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A Case for Using Electronic Health Record Data in the Evaluation of Produce Prescription Programs

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Abstract

Produce prescription programs within clinical care settings can address food insecurity by offering financial incentives through "prescriptions" for fruits and vegetables to eligible patients. The electronic health record (EHR) holds potential as a strategy to examine the relationship between these projects and participant outcomes, but no studies address EHR extraction for programmatic evaluations. We interviewed representatives of 9 grantees of the U.S. Department of Agriculture's Gus Schumacher Nutrition Incentive Grant Program's Produce Prescription Projects (GusNIP PPR) to understand their experiences with and capacity for utilizing EHR for evaluation. Five grantees planned to use EHR data, with 3 main strategies: reporting aggregate data from health clinics, contracting with external/third party evaluators, and accessing individual-level data. However, utilizing EHRs was prohibitive for others due to insufficient knowledge, training and/or staff capacity; lack of familiarity with the Institutional Review Board process; or was inappropriate for select target populations. Policy support for produce prescription programs requires a robust evidence base, deep knowledge of best practices, and an understanding of expected health outcomes. These insights can be most efficiently and meaningfully achieved with EHR data, which will require increased financial support and technical assistance for project operators.

Background

Food insecurity, or lack of access to enough food for an active, healthy life,[1] has emerged as a commonly addressed social need within clinical care.[2] Strategies to help reduce food insecurity among patients include supporting enrollment in federal food assistance programs, providing information and access to on-site food pantries, referring patients to local community resources (eg, food banks), and increasingly, offering referrals for direct financial incentives or subsidies for fruits and vegetables.[3,4] The last 5 years have seen tremendous growth in the prevalence and evaluation of such programs, often referred to as produce prescriptions, though it is difficult to quantify since so many operate within health systems or local community groups. A recent landscape analysis reported more than 100 programs launched between 2010 and 2020.[5] The evidence base has also expanded dramatically, with many produce prescription studies now published annually and 3 recent systematic reviews and meta-analyses reporting significant reductions

in food insecurity,[6] hemoglobin A1c and body mass index,[7] and improvements in daily servings of fruits and vegetables[7,8] across pooled analyses of program participants, though all results should still be interpreted with caution given the heterogeneity of outcome measures in some cases.

One factor in this growth is the 2018 Farm Bill's authorization for the United States Department of Agriculture (USDA) to provide $25 million over 5 years (2019-2023) through the Gus Schumacher Nutrition Incentive Program (GusNIP) competitive grant mechanism to support the

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implementation of Produce Prescription (PPR) projects nationally. Foundational PPR elements include specific enrollment criteria (eg, food insecurity determined by a clinical screening tool, diagnosis or high-risk for diet-related chronic disease, and/or Medicaid enrollment), a referral from a healthcare provider, and redemption of financial incentives to purchase fruits and vegetables (FVs) at participating food retailers (eg, farmers markets, food stores). While GusNIP funding only supports a fraction of nationwide produce prescription programs, the experiences of these grantees, who implement programs across diverse geographies, communities, and patient populations, can provide critical and relevant insights into challenges of implementation and evaluation. In this commentary, we make a case for integrating the electronic health record (EHR) into evaluation of produce prescription programs, based on the experiences of some of these grantees.

GusNIP grantees are required to evaluate impact of PPR projects on FV intake and food insecurity (through participant-level surveys), and associated healthcare use and costs.[9] To meet these objectives, access to data from the EHR is critical, especially since these projects are situated, by definition, within clinical care. The EHR contains multiple sources of data, including administrative (eg, basic demographics, insurance coverage), laboratory, utilization (eg, dates of visits to clinic or emergency room), and cost or charge data associated with utilization, and patient care (eg, diagnostic codes, provider notes).[10]

PPR grantees' experience and capacity to access and utilize these data is unclear. Of few published evaluations that have included EHR data, the process of obtaining that data is not described in detail [11,12]; the authors are not aware of studies that address EHR extraction for programmatic evaluations. Thus, in the summer of 2020, the authors (members of the USDA-supported National Technical Assistance, Evaluation and Information Center's (NTAE) Reporting & Evaluation team) interviewed members of the inaugural cohort of GusNIP PPR grantees to understand their plans and/or capacity to utilize EHR data in their evaluations and the strategies employed for data access and extraction.

What Did We Find?

The initial cohort of GusNIP grantees, 9 PPR projects awarded in 2019, described multiple strategies to accomplish EHR data abstraction and evaluation, but the complexity of data access was prohibitive for some. Of the 9 grantees, 5 conveyed plans to extract data from EHRs; grantee organizations included 1 health system, 3 non-profit organizations, and 1 county municipality. Each grantee engaged between 3 and 40 clinics in 1 or more health system at a time. Participating clinics utilized a broad set of EHR platforms, including EPIC, Ochin EPIC, Cerner, e-ClinicalWorks, NextGen, and the Resource and Patient

Management System (RPMS) of the Indian Health System (IHS), a decentralized, integrated EHR used in tribal facilities.[13] In some instances, PPR grantees worked with multiple clinics utilizing different EHR platforms, which complicated data extraction efforts. Grantees reported that turn-around time for data extraction was 1 to 4 weeks, and sometimes required additional software (eg, SQL, Tableau, SAS). Data reports were described most frequently as being formatted in Excel (and 1 case each of .txt and PDF files).

Barriers to Working With EHR Data

The 4 PPR grantees who relayed plans not to access EHR data made this decision for a variety of reasons, including: EHR data extraction not being a specific GusNIP grant requirement; perceptions that the IRB approval process posed a formidable barrier; having limited capacity of, or funding for, their health care partners; and/or implementing a PPR project whose eligibility criteria did not target a particular health condition (eg, type 2 diabetes) to make collection of health data a priority.

PPR grantees housed and administered in the community, through a non-profit organization, typically conveyed less knowledge of how or whether to access EHR data, compared with projects led by or in close partnership with a healthcare system, but also expressed great interest in EHR data. Sharing EHR data between a health care entity and a community organization is governed by federal laws and regulations (eg, the Health Insurance Portability and Accountability Act of 1996, or HIPAA) and, in some states, state laws and regulations as well. There are also general protections in place at the level of the health system, clinic, or an affiliated university to ensure that patient data is appropriately safeguarded. These complexities make data sharing between some grantees and their health system partners challenging. For this reason, PPR grantees embedded within a healthcare system were more likely to report a plan for utilizing EHR data, were comfortable discussing these approaches, and shared an interest and capacity in problem-solving any obstacles.

Strategies to Working With EHR Data

Grantees identified 3 main strategies for working with EHR data, described below.

1. Reporting Aggregate Data from Health Clinics. In this approach, health clinics extract individual data (eg, participant's blood pressure) from the EHR for all PPR participants, and then report those data in an aggregated, de-identified form to the grantee. Aggregate data includes a summary of the data across all participants, for example, average blood pressure among all participants in the program at

pre- and post-assessments, or average blood pressure of all participants in the program compared to average blood pressure of other patients not participating in the program.

2. Contracting with External/Third Party Evaluators. A common approach, described by 4 out of the 5 grantees with EHR extraction plans, was to contract with an external, third-party evaluator to manage issues related to patient security and privacy (eg, HIPAA), receive EHR data directly from clinical partners, and then provide analysis and/or reporting to the grantee.

3. Accessing Individual-Level Data Directly. Two grantees reported plans to work directly with individual-level data from the EHR. In the first case, the grantee was formerly part of the partnering health system before incorporating as a non-profit organization. For this PPR project, the organization's data/technology manager works directly with each clinical site's informatics technician who de-identifies participant data from the EHR onsite at the clinic. Researchers at this grantee organization stated plans to work directly with the extracted EHR data, for example linking to additional survey data (eg, FV intake, food insecurity, and/or grocery store purchasing) via a unique participant identifier for greater contextual analysis. Note that these analyses require access to participant-level data to connect across multiple datasets. As such, data sharing agreements and/or data management plans that ensure security are required.

> The second grantee who reported directly accessing participant-level EHR data is itself a health system, which has agreed to extract and share de-identified data with their external evaluator. Their data extraction plans include an extensive list of variables, including hemoglobin A1c, lipoprotein profile, height, weight, PHQ9 scores (a measure of depressive symptoms), emergency department utilization, and appointment "no shows." Each participant is assigned a unique identifier to link datasets (e.g., to link survey responses to clinical markers).

Each of the 3 strategies employed by GusNIP PPR grantees to extract EHR data had benefits and limitations. Receiving aggregate, de-identified data from a healthcare system can circumvent HIPAA requirements since no personally identified health information is provided. However, data cannot be matched to individual participants, limiting more robust and meaningful analysis. Alternatively, third-party evaluators offer a range of skills, including how to obtain IRB approval, implementing data sharing agreements that outline data use and privacy, and developing data

management plans that describe how to store data in adequately secure environments consistent with federal regulations. Third party evaluators can be especially helpful when programs operate across multiple clinics with different EHR platforms and policies for data release. Academic researchers are often well-positioned to serve in this role, as are private firms, especially those with expertise working with health data. These evaluators may also be well positioned to collate multiple data streams (eg, EHR, survey, retail transactions). The last strategy, accessing individual-level data directly, may be more feasible when the grantee is closely affiliated with the participating healthcare system or is the health system itself since it requires familiarity with HIPAA compliance, investment in a secure data environment and may incur additional costs for personnel and resources to code, pull, and/or analyze data. Using this approach, individual-level data can be linked to additional program data (eg, food security surveys and/or grocery purchasing) for greater contextual analysis, while the use of at least 2 objective measurements at different time points provides an opportunity to assess clinical changes during or after program implementation.

Advancing the Field

Healthy food interventions like produce prescription programs are critical resources to address food insecurity and increase FV access for individuals experiencing, or at risk for, chronic, diet-related disease. In order to have a demonstrable impact on food insecurity and other clinical health measures, PPR projects will need to be implemented at scale. Such implementation requires a robust evidence base, deep understanding of best practices, and an understanding of expected health outcomes that can be most efficiently and meaningfully evaluated with data from EHRs.

While use of EHR data is less commonly included in published PPR project evaluations to date, models exist from other interventions. Some evaluations of medically tailored meal programs have been able to link program participation with EHR utilization and cost measures (eg, hospitalizations, skilled nursing facility admissions, and total health care expenditures).[14] An evaluation of a program for individuals with type 2 diabetes on Navajo Nation included EHR data like primary care visits, pharmacy visits, counseling and behavioral health services, and radiology, laboratory, dental, and emergency room use.[15] Both of these examples also used medical claims data, a logical next step to build the evidence for program cost-effectiveness; however, accessing claims data involves a separate set of hurdles for program operators.

Expanded access to data from EHRs, as well as access to claims data, could influence or potentially unite interested parties including payers, providers, and policymakers in the

drive toward Medicaid and Medicare reimbursement of produce prescription programs nationally. If broad-scale insurance funding becomes a reality, whether through public or private insurance, pre-existing integration of produce prescription programs with EHRs may even facilitate processes associated with billing since information on program referral and participation can be automatically linked with billing systems. Varied data access strategies through the EHR have implications for future cross-grantee data analysis or pooled analysis. Although GusNIP PPR projects are mandated to share data with national evaluators, this is made nearly impossible without a consistent plan in place for extracting and sharing EHR data. If it becomes clear that access to EHR data will remain prohibitively difficult for some PPR projects, then USDA requirements as mandated for GusNIP in the 2023 Farm Bill may need to change to avoid excluding otherwise promising programs that cannot meet this grant requirement. As the GusNIP grantee pool grows each year, the breadth of experience of incoming grantees conducting impact evaluations, including how to access, extract, and analyze EHR data, will diversify as well.

Overcoming barriers to accessing EHRs for the evaluation of produce prescription programs—funded by GusNIP and elsewhere—will most likely require additional time and/or financial investments from health care organizations to create workflows, support personnel hours required for creating data capture fields, implement data extraction and data use agreements between parties, and extract, clean, code, and analyze data for impact evaluations. It will also require that PPR projects and health care systems develop mutual trust and confidence in each other's adherence to best practices. Moving forward, program funders like USDA can incentivize EHR integration for grantees to support more robust evaluations and increase capacity of grantee programming, including financial support for EHR data extraction, costs around personnel, IRB and training. In spring 2022, the GusNIP NTAE, also supported by USDA through a cooperative agreement, published a Request For Applications to support PPR grantees to extract and share EHR data, and received 9 applications in the first round. We encourage implementers, funders, and researchers to proactively explore these and other opportunities to utilize EHRs in their produce prescription programs; doing so will undoubtedly strengthen the evidence base for the integration of these programs into healthcare delivery.

Author Contributions

RR and HS developed the survey, follow up interview questions, conducted first 2 interviews, organized themes, and drafted the manuscript. RR conducted the remaining interviews. AY, DN, and CBS advised on study design and substantively revised the manuscript. All authors approved the submitted version and agree to be personally accountable for the manuscript.

Declaration of Conflicting Interests

Funding

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