DEVELOPING A FRAMEWORK TO ASSESS OUTCOMES AND IMPACTS OF MEDICALLY-TAILORED FOOD AND NUTRITION SERVICES OFFERED BY THEMETROPOLITAN AREA NEIGHBORHOOD NUTRITION ALLIANCE (MANNA)

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Dedication

To my Mother

Dorothy W. ("Ma-Dot") Durkin

Without whose love and support this work would not have been started

To my Husband

Robert B. Henstenburg

Without whose love and support this work would not have been completed

To my Children

Jeffrey M. Henstenburg and Brian A. Henstenburg

Who never doubted that their Mom would achieve her PhD

To my Father

The late Raymond J. Durkin

Whose belief in education for service to others has made all the difference

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Abstract

Food is Medicine is a healthcare initiative whereby medically tailored food and nutrition services are provided to clients with acute and chronic illness. MANNA is a *Food is Medicine* organization in Philadelphia, PA with the philanthropic mission of providing short-term support of acute stages of life-threatening illness such as cancer, renal disease, diabetes, and others. The goal of MANNA is to expand the number of patients it can serve through health insurance reimbursement of its food and nutrition services. To achieve this goal, MANNA needs to show that its services are effective and cost-saving. To date, MANNA has one peer-reviewed study demonstrating an association between its services and decreased healthcare costs. However, apart from client satisfaction, there is no system in place to routinely collect client outcome data and compare it with program inputs. Therefore, the goal of this research was to begin the process of building a robust and sustainable evaluation framework for MANNA and perhaps for other food/nutrition service settings.

The study used several sources of data to construct the framework. To begin, the researcher examined a sample of MANNA client chart data as well as client satisfaction surveys. This provided a snapshot of client characteristics, health outcomes, and perceptions of care and related services. Then, focus groups were organized with key MANNA stakeholders, staff, and Board of Directors to obtain program provider perceptions of client services and of the most important outcomes to study.

Client medical records, client satisfaction surveys, and stakeholder interviews, provide the basis for an evaluation framework that MANNA may use going forward to

measure medical, psychological, social, and economic impact of a program. Impact information can help estimate the success of a program of geographic expansion that MANNA is planning and identify the resources that will be necessary to achieve that success.

Based on anecdotal stories of client progress, program stakeholders perceive that MANNA clients improve physically and emotionally. These outcomes were not objectively substantiated in the sample chart data, in some cases due to inadequate reporting. One regularly reported health outcome in client charts was body weight, which allowed for a calculated body mass index (BMI) based on reported height. Since most MANNA clients have wasting diseases that would result in a decrease in BMI, it is important to emphasize the lack of significant BMI change over the six-month sample period, i.e., receiving services from MANNA is associated with maintaining body weight. A second finding was the reduction of reported recent hospitalization over the course of the study ($p=0.0077$). There were no other significant findings in an analysis of chart data.

The researcher suggests that MANNA use the National Institutes of Health-sponsored Patient Reported Outcomes Measurement Information System (POMIS) as a starting point for a new evaluation framework. These validated outcomes measures should help clarify the health impact of MANNA food and nutrition services and be consistent with quality measures used by multiple healthcare systems. It is also suggested that MANNA collect additional qualitative and quantitative data within its evaluation

framework including client narratives, dietary intake data, select health measures, and demographic variables associated with health outcomes.

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Chapter 1 Introduction

Food is Medicine is a community-based healthcare initiative whereby patients with acute and chronic illness are provided medically-tailored meals and nutrition counseling in their homes and communities(1,2). There are a handful of non-profit organizations across the US that provide community-based, medically-tailored food and nutrition services (FNS), most of which are member agencies of the Food is Medicine Coalition (FIMC). The FMIC advocates for healthcare policies that incorporate the provision of medically-tailored food and nutrition services into mainstream healthcare systems and associated reimbursement mechanisms(1). One member organization, the Metropolitan Area Neighborhood Nutrition Alliance (MANNA), is in Philadelphia. It offers a full medically-tailored meal plan that includes three meals a day for seven days a week for individuals who are at acute nutritional risk from life-threatening illness including diabetes, cancer, HIV/AIDS, renal disease, congestive heart failure, and others (3). MANNA's medically-tailored food and nutrition services are intended to be "short-term," lasting approximately 6-12 months(4). MANNA also employs a staff of Registered Dietitian Nutritionists (RDNs) who provide nutrition counseling so that clients can adhere to their prescribed therapeutic diet after meal services are discontinued(5). Meals and nutrition counseling are currently provided at no cost to the clients, regardless of income, due, in part, to philanthropic funding(6).

Outcomes and impacts of medically-tailored food and nutrition services, such as those provided by MANNA, have not been well-studied(7,8). However, advocates of the *Food is Medicine* initiative have proposed that future inclusion of these services as

reimbursable within public and private healthcare insurers will depend on the ability of medically-tailored food and nutrition service providers to prove that their services are effective in disease management and/or prevention(2,9). Ultimately, the goal of advocacy efforts is for medically-tailored food and nutrition services to become more widely available as an essential health benefit within Medicaid and Medicare, or as a free preventive service under the Affordable Care Act(9,10). This, in turn, will require the development of more robust outcomes evaluation processes by MANNA and other FIMC member organizations.

Problem Statement

There are few published studies, and no available shared databases, systematic evaluation plans, or best practice models, to which FIMC member organizations can refer when studying the efficacy and effectiveness of medically-tailored food and nutrition services. This leads each provider to keep track of their own program specific metrics. MANNA currently collects annual experience-based data that reflect food consumption, service satisfaction, self-reported health improvement, and food security. MANNA's RDNs also collect and conduct initial assessments and 6-month follow-up assessments of medical and nutritional status to certify client eligibility for services. These data are not published and are similar in type to other medically-tailored food and nutrition programs. A quick review included a comparison of data collection forms published on the web site of other FIMC members and similar organizations including:

- God's Love We Deliver (New York, NY)(11),
- Project Open Hand (San Francisco, CA)(12),

- Project Angel Heart (Denver, Co)(13),
- Food and Friends (Washington, DC)(14),
- Community Servings (Boston, MA)(15),
- Chicken Soup Brigade (Seattle, WA)(16),
- Open Arms of Minnesota (Minneapolis, MN)(17).

Of note, similar experience-based data are also collected by community-based home-delivered meal programs that are part of the Older Americans Act(8,18).

Currently, medically-tailored food and nutrition services are not included as an essential service within Medicaid and Medicare programs or as preventive service within the ACA so are not reimbursable services(2). Rather, services are provided by non-profit organizations that are largely funded by individual and corporate donations and foundation grants(10). There is also a relatively small amount of government funding available through the Ryan White Treatment and Modernization Act for persons with HIV(19).

One of the policy goals of the FMIC is to help member agencies incorporate medically-tailored food and nutrition services into public health insurance programs or within essential benefits of the ACA in order to be considered a reimbursable healthcare service(20). For this to happen, agencies such as MANNA will need to show that their medically-tailored food and nutrition services are an effective component of disease management to Medicaid and Medicare programs, private health insurers, and healthcare organizations(10,21). Potential future outcomes measures needed for this purpose include specific measures of health, medical and nutritional status, as well as the impact of

services on health care utilization, institutionalization, quality of life and mortality(7,22–24). There is also a subset of MANNA's clients who experience acute problems from underlying chronic illness, and, despite best medical efforts, are not likely to improve (MANNA Staff, personal communication). Measures frequently used to assess the quality and effectiveness of program inputs, such as reduced patient use of clinical services, hospitalizations, and morbidity and mortality, need to be modified when serving a population with life-ending chronic illnesses(25).

Statement of Purpose and Research Questions

The purpose of this mixed-methods research was to study a functioning organization (MANNA) that provides medically-tailored food and nutrition services as a community-based healthcare service as part of *Food is Medicine* initiatives. Quantitative and qualitative data were collected and analyzed to help MANNA develop a framework for a systematic plan of outcomes evaluation. This plan ideally could also be utilized by other FMIC members. The systematic plan of outcomes evaluation will support the inclusion of medically-tailored food and nutrition services as a reimbursable healthcare service within mainstream Medicare and Medicaid programs, dual eligible (Medicaid and Medicare) programs such as the Program of All-inclusive Care for the Elderly (PACE), private insurance plans, and/or new or innovative care opportunities offered by the ACA including Accountable Care Organizations (ACOs) and demonstration projects(9).

This study addressed the following research questions:

1. What are the demographic, socioeconomic, medical, and nutritional characteristics of MANNA clients?

2. How do MANNA's current client medical records and satisfaction survey data describe the effects of medically-tailored food and nutrition services?
3. What outcomes are important to MANNA stakeholder groups to show the impact of MANNA's medically-tailored food and nutrition services on clients, families, organizations, and communities?
4. What systematic outcomes data should MANNA collect to show that medically-tailored FNS services have made a positive difference and are consistent with current quality measures?
5. What are appropriate outcomes for a chronically ill population that will not "get better"? For this population, how should impact be measured and what are best sources of data?

Research Approach

This mixed-methods study analyzed demographic, socioeconomic, medical, nutritional, and satisfaction data to describe MANNA's client characteristics and the effects of MANNA's food and nutrition services. First, the researcher drew MANNA's current client medical records for which client satisfaction surveys were also available. This sample of client medical records allowed the researcher to analyze and compare MANNA's client characteristics, potential medical effects of its services, and first-person accounts of benefits or problems.

Next, stakeholder input was solicited to determine which outcomes and impacts were important to MANNA's staff and Board of Directors. These separate data streams were compared to determine which health outcome measures were most appropriate to

include within a framework for systematic plan of outcomes evaluation for MANNA and other community-based, medically-tailored food and nutrition service providers that are part of *Food is Medicine* initiatives.

The researcher performed a retrospective review of client charts from 2015-2016 that matched returned 2016 client satisfaction surveys(26).Client characteristics were summarized with descriptive statistics and significant associations within this data were examined using bi-variate and multi-variate statistical methods.

Qualitative data were also obtained from stakeholder focus groups (MANNA Board of Directors and staff)regarding outcomes and impacts considered important to MANNA's programmatic decision-making. Separate focus groups were conducted for Board of Directors and MANNA staff so that the most significant outcomes for each group could be most openly identified and discussed. The researcher analyzed the focus group transcripts to identify themes embedded in the discussion and narrative(27) that could support creation of outcome metrics.

These data were analyzed to determine if MANNA is collecting the right metrics to assess whether their services are helping clients, and to show any added impacts on families, healthcare organizations, and communities(28). From this assessment, a framework for developing a systematic plan of outcomes evaluation will be provided for use by MANNA and other medically-tailored FNS providers operating with *Food is Medicine* community-based healthcare initiatives(29).

Rational and Significance

The rationale for this study was based on the researcher's desire to determine a framework for systematic outcomes evaluation of medically-tailored food and nutrition services provided by MANNA and other FMIC member organizations. Increased understanding of the outcomes and impacts of medically-tailored meals and nutrition education and counseling for patients at nutritional risk from acute or chronic life-threatening illness will determine whether these services should be made more widely available as a reimbursable healthcare service by public and private health insurers. If shown to have positive outcomes and impacts, the *Food is Medicine* initiative of providing medically-tailored food and nutrition services as a community-based healthcare service has the potential to help address the needs of the current US healthcare systems for higher value healthcare, described as the "Triple Aim": better healthcare outcomes, lowered cost of care, and improved patient satisfaction(1,30).

Chapter 2 Literature Review

Introduction

Food is Medicine is a healthcare initiative whereby medically-tailored food and nutrition services are provided to patients at nutritional risk in their homes and communities. The initiative began approximately 25 years ago with a focus on provision of community-based food and nutrition services as essential services within the Ryan White HIV/AIDS Program, where the goals were improved health outcomes and viral suppression(22). Today, food and nutrition services within the Ryan White HIV/AIDS Program may be provided as a medical service. In addition, the *Food is Medicine* initiative expanded approximately 10 years ago to include provision of community-based, medically-tailored food and nutrition services for other acute and chronic illnesses associated with nutritional risk including cancer, chronic kidney disease, and diabetes among others(31). Advocates of medically-tailored food and nutrition services seek recognition as a healthcare services that offers improved healthcare outcomes and cost savings(2,9). However, there exists little published research on outcomes evaluations for medically-tailored food and nutrition service organizations, which hinders advocacy efforts.

One of the factors that inhibits outcome evaluation of food and nutrition services within a *Food is Medicine* framework is that services have historically been funded through philanthropic and volunteer efforts and have generally not been reimbursed by public or private healthcare insurance(10,32). However due to the possibility of substantial healthcare cost savings, there is currently movement to advocate for inclusion

of food and nutrition services in public and private health insurance plans to increase sustainability of these services beyond that provided by philanthropy(33).For community-based, medically-tailored food and nutrition services to be sustainable in the future, systematic program evaluation will need to show that services are evidence-based, accomplish lasting health improvement, and save healthcare costs. This literature review will describe the outcomes and impacts which have been documented to date for MANNA and other organizations who are part of the *Food is Medicine* healthcare initiative.

Food is Medicine Coalition

The Food is Medicine Coalition (FIMC) is an organization consisting of non-profit organizations across the United States that provides community-based, medically tailored food and nutrition services. While Coalition members have different missions regarding which clients they specifically serve, the commonality is that services are provided to community members who are at nutritional-risk from acute or chronic illness and/or food insecurity. Food may be provided as home-delivered meals, congregate meals, or vouchers, and may also include bagged food donated by individuals or from food pantries and food banks(9). Nutrition services may include nutrition education or counseling provided by a RDN.

Significant FIMC members nationally include the Metropolitan Area Neighborhood Nutrition Alliance or MANNA(Philadelphia, PA)(6), God's Love We Deliver (New York, NY)(11), Project Open Hand (San Francisco, CA)(12), Project Angel Heart (Denver, Co)(13), Food and Friends (Washington, DC)(14), Community

Servings (Boston, MA)(15), Chicken Soup Brigade (Seattle, WA)(16), and Open Arms of Minnesota (Minneapolis, MN)(17). Most organizations provide clients with access to a RDN for nutrition education and counseling, but member organizations vary in what food they provide, how they provide food, as well as what qualifies individuals to receive services.

There currently exists no systematic plan of evaluation for *Food is Medicine* member organizations. However, a review of intake forms shows that coalition members collect a core set of similar client intake information including demographics, medical diagnoses, laboratory values consistent with diagnoses, body weight, medications, and ability to perform activities of daily living including cooking(3,34,35). They also routinely collect factors associated with nutritional risk including dietary prescription, food allergies, chewing/swallowing ability, and access to food and cooking facilities. Some FIMC members also collect client satisfaction surveys that detail satisfaction with the overall food and nutrition services as well as satisfaction with specific foods provided. Satisfaction surveys may also contain self-reported information on health status and food security(18).

FIMC members have examined various aspects of program outcomes. Through the now defunct Association of Nutrition Services Agencies (ANSA), coalition members attempted to develop a universal evaluation tool to assess program impact(36). This evaluation tool is in the form of a similar intake form, consisting of client data detailed above, which is then modified to fit the characteristics of each individual member organization. Some coalition members have had their client and program data compiled

by Emerson Hunger Fellows of the Congressional Hunger Center, which in turn were published as corresponding organization reports(37–39). However, except for the MANNA in Philadelphia, PA, few have conducted research studies or published their outcomes in the research literature.

A program evaluation conducted at Chicken Soup Brigade, a member organization of Lifelong in Seattle, WA, examined 263 nutrition screening reports from clients who had at least two nutrition screens and received meal deliveries at least once/month and 120 client satisfaction surveys (from separate client groups) to determine whether medically-tailored home-delivered meals reduced symptoms of illness, nutrition risk, and food insecurity. Most clients reside in central Seattle and the sample was 50% White, 20% Black, and 5% Latino. Additional client groups were Asian, American Indian, multi-racial or unknown. Approximately 67% of clients in the sample were 65 years and older and prevalent chronic diseases were cardiovascular disease (30%) and diabetes (34%). A Healthy Standard Meal that meets guidelines for fat, fiber, and sodium of the American Heart Association and American Diabetes Association was the main meal served to clients. Overall clients reported a decrease in symptom severity (by an average of 18%) and decrease in number of symptoms (by an average of 32%). The average decrease in overall nutritional risk from benchmark to first year was reported to be 28%. No statistical testing was conducted so it is unknown if these results were statistically significant. The client satisfaction survey showed that most clients agreed or strongly agreed that the nutritional content of their diets and food security improved. The author stated that limitation included unreliability of paper nutrition screening forms and

inability to determine if other social factors played a role in improvements. Lifelong, the parent organization for Chicken Soup Brigade, offers various social services to clients in addition to medically-tailored meals and nutrition services(37).

Community Servings of Boston, MA, published a White Paper which described the results of qualitative interviews and quantitative surveys conducted with healthcare workers who refer clients for food and nutrition services. Fourteen healthcare workers completed interviews and an additional 69 healthcare workers answered a brief on-line survey. Questions centered on healthcare workers' perceptions about the impact of medically-tailored meals for clients with diabetes, HIV/AIDS, and cancer. The clear majority of healthcare workers (95.6%) who were interviewed thought that the program improved the health of clients at least "some" or more. Other perceptions from surveys were that food and nutrition services decreased hospitalizations (67%), improved access to healthy food (94%) and increased knowledge about food and nutrition at least "some" or more (72%). All healthcare workers who were surveyed indicated that they would refer clients to Community Servings again in the future(38).

Food and Friends in Washington, DC, published a report of a pilot study on the impact of their food and nutrition services on client health, symptom management, quality of life, food intake, nutrition knowledge, and body weight and composition. Clients who were eligible and agreed to participate (30 out of a total of 73 eligible) were interviewed on the first day of service and at 30, 60, and 90 days after services started. Client populations studied were those with cancer (66% of sample, mean age 58 years) and HIV/AIDS (33% of sample, mean age 47.9 years). Only half of the clients

participated in interviews at all four time points (15 out of 30). Those who completed the study were considered healthier than the full group as drop outs occurred due to hospitalizations, death, service stoppage, and daily cancer treatments. Ninety percent of study participants were African-American and most had an income below poverty level of less than $12,000 per year. Co-morbidities that were prevalent included hypertension, depression, and neuropathy. More than 80% of clients experienced significant sources of stress including illness, instability in finances and housing, family or personal problems, difficulty with self-care, food insecurity, addiction, and lack of transportation. Both clients with cancer and HIV/AIDS experienced improvement in number of symptoms and a decrease in nutrition risk. The results were not statistically analyzed and there was no control group so the actual role of food and nutrition services in the reported improvements cannot be determined. Clients also reported an improved quality of life that ranged from ability to better care for their families to increased independence to improved food security. Results also included clients' consuming a higher quantity and quality of food, reporting an increase in nutrition knowledge, and experiencing weight stabilization. The conclusion of this pilot study was that medically-tailored meals and nutrition services significantly offset the malnutrition and poor therapeutic compliance to diet that is associated with food insecurity, allowing clients to better manage illness and have an overall improved quality of life(39).

Metropolitan Area Neighborhood Nutrition Alliance (MANNA)

MANNA, a FNS organization in Philadelphia, offers a full medically-tailored meal plan with 22 therapeutic options that includes three meals/day for seven days/week

for individuals who are at acute nutritional risk from life-threatening illness(3,4). Unique to MANNA's mission is that FNS are intended to be short-term, lasting on an average of six to 12 months and are provided at no cost to the client(3). MANNA also employs a staff of Registered Dietitian-Nutritionists who provide nutrition counseling and education(5).

MANNA's food and nutrition services are considered to be Medical Nutrition Therapy (MNT) services, defined as "nutritional diagnostic, therapy, and counseling services for the purpose of disease management which are furnished by a registered dietitian or nutrition professional ... pursuant to a referral by a physician..." per Section 105 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act (BIPA)(40).Medical Nutrition Therapy services conducted by a RDN include the use of evidence-based guidelines for nutrition assessment, intervention, monitoring and evaluation in health promotion and disease management. The main primary diagnoses of MANNA clients include cancer, renal disease, diabetes, HIV/AIDS, and heart disease, all of which have evidence-based food and nutrition interventions for disease management.

The process used for medical nutrition therapy at MANNA is that clients receive medically-tailored meals that model which foods and amounts that clients should have in their diets based on their medical diagnoses. Nutrition counseling provides the corresponding nutrition information and help with eating behavior change to allow clients to continue to adhere to their therapeutic diets after MANNA services are discontinued. The overall goal is for clients to be able to independently manage adherence to their

therapeutic dietand thereby, experience better disease management together with improvement in overall health and quality of life(6).

MANNA published a pilot study which examined its program outcomes in 2013(41). The questions MANNA asked were: 1) Do MANNA services correlate with reduced healthcare expenditures, emergency room visit, and hospital admissions? and 2) Do MANNA clients have lower health care costs and/or better health outcomes than patient with similar conditions who are not receiving MANNA services? MANNA clients who were included in the study were those that had received at least 3 months of uninterrupted service and were members of a specific but unnamed managed care organization between August 1, 2008 and April 30, 2010, coinciding with the start of MANNA's 21 meals per week program. Based on these criteria, the MANNA group consisted of 65 clients who had any health claims with the managed care organization during that designated time period. A comparison group of 633 members was selected based on demographic characteristics and disease diagnosis codes, with specific sub-matching on eight nutrition-related diagnosis codes. Since MANNA eligibility is based on medical diagnosis and nutritional-risk, not socioeconomic status, this type of matching was considered to create the most valid comparison group.

Cost patterns where examined pre-and post-MANNA services for overall healthcare costs. Comparisons were also made between MANNA and control groups for hospital admissions, emergency room visits, number of admissions, length of in-patient stay, and number of patients discharged to home. Results for pre- and post-MANNA services showed that average monthly healthcare costs decreased from $38,937 before

services to $28,183 after three months of services. There was also a decrease in average monthly inpatient costs from $174,320 before services to $121,777 per month after three months of services. Of note, these decreases were not described as statistically significant. When the MANNA group and control group were compared, statistically significant decreases were seen in mean monthly healthcare costs, number of ER visits, inpatient costs, number of inpatient visits, and inpatient length of stay. The study also showed a significant increase in number of individuals discharged to home in the MANNA group compared to the control group. There are three notable limitations to the MANNA pilot study. First, the number of subjects was limited by the low number of clients who submitted claims. Second, while the comparison group was matched to MANNA clients using similar nutrition diagnosis codes, other socioeconomic characteristics were unknown, potentially leading to significant bias. Third, the timeframe was only six months, limiting generalization and projection of long-term trends or effects(41).

In addition to the pilot study on healthcare costs detailed above, client satisfaction data collected by MANNA has been benchmarked to two cohorts from the 2013 National Survey of Older American Act Participants: the northeast census region and those who reported living in urban/suburban areas. For this study, select items were chosen from the Performance Management Outcomes Project (POMP, Administration on Aging, HHS) for inclusion in the 2014 MANNA Annual Client Satisfaction Survey. According to this survey, clients report being very satisfied with the quality and type of meals provided and that meals were medically appropriate, helped clients achieve or maintain healthy weight,

and helped to decrease hospitalizations. Compared to the National Survey of Older American Act Participants northeast and urban/suburban groups, significantly more MANNA clients reported that they experienced food insecurity, that meals helped them eat healthier and that meals improved health. They also reported more satisfaction with the taste and variety of food as well as the overall program compared to the National Survey of Older American Act Participants sample(18).

MANNA has also recently partnered with Health Partners, a Pennsylvania Medicaid-managed care organization in the Philadelphia region, to offer medically tailored food and nutrition services to patients with poorly controlled diabetes who were selected to receive services based on willingness to change eating behavior for improved health outcomes. Health Partners reported reduced healthcare utilization in patients in the six months after receiving MANNA's services. This included fewer hospitalizations and fewer emergency room visits (7%), primary care practitioners (16%)and medical specialists (7%).Health Partners also reported that 26% of patients with diabetes showed lower Hemoglobin A1C levels six months after receiving MANNA food and nutrition services(42).To date, Health Partners has not published its data in the research literature.

Although the data above describe multiple positive outcomes of clients receiving MANNA's services, these results are considered short-term due to the nature of MANNA's mission, which is to address acute nutritional risk due to life-threatening illness (generally for 6-12 months)(3). Important to the sustainability of MANNA's *Food is Medicine* healthcare models is whether clients maintain health improvements and reduced healthcare costs after services are discontinued. It is currently unknown if short-

term gains from medically-tailored meals and nutrition education and counseling are sustained after services are discontinued.

There is little other research on programs that provide medically-tailored home-delivered meals and nutrition counseling as provided by MANNA. A recent study published in 2017 was conducted by Project Open Hand (San Francisco, CA) and researchers in the Department of Medicine at San Francisco General Hospital of the University of California, San Francisco (UCSF)(43).A total of 52 clients diagnosed with either HIV (n=23), type 2 diabetes (n=22) or both (n=7) completed baseline and follow-up assessments after six months of receiving healthy Mediterranean-type meals and snacks designed to provide 100% of energy needs. Assessments were conducted in-person and included measurements of nutritional status (weight, height, and calculated BMI), HbA1c values (for those with diabetes), and responses to validated surveys on the topics of food security, nutritional intake, mental and emotional health, and healthcare behaviors including substance abuse and healthcare utilization. Significant changes in outcomes after 6 months of healthy meals included decreased severity of food insecurity experienced by clients, improved dietary quality, less depressive symptoms, increased medication adherence, and decrease in BMI in clients with diabetes. There were no significant differences after 6 months of meals in BMI measures in clients who were HIV positive, in HbA1c levels in clients with diabetes, and in healthcare utilization among all study participants(43).

One other study looked at the cost-effectiveness of providing MNT and medically-tailored meals for hypertension and/or hyperlipidemia in a prospective clinical

trial for one year in subjects 60 years of age or older(44). Patients were assigned to one of four arms: literature, therapeutic meals, medical nutrition therapy, or medical nutrition therapy plus therapeutic meals. The key outcome measure, quality adjusted life-years (QUALYs), was measured at baseline, mid-intervention (after 6 months), and post intervention (after 1 year) using the Short-Form 36 as the basis for the QUALY calculation. The authors found the probability that the medically-tailored home-delivered meals were cost effective was 95%. The probability that medical nutrition therapy was effective was 90%. However, there was no independent significant effect of the combination of therapeutic meals and medical nutrition therapy on QUALYs. According to this study, both medically tailored home-delivered meals and medical nutrition therapy are separately effective with regard to improving health while lowering healthcare costs(44).

Large multicenter national trials have shown that medical nutrition therapy is effective for diabetes management and blood pressure control(45,46). Multiple evidence-based guidelines have been developed for use of medical nutrition therapy in diet and nutrition-related diseases such as diabetes, chronic kidney disease, heart failure, oncology, and unintended weight loss in older adults and others(47). Even though medical nutrition therapy has been shown to be effective in producing health improvement for diet-related diseases such as diabetes and hypertension, the general efficacy of medical nutrition therapy alone for individuals outside of clinical trials is largely unknown, especially for those with low financial resources that affect the ability to purchase recommended food. A current multicenter trial is testing whether providing

patients with a sodium-restricted DASH diet and medical nutrition therapy for four weeks after hospital discharge will improve health and disease management better than Medical Nutrition Therapy alone (48). These types of clinical trials will be important for verifying whether MANNA's medically-tailored food and nutrition service model produces better health improvement than medical nutrition therapy alone, the current healthcare service typically provided in clinical practice.

Older American Act Food and Nutrition Services

The Older Americans Act (OAA) is a major source of social and nutrition services to older adults in the United States(49). The Older Americans Act was re-authorized in 2016 as PL 114-144 (April 19, 2016). Reauthorization lasts through 2019 and includes food and nutrition services including congregate nutrition services, home-delivered nutrition services, disease prevention and health promotion services, and the Nutrition Services Incentive Program(50). Nutrition Programs of the OAA emphasize adults age 60 and older who have higher social and economic needs. Meals served through the OAA must meet quality standards defined by the Dietary Guidelines for Americans (2015-2020) and provide one-third of nutrient requirements for age according to the Dietary Reference Intakes(51,52).

The OAA Nutrition Programs are administered by State Units on Aging(49). In general, meals provided by the OAA follow OAA's national guidelines and are not targeted to individual needs for disease management as are medically-tailored FNS**.** While the number of modified meal offerings has increased in OAA providers, most within home-delivered meal programs are low sodium (51% of providers) or diabetes-

appropriate (34% of providers)(53). Limitations of OAA programs in regard to providing medically-tailored meals are likely cost issues because the program is not an entitlement program, and many home-delivered meal providers have waiting lists(54). Because of these limitation of OAA Nutrition Programs, home-delivered meals provided by the OAA and medically-tailored home-delivered meals provided by *Food is Medicine* providers can be thought of as complimentary services along a public health to healthcare services continuum that allow older adults to achieve improved health within communities(55).No research studies have examined health outcomes from complementary use of these programs. However, research on home-delivered meal outcomes as part of community-based services of the OAA can shed light on potential outcomes from medically-tailored FNS as a community-based healthcare service.

Older Americans Act Outcomes Research

Research initiatives on the effectiveness of Nutrition Programs of the OAA at the national level have focused on process (program structure, administration, staffing, coordination, processes and service delivery) and meal cost analyses. A national Client Outcomes Study which focuses on nutrient adequacy, socialization opportunities, health outcomes, and whether the programs help older adults avoid institutionalization is currently being conducted(56). However, individual research studies examining health improvement from OAA home-delivered meals programs exist currently and can be used to examine aspects of program effectiveness.

Frongillo and Wolf (2010) examined whether older adult participation in home-delivered meals resulted in improved nutritional status in a longitudinal study of elderly

individuals who received home-delivered meals (HDM) in upstate New York. They compared demographic variables, food security, body weight, and nutritional intake at baseline and at six and 12 months after starting home-delivered meals. They also compared those who received HDM services to those who received other community-based services, but not HDM. The results showed a positive impact of HDM through significantly increased nutrient intake in the HDM group versus the non-HDM group at six and 12 months. Within the HDM group, significant increases in fruit and vegetable variety, vegetable servings, beta-carotene, Vitamin E and magnesium also occurred at six and 12 months. Food insecurity also decreased within the HDM group at six and 12 months although mean body weight did not change(57).

Wright et al.(2015) conducted a pre-test, post-test (at two months) descriptive pilot study which examined the impact of HDM on nutritional status(MNA-SF), dietary intake (24 hour recall), food security (USDA six-item scale), social well-being (WHO-5 questionnaire), and loneliness (Three-Item Loneliness Scale) in 62 adults age 55 years and older who received at least three HDM per week at a Meals-on-Wheels program in Central Florida(58). Significant improvements were seen in nutritional status, calorie and protein intakes, emotional health, and food security(58).

Several review studies have examined whether participation in home-delivered meals improves outcomes for older adults. One systematic review conducted by Campbell et al. (2015) consisted of largely descriptive, cross-sectional studies of small sample size that were focused on specific settings or populations. However, no studies were excluded due to poor quality. All research conducted through 1965-2015 (beginning

of OAA to study period) was included to show the total amount of research that has been conducted to date. Cross-sectional descriptive studies (about half of the studies) reported on client characteristics including that HDM participants were at high nutritional risk, food insecure, and were satisfied with meal programs. Other cross-sectional studies showed that those who receive HDM were a more vulnerable regarding sociodemographic, economic, and functional characteristics. Still others showed that those with poor nutritional status and receiving HDM were less likely that those with poor nutritional status and not receiving HDM to be admitted to a hospital within a 12 month period(8).

Pre-and post-test studies reviewed by Campbell et al. show that in all cases participation in HDM improved nutritional status and risk as well as measures of emotional status such as anxiety and well-being. Large-scale longitudinal studies overall showed that HDM recipients had poorer nutritional status and increased likelihood of being hospitalized or institutionalized. Another groups of studies examined non-randomized interventions involving home-delivered meals such as receiving nutrition education, adding snacks, providing frozen meals, etc. These studies measured nutritional and functional status, hospital readmissions and quality of life and improvement with HDM participation were seen in all studies. Six randomized controlled studies focused on hyperlipidemia or hypertension and HDM, and outcome results were mixed although it was difficult to make comparisons because studies contained different interventions and outcome measurements. Three studies compared clients receiving HDM to clients on a waiting list. Those receiving HDM had improved food security and dietary intake and

those not receiving meals had increased likelihood of experiencing uncontrolled diabetes and hospitalizations. Three studies looked at claims data to see if cost savings could result if HDM were expanded within the Medicaid program and presumably, prevented institutionalization. One study found cost savings from nursing home admission and another found no association between HDM and cost savings from institutionalization. One claims data study found that HDM was associated with lower risk of hospitalization(8).

Zhu and An (2013) examined the effect of home-delivered meals on diet quality and nutrient intake. They used specific criteria for selecting studies that defined food and nutrient intakes as the main outcome and rated the quality of studies as part of their evidence analysis. Out of a total of 396 articles, eight met criteria for inclusion. Six out of eight studies showed that participation in HDMs improved dietary quality, increased micronutrient intakes (Vitamin A, C, B-vitamins, calcium, magnesium, phosphorus, potassium, iron, and zinc), decreased food insecurity and decreased nutritional risk. There was also a decrease in fat and sodium intakes. Participants in HDMs also experienced improved dietary adherence, higher quality of life, and increased socialization opportunities(59).

Medically-tailored Food and Nutrition Services Evaluation

Medically-tailored, home-delivered meal programs and nutritional counseling explicitly address client's medical or clinical needs, thereby being considered a healthcare service. Healthcare services may be evaluated by examining structures, processes, and outcomes(8). Most studies conducted to date on home-delivered meal

programs of the OAA and medically-tailored home-delivered meals from providers within the *Food is Medicine* initiative have measured self-reported variables (i.e. satisfaction, heath status, nutritional intake, food security).Some have measured outcomes such as healthcare cost-savings and utilization (e.g. hospitalizations and ER visits). Few have measured outcomes such as improvement in health status as reflected by changes in laboratory values or other objective tests to determine if perceived improvements (self-reports) reflect better disease management. Outcome studies pose challenges in regard to collecting current laboratory values, time commitment, and reaching clients for follow-up(60).Also, best practices in outcomes research in clients with multiple chronic conditions have not been established(61).

Structure and process measures will continue to be important to understand barriers to disease management in the context of the socioecological model(23,62). However, in order to be considered as a reimbursable healthcare service within the context of current health policy, community-based, medically-tailored food and nutrition service providers, such as MANNA, will have to show outcomes and impacts including, but not limited to, improved health status and quality of life, decreased mortality, and decreased need for high-cost health services including hospital admissions and nursing home placement(7,8). Future evaluations for community-based food and nutrition services should be designed to measure structure and process variables together with outcome variables to fully understand the impact of home-delivered and medically-tailored meals and nutrition counseling on individuals, families, and communities.

Chapter 3 Research Methods

Introduction and Overview

This study employed mixed methods to develop a framework to assess the outcomes and impacts of medically-tailored food and nutrition services at MANNA. MANNA's demographic, medical, nutritional, meal information, and client survey data were used to describe client characteristics and services. Bi-variate and multi-variate statistical methods were employed to describe effects of MANNA's services on potential outcome variables. Qualitative content analysis was used to analyze focus group transcripts to determine the outcomes and impacts that were important to MANNA stakeholders. Last, MANNA's client data, satisfaction surveys, and feedback from MANNA stakeholders were used to choose health outcome measures that form the framework for a systematic plan of outcomes evaluation for MANNA. This framework is also applicable to other community-based, medically-tailored food and nutrition service providers that are part of *Food is Medicine* initiatives.

The first step in the mixed method approach was to review data from MANNA's current client referral and intake forms, recertification forms, and computer database. The main client data examined were demographics, medical diagnosis and treatment, medications, laboratory values, nutritional status and risk factors, food insecurity and client feedback. The type of data currently collected about clients was initially chosen to indicate the need for medically-tailored food and nutrition services, also known as "medical nutrition therapy" (MNT), for clients at nutritional-risk from life-threatening illness. Since MANNA's services are meant to address acute nutritional risk on a short-

term (6 months') basis, data collected upon 6-month follow-up was intended to determine whether clients should be re-certified for an additional 3-6 months of services. This research project analyzed a sample of MANNA's client data to date ("baseline" data) to determine how it described MANNA's client characteristics and whether it was useful for measuring health effects due to MANNA's medically-tailored food and nutrition services. The assumption was that by the end of services, most clients would achieve adequate nutritional status. Another assumption was that clients would achieve the self-sufficiency to buy and prepare foods that are consistent with their therapeutic diet prescription through the examples of the medically-tailored meals provided together with nutrition counseling and education.

Second, qualitative data were obtained from focus groups with MANNA staff and Board of Directors. Focus group data were analyzed to determine stakeholder's views on perceived and expected outcomes of MANNA's services. Stakeholders who participated in focus groups discussed their thoughts regarding the purpose and goals of MANNA, the effectiveness of food and nutrition services, expected client health outcomes and other outcomes including those clients who are not expected to get "better", the ability of clients to be self-sufficient after MANNA services are ended, and MANNA's planned expansion of services. Themes embedded in discussions were identified from focus group transcripts. Discussion themes were compared to results of client chart reviews to determine whether the currently collected client data are consistent with what MANNA stakeholders perceive and expect in term of MANNA's outcomes and impacts.

Third, the researcher reviewed current health outcome measures used to assess the effectiveness of clinical nutrition services (also, Medical Nutrition Therapy, MNT) to determine the appropriateness of their use in community-based FNS. Last, this study compared these health outcome measures with MANNA stakeholder expectations and currently available client outcomes to recommend valid, acceptable, and widely applicable health outcome measures to use within a framework for systematic plan of evaluation for MANNA and other *Food is Medicine* organizations.

Metropolitan Neighborhood Nutrition Alliance (MANNA)

MANNA is a non-profit organization founded in 1990 by seven members of the First Presbyterian Church in Philadelphia. Its initial mission was to provide nutritional support to clients who were experiencing medical crises due to HIV/AIDS. In 1997, MANNA moved to a larger office and commercial kitchen space at 2323 Ranstead Street in Philadelphia. In 2006, MANNA expanded to serve clients with other critical illnesses – cancer, renal disease, cardiac disease and diabetes. To significantly increase its capacity, MANNA moved again in April of 2017 to a state-of-the-art facility on 20th Street in Philadelphia.

During this study MANNA employed 30 staff members and ran a full commercial kitchen to prepare medically-appropriate meals for clients who were at acute nutritional risk from life-threatening illnesses. Volunteers (about 4,200 per year) prepared most of the meals,. Clients received complete nutrition for 3 meals a day, 7 days a week, in a weekly delivery of frozen meals. MANNA's reported that it delivered approximately 75,000 meals/month which equaled one million meals/year throughout Southeastern

Pennsylvania and southern New Jersey. MANNA's recent expansion increased its capacity to 2.5 million meals/year. Most clients received meals and nutrition counseling free of charge due to MANNA's private donations and grant support(32). A smaller number of MANNA's current clients received reimbursable food and nutrition services as part of Pennsylvania Medicaid Programs.

Sample Population

During this study, the MANNA client population was approximately 2,500 clients/year. Of those, approximately 2,000 were served by philanthropic funding and received food and nutrition services for free. Approximately 500 clients were served through a contract with a local Medicaid insurer which provided reimbursement to MANNA for food and nutrition services for clients with diabetes. This study reviewed client data for a sample of MANNA's philanthropic client base which consisted of the following distribution of primary diagnoses: 37% cancer, 22% renal disease, 12% HIV/AIDS, 7% diabetes, 3% heart disease, and 19% other.

To receive services at MANNA, clients were required to have a signed referral from a medical provider or case manager containing data that determined their qualification for medically-tailored food and nutrition services. If a referred patient met criteria for "acute nutritional risk due to life-threatening illness", they were approved for six months of services that included medically-tailored meals, nutrition counseling, or both. Most patients were either referred for medically-tailored meals, or both meals and nutrition counseling (chart reviews). Clients who received additional months of service were recertified by their health practitioner and additional qualifying data were provided.

MANNA Dietitians also collected additional data at initial intake and at the 6-month recertification. Clients were recertified if they continued to meet the criteria of acute nutritional risk and MANNA meals supplied most of their food intake. MANNA's clients were not recertified for additional months of service if they had achieved good nutritional status per client or medical provider report or were non-compliant (defined as unavailable for meal delivery). All forms that MANNA required for initial qualification of services and six months recertification and the 2016 Client Satisfaction Survey are shown in Appendix B.

The sample for this study included clients who received initial approval for six months of medically-tailored FNS and were recertified for an additional three to six months of services between January 1, 2015 and December 31, 2016. Each client had two sets of data: at initial approval and at recertification after six months of receiving services. Clients with any diagnosis served by MANNA during this time period were included. Exclusion criteria included those clients who did not recertify at six months, clients who had received medically-tailored FNS from MANNA prior to January 1, 2015, and clients whose charts were missing or whose information was missing from the database, MealService. There were approximately 632 total clients who met the inclusion criteria for this study based on a review of MealService data.

In addition to initial and recertification data, MANNA also conducted a yearly client satisfaction survey in which paper surveys were delivered to clients with meals and later picked up and returned to MANNA by drivers. MANNA clients returned approximately 230 client satisfaction surveys out of approximately 750 that were

distributed in 2016 (30% return rate). Of these, 103 clients who returned surveys were determined to be within the pool of clients who met inclusion criteria. These were the clients whose charts were reviewed for this study, which is approximately 16% of the total clients who met inclusion criteria (chart and MealService reviews).

Client Data

Data from client charts and the 2016 MANNA Client satisfaction survey were used to answer research questions one and two:

- What are the demographic, socioeconomic, medical, and nutritional characteristics of MANNA clients?
- How do MANNA's current client medical records and satisfaction survey data describe the effects of medically-tailored food and nutrition services?

Data from client charts were entered into the HIPAA-compliant web-based database, REDCap (Research Electronic Database Capture), which was available to graduate students at University of the Sciences. Entered client data included all data categories that were currently listed on the following initial and follow up intake forms and annual client satisfaction survey (Appendix B):

- MANNA Referral Form – initial referral form sent to MANNA from healthcare provider.
- MANNA Nutrition Telephone Assessment – initial intake questions asked by MANNA Registered Dietitians via telephone.

- Health Update Form for Recertification – recertification form sent from healthcare provider, necessary for continuation of services.
- Recertification Information – recertification questions asked by MANNA Registered Dietitians via telephone.
- MANNA Annual Client Satisfaction Survey, 2016 – survey sent annually to active MANNA clients.

Select data were also entered from the MealService data base, including the type of medically-prescribed meal the client received, meal start and stop dates, the reason for stopping, and total number of re-certifications. The data collected from client charts were approved as exempt by the Institutional Review Board at the University of the Sciences. Chart data were analyzed in aggregate with no identifying information.

Client data were entered as categorical data whenever appropriate. The first step the researcher took to determine the data categories was to review client charts to determine what information was collected and documented on MANNA Referral Forms, MANNA Telephone Assessments, Health Update Forms for Recertification, Recertification Information (telephone form), and the 2016 Annual Client Satisfaction Surveys. Approximately 40 charts with corresponding client satisfaction surveys were reviewed for this purpose and categorical answers were developed from the most commonly written responses. The category “other” and text box option for written responses was available for answers that did not match common responses. The researcher then pulled random charts (approximately an additional 40 charts) to

determine whether they were also consistent with the classification scheme that was developed. These charts were those of current active clients, which were filed alphabetically in the Dietitian office. The researcher randomly chose charts from different letters of the alphabet to check the classification scheme. Revisions were made to categories so that they reflected the most common answers in each written category. The categories developed were then reviewed with the Senior Manager of Nutrition and Client Services, a dietitian who oversaw the collection of all data as well as collected client data on a regular basis. Further revisions were made based on her feedback. Last, all categories were checked one final time by randomly checking an additional 20 charts in the same way as described above. In total, approximately 100 charts were reviewed (5% of total yearly clients) and final REDCap data categories and corresponding definitions are shown in Appendix C.

Data collected within REDCap from MANNA client forms, annual client satisfaction survey, and MealService program were downloaded and entered into Excel for descriptive analyses to answer research question one: what are the demographic, socioeconomic, medical, and nutritional characteristics of MANNA clients? Continuous variables were described by mean, standard deviation and percentiles. A histogram and scatterplot were also used to describe data when appropriate. Categorical variables were characterized by the number of responses and proportion of total responses. For both continuous and categorical variables, the total number of responses or values (N) and missing responses or values were calculated.

In addition, excel data from Red Cap were imported into Statistical Analysis Software(SASv9.4, SAS Institute, Inc, Cary, NC) to determine significant associations between initial and follow-up data and satisfaction surveys. Bi-variate and multi-variate statistical methods were used to answer research question number two: how do MANNA's current client medical records and satisfaction survey data describe the effects of medically-tailored food and nutrition services? The researcher used Bowker's Test of Symmetry, McNemar's Test, ANOVA, and t-tests for bivariate statistical analysis and a stepwise multiple linear regression method for multivariate statistical analysis(63).

The 2016 MANNA client satisfaction survey also included written answers to two questions that describe the effects of MANNA's services on clients. Written answers were analyzed for major themes by the researcher.

Focus Groups

Focus group data were used to answer research question three:

- What outcomes are important to MANNA stakeholder groups to show the impact of MANNA's medically-tailored food and nutrition services on clients, families, organizations, and communities?

Focus groups were conducted to obtain information about what outcomes and impacts are important to MANNA stakeholders. Volunteers for the focus groups were recruited from staff and Board of Directors via E-mail. When arriving at the focus group session, every participant was given a brief description of the purpose for the focus group. Upon agreeing to participate, they were given informed consent forms for the focus groups and for audio-recording. The researcher reviewed the forms and answered

any questions. Each participant made the final decision whether to join the focus group session or not.

During the focus group, participants sat with other similar stakeholders (staff or Board Members) for one hour in a designated room at MANNA's site. A moderator led the group in discussion of issues related to MANNA's food and nutrition services using the interview guide shown in Appendix D. Participants were free to leave the group at any time and did not have to say anything if they did not wish to. Focus groups consisted only of discussion. The focus group discussion was recorded digitally so that the moderator was free to interact with the group. To maintain as much confidentiality as possible, participants were asked to refer to each other by first name only during the session. Separate focus groups were conducted for MANNA staff and Board of Directors so that the outcomes and impacts considered most significant for each group could be most openly identified and discussed. The wording for the interview guide was slightly modified to match the role of the stakeholder group that was participating in the focus group. Any staff or Board members who agreed to participate, but who could not attend the focus groups due to scheduling conflicts, were offered the chance to answer focus groups questions in an interview format. Six members of the Board of Directors and ten members of the staff participated in focus group discussions. One member of the Board of Directors answered the focus groups questions in an interview format.

The digital recordings of the focus groups were transcribed verbatim and de-identified by the researcher and an independent third party. Accuracy of the transcripts was checked by the researcher.Common and distinct themes were identified among and

between groups, leading to identification of outcomes and impacts that stakeholders considered to be important for evaluating MANNA's medically-tailored food and nutrition services(27,64).

Health Outcomes Measures

A review of the research literature was conducted to identify health outcomes expected from clinical nutrition care (MNT) for the major diseases served by MANNA. From this review, health outcome measures that had the potential to show the outcomes and impacts of MANNA's medically-tailored food and nutrition services were identified and described. Potential quality measures from the Centers for Medicare and Medicaid Services (CMS)(65), National Quality Forum (NQF)(66), NCQA(67), AHRQ(68), and the Academy of Nutrition and Dietetics(69) were also reviewed, but were not applicable to community-based food and nutrition services at the time of this research. The three streams of data – client medical records, satisfaction surveys, and stakeholder interviews - were considered together with MANNA's current resources, measurement capability, and goals for insurance reimbursement to make a recommendation for which health outcome measures to use as a framework for a systematic plan of evaluation for MANNA and other medically-tailored food and nutrition service providers operating within *Food is Medicine* healthcare initiatives as per research questions four and five:

- What systematic outcomes data should MANNA collect to show that medically-tailored food and nutrition services have made a positive difference and are consistent with current quality measures?

- What are appropriate outcomes for a chronically ill population that will not "get better"? For this population, how should impact be measured and what are best sources of data?

Chapter 4 Quantitative Data Results

Quantitative Data

A chart review was conducted for 103 MANNA clients who had initial and 6-month re-certifications for services between January 1, 2015 and December 31, 2016 and who returned the completed Annual MANNA Client Satisfaction Survey, 2016. Data from client charts were entered into the HIPAA-compliant web-based database REDCap (Research Electronic Database Capture), and included all categories from the following initial and follow up intake forms and annual client satisfaction survey:

- MANNA Referral Form – initial referral form sent to MANNA from healthcare provider.
- MANNA Nutrition Telephone Assessment – initial intake questions asked by MANNA Registered Dietitians via telephone.
- Health Update Form for Recertification – recertification form sent from healthcare provider, necessary for continuation of services.
- Recertification Information – recertification questions asked by MANNA Registered Dietitians via telephone.
- Annual MANNA Client Satisfaction Survey, 2016 – survey sent annually to active MANNA clients.

All clients in this sample were part of MANNA's mission or philanthropic client population, meaning that this client sample received MANNA's food and nutrition services at no cost. Clients were not included in the sample if they received services from insurance reimbursement.

Descriptive Characteristics of MANNA Clients

Descriptive data in the tables that follow show total data points available (N) and number of missing values out of 103 reviewed charts. Categorical variables were

described by number of responses and proportion of total responses and continuous variables were described by mean, standard deviation and percentiles.

Demographic data (Table 1) show that this sample of MANNA clients had very low incomes with an average income of $962 (SD=$653) and a median income of $961 (IQR=$598-$1300) per month. Most clients (77.8%) received supplemental security income (SSI). A small number of clients reported no income, other sources, or only food stamps. This client sample also consisted mainly of older Americans, with a mean age of 65 years and a median age of 66 years (IQR=58-72 years).

Table1: MANNA Referral Form: Age and Monthly Income

	Total (N)	Miss-ing	Mean	St. Dev.	Percentile				
					5%	25%	50%	75%	95%
Age (years)	103	0	65.0	11.1	47.2	58.0	66.0	72.0	85.0
Monthly Income ($/month)	102	1	962	653	0	598	961	1300	2000

Table 2 shows that this sample of MANNA clients was approximately two-thirds female (62.4%) and one-third male (37.4%).Most clients (96.1%) spoke English and a few clients were Spanish-speakers. Clients' marital status were evenly distributed between single (21%), married (26%) and widowed (22%), and the remainder were divorced and separated. About half of the clients (47.1%) lived alone and the other half (52.9%) had other household members. Household size for those who didn't live alone ranged from two (72.9%) to three (25%) people. Only 12% of the sample were veterans. Almost all had a permanent living situation and a full functioning kitchen, both of which were required to receive meal delivery from MANNA.

Table 2: MANNA Referral Form: Demographics

	Total (N)	Miss-ing	Category Number (Percent)				
Ethnic Group	103	0	Af. Amer. 60 (59.2%)	Caucasian 38 (36.9%)	Latino 4 (3.9%)	Other 0 (0%)	
Gender	101	2	Male 38 (37.6%)	Female 63 (62.4%)	Trans 0 (0%)		
Language	77	26	English 74 (96.1%)	Spanish 3 (3.9%)	Other 0 (0%)		
Marital Status	100	3	Married 26 (26.0%)	Single 31 (31.0%)	Divorced 14 (14.0%)	Separated 7 (7.0%)	Widow(er) 22 (22.0%)
Veteran	100	3	Yes 12 (12%)	No 88 (88%)			
Lives Alone	102	1	Yes 48 (47.1%)	No 54 (52.9%)			
# People in House	32	71	One 0 (0%)	Two 23 (71.9%)	Three 8 (25.0%)	Four 1 (3.1%)	Five + 0 (0%)
Income Source	99	4	SSI 77 (77.8%)	TANF 0 (0%)	Food Stp 3 (3.0%)	None 11 (11.1%)	Other 8 (8.1%)
Living Arrange-ments	102	1	Permanent 100 (98.0%)	Non-Perm 2 (2.0%)	Other 0 (0%)		
Full Funct.Kitchen	102	1	Yes 102 (100%)	No 0 (0%)			

Medical information obtained from initial referral forms (Table 3) showed that the primary diagnosis of over half of the client sample was cancer (53%). Renal disease (15.7%), diabetes (7.8%), HIV/AIDS (3.9%), and heart disease (3.9%) were also common diagnoses. One-sixth (16.7%) of the sample's primary diagnoses designated as "other". The most prevalent coexisting conditions were hypertension (58.2%), diabetes

(31.6%), hyperlipidemia (23.5%), heart disease (22.4%), and COPD (13.3%). Other co-existing conditions (<10% of client sample) included depression, renal disease, cancer, wounds/ulcers, and hepatitis. Over 80% of clients also had other wide-ranging co-existing conditions ranging from common conditions such as gastro esophageal reflux disease (GERD) and osteoarthritis to potentially serious conditions such as pulmonary embolism and polycystic liver disease. Overall, most of the client sample had multiple morbidities.

Since cancer was the primary diagnosis of clients, common primary treatments (Table 3) were chemotherapy (40%) and radiation (11.6%). Dialysis was also a primary treatment in 17.9% of clients, as was medication in 32.2% of clients. Prior to beginning MANNA services, 78.2% of clients had a recent hospital stay or ER visit. Common reasons for hospitalization were cancer-related surgery, pneumonia, or exacerbation of a chronic condition such as heart failure, COPD, and diabetes. MANNA's Referral Form has a section for laboratory values and most clients (87.9%) had one or more laboratory values recorded (Table 3) however many specific laboratory values were missing (an overview of laboratory values is shown in Table 4). Notable in Table 3 was that only 4.9% of this client sample was HIV positive given MANNA's history of serving clients with AIDS

One hundred percent of the client sample received medication. Polypharmacy was also common: 20.4% of the client sample received 1-4 medications, 45.2% received 5-9 medications and 34.4% of the population received 10 or more medications. A small number of clients (7.7%, data not shown) were also receiving meal supplements

including protein-calorie supplements (Ensure or Boost) or disease-specific supplements (Glucerna or Novasource). Many clients (70.8%, data not shown) in this sample also had ambulation and/or living environment concerns. Answers varied although commonalities included steps that were difficult to navigate and the need for walker or wheelchair. Extreme fatigue and weakness of clients was also noted.

Regarding health insurance, Table 3 shows that approximately two-thirds (69.4%) of clients were Medicare participants (69.4%), whereas 22.4% were part of the Medicaid program. A small amount (7.1%) had private insurance. Most clients had a physician (91.8%) and about half had seen a dietitian (48%) and/or social worker (54.1%). The largest number of initial referrals came from social workers (43%) and dietitians (32%). Physicians were a relatively small source (11%) of initial referrals. Referral organizations (data not shown) were wide-ranging and mostly included Philadelphia hospitals, cancer centers, dialysis centers, and home health agencies.

Table 3: MANNA Referral Form: Medical Information

	Total (N)	**Miss -ing**	**Category Number (Percent)**				
Primary Diagnosis	102	1	Cancer 53 (52.0%)	Renal 16 (15.7%)	HIV / AIDS 4 (3.9%)	Diabetes 8 (7.8%)	Heart Dis. 4 (3.9%)
							Other 17 (16.7%)
Coexisting Conditions	98	5	Cancer 6 (6.1%)	Renal 7 (7.1%)	HIV / AIDS 0 (0%)	Diabetes 31 (31.6%)	Heart Dis. 22 (22.4%)

			Hyper-lipid. 23 (23.5%)	Neuro-path. 6 (6.1%)	Wound / Ulcer 4 (4.1%)	HTN 57 (58.2%)	COPD 13 (13.3%)
			Depress-ion 7 (7.1%)	Hepatitis 2 (2%)			Other 80 (81.6%)
Primary Treatment	95	8	Chemo 38 (40%)	Radiation 11 (11.6%)	Surgery 17 (17.9%)	Dialysis 17 (17.9%)	Med.s 22 (32.2)
							Other 21 (22.1%)
Recent Hosp/ER Visit	87	16	Yes 68 (78.2%)	No 19 (21.8%)			
Initial Lab Val.s	91	12	Yes 80 (87.9%)	No 11 (12.1%)			
HIV Status	102	1	Positive 5 (4.9%)	Negative 97 (95.1%)			
Med.s / Supp.s	93	10	Yes 93 (100%)	No 0 (0%)			
# of Med.s	93	10	1 – 4 19 (20.4%)	5 – 9 42 (45.2%)	10 + 32 (34.4%)		
Primr'y Med Insurance	98	5	Private 7 (7.1%)	Medicare 68 (69.4%)	Medicaid 22 (22.4%)	Other 0 (0%)	No Ins. 1 (1.0%)
Healthcare Providers	98	5	Physician 90 (91.8%)	Dietician 47 (48.0%)	SW/CM 53 (54.1)%	Other 3 (3.1%)	
Referral Source	100	3	Case Mgr 4 (4.0%)	Soc. Wrkr 43 (43.0%)	Dietician 32 (32.0%)	Physician 11 (11.0%)	Nurse 8 (8.0%)
							Other 2 (2.0%)

Table 4 below provides an overview of laboratory values from the MANNA Referral Forms in the sample charts. Laboratory values were often missing, ranging from 47 % of charts for albumin and glucose to 83% of charts for blood lipid levels such as cholesterol. This may reflect varying diagnoses of clients or illustrate the difficulty of collecting laboratory values as a community-based organization. A thorough discussion of laboratory values and their meaning is presented in Chapter 6.

Table 4:MANNA Referral Form: Laboratory Values

	Total (N)	Miss -ing	Mean	St. Dev.	Percentile				
					5%	25%	50%	75%	95%
Initial Lab Values									
Albumin (g/dl)	58	45	3.6	0.6	2.6	3.1	3.8	4.0	4.5
Glucose (mg/dl)	58	45	140.5	73.1	83.0	96.8	112.0	164.0	285.1
HbA1c (%)	23	80	7.4	2.2	5.0	5.7	6.7	9.2	13.4
Hgb (g/dl)	62	41	11.1	1.7	8.4	9.9	11.1	12.2	13.9
Chol (mg/dl)	18	85	139.0	44.8		104.0	132.5	167.8	
TG (mg/dl)	14	89	138.4	134.7		72.3	96.0	168.5	
HIV* (copies/ml)	3	100	(0<20)						
CD4 (cells/mm^3)	4	99	487.8	161.6		354.8	451.5	657.0	
Kidney Function									
BUN (mg/dl)	12	91	27.4	16.4		12.8	26.5	41.5	
Creatinine (mg/dl)	11	92	5.4	6.4		0.9	1.1	7.5	
Liver Values									
ALT (units/L)	6	97	19.2	7.7		12.0	19.0	26.3	
AST (units/L)	6	97	19.5	8.3		12.5	18.0	25.8	

*HIV viral load was between 0 and <20 copies/ml in 3 client charts

Table 5 shows the anthropometric data (weight, height, BMI, and usual weight) obtained from a combination of the MANNA Referral Form and the MANNA Nutrition Telephone Assessment. Current weight and height were the most complete data available in the client charts. The weight data also confirmed the initial reason for referral: on average, clients' current weight was less than their usual weight by approximately 10 pounds. Average BMI was not a data point on the MANNA Referral Form but was calculated by this researcher. Both the mean BMI (27.1) and the median BMI (25.6) were in the overweight category (25-29.9).

Table 5: MANNA Referral Form: Anthropometric Measurements

	Total (N)	Miss-ing	Mean	St. Dev.	Percentile				
					5%	25%	50%	75%	95%
Height	103	0	65.8	4.4	59.0	63.0	66.0	69.0	73.0
Current Weight (lbs)	102	1	166.4	48.5	97.2	128.5	161.5	195.5	262.9
BMI (kg/m^2)	102	1	27.1	8.1	16.3	20.8	25.6	32.6	43.0
Usual Weight (lbs)	90	13	175.6	46.3	104.6	139.8	175.0	203.3	269.5

The MANNA Nutrition Telephone Assessment conducted by dietitians is summarized in Table 6 below. In this client sample, two-thirds (62.8%) of clients were initially referred for meal delivery and the remainder (37.1%) were referred for both meal delivery and nutrition counseling. The primary nutrition diagnoses for referral (not mutually exclusive categories) were weight loss (43.5%), inadequate intake (40.6%), difficulty with meal preparation (27.5%), and fatigue/weakness (26.1%). Twenty-nine percent of clients were referred for other reasons including the need for a special diet

(diabetic or renal) or physiologic states such as hypoalbuminemia or cachexia. Consistent with weight loss/inadequate intake as a primary reason for referral, 63.3% of the client sample had decreasing weight history, 28.9% had stable weight, and only 7.8% had an increasing weight history. A small number of clients (4.2%) had chewing or swallowing problems and 18.8% had diet restrictions or food allergies. Diet restrictions noted were consistent with the type of meal clients were receiving from MANNA such as "no pork", puree, or low sodium. Others noted foods such as shellfish, eggs, milk, hazel nuts and strawberries.

Table 6: MANNA Nutrition Telephone Assessment: Nutrition Information

	Total (N)	**Miss -ing**	**Category Number (Percent)**				
Reason for Referral	89	14	Nutr Couns 0 (0%)	Meal Deliv 56 (62.9%)	Both 33 (37.1%)		
Primary Nutrition Diagnosis	69	34	Inadequat e Intake 28 (40.6%)	Meal Prep Difficulty 19 (27.5%)	Fatigue / Weakness 18 (26.1%)	Weight Loss 30 (43.5%)	Other 20 (29.0%)
Weight Hist /Status	90	13	Increas'g 7 (7.8%)	Decreas'g 57 (63.3%)	Stable 26 (28.9%)		
Chew/Swall Problems	95	8	Yes 4 (4.2%)	No 91 (95.8%)			
Diet Restr/ Food Allergies	96	7	Yes 18 (18.8%)	No 78 (81.3%)			
Access to Food Prep	55	48	Self 13 (23.6%)	Has Help 26 (47.3%)	Needs Help 5 (9.1%)	No help Avail 2 (3.6%)	Other 9 (16.4%)
Who	22	81	Family	Friend	Neighbor	Org	

HelpsFood Prep?			17 (77.3%)	3 (13.6%)	1 (4.5%)	1 (4.5%)	
How Many Meals/Day	89	14	1 6 (6.7%)	1 – 2 7 (7.9%)	2 16 (18.0%)	2 – 3 9 (10.1%)	3 36 (40.4%)
			3 – 4 7 (7.9%)	4 4 (4.5%)	Varies 4 (4.5%)		
Nutritional Risk Factors	93	10	Good App 37 (39.8%)	Fair App 23 (24.7%)	Poor App 6 (6.5%)	Impr App 3 (3.2%)	Vari App 3 (3.2%)
							Other 21 (22.6%)

The next set of questions were related to the ability to prepare food and number of meals per day. Questions on the initial nutrition intake form were answered in variable ways depending on which dietitian conducted the intake and there were many missing answers. The overall trend was that MANNA clients needed help for meal preparation: 47.3% had help and 23.6% prepared food themselves. Family members provided the most help and a small number of clients received help from friends. The most prevalent categories for number of meals per day were three (40.4%) or two (18%). The most common answer noted to nutritional risk factors was “appetite” and the majority of clients had a good (39.8%) or fair (24.7%) appetite while only a small number (6.5%) had a poor appetite.

Table 7 below describes data that were obtained from the MANNA Meal Service Program, a database that helped MANNA track client services. Most clients (97.0%) in the sample received complete meal service, meaning three meals/day for seven days/week and the remaining (3%) received supplemental meals (dinner only). Tables 7

and 8 show that one-third of the client sample (33%) received the standards diet modification, which is "heart healthy" (high in protein and moderate in carbohydrates and fat) according to American Heart Association Guidelines. Another third (33%) received a diabetic ("Red") diet. Approximately one-fifth (19.4%) of clients in the sample received a renal ("Black") diet. Clients could have up to three modifications. Options included: no pork (15.5%), no beef (8.7%), no seafood (2.9%) and low fiber/low residue/mild spice (2.9%). Some clients (5.8%) also received a high calorie/high protein snack. A small number of clients received low lactose (1.9%), mechanical soft (1%), puree (1%) and a child diet(1%). Specific definitions of the color-coded diets are shown in Table 8 below.

Table 7: Meal Service Information

	Total (N)	**Miss -ing**	**Category Number (Percent)**				
Nutrition Compl/Supp l	100	3	Complete 97 (97.0%)	Supplem'l 3 (3.0%)			
Diet Mod-ification	103	0	Standard 34 (33.0%)	Black 20 (19.4%)	Red 34 (33.0%)	Orange 16 (15.5%)	Brown 8 (7.8%)
			Pink 4 (3.9%)	Neon 5.8%)	Purple 3 (2.9%)	Green 2 (1.9%)	Yellow 1 (1.0%)
			Yell-Yell 1 (1.0%)	Blue 1 (1.0%)			
Counselling – Initial	101	2	Client Intake 64 (63.4%)	Life Span Counsel'g 37 (36.6%)			
Counselling – Recert.	102	1	1 45 (44.1%)	2 32 (31.4%)	3 + 25 (24.5%)		

Meal Status	102	1	Current 21 (20.6%)	Stopped 81 (79.4%)			
Reason for Stopping Meals	81	22	Nutritional Sound 55 (67.9%)	Client Request 8 (9.9%)	Lost Contact 1 (1.2%)	Pending Health Update 4 (4.9%)	Client said nutr stable 2 (2.5%)
			Death 5 (6.2%)	Moved 2 (2.5%)	Moved to LTC Fac'ty 2 (2.5%)	Non-Compl 2 (2.5%)	Death 5 (6.2%)

Table 8: MANNA Diet Definitions

Color	Type
None – 34 (33%)	Standard Heart Healthy
Black – 20 (19.4%)	2 g Na, 2 g K+, Dairy Free
Red – 34 (33%)	Diabetic/Low Fat/Heart Healthy
HPP label	Health Partner Meals
Orange – 16 (15.5%)	No Pork
Brown – 8 (7.8%)	No Beef
Pink – 3 (2.9%)	No Seafood
Neon – 6 (5.8%)	High Kcal and Pro Snack
Purple – 3 (2.9%)	Low Fiber/Low Residue/Mild Spice
Green – 2 (1.9%)	Low Lactose
Yellow – 1 (1%)	Easy to Swallow Mechanical Soft
Yellow Yellow - 1 (1%)	Puree
Blue - 1 (1%)	Child

Clients who received nutrition counseling at the start of services or at recertification are also shown in Table 7. The category "client intake" refers to those who did not receive nutrition counseling (63.4%) upon initial intake. "Life span counseling" indicates those who received nutrition counseling upon intake (36.6%). The category "Counseling-recertification" referred to the total number of re-certifications of the

sample. The minimum criteria for inclusion in this client sample was one recertification, which 44.1% of clients received. However, 31.4% received two recertifications and 24.5% received three or more. Two-thirds of those who stopped receiving meals were designated as nutritionally sound (67.9%) by the dietitians or the client's healthcare provider. Other reasons for stopping meals included: client request (9.9%), death (6.2%), lack of a medical health update (4.9%), nutritionally stable per client report (2.5%), moved to long-term care facility (2.5%), non-compliance (2.5%, missed deliveries).

Data obtained in the Health Update Form for Recertification is shown in Table 9 below. Current diagnoses of recertified clients in this sample were cancer (46.1%), renal disease (14.4%), diabetes (6.2%), HIV/AIDS (4.1%), and heart disease (3.1%). Other diagnoses varied and included Parkinson's disease, COPD, lupus, hepatitis C, anemia, as well as the client having a wound or being post-surgery. The most common treatment plan update was medication (33.0%), followed by chemotherapy (28.4%), dialysis (18.2%), radiation (8.0%), and surgery (3.4%). Other treatment updates (20.5%) included having just finished chemotherapy or radiation, pain management, wound care, need for frequent monitoring, and need for a puree diet and feeding tube. Most of the clients continued to receive medications (98.8%) and polypharmacy continued to be present: 32.5% received 1-4, 43.8% received 5-9, and 23.8% receiving more than 10 medications. Meal supplements (data not shown) continued for a small number of clients, remaining as either a calorie/protein or disease-specific supplement.

About half of the sample (53.3%) had recent hospitalizations (Table 9) for varied reasons including various surgeries (unspecified, toe amputation, removal of infected

pacemaker, Achilles tendon transfer, leg surgery), possible heart attack, pneumonia, flu, COPD flare-up, fever, blood transfusion, dehydration, cellulitis, collapse, radiation treatment, chest pain, wound debridement, high or low blood pressure, neutropenia, abdominal pain, elevated INR, lung infection, lung biopsy, breathing problems, GI bleed, a fall, atrial fibrillation, anemia, iron infusion, alcoholic gastritis, TIA and seizure, post-surgical pain, and nausea. The MANNA Health Update Form for Recertification also had a section for lab values and most clients (88.5%) had one or more laboratory values (an overview of laboratory values is shown in Table 11).

The largest number of provider recertifications were performed by physicians (49.5%) followed by dietitians (25.7%), social workers (11.9%) and nurses (10.9%). Physicians were a relatively small source (11%) of initial referrals. Provider agencies (data not shown) were wide-ranging and similar to those at initial referral including Philadelphia hospitals, cancer centers, dialysis centers, and home health agencies.

Table 9: Recertification Information

	Total (N)	**Miss -ing**	**Category Number (Percent)**				
Current Diagnosis (Recert)	97	6	Cancer 45 (46.1%)	Renal 14 (14.4%)	HIV/AIDS 4 (4.1%)	Diabetes 6 (6.2%)	Heart Dis. 3 (3.1%)
							Other 25 (25.8%)
Treatment Plan Updt	88	15	Chemo 25 (28.4%)	Radiation 7 (8.0%)	Surgery 3 (3.4%)	Dialysis 16 (18.2%)	Med.s 29 (33.0%)
							Other 18 (20.5%)

Med.s / Supp.s	83	20	Yes 82 (98.8%)	No 1 (1.2%)			
# of Med.s	80	23	1 – 4 26 (32.5%)	5 – 9 35 (43.8%)	10 + 19 (23.8%)		
Recent Hosp	92	11	Yes 49 (53.3%)	No 43 (46.7%)			
FU Lab Values	96	7	Yes 85 (88.5%)	No 11 (11.5%)			
Provider Recert	101	2	Case Manager 1 (1.0%)	Social Worker 12 (11.9%)	Diet-ician 26 (25.7%)	Home Hlth Wkr 1 (1.0%)	Phy-sician 50 (49.5%)
			Nurse 11 (10.9%)				Other 0 (0.0%)

The MANNA Health Update Form for Recertification had a "most recent weight" line that was noted as "Very Important – Must Provide!". Client weights, calculated BMI, and change in BMI from the start of services are reported in Table 10 below together with initial weight and BMI. The mean weight of the client sample is the same at intake and re-certification (166.4 pounds).Similarly, the median(161.5 and 162.5, respectively) and IQR weight at intake and recertification were also very close, same as mean, median and IQR for BMI, as confirmed by a lack of change in BMI (median = 0.04).This may indicate that MANNA meals helped clients stabilize their weight.

Table 10: Anthropometric Measurements: Initial vs. Recertification

	Total (N)	**Miss-ing**	**Mean**	**St. Dev.**	**Percentile**				
					5%	**25%**	**50%**	**75%**	**95%**
Weight Initial	102	1	166.4	48.5	97.2	128.5	161.5	195.5	262.9

(lbs)									
Weight Recert. (lbs)	102	1	166.4	48.8	94.3	131.3	162.5	192.0	267.9
BMI Initial (kg/m^2)	102	1	27.1	8.1	16.3	20.8	25.6	32.6	43.0
BMI Recert (kg/m^2)	102	1	27.0	7.8	16.2	20.8	25.4	32.3	41.4
Δ BMI from initial referral	100	2	0.11	2.23		-0.84	0.04	1.02	

Table 11 below provides an overview of laboratory values on the MANNA Health Update Form for Recertification. As with the MANNA Referral Form, many of the laboratory values were missing. The majority of repeated measures were albumin (n=71) and hemoglobin (n=73) followed by cholesterol (n=37), hematocrit (n=34), HgA1c (n=29) and triglycerides (n=29). Of note, more laboratory values were reported on the Health Update form than the Referral Form, perhaps reflecting the requirement for a medical visit for recertification. Changes in laboratory values were difficult to analyze because the Referral Form and Health Update Form often did not contain both values on the same client. Laboratory values would also need to be analyzed with consideration of medical diagnoses and treatment as discussed in Chapter 6.

Table 11: MANNA Health Update Form: Laboratory Values

	Total (N)	**Miss-ing**	**Mean**	**St. Dev.**	**Percentile**				
					5%	**25%**	**50%**	**25%**	**95%**
Recent Hospitalization									
# Days In Hospital	35	68	5.3	6.2	1.0	2.0	3.0	7.0	24.6

Lab Values Re-cert									
Albumin (g/dl)	71	32	3.8	0.5	3.0	3.5	3.8	4.2	4.6
Prealbumin (mg/dl)	4	99	16.8	9.4		6.9	19.0	24.5	
HbA1c (%)	29	74	6.5	1.2	5.0	5.8	6.1	7.1	9.3
Hemoglobin (g/dl)	73	30	11.7	2.9	8.3	10.4	11.6	12.9	14.8
Hematocrit (%)	34	69	33.7	6.8	19.5	30.4	36.0	32.2	43.7
Cholesterol (mg/dl)	37	66	171.2	37.2	115.9	135.0	173.0	197.0	239.4
Triglycerides (mg/dl)	29	74	140.0	85.8	45.5	82.0	120.0	172.0	361.0
HIV* (copies/ml)	3	100	(0-67)						
CD4 (cells/mm^3)	3	100	554.3	255.3		264.0	655.0	744.0	
Kidney Function Re-cert									
BUN (mg/dl)	6	97	25.8	14.9		13.5	22.5	37.0	
Creatinine (mg/dl)	8	95	2.8	3.9		0.7	1.0	4.8	
Liver Values									
ALT (units/L)	3	100	16.7	6.1		10.0	18.0	22.0	
AST (units/L)	3	100	19.7	4.0		16.0	19.0	24.0	

*HIV viral load ranged from0 to 67 copies/ml in 3 client charts

Information from the Health Update Form for Recertification and Recertification Information from MANNA dietitians is shown in Table 12 below. The top nutrition concerns from the Health Update Form were inadequate intake (31.9%) and weight loss (23.2%) followed by difficulty with meal preparation (15. %) fatigue/weakness (14.9%). "Other" nutrition concerns included the need for a therapeutic diet (diabetic, renal, low sodium, etc.), food insecurity, frailty, anorexia/poor appetite, need for blood glucose

control, obesity, mental status changes, dysphagia, no teeth, hypoalbuminemia, iron-deficiency anemia, would healing, tube feeding, and being at risk for malnutrition. On the dietitian's Recertification Form, forty percent of the sample reported changes in health or treatment. Comments ranged from changes in treatment (i.e. chemotherapy schedule, medications) to changes in disease state (lupus worse, cancer spread, health worsened, developed COPD, etc.).

"Current nutrition concerns" on the dietitian's Recertification Form were recorded as appetite in 40/93 charts. Answers were good (17.2%), fair (10.8%), poor (3.2%), improving (8.6%), and variable (3.2%). Other answers were also recorded in 53/93 charts which mostly centered on dietary needs (diabetic diet, renal diet etc.) or the need to gain or maintain weight. This shows how open-ended questions may "drift" over time with various staff interpreting the question differently. A total of 83% of clients received between two and three meals per day and three-quarters (75.3%) of clients received all their meals from MANNA. Twenty percent of clients reported that most of their meals were MANNA meals and 4.5% reported only some of their meals were MANNA meals. Seventy-five percent (75.5%) of this client sample reported that they were not able to maintain their health without MANNA meals. Almost 14% of clients reported that they would be able to maintain their health without MANNA meals and 10.6% reported "maybe". In the comment area, some reported that they could try to maintain their health without MANNA meals but that it would be hard or that they would not eat as much.

Table 12: Recertification Information Form

	Total (N)	Miss-ing	Category Number (Percent)				
Current Nutr Concerns	69	34	Inadequate Intake 22 (31.9%)	Meal Prep Difficulty 11 (15.9%)	Fatigue / Weakness 10 (14.9%)	Weight Loss 16 (23.2%)	Other 38 (55.1%)
Change in H'lth or Treat	94	9	Yes 38 (40.4%)	No 56 (59.6%)			
Curr Nutr Concerns	93	10	Good App 16 (17.2%)	Fair App 10 (10.8%)	Poor App 3 (3.2%)	Impr App 8 (8.6%)	Vari App 3 (3.2%)
							Other 53 (57.0%)
How Many Meals/Day	89	14	1 4.8%)	1 – 2 12 (14.3%)	2 22 (26.2%)	2 – 3 16 (19.0%)	25 36 (29.8%)
			3 + 5 (6.0%)				
How Many MANNA	89	14	All MANNA 67 (75.3%)	Mostly 18 (20.2%)	Some 4 (4.5%)		
Able to Maintain Nutr Health w/o MANNA Meal	94	9	Yes 13 (13.8%)	Maybe 10 (10.6%)	No 71 (75.5%)		
Improved O'all Health	101	2	Yes 97 (96.0%)	No 4 (4.0%)			
Incr # Meals Eaten/Day	102	1	Yes 95 (93.1%)	No 7 (6.9%)			

Impr Energy / Fatigue Level	101	2	Yes 99 (98.0%)	No 2 (2.0%)			
Impr Emotion Hlth / Coping	101	2	Yes 97 (96.0%)	No 4 (4.0%)			
Impr Know'ge Hlthy Food	101	2	Yes 99 (98.0%)	No 2 (2.0%)			
Decr Stress in'Food Prep	100	3	Yes 99 (99.0%)	No 1 (1.0%)			
Partic in Media Oppor	57	46	Yes 28 (49.1%)	No 29 (50.9%)			

Also shown in Table 12 most of the client sample (N=100-102/103) answered specific questions regarding how MANNA helped them. Clients overwhelmingly answered "yes" to whether MANNA improved overall health (96%), increased number of meals eaten per day (93.1%), improved energy/fatigue level (98%), improved emotional health/coping skills (96%), improved understanding of healthy food (98%), decreased stress of preparing healthy food independently (99%).

The quantitative data from the MANNA Annual 2016 Client Satisfaction Survey (Appendix B) is shown in Table 13 below. The researcher chose questions to include in the REDCap database that were based on their relationship to MANNA outcomes. Therefore, specific questions about the quality of food in MANNA meals were not analyzed. An overall view of the quality of MANNA meals was obtained from the question: "How would you rate the quality of MANNA meals overall?" Eighty-three percent of MANNA clients rated meals as excellent (40%) or very good (43%). A small

number of clients rated MANNA meals as good (15%) or fair (2%) and there were no ratings of "poor" in this sample.

Most clients (N=98-103) had answered questions regarding how the MANNA meals program helped them. Clients overwhelmingly answered "yes" to MANNA meals having helped them eat healthier (97.1%), achieve or maintain a healthy weight (93%), feel better (98%), continue to live at home (95%). A lower number of clients answered "yes" to whether MANNA meals helped decrease number of hospitalizations (83.3%), which is consistent with variable reasons for hospitalization obtained in the re-certification data. The next series of questions that asked about food insecurity was also answered by most clients. About half of this sample of MANNA clients (52.0%) did not always have enough money or food assistance to buy the food they needed whereas 48% of clients did. Approximately one-third (29.4%) of clients in the sample had to choose between buying food and medication within the last month, one-quarter (25.5%) had to choose between buying food and paying rent or utility bills within the last month, and one-fifth (19.2%) had to skip meals on one or more days during the last month because they had no money or food assistance to buy food.

Table 13: MANNA Annual 2016 Client Satisfaction Survey

	Total (N)	**Miss -ing**	**Category Number (Percent)**				
MANNA Prog Satisfaction	11	2	Very Satisfied 88 (87.1%)	Somewhat Satisfied 12 (11.9%)	Somewhat Dis-satisfied 1 (1.0%)	Very Dis-satisfied 0 (0.0%)	

Qual of MANNA Meal	100	3	Excellent 40 (40.0%	Very Good 43 (43.0%)	Good 15 (15.0%)	Fair 2 (2.0%)	Poor 0 (0.0%)
Help to Eat Healthier	103	0	Yes 100 (97.1%)	No 3 (2.9%)			
Help Achieve Hlty Weight	100	3	Yes 93 (93.0%)	No 7 (7.0%)			
Help Impr Health	101	2	Yes 98 (97.0%)	No 3 (3.0%)			
Help Feel Better	98	5	Yes 96 (98.0%)	No 2 (2.0%)			
Help Remain @ Home	101	2	Yes 96 (95.0%)	No 5 (5.0%)			
Help Decr # of Hospit'zation	96	7	Yes 80 (83.3%)	No 16 (16.7%)			
Have Enough $ to Buy Food	100	3	Yes 48 (48.0%)	No 52 (52.0%)			
Have to Choose B/t Food & Meds	102	1	Yes 25 (24.5%0	No 77 (75.5%)			
Have to Choose B/t Food & Rent/utilities	102	1	Yes 25 (24.5%)	No 77 (75.5%)			
Had to skip Meals	99	4	Yes 19 (19.2%)	No 80 (80.8%)			
Internet Access	101	2	Yes 59 (58.4%)	No 42 (41.6%)			

Internet Access Type	58	45	Home Computer 18 (31.0%)	Public Computer 7 (12.1%)	Smart Phone 24 (41.4%)	Laptop or Tablet 9 (15.5%)	
Interest in Online Tips & Surveys	99	4	Yes 33 (33.3%)	No 66 (66.7%)			
Aware of Free Nutr Council @ MANNA	103	0	Yes 74 (71.8%)	No 29 (28.2%)			
Had Appt with MANNA Dietician	103	0	Yes 10 (9.7%)	No 93 (90.3%)			

When clients were asked whether they had access to the internet, 58.4% did and 41.6% did not. Of those who had access, having a smart phone was the most common way (41.4%) to access the internet, followed by home computer (31%), laptop/tablet (15.5%), and public computer (12.1%). Although almost two-thirds of clients had access to the internet, only one-third (33.3%) of clients wanted to receive nutrition tips or survey questions on-line. Over two-thirds (71.8%) of clients knew that they could speak to a nutritionist for free at MANNA but only a small number (9.7%) reported that they had an appointment with a dietitian on staff at MANNA.

MANNA Food and Nutrition Service Outcomes

After a thorough review of this sample of client chart data, the researcher considered whether any variables could be analyzed to show meaningful effects of MANNA food and nutrition services as per Research Question # 2 for this study:

How does the current MANNA client assessment and experienced-based data describe its medically-tailored food and nutrition service outcomes? The variables identified as potential outcomes for the intervention under investigation are:

- Number of medications (1-4, 5-9, 10 or more)
- Recent hospitalization (Yes, No)
- Change in BMI

and the following sub-questions were investigated:

1. Is there evidence for a change in proportion of clients who take 1-4 medications, 5-9 medications, and 10 or more medications before and after MANNA intervention?
2. Is there evidence for a change in proportion of clients with recent hospitalizations before and after MANNA intervention?
3. What are mean, median, and distribution of change in BMI for the client sample? Is there evidence for a change in BMI?
4. Is there evidence for a difference in change in BMI based on
    a. primary diagnosis?
    b. referral source (case manager, dietitian, doctor, nurse, social worker, or other)?
    c. medical vs. social referral source
    d. clients who received nutrition counseling and those who did
    e. number of recertifications (1, 2 or 3 or more)?
    f. number of meals eaten per day?

g. whether client ate all MANNA meals, mostly MANNA meals, or some MANNA meals?

h. clients who have enough money for food and those who don't?

5. Can change in BMI be predicted by initial referral source, initial primary diagnosis, clients who received nutrition counseling, number of recertifications, number of meals eaten per day, amount of MANNA meals eaten, and/or clients who have enough money to buy food using a multiple linear regression model?

Number of Medications

The proportions of patients in the three categories for number of medications (1-4, 5-9, 10 or more) at initial intake and at recertification are presented in Table 14. A higher percentage of clients seem to take a lower number of medication at recertification compared to initial intake.

Table 14: Proportion of clients in medication categories 1-4, 5-9, and 10 or more at initial intake and recertification

	Total (N)	Missing	Category Number (Percent)		
Initial # of Meds	93	10	1 – 4 19 (20.4%)	5 – 9 42 (45.2%)	10 + 32 (34.4%)
Recertification # of Meds	80	23	1 – 4 26 (32.5%)	5 – 9 35 (43.8%)	10 + 19 (23.8%)

A significant change in the proportion of clients in the three categories for number of medications from initial intake to recertification was then tested using Bowker's Test of Symmetry(63). Only data from the 76 clients who had answered the question relative

to number of medications at both initial and re-certification time points were included in this matched pair analysis. However, the data did not provide significant evidence of a change in proportion of patients who were in each category for number of medications at initial intake and at recertification (p=0.2398) as shown in Figure 1. Therefore, there is no evidence in the data that the food and nutrition services provided by MANNA significantly affects the number of medications needed by clients.

Table 15: Test of Symmetry comparing number of medications before and after food and nutrition services by MANNA.

Number of medications intake		Number of medications recertification			
		1 to 4	5 to 9	10 or more	Total
	1 to 4	9 11.84%	4 5.26%	2 2.63%	15 19.74%
	5 to 9	9 11.84%	21 27.63%	6 7.89%	36 47.37%
	10 or more	6 7.89%	8 10.53%	11 14.47%	25 32.89%
	Total	24 31.58%	33 43.42%	19 25.00%	76 100.00%
Frequency Missing = 27					

Test of Symmetry	
Statistic (S)	4.2088
DF	3
p-value	0.2398

Hospitalizations

The proportions of clients who had recent hospitalizations at intake and at recertification are presented in Table 15. A lower percentage of clients had a recent hospitalization after starting the MANNA program compared to before.

Table 16: Proportion of clients who had recent hospitalizations at initial intake and recertification

	Total (N)	Miss-ing	Category Number (Percent)	
Recent Hosp/ER Visit Initial Intake	87	16	Yes 68 (78.2%)	No 19 (21.8%)
Recent Hosp Recertification	92	11	Yes 49 (53.3%)	No 43 (46.7%)

A significant change in the proportion of clients who had recent hospitalizations was assessed using McNemar's Test(63). The test was performed using data from the 79 clients who had answered the question at both initial and re-certification time points. The data provide statistically significant evidence of a reduction in proportion of patients who had recent hospitalizations at recertification compared to initial intake (p=0.0077) as shown in Figure 2. Therefore, there is evidence that MANNA food and nutrition services had a significant effect on the proportion of clients who were hospitalized.

Table 17: McNemar's Test comparing proportion of hospitalizations before and after food and nutrition services by MANNA

		Recent hospitalizations at recertification		
Recent hospitalizations/ER visits at Baseline		Yes	No	Total
	Yes	34 43.04%	26 32.91%	60 75.95%
	No	10 12.66%	9 11.39%	19 24.05%
	Total	44 55.70%	35 44.30%	79 100.00%
Frequency Missing = 24				

McNemar's Test	
Statistic (S)	7.1111
DF	1
p-value	0.0077

Change in BMI

The researcher chose change in BMI as the best physiologic variable to define health outcomes within this sample of client chart data. Change in BMI for the overall sample between initial intake and recertification is as follows: mean= 0.11; median =0.04; interquartile range (-0.84 - 1.02). A histogram (Figure 1) of change in BMI for the sample shows that it follows roughly a normal distribution.

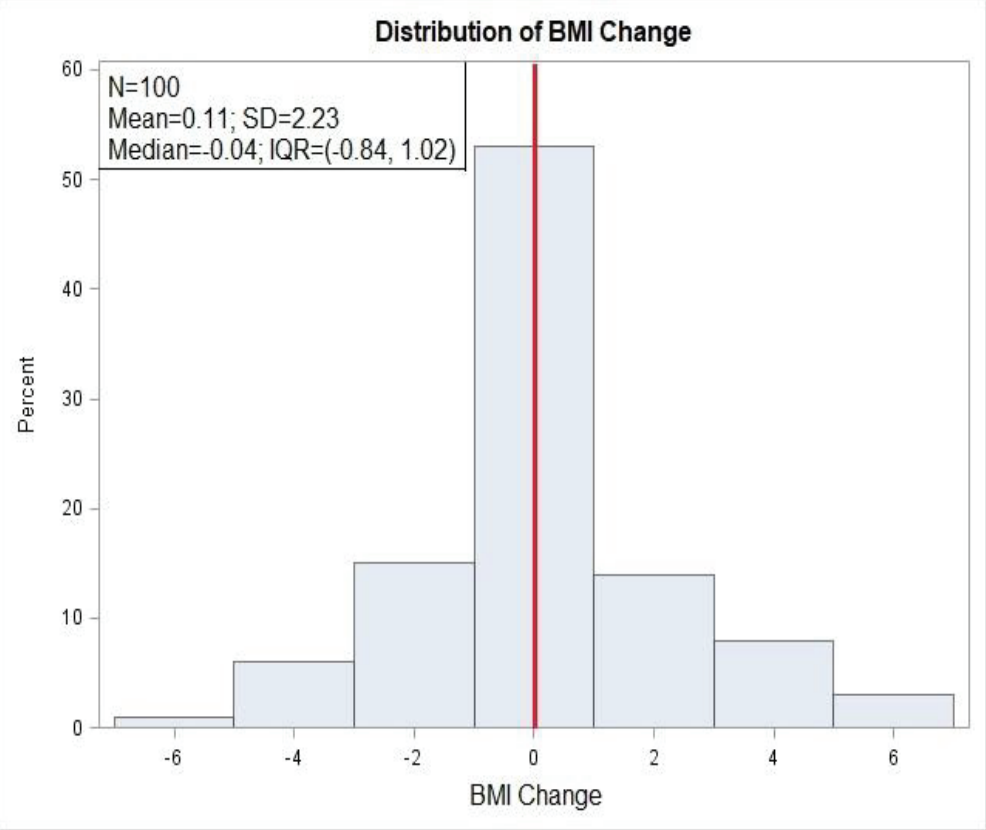

Figure 1:Histogram of Change in BMI

A scatterplot of BMI at baseline and BMI at recertification (Figure 2) shows, as expected, a high correlation of BMI at initial intake and recertification (after 6 months of MANNA services)(63). The scatterplot of BMI at intake vs BMI at recertification also identifies clients that fall into the 4 categories: underweight, normal, overweight, and obese (green lines). Although the change in BMI observed in the sample is small, clients with a low BMI tended to slightly increase their BMI (red line slightly above the 45-degree angle) and clients with high BMI tended to slightly decrease their BMI (red line slightly below the 45-degree line).

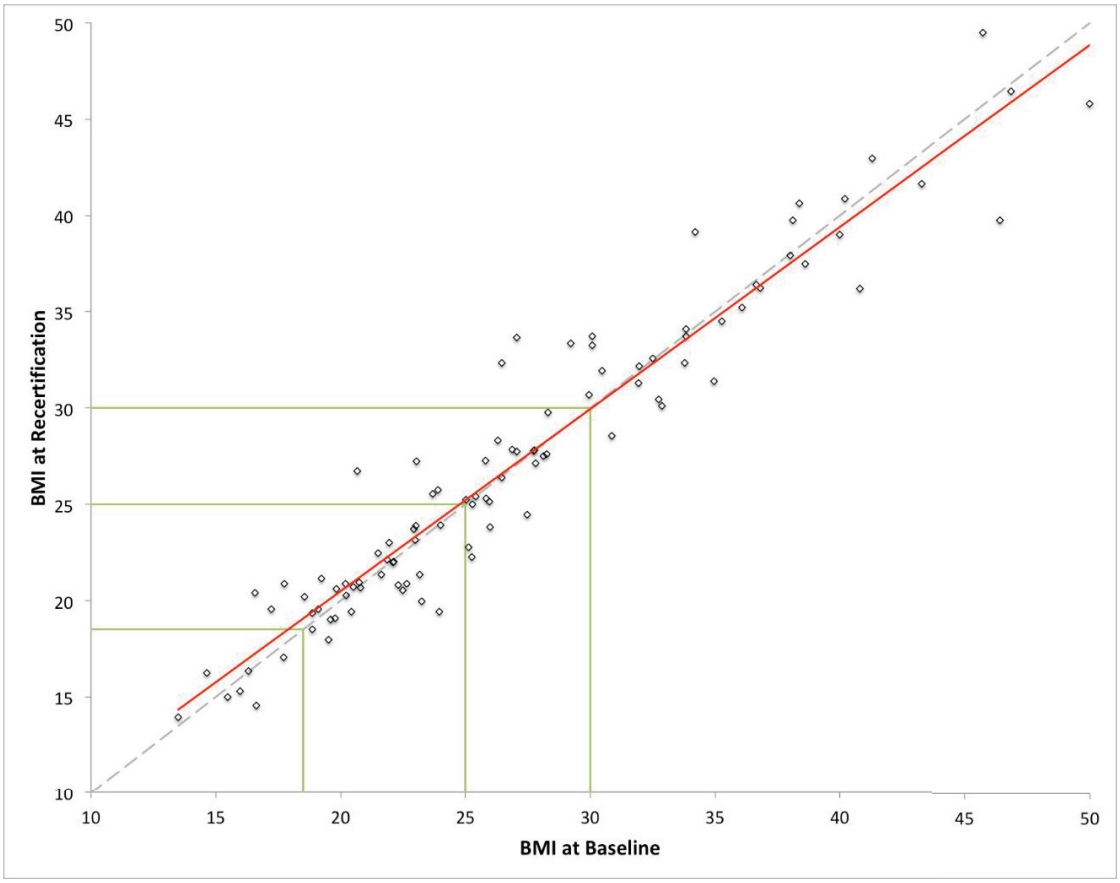

Figure 2: Scatterplot of BMI at recertification and BMI at intake (baseline)

Bivariate analysis with ANOVA showed that there was some evidence of differences in BMI change between at least two of the primary diagnoses (p=0.0391). Primary diagnoses include cancer, renal disease, diabetes, HIV/AIDS, heart disease, and "other". However, no significant difference was found by multiple comparisons with a Bonferroni adjustment. The same held true for BMI change with respect to MANNA meals consumption. There was also some evidence of difference in chance in BMI with respect to clients who consumed all, most, or some MANNA meals (p=0.0473).

However no significant difference was found by multiple comparisons with a Bonferroni adjustment(63).

Additional bivariate analysis with ANOVA found no evidence of any difference between patients with different initial referral sources including case manager, dietitian, doctor, nurse, social worker, or other referral source (p=0.3431). There was also no evidence of any difference in BMI change between patients with one, two, or three or more recertifications (p=0.5335) and no evidence of any difference in BMI chance between number of meals eaten per day (p=0.9564)(63).

Bivariate analysis with t-tests found no evidence of any difference in BMI change between clients who received nutrition counseling and those who did not (p=0.2427), no evidence of any difference in BMI change between different types of medical and social initial referral sources (p=0.5303), and no evidence of any difference between clients with enough money for food and clients without enough money for food (p=0.4277)(63).

In summary, there is no evidence for any difference in BMI between:

a. primary diagnosis (cancer, renal disease, diabetes, HIV/AIDS, heart disease, and "other").
b. referral source (case manager, dietitian, doctor, nurse, social worker, or "other") or referral source as categories medical or social
c. clients who received nutrition counseling and those who did not
d. clients with enough money to buy food and those who do not

Lastly, multivariate analysis was used to determine if change in BMI could be predicted by initial referral source, initial primary diagnosis, clients who received

nutrition counseling, number of recertifications, number of meals eaten per day, amount of MANNA meals eaten, and/or clients who have enough money to buy food. None of the predictors included in the multiple linear regression model significantly affected the outcome as confirmed by a stepwise selection algorithm that removed all of the predictors originally included in the model(63).

Chapter 5 Qualitative Data

Focus Groups

Focus groups were conducted with MANNA staff and Board of Directors to obtain information about what outcomes and impacts are important to MANNA stakeholders. Focus group data were obtained from seven Board Members and ten staff members in separate focus groups. A similar interview guide was used with Board members and MANNA staff (Appendix D). Focus group data was analyzed and summarized by the researcher to describe common and distinct themes among and between groups. Findings and their interpretations are described below.

Experience at MANNA

Staff members who chose to participate in the focus group worked at MANNA between one and 17 years. Most staff members were drawn to a non-profit organization whose mission was focused on helping people through food and nutrition. A few were specifically looking for an organization with a potential healthcare impact. Some staff members who had been with MANNA for many years were originally drawn to its earlier mission to feed people with HIV/AIDS and to provide care and comfort during dying.

Staff members noted several areas in which they felt MANNA had changed since its original mission with HIV/AIDS clients. They described expansion of meal services from a supplemental meal service to a full meal program of three meals/day, seven days/week. MANNA also expanded to other life-threatening diseases so that the program is now based on an evidence-based approach to food and nutrition (i.e. Medical Nutrition Therapy) that is focused on return to health rather than on comfort while dying. They also

noted that MANNA had developed new and innovative ways to help clients, had become a thought leader in "food is medicine", and was currently piloting a larger service area.

Board Members were associated with MANNA between 1 and 10 years and were similarly drawn to MANNA due to their interest and passion in its mission. Some had been with Manna since its original mission and continue to be drawn to its current focus on progressive, innovative service to medically-complicated clients. They feel that MANNA saves lives and helps people get better using food. Several newer Board members joined in the era of its current mission, which is to provide nutritious or medically-tailored meals to people suffering with an acute stage of a life-threatening illness, so were less aware if its history.

Board members also described more recent changes in MANNA that were more business focused including: financial stability, ease of volunteer recruitment, new facilities that allow for significant expansion in number of meals produced weekly, and geographic expansion. MANNA has also achieved contracts with Medicaid plans for insurance reimbursement of services for clients with diabetes. This has also allowed them to support more "Mission" clients, those who receive services at no charge.

MANNA Clients

Staff describes MANNA clients as medically complex, seriously ill and "super utilizers". They also describe clients as vulnerable, alone, lacking support systems, and low income: "a lot of them don't have great support system whether that be family or friends…" They felt that there is no "one type" of MANNA client and that they need help with various issues. Clients were described as feeling grateful and happy that MANNA is

in their lives: “I think the one thing across the board for the most part is they’re grateful.” Staff also felt that clients want to learn about how to manage disease and stay healthy.

The Board of Directors described MANNA clients as being very sick or having health issues of varying severity and are Medicare or Medicaid participants. Board members also described them as vulnerable, underserved/disadvantaged/underprivileged, in need, and grateful: “…In need, underserved, but incredibly grateful for the services that we provide.” Some clients are not underprivileged but are still sick as MANNA serves people of all income levels without charge:“I think of them as being in tremendous need and being vulnerable…because of their illness”. The Board felt that clients lack support systems, are unable to afford food for illness, lack education about food and nutrition, and for the most part live in and around Philadelphia.

Effects of MANNA Services

Many of the client changes described by staff centered on improvements in physical and emotional health. Staff stated that a burden gets lifted, that clients and their family worry less, and that there is stress relief for both clients and caretakers. The outlook on life improves for clients and their “spirit gets lifted”. Physically, their health improves, they gain weight and have the energy to work and provide for themselves, so they also gain independence. Some staff members felt that the “the food saves their life”. Clients also have help getting through treatments and gain physical and emotional strength. They get relief from difficulty of finding sources of medically-tailored meals so that the burden of a therapeutic diet (on top of a complex medical issue) is relieved. Staff also highlighted the educational component of MANNA services, stating that clients get a

better understanding of what they should be eating, portion sizes, and different ways that food can still taste good, but meet their dietary requirements. Clients also try new foods that come with meals and they gain cooking skills (if they attend the free classes offered by MANNA). Last, staff noted that clients see their medical provider to obtain medical information necessary for MANNA services.

The Board described that clients have access to easy, good-tasting meals and don't have to worry about shopping, cooking, and getting a balanced diet. They get nutritious meals and eat regularly. Board members felt that clients have improved physical strength and physical health which helps them to tolerate their treatment. Clients also experience improved mental and emotional health. They have contact with someone and they feel less alone, cared for, and have less stress. As clients see improvement, they feel motivated to fight their illness. Clients "get a second chance (against terrible odds)" and they are able to find their way through their situation. Because of MANNA services, clients can concentrate on healing themselves and on being positive.

MANNA learns about its impact through formal interviews conducted by the Development Department and through surveys such as the Annual MANNA Client Satisfaction Survey. They also assess impact through client interaction with dietitians and through feedback obtained via informal conversations with clients. Staff said that previous MANNA research was also a source of information. One staff member noted that a quality of life questionnaire was currently being used with clients. The Board also felt that they learned about the impact of MANNA in several ways. They discussed the need for both quantitative or "tangible" and qualitative or "intangible" evidence. Tangible

evidence includes in-house studies and peer-reviewed publications. Intangible evidence includes stories from drivers and letters from clients (which are read at Board meetings). The Board also had knowledge of effects from client interviews, direct interaction with clients, and client stories from a video that is shared at MANNA fundraisers.

Essential Outcomes

Staff noted that essential outcomes are healthcare cost savings: less hospitalizations and shorter stays. They stated that laboratory values (e.g. HgA1c) and body weight should be collected pre-, during, and post-MAMMA services, and noted that laboratory values would be different depending on disease state. Staff also described the importance of collecting quality of life indicators. Staff were concerned about the effect of expanded geography and felt that data should be collected about the effects of the delivery system, about client attitudes where MANNA is not known as an organization, and if the questions clients ask are different than those asked in Philadelphia.

The Board also discussed that outcomes will depend on the illness. They considered improvement in physical health important including changes in lab values. Outcomes should include less doctor visits, less medication, disease remission, and decreased re-admissions (especially with "frequent flyers" such as patients with heart failure). They also described that health improvement resulting in healthcare cost savings was a business model for insurance partnerships and increased sustainability. The Board also felt was important to measure pre- and post-diet changes and to determine if diet changes last. They felt that regular client surveys should be conducted and that success stories should be collected. Emotional outcomes ("how the client was feeling") were also

important to measure pre- and post-MANNA. They stated that improvement in motivation, outlook on life, and optimism were important outcomes. Board members would like to see other stakeholder input such as how physicians view the impact of services on their clients as well as the views of insurers, community partners, and politicians. The Board also noted that having both qualitative and quantitative data (tangible/intangible) is what differentiates MANNA and that both should continue to be collected. One Board member noted that it was important to continue to tell the story and institutional history of MANNA.

In terms of capturing outcomes, staff suggested the new computer program ("Client Tracker") would have better capability to categorize and report data. Other possibilities are data sharing contracts with insurance companies or to compare data between similar "food is medicine" organizations in New York, Colorado, San Francisco, etc. However, it was noted that the MANNA model was not like those organizations in terms of clients or services. Two other ideas from staff were to benchmark data against Meals on Wheels or to conduct a randomized control trial, with the latter needing more resources (i.e. grant funding).

The MANNA Board discussed whether surveys could be more automated to get more information both from clients and other stakeholders. For example, survey physicians to see how they view the impact of services. Also obtain the views of insurers, community partners, and politicians. They questioned whether drivers could be better trained to interact with clients as a healthcare system "touchpoint", also potentially for care management. The Board also focused on the capture of business information, stating

that internal accounting practice should accurately capture financial data to know how much each meal costs. This provides the basis for insurers or other healthcare businesses to calculate cost savings and long-term financial benefits. The Board felt that the ability to show insurers financial savings together with positive effects on quality of life would significantly increase business.

Unanswered Questions

A common theme among staff members was that MANNA lacks data about how clients do after the program as well as what the transition off of the program is like. Staff would like to know more about what clients are eating and what they are not eating, if they learn how to eat properly for the condition that they have, and whether they follow their diet as prescribed (similar to how they would take a prescribed drug). They would like to know why some clients get back on the program after several months and about long-term outcomes – one and two years later. They question whether MANNA can do more to address cultural preferences or clients with food allergies. Staff expressed the desire to better understand physiologic outcomes (i.e. lab values) and felt that MANNA could do a better job of putting those in lay terms for those without a clinical background.

Board members would like to see quantifiable data that describes the benefits that come from MANNA: health outcomes, quality of life, etc. They questioned if some of the following examples were measurable: whether MANNA clients were more engaged in community, leaving the house more often, and feeling less stressed about food shopping and preparing the next meal. One Member would like to know and use the top three positive outcomes for MANNA to motivate and encourage people to get involved with

MANNA. The Board also stated that more should be known about who gets better and who doesn't, whether those that do get better, stay better, or come back to MANNA with the same referral, what happens after MANNA stops delivering meals, whether clients really understand what the diet is, whether dietary behavior changes, and if they can manage their diet in the long term. Like staff, the Board wants to know how clients do long-term overall and whether MANNA has improved client's lives (i.e. are they able to get healthy, be productive in society, and how do they approach their health?)

Stakeholders: Donors, Insurers, Volunteers

All donors want to see success in terms of MANNA making a difference although the staff described two general types of donors – those who prefer the "heartstrings" or those that prefer the broader healthcare implications. It was acknowledged that both types of donors want some of each. The staff used various terms for different types of donors. They referred to higher donors being more "sophisticated" or older ("baby boomers") and lower level donors "having less capacity", or being younger ("millennials"). Staff described capacity differences as those that are able to give a smaller amount and want to help someone through a hard time vs. those who can give a significant amount and want to change Philadelphia. Staff noted that younger people tended to come to events but don't donate beyond that because they are largely unaware of MANNA's mission. In contrast, older people follow the organization through newsletters or other forms of communication and tend to donate more regularly and in higher amounts. Last, staff described that high capacity donors are outcomes-focused and low capacity ones are output-focused.

The Board felt that donors want to know that their money is going to the clients and not the marketing or "fluff" of MANNA. Donors want financial transparency in terms of quantification of client costs and overhead costs. Some Board members felt that it depends on the donor – some care about the "heartstrings" and others look for quantifiable outcomes. Some donors look for sustainability, reputation, and integrity of the organization. Others want to know specifically how their money is helping MANNA serve people and what are the immediate outcomes of those services in the context of a strategic plan and potential for longevity.

MANNA staff were quick to state that money, cost savings, and the "bottom line" were most important to insurers as was "meeting mandated standards for things like diabetes care". They stated that insurers take a scientific approach by looking at how improved outcomes from services (such as blood levels) can save them in the long run. Some staff felt that although insurers do want to see cost savings in terms of less hospitalization and medication use, they also care about the well-being of patients and look at "food is medicine" as an important part of their coverage. They felt this was particularly true of Medicaid plans, which currently had incentives to partner with community-based organizations. A few staff felt strongly that a current Medicaid plan they work with considers MANNA to be a partner in healthcare reform, believing in them as an organization rather than considering them to be just a billable vendor. They see the "food is medicine" concept as innovative and want to keep MANNA moving forward in order to grow together.

The Board overwhelmingly felt that insurers cared about cost savings. They want to see lower hospital admissions rates and lower cost/patient. Healthcare businesses want their own mission to align with MANNA and then the "business case" becomes: can MANNA continue to build a healthy population in a cost-effective way that makes financial sense for the organization? The Board also felt that quantitative outcomes data were important to prove that MANNA lowers healthcare costs (because insurers need to make money to provide services). Some Board members noted that improved public relations could lead to business growth if insurers partnered with MANNA, but that cost savings were still foremost.

In terms of what is important to volunteers, the staff felt that working in the kitchen gives volunteers a tangible and immediate feeling of accomplishment. While volunteers may come to MANNA for different reasons, knowing how many meals were prepared during their shift keeps them coming back. Volunteers want to provide a support system for the community that allows clients to get better. Seeing the product (meals) and making sure they get to clients is important to volunteers because they like to be as "hand-on" and as close to clients as possible. Reading messages that MANNA gets from clients means a great deal to them and there is a plan to have an area in the kitchen where volunteers can view these messages. Some volunteers are giving back in a personal way because MANNA helped a close family or friend or because they were previous clients themselves.

The Board also saw the importance of immediate impact for volunteers: "you're producing a meal, delivering a meal, or packaging a meal that is going to be on

someone's table in the immediate future". Volunteers like to feel that they are doing something good for another human being and that they make a difference in someone's life. MANNA encourages corporate groups to come for volunteer experiences. A board member, whose company participates, reported that the experience creates team building, employee engagement, and stronger relationships in the workplace. The Board felt that the new space would draw even more volunteers because "people are more engaged and enthused when they are part of something bigger" and see that is growing rather than standing still.

Nutrition Education and Counseling

MANNA staff felt that the education helps clients, especially ones with specific disease states. One staff member said: "I also think it is like a life line to them a little bit", meaning that the staff serves as somebody clients can call with a question because don't have anybody they can ask a question to. Another staff member said that the educational component (cooking classes, dietitians sitting down talking to clients, learning to food shop at the supermarket) was a talking point with potential donors and corporations because they considered it to be "a great thing for clients". One staff member noted that even though their insurance clients with diabetes had been part of the healthcare system, MANNA often provides their first diabetes education. They stated: "...I think, until they understand it, they won't make a change. But once they understand it, that can start the change."

The Board stated that: "It's almost as important as the meals themselves". When clients come off the program, it's going to allow clients to move forward and fight illness

either now or down the road. One member stated: “It’s been explained to me but I’ve never really understood how much the patients comprehend…”. Some members felt that it offered an opportunity for MANNA to grow with less overhead spending, more impact on clients, and more sustainability. The Board also felt that there is potential for MANNA to market the education piece more than it does. One member asked: “Is there an opportunity to talk about examples of folks being educated and what they’re doing with that education?” Overall, the Board felt that meeting with a nutritionist is a unique opportunity for clients, but there were varying comments about not knowing its effects. One Board members comment illustrated this: “I’d be very interested in knowing if this is the first time they’ve [the clients] ever interacted with a nutritionist, the type of learning that they take away, and if it impacts life over the longer term”.

Client Barriers

The prevalent feeling among staff members was that clients lack the resources they need in order to do well, including but not limited to money, health insurance, grocery stores, cooking equipment, and education. Due to these resource limitations, the staff questioned how much clients are able to take what MANNA has taught them and apply it to their everyday lives. The discussion also centered on poverty as a major hindrance toward clients being able to reproduce meals and sustain optimal health. Staff noted that clients are at or below poverty level, so nutrition education receives low priority. An underutilization of nutrition education and counseling was noted even though all clients are offered the service. One staff member stated: “I think there are so many competing priorities that our clients have that it makes it very hard for them to prioritize

their own health". Regarding insurance clients (whose diagnosis is diabetes), one staff member stated that that there may be clients who come back on the program after doing well so questioned whether it would be more cost-effective to continue to provide meals rather than have clients go back on insulin.

The Board's discussion on this issue focused on lack of financial resources. They acknowledged that healthy food can be expensive and that due to financial limitations, clients may not be able to afford healthy food. A few Board members questioned whether limited food access (due to lack of food stores) was an issue. Clients may also be living in food deserts with a prevalence of "high salt and high sugar foods and no place to get good food". One Board member stated that "fast food and pre-packaged food is easier…and maybe less expensive…". Another thought was whether clients had cooking skills and could put similar meals together for themselves. The need for a support system was suggested if clients are very sick or don't have the motivation.

Staff provided a wide variety of responses to what MANNA could do to help clients overcome barriers. Some felt that MANNA could do more (such as add case management services) but that it doesn't have the capacity. Although there was general agreement about lack of capacity, some felt that they could better understand the needs of clients after MANNA to help find them connections and resources: "I think it's also important to be able to connect them to other resources because MANNA can't do it all and that's not what our mission is". One staff member commented that HIPPA gets in the way of connecting clients with resources because they can't just share client information with other organizations. Another perspective was that MANNA will not be able to have

control over some resources (i.e. clients who are reliant on food from a food pantry) after the MANNA program. However, one staff member suggested that MANNA could use advocacy to try to improve foods available in this regard. MANNA could also better communicate the availability of nutrition counseling from dietitians as a support system. Staff stated that clients are being educated whether they know it or not with meals and weekly nutrition inserts. System-level ideas were to advocate for a "food is medicine" model on a national level that encompasses the whole continuum of nutrition interventions (SNAP, supermarkets, etc.) and for insurance companies to provide clients with a lifetime prescription to MANNA as their "pharmacy" to keep them well.

The Board also discussed a wide variety of responses. The Board felt that MANNA should continue supermarket tours and help clients figure out what the options are for them in a food desert. One Board member suggested developing partnerships with supermarkets for better food access for clients. For example, MANNA could ask supermarkets to donate cards or coupons that can be used for food purchases after services end, however staff time would be needed to develop these partnerships. Board members also suggested follow up with a nutritionist once clients are off the meal program and longer-term outcomes measurement to see who is sticking with the meal program and who isn't after 1 or 2 years. Other ideas were to add a social media aspect for post-MANNA clients as a constant reminder (Facebook page, etc.) and to connect previous MANNA clients, especially those who live in the same area, so they can help and motivate each other. MANNA could possibly use volunteers to help support these efforts.

Geographic Expansion – effect on clients

In terms of the effect of geographic expansion on clients, staff discussed that clients will lose the experience and "touchpoint" of the driver but they will gain increased telephone contact from the dietitians or trained volunteers, which will serve as equally valuable touchpoints as MANNA expands. The staff also described that the touchpoints of the nutrition department are very different because they are so involved. Ramping those up as MANNA ships meals will make the client experience even better. One staff member commented that most MANNA clients (>60%) don't want a relationship with the driver so in that respect, the client experience may not be any different. Another staff member stated that the client experience would not be different except for clients' familiarity with the organization and understanding who MANNA is and what they do. The product would not be different. Staff agreed that most clients outside of Philadelphia have never heard of MANNA, so more telephone follow-up will be crucial: "We have to explain to them exactly who we are, what we are doing, how it's going to help them, and what kind of support system we'll be."

There were two broad topics of discussion by the Board regarding the effect of geographic expansion on clients. First, the Board discussed that geographic expansion will probably change "something", but they would like to replicate the current program as much as possible. The significant piece that is lost for clients is the direct interaction with the volunteers and delivery drivers. One Board member stated: "I feel that part of the MANNA thing is the whole personal delivery." However, during a Board meeting they discussed that the same UPS driver would drop off the meals for clients. The Board also

felt that if MANNA can effectively use UPS drivers, phone consultations and/or telemedicine to develop a personal relationship with clients and meet their needs, then clients should be fine if they are followed through. It was noted that MANNA will need to track client outcomes after meals stop to see if lasting effects are similar to those in clients served by "central" MANNA.

The second topic discussed by the Board is how geographic expansion might work in rural communities. It increases exposure to the MANNAmission, which can decrease isolation and improve hope. In smaller communities, knowing about others who are helped by MANNAcould be the spark that leads to more helping significantly more people. If more people know about MANNA and talk about it as an option, a movement may develop that "feeds on itself" and potentially leads to government support.

The Board's last topic of discussion was the potential for expansion. Members felt that providing state-wide services positively changes the perception and opens-up more opportunities for funding: the more outreach MANNA has and the more services it provides leads to increased client and insurer interest. A final thought was that this can have a snowball effect on organizational growth.

Geographic Expansion – effect on the organization

Because geographic expansion is currently based on insurance contracts, the first issue that concerned staff was the difference between "mission" and insurance clients: mission clients have serious life-threatening conditions and insurance clients have more chronic conditions. Although the MANNA mantra is "food is medicine", insurance clients qualify for MANNA services with different (less acute) criteria and receive earlier

intervention that offsets later problems. MANNA has been able to expand the number of mission clients they see because they expanded the number of insurance contract clients, leading to the ability to hire more people and to be a better organization and a bigger part of the community. And with earlier intervention, clients' overall health is better. A staff member stated: "I don't see a decline in the service that we're providing because of the expansion. I see if anything, improved service". There was some concern expressed about perceptions of volunteers and insurers. Volunteers would likely accept MANNA serving the state, but they may feel that resources are not being used properly if MANNA serves out-of-state residents. Also, if an insurer that is out-of-area is funding the ability to serve more mission clients in Philadelphia, will they want the money to go back to their geographic area? Another concern was: "Protecting… MANNA's name and quality of product is key". The fear was that the level of risk goes up in terms of other organizations taking and using the MANNA model.

The Board described its effect as positive, but for best reception of aMANNA programs outside of Philadelphia, it needs to be considered more than a "Philadelphia thing". One Board member stated: "we need to make sure its consistent delivery of the mission". Another Board member stated: "You know, we hope that we would never lose the original mission, which is we're serving people directly". Other Board members noted that geographic expansion won't changethe MANNA mission because the commitment to keeping and expanding "mission" clients (those who receive free services) will always exist. There was general agreement that expansion won't cause change in the foreseeable future but that MANNA needs to make strategic decisions

about what will be the ultimate model for expansion. A future challenge will occur if there is a significant increase in insurance reimbursement for services, forcing a choice between serving mission clients or insurance clients. Prediction of future action is made more difficult by the uncertainty of future Medicaid expansion. The Board discussed that insurance companies partner with MANNA rather than for-profit companies because of key differentiators: published research, nutritionists, delivery drivers, and non-profit mission-oriented status. One Board member hoped that MANNA doesn't get too big and expand beyond its capability. Overall, Board members felt that medically appropriate meals should be available to everybody so MANNA should expand. Any other organizations who provide similar services should be consistent with MANNA in providing medically appropriate meals – "not just Meals on Wheels".

Client Who Get Better

Staff define getting better through their personal experience and interaction with clients, health information collected, and feedback from clients and/or healthcare providers. For their insurance clients, "better" will be defined with future cost-effectiveness data. Staff also expressed that "…the reason that it's especially difficult [to measure health improvement] is that it's different for everyone" and noted that each client gets an individual evaluation for appropriate length of services. One staff member said that although MANNA services were currently six months to one year, MANNA should address the potential need for long-term services as they move into the future. Another staff member defined "better" in relation to mind, body, and soul: MANNA

relieves the mental stress of having to think about food, clients get better physically, and that volunteers prepare food is meaningful emotionally.

Getting better for Board members meant that MANNA provides the nutrition that helps clients' medical treatment be successful. Members discussed that MANNA also provides clients with the encouragement and mental strength to fight their illness: "It helps them become healthier. It helps them become more positive. It helps them to look forward and I think, dream about a day when they'll be well." A Board member stated that it meant that clients are recuperating. MANNA used to serve clients who passed away but now there are a lot of clients who are surviving and/or become healthy. Letters from clients are also read at Board meetings: "….it all seems like they got better and they're so happy that they had these MANNA meals and it really got them through a tough time." Some Board members cited a study that showed fewer hospital and emergency room visits after MANNA services. Another Board member felt that there is more emotional improvement than health status improvement and that more data on health status is needed. One Board member questioned whether food services might have further impact on society beyond healthcare cost savings and better lives if clients are healthier, return to the workforce, and there is less drain on society (e.g. reduced disability payments, lower crime rates, etc.).

Clients Who "Don't Get Better"

Staff stated that some clients' health does not improve like MANNA would like it or expect it to, but the meal program still has an impact on their mental health. Some don't improve because other factors outside of MANNA affect their ability to be 100% at

the end including the disease itself, lack of support at home, and/or mental health issues or depression. Some clients get better while on the program but then come back later due to external factors. The example provided was that a previous client with diabetes and severe complications said MANNA "saved his life and got me so much healthier" but he still ate poorly per staff observation. A staff member stated: "clearly the education did not stick". Regardless of this observation, staff universally felt that the meal program benefits clients' mental health even when it is not making an impact on their physical health. MANNA acts as a support system – without MANNA clients may have passed away sooner or had a more painful experience.

The Board stated that about half of the clients fit into this category including those with end stage renal disease. There are clients who don't survive their illness, but Board members felt like it's a much smaller percentage than it used to be. There was agreement that MANNA shows clients "that there are folks out there who care about them". The Board discussed that chronic or worsening conditions would not result in regular healthcare outcomes. Regardless, Board members agreed that MANNAprovides emotional support and "have the ability to improve the quality of life at the end stage". These clients also have a tremendous impact on MANNA: "we know everyone who loses their battle and frankly, talk about them".

Staff had diverse thoughts on whether MANNA can help this population. Some staff felt that MANNA cannot help them: "There's always gonna be a gap I think once they're gone – that's on them". Staff also felt that MANNA can't serve chronic conditions right now because there are a lot of other things to do. Another idea was to

find ways to better connect clients to resources in their community. MANNA puts resources on their web site but clients need internet to access that information. Overall, staff agreed: “we have clients with horrible chronic conditions”. They qualify for MANNA based on an acute episode but after that, meals are taken away even though they would really benefit from continuation because their living circumstances don’t change. The staff felt that there need to be more community resources that are designed to treat these chronic conditions: “You need all the continuum of care and MANNA is just a small part of that”. The Board also stated that they were not sure that there is much more that MANNA could do for clients who don’t get better: “I just don’t know what else we could do, given our scope...maybe there’s a partnering opportunity. That may be something that can help people face their challenge in a better way”.

Additional Services

Several staff members felt that MANNA doesn’t need to provide additional services, but Philadelphia should better understand the needs of the community and provide that support. Realistically, all additional services are resource intensive so other organizations need to fill in the gaps because there is only so much MANNA can do. One staff member would like “to see the medical community take a step forward”. The medical community should continue to monitor clients post-MANNA to help them maintain positive health changes. Other staff felt that there were numerous services that MANNA could provide. One idea was to hire a social worker who, together with the dietitians, could provide a range of additional services: home visits, shopping trips, and cooking at client homes. One staff member stated that MANNA does food and nutrition

well and should expand on that strength. MANNA could also facilitate community support groups and develop a recipe book for post-MANNA support. In the future, staff thought that case management could connect clients to services outside of the meal and education program. Perhaps healthcare providers could work out of MANNA a few days a week. MANNA could also have a food pantry program to serve clients coming off the meal program, that ideally would be externally focused and embedded in different wellness centers (if they had the funding).

The Board also had multiple views about whether MANNA could provide additional services. Some pertained to clients and others pertained to the organization itself. Regarding clients, one Board member stated: "It's like the old saying, you can lead a horse to water but you can't make them drink". The thought was that MANNA can provide services, but there are clients who won't eat the meals or take their medications and don't live a healthy lifestyle. Other Board members thought that MANNA could provide information and education with a focus on behavioral economics for better outcomes. Another idea discussed was to utilize dietitians for community education to share knowledge about the role of food in disease prevention and to invest in this locally even though it is not part of their mission. MANNA should continue to engage the clients that get well in a variety of ways and to show that the effects of its services are not just short term but have a lasting impact through sustainable change in people's lives. One Board member suggested that MANNA looks at its core mission to see if it is still meeting it. If its mission has migrated over time or has expanded, how must other aspects of what MANNA is doing be leveraged going forward? One Board member stated: "I

would just like to see them affect more clients, which we're going to in the new space….and I would like to see…more insurance companies get on board…". One Board member wasn't sure what additional services that MANNA could offer and another stated: "I always get nervous of us trying to do too much". There was general agreement among the Board members that MANNA did have opportunities to "scale" without changing its model but that it should continue to "…recognize the inherent perils of scaling outside of your core competencies".

Closing Thoughts

Staff's final thoughts were that they need to think about capacity. They commented that even though they just completed a new facility, they will fill their new space quickly, and need to start planning what the future will look like. Board members didn't have any final thoughts other than that they like being on the Board because it's a fun group of people.

Client Data

Client perspectives of MANNA were obtained from questions 35-37 on the MANNA Annual 2016 Client Satisfaction Survey (Appendix B):

- In general, would you say that the MANNA meals service helped you?
    - How has the MANNA meals service helped you? (Comments)
- In general, do you feel more prepared to make healthy eating choices after the MANNA meal service?

- If so, how has the MANNA meals service helped you better understand nutrition? (Comments)

- Do you have any recommendation to improve the meal service?
  - What recommendations do you have for improving the service? (Comments)

Table 18 shows that 99% said "yes" to the question of whether MANNA meals service helped them whereas 95.1% said "yes" to whether MAMMA meals service helped them understand better nutrition. Thirty-six percent said that they had suggestions about how to improve MANNA meals.The main themes from client comments are described below.

Table18: MANNA 2016 Annual Client Satisfaction Survey (Questions 35-37)

Has MANNA Meals Helped	Total 103	Missing 0	Yes 102 (99.0%)	No 1 (1.0%)
Comments	Total 90	Missing 13		
More Prepared to Make Healthy Choices After MANNA Meals Service	Total 102	Missing 1	Yes 97 (95.1)	No 5 (4.9%)
Comments	Total 76	Missing 27		
Recommendations on How to Improve MANNA Meal Service	Total 100	Missing 3	Yes 36 (36.0%)	No 64 (64.0%)
Recommendations	Total 62	Missing 41		

How MANNA Meals Service Helped Clients

There were three major themes regarding how MANNA meals helped clients: food shopping and preparation, health and nutrition, and food access and security. Many

clients reported that MANNA meals helped them regarding food shopping and preparation because they were fatigued, weak, or disabled due to their illness:

- *"Too exhausted after treatments to cook or plan meals."*
- *"I am very weak. I don't have to worry about how I'm going to get food. It's rare when I have enough energy to buy food."*
- *"It limits the time standing to prepare meals. Usually use a rotator for balance. Currently I'm in a wheel chair because I go to my right"*
- *"Makes it possible to eat a precooked meal vs making it myself in a walker or cane. Thank you!"*

Some clients described more generally that meals are convenient or make life easier:

- *"Meals could be heated up quickly and was a balanced meal."*
- *"MANNA prepackaged foods make it easier for me so I don't have to cook every day."*
- *"It has helped my husband take care of food for me. I have not been able cook or shop for months."*
- *"Made life easier by not having to cook. Gave me a good basis for knowing about healthier food choices."*

There were a variety of comments from clients regarding health and nutrition. These included having a balanced diet, eating healthier foods, helping clients feel better and improving their health, reducing stress, helping with weight gain or loss, and modeling what to eat:

- *"It's shown me the foods I'm allowed to have and the portions."*
- *"It helped me with my eating a healthier diet and helps with my weight."*
- *"Gave me the chance to eat a healthy and balanced diet."*
- *"Saves a lot of stress knowing meals are there."*
- *"I have lost 40 pounds in the last year. I now gain or maintain my weight."*
- *"Heal me with my sickness; I feel much better."*

Clients also described the role of MANNA in improving food access and security with comments that ranged from being able to afford medications and pay bills to having enough to eat:

- *"I take a lot of meds, so I can't buy food and buy all of my meds too."*
- *"Allow me to use funds to pay for medical bills and utilities."*
- *"I skip less days without eating since MANNA's weekly delivery."*
- *"Never going to bed on an empty stomach."*
- *"I eat daily."*

How Meals Service Helped Clients Better Understand Nutrition

Multiple themes were seen in answer to the question of how MANNA has helped clients better understand nutrition. That MANNA provided balance, variety, and correct portion size in meals and improved health knowledge and behavior were most common:

- *"By the variety of foods put together to make a balanced meal."*
- *"By providing a protein portion, vegetable portion and starch and fruit."*
- *"It has shown me how much food I can have and right choices."*

- *"I believe it has helped me eat healthy portions."*
- *"Helped me learn what kind of food I should be eating on a regular basis to stay healthy."*
- *"I have developed a more regular meal schedule."*
- *"I always [knew] what good nutrition [was] but never applied it to myself."*

Other themes were that MANNA provided examples of healthy food and ways to prepare it, emphasized fruit and vegetables, and showed that healthy food can taste good:

- *"MANNA sets an example of good-for-you foods to eat."*
- *"Good food is not too salty and not too sugary and good food includes fruits and vegetables!"*
- *"That you can have healthy and nutritious meals without feeling deprived of taste and deliciousness."*

Recommendations for Improving Meals Service

Main recommendations for improvement were to change the amount of seasonings (including less salt), increase food variety, and provide less food or smaller portions. Some clients also named specific requests for foods to be included with meals. The most common reply however was "none" followed by a comment about how much the food was appreciated. The following are illustrative comments:

- *"More variety of food."*
- *"Less season on the food would be nice."*
- *"I hate to say this but the soups should have more seasoning."*

- *"Sometimes too much food to eat and always have to give some away."*
- *"I would like to get some spaghetti and meatballs and more tomato soups and crackers…"*
- *"I have high blood pressure…. food lower in salt content."*
- *"None! … I am very thankful for this service."*

Chapter 6 Health Outcomes Measures

Introduction

MANNA and other *Food is Medicine* organizations advocate for healthcare policies that incorporate the provision of medically-tailored food and nutrition services into mainstream healthcare systems and associated reimbursement mechanisms including but not limited to Medicaid, Medicare, and private insurance plans, and state-specific demonstration projects(9). To actualize the goal of having medically-tailored meals and nutrition services become a widely available and reimbursed healthcare service, MANNA and other organizations that provide services as part of *Food is Medicine* initiatives will need to show that their services provide desired outcomes and impacts, most notably in the area of health improvement. However there currently exists little published research on health outcomes of medically-tailored food and nutrition service organizations. The call for outcomes research in this area is ongoing, and links to completed and current research are listed on the FMIC web site(70). Published research to date have been pilot studies focused on healthcare cost-savings through decreased healthcare utilization(41) or on outcomes of nutritional status, mental health, and health behaviors as assessed by variousmeasurements and questionnaires(43).

There are several challenges to measuring health outcomes for MANNA and other organizations that provide medically-tailored food and nutrition services. First, the specific type of food and nutrition services provided within *Food is Medicine* healthcare initiatives varies per organization. What MANNA and other organizations have in common is that services are provided to community members who are at nutritional-risk

from acute or chronic illness. However, they vary in the specific way that food and nutrition services are provided, who qualifies for services, and how long services are provided. Food may be provided as home-delivered meals, congregate meals, or vouchers, and may also include bagged food donated by individuals or from food pantries and food banks(71). Nutrition services may or may not include nutrition education or counseling provided by a RDN.

Second, MANNA and other *Food is Medicine* organizations must decide whether they will collect and analyze health outcomes as part of research studies or quality improvement projects. According to the Institute for Healthcare Improvement (IHI), it is important to keep in mind the difference: research is conducted to discover new knowledge, whereas the quality improvement process is meant to bring new knowledge into daily practice(72). In quality improvement processes, measurement is considered a key element of ultimate programmatic change within an organization. Depending on available resources, MANNA and other *Food is Medicine* organizations could also choose to pursue research and quality improvement projects simultaneously because these categories are not mutually exclusive.

With consideration that the history, evolution, services, and resources of each *Food is Medicine* organization is different, there are multiple waysto show the effectiveness of food and nutrition services with health outcome measures(73).This chapter will focus on MANNA when describing potential health outcome measures of value to stakeholders. However, these health outcome measures are also applicable to a wide range of stakeholders within *Food is Medicine* initiatives including but not limited

to healthcare providers, health insurers, healthcare practices and systems, and health policy makers.

Nutrition Assessment and Evaluation

Nutrition assessment measures that show the effects of medically-tailored food and nutrition services, a.k.a. medical nutrition therapy (MNT), encompass four areas: anthropometry, laboratory values, physical examination, and dietary intake(74). Anthropometry includes body measurements such as weight, height, BMI, body composition, and body circumference measures. Laboratory values include blood levels of nutrients or other physiological parameters that reflect nutrient status (e.g. hemoglobin for iron status). Physical examination entails physically examining the body for any signs of nutrient deficiency or physiologic abnormality (e.g. blood pressure). Last, dietary intake assessment involves asking clients about eating behavior via food intake over the last 24 hours (24-hour recall), food intake for the past several months to a year (food frequency questionnaire) or food intake over a defined period of time as recorded by the client (food record).

There has long been a call to nutrition and dietetic professionals to evaluate the health outcomes of MNT in order to show its effectiveness(75). Changes in laboratory values and physical parameters are considered "intermediate" health outcomes because they are thought to lead to reductions in disease-related complications and improved clinical outcomes(76). For example, control of blood pressure, hemoglobin A1C levels, and low density lipoprotein (LDL) cholesterol in diabetes is associated with decreased cardiovascular events, fewer microvascular complications, and lower mortality(45,77). In

this chapter, potential intermediate outcome measures will be described for patients with major diseases served by MANNA including those with cancer, renal disease, diabetes, heart disease, and HIV/AIDS. Outcomes measures will reflect the expected health results of MNT as part of food and nutrition services provided in clinical or community-based settings and as described by accepted professional practice guidelines and/or the Academy of Nutrition and Dietetics' (AND) Evidence Analysis Library(47,78). In practice, MNT includes nutrition assessment, diagnosis, intervention (including nutrition education and counseling), and monitoring and evaluation(79). The goal of MNT is to assess and evaluate an individual's nutritional status and related medical history to determine what is required to achieve a change in eating behavior consistent with disease management(47). For diet-related diseases, it is therapeutic changes in food and nutrient intakes together with medical management that affect intermediate health outcome measures(60).

Since the MANNA program provides a full medically-tailored meal service of three meals per day for seven days per week, changes in eating behavior may not be a significant intermediate health outcome measure while the client is on the program(4). However, Provided services are also intentionally short term since they are focused on improving nutritional status during acute states of life-threatening illness(3). With the availability of nutrition counseling and education from a staff of Registered Dietitian Nutritionists (RDNs), the ultimate goal is for clients to be able to follow their therapeutic diet on their own upon cessation of the MANNA program(5). Other *Food is Medicine* organizations offer a partial meal programs, leaving clients to fill in the remainder of

meals on their own(80). Therefore, expected changes in eating behavior and related food and nutrients intakes as a result of medically-tailored community-based food and nutrition services will also be discussed in this chapter.

Intermediate Health Outcome Measures

Cancer was the most prevalent diagnosis seen by this researcher in the chart analysis described in Chapter 4. Evidence-based recommendations for MNT upon cancer diagnosis and treatment are described in the AND Evidence Analysis Library(47). Poor nutritional status in cancer treatment may lead to poor tolerance to cancer treatment including chemotherapy and radiation. Malnutrition is also associated with higher healthcare utilization, lower quality of life, and increased mortality(81). Once cancer patients are identified as needing oncology services, they should be screened for the presence of malnutrition and if determined to be at-risk, they should receive a complete nutrition assessment and evaluation. Two or more of the following health measures are currently used to identify the presence of malnutrition: insufficient energy intake, unintended weight loss, loss of subcutaneous fat, loss of muscle mass, localized or generalized fluid accumulation, and loss of grip strength(82).

Although these measures taken together can indicate the severity of malnutrition in an individual, the outcomes of optimal nutrition intervention are not yet determined and there is still ongoing discussion of what intermediate health measures are most important for malnutrition evaluation and monitoring(83,84). Historically, laboratory measures of malnutrition such as plasma proteins albumin and pre-albumin were used to indicate protein intake and lean body status in malnutrition assessment. However, these

measures are now considered invalid measures of nutritional status because they have been shown to respond to inflammation commonly present in acute and chronic disease rather than nutritional intake(85). Research on the identification of biomarkers for the assessment and evaluation of malnutrition is ongoing and use of specific plasma proteins as viable health measures may be possible in the future(86).

There are drawbacks to the currently proposed intermediate health outcomes for malnutrition for community-based food and nutrition service providers. Measurements are labor intensive and must be obtained within a clinical setting by a RDN or other healthcare provider trained in physical assessment. Another obvious drawback is that to be useful as health outcomes, measures of energy intake, weight status, and physical assessment would need to be taken immediately prior to the start of services and at specific intervals that coincide with program recertification. While screening and assessment for the presence of malnutrition is an evidence-based standard of care for RDNs working in oncology, it is not yet a widespread standard of medical care. However, screening and appropriate follow up for the presence of malnutrition are currently proposed to be included as "electronic clinical quality measures" in electronic health records (EHR) of healthcare systems which may serve to make these health measures more accessible to community-based food and nutrition service providers in the future(87).

The second most prevalent disease seen by this researcher in the chart analysis described in Chapter 4 is chronic kidney disease (CKD). One of the primary goals of MNT in CKD is to prevent or treat malnutrition (protein-energy wasting) because

patients with CKD who are malnourished have higher morbidity and mortality, including from atherosclerosis and cardiovascular disease(88). Other goals of MNT are to help normalize mineral and electrolyte alterations, and help minimize the impact of other co-morbities such as diabetes, obesity and hypertension on the progression of CKD(47,89). Initial and follow-up assessment of food and nutrient intakes in CKD should include potential biochemical measures affected by diet including but not limited to energy, protein, sodium, potassium, calcium, and phosphorus. The corresponding list of potential biochemical parameters to monitor as health outcomes in CKD is extensive and may include blood glucose, lipid and electrolyte levels, indicators of protein-energy malnutrition, and measures of inflammation, kidney function, anemia, and mineral and bone metabolism(47). Another intermediate health measure considered important in CKD is accurate assessment of body weight. Weight assessment should include current weight, history of weight change, longitudinal weight measures, and clinical judgment of adjusted body weight with consideration of edema or altered fluid balance(47).

Due to the complexity of progressive stages in chronic kidney disease, the challenge for clinicians and community-based food and nutrition service providers alike is obtaining state-of-the art measures that most reflect optimal disease management and health status(90). In addition, quality measures for treatment of CKD are not yet standardized and outcomes are affected by many factors beyond diet including but not limited to the presence of severe disease, contraindication to medications, access to healthcare, or nonadherence(89).

A third diagnosis seen by this researcher in the chart analysis described in Chapter 4 is type 2 diabetes. Diabetes as a chronic disease has clear intermediate health measures that if controlled, lead to improved health and decreased risk of associated co-morbidities including eye, kidney, and nerve disease(91,92). The most common health outcomes measure for diabetes treatment is Hemoglobin A1C (A1C) which reflects average blood glucose levels over approximately 3 months and is a risk factor for complications related to diabetes(93). Therefore, measures of A1C should be obtained on a regular basis as part of diabetes care. The goal for A1C in most adults with diabetes is to maintainvalues at less than 7% although A1C can be slightly higher in patients with co-morbidities or circumstances(91).

Another health measure that reflects the success of MNT in clients with diabetes is body weight and its related body mass index (normal range 18.5-24.9; overweight 25-29.9; obese 30 and above) and waist circumference (less than 35 inches for females and less than 40 inches for males)(94). Overweight and obesity, especially with fat deposited around the waist, are conditions associated with insulin resistance that leads to the development of prediabetes (fasting blood glucose levels of 100-125 mg/dl) and diabetes (fasting blood glucose levels of >125 mg/dl)(47,95). In clients who are overweight or obese, a relatively small reduction in body weight (5-7%)can significantly improve blood glucose levels and A1C values(96). Clients with type 2 diabetes are also at significant risk for cardiovascular disease. Therefore, it is recommended that blood pressure and blood lipids values, specifically low density lipoprotein (LDL) levels, be monitored to achieve outcomes of less than 100 mg/dl and less than 140/80 mm Hg, respectively(97).

For overweight or obese clients, maintaining weight loss of 7% can further support reduced blood pressure, improved blood lipid values, and decreased need for medication(96).

There are a multiple dietary patterns and associated eating behavior changes that can produce positive changes in health outcomes in diabetes including lower A1c levels, optimal medication effects, and improved quality of life(47). Reduced energy intake for weigh loss is a primary health outcome measure in overweight and obese individuals as is consistent calorie intake in normal weight individuals. There are a variety of dietary guidelines that can help clients achieve appropriate calorie intake including MyPlate, Mediterranean Diet, and Dietary Approached to Stopping Hypertension (DASH)(51,98,99). If a client's diabetes is also controlled with oral medication or insulin, MNT that includes carbohydrate counting for appropriate amounts of carbohydrate intake may be indicated(47).

In diabetes there are clear parameters to monitor for intermediate health outcomes, however diabetes care requires close monitoring of plasma values, body weight, and dietary intake so that treatment can be individualized. Individualization requires close contact between clinical settings and community-based food and nutrition service providers for health outcome monitoring. One initiative that is currently accomplishing this is a partnership between MANNA and a Medicaid provider whose goal is to provide optimal care with cost savings by providing diabetic patients with short-term medically-tailored food and nutrition services as part of a disease management protocol. The Medicaid provider has reported that when incorporating a *Food is Medicine*

model into diabetes care, A1C values decreased by 26% and healthcare cost decreased by 27%(100).

A fourth common diagnosis found in the chart review at MANNA is heart disease, including heart failure. Cardiovascular disease management guidelines include appropriate blood lipid values as intermediate health outcome measures(47). These include total cholesterol levels of 200 mg/dl or less, low density lipoprotein (LDL) levels of less than 100 mg/dl, high density lipoprotein (HDL) levels of greater than 40 mg/dl, and triglyceride levels of less than 150 mg/dl(101). Blood pressure is another health outcome that should be monitored and maintained at less than 140/80 mmHg or less than 130/80 mmHg if diabetes or chronic kidney disease is present(102). Obesity is also risk factor for cardiovascular disease so health outcome measures wouldinclude body weight, body mass index (normal range 18.5-24.9; overweight 25-29.9; obese 30 and above) and waist circumference (less than 35 inches for females and less than 40 inches for males)(94).

While there is agreement about the goals for blood lipid levelsfrom MNT in cardiovascular disease, it can be difficult to determine whether levels directly reflect dietary changes. Evidence-based recommendations from professional organizations conflict as to the amount of dietary fat, cholesterol, and other nutrient intakes required to produce optimal plasma lipid levels. Historically, different recommendations for dietary fat intake have existed across organizations including those from the AND Evidence-Analysis Library (2011), The American Heart Association (2013), the National Lipid Association (2015), and the USDA Dietary Guidelines Advisory Committee (2015) due

to differing interpretations of the research literature and/or needs of patients(47,51,97,103). While clinicians must make judgments about which recommendations to use with individuals, community-based food and nutrition service providers provide standard "heart healthy" meals, which may or may not be consistent with a client's therapeutic recommendations. In addition, blood lipid levels have been increasingly managed with medications so therefore may not directly reflect dietary behavior change regardless of food and nutrient recommendations or intake (104).

Another category of heart disease for MANNAclients is congestive heart failure. This is a complicated diagnosis like CKD in regard to intervention, management, and health outcomes. Expected health outcomes from MNT in heart failure overlap with cardiovascular disease with respect to plasma lipid levels. However, assessment may also include physical findings indicative of malnutrition from altered calorie and nutrient needs similar to those monitored in cancer(47,83). MNT should include individual recommendation for calorie, protein, sodium, and fluid intakes and assessment of health outcomes should include related physical and clinical measures(47). Also consistent with CKD, biomarkers that reflect health outcomes in heart failure are wide-ranging, highly technical, and continue to be developed through research focused on optimal evaluation of health status in heart failure(105,106). Recent limited evidence cited within Academy of Nutrition and Dietetics Evidence Analysis Library indicated that patient who received MNT as part of treatment for heart failure had better physical component scores on quality of life measures, less anxiety, and maintained body weight compared to controls.

However, it is unknown if MNT affects hospital readmission, length of stay, and mortality due to lack of research in those areas(47).

A final common diagnosis prevalent in the chart review at MANNA is HIV/AIDS. Health outcome measures related to MNT for HIV/AIDS include body weight and height, body mass index (BMI), and body compartment measures (fat-free mass and fat mass)(47).The goal for clients with HIV/AIDS is to either maintain weight or to gain weight when indicated. Altered body composition, prevalent in clients with HIV infection, can be measured in a clinical setting with bioelectrical impedance analysis(107). A health outcome measure that indicates whether clients may be immunocompromised isCD4 level, a measure that reflects viral load(47). Measurement of food and nutrient intake should include assessment of energy, protein, fat, fiber,sodium, calcium and vitamin D intakes(47). Outcomes related to dietary intake can be assessed by comparing intake to current standards for nutrient intake, Dietary Reference Intakes (DRIs)(108).

As is the case with diabetes, food and nutrition services for clients with HIV/AIDS should be individualized for optimal weight and nutrients intakes (calories, protein, and micronutrients) based on assessment of a client's nutritional status(22,47). Unique to clients with HIV/AIDS is that nutritional support and associated health outcome monitoring are required components of the federal Ryan White/AIDS Program(19,109). This theoretically can support effective health data sharing between clinical and medically-tailored community-based food and nutrition service organizations(22,109).

At the present time, there is a surprising lack of health outcomes from clinically-based MNT or community-based food and nutrition services published in the literature. The Academy of Nutrition and Dietetics has attempted to help nutrition professionals report outcomes by developing and adopting a standardized nutrition assessment and evaluation process called the Nutrition Care Process and Model (NCPM)(110). The NCPM was meant to be incorporated into electronic health records for easier aggregation and reporting of medical nutrition therapy-related health outcomes. Outcome reporting has not been easily accomplished on a national scale, likely in part due to the variety of different types of electronic health records used by health systems throughout the US. This has led to the development of a national aggregate data collection and reporting system for nutrition professionals called the Academy of Nutrition and Dietetics Health Informatics Infrastructure (ANDHII)(111). ANDHII allows nutrition professionals with any practice setting to enter health outcome data resulting from clinical or community-based MNT. Overall, the ultimate goal is to help build support for the efficacy of medically-tailored food and nutrition interventions (a.k.a.MNT) for diet-related disease. However, in order for ANDHII to effectively reach that goal, clinicians and community-based service providers alike will need timely access to well-developed biomarkers that reflect the results of MNT as well as accurate and timely assessment of physical status and food and nutrient intakes of patients and clients. In addition, lack of health outcome reporting could also in part be due to difficulty obtaining laboratory values and reaching patients for follow up as well as time constraints(60). For all of these reasons, it is unlikely that health outcome measures will be easily available to *Food is Medicine*

organizations in the near future. Therefore, it may be more effective for them to collect validated health outcomes measures that are under their control including food and nutrient intake and patient-reported outcomes.

Measurement of Dietary Intake

As previously noted, *Food is Medicine* organizations provide food and nutrition services that include full or partial meal services and/or supplemental foods. Therefore, it is useful for MANNA and other *Food is Medicine* organizations to assess the food and nutrient intake of clients as an intermediate health outcome measure. Depending on the specific purpose, there are several traditional methods of measuring dietary intake: food frequency questionnaires, 24-hour recalls, and food records(112). Most recently, the ability to assess food and nutrient intakes for a community-based population was improved through the Automated Self-administered 24-hour Dietary Assessment Tool (ASA24) developed by the National Cancer Institute(113). This is a free web-based software tool available for clinicians, researchers, and community-based food and nutrition programs to collect and analyze 24-hour recalls or food records.

Once an organization such as MANNA registers with the ASA24 site, clients can enter details about foods, drinks, and dietary supplements consumed using a desktop computer, laptop, tablet, or smartphone. The ASA 24 system does not ask for or use any personal identifying information. Organizations specify a user ID for each client and then download system-generated usernames and encrypted passwords that clients would use to access ASA24. Client's dietary intake data are considered secure per industry standards such that only designated staff and the ASA24 operations team can access client data.

The ASA24 analysis includes 65 nutrients and 37 food groups, which are determined from the USDA's Food and Nutrient Database for Dietary Studies (FNDSS) and the National Health and Nutrition Examination Survey's Dietary Supplements Database(114) The ASA24 system is able to provide analytical reports to MANNA as well as nutrition reports to clients(113). The site's ability to provide dietary analysis information to clients allows it to be used for MNT, providing further support for sustained dietary changes as part of disease management.

Client-Reported Outcome Measures

The most promising valid and accessible outcome measures for community-based food and nutrition service providers in the future are likely in the realm of patient-reported outcomes (PROs). According to the US Food and Drug Administration, patient-reported outcomes are defined as "any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else"(115). Historically, measurement of PROs, especially quality of life measures, have been used extensively in clinical drug trials and other types of clinical research to determine how different therapeutic regimens or medical interventions affect a patient's health and function(116,117). However, measures were often developed for individual trials, leading to data that could not be easily compared between studies or applied to other uses in healthcare.

Recently, there has been increasing interest in applying patient-reported outcomes (PROs) to clinical care assessment, quality improvement processes, and performance measurement(117). The National Quality Forum, the primary national organization

focused on endorsing indicators for healthcare quality and performance has been at the forefront of the push to include the patient's perspectives about the experiences and results of their medical care(115). This has led to development of standardized instruments and tools called patient-reported outcomes measures (PROMs) which allow for quantification of patient's responses to questions about issues such as disease symptomology, physical health and function, emotional health, social and cognitive function, health behavior, and experience with healthcare(25).

A wide range of PROMs have been used to date in research and clinical practice(118). To improve and standardize assessment of clinical outcomes and identify quality indicators, the National Institutes of Health (NIH) funded the development of the next generation of PROMs as part of its 10-year "Roadmap for Medical Research Programs" begun in 2004(119). The result, funded by the NIH Common Fund, is called the Patient Reported Outcomes Measurement Information System (PROMIS®)(120). PROMIS® measures were developed using psychometrically sound techniques and methodology, including item response theory (IRT), from data collected at multiple research centers and with patients with a wide range of chronic diseases and demographic and socioeconomic characteristics(116,121). PROMIS® has better reliability, validity, precision, comparability, and disease-specific applicability than PROMs used previously (such as the Medicare Health Outcomes Survey historically utilized for patient reported outcomes measurements in Medicare) (117,122). In addition, qualitative item review was solicited in patient focus groups during the development of PROMIS® so measures also reflect item choices that are important to patients in regard to treatment outcomes(123).

Since medically-tailored food and nutrition services are considered an intervention during acute phase of life-threatening illness, use of PROMIS® can provide meaningful and validated client-reported outcomes that are similar to those obtained in relation to medical care(124). In addition, its outcomes measures hold several advantages for community-based food and nutrition service providers(125). First, PROMIS® is a free and publicly available resource available through HealthMeasures, the official information and distribution center for four NIH-supported measurement systems(121). PROMIS® also offers the ability to measure four domains of adult assessment including global, physical, mental and social health. An example of a short survey that measures global health is shown in Appendix E.

There are over 200 health measures available within PROMIS® to assess client-reported outcomes in one or more domains and surveys can be administered on paper, by computer, or with an app(126,127). HealthMeasures also provides guidance for assessing PROMs that focus on key domains in specific chronic diseases such as cancer and heart failure(125). Data collection can be minimized for best client compliance with surveys by use of short forms or by using computer-adaptive tests (CATs), also available through HealthMeasures(128). Preliminary evidence indicates that PROMs are well accepted by patients receiving routine medical care so acceptance would likely be similar for clients receiving community-based medically-tailored food and nutrition services(124).

Another advantage of PROMIS® measures for MANNA is that PROMs are assessed using standardized scores. PROMIS® measures use a T-metric where “50 is the mean for a relevant reference population and 10 is the standard deviation of that

population"(129). That allows specific scores for individuals or groups to be defined by how they compare to the scores of others in a reference population in that high and low scores show more or less of a particular measured domain. For example, high scores in the fatigue or physical function realms would indicate that clients have higher levels of fatigue or physical function than the reference population. Conversely, low scores in those realms would indicate that clients experience less fatigue or less physical function compared to the reference population. Changes in scores can also be measured longitudinally to show how PROMs change during and after medically-tailored food and nutrition services provided by MANNA(129).

An ongoing challenges in use of PROMIS® for evaluating the outcomes of food and nutrition services as well as for evaluating medical outcomes is establishing cut-off points that define an "acceptable state" or "meaningful change"(117,130,131). Recent strides were made in the definition of clinically meaningful differences when using PROMIS® for individuals during and after cancer treatment. There has been recently established US population-based reference values for symptom severity and functional status in newly diagnosed cancer patients by age, stage, and cancer type(132). There has also been a call to perform appropriate statistical analyses when interpreting group PROMs in nutrition research and clinical care in order to draw reliable and valid conclusions when using PROMs to support evidence-based care, programming, and policy development(133).

Even though PROMIS® was a NIH initiative, PROMs have gained wider use in clinical practice in other countries such as England and Sweden than in the United

States(134,135). This may be due to multiple factors including the US focus on the development of quality performance measures, largely in the form of process measures, which are in turn are used to compare outcomes between health care insurance plans (Healthcare Effectiveness and Data Information Set - HEDIS), healthcare organizations (CMS Quality Measures), hospitals (Leapfrog Survey) and physicians (Physician Quality Reporting System - PQRS)(136–139). Patient reported outcome measures can become National Quality Forum-verified quality measures, called patient reported-based outcome performance measures (PRO-PM), when enough data can be aggregated and applied to entities that are accountable for services delivered including hospitals, physician practices or accountable care organizations. Only one PROMIS® measure has been verified as a NQF quality measure to date: the PQH-9 (NQF #0711), which measures depression(115).

Current quality and performance measures used in healthcare have limited applicability in the assessment of health outcomes from community-based food and nutrition services because many are based on completing healthcare procedures and services (i.e. “process measures”). Nutrition-related examples in CMS’s electronic quality improvement measures are Hemoglobin A1C Control in Diabetes, Body Mass Index (BMI) Screening and Follow-up, and Controlling High Blood Pressure(140). Even while MANNA provides medically-tailored food and nutrition services that positively affect these health outcomes, to associate positive changes in these parameters with those services, measurements would have to be taken by healthcare providers and made available to MANNA at specific time points (i.e. before services begin and at pre-determined intervals during when services are received). Alternatively, MANNA staff

may take measurements directly from clients to show that medically-tailored food and nutrition services are associated with positive changes in A1C levels, BMI, and blood pressure measurements. Also notable is the fact that these and other measures of healthcare quality are affected by issues other than food and nutrition including but not limited to genetic factors, health status and behavior, healthcare access, food access and insecurity, family and social supports, socioeconomic and demographic characteristics, and environmental factors(23,141). Due to these multifactorial effects, it is possible that changes in biochemical parameters (A1C) or physical measurements (BMI, blood pressure) cannot adequately describe health outcomes from food and nutrition services. In contrast, PPOMs have the potential to more directly reflect effects of services because when they are collected by staff, clients can be encourages to answer how their physical, mental, and social health were specifically affected by medially-tailored food and nutrition services.

In conclusion, validated and accepted PROMs such as those found in PROMIS®, which measure global, physical, mental and social health, are applicable to MANNA and other *Food is Medicine* organizations who want to analyze and evaluate health outcomes data(121). PROMIS® measures provide ease of collection, analysis and reporting which can in turn be tailored to various stakeholders and communities of interest ranging from volunteers and donors to healthcare insurers, Medicare and Medicaid programs, hospitals and health systems, and healthcare providers. Increased collection of health outcome data using PROMIS® can also be used to advocate for reimbursement of services from health

insurers, thereby increasing long-term sustainability of community-based medically-tailored food and nutrition services.

Chapter 7 Discussion, Recommendations, and Conclusion

The purpose of this study was to assess a sample of client data to describe effects of medically-tailored food and nutrition services provided by MANNA, to solicit stakeholder input about the perceived and expected effects of services, and to present MANNA with recommendations for a framework for systematic evaluation. The following presents a synthesis and analysis of data collected for this study and provides recommendations with consideration of the organization's various stakeholders and its goal of becoming a reimbursable healthcare expense.

Mission and Client Characteristics

MANNA started out in 1990 as a charity whose mission was to provide food and palliative care to individuals dying from AIDS. In 2006, it expanded its mission to provide medically-tailored meals to individuals with other life-threatening diseases such as cancer, renal disease, heart disease, and diabetes, among others. This changed its mission from providing palliative food and nutrition to providing short-term medically-tailored meals together with nutrition education and counseling (lasting in most cases six months to 1 year). Their current mission is to help clients through an acute stage of illness until they are physically well and able to manage their food and nutritional needs independently.

As the mission has changed, so too has its client population. MANNA's mission includes providing services at no cost to its clients. Historically, clients with HIV/AIDs were likely from a wide demographic distribution. In contrast, most clients in this sample were older adults(age range 58-72) of low socioeconomic status (monthly income range

$598-$1300). Over half of the client sample reported that they did not have enough money to buy food each month. They were also medically complex: most experienced one or more co-morbidities and took five or more medications daily.

Staff and Board members consistently described that clients had varying needs and lacked support systems. What clients had in common is that they were at acute nutritional risk due to a life-threatening illness. MANNA formally addressed nutritional needs by providing complete therapeutic meal service and nutrition education and counseling so that clients could respond to medical treatment, learn to manage their diet, and get well again. MANNA also informally served as a social support system for clients through dietitian phone calls and driver contacts during meal delivery.

Getting well v. Staying Well

Both the chart and focus group data indicated that MANNA's client population has changed from one of "needing help to get well," to one of "needing help to stay well." Many of the illnesses that MANNA serves are chronic conditions that can be managed, however clients are not likely to recover from them. The goal after MANNA's program ends is for clients to be able to carry out a health-promoting or therapeutic diet independently. This goal may be difficult for clients to achieve due to limited financial resources, and the outright complexities of shopping for and preparing meals that satisfy low salt, low fat, diabetic, or other medically necessary regimes. How long services should last and for whom is an issue that MANNA described as crucial to their future planning.

Effects of Food and Nutrition Services

There were two main findings in the sample chart data regarding the effects of food and nutrition services. The MANNA client chart data indicated that the services supported weight maintenance in clients as shown by stable BMI over 6 months of service (median change in BMI = 0.04, interquartile range = -0.84, 1.02). Medical documentation also indicated that a lower proportion of clients in the sample had a recent hospitalization at the time of recertification (after 6 months of service) versus at initial intake (p=0.0077). Weight maintenance in clients during the study period indicates that MANNA is meeting its mission of nutritional support.

The fact that a significantly lower proportion of clients had a recent hospitalization after 6 months of service is consistent with prior MANNA research. The cause of this finding is unknown however one possibility is that nutritional support as evidenced by maintenance of BMI helped clients avoid preventable hospitalization(82).Another possibility is that since half of the client sample did not always have enough money to buy food, the provision of medically-tailored food may have alleviated financial strain, allowing clients to spend more on needed medical treatments such as medications(43). Since MANNA required clients to obtain medical approval for services, closer contact with medical providers may also have played a role. Last, other social determinants of health may have contributed to this effect including increased social support through the phone contact and nutrition counseling provided by MANNA's Registered Dietitians and/or driver contact during meal delivery(141).

The determination of outcomes from chart data had several limitations. The sample of chart data examined was similar to medical chart data (per the researcher's experience) because it consisted of demographic, medical, and nutritional data that described client characteristics and individual medical management of current illness and it was available on paper within client charts. Most MANNA client data to date had not been entered into a database due to limitations of their MealServe software program which focuses on meal service. Some medical and nutritional data was not measurable because it either consisted of open-ended questions with variable answers or was incomplete or missing and some laboratory values were no longer used to measure nutritional status per current assessment techniques. Body weight and height were the most consistently recorded measures of physical health, which led the researcher to calculate and analyze BMI as the most valid health outcome measure. Emotional health or quality of life were not quantified in the sample of client charts examined.

The effects of food and nutrition services were also shown by client comments from the MANNA 2016 Client Satisfaction Survey. Clients said the services "helped" them and that they felt more prepared to make healthy eating choices. Main themes were that the meals helped clients eat when they were weak from medical treatments or when food was hard to prepare due to disabilities. Clients also said that MANNA meals provided a healthy and balanced diet to help them get well, gave them enough food to eat when they couldn't afford to buy food, provided examples of the healthy food that they should eat, and helped to improve their food knowledge and eating behavior. The limitations of client survey data are that those who sent the survey back may have had

different experiences with MANNA's services than those who did not. The responses were overwhelmingly positive so may also be limited by response bias.

Stakeholder Focus Group Data

Key priorities for health outcomes from food and nutrition services were described by stakeholders as "client's health improves" or "clients get better". Getting better was a general term that applied to either physical or emotional improvement. Stakeholders described that physical improvement could be shown in strength, weight, and "other" health parameters collected in client charts. Stakeholders also described that MANNA services "lifted client spirits" and allowed clients to "worry less", suggesting that key priority outcomes for stakeholders were decreased depression and anxiety in clients. Both staff and Board thought that clients who get better should show improvements in both physical and emotional health. Clients who don't get better physically should still show improvement in emotional health with better nutrition. Last, all stakeholders described that it was essential that health improvements result in healthcare costs savings, potentially through less hospitalizations and shorter hospital stays. Limitations of the focus group data are that due to voluntary recruitment, not all staff and Board members that were invited to participate agreed to do so. Therefore, focus group data may not be a full reflection of all outcomes and impacts that are important to MANNA staff and Board of Directors.

Recommendations for Outcomes and Impacts for a Future Evaluation Framework

MANNA has described the effects and impacts of services in a variety of ways throughout its history. First, as a charity that provided palliative food to clients with AIDS, MANNA collected many stories of those who were grateful for the nourishment it provided. The tradition of client narratives continues today through staff and volunteer interaction with clients, thank you letters, client interviews, and annual client satisfaction surveys. The stories of how MANNA helps individual clients is important to both staff and Board alike, as was shown by the passionate way in which those stories were described within the focus groups. MANNA also uses client stories and comments extensively in its marketing materials (e.g. printed and electronic newsletters). A recent newsletter (Fall, 2017) contained the following client quote: *"I just wanted to thank you. I'm feeling really well. I'm learning to eat the right way. I'm starting to feel really strong. I'm very grateful".*

Around the time that MANNA transitioned to providing medically-tailored meals to clients with a range of life-threatening illnesses, they realized the need for objective measures to show the outcomes and impacts of their services. MANNA commissioned a private research group to design and conduct a research study to measure the effect of their food and nutrition services on healthcare utilization and costs. The results of that study were published in 2013 and showed that such services significantly decreased monthly healthcare costs, hospitalization rates, and duration of hospitalization, when compared to a matched control group(41).

MANNA has a rich history of providing food and nutrition services and has multiple stakeholder groups. Qualitative data is consistent with that history and continues to speak to those stakeholders (volunteers, staff, Board, and donors) who are committed to its role as a charitable organization. Long-term staff and Board members expressed that their affinity to Manna was based on providing "nourishment" to clients, a descriptive term that seemed to encompass social and emotional support in addition to medically-tailored food and nutrition services. In their narratives and stories clients have expressed gratitude for the "nourishment" they received,. Focus groups considered the collection of client stories as core to the MANNA history and tradition. Future qualitative research could include informal client reports, interviews, and surveys or more formal qualitative research studies.

One area of quantitative data to be considered within a framework for systematic evaluation is dietary intake data, an intermediate health outcome that is most directly related to food and nutrition services. Focus groups discussed that it was unknown what clients ate overall and whether clients continued their therapeutic diet after a MANNA program ended, even while clients reported improved nutrition knowledge and better eating behavior. Continuation of therapeutic diets may be difficult for clients to achieve due to limited financial resources and/or other competing priorities, even after nutrition education and counseling by dietitians. Therefore, MANNA could choose to collect quantitative dietary intake data during and after services using publicly available tools such as 24-hour recall methodology (ASA24) described in Chapter 6(114).

Another type of quantitative data that MANNA could consider collecting is patient-reported outcome measures (PROMs), specifically those that are part of the National Institutes of Health-supported Patient Reported Outcomes Measurement Information System (PROMIS®) as part of its framework for systematic evaluation(120). Currently MANNA could be considered as a quasi-healthcare organization, both in its provision of medically-tailored food and nutrition services for a range of nutritionally-related diagnoses and in its pursuit of health insurance reimbursement. Healthcare organizations increasingly provide "evidence-based" services supported by data showing their effectiveness.

Validated patient-reported outcome measures such as those available in PROMIS® would allow collection of data for assessment of physical and emotional health related to food and nutritional services.. In addition, client-reported measures of global health, as available in PROMIS® (Appendix E), may be more understandable to a wide range of stakeholder without a clinical background including most MANNA volunteers, staff, Board and donors. Last, patient-reported outcome measures such as those available within PROMIS® will likely be accepted by healthcare insurers as quality outcome measures in the future, which in turn could further support health insurance reimbursement and healthcare partnerships(142).

A final type of quantitative data to collect in the future is healthcare utilization and cost savings, which MANNA previously collected through a research study(41). Healthcare cost savings data will likely support the ability MANNA to contract with insurance companies as well as the broader advocacy efforts of *Food is Medicine*

organizations for health policy change. Notably, it is difficult to obtain this data because it is not under MANNA's direct control and may require data sharing agreements and/or develop further research studies.

Any outcome measures that MANNA chooses to consider within a framework for systematic evaluation in the future will likely need to be vetted through the lens of the US Preventative Services Task Force description of intermediate health outcomes and their relationship to health outcomes(76). Intermediate health outcomes are "pathologic, physiologic, social, or behavioral measures related to a preventive intervention" such as blood pressure, laboratory values, viral levels, dietary intake, etc. In contrast, health outcomes are defined as "outcomes that patients can experience or feel and affect how long a patient lives or the quality of life or both". The US Preventative Services Task force maintains that improvements in intermediate health outcomes alone are not enough evidence to approve a preventative intervention. Rather, interventions must affect how long a patient lives (reduced morbidity and mortality) or their quality of life(76). Patient-reported outcomes measures available within PROMIS® (Appendix E) include quality of life measures.

Therefore, MANNA could consider focusing its resources on the collection of patient-reported outcomes measures while minimizing the collection of physiologic health parameters to those necessary to qualify for food and nutrition services because of inherent difficulties in collection and assessment of these parameters, as described in Chapter 6. Reduced morbidity from an intervention implies healthcare cost savings, which is important to healthcare insurers even if not explicitly stated by the US

Preventative Services Task Force. Therefore, MANNA could consider using available resources to also pursue medical expenditure data.

With consideration of its multiple stakeholders and of the goal that food and nutrition services be reimbursed by healthcare insurance, the researcher recommends that MANNA consider including the following core measures within a future framework for systematic evaluation:

Quantitative Data

- Select demographic parameters related to health outcomes and healthcare costs including age, gender, race/ethnicity, education, household income and size, and health insurance.
- Food security and SNAP participation
- Primary medical diagnosis
- Co-existing medical conditions
- Current weight and height
- Weight history
- Dietary intake (ASA24)
- PROMIS® Global Health Scale
- Medical expenditure data (with partnerships for data access)

Qualitative data

- Client experiences via report and/or interviews
- Client survey responses (informal or research-based)

Conclusion

MANNA has a long history as a charitable community-based food and nutrition service organization serving clients with HIV/AIDS and has evolved to provide short-term medically-tailored food and nutrition services to clients with a variety of life-threatening illnesses. This organization is entering a new phase with its recent expansion and seeks to make its medically-tailored food and nutrition services more widely available by becoming a reimbursable healthcare benefit. With the advent of evidence-based medicine and value-based care, MANNA will need to show that its services are both effective and cost-saving to achieve that policy goal.

MANNA could choose to include both qualitative and quantitative data in a framework for systematic evaluation of the outcomes and impacts of its medically-tailored food and nutrition services to address the needs of its various stakeholder groups. Qualitative data in the form of client success stories and narratives may be important to stakeholders who are drawn to its charitable history. MANNA could also choose to collect and analyze select demographic variables and health measures, dietary intake data via the Automated Self-administered 24-Hour Recall System (ASA 24) and patient-reported outcome measures of physical and emotional health via Patient Reported Outcomes Measurement System, PROMIS®, for stakeholders who require quantifiable outcomes and impacts. Depending on its future service model(s), MANNA may also consider data sharing and research opportunities with healthcare organizations, health insurers, and academic institutions to further study the effects of medically-tailored food

and nutrition services on disease-specific health outcomes and healthcare utilization and costs.

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Appendix A IRB Approval Letters

USciences
University of the Sciences

INSTITUTIONAL REVIEW BOARD
www.irbnet.org · www.usciences.edu · **215-596-7490** · **Mail Stop 109**

Date:	January 6, 2017
Principal Investigator:	Jule Anne Henstenburg, BS, MS
Project Title:	[983916-2] Food is Medicine: Qualitative study of stakeholder views of a community-based food and nutrition service model at Metropolitan Area Neighborhood Nutrition Alliance (MANNA)

The Institutional Review Board has reviewed and approved using the *Expedited Review* process for the research protocol referenced above.**The study is approved: Start date: January 6, 2017 End date: November 30, 2017**. As the Principal Investigator of this study you assume the following reporting responsibilities:

COMPLIANCE: Principal Investigators and Co-investigators agree to: perform research as outlined and approved by the USciences IRB at all times during the active study; and disclose any financial conflicts of interests when research is sponsored and agree to notify the IRB in writing of any changes in interest during the study.

AMENDMENTS: Any changes in the approved research protocol or consent form must be approved by the IRB prior to implementation. Submit a request for protocol review form, completing only the sections that will change and check the "Amendment" box at the top of the form.

CONTINUING REVIEW: Investigators are required to apply for renewal of study at least 30 days prior to the study expiration listed above for as long as the study is active. IRBNet will attempt to notify you by e-mail before approval expires, but it is ultimately your responsibility to make sure your approval does not expire.

AUDIT OR INSPECTION REPORTS: Investigators are required to provide to the IRB a copy of any audit or inspection reports or findings issued to them by regulatory agencies, cooperative research groups, contract research organizations, the sponsor, or the funding agency.

ADVERSE EVENTS: Investigators must promptly report unanticipated problems or deviations from the approved protocol to the IRB using IRBNet. Serious events should be reported within 24 hours to Dr. Jean-Francois Jasmin at (irb@usciences.edu, 215-596-8512). Non-serious events should be reported in IRBNet to the IRB administrator (irb@usciences.edu, 215-596-7490).

COMPLETION: Notify the IRB when your study is completed (data analysis finished) or terminated Please complete the continuing review or termination report form which can be found in the IRBNet document library.

CONSENT FORMS/APPROVED DOCUMENTS: Investigators may only use the approved forms enclosed with this letter. All subjects should be given a copy of **the stamped approved** consent form. You must retain signed consent documents for at least three years past completion of the research activity.

Enclosures: Approved Consent Form - stamped copy must be used

Thank you for following up with this paperwork.

USciences
University of the Sciences

INSTITUTIONAL REVIEW BOARD
www.irbnet.org · www.usciences.edu · **215-596-7490** · **Mail Stop 109**

Date:	September 16, 2016
Exempt Date:	September 16, 2016
Principal Investigator:	Jule Anne Henstenburg
Project Title:	[942460-1] Food is Medicine: Evaluation of a community-based food and nutrition service model at Metropolitan Area Neighborhood Nutrition Alliance (MANNA)

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*Code of Federal Regulations, Title 45, Part 46 for the Protection of Human Subjects **EXEMPTS** your project from IRB Review. According to Subpart A, 46.101, section b:*

☐ 1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

☐ 2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

☐ 3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

☒ 4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

☐ 5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

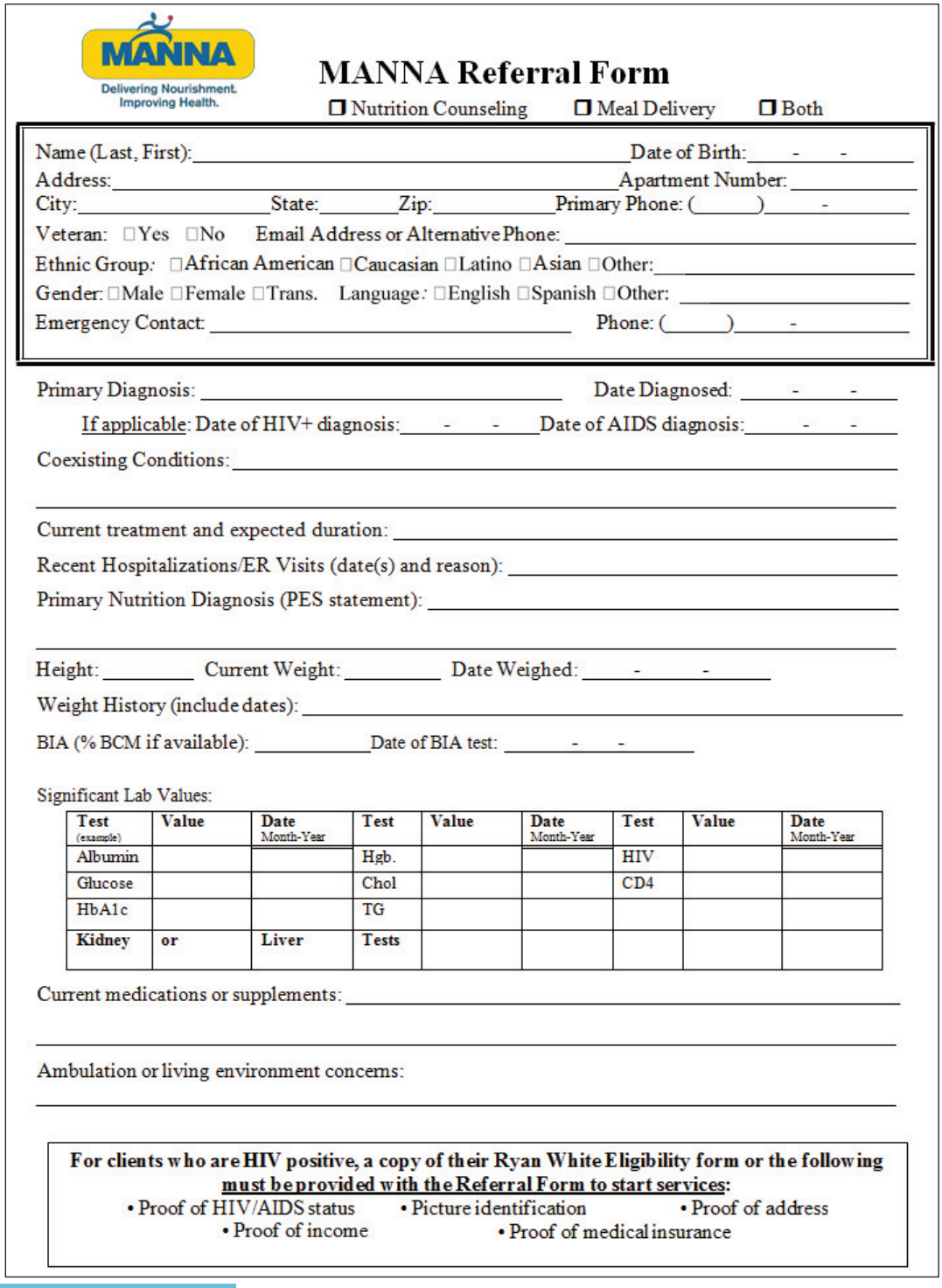
☐ 6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Though the above referenced Protocol is exempt; if there are any changes to this Protocol you are required to submit an amendment to the IRB Committee before instituting these changes.

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within the IRB Administrator's records.

Appendix B MANNA Forms

Referral Form



MANNA
Delivering Nourishment. Improving Health.

MANNA Referral Form

❒ Nutrition Counseling ❒ Meal Delivery ❒ Both

Name (Last, First): _____ Date of Birth: ____ - ____ - ____
Address: _____ Apartment Number: _____
City: _____ State: _____ Zip: _____ Primary Phone: (____) ____ - ____
Veteran: □Yes □No Email Address or Alternative Phone: _____
Ethnic Group: □African American □Caucasian □Latino □Asian □Other: _____
Gender: □Male □Female □Trans. Language: □English □Spanish □Other: _____
Emergency Contact: _____ Phone: (____) ____ - ____

Primary Diagnosis: _____ Date Diagnosed: ____ - ____ - ____
If applicable: Date of HIV+ diagnosis: ____ - ____ - ____ Date of AIDS diagnosis: ____ - ____ - ____
Coexisting Conditions: _____
_____
Current treatment and expected duration: _____
Recent Hospitalizations/ER Visits (date(s) and reason): _____
Primary Nutrition Diagnosis (PES statement): _____
_____
Height: _____ Current Weight: _____ Date Weighed: ____ - ____ - ____
Weight History (include dates): _____
BIA (% BCM if available): _____ Date of BIA test: ____ - ____ - ____

Significant Lab Values:

Test (example)	Value	Date Month-Year	Test	Value	Date Month-Year	Test	Value	Date Month-Year
Albumin			Hgb.			HIV		
Glucose			Chol			CD4		
HbA1c			TG					
Kidney	**or**	**Liver**	**Tests**					

Current medications or supplements: _____
_____
Ambulation or living environment concerns:
_____

For clients who are HIV positive, a copy of their Ryan White Eligibility form or the following must be provided with the Referral Form to start services:
• Proof of HIV/AIDS status • Picture identification • Proof of address
• Proof of income • Proof of medical insurance

Medical Care Provider Information: (Must be completed if applicable.)

Name of Doctor:_____Organization:_____

Phone:(_____)_____-_____ Fax :(_____)_____-_____

Email Address:_____

Name of Dietitian:_____Organization:_____

Phone:(_____)_____-_____ Fax :(_____)_____-_____

Email Address:_____

Name of SW/CM:_____Organization:_____

Phone:(_____)_____-_____ Fax :(_____)_____-_____

Email Address:_____

Eligibility for admission to our program is subject to approval by MANNA.
If your client does not meet our eligibility criteria, our Client Services department will gladly refer your client to another community resource. Our eligibility criteria does not include individuals that may have an inability to shop and cook for themselves due to poverty, mental illness, his/her advanced age and frailness, chronic disease or physical syndrome that he/she has had since birth.

All referral forms are evaluated by the nutrition staff at MANNA. If the client qualifies for the meal program they will be placed on the service for six months and a stop date will be determined at the time of intake. The nutrition staff will follow-up with the client and the Referral Source the month prior to the stop date to complete a Recertification to determine if the client requires and qualifies for additional time on the program. **If you feel your client's services would be for a shorter duration please provide an estimate:_____number of months**

A Recertification will occur in five months from the start of the client's services with MANNA.
Will you continue to follow this client? ❒ Yes ❒ No,
If not, who will? _____

Referral Source Information:

Name:_____Organization: _____

❒Case Manager ❒Social Worker ❒Registered Dietitian ❒Doctor ❒Nurse ❒Other _____

Phone:(_____)_____-_____ Fax :(_____)_____-_____

Street Address: _____

Email Address: _____

How do you prefer to be contacted? ❒ Telephone ❒ Fax ❒ Email

Referral Signature:_____ **Date:** _____

Failure to have the client sign the third page will result in inability to start MANNA services.

Release of Medical Information and Client Agreement

Privacy Notice:

I, Mr./Ms.*_____authorize MANNA to release any relevant information to my care providers. This release is reciprocal, i.e., I am giving my permission for all parties identified above to communicate back and forth with one another. I understand that all information obtained by MANNA will remain confidential and will only be available to MANNA staff and volunteers as necessary for me to receive services. I am aware that I may rescind this authorization any time by notifying MANNA in writing.

Client Signature:_____Date:_____

MANNA MEAL DELIVERY PROGRAM
Release of Liability and Client Agreement

I understand that I am participating in the MANNA meal delivery program (the "Meal Delivery Program"), in which food prepared by MANNA will be delivered to my home by a MANNA staff member or volunteer (a "MANNA Person"). In exchange for my being allowed to participate in the Meal Delivery Program, I agree to the following:

- I am aware that services from MANNA are free of charge and that it is a temporary program.
- **I agree to be home between the hours of 8:00am to 5:00pm on my delivery day to get my meals**. I must call at least one day ahead to cancel or change my delivery, 215-496-2662 x2.
- I understand that if I miss 2 deliveries in 4 weeks or 6 deliveries in six months, MANNA has the right to stop and/or cancel my services.
- I agree to call Client Services right away to inform them of any changes in my address or phone number. 215-496-2662 x117
- I will treat MANNA staff and volunteers with respect and will not be improper or verbally/physically abusive to staff or volunteers. Failure to comply will result in cancellation of service.
- I know that all clients must agree to follow these rules and that MANNA has the right to stop and/or cancel services at any time if I do not comply with these set rules.
- I assume all risks, known and unknown, foreseeable and unforeseeable, in any way connected with or arising out of my participation in the Meal Delivery Program. I accept personal responsibility for any liability, injury, loss, or damage in any way connected with my participation in the Meal Delivery Program.
- I hereby release MANNA and its affiliates, directors, employees, agents, volunteers, donors, representatives, successors, and assigns (each, a "MANNA Party"), from any and all liability for and waive any and all claims for injury, loss, or damage, including attorneys' fees, in any way connected with my participation in the Meal Delivery Program (a "Claim"). This release does not impact my ability to bring claims against MANNA or a MANNA Party for such party's gross negligence or criminal actions.
- This Agreement shall be binding upon my heirs, executors and administrators, and shall inure to the benefit of MANNA and each MANNA Party.

Client signature Date

Please fax forms to (215) 496-9102, Attention: Client Services
Or mail to: MANNA Client Services
420 North 20th Street, Philadelphia, PA 19130

Please call Client Services at 215-496-2662 x5 with any concerns or questions.

Nutrition Telephone Assessment Form

MANNA
Delivering Nourishment. Improving Health.

MANNA Nutrition Telephone Assessment

Client (Last, First): _____ Phone: (___) ___-_____
Address: _____ Apartment Number: _____
City: _____ State: _____ Zip: _____

Current Medical Condition:

Current treatment modality: _____

Recent Hospitalizations: _____

HIV Mode of Transmission: _____ HIV/AIDS Dx date: _____

Current Nutrition Status:

Most recent weight: _____ date of weight: ___-___-_____ Height: _____

UBW: _____ date of weight: ___-___-_____ Weight Status: _____

Chewing/ Swallowing Problems: _____

Diet Restrictions or Food Allergies: _____

Access to Food/Meal Prep: _____

How many meals/day? _____

Nutritional Risk Factors: _____

Demographics:

Marital Status: Married Single Divorced Separated Widow/Widower

Veteran? _____

Lives Alone: Yes No Number of People in Household: _____

Monthly Income: _____ Income Source: _____

Primary Medical Insurance: Private Medicare Medicaid No Insurance Other

House/ Living Arrangements: Permanent Non-Permanent Other

Full Functioning Kitchen: Yes No

Nutrition Plan:

Complete Nutrition: _____ Supplemental: _____

Day: Tues Wed Thurs Fri

Date of First Delivery: ___/___/_____

Diet: _____

Anything that prevents the client from answering the door in 5-10 minutes of the driver getting there? _____

Delivery Instructions: _____

Media: (Clients/family members who are willing to participate in media opportunities)

____ Write a letter ____ Speak at a MANNA event

____ Interviewed off camera ____ Interviewed on camera

Health Update Form

MANNA
Delivering Nourishment. Improving Health.

Health Update Form for Recertification
Please supply health information within 7 days

Patient's Name (Last, First): _____ DOB: _____

Patient Phone #: _____

Current Medical Condition:

Date of most recent appointment: ____-____-____

Current diagnosis and treatment plan: _____

_____

Medications/Supplements: _____

Recent Hospitalizations (date, reason, length of stay): _____

Current Nutrition Status:

Most recent weigh (**Very Important, must provide!**): _____ Date: ____-____-____

BIA test (if available): _____% BCM date: ____-____-____

Current Nutrition Concerns (PES Statement):

_____

_____

If applicable: Date of HIV diagnosis: ____-____-____ Date of AIDS diagnosis: ____-____-____

Significant Nutrition Lab Values (if available):

Test (example)	Value	Date Month-Year	Test	Value	Date Month-Year	Test	Value	Date Month-Year
Albumin		___-___	Hgb/Hct		___-___	VL		___-___
Prealbumin		___-___	Chol		___-___	CD4		___-___
HbA1c		___-___	TG		___-___			___-___

Provider Name: _____ **Agency:** _____

Phone:(_____)_____-_____ Fax :(_____)_____-_____

Email: _____

Relation to consumer: ❒Case Manager ❒Social Worker ❒Registered Dietitian
❒Home Health Worker ❒Doctor ❒Nurse ❒Other _____

Provider Signature: _____ Date: _____

For clients who are HIV positive, a copy of a Ryan White Eligibility card or the following must be provided:

- Proof of HIV/AIDS status
- Picture identification
- Proof of address
- Proof of income
- Proof of medical insurance

Please fax completed form to (215) 496-9102, Attn: Client Services
Concerns? Please call 215-496-2662 x117.

Recertification Form

MANNA
Delivering Nourishment. Improving Health.

Recertification Information

Date:_____ Client ID:_____

Client: _____ Phone # _____

Healthcare Provider: _____ MD RD CM/SW CRNP RN OTHER
Phone# _____ Fax# _____
Date most recent visit: _____
Changes in health or treatment: _____

Have you been hospitalized in the past 6 months? # of times_____ # of days_____
Reason for Hospitalization: _____

Most Recent Weight: _____ Date: _____
Current nutrition concerns: _____

Are you able to maintain your nutritional health at this time without the MANNA meals?
YES NO _____

Over the past 6 months do you feel MANNA'S meal service has helped with:

- Improving your overall health. _____
- Increasing the number of meals you eat per day. _____
- Improving your energy/fatigue level. _____
- Improving your emotional health/coping skills. _____
- Improving your understanding of healthy foods. _____
- Decreasing your stress of preparing healthy foods independently. _____

Would you be willing to participate in future media opportunities?
____ Write a letter ____ Speak at a MANNA event
____ Interviewed off camera ____ Interviewed on camera

_____

☐ The client above was reminded that eligibility to continue to receive MANNA meals is dependent on receiving a health update and nutrition assessment from his or her health care provider.

☐ The client is no longer under medical care or nutrition care is not eligible for meal service.

☐ The client expressed that he or she no longer needs the services and is currently nutritionally stable.

Signature of MANNA staff_____ Date _____

Annual MANNA Satisfaction Survey 2016

Please take the time to answer the following questions to help us to improve your experience with MANNA and give it to your driver next week.

1. Overall, how satisfied are you with the MANNA program?

Very Satisfied ..... ☐ 1
Somewhat Satisfied ..... ☐ 2
Somewhat Dissatisfied ..... ☐ 3
Very Dissatisfied ..... ☐ 4

Think about all the foods that you receive from MANNA meals. Please tell us, how often you are satisfied…

	Always	Usually	Some-times	Rarely	Never
2. With the way the food smells.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
3. With the way the food looks	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
3. With the way the food tastes	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
4. With the variety of foods	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
5. With the way the food is cooked.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Additional information about your MANNA meals …

6. The food is too salty.
Yes ..... ☐ 1
No..... ☐ 2

7. The food is too hot or spicy.
Yes ..... ☐ 1
No..... ☐

8. It tastes like homemade food I used to cook.
Yes ..... ☐ 1
No..... ☐ 2

9. The food is healthy and meets my medical needs.
Yes ..... ☐ 1
No..... ☐ 2

10. MANNA provides quality food each week.
Yes ..... ☐ 1
No..... ☐ 2

The next few questions ask about foods or groups of foods that you eat from your home-delivered meals.

9. When you eat the MANNA meals, do you usually eat the **fruit** when it is provided?
Yes ..... ☐ 1
No..... ☐ 2

10. When you eat the MANNA meals, do you usually eat the **vegetables** that are provided?
Yes ..... ☐ 1
No..... ☐ 2

11. When you eat the MANNA meals, do you usually eat or drink the **soy milk, cheese, yogurt, or mighty shakes** that are provided?
Yes ..... ☐ 1
No..... ☐ 2

12. When you eat the MANNA meals, do you usually eat the **meat, turkey, chicken, or fish** that is provided?
Yes ..... ☐ 1
No..... ☐ 2

13. When you eat the MANNA meals, do you usually eat the **cereal, rice, pasta, or noodles** when they are provided?
Yes ..... ☐ 1
No..... ☐ 2

14. When you eat the MANNA meals, do you usually eat the **dessert** when it is provided?
Yes ..... ☐ 1
No..... ☐ 2

The following questions are about the quality of the meals you receive.

15. How would you rate the quality of MANNA meals overall? Would you say…
Excellent ..... ☐ 1
Very good..... ☐ 2
Good..... ☐ 3
Fair ..... ☐ 4
Poor ..... ☐ 5

Please answer the following questions about the MANNA meals program. Do services received from the MANNA meals program help you to…

		Yes	No
16.	Eat healthier foods	☐ 1	☐ 2
17.	Achieve or maintain a healthy weight	☐ 1	☐ 2
18.	Improve your health.....	☐ 1	☐ 2
19.	Feel better.....	☐ 1	☐ 2
20.	Continue to live at home.....	☐ 1	☐ 2
21.	Decrease amount of hospitalizations	☐ 1	☐ 2

The next questions are about resources.

22. Do you always have enough money or food assistance/food stamps/SNAP to buy the food you need?
Yes ..... ☐ 1
No..... ☐ 2

23. During the past month, did you have to choose between buying food or buying medication?
Yes ..... ☐ 1
No..... ☐ 2

24. During the past month did you have to choose between buying food or paying your rent or utility bills?
Yes ..... ☐ 1
No..... ☐ 2

25. On one or more days during the past month, did you skip meals because you had no food and no money or food assistance/food stamps/SNAP to buy food?
Yes ..... ☐ 1
No..... ☐ 2

26. How do you access the internet?
Home computer..... ☐ 1
Public computer (ex: free library)..... ☐ 2
Smart phone ..... ☐ 3
Laptop or Tablet..... ☐ 4
I do not have access to the internet. ..... ☐ 5

27. Would you be interested in receiving nutrition tips or survey questions online?
Yes ..... ☐ 1
No..... ☐ 2

Please tell us:

		Yes	No
26.	Does MANNA provide you with too much food?.....	☐ 1	☐ 2
27.	Does MANNA provide you with not enough food?.....	☐ 1	☐ 2
28.	The drivers are nice and helpful?.....	☐ 1	☐ 2
29.	The food is packed well & comes without damage?	☐ 1	☐ 2
30.	Do you know how to call MANNA with questions?.....	☐ 1	☐ 2
31.	Are the heating instructions helpful?	☐ 1	☐ 2
32.	Do you know that you can speak with a dietitian for free at MANNA?.....	☐ 1	☐ 2
33.	Have you had any appointments with a dietitian on staff at MANNA?.....	☐ 1	☐ 2
34.	Would you recommend the MANNA meals to a friend?	☐ 1	☐ 2
35.	In general, would you say that the MANNA meals service has helped you?.....	☐ 1	☐ 2

35a. How has the MANNA meals service helped you?

_____

_____

36. In general, do you feel more prepared to make healthy eating choices after the MANNA meals service?
Yes ..... ☐ 1
No..... ☐ 2

36a. If so, how has the MANNA meals service helped you better understand nutrition?

_____

_____

37. Do you have any recommendations to improve the MANNA meals service?
Yes ..... ☐ 1
No..... ☐ 2

37a. What recommendations do you have for improving the service?

_____

_____

Thank you for completing the Survey!!! Please provide us with your contact information:

Name: _____

Address: _____

Phone Number(s): _____

Appendix C REDCap Project Data and Definitions

Demographics	**Fields**
Age	Form category: MANNA Referral Form, "Date of Birth". Changed to age for HIPAA compliance.
Ethnic group	Form category: MANNA Referral Form, "Ethnic Group". Categories are same as listed on form: African American, Caucasian, Latino, Asian, and Other.
Gender	Form category: MANNA Referral Form, "Gender". Categories are same as listed on form: Male, Female, and Trans.
Language	Form category: MANNA Referral Form, "Language". Categories are same as listed on form: English, Spanish, and Other.
Marital Status	Form category: MANNA Nutrition Telephone Assessment, "Marital Status". Categories are same as listed on form: Married, Single, Divorced, Separated, and Widow/Widower.
Veteran	Form category: MANNA Nutrition Telephone Assessment, "Veteran". Written answer: yes/no.
Lives Alone	Form category: MANNA Nutrition Telephone Assessment, "Lives Alone". Categories are same as on form: yes/no.
Number of People in Household	Form category: MANNA Nutrition Telephone Assessment, "Number of People in Household". Categories are numbers as per written response.
Monthly Income	Form category: MANNA Nutrition Telephone Assessment, "Monthly Income". Textbox for written answer.
Income Source	Form category: MANNA Nutrition Telephone Assessment, "Income Source". Categories correspond to those listed in Meal Service: SSI, TANF, Food Stamps, None, and Other; "other "category provides for additional written answers.
Living Arrangements	Form category: MANNA Nutrition Telephone Assessment, "House/Living Arrangements". Categories are same as listed on form: Permanent, Non-Permanent, and Other.

Full Functioning Kitchen	Form category: MANNA Nutrition Telephone Assessment, "Full Functioning Kitchen". Categories are same as on form: yes/no.
Medical Information – Initial	**Fields**
Reason for referral	Form category: MANNA Referral Form. Answers correspond to form categories: Nutrition Counseling, Meal Delivery, Both.
Primary Diagnosis	Form category: MANNA Referral Form, "Primary Diagnosis". Categories are most common conditions listed on MANNA referral form; "other" category provides for additional written answers for primary diagnosis.
Date diagnosed	Form category: MANNA Referral Form, "Date Diagnosed". Answer: written date.
Co-existing conditions	Form category: MANNA Referral Form, "Coexisting Conditions. Categories are most common conditions listed on MANNA referral form; "other" category provides for additional written answers. Note: multiple answers allowed.
Primary treatment	Form category: MANNA Referral Form, "current treatment and expected duration". Categories for primary treatment are most common written answers and correspond to current diagnosis categories; "other" category provides for additional written answers. Duration is not noted due to lack of natation on MANNA referral forms.
HIV status	Form category: MANNA Referral Form, "date of HIV+ diagnosis". Answer: yes/no based on information in Meal Service program. Date is not noted due to lack of natation on MANNA referral forms or within Meal Service program.
Recent hospitalizations	Form category: MANNA Referral Form, "Recent hospitalizations/ER visits (date(s) and reason)". Answer: yes/no; if yes, textboxes allows for reason and date per below.
Reason for hospital visit	Form category: MANNA Referral Form, "Recent hospitalizations/ER visits (date(s) and reason". If yes, reason noted as written answer in text box. .

Date of hospitalization	Form category: MANNA Referral Form; "Recent hospitalizations/ER visits (date(s) and reason". If yes, date answer.
Initial lab values	Form category: MANNA Referral Form "significant lab values". Textboxes correspond to lab value categories designated on form; "other" category allows additional written lab value(s). Date is not noted due to general lack of natation or lack of full date on MANNA Referral Form.
Medications	Form category: MANNA Referral Form, "current medication or supplements". Answer: yes/no based on whether medication is written in or noted as "none".
Number of medications	Form category: MANNA Referral Form, "medication/supplements". Medications are categorized by number corresponding to what is considered a small number of medications vs polypharmacy (defined as 5 or greater medications). This categorization is due to inability to accurately read handwritten listingsof medications on form.
Meal supplements	Form category: MANNA Referral Form, "current medication or supplements". The definition of supplements in this research is liquid meal supplement or meal replacement products.
Ambulation or living environment concerns	Form category, MANNA Referral Form, "Ambulation or living environment concerns" Answer: yes/no from written response; if yes, text box for comments.
Primary medical insurance	Form category, MANNA Nutrition Telephone Assessment, "Primary Medical Insurance". Categories correspond to those listed on form: Private, Medicare, Medicaid, No Insurance, and Other.
Healthcare providers	Form category, MANNA Referral Form, "Medical Care Provider Information". Categories correspond to those listed on form: "Doctor, Dietitian, and SW/CM"; "other" category for none of these healthcare providers.
Referral source	Form category, MANNA Referral Form, "referral sources information". Categories correspond to those listed on form: Case Manager, Social Worker, Registered Dietitian, Doctor, Nurse, and Other.

Referral organization	Form category, MANNA Referral Form, "referral sources information". Textbox for written answer.
Referral date	Form category, MANNA Referral Form, "Date". Answer: written date.
Nutrition Information – Initial	**Fields**
Primary Nutrition Diagnosis	From category: MANNA Referral Form, "Primary Nutrition Diagnosis (PES statement)". Categories are most common nutrition diagnoses listed on MANNA Referral Form; "other" category provides for additional written answers for primary diagnosis.
Height	Form category: MANNA Referral Form, "Height". Answer: textbox is height in inches.
Current Weight	Form category: MANNA Referral Form; "Current weight" (primary sources) or MANNA Nutrition Telephone Assessment, "Most recent weight" (secondary source). Answer: textbox is weight in pounds.
Date of most recent weight	Form category: MANNA Referral Form, "Date weighted" (primary source) or MANNA Nutrition Telephone Assessment, "date of weight" (secondary source). Answer: written date.
BMI	Calculation: BMI calculated from current weight and height.
Usual body weight	Form category: MANNA Nutrition Telephone Assessment, "UBW" or MANNA Referral Form, "Weight history (include dates)". MANNA Referral Form primary source if usual body weight is listed on the weight history line. MANNA Nutrition Telephone Assessment is secondary source if "UBW" is listed. When both are available, matching weights are used as the final data point whenever possible.

Weight history	Form category: MANNA Nutrition Telephone Assessment, "UBW" or MANNA Referral Form, "Weight history (include dates)". Categories are increasing, decreasing or stable per inference from forms. MANNA Referral Form primary source if weight changes are listed on the weight history line. MANNA Nutrition Telephone Assessment is secondary source if "weight status" is noted as increasing, decreasing or stable. When both are available, comparison of answers is used in the final data point whenever possible.
BIA and Date of BIA	Form category: MANNA Referral Form, "BIA (%BCM if available) and "Date of BIA test".
Chewing/swallowing problems	Form category: MANNA Nutrition Telephone Assessment, "Chewing/Swallowing Problems" Answer: yes/no.
Diet restrictions/Food Allergies	Form category: MANNA Nutrition Telephone Assessment, "Diet restrictions/Food Allergies" Answer: yes/no. If yes, textbox is written comments.
Physician Approval of MANNA meals service?	No form category. If yes to "Diet Restrictions/Food Allergies", physician approval of MANNA meals service based on signed approval form present in client chart. Answer: yes/no.
Access to food/meal prep	Form category: MANNA Nutrition Telephone Assessment, "Access to Food/Meal Prep". Categories: self, has help, needs help, or no help available. Categories are based on most common answers noted on MANNA Nutrition Telephone Assessment; "other" category provides for additional written answers.
Who helps with food/meal prep?	No form category: MANNA Nutrition Telephone Assessment, "Access to Food/Meal Prep" Categories: family, friend, neighbor, or organization/agency. Categories are based on most common written comments by Registered Dietitians (personal communication with head Dietitian and chart reviews).
How many meals/day?	Form category: MANNA Nutrition Telephone Assessment, "Access to Food/Meal Prep". Categories listing number of meals/day are most common responses on form.

Nutritional Risk factors	Form category: MANNA Nutrition Telephone Assessment, "Nutritional Risk Factors". Categories: good appetite, fair appetite, poor appetite, improving appetite, or variable appetite. Categories are based on most common answer noted on form; "other" category provides for additional written answers.
Meal Information	**Fields**
Nutrition: Complete or supplemental	Meal Service category: Service/Diet, delivery service. Categories same as listed: complete or supplemental.
Meal start date	Meal Service category: Status/Dates, meal start date. Answer: date listed.
Diet modification	Meal Service category: Status/Dates, Diet modifications. Categories are currently available diet modifications.
Counseling events, initial	Meal Service category: Health/Nutrition, Counseling events. Categories are same as listed: client intake (intake data alone) or Life Span Counseling Session (Nutrition Counselingconducted with intake data) per personal communication with head Dietitian.
Counseling events, recertification	Meal Service program category: Health/Nutrition, Counseling events. Categories: number of re-certifications listed (up to maximum 3 per defined time frame of sample).
Meals current or stopped	Meal Service category: Status/Dates, current or stopped. Categories are same as listed: current or stopped.
Reason for stopping meals	Meal Service program category: Status/Dates, reason for stopping. Categories are reasons for stopping meals as listed in Meal Service program.
Medical Information – Recertification	**Fields**
Recertification date	Meal Service category: Status/Dates, recertification date. Answer: date listed.
Most recent medical appointment	Form category: Health Update Form for Recertification, "Date of most recent appointment". Answer: written date.

Current diagnosis recertification	Form category: Health Update Form for Recertification, "Current diagnosis and treatment plan". Categories based on most common diagnoses listed on form; "other" category provides for additional written answers. Note: responses correspond to "primary diagnosis" on MANNA Referral Form, therefore, categories are the same.
Treatment plan update	Form category: Health Update Form for Recertification, "Current diagnosis and treatment plan". Categories for treatment are most common written answers on form and correspond to current diagnosis categories; "other" category provides for additional written answers. Note: responses correspond to "primary diagnosis" on MANNA Referral Form, therefore, categories are the same.
Medications, recertification	Form category: Health Update Form for Recertification, "medication/supplements". Categories: yes/no, based on whether medication are written in or noted as "none".
Number of Medications recertification	Form category: Health Update Form for Recertification, "medication/supplements". Medications are noted as a number category corresponding to what is considered a small number of medications vs polypharmacy (defined as 5 or greater medications). This categorization is due to inability to accurately read handwritten listingsof medications on form.
Supplements recertification	Form category: Health Update Form for Recertification, "medication/supplements". The definition of supplements for the purpose of this research project is liquid meal supplements or meal replacement products.
Recent hospitalizations recertification	Form category: Health Update for Recertification Form (primary source) "Recent hospitalizations (date, reason, length of stay)" and MANA Recertification Information form, "Have you been hospitalized in the past 6 months?" (# times, # days) (secondary source). Categories: yes/no based on written responses.

Date, Number of days	Form category: Health Update for Recertification Form (primary source) "Recent hospitalizations (date, reason, length of stay)" (primary source) and MANA Recertification Information form "Have you been hospitalized in the past 6 months?" (# times, # days) (secondary source). If yes to recent hospitalizations: written date and text box for number of days.
Reason	Form category: Health Update for Recertification Form, "Recent hospitalizations (date, reason, length of stay)", Health Update for Recertification Form (primary) and MANA Recertification Information form "Reason for hospitalization". Text box for written response.
FU lab values	Form category: Health Update for Recertification Form, "significant nutrition lab values". Textboxes correspond to lab value categories designated on form; "other" category allows additional written lab value(s). Date is not noted due to general lack of notation or lack of full date on form.
Provider recertification type	Form category: Health Update for Recertification Form, "provider name" and "relation to consumer". Categories correspond to those listed on form: Case Manager, Social Worker, Registered Dietitian, Home Health Worker, Doctor, and Nurse; "other" category provides for additional written answers.
Provider agency	Form category: Health Update for Recertification Form, "agency". Text box for written answer.
Nutrition Information – Recertification	**Field**
Most recent weight	Form category: Health Update for Recertification form, "most recent weight (very important, must provide!)" (primary sources) or MANA Recertification Information form (secondary source).
Date of weight measurement	From category: Health Update for Recertification form, "most recent weight (very important, must provide!)" (primary source) or MANA Recertification Information form (secondary source).
BIA value recertification and BIA date recertification	Form category: Health Update for Recertification form, "BIA test (if available), %BCM and date.

Current Nutrition Concerns (PES Statement)	From category: Health Update for Recertification form "Current Nutrition Concerns (PES Statement)"; "other" category provides for additional written answers. Note: responses correspond to "primary nutrition diagnosis" on MANNA Referral Form, therefore, categories are the same.
Changes in health or treatment?	Form category: MANNA Recertification Information form "Changes in health or treatment". Categories from written responses: yes/no; if yes, text box for comments.
Current Nutrition Concerns	Form category: MANNA Recertification Information form "Current Nutrition Concerns". Categories are based on the most common written answers: good appetite, fair appetite, poor appetite, improving appetite, or variable appetite; "other" category provides for additional written answers.
Number of meals eaten per day?	No form category. Categories for number of meals eaten/day are based on the most common written answers on "Current Nutrition Concerns" line; "other" category provides for additional written answers.
All or some MANNA meals?	No form category. Categories: all MANNA meals, mostly MANNA meals, or some MANNA meals. Categories are based on the most common written answers on "Current Nutrition Concerns" line. Head Registered Dietitian verified that no written response after "number of meals eaten per day" means "all MANNA meals" (personal communication).
Able to maintain nutritional health without MANNA meals?	Form category: MANNA Recertification Information form, "Able to maintain your nutritional health at this time without the MANNA meals?". Categories: yes/maybe/no; "other" category provides for additional written answers.
Improved overall health?	Form question: MANNA Recertification Information form. Questions begins with: Over the past 6 months do you feel MANNA meal service has helped with: Improving your overall health? Yes/No
Increased number meals eaten per day?	Form question: MANNA Recertification Information form. Questions begins with: Over the past 6 months do you feel MANNA meal service has helped with: Increasing the number of meals you eat per day? Yes/No

Improved energy/fatigue level?	Form question: MANNA Recertification Information form. Questions begin with: Over the past 6 months do you feel MANNA meal service has helped with: Improving your overall energy/fatigue level? Yes/No
Improved emotional health/coping skills?	Form question: MANNA Recertification Information form. Questions begins with: Over the past 6 months do you feel MANNA meal service has helped with: Improving your emotional health/coping skills? Yes/No
Improved understanding of healthy foods?	Form question: MANNA Recertification Information form. Questions begins with: Over the past 6 months do you feel MANNAmeal service has helped with: Improving your understanding of health foods? Yes/No
Decreased stress of food preparation?	Form question: MANNA Recertification Information form. Questions begins with: Over the past 6 months do you feel MANNA meal service has helped with: Decreasing your stress of preparing foods independently? Yes/No
Willing to participate in future media opportunities?	Form category: MANNA Recertification Information form, "Would you be willing to participate in future media opportunities?". Categories: Yes/No, based on answer most noted on form.
Client Satisfaction Survey 2016	**Fields**
Overall, how satisfied are you with the MANNA program?	Form question: MANNA Annual Client Satisfaction Survey, 2016, "Overall, how satisfied are you with the MANNA program?" Categories same as listed on form: very satisfied, somewhat satisfied, somewhat dissatisfied, very dissatisfied.
How would you rate the quality of MANNA meals overall?	Form question: MANNA Annual Client Satisfaction Survey, 2016, "How would you rate the quality of MANNA meals overall? Would you say…" Categories same as listed on form: excellent, very good, good, fair, poor.

Do MANNA Meals: Help you eat healthier foods? Help you achieve a healthy body weight? Help you to improve your health? Help you to feel better? Help you to continue to live at home? Help decrease the amount of hospitalizations?	Form question: MANNA Annual Client Satisfaction Survey, 2016. "Please answer the following questions about the MANNA meals program. Do services received from the MANNA meals program help you to… eat healthier foods, achieve or maintain a healthy weight, improve your health, feel better, continue to live at home, decrease amount of hospitalizations"?Yes/No
Do you always have enough money or food assistance to buy the food you need?	Form question: MANNA Annual Client Satisfaction Survey, 2016. "Do you always have enough money or food assistance/food stamps/SNAP to buy the food you need?" Yes/No
During the past month, did you have to choose between buying food or buying medication?	Form question: MANNAAnnual Client Satisfaction Survey, 2016. "During the past month, did you have to choose between buying food or buying medication?" Yes/No
During the past month did you have to choose between buying food or paying your rent or utility bills?	Form question: MANNA Annual Client Satisfaction Survey, 2016. "During the past month did you have to choose between buying food or paying your rent or utility bills?" Yes/No
On one or more days during the past month, did you skip meals because you had no food or no money or food assistance to buy food	Form question: MANNA Annual Client Satisfaction Survey, 2016. "On one or more days during the past month, did you skip meals because you had no food or no money or food assistance/food stamps/SNAP to buy food?" Yes/No
Do you have access to the internet?	Form question: MANNA Annual Client Satisfaction Survey, 2016, "How do you access the internet"? One answer was "I do not have access to the internet". This was turned categories "yes/no" with remaining categories in the question below.
How do you access the internet?	Form question: MANNA Annual Client Satisfaction Survey, 2016, "How do you access the internet"? Categories same as listed on form: home computer, public computer, smart phone, Laptop or Tablet
Would you be interested in receiving nutrition tips or survey questions online?	Form question: MANNA Annual Client Satisfaction Survey, 2016, "Would you be interested in receiving nutrition tips or survey questions online"? Yes/No

Do you know that you can speak to a Dietitian for free at MANNA?	Form question: MANNA Annual Client Satisfaction Survey, 2016, "Do you know that you can speak to a Dietitian for free at MANNA?" Yes/No
Have you had any appointments with a dietitian on staff at MANNA?	Form question: MANNA Annual Client Satisfaction Survey, 2016, "Have you had any appointments with a dietitian on staff at MANNA?" Yes/No
In general, would you say that the MANNA meals service has helped you?	Form question: MANNA Annual Client Satisfaction Survey, 2016, "In general, would you say that the MANNA meals service has helped you?" Yes/No
How has the MANNA meals service helped you?	If yes to above: text box for written response.
In general, do you feel more prepared to make healthy eating choices after the MANNA meals service?	Form question: MANNA Annual Client Satisfaction Survey, 2016, "In general, do you feel more prepared to make healthy eating choices after the MANNA meals service?" Yes/No
How has the MANNA meals service helped you better understand nutrition?	If yes to above: textbox for written response.
Do you have any recommendations to improve the MANNA meals service?	Form question: MANNA Annual Client Satisfaction Survey, 2016, "Do you have any recommendations to improve the MANNA meals service?" Yes/No
What recommendations do you have for improving the service?	If yes to above: textbox for written response.

Appendix D MANNA Focus Group(s) Interview Guide

Welcome! We are here today to discuss the outcomes and impacts of MANNA food and nutrition services including how it affect clients, families, and communities. Your input is important in helping improve the client experience and in designing a future evaluation framework. I'd like to start by asking you to introduce yourself by providing your first name only and your position (for staff) **or** affiliation (for Board).

1. Seasonally dependent question…
2. How long have you been associated with MANNA?
3. What drew you to work here in the first place?
4. Has your opinion changed over the period that you've been here in regard to its purpose?
5. How would you describe MANNA clients?
6. What changes for clients as a result of MANNA services?
    a. [If they say, 'get better,' say you will be talking more about this a little later in the discussion. Go on with other thoughts here.]
7. Describe [specific] changes you see in individuals, families, or communities.
    a. Probe: How do you know about these effects?
8. What are some unanswered questions you have (or what do you feel that you don't know) about how MANNA services affect clients?
9. We're using some words today in our discussion, such as effects, impacts, outcomes. And, maybe we need to get a common understanding of what these words mean to you.

a. Discuss effects, impacts, outcomes and any other language they want to use to express their work and how they measure it.

b. [now you should have a good idea of how they describe impact and outcome.]

10. Now let's talk about donors. Here are some examples……What do they want to know about the [impact] of MANNA services? [change word if necessary per above discussion in 9.]

11. When you think about partnerships with healthcare organizations or insurers such as …what kinds of [effects] are important to them?

12. When you think about your volunteers …what kinds of [effects] are important to them?

Now we're going to speak about a few specific programs that are important to MANNA. [Check and make sure everyone is comfortable, or do they need a break.]

13. MANNA has an educational component to its services (i.e. nutrition counseling and education).

a. How do MANNA nutrition education and counseling programs (individual, group, community partners, written materials) help your clients?

i. Probe: How do you know about these effects?

b. Where do you see as the gaps/[barriers] between what MANNA is trying to empower clients to do, and what they can actually do for themselves without MANNA direct support? (After the MANNA program has ended, what do you see as the barriers that may prevent clients from maintaining their health through food and nutrition?)

c. Are there other things that MANNA can do in this area to help clients be more self-sufficient? If so, would you describe them?

Next, I'd like to ask you about your thoughts on expansion.

14. When MANNA expands its services geographically, how do you see that affecting the client experience? What will be the same and what will be different from what you do now [in terms of nutrition counseling and education]? How do you see this affecting client?
15. How do you see this affecting MANNA?
16. Probe: Will this change anything about your essential charter or purpose? (Just in your opinion.)
17. You mentioned before that you expect clients to do [better] as a result of MANNA services. Does this mean that their health improves? Or how are you defining that?
18. What if clients don't improve in terms of actual health status. Are there any clients who fit this category?
    a. Tell me about them.
    b. Given what we've already said about measuring your [impact] on clients, how would you describe your [impact] on these clients who have more chronic or progressively worsening conditions?
    c. Do you have any ideas about how MANNA can improve services for this population?
19. Are there any additional services that MANNA does not provide but that you think would improve their ability to help clients? Please describe.

Before we wrap up, do you have any additional thoughts about MANNA that we haven't discussed today? If yes, please share.

Appendix E PROMIS® Global Health Scale

PROMIS Scale v1.2 – Global Health

Global Health

Please respond to each question or statement by marking one box per row.

		Excellent	Very good	Good	Fair	Poor
Global01	In general, would you say your health is:	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global02	In general, would you say your quality of life is:	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global03	In general, how would you rate your physical health?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global04	In general, how would you rate your mental health, including your mood and your ability to think?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global05	In general, how would you rate your satisfaction with your social activities and relationships?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global09r	In general, please rate how well you carry out your usual social activities and roles. (This includes activities at home, at work and in your community, and responsibilities as a parent, child, spouse, employee, friend, etc.).....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
		Completely	**Mostly**	**Moderately**	**A little**	**Not at all**
Global06	To what extent are you able to carry out your everyday physical activities such as walking, climbing stairs, carrying groceries, or moving a chair?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

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PROMIS Scale v1.2 – Global Health

In the past 7 days…

		Never	Rarely	Sometimes	Often	Always
Global10r	How often have you been bothered by emotional problems such as feeling anxious, depressed or irritable?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

		None	Mild	Moderate	Severe	Very severe
Global08r	How would you rate your fatigue on average?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

Global07r	How would you rate your pain on average?	☐ 0 No pain	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10 Worst pain imaginable