A Comparison of Recruitment Outcomes Using an Alternate Clinical Trial Recruitment Script for

Lifestyle Intervention for the Treatment of Diabetes (LIFT)

by

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Dedications:

To my parents, Ronald and Janice Jones and grandparents, Mose and Mary Eaddy.

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ABSTRACT

Background

Despite noble advancements in clinical research recruitment. Ethnic minorities continue to be disproportionately represented. Identifying variables that contribute to increased participation in such trials can provide valuable insight into the development of recruitment materials for future trials. The purpose of this research is to evaluate participant buy-in and participant volume; and to assess whether disease duration impacts one's decision to participate in the trial.

Methods

This study compares the use of two introductory scripts used during telephone interviews for screening potential subjects for LIFT Diabetes, a randomized controlled trial designed to investigate the effects of delivering contrasting interventions: a community-based intensive lifestyle program and a clinic-based enhanced diabetes self-management program.

Results

The recruitment scripts employed in this study varies in results. There is evidence to suggest that enticing recruitment scripts leads to increased participant buy-in and agreement to participate.

Conclusion

When age is applied to the findings herein, there is ample support for the belief that older adults are more likely to favor detailed study information when deciding to participate in clinical trials. This justifies further research and opens the door for clinical applications of these findings.

BACKGROUND

Diabetes Melliutus (DM) is a chronic disease in which the pancreas does not produce enough insulin, or the body does not use the insulin that it produces efficiently. Insulin is an essential hormone that is necessary for blood glucose regulation in the body. Blood glucose can elevate for several reasons, from eating excess carbohydrates to poor glucose monitoring, or poor adherence to DM medication regimen. In non-diabetics the pancreas autonomously produces adequate amounts of insulin required to move glucose from the bloodstream into the cells (Kharroubi & Darwish, 2015). People living with DM, elevated blood sugar (hyperglycemia), can result in in life threatening complications such as cardiovascular disease (CVD), renal insufficiency, blindness, neuropathy, non-traumatic lower leg amputations and premature death (National Institutes of Health, 2008).

Type 2 DM is characterized by insulin resistance and encompasses a variety of secretory defects. The secretory defects found in type 2 DM are accelerated by obesity, sedentary lifestyle and stress (Wendland et al., 2012). Type 2 DM results in response to several dynamics: impaired insulin secretion, inappropriate hepatic glucose production, or peripheral insulin receptor insensitivity. Pregnancy places women at risk for developing gestational diabetes and results in glucose intolerance and insulin resistance. Development of gestational diabetes significantly increases risk for developing of type 2 DM post-partum by 35% to 60% within 10-20 years (Wendland et al., 2012).

Type 2 DM accounts for nearly 90% to 95% of all diagnosed DM cases (Wu et al., 2014). Risk factors include all risks associated with the development of type 2 DM include older age, family history of DM, prior history of gestational diabetes, obesity, impaired glucose intolerance,

physical inactivity, and race/ethnicity These risks include a combination of lifestyle, environmental, and genetic factors, many of which are a challenge. African Americans, Hispanic/Latino Americans, American Indians, and some Asian Americans and Pacific Islanders are at higher risk for Type 2 DM. Compared to non-Hispanic whites, the risk of diabetes is 18.8% higher for Asian Americans. Disease risk is 66% higher for Hispanics, 77% for non-Hispanic blacks, 87% for Mexican Americans (Cubans, Central and South Americans) and 94% higher for Puerto Ricans. While several factors may contribute to the development type 2 DM excessive weights and obesity are known to significantly increase risk (Bertoni et al., 2005).

Prevalence of Type 2 DM

The increasing prevalence of obesity is paralleled with an alarming increase in incidence and prevalence of type 2 DM. Type 2 diabetes is now a common and expensive disease in the U.S. (Bertoni et al., 2005). Diabetes affects 25.8 million people, equivalent to 8.3% of the U.S. population. 18.8 million individuals are diagnosed with the condition, while 7 million remain undiagnosed (Centers for Disease Control and Prevention, 2013; G. J. Winston et al. (2009). In 2008, the prevalence of diagnosed diabetes was 8.1% of adult men and 7.7% of adult women (Centers for Disease Control and Prevention, 2011). In 2010, 13.0 million, 11.8% of all men aged 20 years or older had diabetes. Within that same year 12.6 million women, approximately 10.8% of the US adult female population had diabetes (Centers for Disease Control and Prevention, 2013). As of 2011 the median age of diagnosis for males was 53.6 years and 55.2 years for females (Centers for Disease Control and Prevention, 2011).

In 2011, 63% of adult incidents of diabetes were diagnosed within the ages of 40 to 64 years. The median age of diagnosis for diabetes in 2011 was 54 years old (Centers for Disease Control and Prevention, 2013). Nearly 16% of these cases were diagnosed between the ages of 18-39 years, and 21% between the ages of 65-79 years (Centers for Disease Control, 2013; Age Disb. 11'), 26.9% of all United States residents 65 and older had diabetes in 2010. The prevalence of diabetes increases sharply among older persons; approximately 27% of those 65 and older had diabetes in 2010 (Centers for Disease Control and Prevention, 2011). In 2004 68 % of all DM related death certificates noted cardiovascular disease (CVD) and 16% noted cerebrovascular accident (CVA) for persons aged 65 and older. Young adults, individuals less than 20 years of age, are equally affected with diabetes. In 2010, 1.9 million new cases were diagnosed in this population (Centers for Disease Control and Prevention, 2011).

Burden of Diabetes Mellitus

The need for type 2 diabetic at risk populations to participate in clinical trial is evident by the fact of increased risk of death is twice the risk of persons of similar age who do not have diabetes (Centers for Disease Control and Prevention, 2012). The complexity involved in managing diabetes complications significantly contributes to the cost of management of the disease. The estimated economic cost of diagnosed diabetes in 2012 was $245 billion, which is a 41% increase from $174 billion in 2007 (American Diabetes Association, 2013).

In North Carolina the rate of diabetes has doubled over the last 20 years and was the state's seventh-leading cause of death in 2012 (Young & Potru, 2011), and accounted for 27% of all North Carolinian deaths in 2014 (North Carolina Department of Health and Human Services

(NCDHHS, 2014). Interestingly, diabetes accounted for 28.2 % of all deaths in Forsyth County, NC in 2014 (North Carolina State Center for Health Statistics, 2014). Since 1995 diabetes prevalence for North Carolinian adults has more than doubled from 4.5% to 9.3% in 2010 (Young & Potru, 2011)(North Carolina Division of Public Health, 2010). In 2010 the direct (medical care) and indirect (lost productivity) costs of diabetes in North Carolina was an estimated $5.3 billion (North Carolina Division of Public Health, 2010). Medical care cost for diabetes totaled $3.6 billion and $1.7 billion for lost productivity (North Carolina Division of Public Health, 2010). The high incidence, increasing prevalence, and enormous cost of diabetes in North Carolina calls for effective diabetes programs to prevent and manage the disease.

Death rates for heart disease and the risk of stroke are 2-4 times higher for adults with diabetes (Centers for Disease Control and Prevention, 2012). People with type 2 diabetes can lose as many as 15 years of life. (North Carolina State PATHS Report, 2014). People with type 2 diabetes can lose as many as 15 years of life (North Carolina State PATHS Report, 2014). Diabetes affects approximately 8% of the US population and is widely known as one of the leading causes of death and disability; and, was reported as the seventh leading cause of death in 2006. Diabetic complications totaled an astounding $174 billion in health care expenditures in 2007. Indirect costs, $58 billion, included expenditures related to disability pay, leave from work and reduced productivity. Even more was spent on direct costs; $116 billion was spent on hospitalizations, medical care, and treatment supplies (National Institutes of Health, 2013).

Burden of Diabetes among Minorities

The burden of diabetes is disproportionately concentrated in minority populations. Higher prevalence was observed among both black (11%) and Hispanic (10.7%) adults compared to

whites (7.0%) (Centers for Disease Control and Prevention, 2011). Prevalence of disease amongst ethnicities concerning age at diagnosis differs slightly but approximately falls within the range of 49 to 55 years of age. In addition, the age at diagnosis for accounted minorities appears to onset earlier. The median age of diagnosis in 2011 for Caucasians was 55.4 years, 49.0 years for African Americans and 49.4 years for Hispanics/Latinos (Centers for Disease Control and Prevention, 2013). Several complications of diabetes (end-stage renal disease, amputation, retinopathy, and neuropathy) are more prevalent in some ethnic minorities (Harris, 2001; Karter et al., 2002; Lanting et al., 2005; Lavery et al., 1996; Young et al., 2003). Surprisingly, studies suggest African Americans with diabetes are not at excess CVD risk compared to whites (Gillum et al., 2000; Karter et al., 2002; Young et al., 2003).

Nonetheless, absolute CVD rates among adults with diabetes are high regardless of race (Bertoni et al., 2005), and CVD is the leading cause of morbidity and mortality in adults with diabetes (Narayan, 2011). In 2010, 14.7 million (12.8%) of all non-Hispanic whites had diabetes. In contrast 4.9 million, 18.7% of all non-Hispanic blacks had diabetes. Current data is insufficient to allow for estimation of diabetes prevalence for other United States ethnic minority populations. National survey from 2007 to 2009 is available and discloses self-reported incidents of diabetes in individuals 20 years or older. The survey indicates, 7.1% of non-Hispanic whites, 8.4% of Asian Americans, 11.8% of Hispanics, and 12.6% of non-Hispanic blacks had diagnosed diabetes. Amongst Hispanics, rates were 7.6% for Cubans and for Central and South Americans, 13.3% for Mexican Americans, and 13.8% for Puerto Ricans (Centers for Disease Control and Prevention, 2012.

Excessive body weight is one of the most prevalent medical problems among minorities with DM despite significant attention and funding (Khan et al., 2009). According to 2005-2008 data from the National Health and Nutrition Examination Survey, 44% of non-Hispanic adults we're overweight or obese, compared with 33% of non-Hispanic white adults (Ogden et al., 2014). Thus, the study of weight-loss treatments for adults, particularly racial/ethnic minority adults, is a significant research focus.

DM related complications can be reduced or delayed by intensive management of hemoglobin A1c (HbA1c), blood pressure (BP), and lipids (Goff et al., 2007). Unfortunately, control of risk factors among adults with diabetes is suboptimal (Bertoni et al., 2008; Saydah et al., 2004). Minority and underserved patients in the US are more likely to have poorer processes of care measures and control of diabetes and related risk factors for complications (Kirk et al., 2005a, 2005b). Studies have suggested minority women with diabetes are particularly less likely to have optimal prevention (Bertoni et al., 2008; Ginger J. Winston et al., 2009). Potential explanations include differential access to healthcare and/or testing. However, although lack of insurance and a usual source of care is a significant problem in our society, differences in diabetes control and outcomes, while reduced, are not eliminated when patients have uniform access (Brown et al., 2005; Karter et al., 2002).

Access to Behavioral Weight loss Programs in Minorities with Diabetes

Poor control of risk factors in African Americans and Hispanics with diabetes may be due to the increased prevalence of overweight and obesity, particularly among women (Robbins et al., 2001). Unfortunately, access to effective behavioral weight loss programs is extremely

limited. Although primary care providers (PCPs) provide 85%-90% of diabetes care in the US, current systems lack the resources needed to provide continuous care (e.g. telephone management of glycemia, behavioral interventions, risk factor reduction, health promotion and periodic examination for complications) (Roman & Harris, 1997)The National Ambulatory Medical Care Survey (NAMCES) demonstrates that half of all visits made by US adults lacked complete height and weight and thus could not calculate BMI; among those with such data with BMI>30 kg/m2, 70% were undiagnosed and 63% received no lifestyle counseling (Ma et al., 2009). NAMCES also suggests African Americans are less likely to receive weight loss and physical activity advice from either African Americans or white physicians (Bleich et al., 2012). Commercial approaches are available (e.g. Weight Watchers); such programs promote modest weight loss; however, adherence typically is low, and they do not focus on diabetes management (Dansinger et al., 2005; Tsai & Wadden, 2005). U.S. minorities are more likely to live in "food deserts," areas with fewer healthy food outlets (Walker et al., 2010). There is evidence that differential access to healthier foods and recreation facilities contributes to the etiology of diabetes and is likely to affect disease control (Auchincloss et al., 2008). Increasing access to effective behavioral weight loss programs for minorities requires an ecological approach that addresses barriers at the level of the community and the medical setting.

Group visits for diabetes have been studied as a way to provide interactive education and typical medical care, and may involve nurses, dietitians, pharmacists, diabetes educators, and a physician (Riley & Marshall, 2010). A systematic review concluded group visits may reduce costs and increase patient satisfaction; however, relatively few studies demonstrated statistically improved HbA1c and other risk factor control (Riley & Marshall, 2010). Importantly, many

insurance companies, including Medicare, will reimburse for such group-based visits. Currently, diabetes education is covered by many insurance programs (including Medicare), albeit at a lower intensity than proposed in LIFT Diabetes. The American Association of Diabetic Educators 7 behaviors include increasing exercise and dietary changes, however a key difference is that weight loss is not the overt goal, rather it is one method, along with other changes in behavior (including medication adherence), aimed at improving diabetes control ("AADE7 Self-Care Behaviors," 2008).

The feasibility of long-term lifestyle changes and the impact on CVD endpoints has been extensively evaluated by the Look AHEAD trial (Ryan et al., 2003). The improvements in risk factors led to an estimated 10-year CVD risk 15% lower than baseline data despite aging one year. These data suggest that weight loss should be the focus of lifestyle approaches to diabetes management. Importantly, even modest amounts of weight loss were associated with improved disease measures (Wing, 2010), and some participants experienced diabetes remission (approximately 11% of ILI vs 2% of the DSE group at 1 year).

Recruitment

Recruitment in clinical trials generally falls behind schedule in up to 86% of all trials, with 13% of trials falling behind by more than 6 months (V. S. Effoe et al., 2016). The use of patient databases to effectively recruit participants for clinical trials has increased in recent years (Kingry et al., 2007; Margitić et al., 1999; Parra-Medina et al., 2004; Reed et al., 2013). The availability of demographic factors, diagnoses, laboratory, and exam parameters creates the potential to use these data to identify protocol-qualified participants and narrow the pool of

potential participants to be screened rapidly and efficiently. The use of electronic medical records (EMRs) may improve participant recruitment by an efficient method for pre-screening individuals based on predefined inclusion/exclusion criteria (V. S. Effoe et al., 2016; Valery S. Effoe et al., 2016; Wilcox et al., 2009). In one community weight loss lifestyle trial which used almost exclusively medical record review to recruit overweight adults with diabetes, the recruitment yield was 21.5% (Parra-Medina et al., 2004).

The use of the electronic medical record (EMR) systems in clinical trials has the potential for providing a highly selective, efficient, and reliable recruiting methodology, which may improve participant recruitment for clinical trials. Employing the EMR as targeted recruitment method has significantly increased amongst principal investigators of academic health care systems across the nation (Richesson & Andrews, 2012). These sophisticated systems have proven efficient methods for preliminary screening of individuals for predefined inclusion/exclusion criteria of clinical trials (V. S. Effoe et al., 2016; Valery S. Effoe et al., 2016; Richesson & Andrews, 2012). Similar evidenced-based DM trials traditionally use community-based recruitment methods such as direct mass mailings, print and digital advertisements, radio advertisements, television advertisements, and provider referrals. Early success in recruiting is a reliable predictor of completing a clinical trial (Haidich & Ioannidis, 2001).

Recruited individuals who refuse to participate once contacted possess unique characteristics from those who undoubtedly agree to participate. Such characteristics include: older age, being of the male gender, ethnic minority; illness state, smoking status, socioeconomic status, and urban residence (Patel et al., 2003). Identifying these characteristics prove useful when identifying the target population of a study. Several research studies work vigorously to

recruit minority populations for studies, as minority populations are under-represented in most health sciences related studies. Low-income urban residents are also difficult to recruit due to inadequate time, child care, transportation, work schedules, housing and unsafe surroundings and even due to mistrust of the field of medical research and healthcare in general (Coleman-Phox et al., 2013). Ineffective performance early on in participant recruitment has the potential to negatively impact study budgets, timeline, and results. Therefore, strategic recruitment approaches are critical for conducting formidable and respected clinical research. Ensuring recruitment efforts are conducted by experienced individuals is essential in achieving this goal.

Goals of participant recruitment include recruiting a sample size that is adequately representative of the target population; and recruiting adequate numbers of individuals to fulfill the sample size and power requirements (Patel et al., 2003). Therefore, ensuring that participants are retained once recruited is crucial to the validity of research studies. Implementation of early retention strategies are essential to study vitality and should be developed in the planning phases of study design (Patel et al., 2003). One of the most important factors of participant retention is the establishment of a relationship with the participants. Establishing participant relationships encourage ongoing participation (Patel et al., 2003). Such relationships are established through consistency and mindfulness with the targeted population. These relationships establish rapport with participants and are significant to study vitality.

Telephone methods of recruitment are often thought of as efficient methods in participant recruitment. Utilization of telephone screening and interviewing for recruitment allows access to participants previously unreachable due to conflicting schedules (Trier-Bieniek, 2012). Telephone interviews have become a favored alternative over face-to-face interviewing.

However, some studies that have relied solely on telephone screening have found that interviewing and recruiting via telephone creates barriers in establishing rapport that does not exist in face-to-face interviewing. Participant recruitment via telephone allows for misinterpretation of tone, mood and more.

A major pitfall of recruiting is the lack of planning and devotion given to it. As mentioned earlier, recruitment is very challenging. New research and staff members often handle recruitment of participants and possess little or no knowledge at all regarding participant recruitment (Patel et al., 2003). Tremendous thought, planning and dedication is needed to ensure that funded studies can provide findings that contribute to the advancement of public health.

Barriers to the enrollment of participants in clinical trials include factors related to healthcare providers, including a lack of interest in the trial, physician bias concerning the therapy under investigation, and concerns about losing the patient to follow-up (V. S. Effoe et al., 2016), as well as factors related to the participants (Blackwell et al., 2011). Specifically, too stringent exclusion criteria may differentially affect the enrollment of particular race/ethnic groups. In the Look Action for Health in Diabetes (AHEAD) trial, African Americans were less likely to be enrolled due to a higher prevalence of one or more of the exclusion criteria (adverse blood pressure levels, heart rate, higher HbA1c, and serum creatinine) (Marsh et al., 2013).

Strategies for recruiting and retaining minority research participants emphasize the importance of community involvement, convenience of meeting times and locations, and rapport with research staff (Hartlieb et al., 2015). Strategies for recruiting and retaining racial/ethnic minority individuals should mirror those recommended for nonminority participants, with the

addition of intensive follow-up activities (Hartlieb et al., 2015). Recruitment of minority participants demands substantial time, and resources of research staff.

LIFT Diabetes was a randomized controlled trial designed to investigate the effects of an approach to delivering two contrasting interventions: a community-based intensive lifestyle program and a clinic-based enhanced diabetes self-management program. The trial recruited 260 overweight and obese adults with type 2 diabetes in Winston-Salem, North Carolina, and immediate surrounding areas. The study was based in Forsyth County, NC, principally composed of Winston-Salem. The county population was 350,670 in the 2010 census; it is quite representative of the US in age, sex, and education (Table 1, page 31). However, other characteristics suggest potential for health disparities: greater minority population and higher proportion living in poverty. Among adults, 41.4% were overweight and 23.3% were obese; minorities were more likely than whites to have a diabetes diagnosis (11.4% vs. 7.5%) (72). In the 2007 County Community Health Assessment, 210 adults were surveyed; DM was the leading health concern of 38%; it was the second ranking disease, only behind cancer (chosen by 41%). In 2010, the Downtown Health Plaza (DHP), a WFBMC clinic site, had 1820 unique patients with diabetes; 67% were African American. Among 126 DHP patients in ACTION to Control Cardiovascular Risk in Diabetes (ACCORD) (64 of them AAs), the mean SBP was 141 mmHg, A1c 8.3%, LDL 105 mg/dl, and BMI 34 kg/m^2. The WFBMC Family & Community Medicine (FCM) Clinic draws patients from the county. Dr. Kirk et al. recently published a chart review including 1,398 FCM DM patients; 44% were African American and only 38% of those had a Hgb A1c of <7% (Kirk et al., 2011).

The goal of the trial was to investigate the effects of two contrasting interventions (*Lifestyle Intervention for Treatment of Diabetes (LIFT Diabetes)*, 2013). The first was a 12-month intensive lifestyle intervention program designed to achieve and maintain weight loss by decreased caloric intake and increased physical activity, and was adapted from the Look AHEAD trial (Ryan et al., 2003). This lifestyle intervention used a community-based model implemented via a partnership between a diabetes educator and community health workers, adapted from HELP PD (Katula et al., 2013).

The second intervention was a clinic-based enhanced diabetes self-management program, which targeted glycemic control and the American Association of Diabetes Educators 7 self-care behaviors ("AADE7 Self-Care Behaviors," 2008) and was delivered by an interventionist/educator. The primary outcome for comparison is the United Kingdom Prospective Diabetes Study cardiovascular disease (CVD) risk score (Almeda-Valdes et al., 2010) at 12 months. The LIFT Diabetes trial aimed to recruit a sample that is 55-60% African American, 10-15% Hispanic, and 25-35% non-Hispanic White (NHW).

To comply with the guidelines of the Health Insurance Portability and Accountability Act (HIPAA),(United States. Congress (104th 2nd session : 1996), 1996) a limited temporary waiver of HIPAA authorization was obtained from the Institutional Review Board (IRB) of the Wake Forest School of Medicine, which permitted study investigators to identify potential subjects for recruitment as allowed under 45 Code of Federal Regulations (CFR) 164.512. The waiver provided access to protected health information to confirm eligibility and facilitate initial contact, after which consent, and HIPAA authorization were sought. All participants in the study provided verbal consent before the telephone screen and a written informed consent at their

initial screening visit. The trial protocol was approved by the IRB of the Wake Forest School of Medicine.

As an interventional study LIFT Diabetes was conducted in accordance with Good Clinical Practices and was registered on clinicaltrails.gov (NCT01806727). The present analysis was approved by the Institutional Review Board (IRB) of Lenoir-Rhyne University. Recruitment-approach effectiveness was not a primary outcome for the parent study, data regarding recruitment source effectives was not available for analysis. All participants were recruited between October 2013 and March 2014 from Winston-Salem, North Carolina, and surrounding areas.

Participants eligible for recruitment into LIFT Diabetes were aged 21 or older, had a confirmed diagnosis of type 2 (DM), a body mass index (BMI) of 25 or greater (27 or greater if on insulin), and a regular source of medical care. As shown in Table 2, page 32, participants with the following conditions were excluded: i) history of cardiovascular disease (CVD)(myocardial infarction, stroke, coronary artery procedure, cardiac rehabilitation, heart failure, valvular disease limiting ability to exercise, significant aortic stenosis or aneurysm, sudden death, myocarditis, hypertrophic cardiomyopathy); ii) history of cancer with expected survival less than 2 years; iii) glycosylated hemoglobin (HbA1c) > 11%, blood pressure > 160/100 mmHg, triglycerides > 600 mg/dl; iv) history of prior weight loss surgery; v) unstable psychiatric disease; vi) unable to walk two blocks without stopping; vii) drug or alcohol abuse; viii) on drugs known to affect body weight (e.g. corticosteroids); ix) pregnancy or breastfeeding; and x) advanced renal disease (estimated glomerular filtration rate, eGFR < 45 ml/min/1.73m^2).

The primary recruitment method employed was the use of the EMR system and subsequent targeted mailings. Individuals with a diagnosis of diabetes mellitus on the problem list in their medical records were identified via an EMR system containing records for Wake Forest Baptist Health (WFBH) patients. These individuals were then initially screened electronically (e-screening) for major exclusions (history of CVD, cancer, prior weight surgery) cited on the problem list. During this initial e-screening phase, a less strict cut-off value was used for clinical and biological parameters such as BMI, blood pressure, HbA1c, triglycerides, and eGFR since these measurements can change significantly over time. A blood pressure value with a systolic reading of 170 mmHg and/or a diastolic of 110 was used for e-screening, in place of the predefined cut-off of > 160/100 mmHg. Individuals remaining potentially eligible were mailed a brochure with an opt-out postcard to return if not interested. If a postcard was not received after 2 weeks, a study staff member reached out to potential participants to determine interest and conduct a telephone screen. To assess the efficacy of the EMR as a screening tool, sensitivity and specificity analyses were done on a random subsample of participants with diabetes on the problem list.

Another recruitment method used was direct referrals from physicians or other healthcare providers, study participants, and study team members. To foster referrals from within the WFBH system, several study investigators made presentations at Internal Medicine and Family Medicine faculty meetings. Referrals from healthcare providers was facilitated using study contact cards that were made available at clinic locations for interested patients to provide their contact information.

Study team personnel attended a total of six health screening events in the community (health fairs and church screenings), where interested participants were either screened on site or contacted later by telephone. The study team also distributed flyers in targeted local pharmacies in the community and different WFBH medical practices. To increase the representation of African Americans in the trial, especially African American men, television advertisements were aired during specific programs and specific times of the day, and a radio interview was done. LIFT Diabetes study advertisements were also printed and published in a local newspaper and magazine, church bulletins, and posted online (on the Wake Forest Baptist Health website for clinical studies and an online press). All study recruitment materials were approved by the Institutional Review Board of the Wake Forest School of Medicine and focused on 3 main criteria: adults aged 21 and above, a diagnosis of type 2 DM, and being overweight or obese.

Participant Screening and Randomization

Participants who expressed interest in the study were screened either via telephone, or face-to-face, using a scripted screening instrument. The subjects in this analysis were all screened by telephone. A total of five telephone screening calls were attempted for each participant and a voicemail was recorded whenever possible. To determine potential eligibility during the phone screen, major exclusions were assessed. A typical telephone screen lasted on average 15 minutes. All calls were made from 1 phone line exclusively designated for this analysis. The investigator then completed a brief introductory script that informed potential participants about the parent study and assessed their willingness to participate in a brief pre-screening interview. During this screening callers were asked how they heard about the study (ad

source). If calls were not answered immediately, an attempt was made to return call within 48 hours at a different time of day than the previous call. Eligibility to progress to the next screening phase was established during the telephone interview, with a few requiring additional chart review by the study physician.

All participants deemed potentially eligible after the telephone screen were invited to attend a clinic visit where additional screening was performed to assess final eligibility. A few participants who qualified after the telephone screen chose not to attend the clinic. During the clinic visit, the following eligibility parameters were assessed: confirmed diagnosis of diabetes, blood pressure ≤ 160/100 mmHg, BMI ≥ 25 kg/m^2, urine dipstick proteinuria < 4+, HbA1c ≤ 11%, eGFR ≥ 45 ml/min, triglycerides ≤ 600 mg/dl, absence of a history of CVD, ability to exercise (using the Physical Activity Readiness Questionnaire), and absence of severe depression (using the Patient Health Questionnaire 9 Instrument). Participants who remained eligible after the first clinic screening visit were invited to a baseline visit, during which they were randomized to one of the two arms of the trial. Subsequent screening procedures and randomization details are described elsewhere (V. S. Effoe et al., 2016).

The duration of recruitment and randomization was dependent on the number of personnel, the duration of clinic visits, and the willingness of eligible individuals to participate.

Use of the original script elicited inquiries regarding participant benefits, study aim, design and overall desire for more information. Such inquiries resulted in disclosure of the non-traditional approach to diabetes management found in LIFT Diabetes and the opportunity to network with other struggling diabetics. After relaying this information, the interviewer (hereafter described as primary investigator) detected positive reception from interviewees that

was initially absent. Analysis of the standardized script revealed minimal disclosure of study design and participant benefits. A desire to increase productivity, efficiency and net return of recruitment efforts prompted the draft of the alternate introductory script that reveals enticing attributes of LIFT Diabetes (see Appendix I and II).

Purpose Statement

LIFT Diabetes was a randomized controlled trial designed to investigate the effects of an approach to delivering two contrasting interventions: a community-based intensive lifestyle program and a clinic-based enhanced diabetes self-management program. The purpose of this research is to evaluate if the use of an alternate introductory script for LIFT Diabetes Pre-Screening Form would increase both participants buy-in and participant volume; and to assess whether disease duration impacts the likelihood of trial participation or unwillingness.

Research Questions

This research was conducted within LIFT Diabetes to evaluate the effectiveness of strategic changes associated with the pre-screening form utilized in participant hone screening's The alternate introductory script for the screening form will be implemented at random during call efforts to answer the following questions:

1. Did use of the alternate introductory screening script for LIFT Diabetes increase participant buy-in?
2. Did use of the alternate introductory script reduce interview time compared to interviews conducted utilizing the standard introduction?

3. What impact does disease duration have on a potential participant's buy-in and subsequent agreement to participate?

METHODOLOGY

Participants: The LIFT Diabetes randomized trial was designed to investigate the effects of two contrasting interventions (a 12-month community-based intensive lifestyle intervention versus a clinic-based enhanced diabetes self-management program) on CVD risk in overweight and obese adults with type 2 diabetes.

The trial protocol was approved by the Institutional Review Board (IRB) of Wake Forest School of Medicine, and a limited temporary waiver of the Health Insurance Portability and Accountability Act (HIPPA) authorization was issued by the IRB, which permitted study investigators to access protected health information to confirm eligibility and facilitate initial contact for recruitment as allowed by government regulations. All participants gave verbal consent before continuing to the telephone screen.

The 100 potential study participants met the above-mentioned inclusion and exclusion criteria of the parent study and were screened in accordance with the recruitment methods described earlier. Patients were excluded from this study analysis if only a introductory screening script was administered; completion of both the introductory screening script and the LIFT Diabetes pre-screening form had to be completed for this study.

The determination of eligibility was defined as a patient allowing the interview to continue following the delivery of the introductory script.

Procedures: This project was a parallel study in support of, LIFT Diabetes; a randomized controlled trial designed to investigate the effects of an approach to delivering two contrasting interventions; a community-based intensive lifestyle program and a clinic-based enhanced diabetes self-management program. To ensure a proper test, the original and alternate introductory scripts were randomized over a period to see if one script was more successful than the other.

To reduce bias, the introductory scripts were randomized by a Wake Forest School of Medicine biostatistician. To examine the effectives of the script revisions, 100 calls to potentially eligible study participants was planned. A total of 50 calls or 50% of the recruitment goal were to be screened with the original introductory script; and the reimaging set of potential participants were to be screened using the alternate introductory script.

A 100-person call list from a query of type 2 diabetes patients from the WFBH system was compiled; and then assessed for randomization of the introductions to each participant. The randomization of the scripts was performed by assigning a number between 0 and 1 was uniformly randomly generated then rounded to 0 (<.5) or 1 (>=.5). “0” was assigned to the original introduction, “1” was assigned to the alternate introduction.

Additional patient lists were generated to allow for an optimal sample size for this project and to account for the exclusion of subjects due to:

1) WFSM staff conducting the screening and interview upon call back from potential participant in the absence of the principal investigator.

2) Language barriers that would result in an inability to effectively communicate with potential subjects throughout the course of the study.
3) Patient dispute of recent or current diagnosis of specified qualifying conditions.
4) Inability to establish patient contact due to incorrect or non-existent contact information.
5) Recent report of patient death or advised of terminal illnesses.

The principal investigator completed all participant calls and interviews for these analyses from the Department of Public Health Sciences at Wake Forest School of Medicine. All screening interviews were completed using the randomized introduction assigned to each patient. Potentially eligible participants were expected to devote approximately 15-30 minutes of time to the pre-screening interview. Data relative to the parent study was collected over the phone using the LIFT Diabetes Pre-Screening form.

Following the reading of either introductory script, the level of potential participant interest was defined as: 1) not interested, 2) interested, or 3) interested, call back; with a final examination of the proportion of participants enrolled for each script. For the purposes of this analyses call duration (mm:ss) was recorded in addition to disease duration (in years).

Statistical analysis

To assess whether the alternate introductory alternate introductory screening script increased participant buy-in, the level of participant interest was examined to determine the proportion of participants enrolled for each script.

Cumulative interview time for the randomized scripts was examined to determine if use

use of the alternate introductory script reduced interview time in comparison to interview times conducted utilizing the standard introduction.

To establish associations between a potential participants self-determined need for interventional education; participants disease duration (in years) was compared to his or her interest level, coded as 0, 1 or 2. To ensure data integrity, self-reported age was reconciled against the date of birth from the EMR for each patient. The "calculated age" from this reconciliation was used to calculate "disease duration" by obtaining the sum of the difference between calculated age and self -report of "age when diagnosed".

Mean values for disease duration (in years) was compared against the proportion of enrolled participant interest or disinterest values for disease duration were calculated for each group. A Chi-square test was used for the categorical data. A non-parametric, Kruskal-Wallis test, was used for continuous traits because of possible non-normality distribution.

RESULTS

Results are presented as mean and standard deviation or a number (percentage) where appropriate. A subset of 29% (n=318) of potentially eligible subjects from the parent study were randomized to either the original or alternate introductory script for this sub analysis. 89.9% or 286 participants were declared eligible for screening. A total of 750 call screening call attempts were made resulting in 84 complete phone screens. A total of 96 (8.7%) telephone screens at 80% power were subjected to the subbasement of introductory scripts, with 50% (n=48) of screens belonging to either the original or alternate scripts for the trial.

Eight of (16.7%) of potential participants from the original script were “not interested”; while 83.3% (n=40) were “interested” and 0% (n=0) identified as “interested, call back”. Administration of the alternate script resulted in fewer 12.5% (n=6) “not interested” potential participants; 75% (n=36%) “interested” and 12.5% (n=6) as “interested, call back.” The proportion of enrolled participants from both versions of the introductory script for the trial were equal with 17.5% (n=7) enrolling from the original script and 19.4% (n=7) enrolling from the alternate script.

The “Alternate Script” had fewer “not interested participants” (12.5% to 16.7%) and also produced a lower mean interview time (10.8 to 11.6 minutes) for those who were interested, although median times were very comparable (10.7 to 10.8 minutes). The “Alternate Script” produced a higher enrollment rate (19.4% to 17.5%) for those who were “interested” and finished the phone interview the same day. The average time spent to complete a telephone screen using the original script was 25 minutes compared to a duration of 17 minutes for interviews conducted using the alternate introductory script. The average disease duration for those screened and enrolled under this assessment from the original script was 7 years while 10 years was the average disease duration for those screened using the alternate script.

DISCUSSION

The goal of recruitment for the LIFT Diabetes trial was to enroll 260 participants, including a target for minority groups higher than that of previous similar trials. Using the EMR as the primary method of recruitment, the recruitment goal was achieved within close to the pre-specified time (recruitment was extended by one week). This report compared and examined

participant buy-in and subsequent recruitment yields following the randomization of introductory scripts used during the pre-screening stages of recruitment for LIFT Diabetes. The resulting interview time associated with each recruitment call was also examined, along with the differential effects of disease state duration on the likelihood of participant interest and enrollment. The primary outcome, "participant buy-in", was determined by participant agreement to continue with the screening interview following administration of the randomized script.

Participants buy-in was greater for those screened with the original script. This is possible as the description belonging to the original script was ambiguous and lacked fundamental information that is imperative for patients to determine his or her eligibility without having to progress to the interview phase of the screening process. However, the proportion of participants expressing disinterest in the trial following administration of the original script was greater when compared to those "not interested" after hearing the alternate introductory script. This is likely as the alternate script provided greater detail concerning the study and detailed enticing benefits about the study that the original introductory script did not.

The alternate script produced a lower yield of initially interested participants than hoped for. However, the proportion of participants enrolled from use of the alternate script was higher, which is consistent with literature that shows that methodical introductory scripts and "patient-facing" study materials in human subjects' research studies is likely to produce favorable screening and enrollment outcomes.

The most significant variable between the two scripts was calculated age. The "alternate script" group was significantly older, suggesting that a sample size of this demographic

appreciates receiving detailed information when contacted about the possibility of participating in a clinical trial; this allows patients to make well informed decisions about their participation.

Use of the alternate introductory script reduced failed to result in significant differences in interview times. Call time averages for both the original and alternate scripts were non remarkable. However, the proportion of participants recently diagnosed with diabetes, either not screened or screened; were either not interested in proceeding to the interview phase or immediately expressed dis-interest at call greeting or amid introductory script delivery. Explanation of these findings remains uncertain and could be due to a variety of reasons such as, institutional reputation, ambiguity and more.

Public Health Implications

Despite noble advancements in diabetes education and self-management, ethnic minorities continue to be disproportionally plagued with the burden of diabetes in the United States. Poor management of diabetes can have catastrophic affects for those diagnosed with the condition and the health care systems that serves them. The participation of ethnic minorities in clinical remains challenging. Failure to include a representative sample population for studies positioned as generalizable fails to produce duplicable results and methods in the future. This also negatively impacts research portfolios and the potential of securing funds from funding sources interested in samples representative of the changing face of our nation.

The use of the electronic medical record (EMR) systems for extensive geographic networks has the potential for providing a highly selective and reliable recruitment methodology to improve participation of these populations in clinical trials.

Continued funding for public health research in this sector relies heavily on replicable methodologies that produce generalizable results. Thus, careful planning and development of clinical trials and interventional studies from proven methodologies are of extreme importance. Works such as these allows for future investigators and study teams to adapt and improve their outlined workflows.

Recommendations

Existing research has shown that the management of HbA1C, blood pressure and lipids can greatly reduce and delay disease related complications, if these determinants (HbA1C), blood pressure and lipids) are rigorously controlled. Control of these relies heavily on weight loss and increased physical activity with special consideration for the individual's lifestyle and environment. Further RCTs are needed to better understand the complex individual and social factors that are contributing to this growing epidemic. However, identifying and recruiting potential participants for such trials can be challenging. Satisfactory recruitment is crucial for producing valid, applicable, and contributable findings in translational research.

Recruitment of subjects for both human subjects research and health programing may be improved by initiating interviews with a mention of exclusion criteria immediately after information needed to compile a record is obtained. Doing so will reduce large amounts of time wasted interviewing individuals deemed ineligible per study protocol. Reduce time by assessing cardiovascular and other disqualifying criteria at the start of the interview. Such programs can prevent or delay the onset of type 2 diabetes mellitus (Pronk, Boucher, Jeffery, Sherwood & Byle, 2014) and the need for such programs in this region is evident. An important component of

successful intervention programs is knowing where best to implement it. (Gesler, Hayes, Arucry, Skelly, Nash & Soward, 2004). Future clinical studies should tailor their recruitment strategies based on the participant demographics of interest. Efficient and effective methods such as the EMR and referrals should be prioritized over labor-intensive, low-yielding methods such as community screenings.

Limitations

Despite the efficiency and cost-effectiveness of the EMR method, there are several limitations to using this approach. First, because the EMR was the primary recruitment method, efforts targeted mainly patients with type 2 diabetes who use the WFBH clinical centers as their source of care. The potential for this is however reduced, as slightly more than a third of the final sample came from methods other than the EMR. Second, the success of the EMR method is dependent on a proper medical coding system. Improper diagnosis coding may lead to misclassification which can reduce the efficiency of the process. The EMR system used at WFBH clinical centers allowed for tagging of specific diagnosis codes which makes e-screening feasible. Third, because the EMR system is not standardized across hospitals and clinical research sites, comparisons of EMR use in recruitment across studies can be challenging.

Due to the potential for miscommunication, non-English speaking patients were excluded; this is evident for the entire sample for LIFT Diabetes.

Limitations of this study included an inadequate sample size. There were an insufficient number of participants that completed the entire screening process (introductory script and screener). As a result, this sample failed to produce statistically significant results.

It is unclear what led to the success (or non-success) over the second period (seasonal effect, more experienced staff making contact, better list of subjects identified, etc.)
Failed to capture "time elapsed" at the conclusion of the delivery of screening script.
The self-reported variable, "age when diagnosed" is highly unreliable due to patients' inability to correctly recall this information and inconsistencies amongst healthcare institutions to affectively record this information in the EMR.

Conclusions

The evidence from this analysis and existing literature provides evidence to suggests that detailed recruitment materials have the potential to increase participant buy-in. Additionally, to clearly define the relationship between disease duration, participant buy-in and subsequent agreement to participate, further analyses are needed. Findings from the LIFT Diabetes recruitment process demonstrates that the EMR is an efficient and cost-effective tool which can be used as a primary recruitment method for future clinical trials. These results show that the EMR approach should be used in combination with other recruitment strategies with proven efficacy in minority groups, such as direct referrals and media advertisements, as this can remarkably increase the recruitment yield for these groups. Future clinical studies will need to tailor their recruitment strategies based on the participant demographics of interest. Efficient and cost-effective methods with modest yields such as the EMR, direct referrals and media advertisements should be prioritized over labor-intensive, low-yielding methods such as community screenings. In conclusion, the identification of patients through the EMR when paired with carefully crafted recruitment materials has the potentially to take a positive step

toward better understanding patient demographics as it relates to clinical trial recruitment. Replication and advancement of these methodologies in various disease niches may prove useful for a variety of other public health disease burdens.

Table 1. Comparison: Forsyth County NC and US		
Characteristic	Forsyth	US
Female	52%	51%
Median Age	37 yr	37 yr
% 65 yr+	13%	13%
% H.S . Graduate	87%	85%
% College Graduate	32%	28%
% White	63%	77%
% African American	26%	13%
% Hispanic	11%	15%
Median Household Income	$46,912	$52,029
Below Poverty Level	15%	13%
Data from the 2008 American Community Survey		

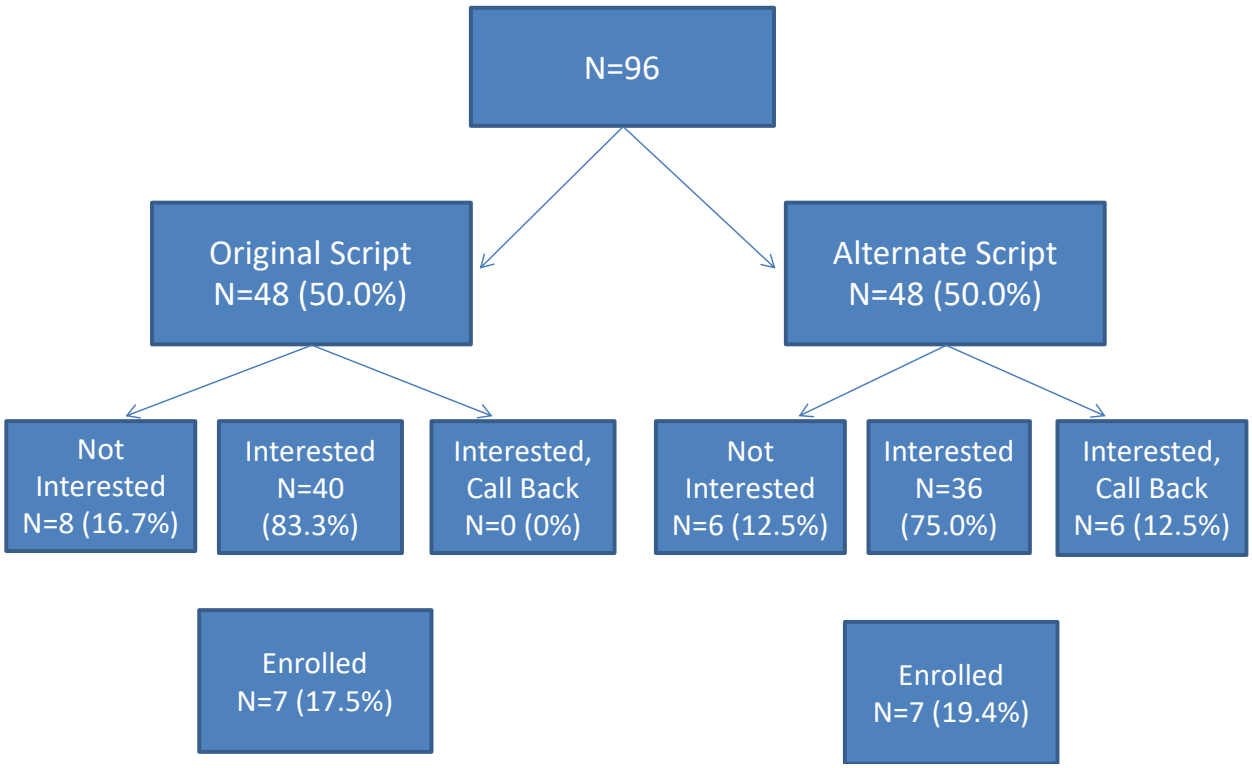
Table 2. Inclusion and exclusion criteria for the parent study

Major Exclusion Criteria	Major Inclusion Criteria
CVD, Cancer	Diagnosed Type 2 Diabetes:
BMI<25.0 kg/m^2	Age 21+
A1c ≥11%	BMI≥25 (≥27 if on insulin)
BP≥160/100 mmHg,	
Triglycerides ≥600 mg/dl	
Unable to exercise	Have a source of medical care
Drug or alcohol abuse	Consent, accept randomization
Advanced renal disease	Able to participate in Forsyth County
Drugs increasing weight (e.g. steroids)	
Unstable psychiatric disease	
Pregnancy, breast feeding	
Prior weight loss surgery	
Current participation in a lifestyle change program or clinical trial affecting CV risk factors	

Table 3. *Demographics, Call Attributes and Enrollment Outcomes for Interested and Enrolled Participants*

	Introductory Script		
Interested	Original (N=40)	Alternate (N=36)	P-value
Age	51.4±12.0 (52.5)	58.3±11.7 (59.0)	0.0229
Race (AA)	24 (60.0%)	19 (52.8%)	0.5259
Gender (Female)	20 (50.0%)	24 (66.7%)	0.1417
Diabetes Duration (Yrs)	7.5±6.2 (6.0)	10.3±10.6 (6.5)	0.5985
Call Duration (minutes)	11.6±4.0 (10.8)	10.8±3.3 (10.7)	0.7003
Enrolled	7 (17.5%)	7 (19.4%)	0.8272

Figure 1. Consort Diagram of Screening Script Randomization



Appendix A

Original Introductory Script for the LIFT Diabetes Pre-Screening Form

Interviewer script:

Hi, my name is _____ with Wake Forest University. Thank you for your interest in the LIFT Diabetes study. This is a study funded by the National Institutes of Health to determine how best to manage your risk factors for developing diabetes complications. This study may include instruction and education on weight loss, increasing physical activity and/or control of HbA1c. We would like to ask you a few questions about your health to see if you qualify for this study. All the information you give us will be kept confidential. Some of the questions are personal and may be sensitive. However, you may refuse to answer any question.

Is this all right with you? Is this a good time for me to ask you these questions?

☐ (yes) Great! ☐ (no) When would be a more convenient time?

Appendix B

Alternate Introductory Script for LIFT Diabetes Pre-Screening Form

Hi, my name is _____with Wake Forest University. I am calling in regards to the LIFT Diabetes Research Study. LIFT is funded by the National Institutes of Health to determine how best to manage risk factors for developing diabetes complications. This study is a non-traditional approach to diabetes management and may include instruction and education on weight loss, increasing physical activity and/or control of HbA1C. The LIFT study may also offer a community atmosphere to you and others like yourself who seek to gain optimal control over diabetes, weight and exercise. This study will run for 2 years and if you qualify to participate, you will be involved in group sessions for the first year of the study. We would like to ask you a few questions about your health to see if you qualify for this study. All information obtained will be kept confidential. Some of the questions are personal and may sensitive. However, you may refuse to answer any question.

Is this all right with you? Is now a good time for me to ask you these questions?

☐ (yes) Great!

☐ (no) When would be a more convenient time?

Appendix C

Relevance to Master of Public Health Program Competencies

Evidence-based Approaches to Public Health

1. Apply epidemiological methods to the breadth of settings and situations in public health practice –the following competency was met in MPH 521 and 555 through the exploration epidemiologic practices employed during historical outbreaks in the US and abroad; Catawba County Norovirus Outbreak of 2012 and course project, "Chlorine Exposure as an Occupational Health Hazard at Lenoir-Rhyne University."
2. Select quantitative and qualitative data collection methods appropriate for a given public health context –the following competency was met in MPH 516, 521, 616 and 617 through internship experiences with Catawba County Public Health during the norovirus outbreak at the Harbor Inn Seafood restaurant in Conover, NC in 2012; and practicum experience(s) within the Department of Public Health Sciences at Wake Forest School of Medicine.
3. Analyze quantitative and qualitative data using biostatistics, informatics, computer-based programming and software, as appropriate –the following competency was met in MPH 516, 616, and 617 through the analysis of data via SPSSS and various statistical calculations preformed through various software programs and during the completion of the capstone project entitled "Lifestyle Intervention for the Treatment of Diabetes (LIFT): A Comparison of Clinical Trial Recruitment Scripts.
4. Interpret results of data analysis for public health research, policy or practice–the following competency was met in MPH 616, 617, 620-622 through analyses of a variety of data sets for

various projects within the Wake Forest School of Medicine Department of Public Health Sciences.

Public Health and Health Care Systems

5. Compare the organization, structure and function of health care, public health, and regulatory systems across national and international settings–the following competency was met in MPH 525 through the exploration of various healthcare systems Course work analysis of US health care systems and comparisons to healthcare systems abroad, where the US was compared to healthcare systems in Australia.

6. Discuss the means by which structural bias, social inequities and racism undermine health and create challenges to achieving health equity at organizational, community and societal levels–this competency was met in MPH 535 and 528 as we explored, in a variety of ways the described elements are woven into the very fabric of health policy both direct and indirect and its detriment to equitable health achievements. This was further observed in practicum experiences in MPH 620-622 as the inability to staff bilingual personnel often resulted in a denial of services or discouragement of individuals to participate in health initiatives.

Planning and Management to Promote Health

7. Assess population needs, assets and capacities that affect communities' health–the following assessment for university's situated in the Triad region of North Carolina that identified a need

for increased education, awareness, and programming initiatives for sexually transmitted diseases.

8. Apply awareness of cultural values and practices to the design or implementation of public health policies or programs–this competency was met in MPH 528, 535 and 540, through the exploration of the unique populations and their needs in Hickory, NC and immediate surrounding areas. Health considerations of the Hmong population was explored as well as the need to adapt both clinical and community health initiatives to familial models of communication and acknowledgement of altered family structure in health education, support, and decisions.

9. Design a population-based policy, program, project, or intervention–the following competency was met in MPH 555, 528 540 through the development of hypothetical programming and initiatives based off real assessments. The resulting efforts were an adolescent smoking cessation program and STD harm reduction-awareness campaign.

10. Explain basic principles and tools of budget and resource management–this competency was met in BUS 515 through in-depth exploration of local healthcare systems. The importance of resource sharing was stressed through a series informative discussion with Douglas Urland, former director of Catawba County Public Health. And during the completion of a project that focused on federal and state laws that govern the Certificate of Need (CON) model.

11. Select methods to evaluate public health programs–this competency was met in MPH 616 and 617 through the evaluation of a health campaign funded by the Maya Angelou Center for Health Equity designed to promote and flu vaccination and uptake amongst lower socioeconomic residents and ethnic minorities in Forsyth County, NC. Outcomes from a series of external advisory board committee meetings and community member focus groups were reviewed to redevelop campaign initiatives and education materials. This resulted in the production of educational materials that clearly reflected the target population.

Policy in Public Health

12. Discuss multiple dimensions of the policy-making process, including the roles of ethics and evidence–this competency was met in MPH 525 through the exploration of numerous policies and ethical considerations through a series of weekly forums. The forums allowed for robust discussion on North Carolina laws, statutes and governances that impact and potentially regulates citizens health and well-being. The competency was further met during the completion of a project that explored NC involuntary commitment laws as an ineffective solution to a much larger and complex epidemic in the state.

13. Propose strategies to identify stakeholders and build coalitions and partnerships for influencing public health outcomes–This competency was met through a variety of coursework in MPH 535 that assisted in the identification of community champions to support and expand and extend the services offered by the AIDS Leadership Foothills-Area Alliance (ALFA).

14. Advocate for political, social or economic policies and programs that will improve health in diverse populations–the following competency was met in MPH 535, through the exploration of opportunities to advance K-12 foods and nutrition programming in US public school systems.

15. Evaluate policies for their impact on public health and health equity–this competency was met in MPH 525 and 535 during the completion of a project that explored the history of the Fluoride Mouth Rinse Program in schools and institutions.

Leadership

16. Apply principles of leadership, governance, and management, which include creating a vision, empowering others, fostering collaboration, and guiding decision making–this competency was met in MPH 523, through exploration of a hypothetical 5-year youth centric prevention program. Collaborative efforts for the program included local youth groups and young-adult speakers who would share their stories and the pitfalls of experimental drug use.

17. Apply negotiation and mediation skills to address organizational or community challenges–this competency was met in BUS 518 through the exploration of contractual agreements between health care entities and “shared use agreements” to meet the needs of a community.

Communication

18. Select communication strategies for different audiences and sectors–the listed competency was met in MPH 555 during the completion of the project entitled “Protect Your Rose” a sexual

health campaign targeted at college aged females that was to employ its health communication messaging to a variety of audiences with unique focus on campus radio listeners and digital tile advertisements to be shared across social media platforms such as Facebook, Instagram, and Twitter.

19. Communicate audience-appropriate public health content, both in writing and through oral presentation–the following competency was met in MPH 555 through the exploration and development of a variety of health communication pieces from disasters to food safety issues to be delivered through multiple communication channels.

20. Describe the importance of cultural competence in communicating public health content–this competency was met in MPH 528, 535, 616 and 617 and through practicum experiences and course explorations of the poor treatment individuals within the US healthcare systems. The breach of ethics and harm caused to men in the Tuskegee experiment examined this concept, along with the importance of understanding the relative regional histories unique to some medical institutions.

Interprofessional Practice

21. Perform effectively on interprofessional teams–this competency was met in MPH 616 and 617 through complex involvement in clinical research teams comprised of physicians, researchers, nurses, diabetes educators, statisticians and more. The practicum experience offered

several opportunities to present thoughts and solutions that were incorporated into various efforts funded by the Maya Angelou Center for Health Equity.

Systems Thinking

22. Apply systems thinking tools to a public health issue–this competency was met in MPH 506 and 535 through the exploration of concepts of rural health and the improvement of sanitation and access to regular sources of healthcare and medication provision.

norovirus

Community Health Concentration Competencies

23. Distinguish how the dynamic interactions among social systems within communities facilitate or inhibit healthy behaviors–the following competency was met in MPH 528, 535 and 540 through participation in programs and projects that showed the failure of well-intentioned programs to lead to healthy eating per the lack of access to the foods educated upon in the reviewed dietary behavior change programs.

24. Evaluate the quality of data (validity, reliability, normalcy, etc.) for proper data management–this competency was met in MPH 620, 621 and 622 through the exploration and cleaning of data sets concerning flu vaccine uptake, cardiovascular disease conditions and diabetes management and education.

25. Justify the need for proper evaluation of programs and policies for the allocation of the necessary resources (time, financial, personnel, planning, etc.) –this competency was met in BUS

518 and MPH 620 through the exploration of the impact of improper budgeting and the resulting effects on programming as it relates to ineffective programming and potential program suspension.

26. Discuss the application of empowerment theories to facilitate the consensus building process–this competency was met in MPH 518 and 620 in through a focus on workforce development and shared goals to allow for optimal productivity.

27. Evaluate community assets and resources that can be used to enable community organizing and improve the health in a community–this competency was met in a variety of MPH courses. Most notably MPH 615 provided the opportunity to explore park use agreements in NC. Review of the examined parks showed that several open access parks were inaccessible to residents for recreation and physical activity.

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