There’s a Mess in the Kitchen!
Evaluating FIM in Real-Life Settings:
Reflections about the Kansas Pilot Project

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

<table>
<thead>
<tr>
<th>Patient Population</th>
<th>Foods</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prediabetes</td>
<td>F/V</td>
<td>Food Security</td>
</tr>
<tr>
<td>Diabetes</td>
<td>Fiber foods</td>
<td>Block Fruit/Vegetable/Fiber Screener</td>
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<tr>
<td></td>
<td>Other</td>
<td>Hgb A1c (A1c Now POC device)</td>
</tr>
<tr>
<td>Setting</td>
<td></td>
<td>Depression (PHQ-9)</td>
</tr>
<tr>
<td>FQHCs</td>
<td></td>
<td>Flourishing &amp; Vitality</td>
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<tr>
<td></td>
<td></td>
<td>BMI</td>
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<td>Blood Pressure</td>
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<td>Program completion (spreadsheet)</td>
</tr>
</tbody>
</table>

- 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

- Patient Demographics
- Patient Health Conditions
- Patient Readiness & Motivations for FIM Enrollment
- Delivery, Variety, Suitability, and Dose of FIM
- Complementary FIM Activities (Culinary Medicine; Group Education; 1:1)
- Healthcare Provider Turnover, Enthusiasm & Engagement
- Setting (Urban, Rural, Frontier)
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

Menu 1
Contains: 14.5oz Green Beans (1), 15oz Sliced Carrots (1), 15oz Unsweetened Apple Sauce (1), 11oz Mandarin Oranges (1), 16oz Whole Wheat Spaghetti (1), 15oz Pasta Sauce (2), 5oz Tuna (3), 14.1oz Oats (1), 32oz 1% Milk (1)

Menu 2
Contains: 15oz Sweet Potato (1), 15oz Green Beans (1), 15oz Pear Slices (1), 15oz Sliced Peaches (1), 16oz Brown Rice (1), 15oz Red Kidneys (1), 4.5oz Chicken Pouch (3), 17.63 oz Corn Flakes (1), 32oz 1% Milk (1)
Many sources of variation: geography

This intervention takes place in six geographically and demographically diverse clinics in Kansas.
### No Surprise Here! Variation in Preliminary Outcomes

<table>
<thead>
<tr>
<th>Clinic</th>
<th>Food security</th>
<th>Fruit &amp; Vegetable intake</th>
<th>Mental Health</th>
<th>A1c</th>
<th>Blood pressure</th>
<th>Body Mass Index</th>
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<tr>
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<td>Vitality</td>
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<td>□</td>
<td>✓</td>
<td>✓</td>
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</tbody>
</table>

**Legend:**
- **Improved**
- **Worsened**
- **No Change ---**
- **Not Reported N/R**

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**Clinic A**
- Food security: ✓
- Fruit & Vegetable intake: ✓
- Mental Health: Depression: □, Vitality: ✓, Flourishing: □
- A1c: □
- Blood pressure: □
- Body Mass Index: □

**Clinic B**
- Food security: □
- Fruit & Vegetable intake: ✓
- Mental Health: Depression: ✓, Vitality: □, Flourishing: □
- A1c: □
- Blood pressure: ✓
- Body Mass Index: ✓

**Clinic C**
- Food security: □
- Fruit & Vegetable intake: ✓
- Mental Health: Depression: □, Vitality: ✓, Flourishing: □
- A1c: □
- Blood pressure: □
- Body Mass Index: □

**Clinic D**
- Food security: ✓
- Fruit & Vegetable intake: ✓
- Mental Health: Depression: ✓, Vitality: ✓, Flourishing: □
- A1c: ✓
- Blood pressure: ✓
- Body Mass Index: |

**Clinic E**
- Food security: ✓
- Fruit & Vegetable intake: ✓
- Mental Health: Depression: ✓, Vitality: □, Flourishing: □
- A1c: □
- Blood pressure: ✓
- Body Mass Index: |

**Clinic F**
- Food security: N/R
- Fruit & Vegetable intake: N/R
- Mental Health: Depression: N/R, Vitality: N/R, Flourishing: N/R
- A1c: N/R
- Blood pressure: N/R
- Body Mass Index: N/R

**All**
- Food security: ✓
- Fruit & Vegetable intake: ✓
- Mental Health: Depression: □, Vitality: ✓, Flourishing: □
- A1c: ✓
- Blood pressure: ✓
- Body Mass Index: |

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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

- **Efficacy Studies**
- **Effectiveness Studies**
- **Implementation Research**

**Hybrid Designs**

**Improved processes, outcomes**

**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
FIM for Diabetes

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

Effectiveness “Real World Settings”

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

Implementation (Scaling & Adaptation)
Food may be medicine, but it is not a single-substance drug.
Food ≠ 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

- Sacred
- Health
- Social
- Moral
- Aesthetic

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

-World Health Organization
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?