Use of Community Health Workers and Patient Navigators to Improve Cancer Outcomes Among Patients Served by Federally Qualified Health Centers: A Systematic Literature Review

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Abstract

Introduction: In the United States, disparities in cancer screening, morbidity, and mortality are well documented, and often are related to race/ethnicity and socioeconomic indicators including income, education, and healthcare access. Public health approaches that address social determinants of health have the greatest potential public health benefit, and can positively impact health disparities. As public health interventions, community health workers (CHWs), and patient navigators (PNs) work to address disparities and improve cancer outcomes through education, connecting patients to and navigating them through the healthcare system, supporting patient adherence to screening and diagnostic services, and providing social support and linkages to financial and community resources. Clinical settings, such as federally qualified health centers (FQHCs) are mandated to provide care to medically underserved communities, and thus are also valuable in the effort to address health disparities. We conducted a systematic literature review to identify studies of cancer-related CHW/PN interventions in FQHCs, and to describe the components and characteristics of those interventions in order to guide future intervention development and evaluation.

Method: We searched five databases for peer-reviewed CHW/PN intervention studies conducted in partnership with FQHCs with a focus on cancer, carried out in the United States, and published in English between January 1990 and December 2013.

Results: We identified 24 articles, all reporting positive outcomes of CHW/PN interventions in FQHCs. CHW/PN interventions most commonly promoted breast, cervical, or colorectal cancer screening and/or referral for diagnostic resolution. Studies were supported largely through federal funding. Partnerships with academic institutions and community-based organizations provided support and helped develop capacity among FQHC clinic leadership and community members.

Discussion: Both the FQHC system and CHW/PNs were borne from the need to address persistent, complex health disparities among medically underserved communities. Our findings support the effectiveness of CHW/PN programs to improve completion and timeliness of breast, cervical, and colorectal cancer screening in FQHCs, and highlight intervention components useful to design and sustainability.

Keywords: cancer prevention; cancer screening; chronic disease; community health worker; FQHC; medically underserved; patient navigation
Introduction

In the United States, disparities in cancer screening, diagnosis, time to treatment, and morbidity and mortality are well documented, and often are related to an individual’s race/ethnicity, income, education, and healthcare access.1,2 To address health disparities, public health approaches that consider the physical, social, cultural, organizational, community, economic, legal, or policy contexts within which people live have the greatest potential benefit.3–5 Specifically, increasing access to quality healthcare for the medically underserved and increasing the capacity of the prevention workforce are key recommendations to effectively address health disparities and achieve health equity.4,6–8

Community health workers (CHWs) and patient navigators (PNs) are members of the prevention workforce who increase access to care for the medically underserved.8–10 A CHW is a nonclinical, frontline, public health worker who is a trusted member and/or has an unusually close understanding of the community served, and can function to bridge the gap between an individual and the healthcare system.11 CHWs are also commonly referred to as promotores de salud, community health representatives, community health advisors, lay health educators, and lay health advisors, among other titles.12 The PN role was originally developed in the early 1990s to address cancer disparities by reducing barriers to timely breast cancer diagnosis and treatment among poor women in Harlem. Since that time, the scope of PNs has expanded across several cancers and the entire cancer spectrum from prevention, detection, diagnosis, treatment, and survivorship to the end of life.13 Today, both CHWs and PNs work to address health disparities across many chronic diseases, and improve health by providing education and advocacy services, addressing individuals’ barriers to care, and linking and navigating patients through the healthcare system, and to financial and community resources. CHW/PN efforts have led to increases in cancer screening and timely completion of diagnostic follow-up and cancer treatment initiation.14–16

Federally qualified health centers (FQHCs) are legislatively mandated to provide primary care for medically underserved communities, and thus are ideal settings for CHW/PN interventions. The U.S. Department of Health and Human Services’ Health Resources and Services Administration (HRSA) currently funds ~1300 FQHCs serving over 22 million patients annually.17 FQHCs are critical to addressing cancer disparities among the medically underserved in the United States,18,19 as FQHC patients often are at greater risk for developing cancer and experiencing worse cancer outcomes compared with the general U.S. population.2 The Affordable Care Act (ACA) established the Community Health Center Fund, providing $11 billion over a 5-year period (2011–2015) for the operation, expansion, and construction of health centers.20,21 Consequently, FQHCs as safety-net healthcare organizations have been increasingly responsible for providing crucial primary care services for vulnerable populations.22 Beyond expanding FQHCs, ACA requires that most insurance plans provide certain in-network preventive health services, including breast, cervical, and colorectal cancer screening, at no cost to patients when obtained in-network. CHW/PN programs can facilitate prevention activities and can help the newly insured and others gain access to primary care and complete cancer screening.19

CHW/PN programs and FQHCs are natural allies. However, little has been systematically documented about the effectiveness of CHW/PN programs conducted in FQHCs for cancer prevention and control. Therefore, we conducted a systematic review of the peer-reviewed literature to identify studies of cancer-related CHW/PN interventions conducted in FQHCs and other HRSA-funded community health centers, and FQHC Look-Alike clinics. FQHC Look-Alikes share a mission with FQHCs to provide primary care to medically underserved communities and are eligible for FQHC reimbursement structures and discounted drug pricing, but are not funded by HRSA and therefore cannot be called FQHCs (https://bphc.hrsa.gov/programopportunities/lookalike). Our objectives were to first identify studies that evaluated the effectiveness of these interventions in addressing cancer prevention and control disparities among the medically underserved (e.g., increasing screening, reducing time to diagnosis and treatment, reducing barriers to care) and to subsequently describe the components and characteristics of those interventions to guide future intervention development and evaluation.

Methods

In January 2014, we searched five databases: PubMed/Medline, Scopus, Web of Science, CINAHL (Cumulative Index to Nursing and Allied Health Literature), and PsychINFO. Search terms utilized were based upon previous research19,23–25 and organized into three categories: (1) position/role, (2) clinical setting, and (3) disease focus (Table 1). We limited the search
Table 1. Search Terms Used to Identify Relevant Literature

| Position/role | Adherence supporter*; Camp health aide*; Client navigat*; Community health advis*; Community health advocate*; Community health aide*; Community health promoter*; Community health representative*; Community health worker*; Community navigator*; Community outreach worker*; Consejer*; Embajador*; Health aide*; Health coach*; Health communicator*; Health guide*; Health navigator*; Health volunteer*; Lay health adviser*; Lay health advisor*; Lay health advocate*; Lay health educator*; Lay health promoter*; Lay health representative*; Lay health worker*; Lay navigat*; Lay outreach worker*; Native American navigat*; Navigat*; Navigation program*; Navigation service*; Navigator nurse*; Nurse navigat*; Outreach worker*; Patient navigat*; Peer counselor*; Peer educator*; Peer health advisor*; Peer health counselor*; Peer health educator*; Peer health promoter*; Peer leader*; Peer navigat*; Promotor* |
| Clinical setting | Community health center*, CHC*; Community health clinic*; Federally Qualified Health Center*, FQHC*; FQHC Look-Alike*; Neighborhood health center*; Neighborhood health clinic*; Tribal health center*; Tribal health clinic*; Indian Health Service clinic*; IHS clinic*; Migrant health center*; Migrant health clinic*; Healthcare for the homeless; Nurse Managed Health Clinic*, NMHC*; Nurse managed health center*; Public health clinic*; Urban health center*; Rural health center*; Urban health clinic*; Rural health clinic* |
| Disease focus | Cancer; Neoplasms |

*Indicates use of wildcard.

FIG. 1. Flowchart illustrating relevancy literature review selection process.

Note: Some citations were excluded based on >1 criterion, so the sum of citations excluded based on single criterion is more than the total number of citations excluded.
### Table 2. Study Characteristics of Relevant Literature (n = 24)

| Abbreviated citation | Study setting | Cancer (continuum) | Priority population | Study design | Position title | Funding | Intervention summary | Outcome measures | Results |
|----------------------|---------------|--------------------|---------------------|--------------|----------------|---------|---------------------|-----------------|---------|
| Battaglia et al.  | Clinic        | Breast, cervical (diagnosis) | Urban women with abnormal breast or cervical cancer screening test result | Quasi-experimental trial. 6 FQHCs participated. 3 assigned breast navigation, 3 assigned cervical navigation. Each group served as control for the other. | Patient navigator | National Cancer Institute | Navigators contacted patients after receipt of the test results and worked to identify barriers and develop strategies with the focus on timely completion of the diagnostic evaluation. | Time to diagnosis and diagnostic resolution for cervical and breast cancer | (1) Navigated women had significantly shorter time to diagnosis than controls ($p = 0.003$) and were more likely to achieve diagnostic resolution. (2) Among women whose abnormal breast cancer test was resolved after 60 days, navigated women had significantly shorter time to diagnosis than controls ($p = 0.019$). No difference was found in time to diagnosis among women whose abnormal results were resolved before 60 days ($p = 0.746$). |
| Burhansstipanov et al. | Clinic and community | Breast (screening, rescreening) | Urban women 39 years of age who reported at least one mammogram but had not been screened within 18 months prior. | Quasi-experimental trial. Control and intervention groups identified by a program database. | Patient navigator | National Cancer Institute | PN provided culturally appropriate education, including a newsletter, and one-on-one assistance with scheduling a mammogram and CBE. Control group received a newsletter. | Screening mammogram self-report during study period | Women who received the navigation intervention were more likely to report being rescreened ($p < 0.05$). |
| Clark et al.  | Clinic | Breast (screening, diagnosis) | Women 18–75 years of age who self-identified as Black or of African descent | Prospective single-arm cohort. 5 FQHCs participated. | Case manager | CDC Center for Community Health and Health Equity; The 2006 Miles and Eleanor Shore Minority Faculty Development Award | Case managers provided tailored services to address barriers to care, patient-clinician communication, social intervention referrals, and促进了 women due for screening or follow-up. | Impact of years of study participation on rates of initial or repeat mammography; Timely follow-up for abnormal results | (1) Increase in screening uptake was observed with increased years of study participation (OR 1.53, $p < 0.05$). (2) There was no difference in rate of timely follow-up for abnormal results during study period compared with before study period. |
| Clark et al.  | Clinic | Cervical (screening, diagnosis) | Urban Black women 18–75 years of age at high risk for inadequate Pap test screening and follow-up | Prospective single-arm cohort. 5 FQHCs participated. | Case manager | CDC Center for Community Health and Health Equity; The 2006 Miles and Eleanor Shore Minority Faculty Development Award | Case managers provided tailored services to address barriers to care, patient-clinician communication, social intervention referrals, and促进了 women due for screening or follow-up. | Years of case management impact on Pap screening; Timely follow-up for abnormal Pap | (1) Women with more years of case management were more likely than women with fewer years to receive Pap tests at recommended intervals ($p < 0.005$). (2) No difference was seen in rate of timely follow-up during case management intervention compared with before case management intervention. |
| Earp et al.  | Community | Breast (screening) | Rural African American women ≥50 years of age | Quasi-experimental trial. 5 intervention counties and 5 control counties. | Lay health advisor, community outreach specialist | National Cancer Institute; Susan G. Komen, Avon Breast Health Access Fund, Pittsburgh Foundation, Kate B. Reynolds Charitable Trust | Lay health advisors promoted awareness and use of breast cancer screening. Community outreach specialists supported lay health advisors through monthly meetings and assistance in organizing activities. | Communitywide mammogram self-report | Between baseline and initial follow-up, mammography use increased in both intervention and control counties, but increased more in the intervention counties ($p = 0.005$), particularly among low-income women ($p = 0.02$). |
| Abbreviated citation | Study setting | Cancer (continuum) | Priority population | Study design | Position title | Funding | Intervention summary* | Outcome measures | Results |
|----------------------|--------------|-------------------|---------------------|--------------|--------------|---------|-----------------------|-----------------|---------|
| Fernandez et al.39   | Community    | Breast, cervical  | Hispanic farmworker women ≥50 years of age | Quasi-experimental trial and pre-post comparison. 2 intervention communities and 2 control communities. | Lay health worker | CDC; National Cancer Institute | Lay health workers provided education in women's homes and gave information about local providers and breast and cervical cancer screening. | Completion of screening tests for breast and/or cervical cancer | Among women who participated in a 6-month follow-up interview, screening completion rates were higher among women in the intervention group than the control group for both mammography (40.8% vs. 29.9%, p < 0.00) and Pap test (39.5% vs. 23.6%, p < 0.005). |
| Gotay et al.29       | Clinic       | Breast, cervical  | Women ≥35 years of age and of Hawaiian ancestry | Quasi-experimental trial, pre-post comparison. 1 intervention clinic, control neighborhoods identified via directory | Lay health educator | National Cancer Institute | Lay health educator-led, talk story group was held in the clinic. Participants discussed experiences and were given information and education. | Compliance with age-specific screening guidelines | Women in the intervention community were more likely to report compliance with Pap test (p = 0.02) and CBE (p = 0.04) guidelines. There were no changes in breast self-examination or mammogram compliance in the intervention community. |
| Honeycutt et al.30    | Clinic       | Colorectal        | Rural, uninsured, low-income individuals aged 50–64 years | Quasi-experimental trial. 4 intervention FQHCs, 9 control FQHCs | Patient navigator | CDC; National Cancer Institute | Navigators conducted chart audits, managed provider reminder systems, coordinated screening and follow-up, provided patient education and appointment reminders, and assisted patients in overcoming barriers to screening | Colonoscopy referral and compliance with recommended screening guidelines | Patients at intervention clinics were almost 5 times more likely to receive a colonoscopy referral (p < 0.05), 8 times more likely to undergo colonoscopy (p < 0.01), and 6 times more likely to be guideline compliant than controls clinics (p < 0.0001) when controlled for age and race. |
| Hunter et al.30       | Community    | Breast, cervical, other chronic diseases (screening) | Uninsured Hispanic women ≥40 years of age living in rural area near the U.S.-Mexico border | RCT. Randomization of women who were offered and received a free comprehensive exam at a community health center. | Promotora | CDC | Intervention included a postcard reminder and a home visit from a promotora who discussed barriers, and facilitate scheduling of appointments. | Receipt of a second annual comprehensive exam (Pap test, CBE, mammogram referral, HPV test, cholesterol, blood glucose, and blood pressure screening). | Receiving the promotora intervention was associated with a 35% increase in rescreening over the postcard-only reminder (RR = 1.35, 95% CI: 1.09-1.62). |
| Jandorf et al.31      | Clinic       | Colorectal        | Urban individuals ≥50 years of age who were noncompliant with colorectal cancer screening guidelines | RCT. Participants from 1 FQHC randomized into navigation or control group. | Patient navigator | National Cancer Institute | Participants received phone calls from navigator. | Completion of fecal occult blood test or endoscopy | Endoscopic exam was completed by 23.7% of navigated patients compared with only 8% of control patients (p = 0.018). There was no significant difference in FOBT completion. |

(continued)
| Abbreviated citation | Study setting | Cancer (continuum) | Priority population | Study design | Position title | Funding | Intervention summary | Outcome measures | Results |
|---------------------|---------------|--------------------|---------------------|--------------|---------------|---------|-----------------------|----------------|---------|
| Katz et al.41        | Community     | Cervical (screening) | Native American, African American, White women ≥40 years of age | RCT, pre-post comparison | Lay health advisor | National Cancer Institute | Intervention participants received home visits and individualized education focused on mammography, and follow-up phone calls from lay health advisor. Control group participants received a physican letter/brochure focused on Pap testing. | Pap test completion | Women in both intervention (OR: 1.70; 1.31, 2.21, p<0.001) and control groups (OR: 1.38; 1.04, 1.82, p=0.025) significantly increased cervical cancer screening compliance. An increase was observed among women at high risk for developing cervical cancer (OR: 1.88; 1.54, 2.28, p<0.001) but not among women who were categorized as low-risk. No significant difference was identified between control and intervention groups. |
| Lasser et al.33      | Clinic        | Colorectal (screening) | Urban English-, Portuguese-, Spanish-, or Haitian Creole-speaking individuals aged 52–80 years not screening compliant | Quasi-experimental trial | Patient navigator | American Cancer Society | Participants received screening brochure, and telephone navigation to discuss the need for CRC screening and screening options. | Completion of CRC screening within 6 months | Of patients who received the navigation intervention, 31% were screened at intervention health center compared with 9% of patients at control health center (p<0.001). |
| Lasser et al.32      | Clinic        | Colorectal (screening) | Urban English-, Portuguese-, Spanish-, or Haitian Creole-speaking individuals aged 52–74 years not screening compliant | RCT. 6 centers, individuals randomized within clinics into navigation or usual care group | Patient navigator | American Cancer Society | Patients received 6 hours of navigation that included education regarding CRC and CRC screening, encouraging and facilitating screening, helping obtain health insurance, assisting with screening scheduling, and meeting them on the day of their colonoscopy. | Completion of CRC screening within 1 year | Intervention patients were more likely to undergo colorectal cancer screening (33.6% vs. 20.0%, p<0.001) and more likely to be screened by colonoscopy (26.4% vs. 13.0%, p<0.001) than patients receiving usual care. |
| Markossian et al.34   | Clinic        | Breast, cervical (diagnosis) | Urban women≥18 years of age with an abnormal breast or cervical cancer screening test | Quasi-experimental trial | Patient navigator | National Cancer Institute | Navigation included identifying and recruiting patients, identifying individual barriers to receiving care, developing and implementing individualized plans to address barriers, and tracking patients through problem resolution. | Time to diagnostic resolution | Compared with controls, the breast navigation group had a shorter time to diagnostic resolution (aHR = 1.65, 95% CI = 1.20–2.28, p < 0.01), and the cervical navigation group had a shorter time to diagnostic resolution for those who resolved after 30 days (aHR = 2.31, 95% CI = 1.75–3.06, p < 0.01). No difference before 30 days (aHR = 1.42, 95% CI = 0.83–2.43). |
| Maxwell et al.46     | Clinic and community | Breast (diagnosis) | Korean American women aged ≥40 years of age who received care at participating clinic and had been referred for and missed their follow-up diagnostic appointments | RCT. 2 clinics participated, women randomized within clinics into navigation or usual care group | Patient navigator | U.S. Army Medical Research and Materiel Command, National Cancer Institute | PNs provided tailored assistance that included appointment reminders, information on the importance of diagnostic follow-up, meeting women at the referral clinic, helping completing forms, and providing information and emotional support. Usual care included phone calls and a letter. | Completion of recommended follow-up exam at 6 months (self-report with some confirmed by chart review) | Among women who completed 6-month follow-up survey, 97% of intervention group women self-reported completion of follow-up diagnostic procedures compared with 67% of women in control group (p<0.001). With all randomized women included in the analysis, self-reported completion of diagnostic procedures was 61% for the intervention group and 46% in the control group (p=0.069). |

(continued)
| Abbreviated citation | Study setting | Cancer (continuum) | Priority population | Study design | Position title | Funding | Intervention summary* | Outcome measures | Results |
|----------------------|--------------|------------------|-------------------|--------------|----------------|---------|-----------------------|----------------|---------|
| Paskett et al.42     | Community    | Breast (screening) | Rural Native American, African American, White women ≥40 years of age who were patients at participating clinics | RCT. 4 community health centers randomized by race and clinic | Lay health advisor | National Cancer Institute | Lay health advisor conducted 3 in-person home visits, with educational materials provided at each visit and follow-up phone calls and mailings after each visit. Control group received educational brochure on screening. | Completion of mammography (medical chart review) | At follow-up, 42.5% of women in the lay health advisor group and 27.3% of women in the control group had a mammogram in the previous 12 months (RR = 1.56, 95% CI = 1.29–1.87, p < 0.001). |
| Percac-Lima et al.35 | Clinic       | Colorectal (screening) | Urban individuals aged 52-79 years not screening compliant | RCT. 1 health center. Patients randomized into navigation or usual care group | Patient navigator | Massachusetts General Hospital; Jane’s Trust; Massachusetts Cancer Prevention Community Research Network; National Cancer Institute | The PN sent an introductory letter or recruited patients at the health center or over the phone. During the initial contact, the navigator educated about CRC screening and explored barriers to screening. Further interactions aimed to overcome personal, cultural, and systemic barriers to successfully complete screening. | Completion of CRC screening | Intervention patients were more likely than control patients to undergo CRC screening (27% vs. 12%, p < 0.001) and more likely to undergo colonoscopy (21% vs. 10%, p < 0.001). |
| Percac-Lima et al.46 | Clinic and community | Breast (screening) | Urban, Serbo-Croatian-speaking women aged 40–79 years who received care at participating clinic and were overdue for or had never had a mammogram | Pre-post comparison in 1 FQHC | Patient navigator | Agency for Healthcare Research and Quality; Susan G. Komen | PN made initial patient contact over the phone or in person. They discussed preventive care and mammograms, assessed barriers to screening, and supported scheduling a mammogram. PN made home visits and organized breast health educational group sessions in community settings. | Completion of mammography (medical record review) | After 1 year of intervention, rates of mammography among eligible Serbo-Croatian-speaking women at the clinic increased to 67.0% from 44.0% at baseline (p = 0.001). |
| Percac-Lima et al.47 | Clinic and community | Breast (screening) | Women 40-74 years of age who self-identified as speaking Croatian, Somali, or Arabic (refugee women) | Quasi-experimental trial (Retrospective program evaluation) | Patient navigator | Agency for Healthcare Research and Quality; Susan G. Komen | PN educated women about breast cancer screening, explored barriers to screening, and tailored interventions individually to help complete screening. | Completion of mammography | After the intervention, screening rates increased in refugee women from 64.1% (95% CI: 49-77) to 81.2% (95% CI: 72–88), making them similar to the rates in English-speaking (80.0%, 95% CI: 73–86, p = 0.66) and Spanish-speaking (87.6%, 95% CI: 82–91, p = 0.07) women (controls). |
| Russell et al.36     | Clinic       | Breast (screening) | Urban African American women 41–75 years of age and at or below 250% FPL and no mammogram in 15 months | RCT. 1 health center, women randomized within clinic into intervention or control group | Lay health advisor | National Cancer Institute; Indiana University School of Nursing/Center for Enhancing Quality of Life in Chronic Illness | Intervention groups received interactive computer instruction on mammography and support from an LHA, who addressed barriers to care and initiated the referral process for interested participants. Control group received a culturally appropriate mammography screening pamphlet. | Completion of mammography | After 6 months, women in the intervention group had a mammography completion rate of 51% compared with 18% for the control group. Women in the intervention group were also more likely to move one or more stages in their stage of screening adoption (76% vs. 39%, p < 0.0001). |

(continued)
| Abbreviated citation | Study setting | Cancer (continuum) | Priority population | Study design | Position title | Funding | Intervention summary* | Outcome measures | Results |
|----------------------|---------------|--------------------|---------------------|--------------|---------------|---------|----------------------|----------------|---------|
| Sauaia et al.43       | Community     | Breast (screening)| Hispanic women 50–69 years of age who were continuously enrolled in one of the selected insurance plans for at least 23 months | Quasi-experimental trial.Churches were selected to receive one of two interventions. | Promotora | National Cancer Institute; Centers for Medicare and Medicaid Services | One group of churches received printed educational materials about breast cancer screening and a second group received the printed brochure and promotora visits. Promotoras approached women during church activities and facilitated groups in participant homes to discuss breast health. | Mammography screening rates (claims data) | After adjusting for age, income, urban versus rural location, disability, and insurance type, women exposed to the promotora intervention had a significantly higher increase in biennial mammograms than did women exposed to the printed intervention (p = 0.03). |
| Warren-Mears et al.45 | Clinic and community | No specific cancer (diagnosis) | Rural American Indian/Alaska Natives ≥18 years of age who were eligible to be seen at a participating clinic and received a cancer diagnosis or abnormality suspicious for cancer. | Quasi-experimental trial. 4 control clinics and 4 intervention clinics | Patient navigator | National Cancer Institute | PN encounters took place at the clinics, at the participant’s home, over the phone. PNs provided education and emotional and psychosocial support, coordinated resources, and facilitated interactions with providers. | Time interval between abnormal finding and definitive diagnosis (assessment of diagnosis by 60, 90, and 365 days) | Patients who worked with a PN had significantly higher odds of obtaining a definitive diagnosis by 365 days than did those without navigation (p = 0.019), but there were no significant differences at 60 and 90 days. |
| Welsh et al.44        | Community     | Breast (screening)| Latina and non-Hispanic White women 50–64 years of age who were enrolled in the state Medicaid program. | Quasi-experimental trial. Churches were selected to receive one of two interventions. | Promotora | One group of churches received printed educational materials about breast cancer screening and a second group received the printed brochure and promotora visits. Promotoras approached women during church activities and facilitated groups in participant homes to discuss breast health. | Mammography screening rates (claims data) | After adjusting for confounders, the promotora intervention had a marginally greater impact than the printed materials in increasing mammogram use among Latinas (p = 0.07). |
| West et al.37         | Clinic        | Breast (screening)| Low-income, rural African American women with no mammogram in previous 2 years | RCT. Patients at 1 FQHC were randomized | Community healthcare worker | 2 phase stepped care intervention: (1) Usual care or personalized letter, (2) tailored letter or phone counseling for women who did not respond to Phase 1. Phone counseling discussed barriers and facilitators to getting a mammogram | Self-reported mammography rates | There were no differences in overall mammography rates 6 months after the first or second phases. However, among women who had never had a mammogram, the tailored call was more effective in promoting mammography than the letter (p = 0.09). |

*Unless otherwise indicated, control groups received usual care.

CBE, clinical breast exam; CRC, colorectal cancer; FQHC, federally qualified health center; HPV, human papillomavirus; PN, patient navigator; RCT, randomized controlled trial.
to articles published in English between January 1990 and December 2013.

A total of 495 articles were identified. Upon initial review, 58 articles were excluded because they were not original research (e.g., general descriptions of patient navigation, commentaries, editorials, book reviews, systematic literature reviews). Two coauthors independently reviewed the remaining articles (abstract and/or full-text), applying the following additional inclusion criteria: (1) U.S. study of CHW/PN intervention with results, (2) conducted in an FQHC or in partnership with an FQHC (including HRSA-funded nurse managed health clinics and community health centers, FQHC Look-Alikes and other health centers that do not receive HRSA funding but provide comprehensive primary healthcare services to medically underserved populations, and Indian Health Service clinics), and (3) focused on cancer. Discrepancies in assessment between the two reviewers were resolved through discussion, instead of a third reviewer. The two reviewers were subject matter experts and principle investigators of the study, and therefore best suited to discuss nuance of an individual article and come to a consensus of its relevancy. An objective third reviewer may not have had the subject matter expertise or the intimate understanding of the study to make a clear judgement about the relevancy of an article.

Of the 495 articles identified by the original searches, 19 met all inclusion criteria. A second tier search examined the bibliographies of the 19 identified articles, along with the bibliographies of published systematic literature review articles identified in the original search (excluded because they were not original research studies). From this secondary search, 85 additional potentially relevant articles were identified and reviewed by the two reviewers using the criteria noted above. Of these, five met the inclusion criteria (Fig. 1). In total, we identified 24 articles as relevant to this review.

Data from relevant articles were abstracted by the two coauthors. Abstracted data included study details (design, data collection method, outcomes and results, and funding source); cancer focus; study setting (HRSA affiliation of clinic, clinic type, clinic name, and number of clinics involved in study); CHW/PN position information (role/title, education/training, whether paid or volunteer, whether full-time or part-time, funding source for position, whether demographically matched to target population, goals for the position, activities conducted, location of activities, method of communication with client, interaction with data systems, supervision, level of integration into medical team); broader intervention information (collaboration or partnerships, program barriers and facilitators, and relevant program policies); and intervention target population information (gender, age, race/ethnicity, rural/urban). Discrepancies in abstracted data were discussed until resolution was achieved.

Results
Study characteristics

The 24 articles included in this review are presented in Table 2. These articles profile CHW/PN interventions conducted in the clinical setting of FQHCs, in the community through partnerships with FQHCs, and in both the clinic and community settings. Interventions targeted cancer screening and diagnosis for breast, cervical, or colorectal cancer. One article focused on cancer, but did not specify the type of cancer for the intervention activities. Interventions focused on medically underserved populations, including Croatian-, Somali-, Arabic-, English-, Portuguese-, Spanish-, and Haitian Creole-speaking; African American, Hispanic, Native American, and Native Hawaiian; in large urban cities, rural counties in the South, a suburban neighborhood in Hawaii, the U.S.—Mexico border region, and Northwest Pacific Tribal clinics.

The studies included in this review represented a variety of study designs. Most studies were either randomized controlled trials (RCTs; n = 9) or quasi-experimental designs (n = 12). Two studies utilized a single-arm cohort design, and one study utilized a pre- and postintervention comparison.

The literature referred to CHW/PNs using numerous titles, reflecting their widely variable roles and responsibilities, including lay health advisor, promotora, community healthcare worker, community outreach specialist, lay health educator, and lay health worker. The title PN was used most commonly in articles profiling clinic-based interventions, while the titles lay health advisor and promotora were more common to articles describing community-based interventions. This article does not distinguish between titles when presenting study results below.

Partnerships are often recognized as essential in the development and implementation of CHW/PN
programs. Some studies included in this review partnered with CDC’s National Breast and Cervical Cancer Early Detection Program to facilitate patients’ referral to screening services.26,27,29–31,34,35–39,40,41–46,47 Other studies involved partnerships with a Community Advisory Panel to monitor and facilitate the community-based research process,26 academic researchers, and community members to develop study methods and conduct analysis,29,37 churches, the state department of public health, and the health center to host the sites of intervention activities,44 and a nonprofit organization to cover costs for navigators and colonoscopies.30 One intervention study was conducted by a coalition of community activists, public health officials, academic researchers, and the Boston Public Health Commission27,28 (data not included in a table).

Of the 24 relevant articles, 22 acknowledged funding from at least one federal agency. The most common federal funding source was the National Cancer Institute,26,29–31,34–39,41–46,49 followed by CDC,27,28,30,37,39,40 Center for Medicaid and Medicare Services,43,44 the Agency for Healthcare Research and Quality,47,48 and the U.S. Army Medical Research and Materiel Command.46 Several articles also cited funding from nonprofit organizations, including the American Cancer Society,32,33 Susan G. Komen,38,47,48 Kate B. Reynolds Charitable Trust,38 Pittsburgh Foundation,38 Avon Breast Health Access Fund,38 and Jane’s Trust.35 Other funding sources included the Massachusetts Cancer Prevention Community Research Network35 and other institutional support.28,35,36

Outcome measures
Reported cancer-related outcome measures for relevant studies included completion of screening,27–29,31–33,35–39,41–45,47–49 followed by time to diagnosis, and completion of diagnostic resolution,26–28,34,46,49 and referral for screening by a CHW/PN.30 One study measured receipt of a follow-up wellness exam as a study outcome (which included breast and cervical cancer screening, blood pressure screening, and blood glucose testing).30

Study results
All but two studies reported statistically significant positive outcomes from the CHW/PN interventions (p ≤ 0.05). One RCT that found a 35% increase in rescreening in the intervention group but reported nonsignificant confidence intervals (RR = 1.35, 95% CI: 0.95–1.92)40 and one quasi-experimental trial identified increased mammography rates in the intervention group, but the increases were not significant when compared to controls (p ≥ 0.07).47 While all studies were conducted among subpopulations that may experience cancer disparities or barriers to care, some studies specifically targeted under-screened or never screened individuals, or those with abnormal cancer screening tests.

Studies that did not specify additional risk factors in the study population (n = 11; prospective single-arm cohort,26 quasi-experimental trials,29,30,38,39,43,44,47 RCT40–42) reported increases in mammography,28,29,38,39,42–44,47 Pap tests,29,39,41 referral to colonoscopy, screening with colonoscopy,30 and receipt of a follow-up wellness exam (including Pap test, mammogram referral, clinical breast exam, and human papillomavirus test)40 among participants after CHW/PN interventions.

Among studies in this review that specifically targeted under-screened individuals (n = 10; RCT,31,32,35–37,46 quasi-experimental trial,33,45 pre-post comparison,48 prospective single arm cohort27), screening rates improved for women overdue for a mammogram or never screened,36,37,45,48 women at risk for inadequate Pap test screening and follow-up,27 and men and women noncompliant with colorectal cancer screening guidelines31–33,35 after participating in CHW/PN interventions. Additionally, among women who missed a follow-up diagnostic appointment for breast cancer, a significant proportion completed their diagnostic procedures after CHW/PN intervention.46

Among studies in this review that specifically intervened among individuals with abnormal screening results (n = 3, all quasi-experimental trial), women with an abnormal breast or cervical screening result had a significantly shorter time to diagnosis than controls for cervical cancer screening26 after 30 days34 and for breast screening34 if resolved after 60 days exposed to a CHW/PN intervention.26 Individuals with a cancer diagnosis or abnormality and who participated in a CHW/PN intervention had significantly higher odds of obtaining a definitive diagnosis within 1 year compared with the control group.49

CHW/PN intervention characteristics
Activities conducted, methods of communication with client, and documentation of activities. Table 3 provides details on activities conducted by CHW/PNs, including how they communicated with their clients and documented their activities. Common intervention
activities included providing education and increasing awareness, identifying and addressing barriers, assisting with scheduling appointments, and attending appointments with clients. Clinic-based CHW/PNs most commonly identified and addressed barriers to care and/or provided referrals for medical and social services, while community-based CHW/PNs more often focused on cancer education and awareness. Most CHW/PNs communicated with clients both in-person and by telephone. Five studies, all of which involved clinic-based interventions, reported that CHW/PNs had access to patient electronic health records (EHRs) and documented their activities and client interactions in the EHR. Other studies noted that CHW/PNs maintained paper records of their activities, and other practices that were not detailed in the articles.

**Training and educational background of CHW/PNs.** Table 4 outlines the topics covered by trainings that CHW/PNs received over the course of the studies and their educational/professional background. Most often, training provided to CHW/PNs included general information related to cancer and health, cancer screening and guidelines, patient support and care, and overview of the project/study. Skill-based training on topics such as motivational interviewing and communication were also provided to CHW/PNs. CHW/PNs usually had a high school education, with or without some healthcare experience, or were college graduates. A few CHW/PNs were certified nurse assistants or functioned as the study research assistant. Some CHW/PNs had previous experience with community breast and cervical education, or were community partners or community members.

**CHW/PN supervision, medical team integration, compensation, and work designation.** Table 5 describes the work environment of CHW/PNs. In these studies, CHW/PNs were more often supervised by the research project manager or study investigator than by health center administrative staff, or outreach coordinators/specialists. Many CHW/PNs communicated directly with providers, and...
were integrated with medical teams. Among studies that included information on CHW/PNs compensation, almost all reported that CHW/PNs were paid. One study used one paid and one volunteer CHW/PN. Only two articles addressed whether CHW/PN were full- or part-time. One used full-time CHW/PNs, and another described utilizing both full- and part-time navigators.

### Discussion

Both the FQHC system and CHW/PNs were borne from the need to address persistent, complex health disparities among medically underserved communities. For decades, community health centers and CHW/PNs have provided culturally competent, comprehensive health services, education, social support, and client advocacy. CHW/PNs and FQHCs have independently been recognized as essential to achieving national public health priorities to address health disparities within a changing healthcare environment. Further, there is a growing recognition of the importance of primary care and public health collaborations in reducing health disparities. Understanding how linkages between FQHCs and tertiary care centers with screening, treatment, and diagnostic capabilities are developed and maintained is crucial, as is learning more about scalability and replication of effective CHW/PN interventions, and chronic disease versus disease-specific models of CHW/PN programs.

This systematic literature review sought to identify and describe CHW/PN initiatives in FQHCs related to cancer prevention and control according to key

### Table 4. Training Received by Community Health Worker/Patient Navigators Participating in the Intervention Studies, According to Location of Intervention

| Training contenta | Number of studies | Study references |
|-------------------|-------------------|------------------|
| General cancer/health | 11 | 32,33,29,38,41,42,48,47–46 |
| General screening/guidelines | 10 | 27,28,32,33,38,45,46,48 |
| Patient support care | 4 | 36,49,47,48 |
| Communication skills | 4 | 32,33,36,37 |
| Motivational interviewing | 4 | 32–35,48 |
| Project information | 4 | 40–42,46 |
| Diagnosis/treatment | 3 | 45,46,48 |
| Assessing and overcoming barriers | 3 | 35,36,47 |
| Screening programs/resources | 3 | 27,38,46 |
| Computer skills and administrative procedures | 3 | 41,42,45 |
| Culturally appropriate care | 2 | 27,28 |
| Routine core competency assessments (content not described) | 1 | 26 |
| Providing referrals | 1 | 36 |
| Confidentiality | 1 | 45 |
| Not discussed | 7 | 30,31,34,39,43,44,49 |

### Table 5. Community Health Worker/Patient Navigator Supervision, Medical Team Integration, Compensation, and Work Designation

| Supervisiona | n | References |
|--------------|---|------------|
| Research project manager/investigator | 7 | 32–35,37,46,48 |
| Health center administrative staff | 2 | 26,44 |
| Social worker navigator | 1 | 34 |
| Outreach coordinator/specialist | 1 | 38 |
| Title not specified | 2 | 41,42 |
| Not discussed | 12 | 27–31,36,39,40,43,45,47,49 |

| Medical team integrationa | n | References |
|--------------------------|---|------------|
| Communicate directly with providers | 4 | 27,28,32,33 |
| Integrated into health center team | 3 | 26,30,49 |
| Limited contact with clinicians | 1 | 35 |
| Not discussed | 16 | 29,31,34,36–48 |

| Compensationa | n | References |
|---------------|---|------------|
| Paid | 11 | 26,28,30,31,35,36,38,42,44,47,49 |
| Volunteer | 1 | 38 |
| Not discussed | 13 | 27,29,32,33,34,37,39–41,43,45,46,48 |

| Designationb | n | References |
|--------------|---|------------|
| Part-time | 1 | 47 |
| Full-time and part-time | 1 | 35 |
| Not discussed | 22 | 26–34,36–45,48,49 |

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aArticles may be included in more than one category.

bCategories are mutually exclusive.
intervention components commonly used to measure public health institutional and programmatic capacity and sustainability. In doing so, we found that CHW/PN programs can improve completion and timeliness of breast, cervical, and colorectal cancer screening and diagnosis among the medically underserved populations served by FQHCs. The outcomes in these studies clearly illustrate that FQHC-CCHWs/PNs partnerships can serve the unique needs of diverse and underserved communities in both clinical and community settings.

The studies included in this review were largely supported through federal funding and led by academic institutions. The controlled research environment allows investigators to examine the impact of CHW/PN interventions on screening and diagnostic outcomes in FQHC patients, but these controlled environments often do not reflect the strained reality of real-world CHW/PN programs where resources, training, supervision, and support are often less robust than in federally funded studies. A significant programmatic barrier to the integration of CHWs/PNs into most FQHCs is that CHW/PN services are not billable or reimbursable. Safety net institutions, like FQHCs, which serve populations with limited resources to support themselves and their families when cancer is diagnosed, are unlikely to have sufficient resources for CHW/PN programs and interventions (although it has occurred). On the contrary, health systems targeting and caring for insured, employed, and educated patients are more likely to have cancer patient navigation programs. Ongoing cost-analysis studies and healthcare utilization studies of chronic disease CHW/PN programs are critical, have documented costs and healthcare savings when CHWs are utilized, and may provide evidence of the value of sustainable funding for these services in clinical settings serving the medically underserved.

In addition to sustainable funding strategies, inconsistent training and nonuniform competency standards have been recognized as barriers to broader integration of CHW/PNs into public health programs. This study found that training content and educational/professional background varied for each of these studies, and that aspects of occupational regulation critical to establishing credibility and scope of practice, such CHW/PN supervision, integration into the medical team, paid or volunteer status, and part-time or full-time status, were not as often discussed.

Noted barriers and facilitators to FQHC-affiliated CHW/PN programs
Barriers reported in the literature should be considered when conducting future intervention research. For patients, the inability to take time off work to attend screening, lack of reliable transportation and childcare, and cost of copayments; housing concerns and instability; and migrant or immigrant status were noted as impediments to participating in screening. Barriers faced by programs and health centers that may impact program outcomes include the inability to retain skilled bilingual PNs; lack of onsite mammography; framing a navigation program for “cancer patients”; and the paper records and the inability to track screening tests conducted outside the clinic.

Several facilitators to implementation of CHW/PN interventions in FQHCs were reported, and include partnering with churches when working with Hispanic communities, ensuring a common language is spoken between CHWs/PNs and their clients, ensuring open communication between clinicians and PNs working in the clinic, incorporating Community Guide-recommended strategies into the CHW/PN intervention, allowing CHWs/PNs flexible work hours and scheduling, supporting initial and ongoing training, allowing CHW/PN access to EHRs, providing reduced-cost screening, promoting multiple types of screening exams at one time, incorporating a community advisory panel into CHW/PN program activities, and facilitating access follow-up care through National Breast and Cervical Cancer Early Detection Program (NBCCEDP).

Policy implications
Numerous policy initiatives light the path forward for the integration of CHW/PNs into primary care and public health. Effective January 2014, CMS created a final rule (CMS-2334-F) that opens up payment opportunities for preventive services by nonlicensed individuals (e.g., CHWs) recommended by physicians or other licensed practitioners of the health arts. The rule change presents an important opportunity for enhancing the focus on prevention through the Medicaid program. ACA also offers state Medicaid programs the opportunity to create Health Homes for beneficiaries living with chronic illness, and several states have Medicaid state plan amendments that explicitly include or refer to CHWs. Finally, ACA creates funding for state innovation models (SIM) designed to support states in the development and testing of state-based models for multi-payer payment and healthcare.
delivery system transformation. Of six states currently implementing their SIM designs, four have included CHWs in their plans. In Round One of the SIM initiative, nearly $300 million was awarded to 25 states to design or test improvements to their public and private health payment and delivery systems (https://innovation.cms.gov/initiatives/state-innovations/).

Another opportunity to support integration of CHWs/PNs into FQHCs and other community-based primary care setting is the patient-centered medical home model. The patient-centered medical home is a way of organizing primary care that emphasizes care coordination and communication, treatment of the many needs of patients at the same time, increased access to care, and empowerment of patients to be partners in their own care. The development of a CHW/PN program in a health center may assist in meeting the requirements for patient-centered medical home designation.

Strengths and limitations. To our knowledge, there has been no assessment of CHW and PN activities in FQHCs on a national, state, or local scale. The results of this systematic literature review provide an overview regarding cancer prevention and diagnostic CHW/PN programs in FQHCs targeting the medically underserved that can be used to design future interventions. We note several limitations to our systematic literature review methods and results. Studies were limited to those published in the peer-reviewed literature. This may have limited study to those conducted by or in partnership with academic researchers. The peer-review literature does not capture all CHW/PN activities ongoing at FQHCs as programs may not have the capacity to effectively evaluate and publish their work, and FQHC-designation may not have been included in the study site description. The studies included in this review varied in design and methodology (RCTs, quasi-experimental trials, and pre-post comparison) and the impact of those variations to study outcomes was not assessed, but should be acknowledged when interpreting the results of this literature review. Additionally, the reporting period for this review ended in December 2013, potentially excluding additional literature relevant to the search.

Conclusion

Better partnering and integration of public health and primary care interventions and systems can change the context within which chronic disease occurs and reduce health disparities. As evident in this review, CHW/PN interventions implemented in FQHCs or coordinated with FQHCs are effective in increasing cancer screening and the timeliness of diagnostic resolution among medically underserved populations. Bridging the community-clinical divide is critical to supporting disadvantaged communities to gain access to primary care, including cancer screening. Although evidence supports engaging CHW/PNs in the national health delivery system, lack of sustainable resources for these programs, including reimbursement for services, remains a challenge. Local, regional, and state programs will likely need to continue innovating and collaborating to develop and sustain systems and programs for the medically underserved in their communities. Looking forward, national public health agencies must continue to promote the development and adoption of evidence-based interventions and strategies that will reduce health disparities. Achieving health equity in cancer and other chronic diseases is a real and pressing priority for public health, and fostering collaboration between CHWs/PN programs and FQHCs and other community-based settings is potentially a very powerful tool to achieve public health goals.
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**Abbreviations Used**

ACO = Affordable Care Act  
CHW = community health worker  
FQHC = federally qualified health centers  
EHR = electronic health record  
HRSA = Health Resources and Services Administration  
PN = patient navigator  
RCT = randomized controlled trial  
SIM = state innovation models

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