For short- to medium-term projects or evaluations, you may be more likely to show results in intermediate outcomes versus long-term health outcomes (e.g., lowered A1C levels). Consistent program implementation (i.e., fidelity, which often comes from an established program) and a robust evaluation are necessary to show causal impacts.

CONSIDER LOGISTICS, PROCUREMENT, COST, & RESOURCES

Objectives

- Identify existing infrastructure assets, gaps, and experience in procurement across organizations.
- Consider creative adaptations or community-based solutions to gaps in supply chain infrastructure.
- Ascertain the approximate level of resources needed for initial, and perhaps sustained, programming.
- Identify resources potentially available from engaged organizations, philanthropy, and grants, for new programming.
- Weigh the anticipated health benefits of food with more demanding handling requirements against the challenges of developing and maintaining new infrastructure.
- Weigh the anticipated benefits and price point of each model against the capacity to develop funds for pilot testing a program.

Model Comparison

	Medically-Tailored Meals	Nutritionally-Tailored Food Packages	Nutritious Food Referrals or Packages
Food provided/ procure-ment	Full nutrition often provided	Healthy food; ranges from providing all food groups to fruit and vegetables only	Often produce only; may allow for redemption of other healthy food items or include them in food package
Infrastructure, Staffing, and Facility	• Temperature control required from preparation to patient home, e.g. through temperature controlled trucks, packaging, and storage. • Professional kitchen; • *Staffing:* Chef, RDN or equivalent	• Temperature control may be required, e.g., through temperature-controlled trucks, packaging, and storage. • More physical space to store/ transport bulk foods versus meals • Temperature control may be required depending on food selection • *Staffing:* RDN or equivalent	• Food storage, transport, and related refrigeration/ temperature control may be handled through existing infrastructure (e.g., vouchers redeemed for food supplied to an existing market).
Cost	Highest cost	Medium cost	Lower cost
Reimburse-ment/ Coverage	• Reimbursed through some Medicare-Advantage Plans and a Medicaid Waiver in a limited fashion for eligible patients • Could be financially supported through agreement with insurer	Could be financially supported through agreement with insurer	Could be financially supported through agreement with insurer

Questions to Consider

- What are the infrastructure assets and gaps? What are the resource implications? Can these be addressed with existing (adaptation of) resources, or would new funding streams (e.g., capital development) be needed?
- What resources are already available to support a FIM intervention? Are there constraints with existing resources?
- Are new resources or sources of funding needed? What are potential sources of new resources or funding?
- What federal and state policies may encourage or make it harder to implement a FIM intervention? (Consider current Medicare and Medicaid policies, such as the MI Choice Waiver or Michigan's Comprehensive Health Plan Contract for their Medicaid Health Plans.)
- Is procurement of food for the pilot a perceived challenge?
- What is the capability at each stage of the supply chain?

Supporting Information

Procurement

- Procurement of fresh and healthy food may be difficult in rural areas. Serving small families with a FIM program is an option for limiting procurement needs (and food costs) while ensuring adequate consumption from the family member(s) targeted through the program. Healthy, minimally processed, foods may need to replace fresh foods; e.g., canned vegetables instead of fresh vegetables.
- Another option is to think about how the project could help to build the healthy food supply chain in the region. Large institutions especially may be able to leverage their purchasing power to increase local or sustainable foods in the area. An example is the school districts that have combined their purchasing power in order to source more healthy, local and whole foods.[29]
- Creative solutions to procurement may require thinking across sectors. An example is community-supported agriculture, in which the procurement solution—i.e., supporting a local farm to produce fruits and vegetables—is embedded in the intervention.

Cost and Infrastructure

- *Costs May Be Higher for MTM Programs*. A medically-tailored meal program may cost more than a nutritionally-tailored food packages program or a nutritious food packages or referrals/prescription program, both to start-up and recurring operational costs.
- Major cost factors for consideration include (1) infrastructure, (2) staffing, (3) distribution, and (4) food costs.
  - Medically-tailored meal programs incur the costs of not only procuring food, but tailoring and preparing meals which requires an RDN and a chef.
  - Food-package programs may require additional infrastructure be developed (e.g., temperature controlled storage, commercial kitchen), while nutritious food packages/referral programs are more likely to rely on existing infrastructure (e.g., farmers' markets, grocery stores).
  - MTMs often offer full nutrition, which would include a protein source, such as meat (a higher priced item).

  - Distribution may be more costly if doing home delivery. Food packages are bulkier than meals which may result in higher prices to store or deliver.
  - The extent to which you can rely upon existing and/or under-utilized infrastructure, the better in terms of program costs. Food referral programs are often designed to tap into existing infrastructure; e.g., redeeming vouchers at existing farmers' markets.
  - Cost will depend on the infrastructure and resources available and your program design. For example, if you plan on establishing an on-site food pantry or "farmacy" for a food package program, the cost and resource needs may rival those of a medically-tailored meal program.
- Programs can be designed to creatively leverage resource. For example, health care organizations could look into partnering with programs that have existing delivery infrastructure (e.g., Munson Medical Center and Meals on Wheels[30]) or with schools that have full service kitchens (e.g., to create school-community kitchens as resource hubs[31]).

Reimbursement/Coverage

In Michigan, meals (such as medically-tailored meals or those from Meals on Wheels organizations) are covered by insurers in limited circumstances, such as for older adults or persons with disabilities.

- Medically-tailored meals are reimbursable through some Medicare-Advantage plans for qualifying patients. Medicare-Advantage plans typically only cover meals for a few weeks out of the year for eligible patients, such as those with chronic conditions or who have been recently discharged.[32]
- Medicare Advantage could cover programs that provide groceries or unprepared food,[33] but as of October 2020, food packages and referrals/vouchers have not been covered by insurers as a reimbursable service, to our knowledge.
- Under Standard Medicaid, federal requirements do not allow for the reimbursement of food or meals, unless the state has gained federal approval to waive these requirements.[34]
  - The MI Choice Waiver, a1915(c) Waiver, allows Medicaid to cover home-delivered meals for low-income older adults or persons with disabilities where meals may help them stay in their home.[35] This waiver may allow for the coverage of groceries or unprepared food,[36] but has not been used this way in Michigan to our knowledge.
    - Other states have covered food or meals through a Section 115 Demonstration Waiver.
- However, Medicaid Managed Care Organizations (MCOs), could cover food or meals through regulatory flexibilities and with positive financially implications.[37,38]
- In some cases, private companies have contracted with health plans to provide meal services.[39]
- Health systems, hospitals, and insurers may decide to financially support a food or meal program that helps them meet health and care goals, especially those tied to state and federal funding. For example, hospitals with funding tied to reducing readmissions, may provide food as part of a transition-to-home from the hospital service.[40] Michigan's Sample Comprehensive Health Plan Contract[41] provides insight on current goals and related funding implications of Michigan's Medicaid Health Plans.

DESIGN THE INTERVENTION

Objectives

- Identify the parameters of service delivery that align with program scope and nutrition goals.
- Consider community assets and collaboration opportunities for redemption or pick up sites and delivery.
- Consider the broader question of how programs may support the broader local food environment and economy.
- Weigh the service delivery features in light of the participant's and community's needs and culture.

Model Comparison

	Medically-Tailored Meals	Nutritionally-Tailored Food Packages	Nutritious Food Referrals or Packages
Tailored or non-tailored	Tailored, often multiple menus tailored for different needs	Tailored, may provide some consumer choice	Non-tailored (i.e., healthy food), vouchers often provide consumer choice
Frequency and Duration	Near total, nutrition may be provided (e.g., 2 to 3 meals per day, 5 to 7 days per week). Duration of several months is typical. An example of a delivery policy can be found at https://mannapa.org/services/for-clients/	Food packages distributed weekly to monthly. Duration of several months is typical	Variable. • Lower dosage interventions were one-time only or up to four vouchers. Moderate dosage interventions were around 13 distributions/redemptions. A higher dosage intervention was once a week for 24 weeks. • Frequency was often weekly or bi-weekly and sometimes tied to office visits or survey completion.
Amount of Food/ Voucher	Near total nutrition may be provided (e.g., 2 to 3 meals per day, 5 to 7 days per week).	• Supplements total nutrition (e.g., providing 20% to 25% of food needs per month)[42] • May provide food for the family to account for sharing	• Individual vouchers may range from $5 to $25 each. Vouchers could be incentive-type; e.g., spend $5 and get $5. • May provide food for the family to account for sharing
Distribution/ Redemption	Meals are often delivered directly to patients.	Food may be delivered directly, or picked up on-site at the health care location or at a community-based location	Prescription filled through pre-packaged food (e.g., CSA box) or by redeeming voucher for food, usually at a retail establishment (e.g., farmers market, grocery store). Redemption can happen on-site at the health care location (e.g., co-located farmers market accepts vouchers, food package distributed in doctor's office) or off-site (e.g., grocery store, CSA box picked up at farm).

Questions to Consider

- How can you increase the likelihood that the person for whom the food is intended consumes the food? Is their value in providing food to the whole family?
- Are the duration and frequency intended to completely fill or supplement the expected meal gap?
- What will happen to the individual/family when the program ends? What service delivery features can be readily sustained by participants after a pilot?
- What are the assets and barriers to accessing healthy food in the community?
- What service delivery features, such as convenient redemption/distribution locations, would facilitate access to the program?
- How could service delivery features support the local food environment/economy and increase food access in the community, e.g., by investing in local retailors, growers, or others in the food supply chain?
- How could service delivery features support collaboration and help participants connect with existing community resources?

Supporting Information

Tailored or Non-Tailored

- The amount of medical tailoring varies; for example, a meal/food package could be tailored to an individual—their health goals and conditions and the specific medications they are taking—or more generally to a condition, such as providing meals/food that would typically support the needs of a person with kidney disease, heart disease, or diabetes. The latter is sometimes referred to as nutritionally-tailored and may be a lower touch and lower cost version of a medically tailored meal.
- Non-tailored meal interventions would likely be lower touch and cost than MTMs as they would not require a registered dietician, nor the development of different options for different health needs.

Distribution/Redemption

- Programs may deliver meals/ food directly to participants or have them pick-up or redeem vouchers on-site at the health care facility or another location in the community.
  - Shipping may be an option for home delivery; MANNA is shipping meals and in the process, expanding their ability to serve "extreme rural areas."[43]
  - There are also blended models; for example, Project Angel Food delivers meals to a hub and volunteers or a community partner distributes them to the community.[44]
- Redemption/distribution of the food may be tied to other program goals or help participants connect to existing community resources. Redemption/distribution at health care facilities may incentivize patients to show up for routine care. Redemption/distribution may facilitate a patient connecting with existing food or health resources, such as nutrition education or Double Up Food Bucks that may be operating at farmers' markets or retail locations.
- Take into account accessibility to the redemption/distribution location. The fewer barriers to access, the more likely people will enroll and retain in the program. Many communities lack access to food retailors that offer healthy, quality foods. Access concerns have been mitigated

in some programs by providing an opportunity to redeem the voucher on-site where it was received (e.g., at the health clinic or hospital).
  - For example, the voucher could be redeemed at a health clinic or hospital for a box of bulk food or food selected at a farmers' market, mobile market, or pantry.
- Programs could range from providing a single voucher to be redeemed for healthy food to providing near total nutrition for several months. When deciding on the duration and amount of food, consider the outcomes you hope to achieve in your program.
  - For example, a one-time voucher may meet the acute, emergency food needs of a patient but is unlikely to affect the overall health of a patient.
- FIM programs are not designed to go on indefinitely, so it is best to plan for how to transition patients out of the program. For example, by gradually reducing the amount of food provided over the last few weeks of the program or by providing referrals to other food assistance resources.
- Consider how the program could impact the local food environment and local economy, writ large, by generating business for local retailers or growers. For example, by ensuring a regular source of revenue from program participants, local food retailers may be more inclined to provide fresh fruits which would benefit healthy food access for the entire community.
  - Similarly, local food procurement would benefit local growers. When vouchers are redeemed or food for food boxes is procured locally, the food dollars stay in the local economy.

Amount and Type of Food (or Voucher)

- Prior experience has shown that families share food. Therefore it is important to provide nutrition for the whole family and/or limit the pilot to small households to ensure adequate nutrition for the patient in the pilot.
- It will be important to define a household size (or range) for participation in the pilot. Targeting families of a similar size will may ease implementation by allowing for the amount of food to be provided per family to be the same or similar
- You may want to assess the food needs of potential program participants. For example, one intervention was informed by baseline data collected during a pilot on how long program participants' diabetes-appropriate food lasted in a month.[45]
- Not unexpectedly, there will be potential difficulties in transporting the food. For example, one intervention found that the amount of food they could provide was limited by capacity of partners (in this case, food banks) and challenges for participants transporting food, such as by public transport, up stairs, or in icy weather.[46] Consider procurement challenges of food partners.
- The type and amount of food provided may be constrained by food availability; for example interventions such as MTMs, that provide near total nutrition, would require procurement of all food groups. Food banks, frequent partners in FIM interventions, may have difficulty procuring adequate amounts of some foods, such as meat and dairy. Fresh fruits and vegetables may also be difficult to procure in some areas, including rural areas.

OTHER CONSIDERATIONS

Once your organization has worked though the key action steps in the earlier sections and identified model parameters that make sense for your setting, there is more work to be done prior to launching any intervention. The following are some critical areas for developing, implementing, and assessing FIM programs.

Collaboration Readiness

- Readiness of partners
- History of collaboration
- Data collection and sharing. Memorandums of Understanding are important for defining data sharing between the food banks and health care system; these also serve to reinforce the nature of the relationship as a partnership, rather than as vendor and buyer.

Development

- Recruitment into the program
- Retention in the program

Nutrition Education

- Consider evidence base program for health eating or managing chronic diseases (should this be target population) through diet, such as Cooking Matters and PATH.
- Some programs provide consultations with registered dieticians. There is precedence for these being done over the phone, which could be necessary in rural areas and in a pandemic.
- Other options could be healthy recipes, basic nutrition education, food safety materials. If food is provided recipes is important

Referrals and screening

- Referrals to other food programs; e.g., pantries or SNAP
- Screening for social determinants of health, food insecurity

Evaluation

- Partnership with a researcher for process and impact evaluation
  - Process evaluation and assessment of client and partner feedback to ensure program is being implemented with fidelity and that changes are made as needed based on feedback from partners and participants
  - *Impact evaluation*. Evaluation to assess impact on food insecurity, eating behaviors, health outcomes, utilization, and cost metrics.
- Pilots to further assess logistics and test data collection tools.
- *Level of rigor*. Showing measurable impacts of a program on health outcomes is a high bar. Attempting this type of research involves a consistently implemented program (high fidelity), a robust evaluation, and time. It is urgent to attend to the prerequisites to robust measurement of health outcomes: a capacity-to-measure process, fidelity, and intermediate outcomes (e.g., dietary and health behavior).

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END NOTES

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[2] Scott L. Hummel, et al., "Home-delivered meals postdischarge from heart failure hospitalization," *Circ Heart Fail*. 11(8) (August 2018 Aug): e004886.

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