EARLY IDENTIFICATION AND TREATMENT OF MULTIPLE MYELOMA IN PRIMARY CARE

by

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ABSTRACT

PHILWYNA SARIAN BANKS LEDBETTER. Early identification and treatment of multiple myeloma in primary care (Under the direction of DR. MAREN COFFMAN)

BACKGROUND: Multiple myeloma is the second most prevalent hematological malignancy worldwide and the most common hematologic malignancy affecting the African American population. Multiple factors contribute to these marked disparities in the African American population, including lack of awareness in primary care providers. Identifying myeloma in primary care remains challenging, increasing delay in diagnosis for many patients.

OBJECTIVE: The objective of this scholarly project was to evaluate change in knowledge and self-efficacy following the delivery of an educational intervention to primary care providers.

METHODS: The project design was a single group education session with a pre- and post-test. A survey was administered to primary care providers before and after an educational intervention delivered in a single 1-hour face-to-face session. Content taught to providers included definition, incidence, prevalence, risk factors, diagnostic criteria, specific tests performed, and referral information of multiple myeloma. The intervention was followed by a chart audit of patients who presented to primary care clinics with myeloma symptoms.

RESULTS: After the intervention, primary care providers demonstrated increased knowledge and improved self-efficacy. The difference in knowledge between the pre-test and post-test was statistically significant ($p<0.000$). Knowledge scores increased 20 points on average. P-score was 0.008, highlighting a clinically significant finding. Self-

efficacy regarding identification and interventions related to suspecting and/or diagnosing multiple myeloma improved, with all 5 items showing statistically significant improvement.

CONCLUSION: Following the educational intervention, the primary care providers experienced an improvement in knowledge and self-efficacy. Educational interventions are recommended to improve knowledge and self-efficacy in identifying multiple myeloma in the primary care setting. Due to limited research on this topic, may help improve outcomes for this patient population.

DEDICATION

To my husband and unborn child. Because of you, I am able.

ACKNOWLEDGEMENTS

I would like to acknowledge Dr. Maren Coffman for your unwavering support and expert collaboration throughout this project. Thank you for continually pushing and guiding me towards the finish line. I would like to recognize Dr. Cesar Rodriguez for continually pushing me towards my goals, no matter how large. I would also like to recognize Dr. David Langford, Dr. Jonathan Marks, and the University of North Carolina at Charlotte faculty and staff for their assistance throughout the completion of this program. Acknowledgements to my work family at Wake Forest Baptist Health Comprehensive Cancer Center for being the many voices of knowledge and reason. To my village of friends and family, thank you for always believing in me.

To my parents, thank you for always supporting me. Thank you for working so hard and sacrificing so much in order to see me succeed. I will never be able to repay you. I love you both dearly.

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CHAPTER 1: INTRODUCTION

1.1 Introduction

In the United States, cancer is the second leading cause of death, accounting for nearly 590,000 in 2015 alone (American Cancer Society [ACS], 2017). Diagnoses of over 1.6 million new cases are expected in 2017 (ACS, 2017). Among most types of cancer, African Americans have the highest incidence and shortest survival rates and in comparison with all other racial and ethnic groups, bear a disproportionate share of the nation's cancer burden (ACS, 2017). Despite the reduction in cancer mortality rates for both Caucasians and African Americans, racial disparities persist. These ethnic and racial disparities are considerably apparent in multiple myeloma.

1.2 Background

Population-based studies have shown variation in disease incidence and clinical presentation among myeloma patients from different ethnic, racial, and geographical locations (Cohen et al., 1998; Kyle et al., 2006; Landgren et al., 2014). The same variation has been identified in monoclonal gammopathy of undetermined significance (MGUS), a known precursor condition of multiple myeloma. Among racial/ethnic minority groups, African Americans continue to have the highest incidence of multiple myeloma. Moreover, despite evidence that African Americans are less likely to have aggressive forms of myeloma, they have higher rates of mortality related to the disease. Research suggest that multiple factors contribute to these marked disparities, including lack of awareness in primary care providers and in patients (Kumar, Little, & Davis, 2017).

Knowledge about myeloma is typically inadequate, and, as a result, discourse about the condition within African American communities is limited. Many patients within this ethnic community have indicated that trust is determined by the interpersonal and technical competence of the provider—highlighting the importance of skill within community providers (Jacobs et al, 2006). However, there continues to be a heightened sense of mistrust for healthcare systems. This mistrust can lead to further delay in diagnosis and increase in complications on presentation.

Among other factors, the reduction of health disparities remains rooted in the quality, quantity, and skills of health care providers. The IOM report, *Ensuring Quality Cancer Care*, stresses the importance of patients receiving quality services along the full span of the cancer care continuum (Hewitt & Simone, 1999). More than half of the patients who present with early symptoms of multiple myeloma are seen by primary care providers (Landgren, 2017). Unfortunately, identifying myeloma in primary care remains challenging because the disease's symptomology is non-specific (Shephard et al., 2015). A study conducted by the Leukemia and Lymphoma Society (n.d.) stated that a large number of participants with myeloma reported that their diagnosis was delayed because of "missed signs or lack of knowledge about their rare condition" (p. 13).

As a result of these deficits in understanding, primary care providers typically do not recognize the importance of performing additional tests and the necessity of taking precautions necessary for diagnosis and treatment of the disease (Kumar, Little, & Davis, 2017). In addition, providers' lack of training and skills quantitatively and qualitatively inhibits delivery of cancer care screening and diagnostic evaluations (Zapka & Lemon, 2004).

1.3 Problem Statement

Among primary care providers, knowledge and awareness of multiple myeloma are inadequate, and these deficits results in delay, and ultimate failure in identifying symptoms and making a diagnosis. Initiating a complete investigation of myeloma requires the recognition of symptoms and knowledge about populations at elevated risk, including the barriers to care that those populations face—all crucial pieces of the cancer care continuum. To ensure early treatment, primary providers' knowledge of multiple myeloma and awareness of the effects of the disease on African Americans and their communities are critical in early identification and diagnosis. Such early identification could lead to prevention of secondary complications and reduction of mortality rates.

1.4 Purpose of the Project

Detecting multiple myeloma in primary care requires education on recognition of symptom patterns, screening tools, and patients at increased risk. Therefore, the purpose of this project was to target primary care providers and utilize a disease-specific, culturally appropriate educational training program to discuss incidence, prevalence, assessment, and use of screening tools for the early identification of multiple myeloma,

1.5 Clinical Question

The guiding PICO question was: How does disease-specific education about multiple myeloma affect recognition of symptoms and use of screening tools by primary care providers?

1.6 Project Objectives

All of the priorities for cancer services are affected by actions in primary care; such priorities include reducing the risk of cancer, early detection, and timely access to

specialist treatment. The objectives of this Doctor of Nursing Practice (DNP) scholarly project were threefold: (1) examine trends in symptom recognition and delay in diagnosis at Wake Forest Baptist Medical Center (WFBMC) using a retrospective chart audit; (2) design and implement a primary care focused educational program on multiple myeloma; and (3) examine the effectiveness of an educational intervention program in increasing the knowledge of primary care providers in the recognition and management of patients with multiple myeloma. With this provider-focused intervention, the desired outcomes included an increased knowledge of symptoms, diagnostic evaluations, and the identification of at risk populations. The project provided education on recognition and diagnosis of myeloma in all adults, however, emphasized African Americans due to the delay in diagnosis in this population.

CHAPTER 2: LITERATURE REVIEW

2.1 Search Terms

A literature review was conducted to better understand (a) health disparities in the diagnosis and treatment of adults at risk for or diagnosed with multiple myeloma, (b) the impact of primary care on cancer diagnosis, and (c) provider education training programs related to cancer diagnosis and care. A literature search of the PUBMED, CINAHL, Cochrane, National Cancer Institute, Leukemia & Lymphoma Society, and Google Scholar databases from the University of North Carolina at Charlotte used the search terms *multiple myeloma and African Americans, treatment of multiple myeloma, disparity in multiple myeloma, cancer disparity and African Americans, cancer education and African Americans, primary care and myeloma, primary care and cancer education, continuing education for primary care providers,* and *disparity in treatment of multiple myeloma*. Advanced search criteria were used to narrow the results to English-language articles published from 1990 to 2017. Typically, articles within a literature review are constrained within the past five years; however, the salient literature review used within this project was expanded. This decision was conducted to support the vast amount of research that was done on disparities in multiple myeloma between the years 2000 and 2016. Exclusion criteria included articles prior to 1990.

Articles were assessed using the Grading of Recommendations Assessment, Development and Evaluation criteria (Brozek et al., 2009). Additional filters applied included publication in the English language and limitation to studies of the adult population. The terms *following diagnosis of multiple myeloma* and *following cancer* were used interchangeably as were the terms *multiple myeloma* and *myeloma,* and

primary care provider and *general care provider*. Several professional organization websites were also examined.

2.2 Failure to Detect

Symptom recognition. Primary care is the main setting where cancer is diagnosed or at least suspected. However, in primary care, diagnosing cancer can be difficult because patients can present with symptoms that can be caused by cancer or, alternatively, by other conditions (Rubin et al., 2015). Symptoms of multiple myeloma are usually non-specific; common manifestations include back pain, fractures, weight loss, and recurrent bacterial infections (Baz & Bolwell, 2009). The multiplicity of potential causes of such symptoms reduce the likelihood that primary care providers will suspect cancer as an etiology. This diagnostic difficulty, in combination with its rarity in primary care, results in low predictive value for individual symptoms (Koshiaris et al, 2018). For this reason, patients tend to have longer primary care intervals and a higher percentage of multiple pre-referral consultations (Swann et al, 2018). In addition, patients with predominant back pain or renal failure tend to initially be referred to orthopedics or nephrology—well before these present to a hematologist for evaluation (Kariyawasan et al., 2007). Because less than one percent of patients report with back pain have a tumor or metastasis, primary care providers tend to not evaluate cancer as a causal factor.

Non-specific symptoms are characterized by uncertainty, and skills are needed to differentiate patients who might be at risk for cancer from patients who present with self-limiting problems (Green, Atkin, & Macleod, 2015). Providers have stressed that patients with vague symptoms, which over time turned out to be caused by cancer, were

more likely to receive a later diagnosis because their symptoms did not meet urgent referral criteria (Green et al., 2015). Providers also applied a "watch and wait" safety-net approach to some patients because the providers were aware that in primary care, diagnosis often emerges over time (Green et al, 2015).

Cancer screening. Through their provision of preventative services, primary care providers are in a crucial position to decrease cancer mortality and morbidity. These providers play a key role in earlier diagnosis of cancer in symptomatic patients, and subsequent access to treatment after diagnosis (Miser, 2007). Many studies have shown that having a primary care physician is associated with higher rates of early detection of breast, cervical, and colon cancer (Miser, 2007). However, studies have found that primary care physicians are not screening patients—especially African American patients—for cancer at intervals recommend by national organizations (Bach et al., 2004; Wu & Modlin, 2012). Historically, screening rates for most diseases, including varying cancers, are lower among African American patients than among Caucasian patients. Further, in comparison with Caucasian patients, African American patients more often receive diagnoses when diseases are at a relatively advanced stages (Bach et al., 2004; Wu & Modlin, 2012).

2.3 Failure to Diagnosis

Promptness of primary care providers. Early diagnosis of cancer leads to improved outcomes for patients, including prolonged survival and reduction of the frequency and severity of complications. Previous research has highlighted that delays during the period between the first presentation of symptoms and diagnosis have been attributed to the patient, the primary care provider, and the health care system, with a

large proportion of delays attributed to primary care (Rubin, Vedsted, & Emery, 2011). In a correlational study (Lyratzopoulos et al, 2013), the number of consultations with primary care before referral to specialist or hospital was increasingly being used as a measure of the promptness of cancer diagnosis.

Patients with cancers requiring greater number of consultations tend to have longer primary care intervals (Lyratopoulos et al, 2013). As a result of vague symptoms and lack of disease knowledge, over half of patients with symptomatic myeloma experience three of more consultations to primary care before they are referred for specialist care (Koshiaris et al, 2018). Patients with myeloma begin experiencing symptoms, on average, one month prior to seeking help. Out of these patients, nearly 25% of patients wait 3 months to seek medical help (Koshiaris et al, 2018). Furthermore, after presenting to primary care with symptoms, the average time to diagnosis was 108.6 days, with 25% of patients waiting longer than 6 months for diagnosis (Kariyawasan et al, 2007; Koshiaris et al, 2018).

Delays in diagnosis of multiple myeloma allow complications to occur, including pathological fractures, irreversible failure and spinal cord compression—all of which are considered medical emergencies and limit the opportunity for initiating effective treatment (Koshiaris et al, 2018). Patients who had a delay of greater than 6 months were more likely to have an increased number of complications, higher staging, and reduced disease-free survival, measured both from onset of symptoms and from time of diagnosis (Kariyawasan et al, 2007). Early diagnosis of cancer leads to improved outcomes for patients, including prolonged survival and reduction in complications.

Race was significantly associated with the timeliness of diagnostic workup that patients with myeloma receive (Friese et al, 2009). Delays were seen with non-Caucasian adults, patients with lower socioeconomic status, female gender and older age patients (Lyratopoulos et al, 2013; Friese et al, 2009). This further emphasizes the importance of prompt recognition of symptoms and referral with at risk populations, in the reduction of complications related to cancer diagnosis and treatment.

2.4 Strategies to Reduce Failures

Cancer education in primary care. Improving medical education in cancer is essential to reducing delay in diagnosis. Provider education is the most important aspect of integration of cancer care in primary care and other varying sectors (Rubin et al, 2015). Practicing providers report that lack of both training and confidence as barriers to delivering cancer screening interventions (Zapka & Lemon, 2004). Lyratopoulos et al (2013) found that raising awareness of the importance of persistent symptoms among patients may also help reduce time between consultation intervals and therefore improve timeliness of diagnosis. Primary care providers need targeted, evidence-based educational interventions to appropriately address the lack of knowledge related to prompt diagnosis.

Continuing educational efforts are needed to support the diagnostic process after presentation to a primary care provider, including the use of decision support and risk assessment tools, and widening of access to specialist (Lyratzopoulos, 2014). A systematic review (Goulart et al, 2011) showed promising outcomes of educational interventions related to skin cancer for primary care providers. Face-to-face counseling and education of providers has also been found to be effective (Green, Atkin, & Macleod,

2015). The results of studies targeting providers and clinic management systems suggest that provider-directed educational interventions were effective in increasing colorectal cancer screening rates by 10 to 15% (Naylor, Ward, & Polite, 2012).

2.5 Theoretical Framework

The cancer care continuum includes risk assessment, primary prevention (screening), secondary prevention (detection and diagnosis), treatment, recurrence surveillance, and end of life care. The theoretical framework that supported this project was the quality in the Continuum of Cancer Care model. This model has four conceptual needs: (a) to emphasize the relationship of services and processes of care to outcomes, (b) identify the potential for failures in between and during key types of care, (c) to consider complex environmental factors that impact care, (d) to suggest strategies available to health plans, organized health systems, and medical practices to improve performance (Zapka, Taplin, Solberg, & Manos, 2003). It provides a systematic approach for assessing factors that influence all types of cancer and the transitions between them. This includes secondary prevention, the identification and treatment of individuals with/without signs or symptoms of cancer. The Continuum of Cancer Care model emphasizes that in order to improve short and long term patient and systems outcomes, we must address failures in care (Zapka, Taplin, Solberg, & Manos, 2003). Risk assessment, detection, and diagnosis are primary provider related processes that directly impact patient outcomes. Failures in these domains can potentially lead to delay or missed diagnosis, ultimately contributing to negative patient outcomes.

The Continuum of Cancer Care model provides strategies for clinical decision support. Gaps in clinician information and skill can be addressed by a number of

decision support strategies, which include: provider orientation and education and close collaboration between primary care and specialty clinicians (Zapka, Taplin, Solberg, & Manos, 2003; see Figure 2.1). For the purposes of this project, failures in clinician information and skill were addressed. Using this model, provider education can reinforce expected standards and encourage collaboration between primary care and specialty clinicians for high-quality cancer care (see Figure 2.2).

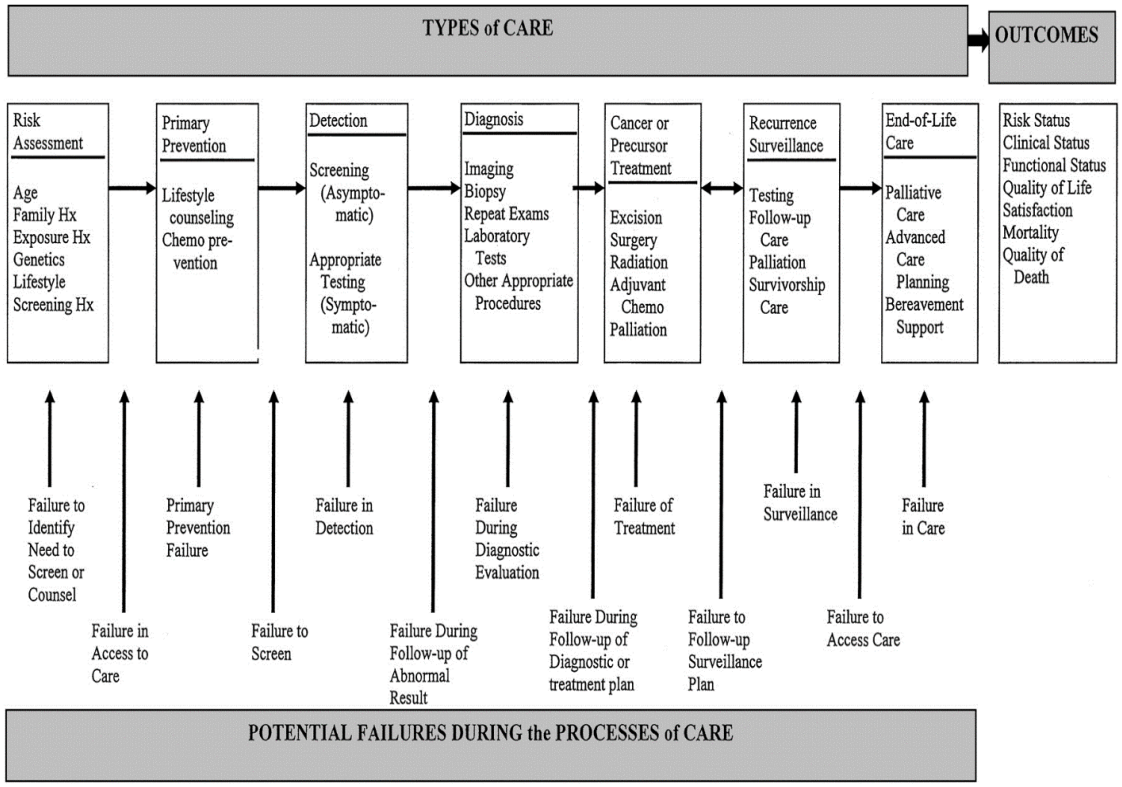

Figure 2.1 Cancer Care Continuum

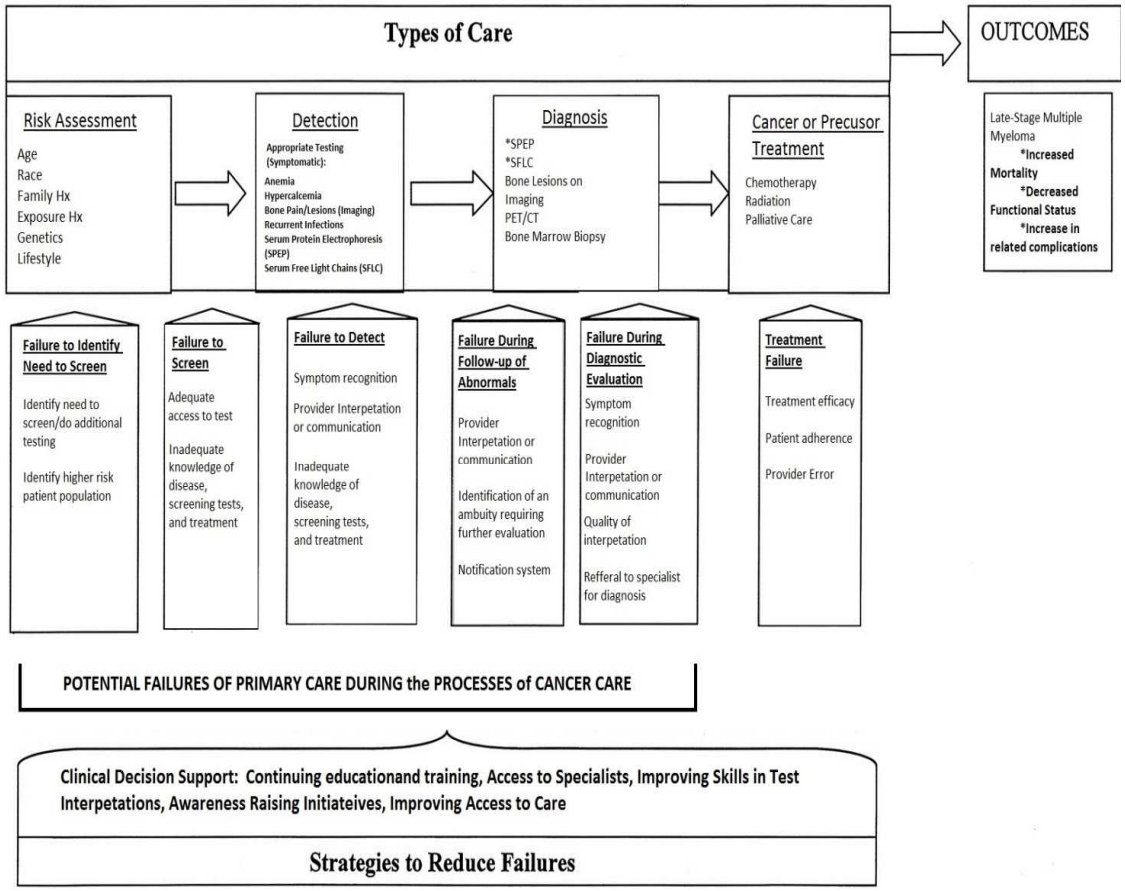

Figure 2.2 Cancer Care Continuum in Myeloma

CHAPTER 3: METHODS

3.1 Project Design

This project delivered an educational intervention and tested primary care providers' understanding of multiple myeloma, recognition of symptoms, and its effects on the African American patients seen in the clinics. A retroactive chart audit was done prior to the educational intervention in order to examine prior trends in symptom recognition and delay in diagnosis at WFBMC. The project intervention consisted of a single group education session with a pre- and posttest. This was followed by a post-intervention chart audit that assessed change in practice behaviors of participants. Descriptive statistics was used to determine the effectiveness of the educational session—including data obtained from post-intervention chart audit.

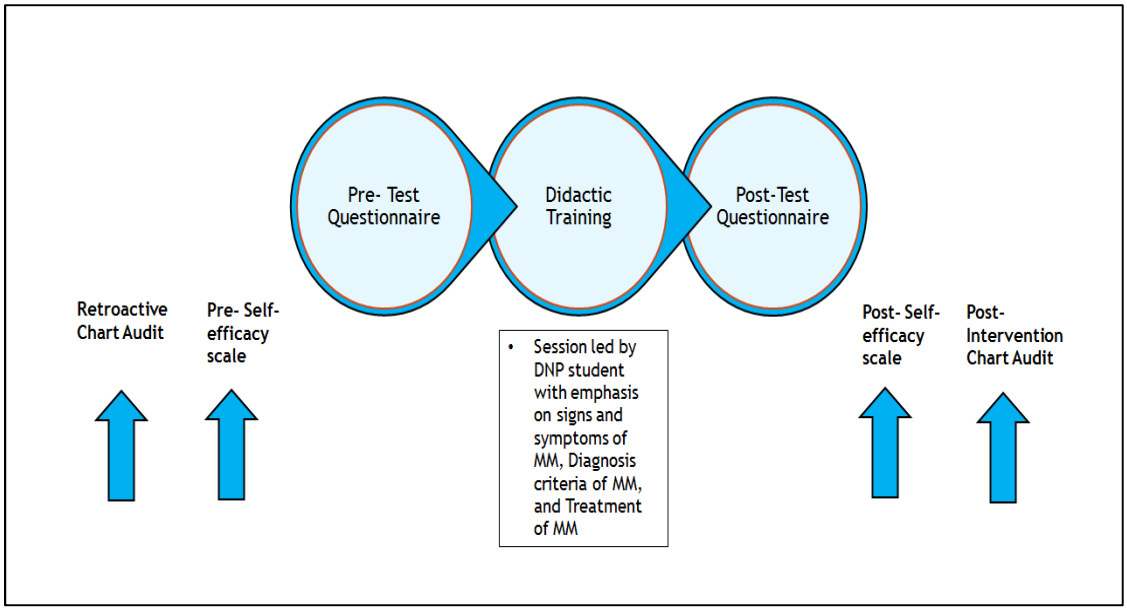

Figure 3.1 Project Design

3.2 Setting

The project took place at WFBMC family practice clinic, a 1,535 bed facility located in Winston-Salem, NC. As a level 3 trauma center, the medical center has over 71 family medicine care clinics, including internal medicine, family medicine, and pediatrics.

3.3 Population

The project's population was a convenience sample of family medicine residents within their first, second, or third year during 2018, and advanced practice providers, including physician assistants and nurse practitioners at WFBMC in Winston Salem, NC. Inclusion criteria was providers who: (a) were current residents, nurse practitioners, physician assistants, or fellows in the family medicine department at WFBMC; (b) were able to, have, or currently working in the family medicine clinic/primary care clinic at WFBMC; and (c) currently held an active license to practice under a national accredited body. Exclusion criteria included: (a) providers who did not practice in family medicine; and (b) family medicine providers that did not practice currently at the family medicine clinic at WFBMC.

The chief resident, who coordinated scheduling education programs and efforts, granted permission for the educational program to be held during one of the hour-long conferences held every Tuesday and Thursday. Attendance at this noon conference is required for the providers, and generally 15 individuals attend.

3.4 Confidentiality and Privacy

A waiver of the requirements for signed informed consent was requested as the research presented no more than minimal risk of harm to subjects and involved no procedures for which written consent is normally required. By completing the pre- and

posttests and attending the educational session, participants agreed to participate in this scholarly project. Every effort was made to keep participant identifying information confidential during and after the recruitment process. Data access was limited to project staff only. Records were stored in a cabinet in a locked office and on a password protected computer. Participant information that was collected as part of this research project was not used or distributed for future research.

3.5 Data and Safety Monitoring

The principal investigator (PI), co-investigator (CoI), and project coordinator were responsible for the overall monitoring of the data and safety of project participants. The PI was assisted by other members of the project staff including the CoI and project coordinator.

3.6 Retrospective Chart Audit

A query of the electronic medical record system, EPIC, was done to identify patients diagnosed with multiple myeloma within the previous five years who presented to WFBMC primary care with specific symptoms including anemia, hypercalcemia, bone pain, neuropathy, renal failure, recurrent infections, or other factors that would have prompted myeloma evaluation or referral for specialized care. Inclusion criteria for the chart audit were: 1) patients diagnosed with multiple myeloma at WFBMC; 2) patients seen in family medicine at WFBMC with diagnosis of anemia, hypercalcemia, bone pain, neuropathy, renal failure or insufficiency, and recurrent infections prior to multiple myeloma diagnosis; and 3) patients with first primary or family care consultation for identified symptoms between January 1, 2013, to October 1, 2018. Exclusion criteria included 1) patients with primary or family care providers within other healthcare

systems; 2) patients diagnosed with multiple myeloma prior to first visit with WFBMC family medicine or primary care provider; and 3) patients diagnosed with multiple myeloma outside of WFBMC. ICD9/ICD10 codes were used for each diagnosis included in during data extraction. Data was extracted into a predefined spreadsheet (Appendix D). Additional characteristics extracted included sex, age, race, clinical diagnosis, prior history of cancer, routine test obtained, calcium and hemoglobin level at time of visit, bone pain, treatment recommendations, and referrals made during visit. Using the spreadsheet, data was transcribed into REDCap for organization and analysis. In total, 15 patient charts satisfied the inclusion criteria with 149 charts excluded.

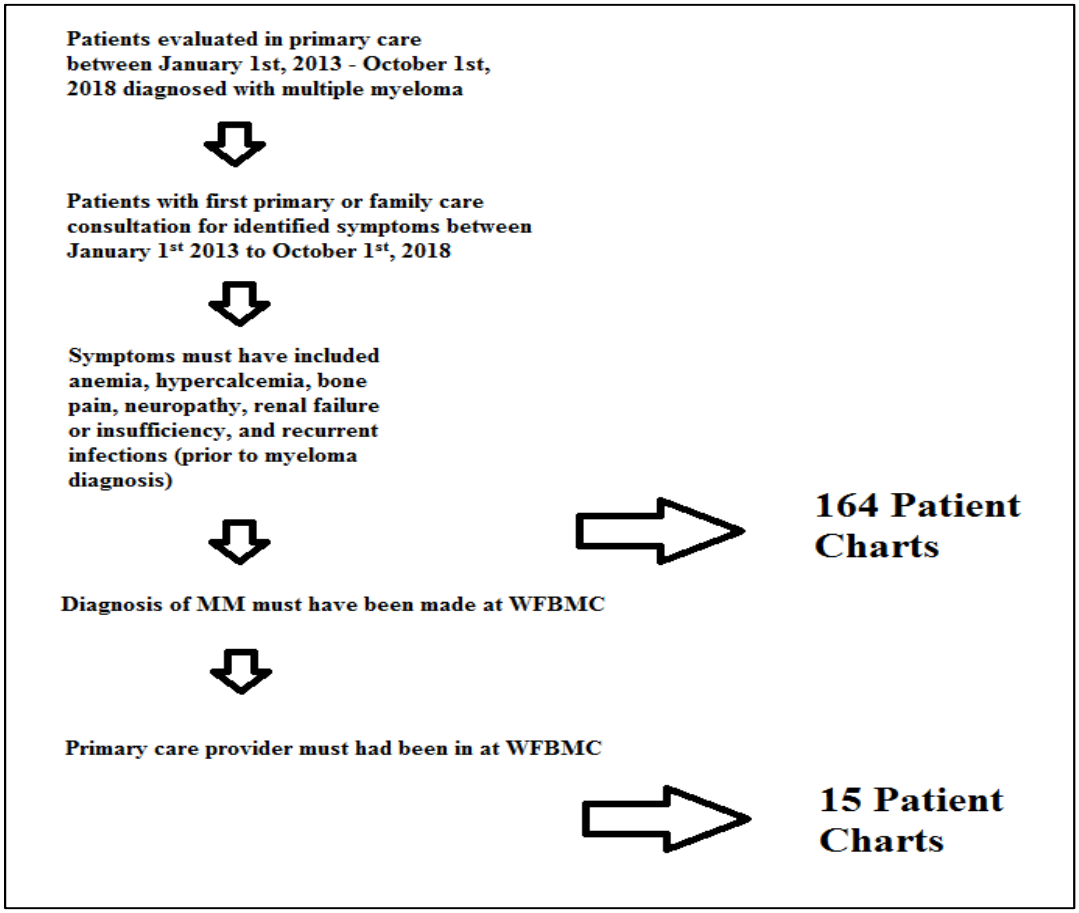

Figure 3.2 Retrospective Chart Audit

3.7 Data Collection Tools and Measures

For the educational intervention, the data collected was both quantitative and qualitative in nature, and was conducted in two phases. There were three parts of the data collection tool in phase one: pretest, posttest, and self-evaluation.

The pretest was a questionnaire developed by the project manager and clinical expert using questions from the Medical Knowledge Self-Assessment Program (MKSAP), an internal medicine board review. Comprised of 10 multiple choice questions, the test covered specific topics included in the educational program. This questionnaire assessed current knowledge of diagnosing multiple myeloma in the primary care setting—focusing questions on definition, incidence, prevalence, risk factors, diagnostic criteria, specific tests performed, and referral information. The test also included demographic information including participants' years of experience in family medicine and education received regarding multiple myeloma in their academic career. An example of the pretest questionnaire appears in Appendix A.

After the participants received the educational intervention, a posttest was given. The posttest was based on information taught during the educational program, and was an exact replica of the pretest questions. Both the pretest design and the posttest design were used to assess the effect of the education intervention on the participants' knowledge level and skill set. An example of the posttest questionnaire appears in Appendix B.

The third part of data collection was directed towards self-efficacy, and clinical practice behaviors regarding the diagnosis of multiple myeloma in the primary care setting. Using a 5-item self-efficacy-scale, participants were asked to rate their level of self-efficacy, knowledge and skills, regarding identification and interventions related to

suspecting and/or diagnosing multiple myeloma in their practice setting, both pre- and post-intervention. An example of the complete scale appears in Appendix C.

The second phase of data collection included chart audits. A query in the electronic medical record system, EPIC, was performed to obtain charts of patients who presented to primary care with specific symptoms of myeloma including anemia, hypercalcemia, bone pain, neuropathy that had the either a serum protein electrophoresis (SPEP), serum free light chain (SFLC), Immunofixation, urine protein electrophoresis (UPEP) or imaging performed between November 20, 2018 to February 28, 2019. A query of patients was performed of the same clinic five years prior to identify patients diagnosed with multiple myeloma, who presented to primary care with specific symptoms of myeloma including anemia, hypercalcemia, bone pain, neuropathy, renal failure, recurrent infections or other factors that would have prompted myeloma evaluation or referral for specialized care. Additional data from the chart that was analyzed included age, sex, and race.

3.8 Educational Intervention

A pretest consisting of 10 questions related current knowledge of diagnosing and treating myeloma was given prior to the intervention. Participants were also asked to rate their level of self-efficacy, knowledge, and skills using a pre-intervention 5-item self-efficacy scale. The single 1-hour educational session was held on November 20, 2018. The educational session was presented via Microsoft PowerPoint presentation and focused on definition, incidence, prevalence, risk factors, diagnostic criteria, specific tests performed for diagnosis, and referral information for multiple myeloma. Participants were given the opportunity to ask questions at the end of the session. Immediately after

the educational session, a posttest was administered to the participants. The participants were then asked to rate their level of self-efficacy, knowledge, and skills using a post-intervention 5-item self-efficacy scale. The forms were collected prior to participants exiting.

3.9 Resources and Support

Project implementation was supported by the Maya Angelou Center for Health Equity, which sponsors programs and educational activities related to cancer disparities in Forsyth and Guilford counties, with the goal of increasing access to underserved communities and promoting enhanced outreach and screening effectiveness.

CHAPTER 4: RESULTS

4.1 Demographics

The project sample consisted of 11 (n = 11) members of the family medicine clinic at Wake Forest Baptist Health. The majority of the sample were male (n = 7, 63%) (Figure 4.1) and ages ranged from 27 to 36 (Figure 4.2). The majority of participants were ages 27 to 32 (n = 9) and 33 to 38 (n = 2). Of the 11 participants, 36% were third year residents, 36% were second year residents, 9% were first year residents, 9% were fourth year fellows, and 9% were faculty members. Further, 45% of participants had 1 to 2 years of experience in family medicine, 45% had 3 to 4 years of experience, and 9% had greater than 5 years of experience. The majority of participants saw between 12 to 24 patients (54%) each clinic day, with 45% of participants seeing 7 to 12 patients per clinic day (Figure 4.3).

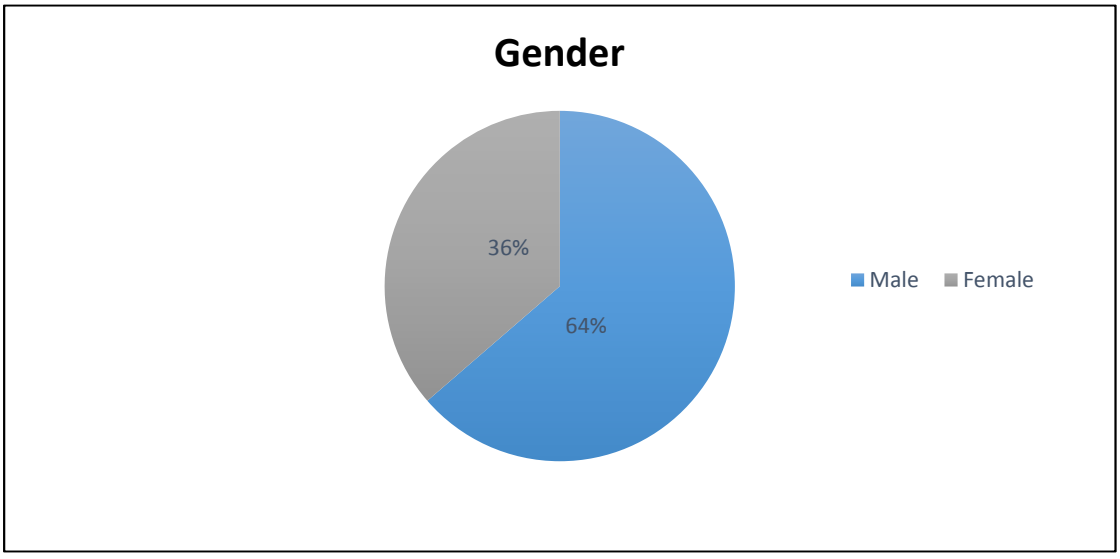

Figure 4.1 Gender Stratification

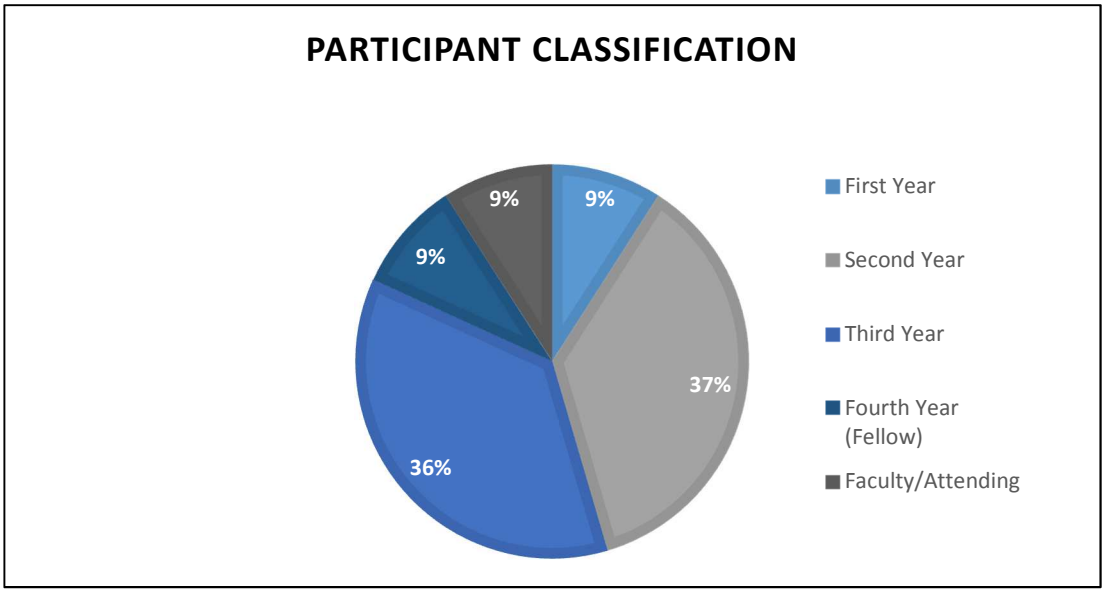

Figure 4.2 Participant Classification

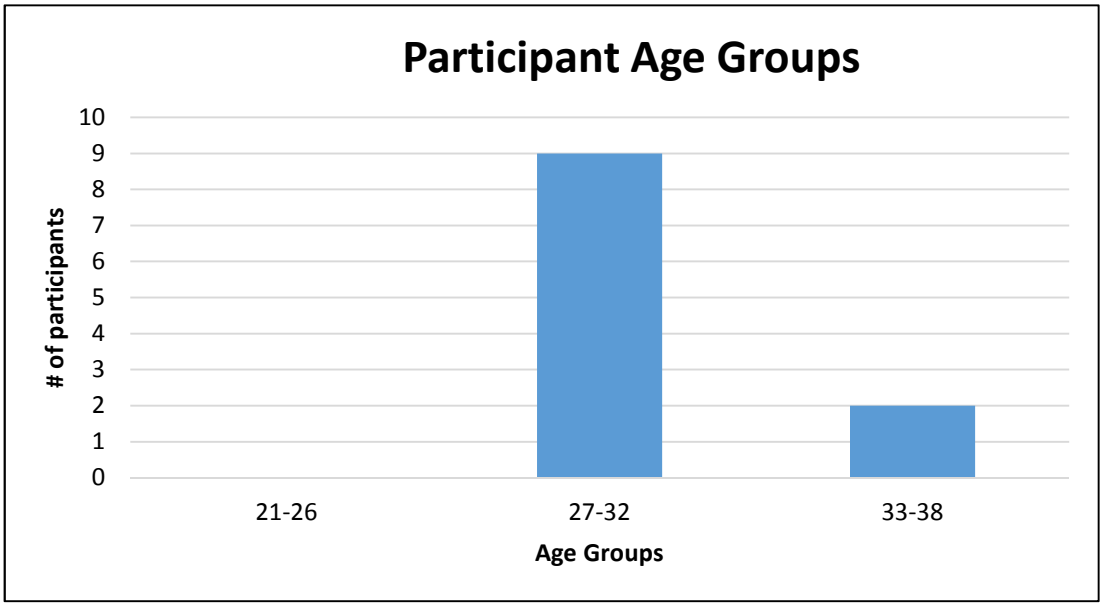

Figure 4.3 Participant Age Groups

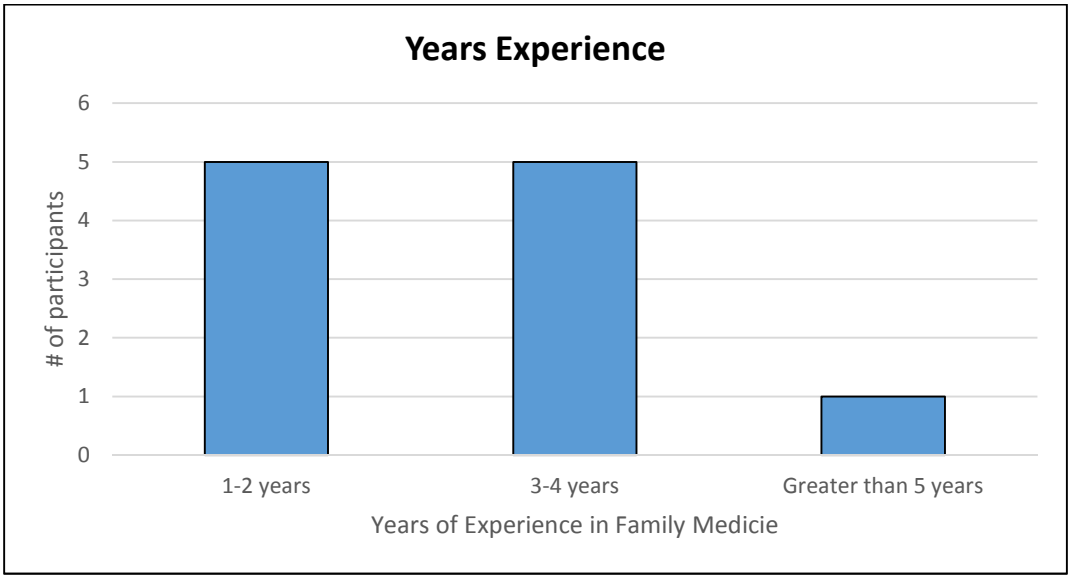

Figure 4.4 Years of Experience

4.2 Retrospective chart audit data

The number of days (calculated in months) to diagnosis was determined using the primary care interval, defined as the first consultation for myeloma-related symptoms to diagnosis. The mean number of months to diagnosis was calculated based on total average of months for each patient from first consultation to primary care to diagnosis. After presenting to primary care with symptoms, the average time to diagnosis was approximately 4.3 months at WFBMC (Figure 4.5). This is in comparison to the national average of 108.6 days, or 3.57 months (Kohiaris et al, 2018). The most common presenting symptom to primary care was bone and back pain, secondary to renal failure or insufficiency (Table 4.6). Of the racial demographics, 33% of patients were African American, 53% were Caucasian, and 13% were Hispanic. This is consistent with the population of Winston-Salem, NC, which is uniquely 56.2% Caucasian, 34.7% African American, and 14.9% Hispanic or Latino. Additionally, males accounted for 53% of the patients, and 47% were female.

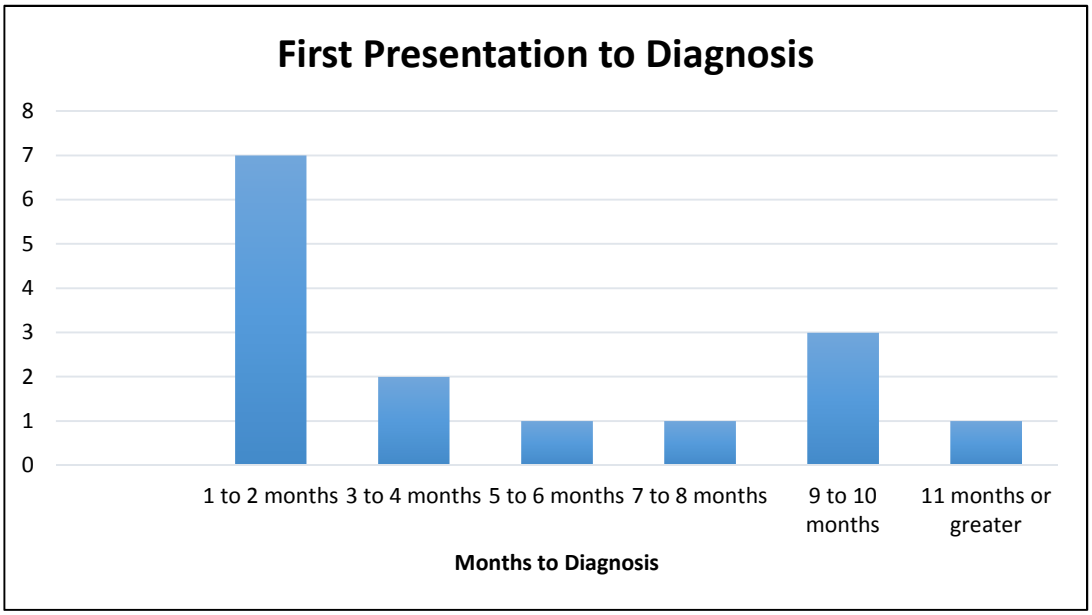

Figure 4.5 First Presentation to Diagnosis

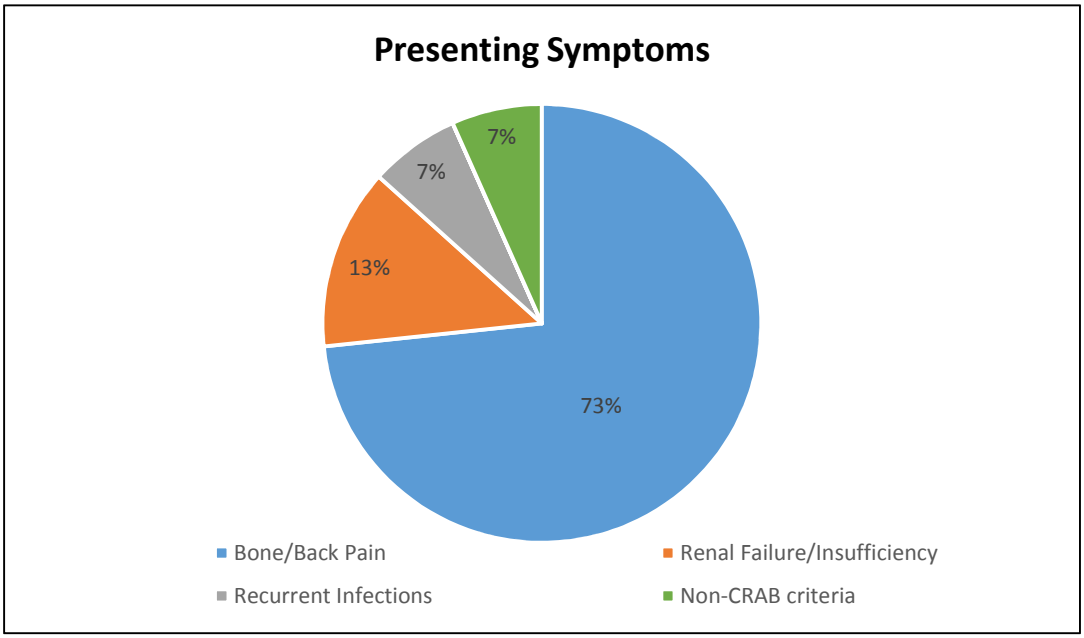

Figure 4.6 Most Common Presenting Symptoms

Table 1: Chart Audit Demographics

Demographics	Number of Patients
Race	
African American or Black	5 (33%)
Caucasian or White	8 (53%)
Hispanic	2 (13%)
Other	0 (0%)
Age	
Less than 40	0 (0%)
40-50	1 (7%)
50-60	4 (27%)
60-70	3 (20%)
70-80	5 (33%)
80-90	2 (13%)
Sex	
Male	8 (53%)
Female	7 (47%)

4.3 Knowledge

The content specific pre- and posttest was administered immediately before and following the educational session. The pretest and the posttest were both comprised of 10 identical questions to evaluate the efficacy of the education that was provided. When compared to the pretest, the posttest showed an increase in knowledge following the provided educational intervention. The mean number of correct answers from the pretest was 6.3. The mean number of correct answer from the posttest (post intervention) was 7.8, with a median change of 20. To evaluate a statistically significant increase in knowledge regarding the assessment of multiple myeloma in primary care, a Wilcoxon signed rank test analysis was used to compare the pretest, which evaluated baseline

knowledge, with the posttest which evaluated the efficacy of the educational intervention. Table 4 shows that the changes were statistically significant ($p < 0.05$) for all 5 items.

Table 2: Descriptive Statistics with Wilcoxon signed rank test

Basic Statistical Measures			
Location		**Variability**	
Mean	-14.54	**Std Deviation**	12.13

Wilcoxon Sign Rank		
Test	**p Value**	
Signed Rank	**Pr > = |S|**	0.008

4.4 Self-efficacy

Self-efficacy scores were obtained using a 5-item scale. Participants were administered a 5-item questionnaire that measured their self-efficacy level for identifying and providing intervention related to multiple myeloma in the family care setting, using a scale ranging from 1= Strongly Agree to 5 = Strongly Disagree. These items were identical on the pre- and post-questionnaire.

Analysis revealed an increase in overall percentage of Strongly Agree and Agree on all 5 items from 16% on the pretest to 47% on the posttest, indicating an increase in responses showing agreement with self-efficacy of 31%. Next, Wilcoxon signed rank test was used to determine if these changes were statistically significant. Figure 4.9 shows that the changes were statistically significant ($p < 0.05$) for all 5 items.

Table 3: Self-Efficacy Pre- and Posttest Means by Item

	Self-Efficacy Pre- and Posttest Means					
		Pretest			Posttest	
Self-Efficacy Item	% Strongly Agree and Agree	% Uncertain	% Disagree and Strongly Disagree	% Strongly Agree and Agree	% Uncertain	% Disagree and Strongly Disagree
1	0%	27%	73%	27%	64%	9%
2	18%	27%	55%	55%	36%	9%
3	18%	36%	45%	45%	55%	0%
4	18%	36%	45%	55%	36%	9%
5	27%	27%	45%	55%	45%	0%
Total	16%	31%	53%	47%	47%	5%

Table 4: Self-Efficacy Pre- and Posttest Results – Wilcoxon sign rank test

Wilcoxon Sign Rank Test for Adequate Knowledge		
Test	**p Value**	
Signed Rank	**Pr >= |S|**	0.002
Wilcoxon Sign Rank Test for Ability to Identify At Risk Patients		
Test	**p Value**	
Signed Rank	**Pr >= |S|**	0.008
Wilcoxon Sign Rank Test for Ability to Identify Suspect Cases		
Test	**p Value**	
Signed Rank	**Pr >= |S|**	0.016
Wilcoxon Sign Rank Test for Assessment Skills		
Test	**p Value**	
Signed Rank	**Pr >= |S|**	0.008
Wilcoxon Sign Rank Test for Ordering and Interpreting Tests		
Test	**p Value**	
Signed Rank	**Pr >= |S|**	0.008

CHAPTER FIVE: DISCUSSION

5.1 Summary

Accelerating progress in eliminating racial disparities requires access to services for prevention, early detection, and high quality treatment (DeSantis et al., 2016). A significant problem that contributes to disparities in multiple myeloma is the vast deficits in primary care provider's knowledge, which ultimately led to delays in diagnosis in this patient population. The intent of this project was to evaluate the impact of providing a disease-specific, culturally appropriate educational training program on incidence, prevalence, assessment, and use of screening tools for the early identification of African Americans with multiple myeloma on knowledge and self-efficacy. Overall, the completed program supported evidence that using a provider-directed educational intervention increased knowledge and self-efficacy. Mean scores on post-educational intervention showed improvement from pretest to posttest, indicating improvement in knowledge of multiple myeloma management with score increasing by 20 points on average. P-score was 0.008, highlighting a clinically significant finding. Participants increased their knowledge of assessment, use of screening tools, and identifying at risk populations.

Self-efficacy results showed that providing disease specific education has the potential to improve family medicine providers' self-efficacy for identifying suspected multiple myeloma. In addition to clinical significance, self-efficacy findings showed a statistically significant increase for each of the 5-items despite the small sample size. Providing disease specific education on multiple myeloma in the primary care setting is a

potential strategy to help primary care providers feel more confident in early identification of multiple myeloma in their patient population.

5.2 Limitations

Limitations to this scholarly project included the sample size and time to complete the intervention phase. It was anticipated that the project would engage more participants, however, there were only 11 family medicine providers that attended the intervention and completed the pretest, posttest, and self-efficacy survey for comparison. This is likely due to the time required to complete the pre- and posttest. The educational content was delivered to 17 participants, but 6 did not complete the posttests required for analysis. Despite the small sample size, the analysis resulted in statistically significant findings.

The use of residents, fellows, and providers with less experience within family medicine also posed as an additional limitation on the project. Using residents and fellows may not lead to the long term cultural impact in which was indicated for the project. This is due to the fact that many residents and fellows do not continue their practice at the site of residency after graduation. In order to facilitate long term impact on direct patient care, there needs to be a more focused approach to providers that are established within the communities—including those with more years of experience in family and community medicine.

Lastly, the time available to conduct the intervention did not allow enough time to complete a robust post-intervention chart audit. Information obtained from the 15 charts reviewed as part of the chart audit provided a baseline of data on delay in diagnosis at WFBMC in comparison with the national average. However, the post-intervention

period of 3 months was found to be inadequate to assess change in practice behaviors, due to the few cases of multiple myeloma diagnosed in the primary care setting. Because it was anticipated that only 1 or 2 patients would be diagnosed in the 3 months following the intervention, it was determined that this would be an inadequate sample size for comparison purposes, the post-intervention chart audit was not completed.

5.3 Implications for Future Research and Recommendations

Primary care providers have an increasingly important role to play in the delivery of cancer prevention and detection services to patients; therefore, playing an important role in the cancer care continuum (Gorinn et al, 2000). The results of this scholarly project has shown that education is lacking and needed for primary care providers on both suspecting and diagnosing multiple myeloma in the primary care setting. However, with disease specific educational interventions, knowledge, and self-efficacy levels of primary care providers can improve. Continuous education such as seminars and educational sessions are essential to increase understanding of the early symptoms of multiple myeloma among primary care providers and the diagnostic tests available for use in that setting. Providing educational opportunities during medical school, advance practice programs, and residency training along with subsequent continuing medical education can provide knowledge, attitudes, and skills that predispose providers to promote additional screening for patients (Zapka & Lemon, 2004).

Future studies could also widen the sample population to other disciplines that commonly encounter multiple myeloma patients, such as Orthopedics and Nephrology. Additionally, future research should establish long term follow up with educated providers to evaluate the impact on direct practice. This also includes providing routine

education that may effectively reduce delay in diagnosis, especially in the African American population. The potential for patient outcomes to improve significantly, with meaningful reductions, is apparent. However, more research is required in order to do so.

Additionally, results from the project highlight the need to further development of cancer disparities programs. Such programs foster intensive collaborations between minority-serving institutions in order to further develop approaches to understand and reduce the significant disparities in cancer outcome observed in minority and socio-economically disadvantaged populations. Further integration of community development programs and health education interventions can be established to target communities in order to improve patient outcomes within specific racial and ethnic groups.

5.4 Conclusion

Early recognition and referral of multiple myeloma patients before they develop significant disease burden is especially important as it has been demonstrated to translate into improved patient outcomes. Primary care providers experienced an increase in knowledge and self-efficacy in knowledge of multiple myeloma in the primary care setting following an educational intervention. The implementation of disease-specific education in the primary care setting may help to reduce delay in diagnosis for multiple myeloma patients.

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Appendix A

Pre-Test Questionnaire

Demographic Information:

1. **Name: _____**
2. **Age: _____**
3. **Year of residency or fellowship (if applicable): _____**
4. **How many years of experience do you have in family medicine? _____**
5. **On average, how many patients do you evaluate on clinic days? _____**

Please answer the follow questions.

1. A 76 year old African American woman is evaluated because of malaise and anorexia for 1 week. She has hypertension treated with hydrochlorothiazide (HCTZ).

   On physical examination, the supine blood pressure is 150/95 mm Hg, pulse rate is 82 per min, respiration rate is 20 per min, and temperature is 37.4 degrees celcius. The blood pressure is 125/80 mm Hg and the pulse rate 96 per min while standing. The remainder of the examination is unremarkable.

Hematocrit	29%
Blood Urea Nitrogen	62 mg/dL
Serum creatinine	4.6 mg/dL
Serum sodium	134 meq/L
Serum potassium	5.0 meq/L
Serum chloride	114 meq/L
Serum bicarbonate	15 meq/L
Serum calcium	12.5 mg/dL
Serum phosphate	8.5mg/Dl
Urinalysis	Specific gravity 1.007; trace proteinuria; no glucosuria or ketonuria

   Which of the following is the most likely diagnosis?
   a. Hypercalcemia secondary to HCTZ
   b. Milk-alkali syndrome
   c. Multiple Myeloma
   d. Primary hyperparathyroidism

2. A 62 year old Caucasian male is evaluated for a 4 day history of progressive worsening fatigue, forgetfulness, constipation, excessive thirst, and increased

urination. He has no pain. His only significant medical history is a diagnosis of right lower lobe pneumonia due to *Streptococcus pneumonias* 3 months ago.

On physical examination, he appears somnolent but is arousable. Temperature is 37.1 degrees Celsius, BP is 110/70 mmHg, pulse rate is 120/min, respiration rate is 17/min. The oral mucosa is dry, and the conjunctivae are pale. The lungs are clear.

Hemoglobin	8.9 g/dL
Leukocyte count	2500/uL
Platelets	150,000/uL
Calcium	13.6 mg/D
Creatinine	2.9 mg/dL
Protein	
Total	7.6 g/dL
Albumin	3.3g/dL
Urinalysis	Negative for protein

A peripheral blood smear shows normochromic, normocytic erythrocytes with rouleaux formation and no evidence of teardrop erythrocytes or immature myeloid and erythroid cells.

A chest radiograph shows osteopenia of all ribs. No pulmonary parenchymal infiltrates are seen.

Which of the following is the most likely diagnosis?

a. Acute myeloid leukemia
b. Chronic lymphocytic leukemia
c. Metastatic small cell lung cancer
d. Multiple Myeloma

3. A 52 year old man is evaluated for low back pain of 3 months' duration that is no radiation, progressive, and worse with ambulation. He reports no preceding injury. Medical history is notable for smoldering multiple myeloma, diagnosed 1 year ago. He has been stable since that time. His only medication is as-needed acetaminophen.

   On physical exam, temperature is 36.8 degrees Celsius, BP 132/82 mm Hg, pulse rate is 70/min. and respiration is 14/min. No focal neurologic findings are noted. He has pain to palpation of the lower lumbar spine. The remainder of the examination is unremarkable.

   Laboratory studies show a hemoglobin level of 13g/dL, serum creatinine level of 1.0 mg/dL, and serum calcium level of 9.8 mg/dL. Plain radiographs of the

lumbosacral spine demonstrate degenerative disk changes in the lumbar spine but no lytic lesions or fractures.

Which of the following is the most appropriate management?

a. Chemotherapy
b. MRI of the lumbar spine
c. Symptomatic treatment and routine follow up
d. Zoledronic acid

4. A 48 year old African American man is evaluated for severe mid-upper back pain following a minor fall 1 day ago. He also notes progressive fatigue of 6 months' duration and a 6.8-kg (15lb) weight loss. Medical history is notable for an 80-pack year smoking history, although he is currently a nonsmoker.

   On physical examination, temperature is 37.3 degrees Celsius, blood pressure is 112/74 mm Hg, pulse rate is 98/min, and respiration rate is 18/min. BMI is 22. The cardiopulmonary examination is unremarkable. He has no lymphadenopathy or hepatosplenomegaly. Point tenderness to palpitation is noted over the mid-thoracic spine. No skin changes or peripheral edema are observed.

Hemoglobin	11 g/dL
Leukocyte count	4800/uL
Platelets	155,000/uL
Calcium	11.8 mg/dL
Creatinine	2.9 mg/dL
Protein	
Total	6.3 g/dL
Albumin	2.8 g/dL
Urine protein-creatinine ratio	2300mg/g
Urinalysis	Trace protein, no blood, 0 erythrocytes, and no casts

   A chest radiograph shows no infiltrates and a normal cardiac silhouette. Radiograph of the thoracic spine reveal osteopenia with a compression fracture of T6.

   Which of the following is the most appropriate diagnostic test to perform next?

   a. 1.25-Dihydroxyvitamin D measurement
   b. Intact PTH measurement
   c. PT protein measurement
   d. Serum protein electrophoresis and free light chain test

5. The proliferation of plasma cells can result in which of the following diseases?
    a. Chronic lymphocytic leukemia
    b. Multiple myeloma
    c. Chronic myelogenous leukemia
    d. Polycythemia rubra vera

6. A 77 year old woman is evaluated after a high serum total protein level was found during routine laboratory testing. Medical history is noncontributory.

    On physical examination, vital signs are normal and examination findings are unremarkable, with no organomegaly or lymphadenopathy.

Hemoglobin	13.5 g/dL
Leukocyte count	5500/uL
Platelets	230,000/uL
Calcium	9.0 mg/dL
Creatinine	1.0 mg/dL
Protein	
Total	10.1 g/dL
Albumin	4.0 g/dL

    Serum protein electrophoresis shows a monoclonal spike of 1.8 g/dL, which is further identified as an IgG – Kappa serum immunofixation. A bone marrow aspirate reveals 6% plasma cells. A skeletal survey does not show any lytic lesions.

    Which of the following is the most likely diagnosis?
    a. AL (light chain) amyloidosis
    b. Lymphphoplasmacytic lymphoma (Waldenstrom macroglobulinemia)
    c. Monoclonal gammopathy of undetermined significance
    d. Multiple Myeloma

7. A 52 year old woman is evaluated for an elevated serum protein level discovered during a routine examination for a life insurance policy. She is asymptomatic. Medical and family history is are unremarkable, and she takes no medications.

    On physical examination, vital signs are normal, and the reminder of the examination is unremarkable.

Hemoglobin	13.4 g/dL
Leukocyte count	6400/uL
Platelets	224,000/uL
Calcium	9.6 mg/dL
Creatinine	0.7 mg/dL

IgA 2080 mg/dL

Serum protein electrophoresis and immunofixation reveal a monoclonal IgA Kappa band measuring 1.8 g/dL. A 24 hour urine protein electrophoresis reveals 80 mg of total protein and trace monoclonal free kappa light chains that are too small to quantify.

A bone marrow aspirate and biopsy reveals clonal plasma cells representing 8% of the overall marrow cellularity. A skeletal survey demonstrates no lytic lesions, osteopenia, or fractures.

Which of the following is the most appropriate diagnostic test to perform next?

a. MRI of cervical, thoracic, and lumbar spine
b. Serum Beta2 – micoglobulin measurement
c. Serum free light chain testing
d. Serum lactate dehydrogenase measurement

8. The incidence of monoclonal gammopathy of undetermined significance (MGUS) is found to be in approximately 1% to 2% of adults. The incidence is higher in patients older than 70 years old. Which ethnicity is MUS higher in?
    a. Caucasians
    b. Asians
    c. African Americans
    d. Hispanics

9. Which factors are predictive of progression to plasma cell proliferative disorder over 20 years?
    a. Non-IgG monoclonal gammopathy of undetermined significance, abnormal free light chain ratio and M spike of greater than 1.5 g/dL
    b. Non-IgG monoclonal gammopathy of undetermined significance, and M spike of greater than 1.5 g/dL
    c. Non-IgM monoclonal gammopathy of undetermined significance, abnormal free light chain ratio and M spike of greater than 1.0 g/dL
    d. Non-IgA monoclonal gammopathy of undetermined significance, abnormal free light chain ratio and M spike of greater than 2.0 g/dL

10. A bone marrow biopsy is required to make the diagnosis MGUS, smoldering myeloma, and active multiple myeloma.
    a. True
    b. False

Appendix B

Posttest Questionnaire

Name: _____

Please answer the follow questions.

1. A 76 year old African American woman is evaluated because of malaise and anorexia for 1 week. She has hypertension treated with hydrochlorothiazide (HCTZ).

   On physical examination, the supine blood pressure is 150/95 mm Hg, pulse rate is 82 per min, respiration rate is 20 per min, and temperature is 37.4 degrees celcius. The blood pressure is 125/80 mm Hg and the pulse rate 96 per min while standing. The remainder of the examination is unremarkable.

Hematocrit	29%
Blood Urea Nitrogen	62 mg/dL
Serum creatinine	4.6 mg/dL
Serum sodium	134 meq/L
Serum potassium	5.0 meq/L
Serum chloride	114 meq/L
Serum bicarbonate	15 meq/L
Serum calcium	12.5 mg/dL
Serum phosphate	8.5mg/Dl
Urinalysis	Specific gravity 1.007; trace proteinuria; no glucosuria or ketonuria

   Which of the following is the most likely diagnosis?

   e. Hypercalcemia secondary to HCTZ
   f. Milk-alkali syndrome
   g. Multiple Myeloma
   h. Primary hyperparathyroidism

2. A 62 year old Caucasian male is evaluated for a 4 day history of progressive worsening fatigue, forgetfulness, constipation, excessive thirst, and increased urination. He has no pain. His only significant medical history is a diagnosis of right lower lobe pneumonia due to *Streptococcus pneumonias* 3 months ago.

   On physical examination, he appears somnolent but is arousable. Temperature is 37.1 degrees Celsius, BP is 110/70 mmHg, pulse rate is 120/min, respiration rate is 17/min. The oral mucosa is dry, and the conjunctivae are pale. The lungs are clear.

Hemoglobin	8.9 g/dL
Leukocyte count	2500/uL
Platelets	150,000/uL
Calcium	13.6 mg/D
Creatinine	2.9 mg/dL
Protein	
Total	7.6 g/dL
Albumin	3.3g/dL
Urinalysis	Negative for protein

A peripheral blood smear shows normochromic, normocytic erythrocytes with rouleaux formation and no evidence of teardrop erythrocytes or immature myeloid and erythroid cells.

A chest radiograph shows osteopenia of all ribs. No pulmonary parenchymal infiltrates are seen.

Which of the following is the most likely diagnosis?

e. Acute myeloid leukemia
f. Chronic lymphocytic leukemia
g. Metastatic small cell lung cancer
h. Multiple Myeloma

3. A 52 year old man is evaluated for low back pain of 3 months' duration that is no radiation, progressive, and worse with ambulation. He reports no preceding injury. Medical history is notable for smoldering multiple myeloma, diagnosed 1 year ago. He has been stable since that time. His only medication is as-needed acetaminophen.

   On physical exam, temperature is 36.8 degrees Celsius, BP 132/82 mm Hg, pulse rate is 70/min. and respiration is 14/min. No focal neurologic findings are noted. He has pain to palpation of the lower lumbar spine. The remainder of the examination is unremarkable.

   Laboratory studies show a hemoglobin level of 13g/dL, serum creatinine level of 1.0 mg/dL, and serum calcium level of 9.8 mg/dL. Plain radiographs of the lumbosacral spine demonstrate degenerative disk changes in the lumbar spine but no lytic lesions or fractures.

   Which of the following is the most appropriate management?

   e. Chemotherapy
   f. MRI of the lumbar spine
   g. Symptomatic treatment and routine follow up

h. Zoledronic acid

4. A 48 year old African American man is evaluated for severe mid-upper back pain following a minor fall 1 day ago. He also notes progressive fatigue of 6 months' duration and a 6.8-kg (15lb) weight loss. Medical history is notable for an 80-pack year smoking history, although he is currently a nonsmoker.

   On physical examination, temperature is 37.3 degrees Celsius, blood pressure is 112/74 mm Hg, pulse rate is 98/min, and respiration rate is 18/min. BMI is 22. The cardiopulmonary examination is unremarkable. He has no lymphadenopathy or hepatosplenomegaly. Point tenderness to palpitation is noted over the mid-thoracic spine. No skin changes or peripheral edema are observed.

Hemoglobin	11 g/dL
Leukocyte count	4800/uL
Platelets	155,000/uL
Calcium	11.8 mg/dL
Creatinine	2.9 mg/dL
Protein	
Total	6.3 g/dL
Albumin	2.8 g/dL
Urine protein-creatinine ratio	2300mg/g
Urinalysis	Trace protein, no blood, 0 erythrocytes, and no casts

   A chest radiograph shows no infiltrates and a normal cardiac silhouette. Radiograph of the thoracic spine reveal osteopenia with a compression fracture of T6.

   Which of the following is the most appropriate diagnostic test to perform next?

   e. 1.25-Dihydroxyvitamin D measurement
   f. Intact PTH measurement
   g. PT protein measurement
   h. Serum protein electrophoresis and free light chain test

5. The proliferation of plasma cells can result in which of the following diseases?
   a. Chronic lymphocytic leukemia
   b. Multiple myeloma
   c. Chronic myelogenous leukemia
   d. Polycythemia rubra vera

6. A 77 year old woman is evaluated after a high serum total protein level was found during routine laboratory testing. Medical history is noncontributory.

   On physical examination, vital signs are normal and examination findings are unremarkable, with no organomegaly or lymphadenopathy.

Hemoglobin	13.5 g/dL
Leukocyte count	5500/uL
Platelets	230,000/uL
Calcium	9.0 mg/dL
Creatinine	1.0 mg/dL
Protein	
Total	10.1 g/dL
Albumin	4.0 g/dL

   Serum protein electrophoresis shows a monoclonal spike of 1.8 g/dL, which is further identified as an IgG – Kappa serum immunofixation. A bone marrow aspirate reveals 6% plasma cells. A skeletal survey does not show any lytic lesions.

   Which of the following is the most likely diagnosis?

   e. AL (light chain) amyloidosis
   f. Lymphphoplasmacytic lymphoma (Waldenstrom macroglobulinemia)
   g. Monoclonal gammopathy of undetermined significance
   h. Multiple Myeloma

7. A 52 year old woman is evaluated for an elevated serum protein level discovered during a routine examination for a life insurance policy. She is asymptomatic. Medical and family history is are unremarkable, and she takes no medications.

   On physical examination, vital signs are normal, and the reminder of the examination is unremarkable.

Hemoglobin	13.4 g/dL
Leukocyte count	6400/uL
Platelets	224,000/uL
Calcium	9.6 mg/dL
Creatinine	0.7 mg/dL
IgA	2080 mg/dL

   Serum protein electrophoresis and immunofixation reveal a monoclonal IgA Kappa band measuring 1.8 g/dL. A 24 hour urine protein electrophoresis reveals 80 mg of total protein and trace monoclonal free kappa light chains that are too small to quantify.

A bone marrow aspirate and biopsy reveals clonal plasma cells representing 8% of the overall marrow cellularity. A skeletal survey demonstrates no lytic lesions, osteopenia, or fractures.

Which of the following is the most appropriate diagnostic test to perform next?

e. MRI of cervical, thoracic, and lumbar spine
f. Serum Beta2 – micoglobulin measurement
g. Serum free light chain testing
h. Serum lactate dehydrogenase measurement

8. The incidence of monoclonal gammopathy of undetermined significance (MGUS) is found to be in approximately 1% to 2% of adults. The incidence is higher in patients older than 70 years old. Which ethnicity is MUS higher in?
    a. Caucasians
    b. Asians
    c. African Americans
    d. Hispanics

9. Which factors are predictive of progression to plasma cell proliferative disorder over 20 years?
    a. Non-IgG monoclonal gammopathy of undetermined significance, abnormal free light chain ratio and M spike of greater than 1.5 g/dL
    b. Non-IgG monoclonal gammopathy of undetermined significance, and M spike of greater than 1.5 g/dL
    c. Non-IgM monoclonal gammopathy of undetermined significance, abnormal free light chain ratio and M spike of greater than 1.0 g/dL
    d. Non-IgA monoclonal gammopathy of undetermined significance, abnormal free light chain ratio and M spike of greater than 2.0 g/dL

10. A bone marrow biopsy is required to make the diagnosis MGUS, smoldering myeloma, and active multiple myeloma.
    a. True
    b. False

Appendix C

Self-efficacy Scale

Please circle your response to the following statements using the following criteria

1 – Strongly Agree
2 – Agree
3 – Uncertain
4 – Disagree
5 – Strongly Disagree

1. I believe that I have adequate knowledge and skills regarding diagnosis and treatment of multiple myeloma in the primary/family care setting.

   1 2 3 4 5

2. I am confident in my ability to identify patients at risk for multiple myeloma.

   1 2 3 4 5

3. I am confident in my ability to identify suspected cases of multiple myeloma

   1 2 3 4 5

4. I am comfortable with my assessment skills to diagnosis myeloma

   1 2 3 4 5

5. I am comfortable ordering and interpreting tests used to diagnosis multiple myeloma

   1 2 3 4 5

Appendix D

DATA COLLECTION FORM

Subject ID	Sex	Age	Race	Clinical Diagnosis/Reason for Visit to Primary Care Provider	Prior history of Cancer	Tests done during visit	Calcium Level at time of visit	Imaging done during visit	Hemoglobin at time of visit	Did patient have bone pain at time of visit or at prior visits to PCP?	Treatment Recommendations	Referral Made

Appendix E

Wake Forest School of Medicine

Department/Section of Hematology/Oncology

The Early Identification and Treatment of Multiple Myeloma in African Americans in Primary Care

Cesar Rodriguez, MD Principal Investigator
Philwyna Banks, MSN, OCN, MP-C, Co-Investigator

SUMMARY

You are invited to participate in a research study. You are invited to be in this study because you are either a current resident, nurse practitioner, physician assistant or fellow in the Family Medicine Department at WFBMC. Your participation in this research will involve a pre-test, post-test, and a class lasting about 1 day.

All research studies involve some risks. A risk to this study that you should be aware of is confidentiality.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. There are no consequences if you choose not to participate.

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at 336-716-4542.

INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you are a current resident, nurse practitioner, physician assistant or fellow. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to target primary care providers and utilize a disease specific, culturally appropriate educational training program to discuss incidence, prevalence, assessment and the use of screening tools for the early identification of African Americans with multiple myeloma so that they be implemented into practice.

WHAT IS INVOLVED IN THE STUDY?

This study will test primary care providers' understanding of multiple myeloma and its effects on the African American community. The study design will be a single education session with a pre- and post-test. The study will take place at Wake Forest Baptist Health Hospital in the department family medicine. The educational interventions will be held on the seventh floor conference room within the comprehensive cancer center.

Appendix F

MEMORANDUM

To: Cesar Rodriguez Valdes, M.D.
Philwyna Banks, NP
Int Md-Hematology_Oncology

From: Jeannie Sekits, Senior Protocol Analyst, Institutional Review Board

Date Approved: 8/6/2018

Subject: Expedited Review: IRB00051114
The Early Identification and Treatment of Multiple Myeloma in African Americans in Primary Care

Study Documents:
Protocol Version: DNPProposalUpdated_PhilwynaBanks 7 3 18.docx; Informed Consent Version: Consent Waiver Sheet 7 5 18 clean.docx; Other Documents: Appendix A -Pre.docx, Appendix B -Post.docx, Appendix C- Likert.docx

This research study qualifies for expedited review under the Federal Regulations [45CFR46.110]. These regulations allow an IRB to approve certain kinds of research involving no more than minimal risk to human subjects. The risks of harm anticipated in the proposed research are not greater than those ordinarily encountered by the general population in daily life or during the performance of routine physical, laboratory, or psychological exams or tests. [45CFR46.102(i)].

Upon review of the research, the IRB finds that this study is classified as Expedited Category 5.

Upon review of the research, the IRB finds that this study is classified as Expedited Category 7.

This research meets the criteria for a waiver of consent entirely according to 45 CFR 46(d).

This research meets criteria for a waiver of written (signed) consent according to 45 CFR 46.117(c)(2).

This research meets the criteria for a waiver of HIPAA authorization according to 45 CFR 164.512.

IRB approval is for a period of 12 months from 8/6/2018**.** Please notify the Office of Research when the project is complete.