

A Community Engagement Method to Design Patient Engagement Materials for Cardiovascular Health

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ABSTRACT

PURPOSE EvidenceNOW Southwest is a cluster-randomized trial evaluating the differential impact on cardiovascular disease (CVD) care of engaging patients and communities in practice transformation in addition to standard practice facilitation support. The trial included development of locally tailored CVD patient engagement materials through Boot Camp Translation (BCT), a community engagement process that occurred before practice recruitment but after cluster randomization.

METHODS We introduce a cluster randomization method performed before recruitment of small to medium-size primary care practices in Colorado and New Mexico, which allowed for balanced study arms while minimizing contamination. Engagement materials for the enhanced study arm were developed by means of BCT, which included community members, practice members, and public health professionals from (1) metropolitan Denver, (2) rural northeast Colorado, (3) Albuquerque, and (4) rural southeast New Mexico. Outcome measures were messages and materials from BCTs and population characteristics of study arms after using geographic-based covariate constrained randomization.

RESULTS The 4 BCTs' messages and materials developed by the BCT groups uniquely reflected each community and ranged from family or spiritual values to early prevention or adding relevance to CVD risk. The geographic-based covariate of a cluster randomization method constrained randomization-assigned regions to study arms, allowing BCTs to precede practice recruitment, reduce contamination, and balance populations.

CONCLUSIONS Cluster-randomized trials with community-based interventions present study design and implementation challenges. The BCTs elicited unique contextual messages and materials, suggesting that interventions designed to help primary care practices decrease CVD risk may not be one size fits all.

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INTRODUCTION

Communities, patients, and families can play a role in practice improvement, and there have been increasing calls to engage them in practice transformation efforts, including by the Institute of Medicine,¹ Patient-Centered Medical Home standards,² and the requirements of the Centers for Medicare & Medicaid Services program Comprehensive Primary Care Plus.³ The benefits of engaging patients and families in the care of individual patients is well established.⁴⁻¹¹ The outcomes of engaging communities, patients, and families at the practice level, however, are less well documented.^{12,13} The EvidenceNOW: Advancing Heart Health in Primary Care is an Agency for Healthcare Research and Quality grant initiative dedicated to using the latest evidence to improve the heart health of Americans. EvidenceNOW Southwest is a regional cooperative that has sought to test the differential impacts on cardiovascular disease (CVD) of interventions focused on patient, family, and community engagement to standard practice transformation approaches.

Conflicts of interest: authors report none.

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In EvidenceNOW Southwest, enhanced-arm practices received practice facilitation plus additional support to engage patients and families in practice transformation. These practices were able to order free heart health materials that were developed through a community engagement method known as Boot Camp Translation (BCT) in 4 communities within the enhanced-arm geographic regions (2 in Colorado, 2 in New Mexico). Community members and health professionals worked together to learn about complex health topics and national guidelines so the community-academic partnership could then translate those messages into ones that are relevant and meaningful to their local community.^{14,15} The process aimed not to seek perfect community representation but rather to harness local expertise to create locally tailored products and messaging.

There were 3 major study design challenges in our randomized trial to evaluate the impact of a community engagement method on practices. First, cluster randomized trials, commonly used in practice-based studies that involve randomization at the level of the practice,¹⁶⁻¹⁸ incur risk of contamination if used with interventions occurring at the community level where there might be standard and enhanced-arm practices in close proximity. Second, in our study, communities in which the community engagement method occurred needed to be identified before practice recruitment. In this case, BCT communities had to be selected so that materials would be ready for use by the enhanced-arm practices at the start of the intervention period. A potential solution to these problems was to define geographic regions as the units for randomization. This raises the third issue, however, of potentially having unbalanced study arms. Randomization methods that improve study arm balance in terms of underlying populations and regional differences are essential for community-based trials.¹⁹

We describe (1) the results of 4 BCTs in unique communities across diverse regions of Colorado and New Mexico and (2) approaches to study design challenges for a randomized trial evaluating the effect of patient, family, and community engagement on practice transformation and cardiovascular risk reduction.

METHODS

Study Setting

The EvidenceNOW Southwest Cooperative is a collaborative effort between Colorado and New Mexico and covers the diverse geographic and cultural regions across both states. It is one of 7 regional cooperatives funded by the Agency for Healthcare Research and Quality to help small and medium-size primary care

practices across the country use the latest evidence to improve cardiovascular health. The project was approved by both the Colorado Multiple Institutional Review Board and the University of New Mexico Human Research Protections Office.

EvidenceNOW Southwest Intervention

Practices within both the standard and enhanced arms received the following: ongoing practice transformation support from a trained practice facilitator, support from a clinical health information technology advisor, connection to a regional health extension agent (regional health connector in Colorado, health extension rural officer or HERO in New Mexico), and opportunity to attend biannual collaborative learning sessions in which knowledge is shared across practice teams (also attended by practice facilitators, regional health connectors/health extension regional officers, and clinical health information technology advisors).

Enhanced-arm practices received additional support to increase patient, family, and community engagement within their practice transformation efforts through the use of BCT materials and support to engage patients and families in practice transformation efforts. Because CVD guidelines are relatively inaccessible to the general population owing to medical complexity and jargon, the intention of the BCTs was to allow communities to create materials to provide CVD education in a way that may be more relevant to enhanced-arm communities and practices. Throughout the project, printed BCT materials from all 4 BCTs were available for order at no cost to all enhanced practices (regardless of their geographic proximity to the BCT). Processes and outcomes related to utilization of BCT materials are being tracked and will be reported in a later publication after the completion of the study.

EvidenceNOW Southwest Study Design

Because of the intent to implement the community engagement method (ie, BCT) at the community and regional level, randomization at the level of the primary care practice was not feasible. There was concern about the strong potential for contamination between study arms if standard intervention practices were located in regions from which BCT participants would be recruited and their products would be promoted. Additionally, because the timeline of the study required beginning BCT activities before actual practice recruitment and enrollment, it was necessary to select regions for the BCTs that would include only those practices from the enhanced intervention study arm. We therefore defined geographic regions (ie, cluster) as the unit of randomization. Finally, regional differences across 2 states in underlying population

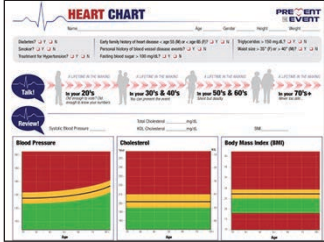

characteristics were considerable, and simple randomization could result in unbalanced study arms, requiring approaches for achieving balanced study arms in terms of the underlying populations and resources.

Covariate Constrained Randomization

Because EvidenceNOW Southwest is a cooperative study across 2 states, and local knowledge about geographic regions was key to informing design decisions, randomization was carried out separately in each state.

In Colorado, we used data from the most recent US Census, Health Landscapes, the Cold Spotting Colorado project,²⁰ and local knowledge about geography and proximity to health care services to define 26 regions consisting of 1 or more counties that are roughly equivalent to the Colorado Health Statistics Regions. These were split into 2 strata for randomization: (1) Front Range and Eastern Plains and (2) mountains and Western Slope. Within each stratum, we used covariate constrained randomization^{21,22} to achieve balanced study arms with respect to population and health resource characteristics. Variables included total population of the region, average county population, percentage at or below poverty level, median income, percentage white, percentage Hispanic, number of primary care physicians per 10,000 population, number of physician assistants/nurse practitioners per 10,000 population, unemployment rate, and number of uninsured adults aged 18 to 64 years old. The goal was to define clusters as groups of counties that were relatively homogeneous and large enough to facilitate implementation of BCTs without undue risk of contamination into the standard intervention counties, as well as to achieve balanced study arms on underlying population characteristics.

Table 1. Population Characteristics of Standard and Enhanced Regions

Characteristic	Greeley, Colorado ^a	Denver, Colorado ^b
Community description	Largely rural agricultural communities Population ~75,000 Approximately 30% Hispanic Lower average income and higher rates of poverty than rest of state	Population >3 million Among fastest growing urban centers in the United States 80% White with approximately 30% of its residents identifying as Latino
Themes and messages	Early intervention is key, emphasized knowing personal heart health numbers, including blood pressure, cholesterol, 10-yr ASCVD risk Track health data over time Provide context around CVD risk (What does 7% risk mean for me?) Wanted a conversation starter for patient to discuss CVD risk with health professionals	You only have 1 heart—your life depends on it Know your risk, even if you feel fine Act now to lower your risk Wanted to design products for any age-group Use brochure to grab attention and dig deeper into actions with the Risk Factor Check List
Product description	Heart Chart, a personal tracking tool for blood pressure, cholesterol, BMI and 10-y ASCVD risk, which provides comparison to normal age-related risk over time Recipe cards with information about CVD prevention	An informational brochure about cardiovascular disease prevention labeled “You only have one heart” A similarly themed poster A checklist of CVD risk factors
Example product		

ABCS = aspirin use, blood pressure, cholesterol management, smoking cessation; ASCVD = atherosclerotic cardiovascular disease; BMI = body mass index; CVD = cardiovascular disease.

^a Northeast Colorado.

^b Denver and Golden, Colorado.

^c Parts of Albuquerque and unincorporated San Bernalillo county.

In New Mexico, using data from the US Census Bureau and the US Department of Labor's Bureau of Labor Statistics, we divided the state's 33 counties into 16 regions based upon population size, geography, and proximity to health care services. Using knowledge of local communities and regional differences within the state, we paired the regions into 8 groups and random-

Hobbs, New Mexico

Among eastern-most counties in New Mexico.
 Population ~35,000
 Highest percentage of African American population in the state
 Describe themselves as a part of West Texas, because geographically they are closer to Texas than most other places in New Mexico
 Oil and gas are the main sources of income in the region
 A clean spiritual life requires a healthy physical life—complete spiritual, physical, and mental health are needed to be whole
 Focus on what we can control, not what we can't (eg, family history)
 Heart disease does not discriminate; no matter one's heritage, ethnicity, religion, etc, we are all at risk
 Many members from faith-based community; our bodies are worthy of care
 Taking care of health is actually cheaper ("sale") than consequences of CVD event
 Encouraged implementation in community, but also in practice setting
 Big sign saying "Big Sale!" with information about CVD risk reduction
 Hand-held, heart-shaped fan with "We are all different but we all have heart disease does not discriminate."
 Magnet that reads "Our bodies are miracles... but we have to treat them that way!"

South Valley, Albuquerque, New Mexico

Urban/rural mix; high-density areas are intermingled with agricultural land
 Population ~40,000
 Predominantly Hispanic, with many recent immigrants from Latin America
 Messages aim to elicit a feeling—think about family, love, prevention in a multi-generational sense
 Educate ALL ages and get the entire family involved—youth can help the family change and adults and seniors want to be around for their family
 Focus on Latino communities
 Prevent second chances. Don't wait for something to happen to take action
 "Know your numbers before your 'check heart' light comes on"
 Implement in community, but also in practice setting
 Attention to the need for materials to be in both Spanish and English
 Trifold brochure informational brochure titled "Prevent second chances"
 One-page handout with key heart health numbers in the form of the image of a car dashboard
 Informational poster with a picture of a family
 Grocery bag that says "Cuidalo" and displays the ABCS



ducted, 2 in each state, with regions selected to represent diverse populations. The limited number of BCTs conducted was due to resource limitations to conduct the BCT and produce the resulting materials. Each region in which a BCT occurred had been randomized to the enhanced study arm.

BCTs were conducted in Hobbs, New Mexico, the South Valley region of Albuquerque, northeast Colorado, and the Denver metropolitan area. These regions differed in ethnic diversity, industry, population, and rural-urban mix. Individual community descriptions can be found in Table 1.

BCT Process

The goal of the EvidenceNOW Southwest BCT was to take evidence-based CVD prevention strategies and translate that content into messaging and materials that are relevant and understandable for community members. Through participation in BCT, community members become better prepared to discuss CVD within their communities, and participants developed unique materials for practices and other community agencies to use for patient/community engagement.^{14,15} BCT participants also included practice clinicians and staff, as well as local public health officers, to ensure that the messages and materials would be relevant for use by the practices and local public health.

Each BCT began with an all-day kickoff retreat. For one-half

ized regions within each group, resulting in an even number of regions (8 each) per study arm.

EvidenceNOW Southwest BCT Communities

Once all regions of both states had been assigned to enhanced or standard intervention arms, the regions for the BCTs were identified. Four BCTs were con-

of the retreat, a medical expert presented the current evidence and guidelines for the prevention of CVD, specifically focusing on the ABCS (aspirin use, blood pressure control, cholesterol management, smoking cessation) guidelines. Although each BCT had a different medical expert, presenters used the same set of informational slides across all presentations. After the

presentation, the remaining retreat time was spent brainstorming answers to (1) what does our community need to know about CVD prevention, and (2) what actions do we want people to take around CVD prevention?

After the kickoff retreat, each group had a series of 4 to 6 conference calls interspersed with 3 to 4 in-person meetings over a 6- to 9-month period during which they continued to refine key messages and products. Through these follow-up sessions, each group created a set of locally relevant actionable messages and materials.

Recruitment of BCT Participants

Within each state, participants were recruited through use of different organizations, based on which organizations would have better ties with the community. As a result, in New Mexico, with its well-established health extension system, the health extension rural officers recruited participants. In Colorado, with its long history of community-engaged research, practice-based research networks recruited participants. Participants were selected based on their availability to participate for the duration of the BCT, their ability to engage and be present, their interest in the topic, and the absence of a hidden agenda.

RESULTS

Colorado and New Mexico have a combined population of approximately 7.3 million. Sociodemographic characteristics of the 2 states show considerable diversity in terms of ethnicity, education, population density, disease burden, and health care resources. Covariate-constrained randomization procedures resulted in reasonably well-balanced study arms with respect to key regional population characteristics that might affect study implementation or outcomes (Table 2).

BCT Partners

Community members with varying amounts of experience with CVD were included in the BCT. They had differing skill sets and expertise, as shown in Table 3.

BCT Key Messages and Materials

Each BCT was tasked with translating evidence-based cardiovascular risk-reduction strategies into messaging

Table 2. Population Characteristics of Standard and Enhanced Regions

Variable	Colorado			
	Standard (n = 13)		Enhanced (n = 13)	
	Mean (SD)	Min/Max	Mean (SD)	Min/Max
Total population, No. ²³	137,376 (188,581)	7,264/572,003	197,019 (241,165)	9,358/622,263
Non Hispanic white, % ²³	74.6 (14.8)	53.2/91.5	76.6 (11.2)	52.2/87.9
Hispanic, % ²³	19.7 (13.9)	4.8/42.3	17.5 (9.5)	7.5/38.4
Below poverty level, % ²⁴	14.3 (5.3)	8.4/26.6	12.8 (4.4)	4.3/20.8
Unemployment rate, % ²⁴	8.0 (1.5)	5.0/10.2	8.1 (1.4)	5.2/9.6
Uninsured adults, No. ²⁵	18,489 (26,710)	635/75,329	24,117 (32,218)	1,475/94,305
Median income, \$ ²³	53,302 (11,149)	35,126/73,576	54,803 (15,574)	35,423/95,973
NP per 10,000 ²⁶	8.0 (1.6)	4.8/10.1	8.5 (2.3)	5.5/12.0
Physician ^a per 10,000 ²⁶	5.9 (2.1)	1.2/9.0	6.2 (1.9)	4.1/10.6

Max = maximum; Min = minimum; NP = nurse practitioner.

^a Primary care physician.

and materials relevant to their local communities to be used by practices for patient engagement. The resulting materials varied considerably from one BCT to another.

The Hobbs, New Mexico, BCT included messaging about spirituality and universality of risk regardless of background, producing 3 products, including a heart-shaped fan that could be taken to football games (Table 1). In the South Valley region of New Mexico, messages aimed to elicit feelings around the importance of and responsibility to Latino communities and family. Prevention was a key message, particularly in the context of family. They produced 4 products including a grocery bag with "Cuidalo" printed on it (translation: "Take care of it"). It was culturally important to the participants that this bag be in Spanglish, a combination of Spanish and English. The northeast Colorado BCT emphasized early intervention but focused heavily on numbers (eg, individual CVD risk score, cholesterol levels) and putting those numbers into an easily interpretable context. The group created 2 products, including a heart chart, a personal tracking tool for recording blood pressure, cholesterol, body mass index, and 10-year risk of CVD similar to pediatric growth curves to provide comparison to normal age-related risk over time. The metropolitan Denver BCT also sought to raise awareness and empower patients to act now to lower their risk. They produced 3 products, including a risk factor checklist with questions prompting patients to think about their own CVD risk factors. Table 1 displays a complete description of key messages and products.

Practice Recruitment

After the BCTs were completed, a total of 211 primary care practices were recruited and enrolled from Colorado (n = 158) and New Mexico (n = 53) across the diverse geographic regions of the 2 states. BCT mate-

New Mexico			
Standard (n = 8)		Enhanced (n = 8)	
Mean (SD)	Min/Max	Mean (SD)	Min/Max
39,872 (38,989)	1,975/145,400	97,866 (174,455)	687/667,092
40.3 (18.6)	10.2/75.3	39.9 (12.8)	18.1/67.8
43.5 (18.3)	13.6/81.7	48.7 (14.5)	19.2/76.9
21.7 (6.4)	4.4/35.0	19.9 (5.2)	11.9/28.6
8.0 (3.2)	4.2/19.0	7.0 (1.9)	4.5/10.2
6,547 (6,639)	354/24,747	16,060 (27,611)	98/103,316
41,228 (16,715)	28,275/106,686	39,207 (7,737)	27,430/50,694
3.9 (2.3)	0.0/9.2	3.7 (1.9)	0.0/6.7
7.9 (3.6)	2.1/18.5	6.7 (4.0)	0.0/14.4

intervention practices throughout the Evidence-NOW Southwest project. Messages ranged from family values and spirituality to early prevention and identifying a need for context of CVD risk. Materials written in English were translated into Spanish, and their form ranged from brochures to patient-held health records to novelties, such as fans and grocery bags. Though products from each site were unique—reflecting the key features each community group believed would resonate with their local audiences—each site incorporated the ABCS into at least 1 product. Also, a sense of urgency and importance that heart disease is preventable was observed across all sites. The diverse products were reflective of cultural differences and varying priorities across the regions. We believe tailoring patient engagement materials to specific communities will enhance primary care practices’

materials were available only to practices in the enhanced intervention arm until study completion.

DISCUSSION

Designing a randomized control trial involving community engagement is especially challenging across 2 states with diverse populations, with the need to minimize contamination and to ensure that key population groups are included in the community engagement activities. We defined clusters as geographic regions through a combination of census data and knowledge of local communities, and we used covariate-constrained randomization procedures to allocate regions to balanced study arms before initiating the community engagement method and recruiting practices. By minimizing overall differences between study arms, this procedure enriches heterogeneity within study arms, thus ensuring representation of diverse populations in both study arms.

Unique BCT messages and materials were produced in the 4 selected communities for use by enhanced

capacity to improve evidence-based care by making the messages more relevant for their populations.

There are some key limitations of this study. Randomization of geographic clusters was a necessary study design adaptation. The necessity of completing randomization to identify regions in which to carry out the BCT activities before actual practice recruitment, however, meant that practice-level information, such as CVD burden in their patients, was not available at the time of randomization and could not be included in the procedure. Additionally, available resources limited the number of BCTs to 4 across the 2 states. Given the geographic and ethnic diversity of Colorado and New Mexico, this number was not sufficient to engage all key populations, such as the Native American community.

Future work will evaluate how practices used the BCT materials, how often they used which materials, and the geographic spread of the materials across all enhanced study regions. Future publications will also report on the differential impact of the enhanced

Table 3. Boot Camp Translation Participants by Boot Camp Translation Site

Site of BCT (Region of Recruitment)	Community Partners/ Academic Participants No./No.	Examples of BCT Partner Backgrounds
Hobbs, NM (Hobbs, NM)	12/2	Community health workers, local pastor, county commissioner, educator, survivors and caregivers of people with CVD, local health extension agent
South Valley, NM (parts of Albuquerque and unincorporated Bernalillo County)	10/2	Community health workers, retired environmental engineer, medical assistants, members of a family-run organic farm, social worker, nursing student, local health extension agent
Greeley, CO (Northeast Colorado region)	11/3	Retired teacher and farmer, reading instructor and rancher, retirees, small business owner, public health professional, local practice facilitator, practice manager
Denver, CO (Denver and Golden)	12/3	Community members, pastor, community health worker/Promotora, teacher, retirees (retail manager, business consultant, accountant, engineer), public health student, primary care clinicians, public health professionals

BCT = boot camp translation, CO = Colorado, CVD = cardiovascular disease, NM = New Mexico.

intervention as a whole, which includes both the practices' access to BCT materials and support for practices to engage patients and families in practice transformation efforts.

In conclusion, solutions to study design challenges were feasible and facilitated implementation of a community engagement method while maintaining study integrity. BCT materials from 4 different regions resulted in strong heterogeneity, suggesting that one-size-fits-all program design to help primary care practices decrease CVD risk may not be the best approach.

To read or post commentaries in response to this article, see it online at http://www.AnnFamMed.org/content/16/Suppl_1/S58.

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