

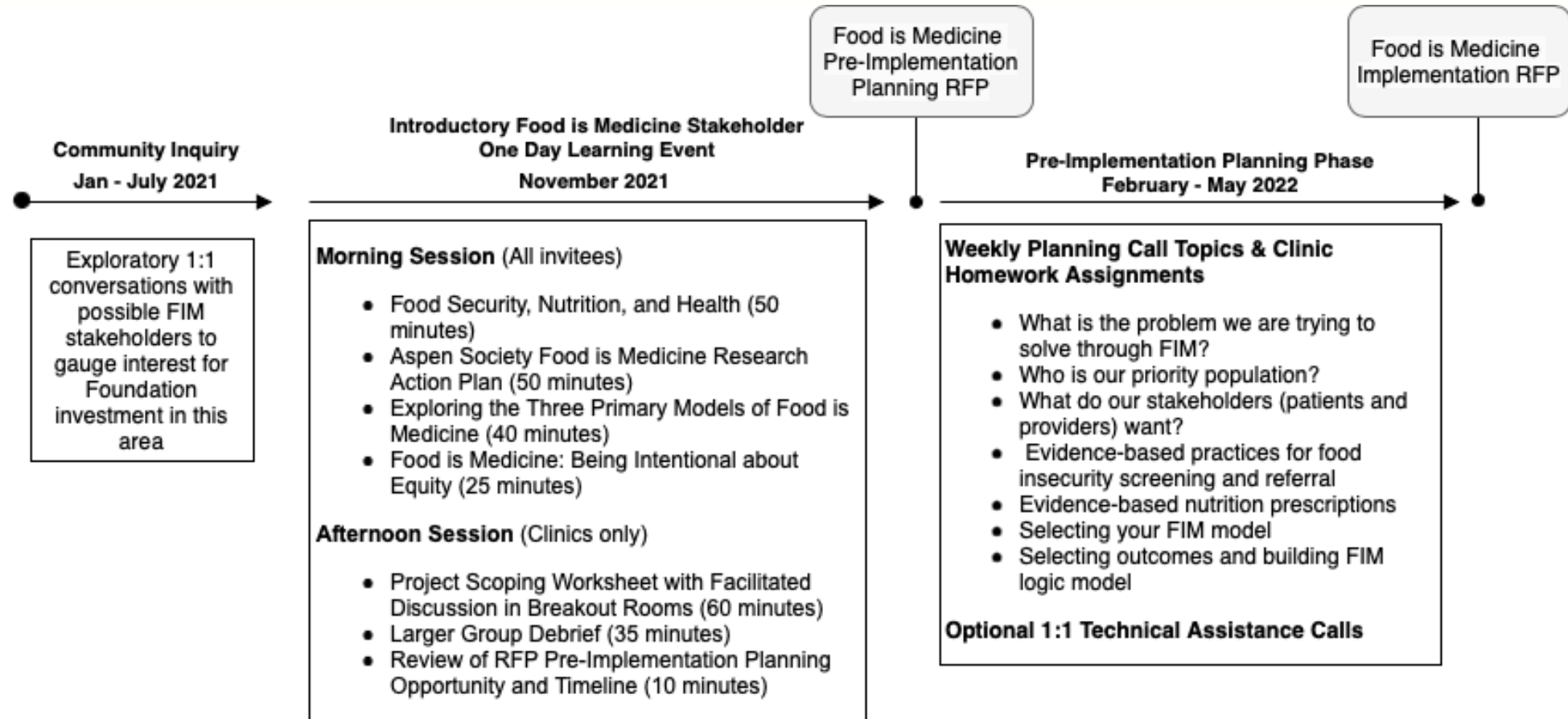
A photograph of a kitchen counter cluttered with various items, including a teacup, a cutting board, a bowl, and kitchen tools. The scene is brightly lit, suggesting a window in the background. The counter is covered with a variety of dishes, including a brown teacup with a tea bag, a white bowl, a cutting board with a red-handled knife, and a small bowl. In the background, there are more kitchen items like a metal pot, a glass, and a container of utensils.

# **There's a Mess in the Kitchen!**

## **Evaluating FIM in Real-Life Settings: Reflections about the Kansas Pilot Project**

**Marianna Wetherill, PhD, MPH, RDN/LD | Kristina Bridges, PhD | Susan Harvey, PhD**

# Sunflower Foundation FIM Program Timeline



**Figure 2.** Overview of pre-implementation planning approach for food is medicine (FIM) interventions across multiple clinic sites in Kansas.



# Each Clinic Thoughtfully Planned their FIM Program

## Food is Medicine

WINTER/SPRING 2022 - SESSION 1 HOMEWORK\*


### PATIENT INTERVIEW GUIDE

**OPENING STATEMENT:**

"Hello, my name is [NAME] and I'm a [ROLE] at [CLINIC]. A few people on our team are thinking about starting a healthy food program at [CLINIC] for people with diet-related health conditions. We would like to get input from patients who are receiving care at [CLINIC] for [DISEASE]. [If possible: Dr. [NAME] or Nurse [NAME] suggested that I call you for this important feedback.] Feedback from patients with [DISEASE] can help us plan the best program possible. Would you be willing to visit with me for about 15 minutes? If it's not a good time right now, is there another time when I could call back?"

**QUESTION PATH:**

1. Can you tell me what kinds of conversations, if any, you have had with your care team at this clinic about the role of food or nutrition in the treatment for [DISEASE]? This can include conversations with doctors, nurses, social workers, case managers, pharmacists, or nutritionists.
2. When you hear the term "food as medicine for [DISEASE]", what thoughts, questions, or other words come to mind?
3. How do you believe your current diet affects your health?
4. What foods do you feel are most important to help support people living with [DISEASE]?
5. Thank you for your thoughts so far. I'd like to confirm I've made note of all your key points. [SUMMARIZE RESPONSES TO QUESTIONS 1-4.] Have I missed anything?

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FOOD IS MEDICINE  
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## Food is Medicine

WINTER/SPRING 2022 - EHR ASSIGNMENT\*


### ELECTRONIC HEALTH RECORD SEARCH QUERY ASSIGNMENT

Scoping and planning activities for a food is medicine initiative involve review of information from a combination of qualitative and quantitative sources. In addition to patient and provider interviews (qualitative information), we recommend that you explore data from your electronic health records to better estimate the volume and health status of defined patient populations within your clinic. This assignment and future FIM planning activities will involve a series of search queries into your EHR/medical records. If possible, invite your IT/medical records manager to be part of your FIM planning team. If this position cannot formally participate, please let them know that you will likely need their assistance to complete a few planning assignments.

In your application for this planning project, teams were asked to identify one or more priority populations that could be served through a FIM project. To complete this assignment, you will need to identify two health conditions that you believe would be prime candidates for a FIM project at your site. You can use the health conditions you identified in the application or use this opportunity to explore other health conditions.

**For each priority population, work with your electronic medical records team to obtain estimates for the following:**

- How many people with [DISEASE 1] visit [CLINIC] each year?
- How many times per year do people with [DISEASE 1] visit [CLINIC]? (Provide the average number and the range of visits.)
- What is the zip code distribution for patients with [DISEASE 1]?
- For each provider, how many patients with [DISEASE 1] are on that provider's panel?
- Of people with [DISEASE 1], how many are "in control"? Use national guidelines for "in control" or consult with physician or clinical quality improvement personnel at clinic for guidance.
- What are the demographics of people with [DISEASE 1] who receive care at this clinic? Attempt to obtain estimates for sex, age categories, insurance type, employment. What other services do people with [DISEASE 1] access at this clinic? Consider utilization of community health workers, participation in nutrition classes, medical case management, etc.

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## Food is Medicine


WINTER/SPRING 2022 - SESSION 2 HOMEWORK\*

### SCREENING & REFERRAL

Now that you have identified two potential priority populations, you will gather information about how your clinic currently approaches food insecurity screening and related referral for these population(s). Before jumping into the assignments, we recommend that you sit down with your team to complete steps 1-5.

1. Obtain a copy of your clinic procedures for food insecurity screening, along with a copy of the screening tool that your clinic uses. Note: Your food insecurity screening procedures may be part of a larger social determinants of health screening procedures. Review these together as a team.
2. What tool is being used? If you aren't sure of the name of the tool, just make a note of the questions that are asked.
3. What is the mode (self-report or provider interview) and frequency of screening (each visit; annually)?
4. How is food insecurity screening documented in the medical chart? (e.g., scanned copy that requires manual review or results entered in standardized field that allows for systematic searching)
5. How are providers notified of, and expected to respond to, a positive food insecurity screen?

If no clinical food insecurity screening system is in place, your alternative assignment for the Electronic Health Record Search Query Assignment #2 Homework is to select and pilot test an established screening tool and to develop new written screening procedures. Food insecurity screening can be implemented through the Hunger Vital Sign tool, the ISBARISE tool, or any other validated method designed to identify uncertain or limited access to a healthy food supply. (Assistance selecting a screening tool and developing a screening procedure is available upon request.)

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## Food is Medicine

WINTER/SPRING 2022 - HOMEWORK #3\*

### LOGIC MODEL


We would like your team to complete a logic model for your clinic's FIM project. Use the template provided and fill in items for each of the following categories:

**Inputs**  
This is the knowledge, training, person power, partnerships, and physical resources you have at the beginning of a project. These are all the things that make your project possible.

**Activities**  
These are the things you will do. The tasks that must be accomplished to achieve your goals. It's helpful to break large activities into smaller tasks and list each separately. For example, instead of "distribute food to patients," list smaller components like: finalize meal/food plan, secure produce/food supplier, aggregate/store food, package food, deliver food, etc.

**Outputs**  
These are the quantifiable results from each activity. These will be your process outcomes for the project. You can make sure that each activity was completed adequately by measuring your outputs (# New/existing partnerships, # Patient engagement hours/meetings, # Enrolled, # and variety of food items offered, # meals delivered, # SNAP enrollments completed, etc.)

**Short term goals**  
Immediate effects of project (weeks-months). Immediate food needs met for patients during the program. Patients enrolled in SNAP. Patients increase intake of fruits and vegetables. Patients' cooking skills/knowledge increases.

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# Each Clinic Chose Similar Health Conditions & We Collaboratively Standardized Shared Outcome Measures

## Patient Population

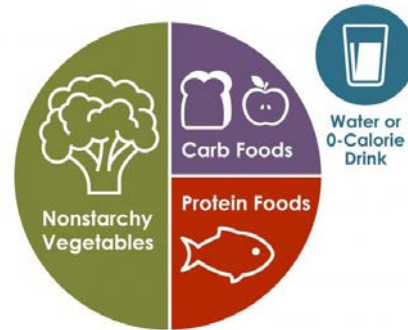
- Prediabetes
- Diabetes

## Setting

- FQHCs

## Foods

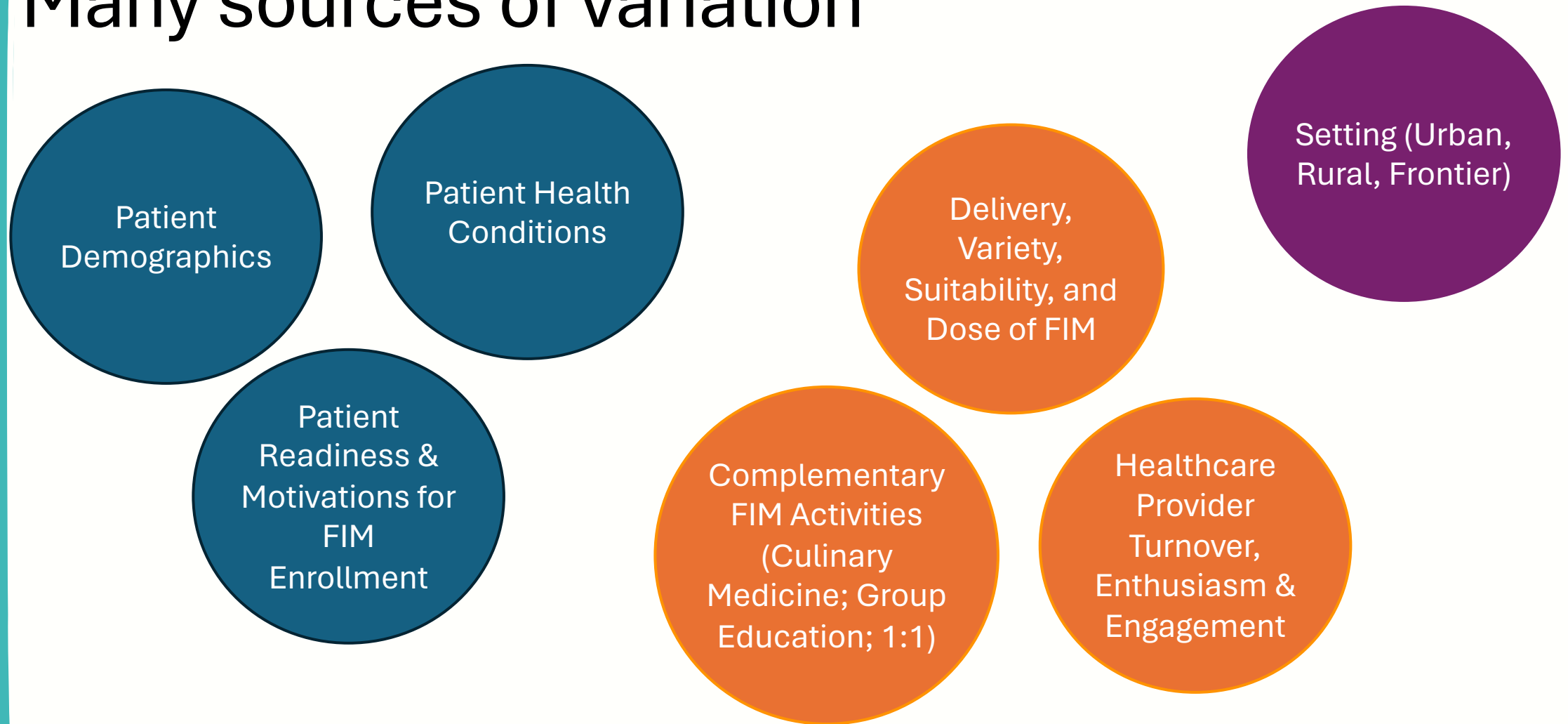
- F/V
- Fiber foods
- Other



## Outcomes

- Food Security
- Block Fruit/Vegetable/Fiber Screener
- Hgb A1c (A1c Now POC device)
- Depression (PHQ-9)
- Flourishing & Vitality
- BMI
- Blood Pressure
- Program completion (spreadsheet)

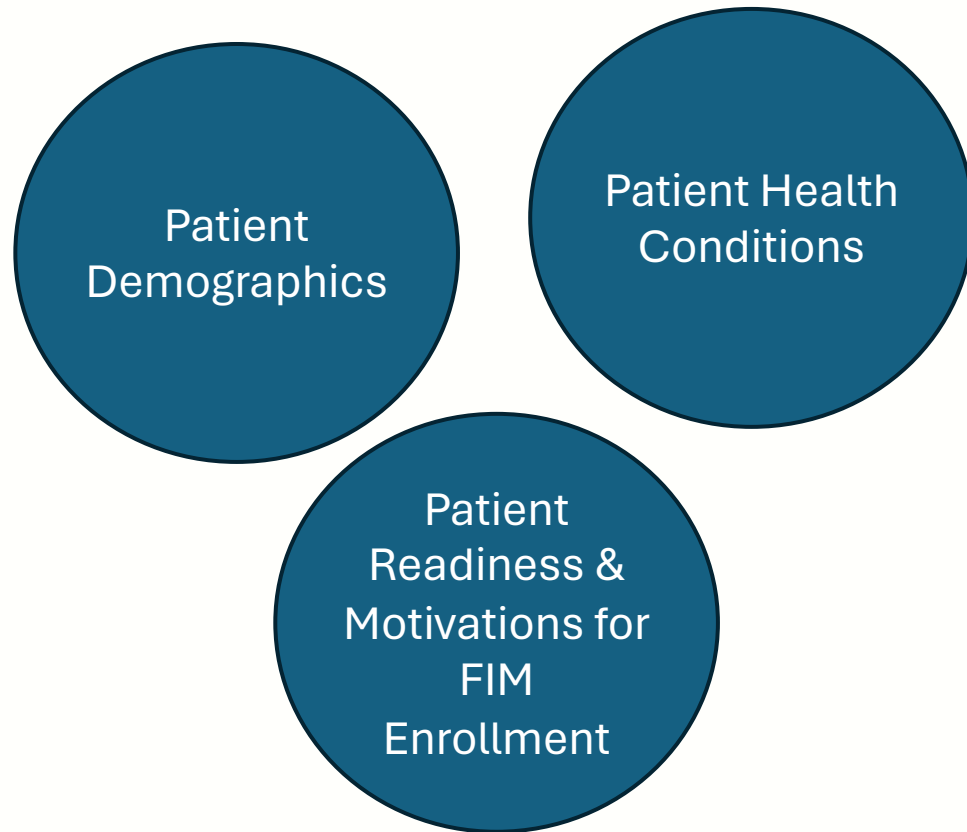
# Many sources of variation



Which recipes (FIM Interventions) are we ACTUALLY testing?



# Many sources of variation: Patient-level

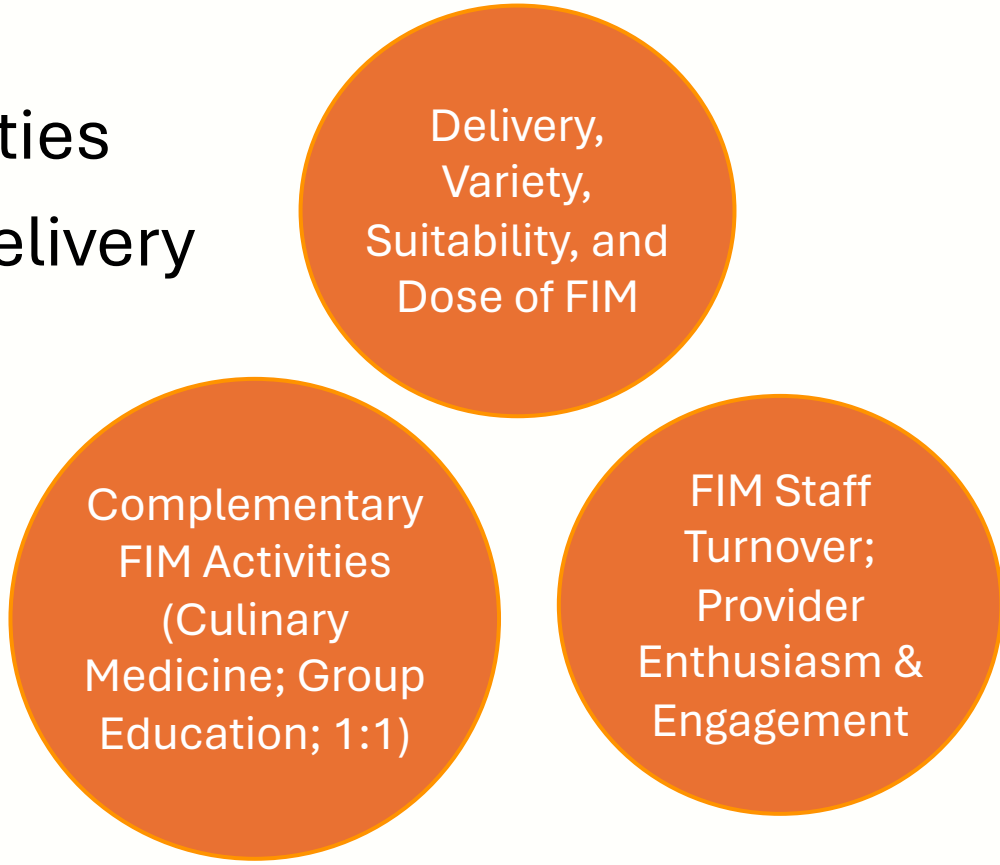


- Starting degree of glycemic control (6.6% to 11.4% clinic-level average)
- Starting BMI (25 to 40)
- Co-morbidities, e.g., Stage II hypertension (0% to 33%)



# Many sources of variation: Intervention

- Food
- Type and Mode of supportive activities
- Who is delivering and tone of the delivery



Delivery,  
Variety,  
Suitability, and  
Dose of FIM

Complementary  
FIM Activities  
(Culinary  
Medicine; Group  
Education; 1:1)

FIM Staff  
Turnover;  
Provider  
Enthusiasm &  
Engagement





Produce box items varied according to season and availability











Dried/canned good boxes include F/V, rolled oats, WW pasta, brown rice, beans, tuna, chicken, milk, and other shelf-stable items



Frequency of food box delivery dependent on geographic location of clinics





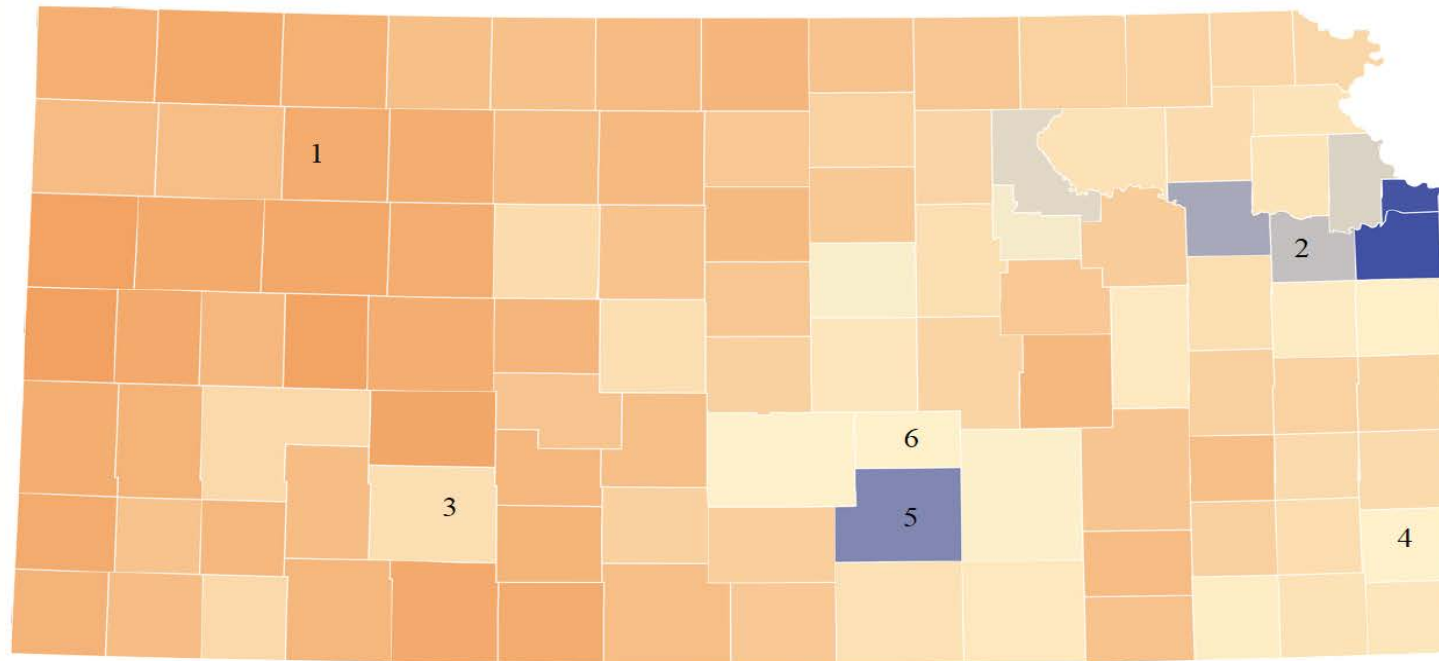
# Many sources of variation: Intervention





# Many sources of variation: geography

Setting (Urban, Rural, Frontier)



- 1. Hoxie Medical Clinic (Sheridan County Health Complex)
- 2. Heartland Community Health Center
- 3. Genesis Family Health
- 4. Community Health Center of Southeast Kansas
- 5. HealthCore Clinic
- 6. Health Ministries Clinic



**This intervention takes place in six geographically and demographically diverse clinics in Kansas.**

# No Surprise Here! Variation in Preliminary Outcomes

Clinic	Food security	Fruit & Vegetable intake	Mental Health			A1c	Blood pressure	Body Mass Index
			Depression	Vitality	Flourishing			
A	✓	✓	✗	✓	✗	✗	✗	---
B	✗	✓	✓	✗	✓	✓	✓	✓
C	✗	✓	✗	✓	✗	✓	✓	---
D	✓	✓	✓	✓	✓	✓	✗	---
E	✓	✓	✓	✗	✗	✓	✓	---
F	N/R	N/R	N/R	N/R	N/R	N/R	N/R	N/R
All	✓	✓	✗	✗	✓	✓	✓	---

Improved 

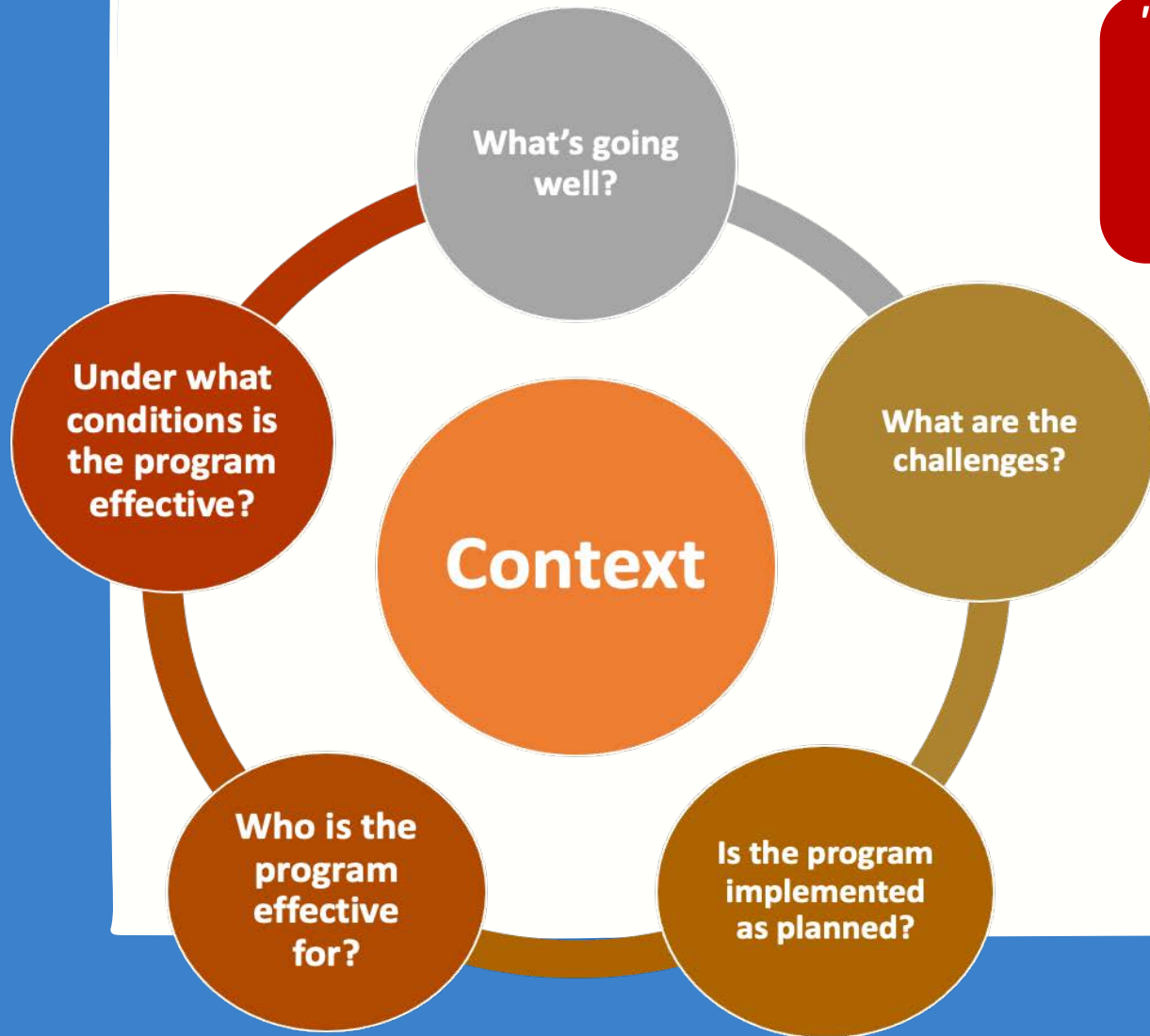
Worsened 

No Change ---

Not Reported N/R

# Qualitative Evaluation isn't Optional

***"Whenever possible, qualitative research should be used to complement quantitative data."***  
(Aspen Institute FIM Research Action Plan)



Does an apple a day keep  
the doctor away?

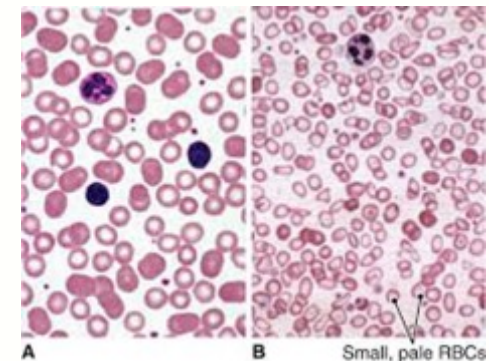
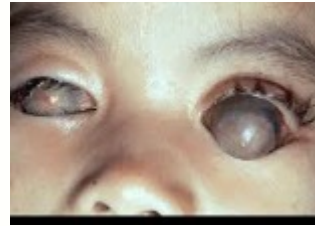




# Short-latency “Index” deficiency diseases

- Xerophthalmia “dry eyes” (Vitamin A)
- Pellagra (Niacin)
- Beriberi (Thiamine)
- Neural Tube Defects (Folic Acid)
- Scurvy (Vitamin C)
- Rickets (Vitamin D)
- Anemia (iron; folic acid; B12)
- Goiter (Iodine)

Occur in very high frequency among  
those with low nutrient intakes



# Long-latency deficiency (or excess) diseases

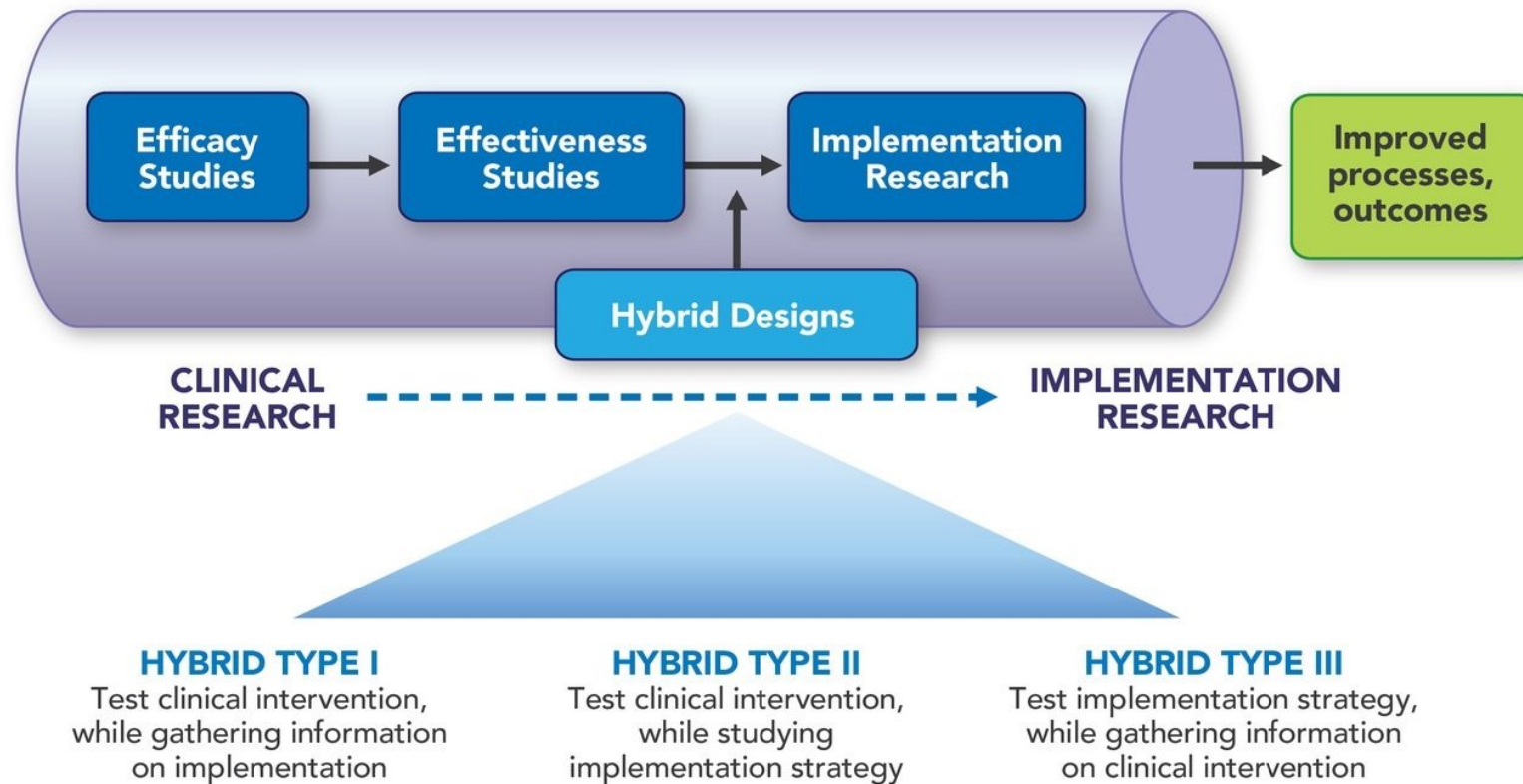
- Cardiovascular disease
- Osteoporosis
- Cancer
- Diabetes
- Hypertension
- Cognitive decline
- Renal insufficiency

**Imbalance** in nutrients may lead to one of many diseases based on the person's life course exposures, genetics, and other lifestyle factors



For the most part, FIM interventions are prioritizing **long-latency deficiency** diseases, yet applying **short-latency deficiency** disease **expectations** in their evaluation design.

# The traditional road toward healthcare intervention development





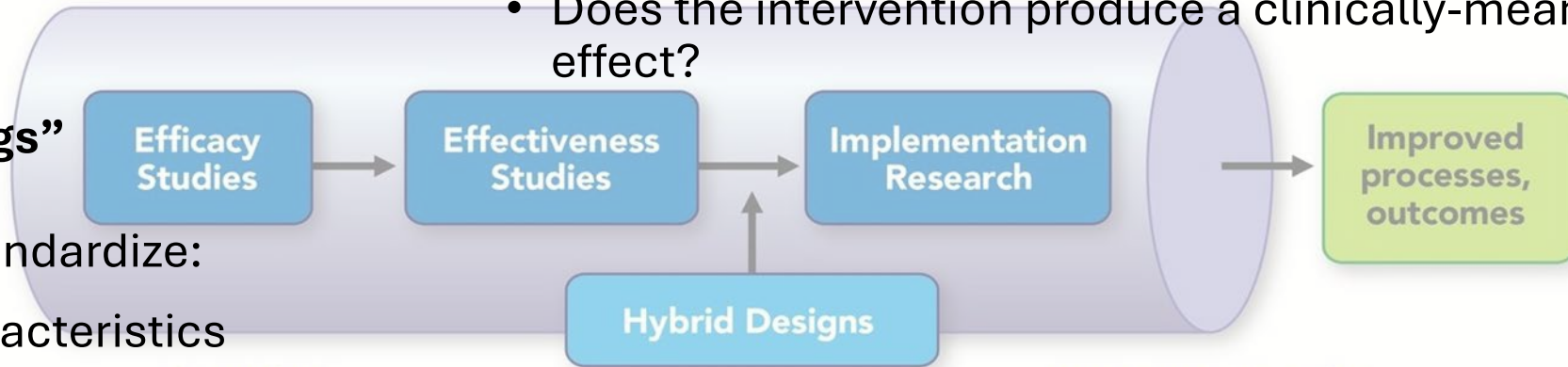
# FIM for Diabetes

## Effectiveness “Real World Settings”

- How well does this work in routine clinical practice?
- Does the intervention produce a clinically-meaningful effect?

## Efficacy

### “Ideal Settings”



Attempt to standardize:

- Patient characteristics
- Provider characteristics
- Condition under investigation
- Duration of disease
- Drug regimens
- Co-morbidities

**Treatment itself** should be well-defined

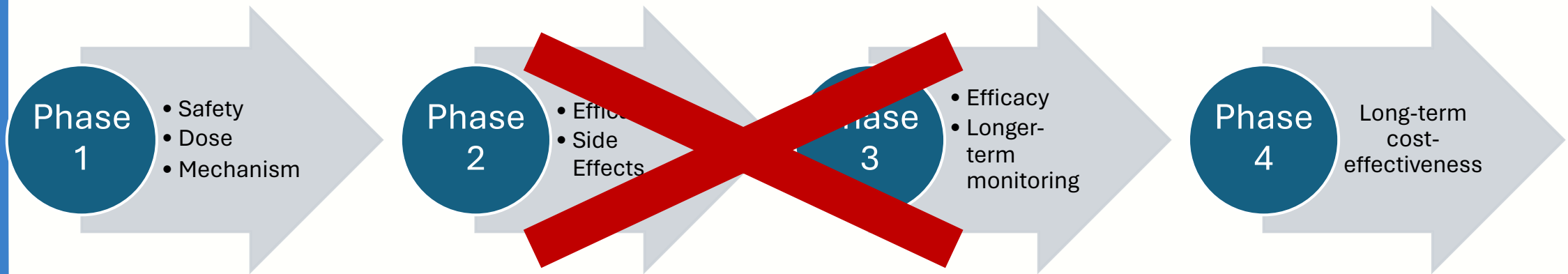
## Implementation (Scaling & Adaptation)

**HYBRID TYPE I**  
Test clinical intervention,  
while gathering information  
on implementation

**HYBRID TYPE II**  
Test clinical intervention,  
while studying  
implementation strategy

**HYBRID TYPE III**  
Test implementation strategy,  
while gathering information  
on clinical intervention

# The traditional approach for drug testing and approval



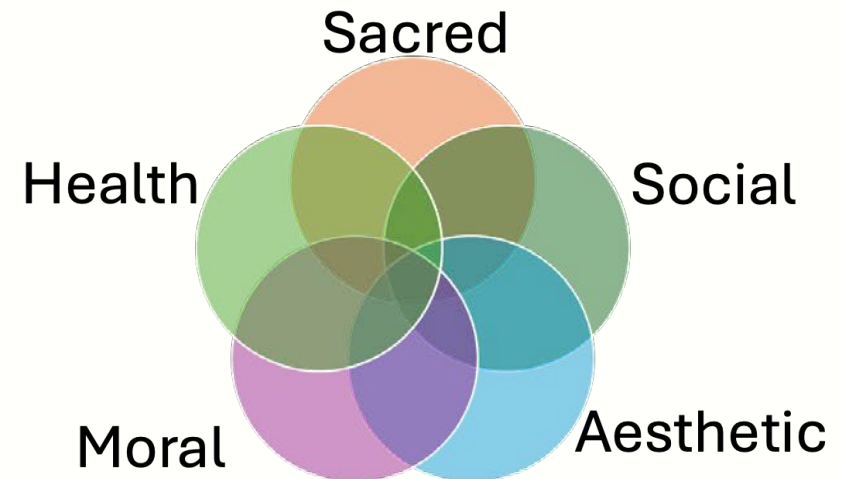
Food may be medicine, but it is **not** a single-substance drug.



# Food $\neq$ Drug

- Unlike medications, FIM has the potential to foster patients' personal relationship with food that can enhance life purpose and meaning, which can exert multiple health benefits
- Broader mental health and positive psychology constructs may strengthen future evaluation designs

# Meaning of Food in Life

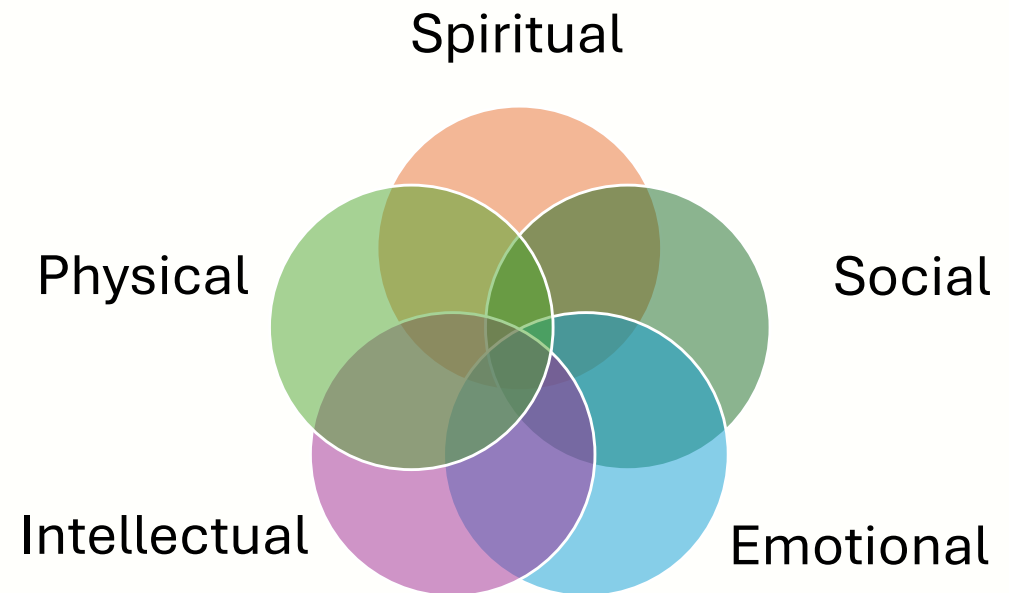


# Food = Health

"Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity."

-World Health Organization

# Dimensions of Health





# Additional Considerations for Future Evaluations

- What matters most? Food, complementary activities, or both?
- How does FIM affect *provider* satisfaction/burnout? Programs are resource and personnel-intensive, yet anecdotally rewarding.
- Since FIM is not a single-agent drug, how can we evaluate FIM more holistically and escape reductionistic mind-traps traditionally used for proving a medication's worth?
- Should we pause to focus on initial mechanistic and efficacy studies for MTG and Produce Rx interventions to confirm needed dose of target foods before jumping to effectiveness and implementation studies? Or, does this perpetuate reductionistic thinking?
- How can we feasibly execute community-engaged, action-oriented FIM programs that are responsive to community needs, but that also meet payee expectations for “proof” within the traditional paradigm of healthcare intervention development?