Research paper

Study protocol for a Community Health Worker (CHW)-led comprehensive neighborhood-focused program for medicaid enrollees in detroit

Michele Heisler [a,b,c,1], Adrienne Lapidos [d,*,1], James Henderson [h], Rebeca M. Guzman [e], Jason Wolfe [f], Patricia Meyer [f], David Law [g], Edith C. Kieffer [k], Caleb Ernst [f], Valentina Djelaj [e], Joneigh Khaldun [e,1], John Z. Ayanian [b,f,i,j]

[a] Veterans Affairs Center for Clinical Management Research, VA Ann Arbor Healthcare System, 2215 Fuller Road, Ann Arbor, MI, 48105, USA
[b] Department of Internal Medicine, University of Michigan Medical School, 1600 Plymouth Road, Ann Arbor, MI, 48109, USA
[c] Department of Health Behavior and Health Education, School of Public Health, University of Michigan, 1415 Washington Heights, 1700 SPH I, Ann Arbor, MI, 48109, USA
[d] Department of Psychiatry, University of Michigan Medical School, 1600 Plymouth Road, Ann Arbor, MI, 48109, USA
[e] Detroit Health Department, 3245 E. Jefferson, Suite 100, Detroit, MI, 48203, USA
[f] University of Michigan Institute for Healthcare Policy & Innovation, 2800 Plymouth Road, North Campus Research Complex, Building 16, Ann Arbor, MI, 48109, USA
[g] Joy-Southfield Community Development Corp, 18917 Joy Road, Detroit, MI, 48228, USA
[h] Consulting for Statistics Computing & Analytics Research, University of Michigan, 3550 Rackham, 915 E. Washington St, Ann Arbor, MI, 48109, USA
[i] Department of Health Management and Policy, School of Public Health, University of Michigan, 1415 Washington Heights, 1700 SPH I, Ann Arbor, MI, 48109, USA
[j] Gerald R. Ford School of Public Policy, University of Michigan, 735 S. State St, Ann Arbor, MI, 48109, USA
[k] University of Michigan School of Social Work, 1080 South University, Ann Arbor, MI, 48109, USA
[l] State of Michigan Department of Health and Human Services, USA

ARTICLE INFO

ABSTRACT

Residents of low income neighborhoods disproportionately experience poor health, and many have unmet social needs. Clinical trials have shown the efficacy of Community Health Worker (CHW) programs in improving outcomes for a variety of health conditions. An important next step is developing and evaluating financially sustainable CHW program models in real-life settings. This program evaluation examines health care utilization among participants in a geographically targeted program led by salaried CHWs from three Medicaid health plans. Beneficiaries who reside in the Cody Rouge neighborhood of Detroit and had more than 3 Emergency Department (ED) visits or at least 1 ambulatory care-sensitive hospitalization in the prior 12 months are eligible for the program. Health plan CHWs assigned to the program reach out to eligible beneficiaries to provide an assessment; link them to resources; and provide follow-up. At 12-month follow up, claims data on ED visits, ambulatory care-sensitive hospitalizations, primary care visits, and related costs will be compared between beneficiaries who participated and eligible beneficiaries randomized to receive usual outreach. We hypothesize that patients enrolled in the CHW intervention will experience a reduction in acute care usage resulting in cost savings compared to those receiving usual health plan outreach. This study is among the first to evaluate the impact on health care utilization of augmented services delivered by health plan CHWs for high-utilizing health plan members as part of a health plan-community-academic partnership. This study will provide important information on CHW program sustainability and provide insights into effective implementation of such programs.
Trial registration: NCT03924713.

1. Introduction

Residents in low-income urban neighborhoods disproportionately

experience poor health and unmet social and economic needs. These individuals are at higher risk of developing chronic medical conditions, have barriers to disease management, and have high rates of Emergency

Department (ED) utilization and hospital admissions that might have been avoided with regular primary care [1–10]. Poor health can lead to high rates of workplace absenteeism and problems with seeking and sustaining employment [11]. Since the 2014 launch of the Healthy Michigan Plan – Michigan's Medicaid expansion under the Affordable Care Act – many Detroit residents have gained coverage under the program [12]. Currently, more than 90,000 Detroit residents are enrolled in the Healthy Michigan Plan through Medicaid managed care plans [13]. Yet insurance alone does not necessarily translate into improved health, especially for vulnerable populations [14].

One effective approach to reach vulnerable individuals facing barriers to accessing care is outreach and support from Community Health Workers (CHWs). Defined as trained frontline health workers who are trusted members of – or closely connected to – the population served, CHWs share characteristics such as culture, language, or community with those they serve [15]. CHWs can provide outreach, advocacy, counseling, and health education to members of their community, and can establish links to health and social services. A growing body of evidence has demonstrated the effectiveness of CHWs in improving health outcomes among vulnerable populations. In randomized controlled trials, CHWs have improved clinical outcomes in areas such as diabetes [16–22], heart disease and hypertension [23–26], cancer screenings and literacy [27–29], readmission rates [30–32], and mental health [33–37]. Components of CHW programs supported by strong evidence include providing chronic disease care services; inclusion in team-based care models; certification based on core competencies; certification to establish standards for specialty areas; supervision by health care professionals; and reimbursement of services by Medicaid payment [38]. Some efficacy trials have shown that well-designed CHW programs can decrease acute care utilization and result in cost-savings [17,33,39–41].

Despite this growing body of evidence, research on CHW programs that operate sustainably in real-life settings is still limited. The impact of most CHW initiatives remains limited by their dependence on short-term grants. For any model to be sustainable, a payer must cover the costs of CHW services, or alternatively, a fee-for-service billing code for CHW services must be established.

Our study addresses this gap in the literature by evaluating a sustainable CHW program that was developed and implemented by Medicaid health plans. As of January 2016, evidence on the effectiveness of CHW programs led Michigan's Department of Health and Human Services to require that its Medicaid health plans provide CHW services to their enrollees, either with CHWs they hire or through contracts with CHW programs. As Medicaid health plans in Michigan are required to implement CHW programs to be awarded managed care contracts by the state, Michigan offers an excellent opportunity to evaluate the effectiveness of CHW services in improving utilization patterns. Such data are necessary to inform payers of the financial feasibility of developing CHW programs.

2. Methods

2.1. Partnership and setting

Comprehensive, neighborhood-based CHW initiatives with sustained financing across participating payers could both improve community health and social outcomes and reduce costs by decreasing high-cost utilization. To test this hypothesis, investigators from the Institute for Healthcare Policy and Innovation (IHPI) at the University of Michigan (UM), the Detroit Health Department, the Joy-Southfield Community Development Corporation, three Medicaid health plans serving Detroit, and other Detroit health system and community partners developed an innovative CHW-led demonstration project in Detroit's Cody Rouge neighborhood. A low-income, predominantly African-American neighborhood of approximately 36,000 residents, Cody Rouge has one of the highest concentrations in Detroit of high-utilizing and under-utilizing Medicaid and Healthy Michigan Plan enrollees across all participating

health plans. It also has strong community organizations and a federally-qualified health center. Over a 12-month period before implementing the demonstration project, the research team conducted semi-structured interviews with stakeholders from 10 Cody Rouge-based community health and social services organizations to inform program development, implementation, evaluation, and dissemination. These pre-implementation interviews also helped establish a Community Advisory Committee comprised of representatives from key neighborhood organizations that meets quarterly to help inform program activities.

2.2. Study objectives

This 12-month randomized evaluation rigorously assesses whether a neighborhood-focused CHW program implemented by multiple insurance providers in collaboration with the Detroit Health Department and local Cody Rouge social service and health care organizations will improve participating health plan members' health service utilization compared with eligible health plan members who have not yet received the augmented CHW services. The specific aims are:

1. To determine the program's effect on health care utilization, health care costs, and return on investment among high-utilizing participants at 12-months compared to participants not yet enrolled in the program;
2. To evaluate the program's effect on key patient-centered outcomes among participants (including satisfaction with services and attainment of goals); and
3. To evaluate the program's barriers and facilitators to adoption, implementation, maintenance, and potential spread.

The three components of the evaluation are: 1) analysis of health plan claims data; 2) an anonymous participant survey; and 3) interviews with CHWs and partnership stakeholders. As the evaluation is of a program being offered by the Medicaid Health Plans, and the health plans conduct their own randomization processes, the relevant IRBs reviewed the study and determined the outcome data analysis to be nonregulated, and the satisfaction survey and qualitative interviews to be exempt. The evaluation protocol is registered at ClinicalTrials.gov (NCT03924713).

2.3. Participant eligibility criteria

Adult enrollees in any of the 3 participating Medicaid health plans are eligible for the CHW demonstration project if they reside in the Cody Rouge community and meet the following criteria: 1) enrolled in one of the participating Medicaid plans; 2) either have had more than 3 ED visits in the prior 12 months, or at least 1 ambulatory care-sensitive hospitalization in the prior 12 months; and 3) have not been previously randomized to either study arm.

2.3.1. Study arms

Active treatment. Each of the 3 participating health plans have assigned one or two of their salaried CHWs to participate in the demonstration project. Each plan assigned CHWs who were African Americans from Cody Rouge or other neighborhoods in Detroit. In the fall of 2017, assigned CHWs underwent training led by an experienced CHW trainer employed by the Detroit Health Department, under a trainer contract with the Michigan Community Health Worker Alliance (MICHWA). Although each health plan had already conducted in-house training of their CHWs, MICHWA's standardized core-competency-based training ensured that the CHWs share a common set of skills and approaches that are aligned with the national C-3 consensus competencies [42]. The MICHWA training program covers key topics such as the role of CHWs, advocacy, and outreach; communication skills and cultural competence; teaching and capacity building; and strategies to assess needs and link to resources.

Every month during the project period, each health plan compiles a list of health plan members eligible for the intervention based on the criteria listed above. From this list, a subset of health plan members is randomized to receive either the CHW intervention or usual health plan services for which they are eligible. Those not randomized to either arm remain potentially eligible for future assignment to one of the two arms. The unit of randomization is the individual health plan member. After randomization, each CHW receives a list of health plan members who have been randomized to the intervention group. The CHWs proactively reach out to each health plan member on their list, either by phone or in person, to offer their services. Any member can refuse services if they so choose. For the primary intent-to-treat analysis, the arms are therefore balanced by design.

Health plan members participating in the CHW demonstration project meet one-on-one with their health plan's CHW who 1) conducts an initial comprehensive health, behavioral, and social needs assessment; 2) develops an individualized 'action plan' to address identified needs; 3) links members to necessary services and works with neighborhood-based health care and social services organizations to address each individual's unique needs; and 4) provides follow-up support as needed. CHWs work closely with local organizations to strengthen community capacity to bridge gaps between healthcare services and community-level social determinants of health. Duration of follow-up support depends on identified needs and required support as determined by the CHW. Caseloads of each CHW at any one time range from 30 to 50 health plan members.

While each CHW only provides services to his or her own health plan's eligible members, all program CHWs follow the same outreach protocol to ensure that eligible members are informed of their eligibility and maximize the intervention's "reach"; assess the same domains in their comprehensive assessments; follow similar counseling and action plan protocols; and follow similar follow-up protocols. Each CHW completes brief encounter forms to enable tracking of contacts with each participant, key domains covered in each contact, and referrals made and completed. Every time a CHW reaches out to an identified study participant they create a new encounter tracking form entry that contains a unique study ID and identifies: how the enrollee was contacted; if the CHW provided a service referral and, if so, the type of service referred; if the CHW started a follow-up action plan; if the enrollee accessed a previously referred resource; how the CHW ended the encounter (case closed or continue to follow-up with the client); and if the enrollee was offered and participated in an anonymous program satisfaction survey.

Each health plan CHWs meets together at regular intervals with a Master MICHWA trainer employed with the Detroit Health Department (RG). In these sessions, they reinforce skills and approaches from the initial MICHWA training, discuss shared barriers to reaching and engaging participants and strategies to overcome these, and share information on Cody Rouge-specific resources and programs. While CHWs do not reveal identifying features of individual cases, these "reflective consultation" sessions build a sense of community and mutual support among the CHWs and provide opportunities for ongoing booster support and program-specific training.

Usual Care treatment. Because the pool of all eligible patients exceeds the assigned CHWs' manageable caseload over the 12-month evaluation period, each month a subset of eligible patients is randomized by the health plans to either the CHW program or a control arm. Members randomized to the control arm remain eligible for usual health plan outreach services. Each health plan has algorithms for identifying which health plan members meet criteria for existing outreach services (e.g., not meeting Healthcare Effectiveness Data and Information Set [43] quality measures).

2.3.1.1. Outcomes. To meet Aim 1, we will assess the project's effect on health care utilization, costs, and return on investment as measured by ED visits, ambulatory care-sensitive hospitalizations, and primary care use at 12 months, compared to the eligible beneficiaries randomized to receive usual health plan services over the evaluation period. We hypothesize that over 12 months, the CHW program will decrease use of high-cost acute care services in high-utilizers compared to non-participants. We also hypothesize that over 12 months, the CHW program will decrease costs in high-utilizers compared to non-participants, and that cost savings will exceed program costs.

To meet Aim 2, we will evaluate the project's effects on key patient-centered outcomes among participants in the program who agree to complete the anonymous survey, including satisfaction with services, attainment of key goals, and self-reported utilization. We will assess the extent to which participants subjectively attribute any positive health changes to their CHW. We hypothesize that upon completion of the CHW program, participants will report significant improvements in attainment of behavioral, health, and social goals, referrals made and completed, and high satisfaction with CHW services.

To meet Aim 3, we will evaluate barriers and facilitators to adoption, implementation, maintenance, and potential spread. Using an integrated RE-AIM framework [44] and the Consolidated Framework for Implementation Research (CFIR) [45], we will conduct semi-structured qualitative interviews with CHWs, key informants, and community partners over the course of the study. CHW interviews take place at baseline, mid-implementation, and at the end of the project, and other key informant interviews take place at mid-implementation and at the end of the study. The interview protocols focus on key informants' subjective impressions of implementation domains such as facilitators, barriers, complexity, and resources. The interviews also elicit stories about encounters between the CHWs and their clients that illustrate both positive and negative experiences in the field. CHW interviews are audio-recorded, transcribed verbatim, and coded for themes. We hypothesize that satisfaction of participating CHWs will be high, and other key stakeholders will find the program acceptable while providing important feedback for ways to continue to improve and refine the program.

2.3.1.2. Participant timeline. Table 1 outlines the data collection points of the research evaluation.

2.3.1.3. Sample size. We will enroll at least 125 health plan members per arm. Among high-utilizers, we anticipate a mean of 2 ED visits per year in the usual health plan services arm. We expect a reduction in mean ED visit by 0.65 per year to be clinically meaningful, and the proposed sample size will give 80% power to detect this difference with a 0.05-level two-sided test, assuming 0.01 within-CHW correlation. For hospitalizations, we expect 1.5 hospitalizations over 12 months in the control arm, and the proposed sample size will give 80% power to detect a difference in the number of hospitalizations of 0.37 between the two groups.

2.3.1.4. Recruitment. Health plan members. Health plan data on enrollees participating in the CHW demonstration program and all those randomized to receive usual health services over the 12-month period will be included in the primary analysis. The program CHWs also offer participants the opportunity to complete a satisfaction survey on an iPad following a visit at which it is determined that their identified needs have been met as best as possible, or, if only one visit takes place, after their first meeting. Enrollees can participate in the CHW demonstration project even if they elect not to participate in the survey. In order to minimize the risk to enrollees' confidentiality, surveys are anonymous. As such, the study team has no contact with participants. No identifying information is asked on the survey, and all data in responses is described in aggregate.

CHWs. Health plan CHWs were invited to participate in optional, periodic semi-structured interviews during their CHW training at the

Table 1
Timeline.

Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19+
New enrollment of CHW program participants	X	X	X	X	X	X	X	X	X	X	X	X	x	x	x	x	x	x	
Intervention Period	X	X	X	X	X	X	X	X	X	X	X	X	x	x	x	x	x	x	
Conduct brief implementation assessment interviews with CHWs and stakeholders	X			X			X			X			X						x
Collect 12-month follow-up data from health plans													X	X	X	X	X	X	X
Analyze 12-month data																			X
Write reports and manuscripts			X			X													X
Prepare dissemination plan					X											X	X	X	X
Disseminate results			X			X													X

Michigan Community Health Worker Alliance (MiCHWA). For those who agree, a qualitative semi-structured interview was conducted prior to the launch of the demonstration project. CHWs are then followed longitudinally at 6 and 12 months with further interviews.

2.3.1.5. Group allocation. Health plan members are randomized by the health plan to the CHW program or usual health plan services each month, at which time the health plan provides each CHW with the list of members who are eligible for the CHW demonstration project. The CHW then reaches out to each member assigned to them to provide CHW services. To ensure adequate representation of the neediest members, randomization is stratified so that half of each arm consists of patients with 5 or more ED visits in the prior 12 months and half with fewer than 5.

2.3.1.6. Data collection methods. Health plan members. Data on enrolled health plan members in both the CHW program and usual health plan services groups will be obtained from the health plan data sets, including utilization and standardized costs. Only health plan members who are enrolled in the intervention arm will receive anonymous surveys.

CHWs. Data on CHW experiences will be obtained through semi-structured interviews, administered at three time points (baseline, mid-implementation, and post-implementation).

2.3.1.7. Data management. Throughout the study, UM Institutional Review Board (IRB) and HIPAA guidelines will be followed to ensure the privacy and integrity of the data collected. To minimize the risk of a breach of confidentiality, we will take the following steps. First, the data sets shared by the health plans with the study team will be limited data sets – that is, the only potentially identifying information is dates of health care service. Second, enrollee surveys will be anonymous and be administered by non-study staff so that the research team never interacts with participants in person or has access to their protected information. Third, CHWs will be assigned a unique study ID for the purpose of storing their data and linking longitudinal interviews over time. Fourth, prior to each qualitative interview, participants will be led through a verbal consent process in which the researcher emphasizes the voluntary nature of participation, how their data will be used and stored, and the importance of carefully considering the extent to which they will choose to share potentially sensitive information outside of the scope of the non-sensitive questions being asked. The researcher will also ask the interviewee to refrain from mentioning people's names or employers. All electronic data, including interview audio files and transcripts, will be stored on a secure server. Following transcription of an audio file, all identifying data in the transcript will be removed and the audio file deleted.

Study staff members will be required to complete annual training on privacy and HIPAA, as well as biannual training on human subjects protection. All research findings will be presented in aggregate only, including the qualitative CHW data.

2.4. Statistical methods

We will first compare the two study arms to check for balance in terms of their age, gender, prior year ED visit and ambulatory care sensitive and all hospitalization rates, and prevalence and count of baseline comorbid conditions. To assess whether the CHW intervention successfully decreases use of high-cost services (**Aim 1**), our primary outcomes will be ED visits and hospitalizations over a 12-month period. To compare the rates between arms, for ED visits and hospitalizations, we will use separate Poisson regression models with each having a CHW arm indicator as the primary predictor. We will adjust for age, gender and rate of utilization in prior year. To adjust for potential trends over time, we will adjust for month of enrollment using binary indicator variables. To take into account potential within-CHW dependencies, we will fit the Poisson model using generalized estimating equations (GEE) with CHWs as clusters. We will assess the fit of the GEE model at the patient and CHW (cluster) level using various diagnostics and plots. Adjusted rate ratios along with their 95% confidence intervals will be estimated based on the model and reported as a summary measure of comparison. We will use similar approaches to examine differences in primary care visits between groups.

As a planned secondary analysis, we intend to classify a subset of health plan members randomized to the treatment arm as *active treatment participants*. Active participants will be defined as (1) those whom the CHWs designate as partially or fully engaged and, also, (2) members for whom a CHW performed an action on behalf of. We will repeat the analyses above (and below) controlling for active treatment status and compare the active treatment group to both controls and inactive treatment members. While these comparisons will unavoidably conflate treatment and selection effects, they will provide a useful upper bound on the likely treatment effect among active participants. In tertiary analyses, we will adjust for the selection effects using propensity scores provided adequate propensities can be estimated from available data.

Standardized costs will be computed using Medicare standard allowed amounts for all outpatient services, emergency services, and inpatient hospitalizations (based on DRG). Costs will then be Windsorized to the 98th percentile across all arms to reduce the influence of potential outliers. To compare costs between groups, we will model costs as Gamma distributed and use GEE models otherwise identical to those described above.

To assess the effect of the CHW intervention on patient experiences (**Aim 2**), we will report descriptive statistics from the participant survey, which assesses satisfaction with services, whether their reported social, referral, and or medical needs were met through the program, self-report of health and healthcare utilization changes, and subjective beliefs about whether they attribute any health, social need, or healthcare utilization changes to their work with their CHW.

To evaluate barriers and facilitators to adoption, implementation, maintenance, and potential spread (**Aim 3**), we will administer semi-structured qualitative interviews that are informed by an integrated RE-AIM and the Consolidated Framework for Implementation Research (CFIR). Both deductive codes (generated by implementation science concepts) and inductive codes (generated by the data) will be applied to

interview transcripts. We will conduct within-case and cross-case analyses to understand each key informant's experience with the demonstration project and to identify themes. Techniques used in grounded theory methodology [46] will be utilized, including constant comparison and inductive identification of themes from the data. Preliminary descriptive codes will be developed through discussion based on study aims, implementation science domains, and review of the transcripts. The team will refine the coding scheme to produce a codebook through iterative coding of the same data. Finally, all transcripts will be coded using this codebook. The research team will attempt to triangulate the resultant themes with quantitative results when possible.

2.4.1. Approach to missing data

There are two forms of potential missingness in the health-care utilization data. First, we expect some randomized participants to leave their respective health plans prior to the 12-month end point and be censored. To account for this, our generalized linear model will include an offset of the (log) number of months follow up divided by 12. Missingness among demographic and control variables should be minimal, but if present we will utilize multiple imputation via chained-equations to account for this [47,48].

2.5. Discussion

It is well recognized that most of what determines health occurs outside of a healthcare system. However, many health system-based interventions designed to address population health do not sufficiently address social determinants of health, lack sufficient community engagement, or do not create sustainable positive population level outcomes. This may be due to lack of sufficient engagement of community members in the development and implementation of initiatives, limiting community buy-in and potentially stifling effective solutions obtained from those who live in the communities most affected by poor health outcomes. While CHW models are a potential model to improve population health outcomes, lack of sustainable funding limits scalability of such models. Furthermore, time-limited interventions based on grant availability can erode community trust in the organizations that employ them, further jeopardizing effectiveness and acceptability of such interventions over the long term.

In order to meet the need for evidence to inform financially sustainable CHW models, this evaluation was designed to measure the impact of a CHW intervention on health care utilization among enrollees in three Medicaid health plans serving the Cody Rouge neighborhood of Detroit. This health plan-led CHW program incorporates best practices from efficacy trials of CHW programs. Because Medicaid contracts now require Michigan health plans to employ CHWs or contract for CHW services, this study makes an important contribution by evaluating a potentially financially sustainable model of CHW deployment. Michigan is a leader among states in requiring that health plans deploy CHWs with potential for expanding the percentage of members receiving these services. If the current demonstration project is effective in improving utilization outcomes, this evidence may encourage health plans in other states to adopt this model, particularly if we find that the program has a positive return on investment by reducing health care costs relative to usual care. This model has the potential to contribute to sustaining CHW programs that are still largely dependent on time-limited grants.

A distinctive feature of this demonstration project is the partnership among three Medicaid health plans, a city health department, and a key local community organization. The partners work cooperatively to implement and evaluate a CHW program incorporating best practices and targeting a high-need urban neighborhood. Health plans are especially well-positioned to effectively address key population health needs because the vast majority of health care spending in the United States flows through them. Health plans bear financial risk for patients; thus, targeting investments to address social, behavioral, and medical needs that contribute to high beneficiary health care costs, including acute

care utilization and poor health outcomes, can make financial sense. While maintaining their distinct identities [49], the plans worked together to define priority beneficiary populations the program would reach out and serve and agreed that their plan CHWs assigned to the program could participate in the shared MICHWA training and follow shared intervention protocols. The health department assigned an employee who was a Master MICHWA trainer to convene the joint CHW "reflective supervision" sessions that all CHWs attended at regular intervals to share experiences and information. In order to strengthen efforts to reach beyond health care settings to improve health, this is the type of multi-sectoral partnerships that need to be forged and learned from.

This demonstration project should be understood in the context of some limitations. First, the evaluation is not powered to analyze results for subgroups within the CHW program and usual health care service arms, although we will explore potential trends. Therefore, while we will be able to determine whether the intervention had an effect on health utilization and costs compared to eligible individuals who were not enrolled, we will not be able to determine whether demographic or other baseline differences influenced the results. Second, unlike RCTs designed within a single health system by investigators, the current study involves implementation by three separate health plans with differing histories and practices. The study team worked with the CHWs and their supervisors before the launch of the program to establish standard operating guidelines with respect to practices such as number of outreach phone calls and community visits, assessment domains, and "action plan" approaches. However, each health plan has its own culture and workflow, which may introduce subtle differences among the three groups, as well as unknown variables in intervention delivery. Third, privacy concerns made it infeasible to audio-record meetings or otherwise introduce fidelity or uniformity checks for CHW intervention behavior. However, upon data analysis we will be able to analyze potential differences in self-reported CHW behaviors on the encounter forms that they complete for the project. Fourth, because all assessments are of aggregate data, we cannot connect self-reported outcomes that can be linked to individual participants. Thus, we will not be able to determine mediators and moderators of specified outcomes.

Notwithstanding these limitations, the evaluation of this program represents one of the first efforts to examine the return on investment of a real-life CHW program conducted by Medicaid health plans with their own salaried CHWs targeting beneficiaries who live in a specific urban neighborhood. The Cody Rouge community includes several hub organizations that collectively address multiple determinants of health - both clinical and community-based. However, psychosocial factors associated with high levels of poverty, unemployment and social isolation present formidable barriers to accessing clinical and social services. Insights gained from this CHW pilot will help in efforts to overcome those barriers. This study will show the extent to which a model of CHW services affects healthcare utilization and costs, and will also assess satisfaction of participants and CHWs with such services. If the results of this evaluation show benefits of this model of CHW intervention, these results have the potential to increase the implementation of other similar programs and to inform public policy on sustainable financing of CHW services.

2.5.1. Harms

The evaluation research component of this project involves no treatments or procedures, as the CHW intervention is delivered within existing Medicaid health plan practices and workflow. Only the method of generating CHW-eligible health plan members and the additional provision of MiCHWA training and shared protocols differentiates this demonstration project from usual practice. As the patient data sets are limited and the surveys are anonymous, there is minimal risk to health plan members enrolled in the study. Within the qualitative interview portion of the study, CHWs are led through a verbal consent process which includes a statement that is a small risk of a breach of

confidentiality and as such, responses should be carefully considered in the context of future employability.

2.5.2. Trial status

CHW enrollment started in October 2017. Health plan member enrollment began in March 2018 and will continue through June 2019.

Declarations

Ethical approval, consent to participate, and protocol amendments

The study protocol was approved in three separate applications to the UM IRB. As the health plans administer the CHW program as part of their services and also conduct the randomization protocol, the limited data set analysis was approved as "not regulated" as study HUM00136277 and does not involve an informed consent process. The patient survey was approved as exempt human subjects research as study HUM00137251 and involves reviewing a "consent terms" page prior to participation. The CHW interviews were approved as exempt human subjects research as study HUM00137292. Verbal informed consent was obtained from all CHW interviewees. As all components of the protocol are exempt or not regulated, written informed consent is not required for participants and the IRB does not require notification of changes to the protocol.

Confidentiality

Health plans share only limited data sets with the study team. The only potentially identifying information in these data sets is dates of health care service. Data Use Agreements are in place between UM and each of the 3 health plans. Health plan member surveys are anonymous. Transcripts of CHW interviews are identified solely by a study ID number. The database linking the study ID numbers to personally identified information are stored in a limited-access folder on a secure server. During the analysis phase of the project, the data manager will create analytic datasets for statisticians and investigators that are de-identified per HIPAA guidelines.

Consent for publication

Not applicable.

Availability of supporting data

Final data sets underlying publications resulting from this research will be shared upon request. Members of the scientific community who would like a copy of the final data sets (i.e., data sets underlying any publication) from this study can request a copy by e-mailing Dr. Michele Heisler at mheisler@umich.edu. The investigator should state their reason for requesting the data and their plans for analyzing the data. De-identified data will be provided after requestors sign a Letter of Agreement.

Ancillary and post-trial care

Not applicable.

Competing interests

There are no competing interests for any of the authors.

Authors' contributions

MH and AL drafted the manuscript. MH and AL conceived of the study, created the application that succeeded in obtaining the funding, and are the co-principal investigators of the study. EK and JZA participated in the conception and design of the study. All authors reviewed, contributed to, and approved the final manuscript.

References

[1] L.S. Barnard, D.J. Wexler, D. DeWalt, S.A. Berkowitz, Material need support interventions for diabetes prevention and control: a systematic review, Curr. Diabetes Rep. 15 (2) (2015) 574.

[2] S.A. Berkowitz, H.K. Seligman, N.K. Choudhry, Treat or eat: food insecurity, cost-related medication underuse, and unmet needs, Am. J. Med. 127 (4) (2014) 303–310, e3.

[3] A.E. Bonomi, M.L. Anderson, F.P. Rivara, R.S. Thompson, Health care utilization and costs associated with physical and nonphysical-only intimate partner violence, Health Serv. Res. 44 (3) (2009) 1052–1067.

[4] B. Booske, J. Athens, D. Kindig, H. Park, P. Remington, County Health Rankings Working Paper: Different Perspectives for Assigning Weights to Determinants of Health, University of Wisconsin Population Health Institute (UWPHI), 2010.

[5] Centers for Disease Control and Prevention, National Health Expenditures, Average Annual Percent Change, and Percent Distribution, by Type of Expenditure: United States, Selected Years 1960-2014..

[6] M.B. Kushel, R. Gupta, L. Gee, J.S. Haas, Housing instability and food insecurity as barriers to health care among low-income americans, J. Gen. Intern. Med. 21 (1) (2006) 71–77.

[7] J.M. McGinnis, P. Williams-Russo, J.R. Knickman, The case for more active policy attention to health promotion, Health Aff. 21 (2) (2002) 78–93.

[8] G. Miller, C. Roehrig, P. Hughes-Cromwick, C. Lake, Quantifying national spending on wellness and prevention, Adv. Health Econ. Health Serv. Res. 19 (2008) 1–24.

[9] M.R. Patel, J.D. Piette, K. Resnicow, T. Kowalski-Dobson, M. Heisler, Social determinants of health, cost-related nonadherence, and cost-reducing behaviors among adults with diabetes: findings from the National Health Interview, Survey. Med Care 54 (8) (2016) 796–803.

[10] F.P. Rivara, M.L. Anderson, P. Fishman, A.E. Bonomi, R.J. Reid, D. Carrell, R. S. Thompson, Healthcare utilization and costs for women with a history of intimate partner violence, Am. J. Prev. Med. 32 (2) (2007) 89–96.

[11] A. Burdorf, M. Schuring, Poor health as cause and consequence of prolonged unemployment: mechanisms, interventions, and policy recommendations, in: Sustainable Working Lives, Springer, Netherlands, 2015, pp. 215–227.

[12] J.Z. Ayanian, Michigan's approach to Medicaid expansion and reform, N. Engl. J. Med. 369 (19) (2013) 1773–1775.

[13] Healthy Michigan Plan, Healthy Michigan Plan County Enrollment, 2019. Accessed 18 March 2019; Available from: https://www.michigan.gov/documents/mdch/HMP_County_Breakdown_Data_455353_7.pdf.

[14] K. Baicker, S.L. Taubman, H.L. Allen, M. Bernstein, J.H. Gruber, J.P. Newhouse, E. C. Schneider, B.J. Wright, A.M. Zaslavsky, A.N. Finkelstein, G. Oregon Health Study, The Oregon experiment–effects of Medicaid on clinical outcomes, N. Engl. J. Med. 368 (18) (2013) 1713–1722.

[15] American Public Health Association, Support for Community Health Workers to Increase Health Access and to Reduce Health Inequities, AHPA Policy No 20091, 2009. Accessed 18 March 2019; Available from: https://www.apha.org/policies-and-advocacy/public-health-policy-statements/policy-database/2014/07/09/14/19/support-for-community-health-workers-to-increase-health-access-and-to-reduce-health-inequities.

[16] B.M. Campos, E.C. Kieffer, B. Sinco, G. Palmisano, M.S. Spencer, G.A. Piatt, Effectiveness of a community health worker-led diabetes intervention among older and younger latino participants: results from a randomized controlled trial, J Geriatr 3 (3) (2018). PMID:30345345.

[17] T.L. Gary, M. Batts-Turner, H.C. Yeh, F. Hill-Briggs, L.R. Bone, N.Y. Wang, D. M. Levine, N.R. Powe, C.D. Saudek, M.N. Hill, M. McGuire, F.L. Brancati, The effects of a nurse case manager and a community health worker team on diabetic control, emergency department visits, and hospitalizations among urban African Americans with type 2 diabetes mellitus: a randomized controlled trial, Arch. Intern. Med. 169 (19) (2009) 1788–1794. PMID:19858437.

[18] E.C. Kieffer, D.B. Welmerink, B.R. Sinco, K.B. Welch, E.M. Rees Clayton, C. Y. Schumann, V.E. Uhley, Dietary outcomes in a Spanish-language randomized

controlled diabetes prevention trial with pregnant Latinas, Am. J. Public Health 104 (3) (2014) 526–533. PMID:23763411.

[19] J.A. Long, E.C. Jahnle, D.M. Richardson, G. Loewenstein, K.G. Volpp, Peer mentoring and financial incentives to improve glucose control in African American veterans: a randomized trial, Ann. Intern. Med. 156 (6) (2012) 416–424. PMID: 22431674.

[20] W. Palmas, D. March, S. Darakjy, S.E. Findley, J. Teresi, O. Carrasquillo, J. A. Luchsinger, Community health worker interventions to improve glycemic control in people with diabetes: a systematic review and meta-analysis, J. Gen. Intern. Med. 30 (7) (2015) 1004–1012. PMID:25735938.

[21] M.S. Spencer, E.C. Kieffer, B. Sinco, G. Piatt, G. Palmisano, J. Hawkins, A. Lebron, N. Espitia, T. Tang, M. Funnell, M. Heisler, Outcomes at 18 Months from a CHW and peer leader diabetes self-management program for latino adults, Diabetes Care 41 (7) (2018) 1414–1422. PMID:29703724.

[22] T.S. Tang, M.M. Funnell, B. Sinco, M.S. Spencer, M. Heisler, Peer-led, empowerment-based approach to self-management efforts in diabetes (PLEASED), Ann. Fam. Med. 13 (Suppl 1) (2015) S27–S35. PMID:26304969.

[23] J.K. Allen, C.R. Dennison-Himmelfarb, S.L. Szanton, L. Bone, M.N. Hill, D. M. Levine, M. West, A. Barlow, L. Lewis-Boyer, M. Donnelly-Strozzo, C. Curtis, K. Anderson, Community Outreach and Cardiovascular Health (COACH) Trial: a randomized, controlled trial of nurse practitioner/community health worker cardiovascular disease risk reduction in urban community health centers, Circ Cardiovasc Qual Outcomes 4 (6) (2011) 595–602. PMID:21953407.

[24] H.G. Balcazar, H. de Heer, L. Rosenthal, M. Aguirre, L. Flores, F.A. Puentes, V. M. Cardenas, M.O. Duarte, M. Ortiz, L.O. Schulz, A promotores de salud intervention to reduce cardiovascular disease risk in a high-risk Hispanic border population, 2005-2008, Prev. Chronic Dis. 7 (2) (2010) A28. PMID:20158973.

[25] J.N. Brownstein, L.R. Bone, C.R. Dennison, M.N. Hill, M.T. Kim, D.M. Levine, Community health workers as interventionists in the prevention and control of heart disease and stroke, Am. J. Prev. Med. 29 (5 Suppl 1) (2005) 128–133.

[26] L.A. Cooper, D.L. Roter, K.A. Carson, L.R. Bone, S.M. Larson, E.R. Miller 3rd, M. S. Barr, D.M. Levine, A randomized trial to improve patient-centered care and hypertension control in underserved primary care patients, J. Gen. Intern. Med. 26 (11) (2011) 1297–1304. PMID:21732195.

[27] S. Arshad, K.P. Williams, A. Mabiso, S. Dey, A.S. Soliman, Evaluating the knowledge of breast cancer screening and prevention among Arab-American women in Michigan, J. Cancer Educ. 26 (1) (2011) 135–138. PMID:20443095.

[28] S.I. Hou, K. Roberson, A systematic review on US-based community health navigator (CHN) interventions for cancer screening promotion–comparing community- versus clinic-based navigator models, J. Cancer Educ. 30 (1) (2015) 173–186. PMID:25219543.

[29] K.B. Roland, E.L. Milliken, E.A. Rohan, A. DeGroff, S. White, S. Melillo, W.E. Rorie, C.C. Signes, P.A. Young, Use of community health workers and patient navigators to improve cancer outcomes among patients served by federally qualified health centers: a systematic literature review, Health Equity 1 (1) (2017) 61–76. PMID: 28905047.

[30] R.B. Balaban, F. Zhang, C.E. Vialle-Valentin, A.A. Galbraith, M.E. Burns, M. R. Larochelle, D. Ross-Degnan, Impact of a patient navigator program on hospital-based and outpatient utilization over 180 days in a safety-net health system, J. Gen. Intern. Med. 32 (9) (2017) 981–989. PMID:28523476.

[31] R. Cardarelli, M. Horsley, L. Ray, N. Maggard, J. Schilling, S. Weatherford, F. Feltner, K. Gilliam, Reducing 30-day readmission rates in a high-risk population using a lay-health worker model in Appalachia Kentucky, Health Educ. Res. 33 (1) (2018) 73–80. PMID:29474535.

[32] A.A. Galbraith, D.J. Meyers, D. Ross-Degnan, M.E. Burns, C.E. Vialle-Valentin, M. R. Larochelle, S. Touw, F. Zhang, M. Rosenthal, R.B. Balaban, Long-term impact of a postdischarge community health worker intervention on health care costs in a safety-net system, Health Serv. Res. 52 (6) (2017) 2061–2078. PMID:29130267.

[33] S. Kangovi, N. Mitra, D. Grande, H. Huo, R.A. Smith, J.A. Long, Community health worker support for disadvantaged patients with multiple chronic diseases: a randomized clinical trial, Am. J. Public Health 107 (10) (2017) 1660–1667. PMID: 28817334.

[34] S. Kangovi, N. Mitra, L. Norton, R. Harte, X. Zhao, T. Carter, D. Grande, J.A. Long, Effect of community health worker support on clinical outcomes of low-income patients across primary care facilities: a randomized clinical trial, JAMA Intern Med 178 (12) (2018) 1635–1643. PMID:30422224.

[35] E.C. Kieffer, C.H. Caldwell, D.B. Welmerink, K.B. Welch, B.R. Sinco, J.R. Guzman, Effect of the healthy MOMs lifestyle intervention on reducing depressive symptoms among pregnant Latinas, Am. J. Community Psychol. 51 (1–2) (2013) 76–89. PMID:22638902.

[36] K. Kim, J.S. Choi, E. Choi, C.L. Nieman, J.H. Joo, F.R. Lin, L.N. Gitlin, H.R. Han, Effects of community-based health worker interventions to improve chronic disease management and care among vulnerable populations: a systematic review, Am. J. Public Health 106 (4) (2016) e3–e28. PMID:26890177.

[37] M.S. Spencer, J. Hawkins, N.R. Espitia, B. Sinco, T. Jennings, C. Lewis, G. Palmisano, E. Kieffer, Influence of a community health worker intervention on mental health outcomes among low-income Latino and African American adults with type 2 diabetes, Race Soc Probl 5 (2) (2013) 137–146. PMID:26448789.

[38] Centers for Disease Control and Prevention, Policy Evidence Assessment Report: Community Health Worker Policy Components, 2014. Available from: https ://www.cdc.gov/dhdsp/pubs/docs/chw_evidence_assessment_report.pdf. (Accessed 11 September 2019).

[39] H.E. Jack, S.D. Arabadjis, L. Sun, E.E. Sullivan, R.S. Phillips, Impact of community health workers on use of healthcare services in the United States: a systematic review, J. Gen. Intern. Med. 32 (3) (2017) 325–344. PMID:27921257.

[40] C. Cross-Barnet, M. Skillman, R. Dhopeshwarkar, R. Singer, R. Carpenter, M. Freij, S. Campanella, L. Snyder, E. Colligan, Higher quality at lower cost: community health worker interventions in the health care innovation awards, J. Health. Disparities. Res. Prac. 11 (2018) 150–164.

[41] M. Viswanathan, J.L. Kraschnewski, B. Nishikawa, L.C. Morgan, A.A. Honeycutt, P. Thieda, K.N. Lohr, D.E. Jonas, Outcomes and costs of community health worker interventions: a systematic review, Med. Care 48 (9) (2010) 792–808.

[42] Michigan Community Health Worker Alliance, MiCHWA CHW curriculum, Accessed 18 March 2019; Available from: http://www.michwa.org/ch w-training/#Core%20Competency%20Objectives.

[43] M.B. Buntin, A.K. Jain, S. Mattke, N. Lurie, Who gets disease management? J. Gen. Intern. Med. 24 (5) (2009) 649–655. PMID:19308336.

[44] J. Forman, M. Heisler, L.J. Damschroder, E. Kaselitz, E.A. Kerr, Development and application of the RE-AIM QuEST mixed methods framework for program evaluation, Prev Med Rep 6 (2017) 322–328.

[45] L.J. Damschroder, D.C. Aron, R.E. Keith, S.R. Kirsh, J.A. Alexander, J.C. Lowery, Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science, Implement. Sci. 4 (2009) 50. PMID:19664226.

[46] K. Charmaz, Constructing Grounded Theory, Sage, 2014.

[47] S. van Buuren, Multiple imputation of discrete and continuous data by fully conditional specification, Stat. Methods Med. Res. 16 (3) (2007) 219–242.

[48] I.R. White, P. Royston, A.M. Wood, Multiple imputation using chained equations: issues and guidance for practice, Stat. Med. 30 (4) (2011) 377–399. PMID: 21225900.

[49] M. Heisler, A. Navathe, K.B. DeSalvo, K.G. Volpp, The role of US health plans in identifying and addressing Social Determinants of Health (SDOH): rationale and recommendations, Popul. Health Manag. 22 (5) (2019) epub ahead of print.