

An Evaluation of a Comprehensive Cardiovascular Disease Risk Reduction Program in an Appalachian Free Clinic

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Abstract

Effective cardiovascular disease (CVD) risk reduction challenges healthcare clinicians in spite of scientific advances. Managing CVD is more challenging in specific populations (Appalachian, high risk, impoverished, served by charitable clinic). Purpose: This study evaluated if a comprehensive CVD risk reduction program was effective in reducing risk factors in this population. Methods: A retrospective analysis of 125 records of participants of the CVD risk reduction program and a matched sample of 125 records from non-participants was conducted. Variables included hemoglobin A1C, body mass index, cholesterol, and blood pressure. Results: There was an overall reduction in CVD risk factors in both the education and non-education groups. However, the results could not be attributed solely to the risk reduction education program. Conclusions: Confounding variables (voluntary participation, incentives, patient/clinician relationship dynamics, self-motivation) may have contributed to outcomes. Future study may illuminate processes of self-care that encourage patient self-care efforts. Clinical relevance: Advanced nurse practitioners in busy primary care settings are expected to find ways to invite and engage impoverished, disadvantaged, patients in the effective self-management of CVD. This article provides insights into the challenges that clinicians face.

Keywords: Cardiovascular disease; Primary health care, Patient education; Qualitative methodology; Cultural issues

Approximately 17 million people die each year from cardiovascular disease (CVD) making it the leading cause of death worldwide¹. Sequelae of CVD, such as heart disease and stroke are leading causes of morbidity and mortality in the United States (US)². Although it is true that CVD is a leading cause of death in the US (179/100,000), the age adjusted mortality rate for CVD in West Virginia (WV) is even higher at 322.4/100,000³. This is even more concerning when one considers that the WV older adult population (age over 65-years-old) is currently 17.7%. This is disproportionately higher than the U.S. average of 15.2%³. Effective CVD risk reduction continues to challenge healthcare clinicians despite many scientific advances and options for therapy. Behavioral approaches for reducing CVD risk supplement medical interventions but are not usually available on-site or at the point of care. It is important to create supportive relationships with patients to enhance behavioral change¹. In the context of usual and customary primary care, addressing the literacy and self-efficacy needs of patients, to support risk reduction, is generally limited and left up to the patient. However, when the population living in Appalachia is high risk and impoverished, and the primary source of care is a charitable clinic, the priority for addressing self-care behavior by tackling literacy and self-efficacy needs related to CVD risk factors increases significantly. People living in WV lead the nation in poor health indicators, especially the sentinel CVD risk factors of diabetes, obesity, hypertension, smoking, and hyperlipidemia⁴. In WV, the age adjusted mortality rate for diabetes is 31/100,000, while nationally the rate is lower at 22/100,000³.

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Uninsured, poor individuals encounter more morbidity and earlier mortality because of CVD, in part due to socioeconomic and cultural challenges⁵. Medically underserved populations are at increased CVD risk and effective evidenced-based clinical approaches are especially needed to reduce CVD risk in these populations⁶. Although lifestyle interventions can reduce CVD risk by as much as 44%, clinicians lack motivation to integrate risk reduction programs into practice because of time, expense, and reimbursement limitations⁷. The capacity to manage and engage patients in proactive, meaningful interactions is an important construct in population health management and patient-centered care⁸. This paper presents our approach to addressing CVD risk reduction in the primary care setting and presents the results of a retrospective chart review, which evaluated the effectiveness of such a strategy to reduce CVD risk in a high risk population.

Review of Literature

The chronic care model (CCM) provides valuable insight related to the need for this study and for advanced practice nurses to effectively support the management of chronic illness in primary care settings⁹. The CCM is a well-established and scientifically documented systems type approach to healthcare delivery. There are six components of the model, three of which are particularly cogent to this study: (1) use of evidence-based guidelines, (2) clinician leadership in team care, and (3) use of self-management support methods. In addition, the CCM focuses on improving the health of vulnerable populations experiencing access barriers as a result of social, economic, and behavioral challenges¹⁰. Premised on Orem's theory of self-care¹¹ focused on key processes supporting self-care in the context of chronic illness. These processes involve patients' in developing and applying their abilities to make reasoned decisions and to weigh the potential advantages of achieving and sustaining well-being, health, and self-efficacy goals. This middle-range theory imbeds the application of these new skills into three realms of self-care behavior: self-care maintenance, self-care monitoring, and self-care management. Self-care monitoring is of particular relevance to this study as patients' experience/skills, motivation, cultural beliefs/values, confidence, habits, functional/cognitive ability, extended support, and access to care are important levers which, if appropriately manipulated, may directly impact the success or failure to achieve desired health outcomes¹¹.

The theory of self-care of chronic illness served as the primary theoretical framework for this study. In addition, a growing body of evidence suggests that clinicians can better support self-care behavior by providing venues conducive to peer/family interactions and by establishing new partnerships with community organizations¹². Lorig, Sobel, and Stewart defined a scope of skills that patients must effectively acquire to self-manage chronic illness¹³. Five core skills of self-management support programs were identified, and tested. These skills include problem solving, decision making, resource utilization, patient-provider relationship, and taking action. Citing an abundance of literature regarding self-care of chronic illness, the authors consistently emphasized the importance of clinicians teaching patients new skills, and empowering application of new skills when faced with challenging health situations. This approach is thought to create better health consumers and to help control healthcare costs. Implementation of self-care support programs in primary care practices is challenging but beneficial to patients and practitioners. In one study evaluating the implementation of a brief diabetes self-care support interventions designed for resource-poor community clinics, nearly 60% of participants achieved the goals identified on action plans when frequent interactions with clinical staff occurred. However, it was noted that telephonic interactions were challenging to manage and sustain in the busy clinical setting¹⁴.

The effectiveness of multidisciplinary group visits incorporating diabetes self-management education in a family practice setting serving a population of Appalachian people demonstrated improvements in glycemic control, knowledge, and self-efficacy¹⁵. This approach may be beneficial in improving health outcomes in underserved populations. However, lack of reimbursement was identified as a barrier to more widespread integration into family practice delivery systems¹⁵. The lack of practice attribution or the concept of "patients committed" to a certain clinician for at least one year, coupled with multiple other confounding variables make scientific study especially challenging, and cost-time prohibitive in a busy primary care practice¹⁶. The literature reveals many perspectives about the impact integrated models of care may have on reducing risk, however, the evidence based on well-designed empirical studies remains limited¹⁷. The retrospective chart review is an effective way to evaluate programmatic outcomes in primary care settings.

Methods

This retrospective chart review examined the effect of an intentionally developed education program designed to help impoverished individuals reduce CVD risk factors. The program was provided, but had not been evaluated for outcome variables, which affect the health of this targeted population.

Setting

The WV charitable clinic model offers a comprehensive array of primary care services, self-management support, pharmaceutical products, and access to specialty medical/dental care. Resources to support clinic operations come from philanthropy, state funding, hospital support/partnership, medical volunteers, and multiple community social service partnerships¹⁸. Advanced practice nurses provide care continuity with the support of a team of staff comprised of medical assistants, social workers, and behavioral health practitioners. The clinic represents this community's compassionate commitment to assure every resident access to healthcare, regardless of socioeconomic status. Remarkably, the clinic has sustained this effort for over 32 years¹⁹. The population served by the clinic is comprised of uninsured, impoverished, adult residents of WV. The demographic composition of people accessing free primary care at the clinic is largely Caucasian (79%), African Americans (18%), and other (3%). Sixty-six percent of clinic users are females. All patients meet or are below 150 percent of the federal poverty level. Evidence of low-income status and lack of health insurance are requirements to access any healthcare service from the clinic. This includes medications offered through patient assistance programs by pharmaceutical companies¹⁹.

The CVD risk reduction program was comprised of several topic areas including tobacco cessation, weight reduction, healthy cooking, and physical activity classes. Specific curricular content focused on self-management of diabetes and CVD. Patients receiving care at the clinic were assessed regularly for their "readiness to change" at least one CVD or other risk factor to improve health and quality of life. When patients demonstrated a desire to prepare or take action to change, they were encouraged to participate in the CVD risk reduction education program. The CVD risk reduction education program was designed to address common access barriers challenging this population, such as transportation and day care costs, as well as literacy/numeracy deficits. Learning sessions were offered several times during the week and in the early evenings to encourage patient participation when at the clinic. Appointments coincided with learning sessions to support self-care efforts and interests, as much as possible. The small-group interactions among patients sharing common health and socioeconomic challenges helped to identify and alleviate literacy issues. Patients were encouraged to attend at least two sessions each month. Any patient could elect to attend one or more learning session instead of sitting idly in the waiting room. The curricula activities incorporated Appalachian cultural health beliefs, especially focusing on empowering individuals to make healthy lifestyle changes that were within their control. Licensed staff and credentialed community led the interactive learning sessions. Lay community members offered personal insights and testimony that were especially helpful to participants, as well.

Study Design

This retrospective chart review assessed whether the CVD risk reduction program was an effective strategy to reduce CVD risk in uninsured, Appalachian population. Outcome variables included systolic and diastolic blood pressure (BP), body mass index (BMI), glycosylated hemoglobin (HgA1c), and total cholesterol. Human subjects' approval was obtained to conduct this review. A power analysis revealed that 250 charts were needed; therefore, 125 charts from the education group and 125 charts of patients who were not committed to the education program were randomly selected. An analysis of clinical care and patient outcomes was performed after charts were identified from a possible pool of about 900 records (representing active patients at the charitable clinic from November 2011 through November 2012). Medical records were selected for review based on the following criteria: (1) demonstration of one or more CVD risk factors, and (2) active patient status for the full year (November 1, 2011 to November 30, 2012). The non-education group received usual and customary service offered at the clinic over the course of the year, and was not excluded from participation in the CVD risk reduction education offerings.

Statistical Analyses

A statistical analysis was performed using SPSS Version 20. Demographic data were analyzed using descriptive statistics (means, percentages, standard deviation, and variance).

Clinical data on matched pairs were analyzed using paired-*t* tests and analysis of variance (ANOVA). All statistical tests were performed with level of significance set at $\alpha < 0.05$ and confidence intervals set at 95%.

Results

This retrospective chart review answered the question "Did the CVD risk reduction education program reduce CVD risk in this population?" Table 1 depicts the demographic frequencies of the charts reviewed matched the overall clinic population in gender, and race/ethnicity. Both groups (education and non-education) were comparable in terms of distribution of risk factors. The self-selected education group was slightly older and experienced a higher frequency of comorbid conditions when compared to the non-education group (Table 1). Table 2 summarizes multiple comparisons of the findings from charts reviewed for the two groups using paired-*t* tests and ANOVAs for each risk factor. Of note is that the education group contained nearly 25% more people who had a diagnosis of diabetes, although HgA1c level means were nearly identical.

Systolic BP

In the non-education group at baseline, the chart review revealed that 36.7% had a systolic BP that was abnormal (>140) ($n=123$, mean 137.69, SD 13.741), and 37.4% of the education group registered an abnormal systolic BP ($n=123$, Mean 134.39, SD 19.098). At the one year measurement interval, 42.5% of the non-education group registered an abnormal systolic BP ($n=97$, mean 137.2, SD 19.98), and 31.25% in the education group had an abnormal systolic BP ($n= 102$, mean 133.7, SD 19.0). Chi-square test performed to assess the change in mean systolic BP was significant for both groups (chi-square, $df7$, $p = 0.03907$).

Diastolic BP

In the non-education group, 17% had an abnormal baseline diastolic BP (>90 mmHg) ($n=123$, mean 81.7, SD 10.098), and 15% of the education group had an abnormal baseline diastolic BP ($n=123$, mean 82.40, SD 10.231). At the one year measurement chart review 19.5% of non-education group registered an abnormal diastolic BP ($n= 111$, mean 82.36, SD 9.44), and 15.6% of the education group registered an abnormal diastolic BP ($n= 102$, Mean 81.96, SD 9.25). There was a 2% increase in the mean diastolic BP in the non-education group versus a 0.6% increase in the education group. Chi-square test to assess the change in mean diastolic BP was significant for both groups (chi-square, $df7$, $p= 0.03819$).

Cholesterol

In the non-education group, 39.8% had an abnormal baseline cholesterol level (>200) ($n= 103$, mean 193.7, SD 41.175), and 41.5% of the education group had an abnormal value at baseline ($n= 118$, mean = 193.1, SD 49.645). After one year, 36.6% of the non-education group registered an abnormal cholesterol level ($n=85$, mean 184.6, SD 44.082), and 24.2% of the education group had an abnormal cholesterol value ($n=92$, mean 179.40, SD 42.763). The chi-square test to assess the change in mean cholesterol level for both groups was significant (chi-square, $df7$, $p = 0.0417$).

BMI

Eighty-seven percent of the non-education group registered an abnormal baseline BMI (>25) ($n= 123$, mean 34.2, SD = 8.5), and 90.24% of the education group had an abnormal baseline BMI ($n= 123$, mean 34.7, SD 8.4). At the one year measurement 88.5% of the non-education group had an abnormal BMI ($n=110$, mean 34.86, SD 8.6), and 94.7% of the education group had an abnormal BMI ($n=102$, mean 34.7, SD 8.6). Both groups documented a mean increase in weight. The chi-square test to assess the change in mean BMI for both groups was significant (chi-square, $df 7$, $p=0.0019$).

Hemoglobin A1c

In the non-education group, 27.6% had an abnormal HgA1c level (>7.0) at baseline chart review ($n=37$, mean 6.79, SD 1.561), whereas 26.4% of the education group had an abnormal baseline HgA1c ($n=66$, mean 6.87, SD 2.018). At the one year measurement interval, 23% of the non-education group had an abnormal HgA1c ($n=37$, mean 6.94, SD 2.359), and 30% of the education group had an abnormal HgA1c level ($n=66$, mean 6.81, SD 1.860). Chi-square test to assess the change in mean HgA1c level for both groups was not significant (chi-square, $df 7$, $p=0.9942$). Table 3 depicts the results of the paired *t*-tests performed to determine significance of difference in pre and post measurements among patients from both groups.

There were no significant differences in outcomes for either group, except for a change in cholesterol levels in the education group. Additionally, two-way ANOVA tests performed for each CVD factor to determine differences within or between group means for each of CVD risk factor found no significant difference between the means of either group for any CVD risk factor. Figure 1 demonstrates the frequency of CVD risk factors in both chart review groups at baseline and at one year. The number of CVD risk factors was reduced in both groups. The percentage of patients in the education group with only one risk factor increased five-fold (from 5% to 25%), and the non-education group realized a 3 fold increase.

Discussion

This retrospective chart review evaluated whether a comprehensive CVD risk reduction education program reduced CVD risk factors. Changes in the difference in means for all clinical factors (except HgA1c in both groups) were likely due to confounding factors rather than the CVD risk education program. For example, access to patient assistance programs resulted in pharmaceutical companies providing free or low cost medication. Education group patients were provided a one month supply of medications at each visit, rather than the usual care which is to supply two months of medication. This was likely to have affected adherence to medicine regimens. The one month supply also encouraged frequent class attendance. Blood pressure and cholesterol means decreased in both groups, with cholesterol means dropping nearly 14 points in the education group only. This finding may provide some insight into the combined effect of the education program and medication access/adherence. This strategy is supported by the middle-range theory of self-care of chronic illness designed to increase meaningful and supportive interactions, develop self-care decision making skills, and reinforce health promoting behaviors (Jaarsma et al., 2012). Previous studies of resource-poor community clinics or Appalachian dwelling people have demonstrated favorable effects related to patients' engagement in their own chronic care. However, this study did not support previous findings that educational strategies to enhance patients' self-care efforts (Davis et al., 2012), or self-management activities (Jessee et al., 2012) are effective in improving important healthcare outcomes.

Utilizing the middle-range theoretical model of self-care of chronic illness, one might posit that participants with fewer or better controlled risk factors may have decided to disengage when desired self-care skills were mastered; thus leaving the more complex, intractable patients to continue the self-care journey. This may have biased the findings for the worse. Furthermore, the location and proximity of structured and group learning interactions may have enabled patients from either group to seek health and well-being improvement information in a more self-directed and organic manner. An alternative explanation may be that some patients did not experience early wins or positive outcomes, and therefore elected to forgo further participation in the education program. Over the one year period, the education group had less frequent office visits when compared to the non-education group. This finding may support the premise that regular participation in a CVD risk reduction education program leads to new skills, confidence, and self-efficacy in managing health/diseases. However, more study is needed to ascertain the dose-benefit. For example, how often and for how long does a person need to participate, and what are the cost-benefits associated with aligning office visits to coincide with educational opportunities to support CVD risk reduction?

Limitations

Voluntary participation in CVD risk reduction learning sessions by the non-education group was a surprising finding. However, it exposed a confounding factor to consider when evaluating the findings of this review. Thus, the differences between the two groups may have been cancelled out, rendering statistical comparisons of differences of no analytical value. Although tobacco use was originally intended as a variable, this was ultimately not included in the outcomes reports due to unclear and insufficient accuracy of record keeping resulting in a large number of missing data. Additionally, other CVD risk factors for the study were reported in numeric form (i.e. HgA1c, BMI) and tobacco use was reported in narrative form, thus increasing the rate of omission of those data, making an accurate comparison impossible. Incomplete records in the education group were nearly 50% higher than in the non-education group. Reasons for this lack of documentation were not assessed. However, factors that may have contributed to incomplete records include data entry shortfalls and patients leaving the practice. The transient nature of the population served is an ongoing challenge in charitable clinics (P. White, personal communication, 2014). Future studies should attempt to determine the reason for data loss or patient transiency.

Recommendations

Future studies should include a process to assess reasons for disengaging from the program. Program evaluation and continuing development should monitor attrition and ascertain motivations for discontinuing attendance to inform programmatic changes and enhance retention. Study design should control for program self-selection, limit unregistered users, and provide incentives upon return for interval measurements. Tobacco use, a well-established CVD risk factor (Ambrose & Barua, 2004), should be included in future research studies. To increase accuracy of data entry, clinics should consider how tobacco use might best be recorded, and what type of reminder might best cue the practitioner to report these critical elements of patient care. This may be achieved more successfully if the electronic medical record recorded tobacco use as an assigned numeric value (i.e. non-smoker=0, 1-5 cigarettes a day=1, ½ packs per day=2, 1 pack per day or more=3), making reporting more reliable and the comparison of pre/post tobacco use both within and between groups easier. Future studies should assess and control for the effect of confounding factors contributing to findings. This includes methods to sustain educational program attendance; such as incentives for medication access, transportation assistance, and rewards for goal achievement. Readily accessible validation of learning, trusted clinician-patient relationships, self-motivation support, and self-learning behaviors may be necessary to sustain healthy lifestyles.

Conclusion

The findings of the chart review demonstrate that CVD risk factors were reduced in the education and non-education groups. This program evaluation supports the necessity for a multi-focal approach to reducing CVD risk in disenfranchised populations. These strategies include (1) practitioner access to and use of evidence-based clinical interventions, (2) convenient access for patients to engage in culturally relevant risk reduction education, and (3) a clinical philosophy of patient-centeredness with respect for self-determination. Cardiovascular disease will continue to challenge people of Appalachia, but with access to evidence-based care and the implementation of supportive strategies to reduce modifiable risk factors, improvements in health status can be realized (Zuniga et al, 2003).

Acknowledgements

This study was funded in part by two grants from the Capstone College of Nursing; the Epsilon Omega Chapter of Sigma Theta Tau International Research Grant, and the Roberson Research Award (administered by Epsilon Omega Chapter of Sigma Theta Tau International). The authors would like to thank Terri Bliziotis, RN, MPH, PCMH-CCE, a champion of the pursuit of quality healthcare for underserved populations for her assistance with this study.

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Table 1: Demographic Characteristics of Education and Non-Education Groups

Characteristics of Education and Non-Education Groups		
Attributes	Education Group	Non-Education Group
Demographics		
Age (mean)	49.7	48
Gender	F = 68% M= 32%	F=64% M= 36%
ICD-9 Diagnostic Code Composition Key Risk Factors		
250 – Diabetes	38%	22%
410 - Hypertension	36.7%	42.5%
272 - Dyslipidemia	41.5%	39.8%
278 - Obesity	90.2%	87%
Utilization of Clinical Services		
Mean OV* Frequency	2.7	3.2
Mean Frequency of Participation in Education Topics		
Nutrition	2.2	1.7
Diabetes SM**	3.3	2.8
Exercise	2.2	1
Weight Loss	3	4.8
Quit Tobacco	2.7	3
Healthy Heart	7	6

*office visit; **self-management

Table 2: Comparisons of CVD Risk Factor Means in Education and Non-Education Group

Comparisons of CVD Risk Factor Means in Education and Non-education group								
Baseline								
Education					Non-Education			
CVD Factors	N	mean	Std. Deviation	Variance	N	Mean	Std. Deviation	Variance
Systolic BP	123	134.9	19.513	380.764	123	137.6	19.741	389.723
Diastolic BP	123	82.9	10.231	104.672	123	83.2	10.098	101.378
BMI	102	34.74	8.498	72.213	123	34.22	8.577	73.571
HgA1c	106	6.76	1.799	3.235	76	6.74	1.863	3.472
Cholesterol	118	193.11	49.645	2464.646	103	193.73	41.175	1695.357
1 Year Interval								
	N	mean	Std. Deviation	Variance	n	Mean	Std. Deviation	Variance
Systolic BP	102	133.7	19.038	364.731	111	137.2	19.983	399.326
Diastolic BP	102	81.3	9.253	85.623	111	83.1	9.443	89.161
BMI	102	34.77	8.659	74.985	110	34.86	8.629	74.456
HgA1c	79	6.85	1.857	3.449	63	6.76	2.066	4.269
Cholesterol	92	179.4	42.76	1828.705	85	184.64	44.082	1943.187

Table 3: Paired T-Test Results for Education and Non-education groups For All CVD Risk Factors

Paired T-Test Results for Education and Non-education groups For All CVD Risk Factors						
	Education			Non-education		
	T	df	Sig	T	Df	Sig
Systolic BP	.549	101	.584	.038	96	.970
Diastolic BP	1.275	101	.205	-.020	110	.984
BMI	.036	101	.972	-.799	109	.426
HgA1c	.171	65	.865	-.333	36	.741
Cholesterol	2.023	89	.046	1.145	69	.256

Figure 1: Comparison of CVD Risk Factor Reduction at Baseline and Post Education

