

Office of Management and Budget

**Section B
Supporting Statement
For
Case Studies in Patient-Centered Care Collaboration to
Improve Minority Health**

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**Prepared for:
Office of Minority Health
U.S. Department of Health and Human Services
The Tower Building
1101 Wooton Parkway, Suite 600
Rockville, MD 20852**

**Prepared by:
Westat
1650 Research Boulevard
Rockville, MD 20850**

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B. Statistical Methods

1. Respondent Universe and Sampling Methods

While not a program evaluation per se, the goal of this project is to improve our understanding of what is necessary to facilitate the dissemination of evidence based CER. To that end, a case study methodology is being employed to address the study objectives using focus groups, surveys, and key informant interviews. From that perspective the sample is purposeful in both the selection of the sites and the selection of the minority serving health providers (pharmacists, health educators, and clinic-based community health workers) and health center patients and residents of the public housing facilities (consumers) who are eligible to participate in the evidence-based programs based on their race/ethnicity and health condition.

Participants. In order to ensure a varied selection of patients to participate in each of the case studies, the following selection procedures are used.

For Chicago. The number of patients participating in the HELP intervention is: 50 African Americans and 50 Hispanics/Latinos from the Lawndale Christian Health Center (LCHC). A screening tool will be used to determine program eligibility for patients who receive services at the participating clinic and have diabetes or hypertension. The target health conditions are: hypertension, diabetes, and obesity. The selection criteria, for inclusion are: African Americans or Latinos; overweight or obese (BMI > 25) and Type 2 diabetes (Hb1A1c > 7.5) or hypertension; 18 to 65 years of age; non pregnant; ability to perform self-care; not travelling during the intervention period; and male or female. The criteria for exclusion are: psychiatric diagnoses, alcohol or substance abuse, seizures, myocardial infarction or stroke within past 6 months, terminal illness, pregnancy, and cognitive impairment.

Within the LCHC patient database, it is estimated that approximately 600 active health center patients will be eligible to participate in the HELP program. Of this number, 200 patients will be identified through preliminary

screening of their electronic medical record. The selected consumers will receive a letter inviting them to participate in HELP. Each of the 200 patients will be asked to call the LCHC to indicate their interest. When they call, the Center’s administrative staff will administer the paper and pencil screening tool to patients to complete the screening process. Center staff will follow-up, further discuss the program with the patients, and assess additional eligibility requirements. Of this subgroup, 100 patients will be randomly selected for enrollment in the HELP program.

See Exhibit 2 for the preliminary numbers of patients expected to participate in the Chicago study. Given the size of the intervention class, four concurrent cycles of the class will be implemented with maximum class sizes of 25 patients per class. Focus groups will be conducted with a total of 40 participants, reflecting the selection of 10 participants from each class. There will be one focus group conducted in Spanish for Spanish speaking participants, one group conducted in English for Hispanic English- speaking participants, and two groups conducted in English for African American participants.

Exhibit 2. Chicago Hub Preliminary Stats for Targeted Residents of Lawndale Christian Health Center (LCHC) Facilities

LCHC	Hypertension	Diabetes	Obesity	Total
African American	16	20	14	50
Hispanic	16	20	14	50
Total	32	40	28	100

For Houston. The racial/ethnic target populations of the four senior residential facilities where patients will be recruited are as follows: African Americans (n=351), Asian Americans (n=173), Hispanics/Latinos (n=149). The health conditions included are diabetes and hypertension; and the focus is on patients who are 55 years and older and take at least 1 medication. The selection criteria, for inclusion are as follows. Diabetes Focus: Age 55 years & older, member of target ethnic groups, resident of 1 of the participating facilities, taking at least 1 medication for diabetes at time of recruitment, and access to a telephone at home. Hypertension Focus: Age 55 years &

older, member of target ethnic groups, resident of 1 of the participating facilities taking at least 1 medication for hypertension at time of recruitment, and access to a telephone at home.

The target populations for the four facilities are presented in Exhibit 3; this represents the number of residents who meet the racial and ethnic criteria. Exhibit 4 provides the estimated number of residents from two of the four sites who meet two criteria: race and ethnicity, and health condition. Data were not available for the other two sites. Given the relatively small number of residents in the four facilities who may meet the study criteria for racial/ethnic group and health condition, the Houston staff may not sample the residents, but include the entire population of eligible residents. Program capacity for this intervention is 100 patients, approximately 25 per residential facility. Focus groups will be conducted with 30 participants in Houston.

Due to the small sample sizes, we will not conduct statistical tests of the differences between groups, because they would be underpowered. But we will analyze each participants' individual pre and post survey changes for the purpose of informing them of any changes that have occurred between the pre and post-intervention measurements.

Exhibit 3. Target Population Demographics: Houston Housing Authority (HHA) Sites

Target Population	Telephone	Lyerly	Bellerive	Historic Oaks of APV	Totals
African Americans	73.5% (n=136)	65.5% (n=114)	25.5% (n=39)	38.5% (n=62)	351
Asian Americans	5.9% (n=11)	6.9% (n=12)	47.7% (n=73)	47.8% (n=77)	173
Hispanic/Latinos	20.5% (n=38)	27.6% (n=48)	26.8% (n=41)	13.7% (n=22)	149
Total	185	174	153	161	673

Exhibit 4. Houston Hub Preliminary Stats for Targeted Residents of Houston Housing Authority Facilities by Health Condition: Lylerly and Bellerive Only

Lyerly Housing (potential participants)	Hypertension only	Diabetes only	*HTN and DM	Total
African American	13	3	10	26
Asian American	1	0	1	2
Hispanic	3	5	8	16
Total	17	8	19	44

*HTN=hypertension, DM= diabetes mellitus

Bellerive Housing	Hypertension	Diabetes	HTN and DM (inclusive of columns 1 & 2)	Total
African American	9	11	8	28
Asian American	6	4	4	14
Hispanic	12	11	5	28
Total	27	26	17	70

*HTN=hypertension, DM= diabetes mellitus

Tables will be constructed to describe the change across projects on client outcomes. It will not be possible to conduct statistical tests of changes between baseline and followup.

Implementation Staff. In Chicago, providers participating in the HELP intervention will be recruited through the health clinic partner, Lawndale Christian Health Center. Lawndale will recruit and select the CHWs to participate in this program based on the following criteria: experience implementing similar programs in the clinic, experience working with participants who have similar demographic characteristics as the targeted population, language skills, and availability.

In Houston, the pharmacists and health educators will be recruited through Texas Southern University. Flyers detailing the responsibilities and qualifications for the pharmacists' consultant positions were submitted to local professional pharmacy organizations and emailed to alumni of the

College of Pharmacy and Health Sciences at Texas Southern University. The PCCC Local Hub staff reviewed the initial documents (resume, cover letter, two reference letters, and a copy of pharmacist license) submitted by interested candidates to select interviewees. Interviews were conducted by the principal and co-principal investigators, and project director. Following an orientation of the project, the interviews focused on candidates' interest and experience working with senior populations specifically with hypertension and diabetes; education and clinical training; scheduled availability to complete trainings and delivery of services; as well as ability to read and write at least one of the languages spoken by the target populations.

The most suitable candidates will be selected based on the qualifications needed to successfully implement the proposed intervention: ability to work cooperatively as a member of a team; knowledge of a wide range of medications and therapies; patient communication abilities, which are necessary to answer patient inquiries about their treatments; demonstration of effective verbal and written communication skills; and multilingual in English, Spanish, Vietnamese, Chinese (Mandarin, Cantonese). Candidates selected will also demonstrate experience working with senior populations, experience in disease state management and knowledge of current medications and treatment guidelines for diabetes and hypertension. The health educators will be recruited and selected by the director of the Harris County Hospital District's health education department who assigned three health educators to work with the local hub's intervention. These health educators will be selected based on their previous work with the seniors of the HHA and the surrounding community as well as their ability to speak the languages of the communities of interest.

Focus group sessions will be conducted with the population of providers in each site. This includes all 5 of the implementation staff including CHWs, health educators, and trainers in Chicago; and, all 10 pharmacists and health educators in Houston.

Facility Administrators. The administrators in Chicago will be recruited and selected through the participating health clinic, Lawndale Christian

Health Center. These interviewees will be selected based on their involvement with the program. The clinic administrator and physician will be actively involved in the clinic operations, and the physician will have a caseload of patients that mirror the demographic and health conditions of the participants. Key informant interviews will be conducted with the one facility administrator and one physician in Chicago from the health clinic.

The administrators in Houston will be recruited and selected through the city of Houston's Housing Authority (HHA). The local hub contacted the HHA's director of client services regarding their interest in partnering with the local hub to implement a pharmacist led home based model that focused on disease state management in diabetes and hypertension in their senior housing communities. The director coordinated a meeting between the local hub staff and the resident coordinator of client services. This meeting resulted in the HHA's assignment of four facilities managers to serve on the local workgroup and assist with logistical coordination of the program. They are the gatekeepers to the targeted populations and serve as liaisons between the local hub and community of potential participants. In Houston, key informant interviews will be conducted with four administrators from the four residential buildings.

Local Hub Members. Key informant interviews will be conducted with the Local Hub Members. In Chicago, key informant interviews will be conducted with all 12 members.

The local hub group was recruited by the former dean of the College of Pharmacy and Health Sciences. The principal and co-investigators have expertise and experience in disease state management and knowledge of current medications and treatment guidelines for diabetes and hypertension; experience working with the senior population; and implementing community based programs/research. In Houston, key informant interviews will be conducted with all 10 members.

Steering Committee Members. The committee members were selected based on their reputations either individually or through their organizations as experts in health disparities research and practice. They were nominated

and approved by OMH to serve on the committee. Surveys will be administered to the entire 12 member Steering Committee.

2. Information Collection Procedures

Information collection procedures will vary by local hub site. This project will not interfere with ongoing program operations. Should it be needed, accommodations will be made for any participants who have disabilities.

In Chicago, once participants are randomly selected from the health clinic patient database through their electronic medical record, a letter will be sent to them inviting them to participate in HELP. They will be asked to call the health center and indicate their interest in participating. When they call, the clinic administrative staff will administer the paper and pencil screening tool to patients; the Center's staff will follow-up, further discuss the program with the patients, and assess additional eligibility requirements. If the patient is deemed eligible and agrees to participate, they are enrolled in the program. Having an electronic medical record is required to satisfy initial eligibility criteria. . It is anticipated that of those who are eligible to participate, 100 people will enroll in HELP.

Once participants' agree to enroll and participate in the program, CHWs and clinic staff will first have the patients sign a consent form. Baseline and post program information will be obtained by CHWs/program staff when patients attend the first and last sessions. The focus group will be conducted after the last session. In instances where clients are no longer participating in or have dropped out of the intervention, staff from the program will locate the patients and conduct the post-intervention interviews. These interviews are intended to be conducted face-to-face, as needed they can be conducted over the phone. The forms will be available in Spanish and English, and those who have literacy problems will be offered assistance in completing the form.

Unique participant identification numbers and case numbers will be used to facilitate matching baseline and post-intervention data, but no identifying

information will be provided to staff. The data for those patients with baseline and post-intervention data will be matched using a unique encrypted identifier. Completed questionnaires will be kept in a locked file. Focus groups will be conducted by staff from the local hub who have not been directly involved with the program participants.

In Houston, once participants have been recruited by the local hub staff, program staff will have patients sign a consent form to acknowledge their participation in the program and consent to complete program questionnaires, as well as consent to have their clinical data (blood pressure readings, measure diabetic HbA1C levels, and weigh patients) measured. The baseline and post program paper and pencil data collection forms will be administered and completed by the pharmacists and Houston Hub staff. The focus group will be conducted after the last session. The forms will be available in English, Spanish, Chinese, and Vietnamese depending on frequently spoken language of the participating population. Pharmacists and staff will administer the forms in the preferred language of the patient. Unique patient identification numbers will be used to facilitate matching baseline and post-intervention data, but no identifying information will be provided to project staff. Paper forms will be given to project staff for data entry and analysis. Completed questionnaires will be kept in a locked file and the computer database will be password enabled so that only project staff can access the information. Focus groups will be conducted by staff from the local hub who have not been directly involved with the program participants.

3. Methods to Maximize Response Rates

A number of methods will be used to maximize the response rates, they include:

- **Weekly Contact with Participants in Chicago and Bi-weekly Contact with Participants in Houston**—The consistent and scheduled contact with the participants in both cities will minimize the attrition rates for these programs (McGonagle, Couper, & Schoeni, 2011). In Chicago, the classes are held each week for 12 weeks with data collection occurring in weeks 1 and 12. In Houston,

the contacts are twice a month with data collection occurring in the first and last sessions.

- **Incentives**—Chicago will provide a \$15 gift card to participants as an incentive at the mid-point and upon completion of the program. Those selected for the focus group will also receive a \$15 incentive for their participation. They will also receive bus passes to eliminate any transportation barriers they may have. Houston will provide incentives to patients to increase the likelihood of the participants attending and completing the post-intervention surveys; participants will receive a \$15 gift card as an incentive upon completion of the program.
- **Well Trained Staff**— All staff delivering the programs will be well trained before any interactions with the participants. They will be trained on the curriculum as well as their interactions with participants. For example, the Houston pharmacists will be trained in motivational interviewing to reinforce their educational approach with the participants. Staff will be well prepared to deliver the curriculum and keep the interest of the patients high, which will lead to a high retention rate.
- **Good Contact Information**—Staff will be trained to obtain good contact/locator information for each participant. If someone leaves the intervention, the staff will attempt to obtain the post-intervention information.

4. Tests of Procedures

The data collection tools were pilot tested prior to submission to IRB and OMB. A small number of patients, three to five, were given the baseline and post-intervention tools to complete. These patients had similar characteristics as the patients who will enroll in the interventions. They will meet the eligibility criteria for race and ethnicity and health condition. Feedback from this activity was be used to revise the questionnaires. The other surveys - implementation staff, facility administrators, local hub members, and steering committee members - have also been pilot tested with minimal to no modifications.

5. Statistical Consultants

Responsible individuals for OMH are:

Jamila R. Rashid, PhD, MPH
Associate Director for Research and Policy
OMH, OASH, OS, HHS
240-453-6154
Jamila.rashid@hhs.gov.

The Chicago and Houston staff designed the data collection with input from the Westat staff. They will be responsible for data collection. Data analysis will be conducted by the Westat staff. The individual responsible for statistical consultation of this data collection is:

Joseph Sonnefeld,
Senior Study Director
Westat
301-251-1500.

References

- Castiglioni, L., Pforr, K., and Krieger, U. (2008). The Effect of Incentives on Response Rates and Panel Attrition: Results of a Controlled Experiment. *Survey Research Methods*, 2(3), 151-158.
- McGonagle, K. A., Couper, M.P., and Schoeni, R.F. (2011). Keeping Track of Panel Members: An Experimental Test of a Between-Wave Contact Strategy. *Journal of Official Statistics*, 27(2), 319-338.