

Costing a population health management approach for participant recruitment to a diabetes prevention study

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Abstract

Background

Limited research has reported the economic feasibility—from both a research and practice perspective—of efforts to recruit and enroll an intended audience in evidence-based approaches for disease prevention. This study aims to retrospectively assess and estimate the costs of a population health management (PHM) approach to identify, engage, and enroll patients in a Type 1 Hybrid Effectiveness-Implementation (HEI), diabetes-prevention trial.

Methods

We used descriptive analyses and activity-based costing to estimate the recruitment costs of a PHM approach integrated within a HEI trial. Measures included total costs and costs per participant screened and enrolled to ensure trial accrual rates were achieved. We took the perspective of a healthcare system which may adopt, and possibly sustain, the strategy in the typical practice. We also estimated replication costs based on how the strategy could be applied in healthcare systems interested in referring patients to a local diabetes prevention program from a payer perspective. In this case, we examined differences in cost based on requirements for and types of, glucose testing, and by labor activities and non-labor resources associated with recruitment using sensitivity analyses.

Results

The total recruitment and enrollment costs were \$389,949 to accrue 599 participants over approximately 15 months. The average cost per screened and enrolled participant was \$276 and \$651, respectively. Primary costs included hemoglobin A1c testing (\$83,106), recruitment screening calls (\$48,791), and personnel time (\$96,187). Translating to the typical settings, total recruitment costs for replication was estimated as \$192,625 (range: \$42,523-\$208,876). Sensitivity analysis results indicated replication costs would be approximately \$229 - \$430 per patient enrolled if glucose testing was necessary, based on the Medicare covered services. For a private payer perspective, and without glucose testing, per-participant screening and enrollment costs were estimated at \$30.

Conclusions

A PHM approach can be used to accrue a large number of participants in a short period of time for an HEI trial, at a comparable cost per participant. However, when trial requirements are removed and PHM approaches are used as a method for healthcare systems to identify and enroll patients in a local program—the costs are relatively low.

Contributions To The Literature

- Reach is a key implementation outcome, yet costs of recruitment for patients to participate in EBIs are often overlooked when estimating the economic feasibility.
- Population health management, a multicomponent strategy that includes identifying subpopulations of patients who would benefit from a given EBI and examining the characteristics of these populations using available health record data, holds the potential of maximizing reach into the intended audience.
- The current study demonstrates a pragmatic approach for costing a multicomponent recruitment strategy in a type 1 hybrid effectiveness-implementation trial of a digital diabetes prevention program that could be replicated when testing other EBIs.

Background

Prediabetes, the predecessor of diabetes, is a leading contributor to lifetime healthcare costs due to its high prevalence [1]. Approximately 84 million (or one in three) adults in the U.S. have prediabetes with an estimated convert rate of type 2 diabetes (T2D) of 5–10% per year [2]. A number of efficacious weight loss interventions that combine healthy eating and physical activity plans with behavioral strategies to promote weight loss have been developed for this population, the most well-known of which is the lifestyle intervention from the Diabetes Prevention Program (DPP) [3]. The Centers for Disease Control and Prevention (CDC) Diabetes Prevention Recognition Program developed standards to track and ensure the quality of lifestyle intervention programs, and currently recognizes both in-person and virtual/online/digital programs to support relevant behavior changes [4]. To date, most of these programs have been delivered in person [5, 6], limiting program scalability and accessibility for at risk individuals dealing with time and/or transportation barriers. In a recent review study of identifying factors leading to successful implementation of DPP in real word settings [7], Aziz and colleagues emphasized that even modest weight loss can have significant population-level impact if a high proportion of at-risk individuals participate in the programs. Unfortunately, engaging participants in these lifestyle programs has been a challenge [8]. In the most recent National Health Interview Survey, of respondents at risk for diabetes, only 2.4% reported participating in a diabetes prevention program [9].

To address low participation rates digital platforms provide the appeal of scalability and the ability to overcome barriers often associated with in-person diabetes prevention interventions. Specifically, the use of asynchronous sessions that allow for social support and coaching when and where is most convenient for a given participant addresses issues with scheduling and travel time [10]. Digital DPPs have also demonstrated success at supporting participant weight-loss in similar magnitude as in-person programs [11–13]. Still, the challenge of engaging populations at risk for diabetes persists. Indeed, 25% of people at risk for diabetes indicate that they would like to participate in a DPP if it were available [9]. Unfortunately, there has been limited research on methods to recruit or engage potential participants in either in-person or digital DPPs [14, 15].

Evidence based interventions (EBIs) are faced with the challenge of ensuring clinical effectiveness while attracting a broad and representative sample of the target population [16]. The need for multi-component strategies which maximize reach (i.e., the number, proportion, and representativeness of participants) [17] is paramount given the challenges faced by in-person and digital DPPs. Processes which efficiently identify patients at risk of developing T2D and engage primary care providers (PCPs) are needed and seldom reported in the literature [18]. Population Health Management (PHM) is gaining traction as highly relevant for organizations aiming to provide primary care services while tackling the challenges associated with the management of health care delivery and payment systems [19]. In primary care settings, proactive PHM would include, for example, identifying subpopulations of patients who would benefit from a given EBI, examining the characteristics of these populations using available health record data, creating reminders for patients and providers, tracking performance measures, and making data widely available for clinical decision making at the practice level [20, 19]. A prominent barrier to EBI implementation is a paucity of evidence on the startup costs, or costs related to the uptake of such an approach within existing healthcare or community-based systems [21, 22]. Assessing costs of recruitment and enrollment is an important first step towards understanding the economic feasibility of adopting and implementing a PHM approach in the delivery of digital DPPs with the goal of maximizing reach into the intended audience.

The success of participant recruitment is related to several factors including staffing resources, length of intervention, post-intervention follow-up duration, and costs [23–25]. However, most intervention studies often overlook the importance of recruitment costs and resources and it is seldom reported in the literature [22, 26–28]. Information associated with the resources and potential costs associated with recruitment activities and process are critical to decision makers in charge of resource allocation and upfront investment within limited budgets. Moreover, underestimating the costs associated with participant recruitment can contribute to recruitment problems, which inhibits or delays the translation of EBIs into practice [24]. The objectives of this study were to (1) assess the costs of applying a PHM approach to reach patients at risk of diabetes and enroll them in a clinical trial comparing a digital DPP to an enhanced standard of care, and (2) estimate the potential cost variation if replicated or sustained in general practice with modifications that reflect PHM approaches typical for chronic disease. It is anticipated that this information will be useful for informed decision making in the widespread adoption of lifestyle interventions targeting diabetes prevention and the reduction of cardiovascular disease risk (e.g. obesity, diet, and hypertension) in healthcare settings.

Methods

Setting and overview of the PREDICTS trial

The Preventing Diabetes with Digital Health and Coaching for Translation and Scalability trial (PREDICTS) is a Type 1 Hybrid Effectiveness-Implementation trial (HEI) that was conducted to determine the clinical effectiveness of a technology-enabled and adapted DPP lifestyle intervention to reduce hemoglobin A1c (HbA1c) and body weight of patients with prediabetes in an integrated healthcare

system. As a Type 1 HEI trial [29], secondary aims related to examining the dissemination and implementation context included the assessment of potential reach [30] recruitment costs, and potential for adoption and sustained implementation of digital diabetes prevention strategies within a typical healthcare setting. The PREDICTS trial recruited 599 overweight or obese adults with prediabetes, determined by the HbA1c range of 5.7%-6.4%. The study protocol and details about participant recruitment and intervention reach are presented in detail elsewhere [5, 30]. In brief, eight clinics within the Nebraska Medicine healthcare system in the Greater Omaha area participated in the trial, from which 22,642 patients aged 19 and older who were at risk of T2D and had a Body Mass Index ≥ 25 kg/m² were identified via an electronic health record (EHR) system query. Partnering PCPs reviewed health records of 11,313 of the resulting patient pool, and those who were not excluded from participation after physician review were sent a recruitment packet inviting them to participate in the trial. Packets included an opt-out postcard for patients to return if not interested. Trained study staff members contacted potential participants who did not return the opt out postcard within 2 weeks by outreach phone call to determine interest and conduct a telephone screening to further assess eligibility. A total of 2,796 patients were telephone screened, 30% of which were found ineligible due to not meeting the inclusion criteria (see Wilson et al. [30], under review). In total, 1,412 patients who passed the telephone screening attended an in-person screening at which HbA1c was assessed to determine final eligibility. Of these, 630 were found eligible and 599 of them were enrolled in the trial.

Participants were randomly assigned to the digital DPP (the intervention arm, n = 299) or to the enhanced standard of care (n = 300). The digital DPP is a technology-based delivery of the DPP lifestyle intervention [3] that consists of small group support, personalized health coaching, digital tracking tools, and weekly behavior change curriculum approved by the CDC Diabetes Prevention Recognition Program (the Omada Health Program®) [11]. Using internet-enabled devices (laptop, tablet or smartphone), program participants can asynchronously complete weekly interactive curriculum lessons, privately message a health coach for individual counseling, track weight loss and physical activity using a wireless weight scale and pedometer, and monitor their engagement and weight loss progress. The program is inclusive of an initial 16-week intensive curriculum focusing on weight loss and a subsequent 36-week curriculum focusing on weight maintenance, with a total of 12 months of educational lessons. Participants in the control arm were provided with a one-time, two-hour diabetes prevention education class, consisting of detailed information on current recommended levels of physical activity and healthy food choices involving portion size, eating regular meals, and a well-balanced diet based on the CDC My Plate recommendations, and the development of a personal action plan. The recruitment phase of the PREDICTS trial occurred over the 15-month duration from November 2017, through March, 2019, when the last eligible participant was randomized.

Analytical framework

We designed the analytic approach to address two primary issues. First, we focused on determining the cost needed for a large HEI randomized controlled trial to accrue the proposed sample size over a finite period of time (e.g., 599 participants over 15 months). This reflects the actual costs of recruitment and

enrollment for the HEI trial. Second, we focused on sensitivity analysis to determine the potential costs of our PHM approach if it were to be used by a healthcare system for recruitment and enrollment to a local program (not a clinical trial) that aligned with the CDC Diabetes Prevention Recognition Program requirements. The analytical approach followed the best practice guidelines for the costing of prevention interventions [31, 32] and the modified cost assessment procedure proposed by Ritzwoller et al. [26], consisting of five elements: 1) perspective of the analysis, 2) identifying costs components, 3) capturing relevant costs, 4) data analysis, and 5) sensitivity analysis.

The recruitment costs were assessed from the organizational (i.e. healthcare system) perspective given that organizations are making the decision of whether or not to integrate such programs into their practices and thus bear the costs of implementing such programs. All costs were categorized as labor and non-labor costs and expressed as 2018 US dollars. For the collection and analysis of costs, we utilized a micro-costing approach with activity-based costing strategy [33], a method that is widely adopted in healthcare, to explicitly identify, measure, and value all resources used to recruit participants for the study. Specifically, total labor costs were estimated by summing the costs of each recruitment activity, which was calculated by multiplying the total activity time (in hours) by the per-hour cost of resources.

Costing a PHM approach for participant recruitment and enrollment

Step 1: identify labor cost components by recruitment activities and associated labor hours

The diabetes prevention trial applied a PHM approach that holds the potential to be automated within existing healthcare systems to identify, screen, enroll, and engage potential participants. To better capture the recruitment costs, in which the majority are activity-based, we created a process map (Fig. 1) to illustrate the study recruitment process with each steps reflecting an activity in the participant recruitment process from initial identifying individuals at risk, ordering screening tests, conducting screening tests, managing screening test results, to the final enrollment in the preventive services. All the identified recruitment activities were further categorized into three sections: participant identification, participant eligibility screening, and eligible participant intake and enrollment. At the end of the recruitment phase, members of the research team estimated the average number of hours per weeks they spent on the specific task, supplemented by the regular documentation of average times spent on each subcategory by project management tracking of the recruitment progress and resource use. We further multiplied the average hours per week by the number of weeks dedicated to a recruitment activity to derive the total numbers of labor hours on a specific task in the entire recruitment process.

Participant Identification

A computer programmer applied pre-specified inclusion and exclusion criteria to identify potential eligible participants via EHR query [5]. Once a list of potential participants was generated, a physician champion engaged PCPs at each of the participating clinics for patient list review and clearance, or potential participant referral. A recruitment packet consisting of a physician invitation letter, a study description, and an opt-out postcard was prepared and mailed to potentially eligible patients. A total of 14 recruitment packet preparation sessions were conducted to prepare and send 10,770 invitation packets by postal mail.

Participant Eligibility Screening

Research assistants conducted a telephone screen call to assess specific inclusion and exclusion criteria for all patients who did not return the opt-out postcard. After initial eligibility was determined, a screening visit was scheduled and the initial screening packet, containing screening instruction, direction to the screening location, and a copy of the informed consent was prepared and sent by postal mail or email (based on participant preference). Research assistants and clinical staff (e.g., research nurse coordinators, medical assistants, or phlebotomists) conducted the screening assessment session, including HbA1c testing, blood pressure, weight, height, and resting heart rate measurements at eight different primary care clinics across the metropolitan area.[30]

Eligible Participant Intake and Enrollment

Participants found eligible by HbA1c screening completed an in-person baseline assessment prior to being randomized into one of the trial conditions. Research staff conducted all the assessment and data collection activities (survey questionnaires and waist circumference measurement) at the baseline visit.

Step 2: Determine hourly wage rates

Labor costs were estimated based on time spent on each recruitment activity (i.e., activity-based costing), outlined on the process map (Fig. 1), conducted by the staff members and a full-time project manager who oversaw all aspects of the study, including staff recruitment, orientation and training, meeting and planning, coordinating between clinics, IRB related tasks, and corresponding hourly wages. Number of hours worked was also tracked using bi-weekly timesheets of all research personnel. The per-hour salary rate for personnel who conducted the EHR query with computer programming and PCPs who reviewed the list of their potentially eligible patients to exclude any patients for reasons related to safety and appropriateness of the intervention were estimated at \$44.29 and \$124.87, respectively. These rates were calculated based on annual salaries plus fringe benefits at a standard rate of 28%. All the other recruitment activities were conducted by the non-clinical research staff and clinical research staff at an hourly rate of \$16.35. Costs associated with the full-time project manager were estimated based on the actual 2017–2019 salaries.

Step 3: Determine non-labor costs

Non-labor costs for telecommunication service subscription, appointment reminder service subscription, equipment, and supplies were based on actual amounts spent and were tracked from receipts and

payment invoices. The research team collected non-labor costs, further categorized each as fixed or variable. Variable costs were reported as unit costs and multiplied by the number of participants or the item purchased. These costs included point-of-care HbA1c fingerstick test and venipuncture HbA1c test, iPads and cases, scales, gulick tape, stadiometer, and safety box. Fixed costs included recruitment materials, the Appointment Reminder software subscription, and telephone and cellphone services. A detailed listing of the materials and services, and individual costs, grouped into operational services, operational supplies, and medical supplies, are provided in Table 1. Other non-labor costs include research staff travel costs for assessment sessions, which was accrued at a rate of \$0.25 per mileage. We did not take into account the overhead or space costs, because the study-related screening and assessment sessions occurred outside of regular business hours (in the weekday evenings or Saturday morning).

Table 1
PREDICTS trial recruitment costs.

Activity/category	Time, hours	Number	Costs (\$)
Labor costs			
A full-time project manager, including fringe benefits			\$96187
Participant identification			
EHR query	472		\$20906
PCP recruit & review	132		\$16482
Recruitment packet preparation	236		\$3850
Participant eligibility screening			
Participant screening calls & schedule	2984		\$48791
Screening visit packet preparation	132		\$2158
Preparation for screening visits, non-clinical	396		\$6475
Ordering of HbA1c testing & PCP signed off	24	1412	\$2939
Screening visit	1476		\$24133
Follow-up for screening visit	230		\$3752
Eligible participants intake & enrollment			
Baseline visit packet preparation	77		\$1259
Preparation for baseline visits	96		\$1574
Baseline visit	790		\$12917
Follow-up for baseline visit	66		\$1071
<i>Total labor costs</i>	7109		<i>\$242493</i>
Non-labor costs			
Operational Service			
Mail/Postage			\$7745

^aThe hourly wage for EHR query and PCP recruit and review activities were \$44.29 and 124.87, respectively. Otherwise, the hourly wage for other activities was \$16.35.

^bThe screening protocol was switched to a lab HbA1c testing from a POC HbA1c fingerstick test to determine eligibility 6 months after the initiation of study recruitment due to a high proportion of false positive POC results (52%) (see Wilson et al. [30] for more detail)

Activity/category	Time, hours	Number	Costs (\$)
Telephone/cellphone, monthly fee, device, & data plan			\$2895
Venipuncture HbA1c test ^b		837	\$78678
Operational/medical supplies			
Incentives		1412	\$35300
iPad & iPad cases		15	\$6636
AppleCare			\$869
Apple pencil		1	\$129
Safety box		2	\$71
Printing			\$5447
Appointment Reminder App subscription fee			\$1035
Others			\$1415
Clinical supplies (e.g. gauge butterflies, syringe, vials, and sharp container)			\$1633
Gulick tape		10	\$484
POC HbA1c test ^b		575	\$4428
Stadiometer		2	\$301
Sphygmomanometer, stethoscope, arm pressure monitor, & scale			\$390
<i>Total non-labor costs</i>			<i>\$147453</i>
<i>Total recruitment costs</i>			<i>\$389949</i>
Total costs per screened patient			\$276
Total costs per enrolled patient			\$651

^aThe hourly wage for EHR query and PCP recruit and review activities were \$44.29 and 124.87, respectively. Otherwise, the hourly wage for other activities was \$16.35.

^bThe screening protocol was switched to a lab HbA1c testing from a POC HbA1c fingerstick test to determine eligibility 6 months after the initiation of study recruitment due to a high proportion of false positive POC results (52%) (see Wilson et al. [30] for more detail)

Data analysis

We used descriptive analyses to estimate the total number of labor hours, and total labor and non-labor costs associated with study participant recruitment. Measures included total recruitment costs broken

down into labor and non-labor costs, and costs per participant screened and recruited by dividing total recruitment costs by the number of participants screened and enrolled. Additionally, exploratory descriptive analyses were conducted to estimate the cost to replicate the PHM approach for participant recruitment for preventive interventions.

Estimated costs for replication

For the estimate of replication costs, we used the process map (Fig. 1) to map replication resources needed to guide our cost estimate. We focused on activities that would be required for a healthcare system to implement the PHM strategy. We excluded any tasks, activities, and expenses that dealt with the clinical trial protocol development, clinical trial assessment and data collection, and any other clinical trial-related activities that would not need to be replicated if the study were continued at the organization or if it were replicated or adopted in another setting.

We further conducted one-way (deterministic) sensitivity analyses (varied 1 input parameter at a time) to evaluate the uncertainty and variation of the recruitment cost estimates to the parameter assumptions or in a variety of settings and circumstances. Specifically, we first calculated the minimum and maximum plausible values for each parameter by varying the original costs by 50% [34] if not specified. Each input variable further labeled as required vs. optional depending on whether they are identified as needed resources during the replication process. For labor costs, we varied the per-hour salary amount and the hourly wage for study personnel. The percentage of computer programming time used to query the EHR ranged from 50–150%, because it is the essential element for a recruitment strategy applying a PHM approach. In addition, we considered that PCPs reviewing potential participant list as an optional activity because it is not required when referring patients to CDC-recognized DPP programs. We assumed discounted resources associated with participant screening calls and schedule, and follow-up for screening visit and enrollment (varied from 50%-100%) because a telephone screening for a randomized trial is more laborious than a general screening call to offer a preventive service and less intensive follow-up. For non-labor costs, we varied the cost of HbA1c testing (\$94 per unit) to be compatible with other glucose testing (i.e., fasting glucose test (\$39 per unit), and 2-hour oral glucose tolerance test (\$105 per unit)) using local institutional expenses. Currently, HbA1c testing is not reimbursed by Medicare, even though the testing result is used to determine the eligibility to enroll in a Medicare DPP program [35, 36]; whereas the glucose testing is not required for participation in CDC-recognized DPPs. Therefore, the cost range of a glucose testing was assumed between 0 (not required) to 100% (required). For the optional activities or resources, we assumed that the cost range between 0% and 100%. These range estimates were derived via expert consensus from the study investigators. We used tornado diagrams [34] to summarize the effects of varying key input parameters one at a time on the replication costs. The parameters were sorted in descending order by their influence on the cost outcomes. The longer bars indicated the most important parameters. In addition, we conducted a scenario analysis to estimate the potential replication costs of recruitment when considering different stakeholders (e.g., Medicare, or private payers).

Results

Recruitment costs for the PREDICTS trial

Labor costs

Table 1 reports the personnel time in hours and costs associated with these recruitment activities. The labor hours summed to 840 hours, 5,241 hours, and 1,029 hours, for activities of participant identification, eligibility screening, and eligible participant intake and enrollment, respectively. The total labor costs summed to \$242,493, including a full-time project manager. The majority (74%) of labor hours were accrued by the participant eligibility screening with the costs of \$88,247, followed by eligible participant intake/enrollment (14%), and participant identification (12%). Activity-associated labor costs were primarily attributable to the participant eligibility screening (60%), in which costs related to screening calls, scheduling screening visits, ordering HbA1c testing, PCP patient approvals, delivering reminders to participants, preparing for screening visits, conducting screening sessions (n = 132 sessions over 15 months), and follow-up phone calls. Participant identification via the EHR system and targeted mailing accounted for 28% of the total recruitment activity-related labor costs (\$41,239), followed by eligible participant intake and enrollment (11%, \$16,820). The differences in rankings in terms of amounts of time spent and costs between sections of participant eligibility screening and participant intake and enrollment attributed to the different hourly wages between study personnel who were conducting the EHR query, PCP recruitment and review process, and staff who made the screening and scheduling calls.

(insert Table 1 here)

Non-labor costs

Non-labor costs are presented in Table 1 and summed to \$147,456. The vast majority of non-labor costs were associated with HbA1c testing/point-of care HbA1c used to define patients' eligibility (\$83,106 56%), followed by the incentives to compensate patients' time for participating in the screening activities (\$35,300, 24%).

Total recruitment costs

The total recruitment costs (labor and non-labor costs) were \$389,949, which translated to \$276 per participant screened and assessed (n = 1,412) and \$651 per participant enrolled (n = 599) in the PREDICTS trial.

Estimated costs for replicating the PHM approach for recruitment

Sensitivity analysis

The process map (Fig. 1), depicting the flow of the recruitment activities employing a PHM approach, reveals that many activities associated with the trial could be omitted when used in typical healthcare

system practice. As shown in Table 2, based on the recruitment activities (not trial-associated) and non-labor resources that may be required for the future replication, the total recruitment costs for replication were estimated at \$192,625 (range: \$42,523-\$208,876) for programs with the similar scale. It translated to \$136 (range: \$30-\$148) and \$322 (range: \$70-\$349) per patient screened and enrolled, respectively. With the percentage effort assumption made for each activity, Fig. 2 presents one-way sensitivity analysis results with a tornado diagram that summarizes the effect of variation in input parameters (recruitment labor activities or non-labor resources) one at a time on total replication estimate. The recruitment activity and non-labor resource with the greatest impact on the replication costs was the glucose testing, as the estimates range from not increasing current costs to reducing by \$83,106.

Table 2
Estimate replication costs and assumptions for replication for sensitivity analyses

Activity/cost category	Cost estimates	Needed for replication?	Range
Labor costs			
Participant identification, screening, & enrollment			
EHR query	\$20906	Required, fixed	50–150%
PCPs recruit & review	\$16482	Optional, fixed	0-100%
Recruitment packet preparation	\$3850	Required, variable	50–150%
Participant screening calls & schedule ^a	\$48791	Required, variable	50–100%
Screening packet preparation	\$2158	Optional, variable	0-100%
Ordering of glucose testing & PCP signed off	\$2939	Optional, variable	0-100%
Follow-up for screening visit & enrollment	\$3752	Required, variable	50–100%
Non-labor costs			
Recruitment packet postage	\$7745	Required, variable	50–150%
Telecommunication	\$2895	Optional, fixed	0-100%
Glucose testing	\$831068	Optional variable	0-100%
<i>Total replication costs</i>	<i>\$192625</i>		<i>\$42523-\$234628</i>
^a The cost range of replication was discounted due to the screening for a randomized trial is more laborious than screening to offer a preventive service.			

Scenario analysis

Varying the screening methods used to determine the program eligibility, especially for a Medicare population, resulted in an estimated total replication cost ranging from \$137,053 to \$164,587 and a reduction of cost for the fasting blood glucose test to between \$229 and \$275 per enrolled patient. However, the cost per patient enrolled was estimated between \$307 and \$430 if using a 2-hour, post-glucose challenge test.

When considering the private payer as the potential decision maker, the recruitment activities of glucose testing and associated activities (PCP recruit and review, screening packet preparation, glucose testing, ordering of glucose testing and PCP approvals, and telecommunication) may not be needed. Removing these cost components/activities, the replication costs of recruitment and referring eligible patients to CDC-recognized DPPs were estimated at the lower bound of the replication costs of \$42,523, translated to \$30 per patient assessed and \$71 per patient enrolled.

Discussion

The potential to reach individuals for whom an intervention is intended is often understudied and overlooked in determining intervention impact, justifying the economic feasibility of EBIs, and thus the costs associated with recruitment activities are underreported. In this study, we aimed to assess the costs of using a PHM approach to identify, engage, and enroll patients in a type 1 HEI, digital diabetes prevention trial and estimate the potential costs of applying this PHM approach if replicated in typical practice. Our study results indicate that the total recruitment costs of the PREDICTS trial were \$389,949, in which 62% were labor activities and 38% were non-labor resources, translated to \$276 and \$651 per participant screened or enrolled/randomized. This information may be helpful to other research groups as they plan for accruing a large number of participants over a short period of time. We also examined what costs could look like for a healthcare system interested in identifying and engaging patients in a CDC-recognized diabetes prevention program. As cost is considered a key factor when considering the implementation of an EBI [32], our results provide additional cost information on a potential upfront investment regarding the infrastructure and capacity required in the pre-implementation phase (i.e. participant recruitment) for an EBI [18].

As indicated in the sensitivity analysis, glucose screening was one of the key parameters in the cost estimates of recruitment replication. Per CDC-recognized DPP eligibility criteria [37], patients may not need to have a glucose testing (HbA1c, fasting plasma glucose, or 2-hour plasma glucose testing) to be referred to the program if they met other criteria, such as have a diagnosis of prediabetes or history of gestational diabetes, or if they take the self-report risk test and receive a high-risk result. Without accounting for the glucose testing, the replication cost was \$109,519 (\$78 per patient screened, Table 2). Further excluding other optional recruitment labor activities or resources, the replication costs can be as low as \$30 per patient screened based on the perspective of private payers. In a recently published pragmatic DPP trial conducted in the Veteran Affairs (VA) healthcare system, Damschroder and colleagues reported that the labor cost to recruit participants was \$68 per participant assessed and \$330 per participant identified to be eligible for VA-DPP [18]. Different from a PHM approach by integrating EHR

computer programming in the recruitment process used in our HEI trial, they engaged PCPs to refer potential eligible patients for participation and did not account for the activities of participant identification and screening, which may contribute to the cost difference. This is reflected by the fact that 21% of the target population in their study were eligible compared to 45% in the PREDICTS trial [30]. Unlike their approach, which relied on PCPs to refer patients in the face of other competing demands, our approach presents a great potential to minimize missed opportunities to efficiently identify and engage high-risk individuals before they progress to diabetes [18]. While the comparison of a pragmatic trial costs to our PHM sensitivity analysis results is not ideal, it does appear that the economic feasibility of applying a PHM approach to increase program reach may be cost-efficient for identifying and recruiting potential participants for the DPP programs.

In the PREDICTS trial, we applied HbA1c testing to determine the eligibility with a cost of approximately \$82-\$94 per patient. Not surprisingly, the cost of HbA1c testing is higher than the other glucose testing methods as it reduces the burden of patient waiting time and inconvenience (i.e., fasting). However, it is not reimbursed by Medicare as one of the diabetes screening methods to determine the eligibility for Medicare DPP. Healthcare systems decision makers should balance the potential patient costs (e.g., time and discomfort) and screening costs when considering adopting this recruitment strategy targeting the Medicare population. Furthermore, reimbursement for diabetes screening is critical to supporting and scaling population-level strategies to prevent diabetes [35]. Results from the scenario analysis reveal that the replication costs of this recruitment strategy can vary significantly based on the potential stakeholders and their designated eligibility criteria.

Underestimating recruitment costs compounds existing recruitment problems, such as underrepresentation of minority or gender groups or the absence of attractive program features, and could delay or prohibit the translation of evidence-based programs like a digital DPP into practice [26, 38, 33, 39]. The current study provides insight on the cost of using a PHM approach to improve program reach, with the potential to be automated in the EHR system, for participant recruitment in a digital diabetes prevention trial. The use of the EHR system, the involvement of PCPs reviewing the potential participant list, and sending out the physician endorsed invitation letter are identified as fundamental elements within this PHM approach. These elements could help with the future design of an automated risk assessment in clinical populations and further prompt outreach to high-risk patients to encourage subsequent diabetes screening tests and interventions to prevent diabetes or other preventive services [35], and improve participant recruitment in clinical trials [40].

Limitations

Some limitations need to be acknowledged. First, similar to the studies of costing behavioral lifestyle interventions retrospectively [41], the current study may suffer from issues related to recall bias for self-reported hours on the recruitment activities. However, retrospective cost capture may be a practical and low-burden method [26], especially when studies involve community partners. For the labor time, we asked multiple staff members to report hours spent on similar tasks and averaged the reported hours,

which should partially alleviate this concern. Second, it is challenging to disentangle upstream resources and activities, such as staff training and planning, from the resources needed for study implementation, intervention delivery, and participant retention. The implementation of the study would not be possible without the startup and infrastructure setup in the pre-implementation phase of the trial. Third, it is possible that we overestimated the replication costs when implementing this recruitment strategy in a real-world setting regardless of the sensitivity analysis exercises. Some of the operational costs (e.g., mail postage or telecommunication) or labor resources may have been shared costs in an existing system. Finally, as healthcare systems differ in available resources, organizational capacity, system characteristics, service scope, marketing/communication ability, and patient components, further investigation into other healthcare systems is warranted to increase the generalizability.

Conclusions

To facilitate the uptake and scale up of DPP-like programs, Damschroder and colleagues pointed to the need for referral processes that are (1) compatible and integrated with existing clinical processes; (2) effective in identifying and engaging high-risk participants; and (3) easy to use [18]. Our study presents a pragmatic approach for costing recruitment activities of a PHM approach to maximize program reach as well as the replication costs for applying this approach to other healthcare settings. This estimated cost information can inform future clinical system changes to improve the reach of existing evidence-based health promotion and disease prevention interventions.

Abbreviations

PHM, population health management; HEI, hybrid effectiveness-implementation; T2D, type 2 diabetes; DPP, Diabetes Prevention Program; CDC, Centers for Disease Control and Prevention; EBIs, evidence based interventions; PCPs, primary care providers; PREDICTS, the Preventing Diabetes with Digital Health and Coaching for Translation and Scalability trial; HbA1c, hemoglobin A1c; HER, an electronic health record; IRB, institutional review board; VA, veteran affairs.

Declarations

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Authors' contributions

TM conceived of the study, conducted the analyses, and drafted the manuscript. JK, FA, and PE aided with design and interpretations of cost analysis and results, and provided critical input on the full manuscript. KW and FS oversaw data collection and cleaning, aided with interpretations of analysis

results, and provided critical input on the full manuscript. All authors worked on the interpretation of data and critical review and approval of the final manuscript.

Availability of data and materials

Deidentified data are available on request.

Ethics approval and consent to participate

The research staff obtained trial participant's consent at the screening visit. The trial was approved by the University of Nebraska Medical Center Institutional Review Board and Western IRB and is registered at clinicaltrials.gov (identifier: NCT03312764).

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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References

1. Dall TM, Yang W, Halder P, Pang B, Massoudi M, Wintfeld N et al. The economic burden of elevated blood glucose levels in 2012: diagnosed and undiagnosed diabetes, gestational diabetes mellitus, and prediabetes. *Diabetes care*. 2014;37(12):3172-9.
2. Centers for Disease Control and Prevention. National diabetes statistics report, 2017. Atlanta, GA: Centers for Disease Control and Prevention, US Department of Health and Human Services. 2017.
3. Knowler WC, Barrett-Connor E, Fowler SE, Hamman RF, Lachin JM, Walker EA et al. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *The New England journal of medicine*. 2002;346(6):393-403.
4. Centers for Disease Control and Prevention. Diabetes Prevention Recognition Program <https://www.cdc.gov/diabetes/prevention/pdf/dprp-standards.pdf>. Accessed November 5 2019.

5. Almeida FA, Michaud TL, Wilson KE, Schwab RJ, Goessl C, Porter GC et al. Preventing diabetes with digital health and coaching for translation and scalability (PREDICTS): A type 1 hybrid effectiveness-implementation trial protocol. *Contemporary Clinical Trials*. 2019;105877. doi:<https://doi.org/10.1016/j.cct.2019.105877>.
6. Porter GC, Laumb K, Michaud T, Brito F, Petreca D, Schwieger G et al. Understanding the impact of rural weight loss interventions: A systematic review and meta-analysis. *Obesity Reviews*. 2019;20(5):713-24.
7. Aziz Z, Absetz P, Oldroyd J, Pronk NP, Oldenburg B. A systematic review of real-world diabetes prevention programs: learnings from the last 15 years. *Implementation science*. 2015;10(1):172.
8. Ali MK, Bullard KM, Imperatore G, Benoit SR, Rolka DB, Albright AL et al. Reach and Use of Diabetes Prevention Services in the United States, 2016-2017. *JAMA network open*. 2019;2(5):e193160-e.
9. Venkataramani M, Pollack CE, Yeh H-C, Maruthur NM. Prevalence and correlates of Diabetes Prevention Program referral and participation. *American journal of preventive medicine*. 2019;56(3):452-7.
10. Sepah SC, Jiang L, Peters AL. Translating the Diabetes Prevention Program into an online social network: validation against CDC standards. *The Diabetes educator*. 2014;40(4):435-43.
11. Sepah SC, Jiang L, Ellis RJ, McDermott K, Peters AL. Engagement and outcomes in a digital Diabetes Prevention Program: 3-year update. *BMJ Open Diabetes Research and Care*. 2017;5(1):e000422.
12. Castro Sweet CM, Chiguluri V, Gumpina R, Abbott P, Madero EN, Payne M et al. Outcomes of a digital health program with human coaching for diabetes risk reduction in a Medicare population. *Journal of aging and health*. 2018;30(5):692-710.
13. Michaelides A, Raby C, Wood M, Farr K, Toro-Ramos T. Weight loss efficacy of a novel mobile Diabetes Prevention Program delivery platform with human coaching. *BMJ Open Diabetes Research and Care*. 2016;4(1):e000264.
14. Ali MK, Echouffo-Tcheugui JB, Williamson DF. How effective were lifestyle interventions in real-world settings that were modeled on the Diabetes Prevention Program? *Health affairs*. 2012;31(1):67-75.
15. Ali MK, Wharam F, Duru OK, Schmittiel J, Ackermann RT, Albu J et al. Advancing Health Policy and Program Research in Diabetes: Findings from the Natural Experiments for Translation in Diabetes (NEXT-D) Network. *Current diabetes reports*. 2018;18(12):146.
16. Estabrooks P, You W, Hedrick V, Reinholt M, Dohm E, Zoellner J. A pragmatic examination of active and passive recruitment methods to improve the reach of community lifestyle programs: The Talking Health Trial. *International Journal of Behavioral Nutrition and Physical Activity*. 2017;14(1):7.
17. Glasgow RE, Harden SM, Gaglio B, Rabin B, Smith ML, Porter GC et al. RE-AIM Planning and Evaluation Framework: Adapting to New Science and Practice With a 20-Year Review. *Front Public Health*. 2019;7:64. doi:10.3389/fpubh.2019.00064.
18. Damschroder LJ, Reardon CM, AuYoung M, Moin T, Datta SK, Sparks JB et al. Implementation findings from a hybrid III implementation-effectiveness trial of the Diabetes Prevention Program (DPP) in the Veterans Health Administration (VHA). *Implementation Science*. 2017;12(1):94.

19. Li Y, Kong N, Lawley MA, Pagán JA. Using systems science for population health management in primary care. *Journal of primary care & community health*. 2014;5(4):242-6.
20. Berwick DM, Nolan TW, Whittington J. The triple aim: care, health, and cost. *Health affairs*. 2008;27(3):759-69.
21. Powell BJ, Fernandez ME, Williams NJ, Aarons GA, Beidas RS, Lewis CC et al. Enhancing the impact of implementation strategies in healthcare: a research agenda. *Frontiers in public health*. 2019;7:3.
22. Vale L, Thomas R, MacLennan G, Grimshaw J. Systematic review of economic evaluations and cost analyses of guideline implementation strategies. *The European Journal of Health Economics*. 2007;8(2):111-21. doi:10.1007/s10198-007-0043-8.
23. Lovato LC, Hill K, Hertert S, Hunninghake DB, Probstfield JL. Recruitment for controlled clinical trials: literature summary and annotated bibliography. *Controlled clinical trials*. 1997;18(4):328-52.
24. Sadler GR, Ko CM, Malcarne VL, Banthia R, Gutierrez I, Varni JW. Costs of recruiting couples to a clinical trial. *Contemporary clinical trials*. 2007;28(4):423-32.
25. Beaton SJ, Sperl-Hillen JM, Von Worley A, Fernandes OD, Baumer D, Hanson AM et al. A comparative analysis of recruitment methods used in a randomized trial of diabetes education interventions. *Contemporary clinical trials*. 2010;31(6):549-57.
26. Ritzwoller DP, Sukhanova A, Gaglio B, Glasgow RE. Costing behavioral interventions: a practical guide to enhance translation. *Annals of Behavioral Medicine*. 2009;37(2):218-27.
27. Speich B, von Niederhäusern B, Schur N, Hemkens LG, Fürst T, Bhatnagar N et al. Systematic review on costs and resource use of randomized clinical trials shows a lack of transparent and comprehensive data. *Journal of clinical epidemiology*. 2018;96:1-11.
28. Grimshaw J, Thomas R, MacLennan G, Fraser C, Ramsay C, Vale L et al. Effectiveness and efficiency of guideline dissemination and implementation strategies. *International Journal of Technology Assessment in Health Care*. 2005;21(1):149-.
29. Curran GM, Bauer M, Mittman B, Pyne JM, Stetler C. Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. *Medical care*. 2012;50(3):217.
30. Wilson K, Michaud T, Almeida F, Schwab R, Porter G, Aquilina K et al. Using a population health management approach to enroll participants in a diabetes prevention trial: Reach outcomes from the PREDICTS randomized clinical trial. 2020 (under review)
31. Foster EM, Porter MM, Ayers TS, Kaplan DL, Sandler I. Estimating the costs of preventive interventions. *Evaluation Review*. 2007;31(3):261-86.
32. Ingels JB, Walcott RL, Wilson MG, Corso PS, Padilla H, Zuercher H et al. A prospective programmatic cost analysis of Fuel Your Life: A worksite translation of DPP. *Journal of occupational and environmental medicine*. 2016;58(11):1106.
33. Raghavan R. Dissemination and implementation research in health: Translating science to practice. 2nd ed. The role of economic evaluation in dissemination and implementation research. New York: Oxford University Press; 2018.

34. Briggs AH, Weinstein MC, Fenwick EA, Karnon J, Sculpher MJ, Paltiel AD et al. Model parameter estimation and uncertainty: a report of the ISPOR-SMDM Modeling Good Research Practices Task Force-6. *Value in Health*. 2012;15(6):835-42.
35. Bowen ME, Schmittiel JA, Kullgren JT, Ackermann RT, O'Brien MJ. Building toward a population-based approach to diabetes screening and prevention for US Adults. *Current diabetes reports*. 2018;18(11):104.
36. Centers for Medicare and Medicaid Services. Medicare Provides Coverage of Diabetes Screening Tests. <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/se0821.pdf>. Accessed November 1 2019.
37. Centers for Disease Control and Prevention. National Diabetes Prevention Program- Program Eligibility. <https://www.cdc.gov/diabetes/prevention/program-eligibility.html>. Accessed November 5 2019.
38. Leslie LK, Mehus CJ, Hawkins JD, Boat T, McCabe MA, Barkin S et al. Primary health care: potential home for family-focused preventive interventions. *American Journal of Preventive Medicine*. 2016;51(4):S106-S18.
39. Jordan N, Graham AK, Berkel C, Smith JD. Costs of Preparing to Implement a Family-Based Intervention to Prevent Pediatric Obesity in Primary Care: a Budget Impact Analysis. *Prevention Science*. 2019;20(5):655-64.
40. Effoe VS, Katula JA, Kirk JK, Pedley CF, Bollhalter LY, Brown WM et al. The use of electronic medical records for recruitment in clinical trials: findings from the Lifestyle Intervention for Treatment of Diabetes trial. *Trials*. 2016;17(1):496.
41. Diabetes Prevention Program Research Group. Costs associated with the primary prevention of type 2 diabetes mellitus in the diabetes prevention program. *Diabetes care*. 2003;26(1):36-47.

Figures

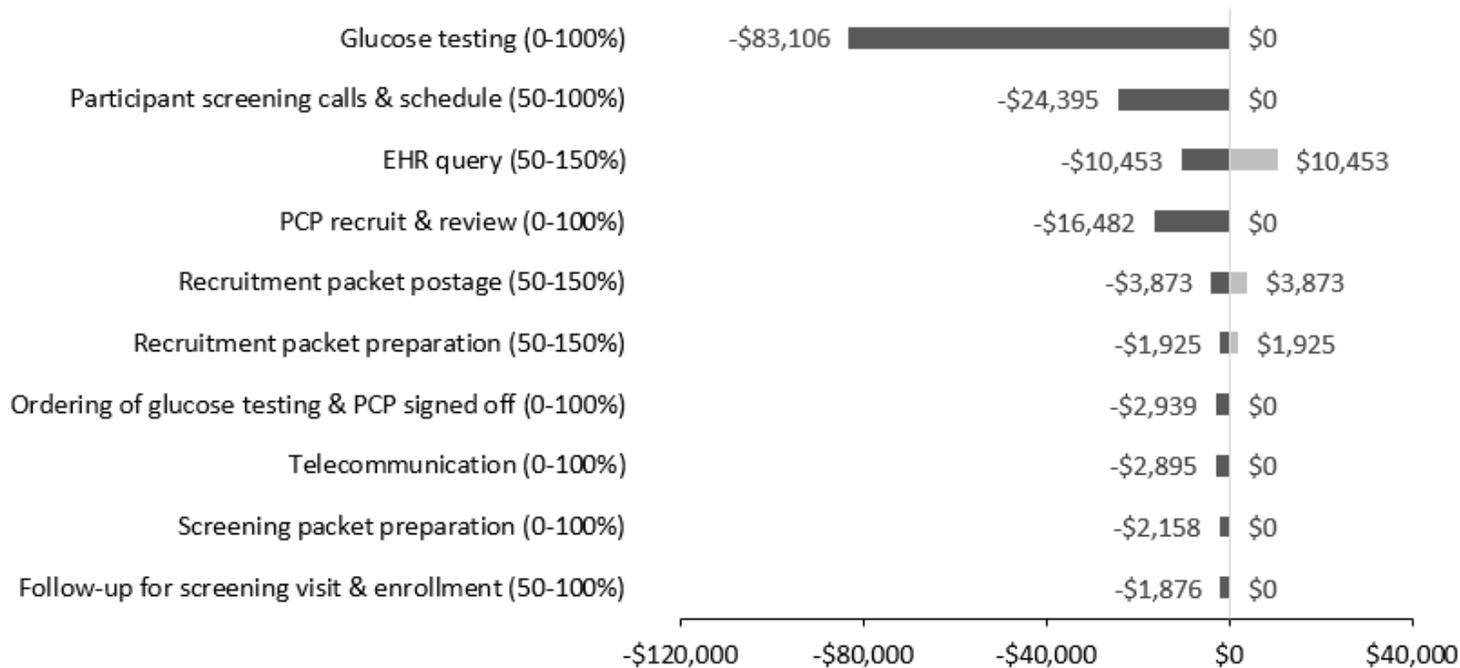


Figure 2

One-way Sensitivity testing around replication estimates for key recruitment activities and resources. Note: Each row shows the changes in cost, across the range of replication estimate values, from the total replication estimate. The parameters are sorted in descending order by their impact on the recruitment estimates. Longer bars indicate the most important parameters, giving the diagram its “tornado” appearance.

Supplementary Files

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