Perceptions and Experiences of Patients living with Type 2 Diabetes on Diabetic Foot Complications: A Research Grant Proposal for a Qualitative Study

Master of Public Health Integrating Experience Project

Research Grant Proposal Framework

By

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List of Abbreviations

AMD	**Armenian Drams**
AUA	**American University of Armenia**
BMI	**Body Mass Index**
DFC	**Diabetic Foot Complications**
DFI	**Diabetic Foot Infections**
DFU	**Diabetic Foot Ulcerations**
DKA	**Diabetic Ketoacidosis**
DM	**Diabetes Mellitus**
DPN	**Diabetic Peripheral Neuropathy**
FPG	**Fasting Plasma Glucose**
GDM	**Gestational Diabetes Mellitus**
IDF	**International Diabetes Federation**
IRB	**Institutional Review Board**
MODY	**Maturity Onset Diabetes of the Young**
NHS	**National Health Service**
NKHS	**Non-Ketotic Hyperosmolar State**
OGTT	**Oral Glucose Tolerance Test**

PAD	**Peripheral Artery Disease**
UK	**United Kingdom**
WHO	**World Health Organization**

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For my little niece, Isra Aara Ibrahim Shafeeu

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During my long stay here, Armenia has been kind to me. Armenians are the kindest, warmest people I have met. Hence, with this paper, I hope to contribute to the improvement of the health of the Armenian population and try to repay this wonderful country for the experience of a lifetime! Thank you!

1. Abstract

Diabetes Mellitus (DM) is currently one of the most common chronic diseases in the world. The disease prevalence and significance are on the rise, due to evolving lifestyle changes that result in reduced physical activity and increased obesity among the population. Data from WHO indicates that the number of individuals living with diabetes has increased from over 108 million in the year 1980 to over 422 million in 2014.

Of the many complications of diabetes, Diabetic Foot Complications (DFC) have proved to be a concerning public health problem. It is one of the most distressing complications of diabetes that, not only worsens the patient's condition, but also has a tremendous socioeconomic impact on the patient. Globally, a lower limb is lost every 30 seconds due to the consequence of this complication.

Studies that focus on the epidemiology, costs and other aspects of DFC are extremely rare in the former Soviet Union and Eastern European countries. In the Republic of Armenia, diabetes and its related adverse effects are a growing public health concern. The International Diabetes Federation (IDF) estimates that by the year 2030, every tenth person in Armenia will be affected by diabetes. The intention of the proposed study is to contribute to the data available on DFC in Armenia by exploring the perceptions and experiences about DFC and everyday foot self-care practices among patients diagnosed with diabetes type-2 living with active DFC and residing in the Republic of Armenia. The study findings will be shared with physicians and specialists to help them to get a better understanding of the situation and to apply more effective approaches for counseling and management of patients with DFC.

As the proposed study is exploratory in its nature, it will employ a qualitative approach with utilization of face-to-face, in-depth interviews. The study instrument was constructed based

on prior similar studies conducted in the UK, Ghana and Bangladesh. The instrument covers specific areas such as knowledge, foot self-care, access to services, financial costs, quality of life and expectations from treatment. Convenience sampling will be used to select the study participants. The study participants will be selected among patients diagnosed with type-2 diabetes with current DFC, living in the Republic of Armenia and registered in one or two chosen medical centers from each of the 11 provinces (Yerevan city and10 marzes) in Armenia.

A team of two personnel who will be trained in qualitative research methods will conduct the study. While both the personnel will be involved in conducting the interviews and data analysis processes, one of them will also carry out the responsibilities of the project manager. With 12 to 15 interviews being the recommended number of interviews before saturation is reached, 22 interviews will be conducted to ensure maximum data collection. Data analysis will be carried out via thematic content analysis methods. This study proposal was approved by the Institutional Review Board of the American University of Armenia. The total estimated budget of the proposed study is 1,390,958AMD. The study is designed to be conducted within a duration of 2 months. This grant proposal will be submitted to Everyone's Learning Center – Male', Maldives.

2. Aim of the study

Studies that focus on the epidemiology, costs and other aspects of diabetic foot complications (DFC) are extremely rare in the former Soviet Union and Eastern European countries.[1] The intention of this study is to contribute to the data available on DFC in the Republic of Armenia. The aim of this study is to explore the perceptions and experiences about DFC and foot self-care methods and practices among patients diagnosed with diabetes type-2

living with active DFC and residing in the Republic of Armenia. The study findings will be shared with physicians and specialists in order to help them to get a better understanding of the situation and to apply more effective approaches for counseling and management of patients with DFC.

3. Background

Diabetes Mellitus (DM) is currently one of the most prevalent chronic diseases in the world.[2] The disease prevalence and significance are on the rise, due to evolving lifestyle changes that result in decrease in physical activity and increased rates of obesity among the population.[2] According to the World Health Organization (WHO), "diabetes is a chronic disease that occurs either due to the failure of the pancreas to produce an adequate amount of the hormone insulin (the hormone responsible for regulating blood sugar levels) or due to the body's failure to use the insulin effectively".[3]

3a. Classifications of DM

According the American Diabetes Association, diabetes has been classified and distinguished into the following general categories.[4]

Type 1 diabetes: The etiology of this condition is based on the destruction of the β-cells of the pancreas (that are responsible for producing insulin), via immune related or directly immune mediated pathways that usually lead to a state of absolute insulin deficiency.[4 5] Type 1 diabetes was formerly known as a disorder that specifically affected children and adolescents.[5] However, the disease is currently diagnosed at any age.[5] Polydipsia, polyuria, polyphagia and

hyperglycemia are the main diagnostic findings in patients with the disease.[5] Lifetime treatment with exogenous insulin is indicated in these patients.[5]

Type 2 diabetes: A progressive defect in insulin secretion and resistance to insulin are the major known causes of type 2 diabetes.[4] This variety of diabetes is the most predominant of all, as it encompasses 90% of all cases of diabetes.[6] Patients with this condition require chronic monitoring and treatment throughout their lives.[6] Measures of self-care, lifestyle modifications and medications are few aspects of the treatment for this condition.[6] Risk factors for the disease include gender (female), increasing age, genetic factors and obesity.[6] In the past few decades, the disease incidence has been notably increasing in parallel with obesity.[6] Uncontrolled type 2 diabetes can result in various complications such as strokes, diabetic retinopathy, heart disease, and nephropathy.[6]

Gestational diabetes (GDM): This category of diabetes can be diagnosed in either of the last two trimesters of pregnancy.[4] It is defined as any level of intolerance to glucose with the initial recognition occurring within the duration of pregnancy.[7] Approximately, about 7% of all pregnant women suffer from GDM.[7] Risk factors for the disease include personal and family history of GDM and obesity.[7]

Specific types of diabetes due to other causes: This category of diabetes includes all other conditions, syndromes and diseases that affect the function and production of insulin.[4] Some examples include, monogenic diabetes syndromes like, maturity onset diabetes of the young and neonatal diabetes, diseases like cystic fibrosis that can compromise the exocrine pancreas and chemical or drug induced diabetes.[4]

3b. Epidemiology of DM

Data from WHO indicates that the number of diabetic patients has increased from over 108 million in the year 1980 to over 422 million in 2014.[8] According to data from the International Diabetes Federation (IDF), diabetes is a concerning global public health issue.[9] While the current estimate is that one in every 11 adults has diabetes, 1 in 2 adults with the disease remains undiagnosed.[9] Three quarters of diabetic patients reside in low and middle-income nations and two-thirds of people with the disease live in urban areas.[9] There are over a million adolescents and children suffering from type 1 diabetes, and 327 million people diagnosed with the disease are of working age.[9] Over 12% of the global health expenditures, which accounts to over $727 billion, is focused on diabetes.[9] At the current rate, WHO predicts that by the time it is the year 2030, diabetes will take its place as the 7th leading cause of death.[8]

3c. Diagnosis and Management of DM

The gold standard for the diagnosis of DM is the measurement of levels of glucose in venous plasma.[10] Other important tests include the HbA1c test, oral glucose tolerance tests and fasting plasma glucose studies.[4 10 11] The American Diabetes Association recommends asymptomatic individuals of any given age who are obese and have other risk factors for diabetes to undergo testing for future risk of diabetes.[4] If the test results are normal, repeat testing is recommended within a period of 3 years.[4] The management of patients with DM often includes an individualized plan that is developed by the primary care provider and the patient.[12] The objective of these management plans is to decrease morbidity and mortality by adhering to the guidelines for prevention, detection and management of complications of the disease.[10] Primary prevention of diabetes focuses on screening of all adults above the age of 45 and encouraging weight loss among overweight people via diet modifications and exercise.[13] Secondary

prevention is utilized after the patient has already been diagnosed with DM.[14] This stage of prevention focuses on achieving individualized target HbA1c levels with the purpose of delaying or preventing the manifestations of long term complications of DM via modifying diet, encouraging exercise, medication and educating patients about self-management techniques.[13 14] Tertiary prevention is used once the complications have already manifested.[14] The aim of tertiary prevention is to slow down further progression of the complications.[14] It often focuses on screening for kidney complications, lower extremity complications and retinopathy.[13] General preventive measures are also indicated such as advising patients regarding the importance of smoking cessation and prescribing aspirin to reduce cardiovascular risks.[13] Educating patients about self-care techniques is an important key element in these guidelines.[13,15,16] It is important to note that DM is a chronic disease that has no cure, but can be managed successfully. The complications of DM can be countered by utilizing appropriate lifestyle modifications, medications and self-care strategies.[17]

3d. Complications of DM

If left uncontrolled, DM may lead to complications that may cause damage to multiple organ systems, blood vessels and nerves.[18] Complications of DM can be grouped into acute and chronic complications.[19] The main acute complications are diabetic ketoacidosis (DKA) (often seen in type-1 diabetic patients) and non-ketotic hyperosmolar state (NKHS).[19] Both of these complications are associated with volume depletion, relative or absolute insulin deficiency and altered mental state.[19]

As the chronic complications of diabetes can affect various organ systems, they have a significant impact on the mortality and morbidity from the disease.[19] The chronic complications of diabetes are of two types, 1) vascular complications and 2) non-vascular complications.[19] The

vascular complications can be further classified into small vessel(micro vascular) and large vessel(macro vascular) complications.[19] Micro vascular complications such as nephropathy, retinopathy, and neuropathy are known to be relatively specific to diabetes and play a major role in the diagnosis of the disease.[11] The magnitude of high blood glucose levels and the duration of DM are related to the risk of these micro vascular complications.[11] Often, these complications are seen at the time of the diagnosis due to delayed diagnosis.[11] The macro vascular complications affect the heart, the brain and can also cause peripheral vascular disease.[11] These complications are not specific to diabetes.[11] However, diabetes can increase the risk of these macro vascular complications significantly and severely exacerbate the clinical manifestations.[11] Non-vascular complications of diabetes lead to various conditions such as sexual dysfunction, skin changes and gastroparesis.[19] Organs that are affected due to chronic complications of diabetes include organs that are supplied via large vessels such as the heart, the brain and lower limbs.[18] Atherosclerosis - a disease of the arteries (when chronic inflammation and injury cause a plague consisting of cholesterol and fats to build up within the lumen of the vessels causing narrowing and blood flow reduction to organs.[18] These plagues can sporadically rupture and form a blood clot that can potentially totally block the perfusion of blood to a certain organ or part of the body) is thought to be the main cause of large vessel complications in people suffering from DM.[18] [12] Organs that are supplied by small blood vessels such as the eyes, kidneys, nerves and skin are also affected.[18]

3e. Diabetic Foot Complications (DFC)

Of the many complications of diabetes, DFC have proved to be a concerning public health problem.[20] It is one of the most distressing complications of diabetes that not only worsens the patient's condition, but also has a tremendous socioeconomic impact on the patient.[21] DFC

include two main conditions, 1) diabetic foot ulcerations (DFU) and 2) diabetic foot infections (DFI).[22] DFU are defined as "a foot affected by ulceration that is associated with neuropathy or peripheral artery disease of the lower limb in patients with diabetes".[21] DFI are defined as "any soft-tissue or bone infection occurring in the diabetic foot, including osteomyelitis".[22]

Studies assessing the global prevalence of DFC are rare. A systematic review and meta-analysis conducted in 2016, which included studies that contained patient data from five different continents, revealed that the global prevalence of DFU among diabetic patients is estimated at 6.3%.[23] Furthermore, this study revealed that DFU was most prevalent in North America (13% of patients with diabetes suffered with DFU) while the lowest reported prevalence was in the Oceania region (3.0%).[23] While DFC is more commonly seen in Type 2 diabetic patients rather than in patients suffering from Type 1 diabetes, it is also more prevalent in the male gender.[23] The incidence of DFU is on the rise mainly due to high prevalence rates of diabetes and due to the prolonged life expectancy among patients suffering from the disease.[24]

A 25% risk of developing DFU is present during the lifetime of diabetic patients.[20] Across the world, a lower limb is amputated every 30 seconds due to the consequence of this complication.[20,25] Patients with DFC have a risk of death within 5 years that is 2.5 times higher than a diabetic patient who does not have DFC.[26] More than half of DFU eventually progress into becoming DFI.[27] Over 20% of these DFI that reach moderate or severe levels of infection, eventually lead to varying degrees of lower limb amputations.[28,29]

The pathogenesis of DFU is based on the macro vascular complications of diabetes that lead to narrowing of arteries and reduced perfusion to the lower limbs.[30] This can result in decreased delivery of oxygen and medication, affecting the process of healing and increasing the risks of ulcer formation.[30] Furthermore, neuropathy caused by diabetes can damage peripheral

nerves resulting in loss of sensation, deformities, skin pathologies and restriction in joint mobility of the foot.[30] Factors such as poor glucose control, obesity, inadequate self-care and improper foot ware can exacerbate the neuropathic changes causing foot ulcerations.[30] Studies that assessed the risk factors of DFC also mentioned other risk factors such as underlying osteomyelitis, dyslipidemia, foot deformities such as hallux valgus, nail and skin pathology, and previous foot ulceration or amputation.[31–34]

3f. Diagnosis of DFC

Diagnosis of DFC is based on assessing if or not diabetic peripheral neuropathy (DPN), DFI or peripheral artery disease (PAD) is present in a diabetic patient.[35,36] DPN is defined as "the detection of manifestations of peripheral nerve damage in people with diabetes, after excluding other possible causes of peripheral neuropathy".[35,37] The term PAD is used to describe the obstruction of the flow of blood to the extremities, often due to atherosclerotic occlusive disease.[38] Intermittent claudication is the major presenting clinical sign in PAD.[35] In cases of severe PAD, the pain caused during intermittent claudication can be triggered even at rest.[35] The limbs may show signs of critical limb ischemia such as tissue loss and gangrenous changes.[35]

Careful review of patient history and physical examination of the lower limbs is critical in diagnosing DPN.[35] The best predictor for DPN is the combination of clinical signs, neuropathic symptoms and electro-diagnostic tests.[35] Tools and tests used to diagnose DPN include symptom scores, nerve conduction tests, vibration perception, Semmes-Weinstein monofilament and other methods of assessment such as skin and nerve biopsy.[35] Diagnosis of PAD can be conducted by tools and tests such as, the ankle-brachial index, ultrasound velocity spectroscopy and imaging, computed tomographic angiography and contrast angiography.[35] DFI

can be diagnosed based on clinical findings that indicate the presence of either two or more than two signs of inflammation and/or the presence of noticeable purulent drainage.[39,40]

3g. Prevention and Management of DFC

Diabetic patients with low risk of developing DFC should be educated on the importance of self-foot care, the appropriate foot ware and the control and assessment of blood glucose levels.[41] High-risk diabetic patients on the other hand, may require surgical intervention if they present with foot deformities or active ulcers.[41] Practitioners should focus on identifying and treating the underlying disease processes.[42] Ensuring continuous and adequate perfusion of blood to the limbs, local wound debridement and care, infection control and pressure offload from the affected limb are all essential components of management of DFC.[42]

Early screening for risk factors is highly beneficial as early screening can detect modifiable risk factors that can initiate preventive measures.[32] In order to prevent further complications such as amputations, patients with foot ulcers or any sign of infection or ischemia should immediately be taken to specialized centers to initiate revascularization and rehabilitation.[43]

In treating patients with DFC, it is important that health professionals focus on the mental health needs of patients just as cautiously as they do with the physical health needs.[44] Patients with DFC are often anxious, have a sense of hopelessness of fully recovering from the condition and may show emotions that indicate lack of control over the situation.[44–46]

3h. Economic and societal burden of DFC

Diabetic foot complications can have a significant, unfavorable impact on health care systems and health economics.[47] The United States spent over $116 billion on diabetes and its

related complications in 2007.[48] Over one third of these costs focused on the cost of care for DFC.[48] The development of DFC could mean that the patient would be spending over 5.4 times the cost in the 1st year compared to a diabetic patient who does not develop DFC.[48] The cost of treating the most severe DFC can rise up to over eight times as compared to the cost of treating mild DFC.[48] In the United Kingdom, the National Health System (NHS) spent £1.13 billion for the management and treatment of DFC in 2014-2015.[49] This expenditure is higher than the value spent on the management and treatment of three of the four most prevalent cancers in the UK combined.[49–51] The financial cost of management and treatment of the condition can vary with specific interventions.[47] Apart from direct expenditure spent on the treatment and management, there is also indirect expenditure due to factors such as loss of productivity, family status and family costs.[47] While hospital stay is considered as the largest cost component, multiple admissions, critical limb ischemia, major amputation and high dependence were found to be other factors that contribute to high cost of treatment.[52]

Changes in the physical, social and psycho-emotional domains of quality of life are observed in patients suffering from foot complications of diabetes.[53] Furthermore, DFC affects patients in their family, leisure and social activities.[54 55] Patients eventually have to rely on family members or friends for support, as they require assistance in performing basic tasks and activities.[55] Early retirement, work absenteeism and loss of employment are also factors that increase the socioeconomic costs of patients with DFC.[54–56]

In order to prevent the costly and unfavorable outcomes such as amputations, it is important to highlight the need for cost effective and optimized preventive measures and treatment for the disease.[57] A study done in Turkey revealed that the individual and societal economic burden in the region is high.[58] Longer duration of hospital stays, medicine, equipment

and services provided by the hospitals contributed to the high costs of treatment of DFC.[58] To minimize the costs associated with the devastating complications of DM such as DFC, health professionals, patients and even their relatives must play a role in contributing towards the management of the disease.[58] Providing easy accessibility to health services and increasing the number of staff who are experienced at dealing with DM and its complications, are areas that health administrators should focus on.[58] In addition to promoting and developing of proper and effective management of DM related complications, providing continuous education to the patients can contribute to bringing down the cost of care.[58] A study conducted in Russia found that the treatment cost for patients with DFC is €3668 on average.[1] Length of stay and vascular interventions were factors that caused the main variations in the cost of treatment.[1] Moreover, treatment of DFC conducted by multidisciplinary teams at federal medical institutions in Russia, can involve costs that may have disastrous economic consequences for patients who do not have access to public financing.[1]

3i. Situation in Armenia

In Republic of Armenia, DM and its associated complications are a growing public health concern. The International Diabetes Federation predicts that, every tenth person of the population in Armenia will be affected by DM by the year 2030.[59 60] There were over 168,000 cases of diabetes in Armenia in 2017.[59] The prevalence rate of DM in Armenia as of 2016 was 12.3%.[61] While other countries in the region such as Georgia (15.0%) and Turkey (13.2%) had a slightly higher prevalence rate, countries such as Azerbaijan (11.6%), and Iran (10.3%), had a fairly lower prevalence rate of DM during the same year.[62–65] The high prevalence of DM in Armenia can be associated with the increasing rates of risk factors of diabetes type 2 such as, unhealthy dietary habits, high prevalence of obesity and low physical activity.[60] Due to the

absence of a national diabetes registry and various issues associated with effective corporation between the different levels of care, diabetic patients face the risk of receiving low quality treatment, increasing the risk of complications.[60] In 2003, as per the WHO mortality database, the age-standardized death rate (ASDR) per 100,000 due to diabetes in both sexes was 46.7. This value was reduced to 30.8 in 2015 (Appendix 1, data from: WHO Mortality Database. http://apps.who.int/healthinfo/statistics/mortality/whodpms/). However, when compared to all other nations in the region on the same database, the number of deaths in Armenia due to diabetes has remained markedly high after the mid-1990s (Appendix 2, data from: WHO Mortality Database. http://apps.who.int/healthinfo/statistics/mortality/whodpms/).

There is a prominent gap in the literature available on diabetic foot complications in Armenia. A rare study conducted in 2007 revealed that, "inadequate foot self-checking after diabetes diagnosis confirmation, poor blood glucose control, smoking, hypertension, high Body Mass Index (BMI), and longer duration of the disease contributed to the development of diabetic angiopathy of lower extremities in Type 2 Diabetes patients".[66] Unfortunately, evidence suggests that specialized units for the management of DFC in the country are very few in number.[66] The Armenian Association of Diabetic Foot that was formed in the year 2008 as an NGO, has been trying to focusing on the improvement of the situation by sending teams to different provinces, consulting and treating patients with DFC.[60] Unfortunately, these efforts were not very effective, mainly due to infrequency of site visits.[60] Moreover, a study conducted in 2015 that assessed the knowledge regarding Type 2 diabetes related complications and prevention in Armenia concluded that almost 50% of the population of the country were not aware that Type 2 diabetes was actually a preventable condition.[67] Furthermore, very few of the

study participants had knowledge regarding the preventive practices of the DM related complications.[68]

4. Methodology

4a. Study design

As the proposed study is exploratory in its nature, it will employ a qualitative approach with utilization of face-to-face, in-depth interviews with selected study participants who provide the permission to be interviewed. Utilizing the qualitative approach would enable the study to obtain valuable information on individual perspectives of patients suffering from DFC.

4b.Study population and Sampling

Convenience sampling will be utilized in this study. The sampling frame and contact information of the candidates for the study will be obtained from one or two chosen medical centers from each of the 11 provinces (Marzes) in Armenia. In Yerevan city, the two biggest referral centers for patients suffering from DFC, "Armenia" and "Erebouni" medical centers will be included. In all other marzes, the one or two main medical centers located in each Marz center will be included to recruit patients with DFC. These medical centers have both inpatient and outpatient services providing the advantage of having access to not only hospitalized patients but also those receiving outpatient care in the medical centers. All required permissions will be obtained from these medical centers prior to the study.

4c. Recruitment of participants and eligibility criteria

The study participants will be patients, above the age of 18, diagnosed with type-2 diabetes with current DFC, living in the Republic of Armenia and registered in the chosen medical centers. As per a similar study done in the UK[69], patients diagnosed with type-1 diabetes or all types of diabetes other than type-2 will be excluded from this study due to the fact that there may be significant differences in terms of foot health among the different classifications of DM.[69] In addition, patients with communication difficulties will be excluded from the study. The most recent patients from the medical centers will be contacted via telephone, provided with a short description and explanation of the study and asked for permission to be interviewed. After receiving the permission from the participant, arrangements will be made to proceed with the interview. The interviews will take place at locations and times suggested by the participants that will ensure their privacy and will be feasible for the interviewers. Informed consent will be provided to the participant before the interview session begins. The process of study participant recruitment will continue until data saturation is achieved.[70] However, with 12 to 15 interviews being the recommended number of interviews before saturation is reached, 22 interviews will be conducted to ensure maximum data collection.[71,72]

4d.Study instrument and data collection

A short socio-demographic questionnaire will be provided to the participants that would inquire about information such as age, gender, education and socioeconomic status of a participant. The study instrument (Appendix 5) will be an interview guide adopted from literature and constructed based on prior similar studies conducted in the UK, Ghana and Bangladesh. The instrument covers specific areas such as knowledge, foot self-care, access to

services, financial costs, quality of life and expectations from treatment.[73–75]. The questions are accompanied with probes that will direct a trained interviewer to ask open ended questions that are designed to persuade participants to express their thoughts and feelings. The study instrument will be translated into Armenian language and will be pre-tested. During the interview, audio recordings will take place with the permission of the participants. The interviewer will be required to take field notes in parallel with the audio recordings throughout all interviews to avoid loss of data that may occur due to technical errors.

A team of two personnel will conduct the study. While both personnel will be involved in conducting the interviews and data analysis processes, one of them will carry out the responsibilities of the project manager. The duty of the project manager will be to develop the study protocol and ensure the safe and authentic implementation of the project. Even though the study team is required to have prior experience and appropriate background in the field, they will undergo a short self-training program on qualitative research methods in order to ensure ethical and accurate data collection and analysis.

4e. Data management and analysis

Data analysis will be carried out via thematic content analysis methods.[76] The audio recordings to be obtained from the interviews will be used to create transcripts. Preliminary analysis will be carried out simultaneously with the interviews. The content of the transcripts will be analyzed to derive the important quotes that will be further classified into codes via open coding techniques. The generated codes will be used to identify categories and major themes. To evaluate the accuracy of the developed themes, two data analysts will conduct the process individually on each interview before merging their findings as global themes. Furthermore, the computerized qualitative data analysis program, Hyper RESEARCH 2.8 will also be used to

evaluate accuracy. The finalized global themes will be used to summarize and create the final report of the study.

6. Budget

The proposed study will be conducted within a duration of 2 months (Appendix 5). The budget for the study will be spent on three main categories. 1) Personnel, 2) Operational costs and 3) Other. The amounts are allocated based on values for similar job titles and prices of materials existing in the Armenian market. Both members of the team will receive their wages on monthly basis. The total estimated budget for the project is 1,390,958AMD. Details of the budget are available in Table 2 (Appendix 8)

7. Ethical Conduct and Protection of Participants

Ethical approval for the study protocol was received from the Institutional Review Board (IRB) of the American University of Armenia (AUA). Before proceeding with the interviews, the study participants will be presented with the oral consent form. They will also be asked for permission to carry out audio recording of the interview. The participants will be allowed to discontinue the interview at any moment they wish to do so. To protect the participant's confidentiality, ID numbers will be assigned to each participant and will be used throughout the data analysis phase. All participants will be provided with an Armenian version of a summary report of the study and will be given the option to contact the research team to discuss the findings from the study.

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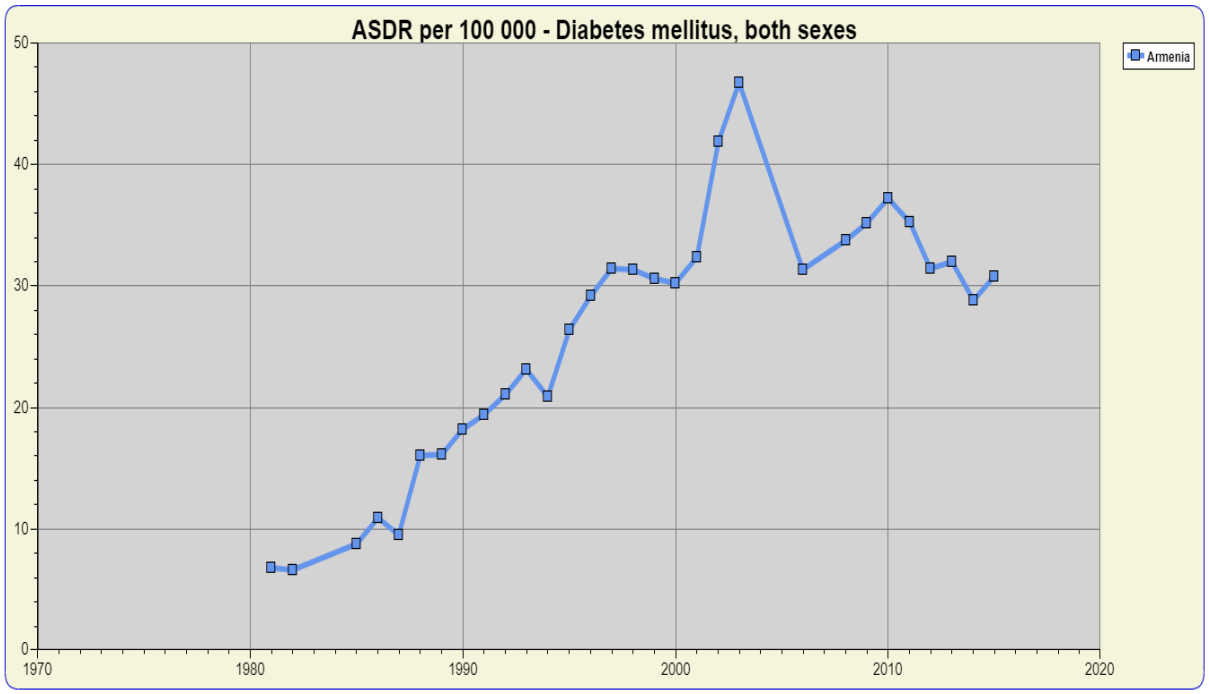
8. Appendix 1

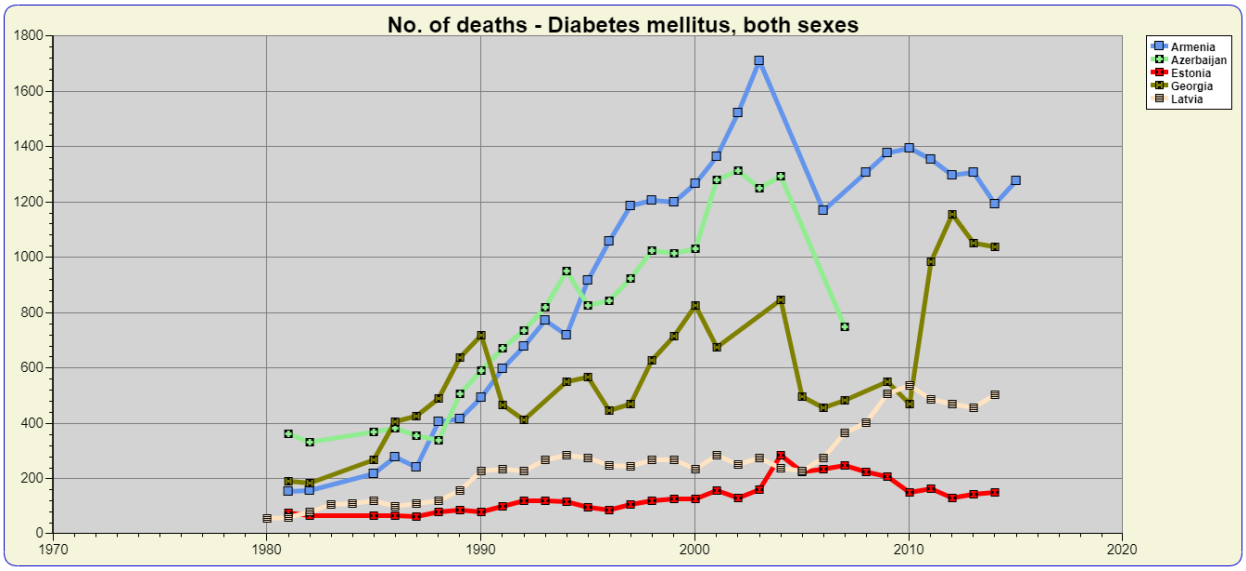
Age standardized death rate per 100,000 in patients with DM for both sexes in Armenia between 1970 and 2020.



Source: WHO Mortality Database. http://apps.who.int/healthinfo/statistics/mortality/whodpms/. Accessed April 20, 2018.

9. Appendix 2

Number of deaths due to DM in both sexes in Armenia, Azerbaijan, Estonia, Georgia and Latvia between 1970 and 2020.



Source: WHO Mortality Database. http://apps.who.int/healthinfo/statistics/mortality/whodpms/. Accessed April 20, 2018.

10. Appendix 3: Consent form (ENGLISH)

American University of Armenia

Institutional Review Board #1

Oral consent form

Title: Perceptions and experiences of pateints living with Type 2 diabetes on diabetic foot Complications(DFC): A qualitative study among type-2 diabetic patients with current presentation of DFC, living in Armenia.

Hello, My name is Ismail Adil, and I am a graduate student of the Master of Public Health program at the American University of Armenia (AUA). Our department is conducting a study to explore the perceptions and experiences of patients living with type-2 diabetes on diabetic foot complications.

I am inviting you to participate in this interview as you are a patient that was registered in a Medical Center in Armenia as a type-2 diabetic patient that currently has a presentation of DFC.

In case you agree to participate in this interview you will be asked a series of questions related to your condition. This interview will take approximately an hour of your time. I assure you that your identity will be protected and any information retrieved from this interview will be confidential. Your answers and opinions will be combined with information obtained from similar interviews with other participants to prepare the final report of this study. Important quotes from this interview may be used in the final report after confirming the absence of any personal identifiable information. I would like to ask your permission to take notes and also conduct an audio recording of this interview

session. All the audio recordings will be destroyed as soon as the analysis phase is over and the final report is compiled.

Your participation in this interview session is entirely voluntary. There will be no penalty against you in case you decline to be part of this interview. During the interview, you are allowed to refuse to answer any question and even stop the interview without providing a reason.

You will not be provided with any financial compensation or personal benefits for participating in the study. Your contribution to this interview will help us gather information about the perceptions and experiences of type-2 diabetic patients who are suffering from DFC that can be shared with physicians and specialists in order to get a better understanding of the condition. There will be no known risk that you will face by participating in this interview.

In case you have any questions regarding this study, please feel free to contact the principal investigator, Dr. Anahit Demirchyan: (060 612562). Furthermore, if you feel like you have been treated in an unprofessional manner or have been affected negatively during this interview you should contact Varduhi Hayrumyan, the Human Participants Protection Administrator of the American University of Armenia: (060) 61 25 61.

Do you agree to participate?

Are you comfortable with conducting an audio recording of the interview?

Please say YES or NO. Thank you. If yes, shall we continue?

11. Appendix 5: Consent form (ARMENIAN)

ՀԱՅԱՍՏԱՆԻ ԱՄԵՐԻԿՅԱՆ ՀԱՄԱԼՍԱՐԱՆ

Գիտահետազոտական էթիկայի հանձնաժողով №1

Բանավոր համաձայնության ձև

Վերնագիր՝ 2-րդ տիպի դիաբետով հիվանդների ընկալումները և փորձառությունը Դիաբետիկ ոտնաթաթի համախտանիշի վերաբերյալ. Որակական հետազոտություն Հայաստանում բնակվող 2-րդ տիպի դիաբետով և դիաբետիկ ոտնաթաթի համախտանիշով հիվանդների շրջանում

Բարև Ձեզ, ես Իսմայիլ Աղիլն եմ՝ Հայաստանի ամերիկյան համալսարանի (ՀԱՀ) հանրային առողջապահության մագիստրոսական ծրագրի ուսանող: Մեր ֆակուլտետը հետազոտություն է անցկացնում՝ ուսումնասիրելու 2-րդ տիպի դիաբետով հիվանդների ընկալումները և փորձառությունը դիաբետիկ ոտնաթաթի համախտանիշի վերաբերյալ:

Ես հրավիրում եմ Ձեզ մասնակցել այս հարցազրույցին, քանի որ Դուք Հայաստանի բժշկական կենտրոններից մեկում գրանցված եք որպես դիաբետիկ ոտնաթաթի համախտանիշով 2-րդ տիպի դիաբետով հիվանդ:

Եթե Դուք համաձայնեք մասնակցել այս հարցազրույցին, Ձեզ կտրվեն Ձեր հիվանդության և ինքնազգացողության հետ կապված մի շարք հարցեր: Այս հարցազրույցը կտևի մոտ մեկ ժամ: Ես հավաստիացնում եմ, որ Ձեր անձի գաղտնիությունը պաշտպանված կլինի, և այս հարցազրույցից ստացված ցանկացած տեղեկություն կպահվի գաղտնի: Ձեր պատասխանները և կարծիքները կընդհանրացվեն այլ մասնակիցների նույնատիպ հարցազրույցից ստացված տեղեկատվության հետ՝ այս ուսումնասիրության վերջնական զեկույցը կազմելու համար: Այս հարցազրույցի կարևոր մեջբերումները կարող են օգտագործվել այդ վերջնական զեկույցում՝ առանց Ձեր անձնական տվյալները նշելու: Ես կցանկանայի Ձեր թույլտվությամբ գրառումներ կատարել, ինչպես նաև ձայնագրել այս հարցազրույցը: Վերլուծության փուլն ավարտելուց և վերջնական զեկույցը կազմելուց հետո բոլոր ձայնագրությունները կվերացվեն:

Ձեր մասնակցությունն այս հարցազրույցին կամավոր է: Դուք որևէ տույժի չեք ենթարկվի, եթե հրաժարվեք մասնակցել: Հարցազրույցի ընթացքում Դուք կարող եք հրաժարվել որևէ հարցի պատասխանելուց կամ նույնիսկ դադարեցնել հարցազրույցը՝ առանց պատճառը նշելու:

Ուսումնասիրությանը մասնակցելը Ձեզ չի նախատեսում որևէ ֆինանսական փոխհատուցում կամ անձնական օգուտ, սակայն Ձեր մասնակցությունը կօգնի մեզ տեղեկություններ հավաքել դիաբետիկ ոտնաթաթի համախտանիշի վերաբերյալ 2-րդ տիպի դիաբետով հիվանդների ընկալումների և փորձառության մասին, որը մենք կփոխանցենք բժիշկներին և մասնագետներին՝ որպեսզի նրանք ավելի լավ

հասկանան այդ հիվանդությունը և ավելի լավ օգնեն հիվանդներին: Դուք որևէ ռիսկի չեք դիմում՝ մասնակցելով այս հարցազրույցին:

Այս ուսումնասիրության վերաբերյալ որևէ հարցի առկայության դեպքում խնդրում ենք դիմել գլխավոր հետազոտողին՝ Անահիտ Դեմիրչյանին՝ (060) 61 25 62 հեռախոսահամարով: Եթե Դուք կմտածեք, որ Ձեզ վերաբերվել են ոչ պրոֆեսիոնալ, կամ որ այս հարցազրույցը բացասական ազդեցություն է ունեցել Ձեզ վրա, կարող եք դիմել Հայաստանի Ամերիկյան Համալսարանի էթիկայի հանձնաժողովի համակարգող Վարդուհի Հայրումյանին՝ (060) 61 25 61 հեռախոսահամարով:

Դուք համաձայն է՞ք մասնակցել:

Դուք համաձա՞յն եք, որ ձայնագրենք այս հարցազրույցը:

Խնդրում եմ պատասխանել՝ ԱՅՈ կամ ՈՉ: Շնորհակալություն:

Եթե այո, ապա շարունակենք:

12. Appendix 6: Demographic questionnaire: Socio-demographic form (ENGLISH)

1. What is your age?	_____
2. What is you gender?	☐ Male ☐ Female
3. What is your marital status?	1. Married ☐ 2. Single ☐ 3. Divorced/Separated ☐ 4. Widowed ☐
4.What is the highest level of education you have completed?	1. Less than secondary school ☐ 2. Secondary school/professional technical ☐ 3. University/higher ☐
5. What is your current employment status?	1. Employed ☐ 2. Self-employed ☐ 2. Unemployed ☐ 3. Student ☐ 4. Retired ☐

13. Appendix 4: Demographic questionnaire: Socio-demographic form (ARMENIAN)

1. Քանի՞ տարեկան եք:	_____
2. Ձեր սեռը	☐Ար. ☐Իգ.
3. Ձեր ամուսնական կարգավիճակը	1. Ամուսնացած ☐ 2. Ամուրի ☐ 3. Բաժանված ☐ 4. Այրի ☐
4. Ի՞նչ **կրթություն ունեք:**	1. Թերի միջնակարգ ☐ 2. Միջնակարգ / մասնագիտական/տեխնիկական ☐ 3. Համալսարան/բարձրագույն ☐
5. Դուք աշխատու՞մ եք:	1. Աշխատում եմ ☐ 2. Ինքնազբաղ եմ☐ 2. Գործազուրկ եմ ☐ 3. Ուսանող եմ ☐ 4. Թոշակառու եմ ☐

14. Appendix 5: In-depth Interview guide (ENGLISH)

Place:

Date:

Time:

Welcome the participant.

Introduce yourself and read out the concent form.

> Hello. Thank you for agreeing to participate in this study. The aim of our study is to explore the perceptions and experiences of DFC and everyday foot self-care practices among patients diagnosed with diabetes type-2 with active DFC. There is no corrrect or wrong answer to the questions that I will be asking you. You are free to stop the interview at any moment you like. Feel free to elaborate on your answers and share your honest opinions and experiences.

Introductory question:

1. When did you first know about your diabetes? When did you first notice a problem in your feet? How did it feel? Did you expect it?

Foot self-care:

2. What are some things you do to look after your feet? Does anyone help you out? How important do you think it is to take care of your feet?

Knowledge:

3. **What do you know about your condition? Were you aware of the foot complications of diabetes before you had the ulcers? What are some things that you know can be done to prevent the condition from getting worse?**

Access to services:

4. How often do you see a health care professional? How do the health care professionals help you in terms of managing your blood glucose levels? What treatment have you undergone so far? Have the treatments been beneficial? Have you screened for other complications of diabetes? Have you been hospitalized due to DFC? What was your longest duration of stay at the hospital?

Financial costs

5. Approximately how much do you spend on treatment? What are your views on the cost of the treatment for your condition? How has this affected you? Has your condition affected your ability to work?

Quality of life

6. Could you explain how this condition has impacted you emotionally? Can you recall or

describe any situations in which you have felt like you have had a lack of control over the situation and a sense of hopelessness due to your condition?

7. How has this condition affected your confidence both in social settings and in the workplace environment?

8. Can you please describe how your condition has affected simple everyday activities? Could you provide some examples?

Expectations from treatment

9. What are your expectations from the treatment you are currently undergoing? Do you expect to fully recover? Why yes or why no? What are some things in your mind that can be done to prevent recurrence or new DFC?

10. Do you have any particular experiences to share regarding your condition?

Thank you for your participation – Your answers have been very informative and interesting!

15. Appendix 6: In-depth Interview guide (ARMENIAN)

Հարցազրույցի ուղեցույց

Վայրը՝

Ամսաթիվը՝

Ժամը՝

Ողջունեք մասնակցին:

Ներկայացեք և կարդացեք իրազեկ համաձայնության ձևը

Բարև Ձեզ: Շնորհակալություն ենք հայտնում այս ուսումնասիրությանը մասնակցելու համար: Մեր ուսումնասիրության նպատակն է հետազոտել 2-րդ տիպի դիաբետով հիվանդների ընկալումները և փորձառությունը դիաբետիկ ոտնաթաթի համախտանիշ վերաբերյալ: Խնդրում եմ ազատորեն պատասխանել մեր հարցերին, հիշելով, որ այստեղ չեն կարող լինել ճիշտ կամ սխալ պատասխաններ, և որ մենք կարևորում ենք միայն Ձեր անկեղծ կարծիքն ու փորձառությունը:

Ընդհանուր

1. Ե՞րբ եք առաջին անգամ իմացել Ձեր հիվանդության մասին: Ե՞րբ եք առաջին անգամ նկատել Ձեր ոտքերի խնդիրը: Դա Ձեզ համար անակնկա՞լ էր:

Ոտնաթաթի խնամք

2. Ի՞նչ եք անում Ձեր ոտքերի խնամքի համար: Ինչ-որ մեկը օգնու՞մ է Ձեզ: Ձեր կարծիքով, որքանո՞վ է կարևոր Ձեր ոտքերի խնամքը:

Գիտելիքներ

3. Ի՞նչ գիտեք Ձեր հիվանդության մասին: Ոտնաթաթի դիաբետիկ բարդությունների մասին գիտեի՞ք նախկինում, թե՞ տեղեկացաք խոցեր ունենալուց հետո: Ըստ Ձեզ, կա՞ն այնպիսի միջոցներ, որոնք կարելի է ձեռնարկել՝ Ձեր ոտքերի վիճակի հետագա վատացումից խուսափելու համար:

Բուժօգնության հասանելիություն

4. Ո՞րքան հաճախ եք այցելում բժշկի: Ի՞նչպես են բժիշկներն օգնում Ձեզ՝ արյան գլյուկոզայի ցանկալի մակարդակը պահպանելու հարցում: Ինչպիսի՞ բուժումներ եք ստացել մինչև օրս: Ըստ Ձեզ, այդ բուժումները արդյունավե՞տ են եղել: Դուք ստուգվե՞լ եք դիաբետի այլ բարդությունների վերաբերյալ: Դուք հոսպիտալացվե՞լ եք դիաբետիկ ոտնաթաթի համախտանիշի պատճառով: Որքա՞ն է եղել հիվանդանոցում Ձեր մնալու ամենաերկար տևողությունը:

Ֆինանսական ծախսեր

5. Մոտավորապես որքա՞ն եք ծախսում Ձեր բուժման համար: Ի՞նչ կարծիք ունեք Ձեր հիվանդության բուժման գնի վերաբերյալ: Ինչպե՞ս է դա ազդել Ձեզ վրա: Ձեր վիճակը ազդե՞լ է Ձեր աշխատելու կարողության վրա:

Կյանքի որակ

6. Կարո՞ղ եք նկարագրել, թե ինչպես է Ձեր հիվանդությունն ազդել Ձեր տրամադրության կամ հուզական վիճակի վրա: Կարո՞ղ եք հիշել կամ նկարագրել այնպիսի պահեր, երբ զգացել եք, որ չունեք իրավիճակի նկատմամբ հսկողություն և հուսալքվել եք Ձեր վիճակի պատճառով:

7. Այս հիվանդությունն ինչպե՞ս է ազդել Ձեր ինքնավստահության վրա՝ տարբեր միջավայրերում կամ աշխատավայրում:

8. Կարո՞ղ եք նկարագրել, թե ինչպես է Ձեր վիճակն ազդել Ձեր առօրյա պարզ գործողությունների վրա: Կարո՞ղ եք բերել որոշ օրինակներ:

9. Ի՞նչ սպասելիքներ ունեք այն բուժումից, որ հիմա ստանում եք: Դուք ակնկալու՞մ եք, որ լիովին բուժվելու եք: Ինչու՞ այո

կամ ինչու՞ ոչ: Ըստ Ձեզ, ի՞նչ կարելի է անել հիվանդության կրկնությունը կանխելու կամ նոր խոցերի առաջացումից խուսափելու համար:

10. Դուք ունե՞ք ինչ-որ փորձառություն՝ կապված ձեր հիվանդության հետ, որի մասին կցանկանայիք պատմել մեզ:

Շնորհակալություն Ձեր մասնակցության համար: Ձեր պատասխանները շատ արժեքավոր և հետաքրքիր էին:

16. Appendix 7: PROJECT TIMELINE

	W1-2	W3	W4-5	W6-7	W8-9
	D1-D14	D15-D21	D22-D35	D36-D49	D50-63
Preparation & printing of questionnaires	X				
Training of interviewers/data analysts		X			
Fieldwork			X	X	
Data analysis			X	X	
Final report					X

*W= Week, D= Day

17. Appendix 8: BUDGET

Table 2. Budget and resources to be submitted to Everyone's Learning Center – Maldives

Cost Type	Unit cost (AMD)	Number	Total (AMD)
Personnel cost			
Project Manager/Interviewer/Analyst	250,000	2 Months	500,000
Interviewer/Analyst	150,000	2 Months	300,000
Subtotal			**800,000**
Operational Costs			
Office rent	80,000	2 Months	160,000
Stationary and paper	20,000	1	20,000
Photocopying and printing of interview guide + consent forms	200	20	4000
Phone call expenses	200	45	9000
Audio recorders	20,000	2 units	40,000
Analysis software	181,522	1 single user license	181,522
Subtotal			**414,722**
Other costs			
Travel	5000 per visit	22 visits	110,000
Unforseen expenses (5% of total budget)			66,236
Subtotal			**176,236**
Total			**1,390,958**