Multi-stakeholder perspectives on the implementation of a clinic-based food referral program for patients with chronic conditions: a qualitative examination

Matthew J. DePuccio,1,2,3 Jennifer A. Garner,2,3 Jennifer L. Hefner,4,5 Nicolette Coover,6 Aaron Clark,4 Daniel M. Walker4,6

1Department of Health Systems Management, College of Health Sciences, Rush University, Chicago, IL 60612, USA
2School of Health and Rehabilitation Sciences, College of Medicine, The Ohio State University, Columbus, OH 43210, USA
3The John Glenn College of Public Affairs, The Ohio State University, Columbus, OH 43210, USA
4Department of Family and Community Medicine, College of Medicine, The Ohio State University, Columbus, OH 43210, USA
5Department of Health Services Management and Policy, College of Public Health, The Ohio State University, Columbus, OH 43210, USA
6The Center for the Advancement of Team Science, Analytics, and Systems Thinking (CATALYST), College of Medicine, The Ohio State University, Columbus, OH 43210, USA

Correspondence to: MJ DePuccio, matthew_j_depuccio@rush.edu

Abstract
Clinic-based food referral programs (FRPs) may help alleviate food insecurity and improve access to nutritious foods by systematically identifying and referring food-insecure primary care patients to community-based food resources. The purpose of this study was to examine the barriers to and facilitators of implementation of an FRP offered to primary care patients who screen positive for food insecurity and have a qualifying chronic condition. We used a multi-stakeholder approach to conduct semi-structured interviews with healthcare providers and administrators from an academic medical center (AMC) (n = 20), representatives of a regional foodbank and its affiliated pantries (n = 11), and patients referred to the FRP (n = 20), during the initial phase of FRP implementation from April to September 2020. Interviews were audio-recorded, transcribed verbatim, and coded using a deductive dominant approach that allowed for the identification of emergent themes. Seven major themes emerged across the two domains of analysis: barriers to and facilitators of FRP implementation. Key barriers were (a) provider time constraints and competing demands; (b) inadequate physician feedback regarding patient use of the program; (c) patient transportation barriers; and (d) stigma associated with food pantry use. Key facilitators of implementation included (a) program champions; (b) screening and referral coordination; and (c) addressing food pantry-related stigma. This study identifies factors that deter and facilitate the implementation of an AMC-based FRP. Our findings highlight opportunities for healthcare and community-based organizations to refine and optimize FRP models toward the ultimate aim of advancing health equity for food-insecure patients.

Lay summary
Food insecurity can make the self-management of diet-related chronic conditions (e.g., diabetes, hypertension, and obesity) difficult. Clinic-based food referral programs (FRPs) can help address the diet-related needs of food-insecure primary care patients by improving access to nutritious foods. However, the factors contributing to successful FRP implementation in primary care settings are underexplored. The focus of this study was to explore the barriers to and facilitators of implementation of an FRP offered to food-insecure primary care patients with chronic conditions seen at an academic medical center using a multi-stakeholder approach. Competing clinical and patient demands, patient transportation barriers, and food pantry-related stigma were salient factors that prevented healthcare providers and patients from engaging fully with the FRP. Inadequate provider feedback about patients’ use of the FRP was also cited as a deterrent to greater provider engagement with the FRP. Critical facilitators of implementation included support and encouragement from program champions and having a coordinated referral process. The intentional branding and presentation of the FRP to eligible patients may have helped encourage its use by destigmatizing the food pantry setting. The impact of optimizing FRP implementation on patient use and program effectiveness warrants further research.

Keywords: Food insecurity, Family medicine, Academic-community partnerships, Social determinants of health, Qualitative research

Implications
Practice: Healthcare and community-based organizations must consider both programmatic processes and contextual factors that may influence effective implementation when expanding and scaling food referral programs (FRPs).
Policy: Fee-for-service payment models may be incongruent with the ability of healthcare and community-based organizations to collaborate effectively on addressing health-related, nonmedical social needs among underserved patients.
Research: As FRPs are expanded and scaled, it will be important to reevaluate barriers and facilitators—including the purposeful inclusion of the patient perspective—to support programs in reaching their target population and advancing broader goals of diet and health equity.
Introduction

Food insecurity is a nonmedical, health-related social need associated with myriad adverse outcomes across the lifespan, including greater risk for and poorer self-management of multiple diet-related chronic conditions [1–5]. There is a bi-directional relationship between food insecurity and health such that having one or more chronic conditions increases the odds of being food insecure [6]. For a household to be food secure, all members must have consistent access to “enough food for an active, healthy life,” including “the ready availability of nutritionally adequate and safe foods” [7]. Fruits and vegetables are generally recognized as a critical, yet an under-consumed, component of a healthy dietary pattern [8].

Clinic-based food referral programs (FRPs) may help to break the mutually reinforcing relationship between food insecurity and diet-related chronic disease by improving access to nutritious foods via the systematic identification and referral of food-insecure primary care patients to local food pantry networks and other community-based food resources. Food pantry-based interventions have the potential to improve dietary outcomes [9, 10], with clinic-based FRPs representing a promising approach for aligning resources and achieving shared goals across sectors [11].

While prior studies have empirically tested the relationship between FRP use and patient outcomes [12, 13], there is a dearth of literature examining factors influencing FRP implementation—which we define as healthcare provider uptake and patient use of the program. Understanding such factors, particularly as they are perceived by the diverse stakeholders involved in and targeted by such programs, is essential to the successful translation of such programs into effective clinical and community practice. The purpose of this study was to examine the barriers to and facilitators of implementation of an FRP offered to primary care patients who screen positive for food insecurity and have a qualifying chronic condition (i.e., diabetes, obesity, hypertension).

Methods

Study setting, sample, and design

The Mid-Ohio Farmacy (MOF) is an FRP implemented collaboratively between a regional foodbank and partnering healthcare providers, including two family medicine clinics affiliated with a large academic medical center (AMC) located in urban neighborhoods that serve a high proportion of lower socioeconomic status patients [14]. Patients over 18 years old with qualifying chronic conditions (i.e., diabetes, hypertension, obesity) are systematically screened for food insecurity and, if insecure, invited to enroll. The MOF uses a validated two-item food insecurity screening tool based on the U.S. Household Food Security Survey [15]. A MOF referral allows patients and their family members to receive fresh produce once weekly (as opposed to once monthly for standard food pantry clients) from one of 16 participating food pantries affiliated with the regional foodbank located throughout the metropolitan area.

The authors used an in-depth case study approach [16] to understand diverse stakeholders’ experiences with and perceptions of an FRP, including factors perceived as deterring or facilitating its implementation and ultimate impact. Three groups of stakeholders were recruited to participate in the study during the initial phase of MOF implementation from April to September 2020: healthcare providers practicing in MOF-affiliated clinics (i.e., physicians, residents, nurse practitioners, and pharmacists) and administrators from the AMC (n = 20), representatives of the regional foodbank and its affiliated pantries (n = 11), and patients referred to the MOF (n = 20). The authors used convenience sampling to recruit healthcare providers via recruitment emails to a list-serv including the two AMC clinics participating in the MOF. In collaboration with AMC and MOF leadership, the authors used purposive sampling to recruit AMC administrators (MOF project champions and institutional leaders with decision-making authority) and representatives of the regional foodbank and its affiliated pantries. Patients referred to the MOF were recruited by N.C. conducting outreach phone calls in reverse order of referral date (i.e., most recent referral was contacted first).

Data collection

Semi-structured interview guides were developed based on the constructs of the FRP’s program evaluation logic model (i.e., inputs, activities, outcomes, and impacts). Specifically, interview questions for all non-patient, implementation stakeholders—AMC administrators and providers, and foodbank and food pantry representatives—focused on the history and logistics of the cross-sector partnership, the barriers and facilitators experienced by these partners during FRP implementation, and their expectations for the program’s impact. For AMC stakeholders, interview questions focused on implementation processes influencing provider uptake including the screening and referral of eligible patients in participating clinics. For foodbank and food pantry stakeholders, implementation-related questions focused on the process of executing (“filling”) the referral. Interview questions for patients asked about factors that either deterred or supported their use of the program, namely their visits to the eligible network of local food pantries, and on their experiences interacting with providers about food insecurity and health. For patients, we additionally conducted a brief survey at the beginning of the interviews asking about demographic information (i.e., age, gender, race/ethnicity, and education), social status (i.e., household size), and the U.S. Department of Agriculture 6-item Food Security screening tool [17]. We used the 6-item food security screening tool to characterize patients as having high/marginal food security, low food security, or very low food insecurity. Requests for copies of the interview guides can be sent to the corresponding author, however, the general topics covered during the interviews are provided in Supplementary Table S1.

Interviews were conducted by M.J.D., J.A.G., N.C., and D.M.W. using the Zoom video conferencing application between May and September 2020. All interviews were audio-recorded and transcribed verbatim using third-party transcription software. All transcripts were checked for accuracy before being uploaded to NVivo 12 [18]. Each AMC, foodbank, and affiliated food pantry representative interview lasted for 33 min (range 18 to 64 min), on average; the patient interviews lasted for 19 min (range 10 to 33 min), on average. Characteristics about patient interviewees are included in Supplementary Table S2. AMC administrators and providers received no compensation for participation. Foodbank and food pantry representatives and patients received a $50 gift card for participating in the study. The Institutional Review
Board of The Ohio State University approved this study, and verbal consent was obtained from all participants.

Data analysis
The coding team was comprised of three authors (M.J.D., J.A.G., and D.M.W.) who led the thematic analysis [19] of all transcripts. All coding team members have doctoral training and previous experience conducting qualitative research in healthcare settings. Transcript coding followed a deductive approach that allowed for the identification of emergent themes [20]. The coding team initially devised a general coding framework of primary codes based on the constructs of the FRP’s program evaluation logic model to use across all stakeholder transcripts, allowing for cross-stakeholder thematic comparisons. Using a team-based coding approach, the coding team applied the initial codebook to a subset of transcripts \((n = 3)\) to start identifying and defining emergent secondary codes. The three coders met regularly to discuss coding progress, review coded transcripts, and split, merge, and refine codes and their definitions [21] until consensus was reached and no further iterations of the codebook were proposed. The coding team applied the final codebook to all transcripts, meeting throughout the coding process to identify and discuss the thematic patterns that emerged across stakeholders. Saturation was reached to the extent that no additional themes were identified across stakeholder groups. Themes from the patient interviews were also validated using a member check with three patients that had been referred to the MOF.

Results
Our thematic analysis generated seven major themes clustered around the two domains central to the research question: (a) barriers to and (b) facilitators of FRP implementation. Four major barriers emerged: (a) Provider time constraints and competing demands; (b) inadequate physician feedback regarding patient use of the program; (c) patient transportation barriers; and (d) stigma associated with food pantry use. The three major themes that emerged for FRP facilitation and use included (a) program champions; (b) screening and referral coordination; and (c) addressing food pantry-related stigma. We elaborate on these themes and provide elucidating quotations in the following paragraphs.

Barriers to FRP implementation
Provider time constraints and competing demands
With many primary care visits lasting only 20 min, physicians described having a hard time addressing patients’ clinical needs and co-occurring food insecurity within the allotted visit time. Any acute care needs took precedence and other priorities, such as providing preventative care services, took significant physician time to complete. This made it difficult for physicians to address patients’ social care needs and integrate food insecurity screening and FRP enrollment into their clinical workflow. As a result, physicians relied on other clinical staff to conduct the food insecurity screenings and engage with patients who screened positive:

So, I used [the screener] on a couple patients, but mostly due to time pressures we also have to get to whatever their visit is actually for. Our medical assistants who room the patient, they would really be the one who do the screener.

(AMC Provider)

The inferiority of food insecurity screening and program referrals (relative to other clinic visit priorities) seemed to manifest in poor patient comprehension of the program despite their being successfully “referred” in the system. Specifically, some patient participants could not remember discussing the FRP with their physician, recall how the FRP worked (e.g., how often they could visit the food pantries to receive fresh produce), or think of the FRP’s name.

I didn’t know what to expect. I didn’t know what the program involved, so I was figuring it all out. (Patient)

Another patient commented:

Never known anything about [the FRP]. I’m just now opening this [brochure] because you’re on the phone. So, if I had opened it prior to that, I probably would have utilized it. (Patient)

Taken together, it seems plausible that information about how to use the FRP, including what to expect and how to pick up food items from the associated food pantry network, was communicated inadequately to some patients, particularly in the context of visits for which competing demands took greater prominence.

Inadequate physician feedback regarding patient use of the program
Physicians reported receiving minimal, if any, feedback regarding patient experiences with and use of the FRP. As one admitted,

Honestly, I haven’t really heard anything [after the referral] […] I know that I referred quite a few people, but I haven’t called up to say, “Hey, did you go to [the food pantry], how did it go? You know, what was the food program like”? (AMC Provider)

Limited feedback and information flow from the pantries back to providers made it difficult for physicians to assess the impact of the FRP. Beyond utilization, physicians also wondered about whether the program was achieving sufficient reach and how it was working, if at all, to influence positive dietary shifts:

I wonder about screening, if we are catching nearly enough of the people who could benefit, how long they are staying in. If they are adding this fresh produce to an already unhealthy diet or using it as a substitute. There are so many questions about implementation and follow up that I have, I’m not sure about the impact of the program. (AMC Provider)

Collectively, this communication gap had a dampening effect on providers’ enthusiasm to enroll patients into the program over time as the initial excitement diminished about the program.

Patient transportation barriers
Unreliable transportation frequently prohibited patients from going to a food pantry to pick up food items. One patient explained,
I don’t have my own car. But also, I have back issues, and I’m also a heart patient. So, a lot of times I’m not physically able to go. (Patient)

Transportation barriers often surfaced during primary care encounters when patients were introduced to the program, as noted by an AMC administrator:

We found out [the patients] didn’t have the transportation to get there to the market. And so we kept hearing that patients would sometimes decline and say, “You know, this is great, I do need this, but I don’t have a way to get there and carry five pounds of fresh produce back to my house because I walk”, or whatever the reason was. (AMC Administrator)

Providers observed this as well, noting its role as an up-front deal breaker for many of their patients:

One of the major issues that’s come up when people are interested in it, is that they, the transportation, they don’t have a way to get there consistently. So that’s one thing that when I bring it up, they ask me, “Oh, will they bring it to my home”? or, “How can I get a ride there”? They’ll be interested until that transportation piece comes into the picture. (AMC Provider)

In confirmation of the administrators’ and providers’ sentiments, patients also identified unreliable transportation as a key barrier to food pantry use. As one patient explained,

I have not [gone to a food pantry] because my car has been down for a couple of months now, so I haven’t been able to do anything […] unless I get somebody to take me and transport me or Uber, so I really haven’t had a chance. (Patient)

Stigma associated with food pantries
Physicians and foodbank representatives regarded the stigmatization of food pantries, in general, as a major deterrent to food pantry utilization by their patients. As one physician explained,

Just like the idea of waiting in line for the food, it’s a sign that [the patients] don’t have money or are of a lower socioeconomic status that like other people can see that it’s a sign that they need help, like maybe a sign of weakness. (AMC Provider)

Similarly, a foodbank representative explained the need to “destigmatize [the] experience” of going to a food pantry in order for patients to use them:

Additionally, though, it’s just hard to get people to come to food pantries. Like, it’s just hard to get people to comply with, medically and also to just step foot in, in this place. (Foodbank Representative)

Another physician noted the defensiveness elicited by some patients in response to the food insecurity screening process and patient perceptions of the program as a “hand-out”:

I think [a few patients] felt like a foodbank or this program was, I guess, not applicable to their needs, and I think it made them feel more insecure about their own societal standing and their own access to these resources. (AMC Provider)

Specifically, physicians heard patients characterize their need in relation to the needs (actual or perceived) of others and justify their disinterest accordingly:

As far as the pride, certainly[…] “Oh, I don’t need that” or “I’m not that bad off” or “Somebody else is struggling more than me, so somebody else can use that, so I really shouldn’t go”, even if they were someone who would qualify [for the FRP]. (AMC Provider)

Patients did not echo concerns about stigma, but did describe only wanting to go to food pantries if absolutely necessary to conserve the resource for others in a position of greater need. As one patient put it,

I would only go [to the food pantry] if I really desperately needed it because I feel like if I have some money to be able to get [the food] we need for the house, I would rather it go to somebody else who doesn’t have something at that time. (Patient)

Facilitators of FRP implementation
Program champions
Support and leadership from program champions, including providers, administrators, and medical educators, was essential to facilitating the initial partnership and implementation, encouraging provider uptake, and promoting ongoing engagement among participating clinics. Such champions were deemed critical to achieving initial program momentum:

And what we find really in, across the network with any of these food and health initiatives, is that there has to be a real champion or else the program will not go. (Foodbank Representative)

Program champions at the AMC, for example, took the initiative to inform primary care staff about their referral rates and encourage greater referral activity during patient visits:

I guess the biggest champion of the program at our site I think was the lead physician because I remember they were sending out reports of how well we were doing referring, so that was good to see. Like, “Okay, how many people are we referring”? And then realize we could probably be referring more or so I think that was helpful. (AMC Provider)

Although such champions were not ubiquitous across participating clinics, the presence of multiple AMC provider or administrator champions was critical to the endorsement of the FRP and the initial uptake of the program.

Screening and referral coordination
Medical assistants played an important coordinating role with respect to the FRP: screening for and identifying patients
with food insecurity and educating eligible patients about the FRP. Some medical assistants enrolled patients into the FRP during the rooming process or when they were scheduling follow-up appointments for patients. Although there were clinic differences in how screening was integrated into visit workflows, FRP enrollment was generally a team effort:

The providers are definitely responsible for deciding if there's a need and if [the patients] meet criteria, you know that type of thing, initiating the process, making that documentation, then the medical assistant takes it from there, does consenting, gets them that card to get someone signed up and lets them know where to go and how to do that process. So, it's 50/50. I mean we do it together. (AMC Provider)

Some medical assistants wrote notes in the electronic health record to remind physicians to discuss the program with the patients or to indicate that a particular patient expressed interest in learning more about the FRP:

Typically, one of our care coordinators or potentially medical assistants will pre-identify patients, I'm not sure by what criteria, who could qualify for the [FRP], and they will write in the word [FRP] in the notes section as a reminder for our team to ask the patient. (AMC Provider)

Addressing food pantry-related stigma
Strategies intended to destigmatize the use of food pantries, including its intentional branding and in-clinic framing, was perceived as an important approach to facilitating FRP implementation. The FRP was marketed strategically as being distinct from the general food pantry and more patient-centric—as a “Farmacy” program:

Unfortunately, there’s still a stigma attached in our society to seeking assistance, so we wanted to take the word ‘pantry’ out of the experience. You know, “I’m going to the market to get food”, trying to help with that dignity and respect piece. (Foodbank Representative)

In the clinic, explaining that the purpose of the FRP was to address access to nutritious foods, specifically, seemed to help minimize such stigma as well. One provider described how they achieved such re-framing:

It’s like, “You’re going just for these fruits and veggies and it’s just a special service that [the Foodbank] is doing for our patients”, it just seemed more like it kind of cut down on that stigma a little bit. (AMC Provider)

Discussion
Social needs referrals from clinical settings, including those aimed at addressing food insecurity, are increasing in prevalence as healthcare providers seek to address social and economic inequities that may impact health [22, 23]. Evaluation of these referral programs has lagged behind their adoption, and has predominantly focused on examining filled referrals and healthcare use [24] rather than on understanding the processes and mechanisms through which program implementation (i.e., provider uptake and patient use) is achieved. Our study fills this gap through a multi-stakeholder analysis of the implementation of an FRP in two family medicine clinics that are part of an AMC.

Several key findings emerged from the study. On one hand, numerous contextual factors surrounding implementation of the FRP—including competing clinical and patient demands, patient transportation challenges, and food pantry-related stigma—were salient barriers that prevented providers and patients from engaging fully with the program. Other barriers, such as inadequate mechanisms for updating physicians on patients’ FRP engagement, also indicate potential deficiencies in program activities or processes that could undermine the sustainability of food insecurity screening, subsequent program referrals, and program impacts on dietary and health outcomes. On the other hand, program facilitators included having program champions, coordinating referrals effectively, and employing strategies to destigmatize food pantry use. These facilitators could potentially improve cross-sector engagement with the FRP and improve patients’ experiences with program onboarding and use.

Our analysis points to several actionable steps that healthcare and community-based organizations can take in improving the implementation of an FRP. To begin, there are several approaches that may help overcome the transportation challenges—perhaps the most tangible barrier related to program and food pantry use. Some food pantries offer pickup directly at clinical sites [25, 26], and other partnerships offer meal delivery [27], yet these approaches may be limited in scalability. Alternatively, many insurance providers, including several state Medicaid programs, currently provide transportation for medical services, either directly, through a ride-share company (e.g., Lyft, Uber), or by offering bus passes. This approach could be expanded to offer similar transportation services for a broader collection of programs addressing health-related social needs—a potential benefit of a social needs referral coming from a healthcare provider.

Next, to address the barrier of provider time constraints and competing demands, more patient-centric education materials could be developed to inform patients about the logistics of program use and potential benefits (i.e., improved access to nutritious foods). These materials could help improve patient comprehension of the program and potential engagement with such programming to improve disease self-management. Also, patients with more clinical and social needs tend to place more demands on providers’ time and thus could benefit the most from these resources. These efforts may also require reminders and reinforcements to effectively translate into increased utilization. For instance, several studies have examined the use of text message reminders to support healthy eating habits [28, 29]. While the evidence regarding these studies is mixed, their use in conjunction with the referral from a provider may help to nudge the patient toward use of the FRP [30]. Other approaches to supporting patient education related to FRPs could leverage the expertise and relationships of community partners [31], such as the food pantries participating in the FRP, that frequently reach individuals in a wider range of locations and modalities than healthcare providers.

A related area of concern that arose in our study is that of stigma related to use of the food pantry. Prior literature on FRPs has also identified stigma as an important barrier
to uptake and utilization [22, 32, 33], yet the existing literature includes limited specific approaches to destigmatizing use of food pantries. Our study highlights addressing food pantry-related stigma as a facilitator of pantry use and identifies potential approaches. Specifically, providers interviewed in our study found that how they communicated and marketed the FRP impacted patient reactions. Future work could consider using simulation exercises to train providers on how to communicate about food insecurity and related programming. Additionally, evaluating the food pantry environment using validated measures, such as the Nutritious Food Pantry Assessment Tool [34], can provide specific insight into attributes (e.g., interactions with providers or the physical space) that may impact perceptions of the affiliated food pantries and of willingness to engage in the program over time. More research is warranted to understand how FRPs can mitigate any stigma associated with program sites, and to develop best practices around program communications that center and mitigate this potential barrier. For instance, in an effort to help reduce food pantry-related stigma, programs like the FRP may benefit from understanding how the framing of marketing materials and public service announcements about food pantries influence patients’ perceptions about using food pantries to address their food insecurity.

Our findings further suggest that lack of provider knowledge about how their patients use the FRP may be a deterrent to higher engagement in the program. This finding aligns with that of a recent scoping review; providers frequently lacked knowledge of referral programs for social needs, as well as time to review programs with patients [35], and relevant data about utilization about programs [36]. These remain challenging issues to address, as the prevailing fee-for-service payment model in the United States does not typically support addressing social needs in clinical care [37] and related training. While clinics can offer grand rounds and other educational sessions about FRPs, these may have limited impacts on self-efficacy related to addressing social needs, and do nothing to ease time-related concerns. Nonetheless, evidence suggests that increasing capacity to address social needs effectively can ameliorate burnout issues amongst primary care providers [38]—an increasingly critical concern that could potentially undermine ongoing efforts to address social needs in healthcare settings. One approach observed in our case study that may help to efficiently balance the knowledge and resource constraints of providers is to establish standardized processes for screening that utilize medical assistants, nurses, and other staff to support screening and referral activities. This approach was identified as a facilitator in our study—consistent with findings suggesting that team-based models of care and those that provide sufficient resources may be best oriented toward social needs referrals [39, 40]. Also, further examination of the roles and responsibilities of program champions in facilitating FRP implementation could also help elucidate best practices that increase the provider capacity to engage with an FRP.

Limitations
This study has several limitations. First, our study focuses on qualitative data gathered from two family medicine clinics within an AMC participating in a single FRP. Thus, our findings may not generalize to other non-AMC clinical settings (e.g., federally qualified health centers) and for which the referral is not to a network of food pantries at which patients received enhanced produce access. Third, the specific FRP under investigation in our study was designed to offer patients experiencing food insecurity with a variety of chronic conditions increased access to fresh produce; alternatively, other FRPs are oriented towards specific disease states [41] or to the general population of food-insecure patients, regardless of clinical criteria. As a result, our findings may have limited generalizability depending on the specific goals and eligibility criteria of an FRP. However, given our multi-stakeholder approach, we are confident that our results have high internal validity and likely provide useful guidance for other clinics implementing an FRP of similar design. Future research is needed to understand the extent to which these organizational- and individual-level factors contribute to the implementation success and ultimate impacts of FRPs.

Conclusion
Addressing health-related, nonmedical social needs, including food insecurity, and advancing health equity requires strong partnerships between healthcare providers and community-based organizations. Our multi-stakeholder evaluation of an FRP provides insight for other healthcare and community-based organizations seeking to develop and support the implementation of similar programs. By leveraging each stakeholder’s existing strengths and relationships in the community, FRPs may help increase access to nutritious food items and support a healthy dietary pattern for food-insecure patients. As FRPs continue to expand and scale up, it will be important to reevaluate these barriers and facilitators—including the purposeful assessment of the patient perspective—to ensure the program is meeting its intended goals of advancing diet and health equity and reaching its target population.

Supplementary Material
Supplementary material is available at Translational Behavioral Medicine online.

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Compliance With Ethical Standards
Conflicts of Interest: The authors declare that they have no conflicts of interest.

Human Rights: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. This study was approved by The Ohio State University Institutional Review Board (Protocol #2019B0575).
Informed Consent: Informed consent was obtained from all individual participants included in the study.

Welfare of Animals: This article does not contain any studies with animals performed by any of the authors.

Transparency Statements

Study registration: This study was not formally registered.

Analytic plan-registration: The analysis plan was not formally pre-registered.

Data availability: De-identified data from this study are not available in a public archive. De-identified data from this study will be made available on a per case basis (as allowable according to institutional IRB standards) by emailing Daniel M. Walker, PhD, MPH (Daniel.Walker@osumc.edu).

Analytic code availability: There is not analytic code associated with this study.

Materials availability: Materials used to conduct this study are not publicly available.

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