Patient experience with expanded Basic Benefits Package coverage for treatment of Hepatitis C in Armenia

Master of Public Health Integrating Experience Project

Program Evaluation Proposal Framework

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List of abbreviations

AMD	- Armenian dram
AUA	- American University of Armenia
BBP	- Basic Benefits Package of state-guaranteed free medical services
CHSR	- Avedisian Onanian Center for Health Services Research and Development of the American University of Armenia
CMS	- Centers for Medicare and Medicaid Services, United States Department of Health and Human Services
DAA	- Direct Acting Antivirals
GDP	- Gross Domestic Product
GHSS	- Global Health Sector Strategy on viral hepatitis 2016–2021
GOA	- Government of Armenia
GS-PEQ	- Generic Short Patient Experience Questionnaire
HCV	- Hepatitis C virus
HIV	- Human Immunodeficiency Virus
IRB	- Institutional Review Board
MOH	- Ministry of Health of Armenia
MTEF	- Medium-Term Expenditure Framework
NCDCP	- National Center for Disease Control and Prevention of the Ministry of Health of Armenia
OOP	- Out-of-pocket payments
PCR	- Polymerase chain reaction
PREM	- Patient Reported Experience Measures

PROM	- Patient Reported Outcome Measures
SPSS	-The Statistical Package for the Social Sciences
THE	- Total Health Expenditure
UHC	- Universal Health Coverage
WHO	- World Health Organization

1. Summary

The World Health Organization (WHO) considers viral hepatitis as an international public health challenge, which, given its global magnitude, is comparable to other major communicable diseases. An estimated 71 million people had chronic Hepatitis C (HCV) infection in 2016, which had resulted in approximately 399,000 deaths, mostly from cirrhosis and hepatocellular carcinoma (primary liver cancer). The prevalence of HCV in adult population (above 18) of Armenia is estimated to be around 4%. Incidence of the viral hepatitis, including HCV, is significantly growing during recent years in Armenia, which is explained by implementation of improved testing procedures since 2016. A year-to-year increase in total incidence of HCV per 100,000 population was 53.1% in 2017, 24.0% in 2018 and 6.7% in 2019.

In May 2019, the Ministry of Health (MOH) of Armenia has approved the "The 2019-2023 Program for prevention and control of parenteral viral hepatitis in the Republic of Armenia". Starting 2019, the Government of Armenia (GOA) has embarked on expanding health coverage and improving the financial risk protection of the population by allocating additional funding from the public budget for the Basic Benefits Package (BBP) services. One of the new BBP programs, which is planned to start in June 2020, will cover provision of free pan-genotype medicine (combined Sofosbuvir/Daclatasvir therapy) for patients with HCV (hereinafter referred to as the Program). The Program will initially cover around 1,000 chronic HCV patients for the first year (2020), aiming at gradual expansion over the next years, depending on availability of additional funds from public budget. According to the draft MOH guidelines, the Program will cover both the preliminary diagnostic tests and provision of the combined Sofosbuvir 400mg/Daclatasvir 60mg therapy. To be covered by the Program, patients should meet certain medical and social criteria. Depending on the HCV genotype and stage of the disease, patients will receive either 12- or 24-weeks treatment course.

The goal of the proposed evaluation is to assess patients experience with the Program during the first year of its implementation (2020-2021). The objective of the study is to assess and describe the concept of patient experience, and its association with demographic and socio-economic characteristics of patients, self-reported health-related indicators, and health care providers' characteristics. The proposed evaluation will be conducted utilizing a cross-sectional, pre-experimental one-shot study design. There will be no baseline measurement, as the intervention (Sofosbuvir/ Daclatasvir therapy) is a new type of HCV treatment that was not widely used in Armenia before. The Program evaluation will be the first in Armenia to address the patient experience with expanded BBP coverage for provision of outpatient medicine, which can set a precedent for the MOH to conduct similar studies in the future for evaluation of health policy initiatives in improving access to pharmaceuticals.

The main outcome (dependent) variable of interest is the patient experience. Independent variables of the study include: socio-demographic characteristics of patients (age, gender, place of residence, education level, marital status, employment status and average monthly expenditure level), health-related characteristics of patients (self-rated health status, duration of the HCV treatment course) and characteristics of health care provider facilities in which the patients has received the treatment (location and ownership status).

The target population of the study includes adult patients with chronic HCV condition (18 years of age and above), living in Armenia, who start the Sofosbuvir/Daclatasvir therapy in 2020, speak Armenian and have a valid telephone number. The National Center for Disease Control and Prevention (NCDCP) staff will provide weekly updates to the study team about the patients who either completed their treatment course or quitted it during the previous week. The patients will then be contacted by phone within two weeks period for the survey. Inclusion of the

patients who decided to quit the treatment will allow to assess whether the factors related to patient experience are associated with their decision not to complete the treatment.

The sample size of the study is 481 patients, which is calculated with the formula for one sample mean and is further adjusted for the finite population correction factor. The patients included in the study will be geographically spread over all regions of Armenia and will receive their treatment in outpatient settings. Therefore, it is suggested to conduct a telephone survey due to logistical considerations and in order to minimize the project costs.

The study instruments are adapted from validated tools used previously in similar studies and include a questionnaire, the telephone interview script, the journal form and the informed verbal consent form, which will be pre-tested prior to the survey. The main outcome variable of interest is patient experience, which will be measured through a set of 13 questions with five-point Likert scale answer options for each question. The questions on patient experience are adapted from the Generic Short Patient Experience Questionnaire (GS-PEQ), which is based on the assessment of six different validated study instruments. A two-day interviewer training will be conducted, and double data entry will be done to minimize the possible effect of random errors. Descriptive statistics will be used for summarizing the data (means and standard deviations for continuous variables and proportions for categorical variables). For analyzing the associations between the continuous outcome variable and the independent variables of interest, regression analysis will be performed.

The training of interviewers and pre-testing of the study instruments will be implemented during July-August of 2020. The full-scale start of the Program evaluation (i.e. the telephone survey) will start when the first HCV patients will be completing their treatment course. Data entry and analysis will be done in parallel with data collection. The survey will continue into 2021 until reaching the sample size. The overall duration of the study (i.e. the Program evaluation) is

expected to be from June 2020 to July 2021. The final stage of the project will be data analysis and reporting, including publishing and disseminating the study findings and discussing them with the key stakeholders.

The study protocol was reviewed by the Institutional Review Board (IRB) of the American University of Armenia (AUA) and was confirmed to comply with locally and internationally accepted ethical standards.

2. Introduction

2.1 Global burden of Hepatitis C

According to the World Health Organization (WHO), "viral hepatitis is an international public health challenge, comparable to other major communicable diseases, including HIV, tuberculosis and malaria".[1] Total global hepatitis C virus (HCV) prevalence is estimated at 2.5% (177.5 million of HCV infected adults, 2016), reaching up to 6.7% in some countries with high disease burden.[2,3] An estimated 71 million people had chronic HCV infection in 2016, which had resulted in approximately 399,000 deaths, mostly from cirrhosis and hepatocellular carcinoma (primary liver cancer).[4] In the WHO Europe region alone, 14 million people are estimated to be chronically infected with HCV; many of them are not aware of their infection.[5] There is limited access to affordable hepatitis testing globally, resulting in only 20% of HCV-infected persons being properly diagnosed with the illness.[6] In May 2016, the World Health Assembly endorsed the Global Health Sector Strategy (GHSS) on viral hepatitis 2016–2021, which sets a goal for elimination of viral hepatitis as a public health threat by 2030 by reducing new infections by 90% and mortality by 65%.[1]

2.2 Situation in Armenia

According to a study conducted in 2018 by the Center for Disease Analysis Foundation, in collaboration with WHO Regional Office for Europe, WHO Country office in Armenia and the Ministry of Health (MOH), the HCV prevalence in adult population (above 18) of Armenia is estimated to be around 4%.[7] After applying a viremic rate of 70% and adjusting for younger ages, it was estimated that there were 66,000 people viremically infected in 2017, correlating to a prevalence of 2.3%. Out of 6 known genotypes of HCV, two represent more than 80% of all

cases in Armenia: genotype I (45.2%) and III (36.6%).[7] In 2019, there were 2,141 newly diagnosed cases of viral hepatitis in Armenia (72.1 per 100,000), from which 1,425 (or around 2/3) were the cases of HCV (48.0 per 100,000). The incidence of the viral hepatitis, including HCV, is now estimated more accurately in Armenia due to implementation of improved testing procedures since 2016. This has resulted in a year-to-year increase in total incidence of HCV per 100,000 population of 53.1% in 2017 (from 23.7 in 2016 to 36.3 in 2017), followed by 24.0% increase in 2018 (from 36.3 to 45.0) and 6.7% increase in 2019 (from 45.0 to 48.0).[9] According to the unpublished data from National Center for Disease Control and Prevention of Armenia (NCDCP), there were around 5,300 patients with HCV in Armenia as of December 2018, from which less than 0.1% were patients with acute conditions, 38.3% were patients with confirmed chronic conditions, and 61.6% were patients with anti-HCV antibodies, which needed further testing with polymerase chain reaction (PCR) method to further differentiate chronic cases.[10]

2.3 Government efforts to address the Hepatitis C problem in Armenia

In May 2019, the MOH of Armenia has approved the "The 2019-2023 Program for prevention and control of parenteral viral hepatitis in the Republic of Armenia".[11] Starting 2017, the MOH has implemented two donor-supported pilot programs of limited scope (each program covering 1,000 patients with chronic condition), providing HCV patients with free medicine. However, large scale interventions for reducing the burden of viral hepatitis cannot rely on external funding in the long-term perspective.

Starting 2019, the Government of Armenia (GOA) has embarked on expanding health coverage and improving the financial risk protection of the population by allocating additional funding from the public budget for the Basic Benefits Package (BBP) services. According to the 2020-2022 Medium-Term Expenditure Framework (MTEF), public spending for health will increase

by 15.6% in 2022 to 126.4 billion Armenian drams (AMD), compared to the approved health budget of 2020 (109.3 billion AMD).[12] One of the new BBP programs, which will be implemented starting May 2020, will cover provision of free pan-genotype medicine (combined Sofosbuvir/Daclatasvir therapy) for patients with HCV (hereinafter referred to as the Program).

2.4 The Program for expanded BBP coverage of Hepatitis C treatment in Armenia

The Program will initially cover around 1,000 chronic HCV patients for the first year (2020), aiming at gradual expansion over the next years, depending on availability of additional funds from public budget. According to the draft MOH guidelines, the Program will cover both the preliminary diagnostic tests, including PCR, ultrasound, blood tests, and provision of the combined Sofosbuvir 400mg/Daclatasvir 60mg therapy. To be covered by the Program, patients should be above 18 years of age, diagnosed with chronic HCV condition, and have liver fibrosis stage 0 to 4. The exclusion criteria for the Program include decompensated liver cirrhosis, hepatocellular carcinoma, having Hepatitis B infection, being pregnant or breastfeeding , and having some other health conditions.[13] Eligible patients will be further prioritized based on their specific medical conditions and social status (i.e. affiliation with socially vulnerable groups of population).

Depending on the HCV genotype and stage of the disease, patients will receive either 12- or 24-weeks treatment course. Patients with genotype 3 and liver fibrosis of stage 4 will receive 24 weeks treatment course, while all other HCV patients, i.e. those with genotypes 1, 2, 3 and 4 with liver fibrosis up to stage 3 inclusive, will receive 12 weeks treatment course. Upon their enrollment into the Program, patients will provide written consent for follow-up monitoring to assess the treatment results and effectiveness.

2.5 Goal and objectives of the program evaluation

The overall goal of the proposed study is to assess patient experience with the Program during the first year of its implementation (2020) in order to provide findings and recommendations that can inform MOH actions for improving the organization and management of the Program (and other similar interventions) in the future. The objective of the study is to assess and describe the concept of patient experience, and its association with demographic and socio-economic characteristics of patients, self-reported health-related indicators, and health care providers' characteristics.

2.6 Research question

The research question is "Explore the association between patient experience (measured by a score) among the HCV patients receiving Sofosbuvir/Daclatasvir therapy in Armenia and the following patient level and organizational factors:

i. demographic and socio-economic characteristic of respondents (age, gender, education level, place of residence, marital and employment status, and family expenses),
ii. health-related indicators (self-rated health status, duration of the treatment course based on the HCV genotype and stage of the disease),
iii. types of health care providers (Yerevan-based vs. regional facilities, public vs. private facilities)."

3. Literature Review

3.1 Challenges of financial risk protection of patients in Armenia

Achieving Universal Health Coverage (UHC) is a global health policy priority, which requires increasing pre-paid funding either from general government revenues or through earmarked health taxes and/or insurance premiums.[14] However, in most of low- and middle-income countries this still remains a challenge, due to low prioritization of health, limited public capacity to tackle the informal sector, and overall economic situation.[15,16]

According to the most recent National Health Accounts report of Armenia, published in 2020, public spending on health as a share of the Gross Domestic Product (GDP) was just 1.3%, and the per capita annual health expenditure was 419.7 USD in 2018.[17] Armenia had one of the highest rates of out-of-pocket (OOP) expenditures as a share of total health expenditures (THE) in the world (84.0%), from which 37.7% were the households spending on outpatient medicine in 2018.[17] Therefore, expanded coverage of outpatient pharmaceuticals is key to improving the financial risk protection of the population in Armenia.

3.2 Direct-acting antiviral treatment of Hepatitis C

For the treatment of HCV, the WHO recommends therapy with pan-genotypic direct-acting antivirals (DAAs), which remain expensive in most countries.[18] Access to modern HCV medicine for many patients globally is limited due to financial barriers.[19] According to WHO's updated 2018 guidelines, the DAA therapy has a potential to cure most patients infected with HCV.[18] The treatment duration is short (usually 12 to 24 weeks), depending on the absence or presence of cirrhosis. The evidence from a number of studies demonstrates that DAAs have drastically improved the treatment outcome of HCV infection over the last years, and that all-oral combination therapy (i.e. the treatment which provides only orally administered medicine and does not involve any injections) is the most desirable option for patients with chronic HCV

infection.[20,21,22] Results from clinical studies regarding the combination of sofosbuvir (a nucleotide polymerase inhibitor) and daclatasvir, a first-in-class NS5A replication complex inhibitor, suggest that it is one of the most effective antiviral therapies, which, when administered orally once a day, demonstrates "low pill burden, good tolerability, and limited drug–drug interactions, in addition to high antiviral potency with 90% sustained virologic response rates".[23] Thus, the intervention strategy selected by the MOH can be considered as following the best international evidence-based practice.

3.3 Assessment of health policy interventions and patient experience

Health care policies, including the new Government initiatives for expanded population coverage require timely monitoring and evaluation to assess their actual impact on accessibility and quality of health care services.[24] It is recommended that the public agencies responsible for health policy evaluate the changes to the delivery and organization of health services before they are implemented nationwide, however, in most of the countries this sequence is rarely followed.[25] Thus, timely evaluation of quality of new BBP services for HCV treatment through assessment of patient experience can further inform MOH policy decisions with evidence-based data and recommendations.

Over the last decade, increased attention has been paid on the assessment of patient experience, which was prompted by several studies and surveys, underlining the role of patient's perspective in measuring the quality of provided health care services.[26,27] A recent systematic review summarizing the data from 55 studies suggests consistent positive associations between patient experience, patient safety and clinical effectiveness across a wide range of diseases, settings, outcome measures and study designs.[28] Defining patient experience can be professionally challenging, though, as it is a complex concept that covers cross-cutting aspects of patient-provider interactions, including satisfaction, engagement, perceptions, and preferences.[29] One of

the global leaders on improving the patient experience in health care, The Beryl Institute, provides the following definition of patient experience: "the sum of all interactions, shaped by an organization's culture, that influence patient perceptions across the continuum of care."[30] Patient experience is not the same as patient satisfaction, although these concepts are still often used interchangeably. While patient satisfaction mainly addresses the extent to which the expectations of the patient were met, patient experience is measured through surveys, which ask patients (or in some cases their families) about their overall experiences with their health care providers.[29] They consider patients' perception of the key aspects of their care (rather than their satisfaction with it), including communication with the medical personnel, understanding their professional instructions, and coordination of their healthcare services.[27] Patient satisfaction is also identified as one of two manifestations of patient experience, the other one being the patient engagement.[31]

Commonly used instruments for measuring patient experience include PROMs (patient-reported outcome measures) and PREMs (patient-reported experience measures), which are questionnaires for assessment of patients' understanding of their health status and their perceptions of their experience whilst receiving care, respectively.[32] The information collected from PROMs and PREMs are used for different purposes, including health services research, improvement of service quality, and for cost-effectiveness evaluations.[33]

While the studies of links between patient experience and clinical safety and effectiveness suggest consistent positive associations between them, the association between health care quality and cost is not always conclusive or consistent, as most studies on this subject have found a small to moderate association between cost and quality, regardless of whether the direction was

positive or negative.[28,34] This indicates that higher costs of service delivery do not necessarily result in improved quality of care, and can also lead to waste of resources.

3.4 Key determinants of patient experience

Patient experience is often defined as a "complex multidimensional phenomenon", which is linked to constructs that can also be challenging to conceptualize, such as patient-centeredness, patient expectations and patient satisfaction.[31] Therefore, literature review provides variety of views on the key determinants of patient experience and on their prioritization. Main factors that are usually mentioned as influencing patient satisfaction include access to care (including waiting times), different parameters of health facilities, and interactions between the patient and providers of care.[35] A systematic review of studies on this subject suggests that health care service quality indicators have the strongest influence among determinants of patient satisfaction, while health providers' interpersonal care quality is considered as one of the most essential.[36] Other factors that impact patient experience include "feeling understood" by providers of care, convenience and clinical atmosphere at the facility, patient-centered integrated care, and transparency of decision making regarding treatment.[38]

An evidence from a cross-sectional survey of 1,379 cancer patients in nine ambulatory cancer clinics in Canada suggests that patient related factors (self-assessed health status, age, and education level) and organizational characteristics (academic affiliation and geographic location of the clinic) had significant association with patient experience.[37]

5. Methods

5.1 Study design

The proposed evaluation will be conducted utilizing a cross-sectional, pre-experimental one-shot study design. There will be no baseline measurement, as the intervention (Sofosbuvir/ Daclatasvir therapy) is a new type of HCV treatment that was not widely used in Armenia before. This proposal is about evaluation of the Program that is planned to start in June 2020 without leaving time for any baseline measurement.

5.2 Study variables and measurement

The main outcome variable of interest is patient experience, which will be measured through a set of 13 questions on most recent patient experience related to HCV treatment with five-point Likert scale answer options for each question. The questions on patient experience are adapted from the Generic Short Patient Experience Questionnaire (GS-PEQ), which was developed in Norway, based on the assessment of six different validated study instruments.[39] Some of the questions were re-phrased to be better adapted to the local context.

Independent variables of the study include: socio-demographic characteristics of patients (age, gender, residential area, education level, marital status, employment status and average income level), health-related characteristics of patients (self-rated health status, duration of the HCV treatment course) and characteristics of health care provider facilities in which the patients has received the treatment (location and ownership status). Four questions measure the demographic and socio-economic characteristics, and they are adapted from study instruments developed by the Avedisian Onanian Center for Health Services Research and Development (CHSR) of AUA and used in previous studies in Armenia.[40,41] Study instrument includes one question on

respondents' self-reported current health status, which is adapted from the 36-item Short Form Health Survey (SF-36) questionnaire.[42]

Table 2 presents the list of variables, their types, and sources.

5.3 Strengths and limitations

The Program evaluation will be the first in Armenia to address the patient experience with expanded BBP coverage for provision of outpatient pharmaceuticals, which can set a precedent for the MOH to conduct similar studies in the future for evaluation of health policy measures. Other strengths of the study are associated with the suggested cross-sectional study design, including:

- large sample size (48% of all patients who will undergo BBP-covered treatment of HCV in 2020 in Armenia, will be interviewed during the telephone survey) resulting in high precision of estimates,
- utilization of validated study instruments, which are adapted from instruments used in previous research in both Armenia and abroad,
- relatively lost costs and simplified logistics of the study.

Potential weaknesses are also inherent to the selected study design, as cross-sectional studies are susceptible to biases such as non-response bias, recall bias, interviewer bias and social desirability bias. However, the risk of recall bias will be minimized as the patients will be contacted for interview within two weeks period after completing or quitting the treatment. Social desirability bias will be partially addressed through conducting a telephone survey instead of face to face interviews. Interviewer bias will be minimized by selection of experienced organization for conducting the study and by proper training of interviewers, who will strictly follow the provided script for telephone interview.

5.4 Threats to Internal Validity

History can be a threat to internal validity, as the study will take 15 months to complete, from which the data collection (telephone interviews) will be conducted over a 10-month period (see Appendix 1 for the schedule of activities). During this period other processes can be going on in the health system, which can affect certain performance parameters of health care providers, and therefore also influence the patients' experience. *Maturation* is not a threat, as it is unlikely that any systematic changes in study population can take place during the study period. *Testing* is not a threat for this study design, since there will be no baseline survey conducted. *Instrumentation* is not a threat, since the telephone survey will be conducted using a validated and pre-tested questionnaire, which will be administered by the same team of trained interviewers. *Statistical Regression* is not a threat, as the selection of the sample population is not linked to any outlying characteristics related to the outcome variable. *Selection* is not a threat, as only one group is included in the study. *Experimental mortality (attrition)* is not a threat due to the study design, as it will be a single-shot telephone survey, excluding the possibility for differential "drop-outs". *Compensatory rivalry* is not a threat, as there will be no control group, so there is no risk for the study participants trying to outperform the other group. *Selection-maturation, selection-history and selection-testing interactions* should not be considered as threats as the selection is not a threat to internal validity.

5.5 Threats to External Validity

Testing-Intervention Interaction Effect is not a threat, as there will be no pre-test (baseline measurement) conducted before the telephone survey. However, it can affect the generalizability of the study results as patient experience surveys in different settings may include a baseline measurement. *Selection-Intervention Interaction Effect* is a potential threat, as this sample of HCV patients may not be necessarily representative of all other HCV patients in other countries

or settings, so it can compromise the generalizability of the study results. *Reactive effects/Experimental Arrangements* is a threat as well, as the participants behavior may be influenced by the evaluation itself, therefore, evaluation outcomes may not be fully generalized for other settings where a similar intervention is implemented without evaluation. *Multiple Intervention Interference* is always present as a threat, since it is impossible to guarantee that in the real world there will be no other interventions happening at the same time in different settings.

6. Setting

6.1 Sampling

The target population of the study includes adult patients with chronic HCV condition (18 years of age and above), living in Armenia. Inclusion criteria will be the following: being adult patients (18 and above) who have started the Sofosbuvir/Daclatasvir therapy in 2020 while living in Armenia; speaking Armenian; and having a valid telephone number.

The sampling frame will be the list of BBP-covered HCV patients who have started the Sofosbuvir/Daclatasvir therapy under the BBP coverage in Armenia during 2020, and either completed the full course (either 12- or 24-weeks) or have quitted it. The sampling frame will be obtained from the database of all known patients with HCV in Armenia, which is maintained by the NCDCP. The database contains basic demographic and contact information of HCV patients and is periodically updated. The study sample will be identified by contacting all eligible patients from the sampling frame until the sample size is reached. It is suggested that the NCDCP staff will provide weekly updates to the study research team about the patients who had either completed their treatment course or quitted it during the previous week. The patients will then be contacted by phone within two weeks period for the survey, which will help to minimize the recall bias. Refusals to participate or non-responses will be accounted for, and the procedure will be repeated until the sample size of 481 patients is reached (see below).

6.2 Sample size

The estimated sample size of the study is calculated with the formula for one sample mean, and is further adjusted for the finite population correction factor, taking into account the relatively small size of the target population (i.e. the number of patients with chronic HCV condition in Armenia):[43]

$$n= (z\sigma/e)^2$$

where:

- n is the estimated sample size

- z is the standard error associated with confidence interval

- σ is the estimated standard deviation

- e is the desired margin of error (precision).

Based on the available evidence from previously conducted studies, the estimated sample size for the current study is calculated based on the following estimates:[44,45]

z = 1.96 for two-tailed, 95% confidence interval analysis

σ = standard deviation of the patient experience score = 0.9

e= desired precision (7%) = 0.07

n= 3.84*0.81/ 0.0049 = 635

Adjusting the sample size with the finite population correction factor:

$$n_{adj} = n/(1+(n-1)/N)$$

where:

n = computed sample size

N = size of the target population

Based on the NSDCP data (see Table 1), we get the following adjusted sample size:

n_{adj} = 635/(1+(635-1)/1,999) = 481

The patients included in the study will be geographically spread over all regions of Armenia and will receive their treatment in outpatient settings. Therefore, it is suggested to conduct a telephone survey due to logistical considerations and in order to minimize the project costs.[47] Evidence from previous studies suggest that telephone surveys for assessment of patient experience can also reduce the social desirability bias.[48,49]

Survey participants will be identified from the list of HCV patients in NCDCP database, which will provide patients' contact details (name and telephone number). The telephone interview will follow the provided script to identify the sampled patient, who will then be provided with the informed consent form. In case the patient agrees to participate in the study, the interviewer will administer the questionnaire by phone. Telephone interviews will be conducted with use of mobile phones to enable greater flexibility to reach the sample population. Using mobile phones instead of fixed landline phone will also reduce the costs of conducting the study, as interviewers will be provided with three pre-paid mobile numbers (one for each mobile operator in Armenia) with unlimited call time within the respective network.

7. Sources of Data

The information will be collected through a telephone survey. The suggested study instrument is a structured, interviewer-administered questionnaire. To ensure that the sampling frame is used properly, and to record the result of each attempt made to reach the selected patients, the study team will use a journal form, which will also contain the available information obtained from the sampling frame on several study variables for their reference (see below).

The telephone interview script is adapted from survey instruments used for Hospital Consumer Assessment of Healthcare Providers and Systems by the Centers for Medicare and Medicaid Services (CMS), United States Department of Health and Human Services.[50] The study instruments (the questionnaire, the informed consent form, the telephone script and the journal form) are provided in Appendixes 2-8.

The following six (out of 11) independent variables are not included in the questionnaire, as the information can be obtained from the HCV patients' database through completing the journal form. The following variables will be collected before the telephone survey:

1. patient's age
2. patient's gender
3. patient's place of residence
4. duration of the treatment course
5. location of health care provider
6. ownership status of health care provider.

The information on other five independent variables will be obtained during the telephone survey (these are the items included in the questionnaire):

1. self-rated health status

2. education level
3. marital status
4. employment status
5. average monthly family expenditure.

The Armenian version of the study instruments will be shared with the MOH for feedback and comments. Study instruments will be pre-tested before the telephone survey to ensure that questionnaire flow is smooth, the questions are clear and response categories are adequate for the survey population, and that translation is accurate. To provide the interviewers with the skills necessary to successfully conduct the survey, a two-day interviewer training will be conducted. Double data entry will be done to minimize the possible effect of random errors.[51]

8. Analysis

The study data will be entered into SPSS software package (version 23.0 or higher). The STATA software package (version 15.0 or higher) will be utilized for statistical analysis.

In case of 10% or more missing data in any of the variables, regression imputation techniques will be used to substitute the missing data. Descriptive statistics will be used for summarizing the data (means and standard deviations for continuous variables and proportions for categorical variables). For analyzing the associations between the continuous outcome variable (patient experience score) and the independent variables of interest (socio-demographic and health-related characteristics of patients, and characteristics of health care provider) regression analysis will be performed. Assumptions for regression analysis will be checked using appropriate tests for linear relationship, independence, homoscedasticity, and normality.

To understand whether selection bias may be considered a study limitation, socio-demographic characteristics of those who refuse to participate will be compared to the study participants, in order to assess whether they significantly differ from each other. The response rate will be calculated at the end of the telephone survey, based on the information from the journal form.

The mean patient experience score of those who completed the full course of the treatment will be compared to the mean score of the patients who quitted the treatment to analyze the potential association between the patient experience and the decision not to complete the treatment.

9. Logistical Considerations

9.1 Schedule of Activities

The first step for implementing the suggested Program evaluation will be obtaining the endorsement of the project from the MOH in order to get access to the HCV patient database. The initial (preparatory) stage of the project, which will also include training of interviewers and pre-testing of the study instruments, can be completed by August 2020. The pre-test stage will include 10 to15 telephone interviews with the first patients completing the treatment under the Program in September 2020. The full-scale start of the Program evaluation (i.e. the telephone survey) is planned to start in October 2020, i.e. when the first HCV patients will be completing their treatment course, and will last for eight months, until May 2021. Data entry and analysis will be done in parallel with data collection. The survey will continue into 2021 until reaching the sample size, i.e. it will also cover the HCV patients who will complete their treatment course, started at the end of 2020, in the first half of 2021. The overall duration of the study (i.e. the Program evaluation) is expected to be 14 months, i.e. from June 2020 to July 2021. The final stage of the project will be data analysis and reporting, including publishing and disseminating the study findings and discussing them with the key stakeholders. Suggested schedule of activities is provided in Appendix 1.

9.2 Budget

The total budget is estimated to be 8,640,000 AMD to conduct the study. Given the suggested study design and timeline, it is assumed that a team of three researchers will be required to conduct the Program evaluation, including a part-time principal investigator/project coordinator, and two part-time interviewers/data analysts. The estimated break-down of costs are provided in Appendix 9.

10. Ethical Considerations

The study protocol was reviewed by the Institutional Review Board (IRB) of the American University of Armenia (AUA) and was confirmed to comply with locally and internationally accepted ethical standards. All participants of the telephone survey will be informed about their rights, i.e. that the participation is voluntary, they could stop at any time and refuse to answer any question they chose, and their confidentiality will be fully respected. After being informed of their rights, all those who chose to participate will be provided with verbal informed consent. The final report will not contain names, phone numbers or other personal information of the respondents or any other details that could identify the participants.

After completion of the telephone survey, spot checks will be conducted to cover at least 10% of the respondents to ensure the quality of the evaluation and to make sure that all ethical norms have been properly followed.

In order to secure proper data management, the completed questionnaires will be stored in a safe location until the final study report will be completed and disseminated. Electronic data (i.e. SPSS databases and STATA log files, tables, graphs etc.) will be stored following the 3-2-1 backup rule, i.e. three copies will be maintained on two different types of storage media with one offsite copy.

The journal forms, which will be the only identifiable data source, will be centrally stored in a safe location during the study period (accessible only to the research team) and will be physically destroyed within one month period after completion of the study and dissemination of the final report by shredding.

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TABLES

Table 1. Data on HCV Patients in Armenia (as of November 2019)

Age	Total	Diagnosis		
		Antibodies to HCV	Acute HCV	Chronic HCV patients
Below 17	22	7	0	15
17-50	2,286	1,361	3	922
51-60	1,500	898	0	602
61-70	856	565	0	291
71-80	324	244	0	80
81 and above	95	83	0	12
Unknown	135	58	0	77
TOTAL n,	**5,218**	**3,216**	**3**	**1,999**
%	**100%**	**61.6%**	**0.1%**	**38.3%**

Source: National Center for Disease Control and Prevention, Ministry of Health, Armenia

Table 2. Variable Types and Sources

Variable		Type	Source
Dependent variable			
Patient experience		Continuous	Telephone survey
Independent variables			
Socio-demographic characteristics	Age	Continuous	Patients' database
	Gender	Binary	Patients' database
	Residential area	Categorical	Patients' database
	Education level	Ordinal	Telephone survey
	Marital status	Categorical	Telephone survey
	Employment status	Categorical	Telephone survey
	Average monthly expenses	Ordinal	Telephone survey
Health-related characteristics	Self-rated health status	Ordinal	Telephone survey
	HCV treatment course	Binary	Patients' database

Health care provider's characteristics	Location of facility	Binary	Patients' database
	Ownership status of facility	Binary	Patients' database

APPENDICES

Appendix 1: Schedule of Activities

Activities	Year / Month													
	2020							2021						
	June	July	Aug	Sep	Oct	Nov	Dec	Jan	Feb	March	April	May	June	July
MOH Program timeline														
Program Evaluation timeline, including:														
Finalization of study instrument														
IRB approval														
Interviewer training														
Pre-testing of study instruments														
Data collection (telephone survey)														
Data entry and analysis														
Final report preparation and dissemination														

Appendix 2: Questionnaire (English version)

Questionnaire for Telephone Survey

For Assessment of Patients' Experience

with Hepatitis C Treatment in Armenia

Interviewer ID _____ Interview N _____

Interview date _____ (DD/MM/YYYY)

Interview start time _____ (hours:minutes) Interview end time _____ (hours:minutes)

A. Current Health Status

A1. In general, how would you rate your overall health? Would you say that it is …

1. ☐ Excellent
2. ☐ Very good
3. ☐ Good
4. ☐ Fair
5. ☐ Poor

77. ☐ Don't know/No answer

B. Patient Experience with Hepatitis C Treatment

B1. During your treatment, did the doctors talk to you in a way that was easy to understand?

1. ☐ Not at all
2. ☐ To a small extent
3. ☐ To a moderate extent
4. ☐ To a large extent
5. ☐ To a very large extent

77. ☐ Don't know/No answer

B2. Do you have confidence in the doctors' professional skills?

1. ☐ Not at all
2. ☐ To a small extent

3. ☐ To a moderate extent
4. ☐ To a large extent
5. ☐ To a very large extent
77. ☐ Don't know/No answer

B3. During your treatment, did the nurses talk to you in a way that was easy to understand?

1. ☐ Not at all
2. ☐ To a small extent
3. ☐ To a moderate extent
4. ☐ To a large extent
5. ☐ To a very large extent
77. ☐ Don't know/No answer

B4. Do you have confidence in the nurses' professional skills?

1. ☐ Not at all
2. ☐ To a small extent
3. ☐ To a moderate extent
4. ☐ To a large extent
5. ☐ To a very large extent
77. ☐ Don't know/No answer

B5. Did you get sufficient information about your diagnosis/ health problems?

1. ☐ Not at all
2. ☐ To a small extent
3. ☐ To a moderate extent
4. ☐ To a large extent
5. ☐ To a very large extent
77. ☐ Don't know/No answer

B6. Did you perceive the treatment as adapted to your situation?

1. ☐ Not at all
2. ☐ To a small extent

3. ☐ To a moderate extent
4. ☐ To a large extent
5. ☐ To a very large extent
77. ☐ Don't know/No answer

B7. Were you involved in decisions regarding your treatment?

1. ☐ Not at all
2. ☐ To a small extent
3. ☐ To a moderate extent
4. ☐ To a large extent
5. ☐ To a very large extent
77. ☐ Don't know/No answer

B8. Did you perceive the health facility's work as well organized?

1. ☐ Not at all
2. ☐ To a small extent
3. ☐ To a moderate extent
4. ☐ To a large extent
5. ☐ To a very large extent
77. ☐ Don't know/No answer

B9. Did you have to wait before you were admitted for services at the health facility?

1. ☐ Not at all
2. ☐ To a small extent
3. ☐ To a moderate extent
4. ☐ To a large extent
5. ☐ To a very large extent
77. ☐ Don't know/No answer

B10. Did you get the impression that the health facility conditions were in good order?

1. ☐ Not at all
2. ☐ To a small extent

3. ☐ To a moderate extent
4. ☐ To a large extent
5. ☐ To a very large extent
77. ☐ Don't know/No answer

B11. Overall, was the treatment you received at the health facility satisfactory?

1. ☐ Not at all
2. ☐ To a small extent
3. ☐ To a moderate extent
4. ☐ To a large extent
5. ☐ To a very large extent
77. ☐ Don't know/No answer

B12. Overall, did you benefit from the care at the health facility?

1. ☐ Not at all
2. ☐ To a small extent
3. ☐ To a moderate extent
4. ☐ To a large extent
5. ☐ To a very large extent
77. ☐ Don't know/No answer

B13. Do you believe that you were in any way given incorrect treatment (according to your own judgment)?

1. ☐ Not at all
2. ☐ To a small extent
3. ☐ To a moderate extent
4. ☐ To a large extent
5. ☐ To a very large extent
77. ☐ Don't know/No answer

C. Demographic and Socio-Economic Status Questions

C1. What is your marital status?

1. ☐ Single
2. ☐ Married
3. ☐ Separated/Divorced
4. ☐ Widowed
77. ☐ No answer

C2. Please indicate highest level of education that you have received:

1. ☐ Secondary school (less than 10 years)
2. ☐ High school completed (10-12 years)
3. ☐ Professional technical education
4. ☐ Institute/University
5. ☐ Post-graduate education
77. ☐ No answer

C3. Are you employed?

1. ☐ Yes
2. ☐ Yes, but on maternity/pregnancy leave
3. ☐ No
4. ☐ Self-employed
5. ☐ Seasonal worker or farmer
6. Student
7. Retired
8. Other *(specify)* _____

C4. On average, how much money does your family spend monthly?

1. ☐ Less than 100,000 AMD
2. ☐ 101,000 to 200,000 AMD
3. ☐ 201,000 to 300,000 AMD
4. ☐ 301,000 to 400,000 AMD
5. ☐ Above 401,000 AMD
6. ☐ Don't know / Don't want to answer

Appendix 3: Questionnaire (Armenian version)

Հեռախոսային հարցման հարցաթերթիկ

Հայաստանում հեպատիտ C-ի բուժման հետ կապված պացիենտների փորձի գնահատման համար

Հարցազրուցավարի ID _____ Հարցազրույցի N _____

Հարցազրույցի ամսաթիվը _____ (օրը/ամիսը/տարին)

Հարցազրույցի սկիզբը _____ (ժամ,րոպե) Հարցազրույցի ավարտը _____ (ժամ, րոպե)

D. Ներկա առողջական վիճակը

A1. Ընդհանուր առմամբ, ինչպե՞ս Դուք կգնահատեիք Ձեր առողջական վիճակը: Ձեր կարծիքով այն …

5.1 ☐ Գերազանց է

5.2 ☐ Շատ լավ է

5.3 ☐ Լավ է

5.4 ☐ Նորմալ է

5.5 ☐ Վատ է

77. ☐ Չգիտեմ/Պատասխան չունեմ

E. Պացիենտների փորձը Հեպատիտ C-ի բուժման հետ կապված

B1. Ձեր բուժման ընթացքում, որքանո՞վ պարզ և հասկանալի էր խոսում բժիշկը Ձեզ հետ :

1. ☐ Ամենևին
2. ☐ Փոքր չափով
3. ☐ Միջին չափով
4. ☐ Մեծ չափով
5. ☐ Շատ մեծ չափով

77. ☐ Չգիտեմ/Պատասխան չունեմ

B2. Որքանո՞վ էիք Դուք վստահում բժիշկների մասնագիտական ունակություններին:

1. ☐ Ամենևին
2. ☐ Փոքր չափով
3. ☐ Միջին չափով
4. ☐ Մեծ չափով
5. ☐ Շատ մեծ չափով
77. ☐ Չգիտեմ/Պատասխան չունեմ

B3. Ձեր բուժման ընթացքում, որքանո՞վ պարզ և հասկանալի էր խոսում բուժքույրը Ձեզ հետ :

1. ☐ Ամենևին
2. ☐ Փոքր չափով
3. ☐ Միջին չափով
4. ☐ Մեծ չափով
5. ☐ Շատ մեծ չափով
77. ☐ Չգիտեմ/Պատասխան չունեմ

B4. Որքանո՞վ էիք Դուք վստահում եք բուժքույրերի մասնագիտական ունակություններին:

1. ☐ Ամենևին
2. ☐ Փոքր չափով
3. ☐ Միջին չափով
4. ☐ Մեծ չափով
5. ☐ Շատ մեծ չափով
77. ☐ Չգիտեմ/Պատասխան չունեմ

B5. Որքանո՞վ էիք Դուք իրազեկված Ձեր ախտորոշման / առողջական խնդրի վերաբերյալ:

1. ☐ Ամենևին
2. ☐ Փոքր չափով
3. ☐ Միջին չափով
4. ☐ Մեծ չափով

5. ☐ Շատ մեծ չափով
77. ☐ Չգիտեմ/Պատասխան չունեմ

B6. Ձեր կարծիքով, բուժումը որքանո՞վ էր համապատասխանում Ձեր իրավիճակին:

1. ☐ Ամենևին
2. ☐ Փոքր չափով
3. ☐ Միջին չափով
4. ☐ Մեծ չափով
5. ☐ Շատ մեծ չափով
77. ☐ Չգիտեմ/Պատասխան չունեմ

B7. Դուք որքանո՞վ էիք ներգրավված Ձեր բուժման վերաբերյալ որոշումների կայացման մեջ:

1. ☐ Ամենևին
2. ☐ Փոքր չափով
3. ☐ Միջին չափով
4. ☐ Մեծ չափով
5. ☐ Շատ մեծ չափով
77. ☐ Չգիտեմ/Պատասխան չունեմ

B8. Ձեր կարծիքով, որքանո՞վ լավ էին կազմակերպված բուժհիմնարկի աշխատանքները :

1. ☐ Ամենևին
2. ☐ Փոքր չափով
3. ☐ Միջին չափով
4. ☐ Մեծ չափով
5. ☐ Շատ մեծ չափով
77. ☐ Չգիտեմ/Պատասխան չունեմ

B9. Մինչև բուժհիմնարկում բուժումը սկսելը Դուք որքա՞ն եք ստիպված եղել սպասել:

1. ☐ Ամենևին
2. ☐ Փոքր չափով

3. ☐ Միջին չափով
4. ☐ Մեծ չափով
5. ☐ Շատ մեծ չափով
77. ☐ Չգիտեմ/Պատասխան չունեմ

B10. Ձեր տպավորությամբ, որքանո՞վ էին լավ բուժհիմնարկի պայմանները :

1. ☐ Ամենևին
2. ☐ Փոքր չափով
3. ☐ Միջին չափով
4. ☐ Մեծ չափով
5. ☐ Շատ մեծ չափով
77. ☐ Չգիտեմ/Պատասխան չունեմ

B11. Ընդհանուր առմամբ, Դուք որքանո՞վ եք բավարարված բուժհիմնարկում Ձեր ստացած բուժմամբ:

1. ☐ Ամենևին
2. ☐ Փոքր չափով
3. ☐ Միջին չափով
4. ☐ Մեծ չափով
5. ☐ Շատ մեծ չափով
77. ☐ Չգիտեմ/Պատասխան չունեմ

B12. Ընդհանուր առմամբ, Դուք որքանո՞վ օգուտ ստացաք բուժհիմնարկում ստացած Ձեր բուժումից:

1. ☐ Ամենևին
2. ☐ Փոքր չափով
3. ☐ Միջին չափով
4. ☐ Մեծ չափով
5. ☐ Շատ մեծ չափով
77. ☐ Չգիտեմ/Պատասխան չունեմ

B13. Ըստ Ձեզ, որքանո՞վ էր Ձեր ստացած բուժումը որևէ ձևով ոչ ճիշտ:

1. ☐ Ամենևին
2. ☐ Փոքր չափով
3. ☐ Միջին չափով
4. ☐ Մեծ չափով
5. ☐ Շատ մեծ չափով
77. ☐ Չգիտեմ/Պատասխան չունեմ

F. Ժողովրդագրական և սոցիալ-տնտեսական կարգավիճակին առնչվող հարցեր

C1. Խնդրում եմ նշել Ձեր ամուսնական կարգավիճակը:

1. ☐ Չամուսնացած
2. ☐ Ամուսնացած
3. ☐ Բաժանված
4. ☐ Այրի
77. ☐ Պատասխան չկա

C2. Խնդրում եմ նշել Ձեր ստացած կրթության ամենաբարձր աստիճան:

1. ☐ Միջնակարգ դպրոց (մինչև 10 տարի)
2. ☐ Ավագ դպրոց (10-12 տարի)
3. ☐ Միջնակարգ մասնագիտական կրթություն
4. ☐ Ինստիտուտ/Համալսարան
5. ☐ Հետբուհական կրթություն (մագիստրատուրա, ասպիրանտուրա)
77. ☐ Պատասխան չկա

C3. Դուք աշխատու՞մ եք:

1. Այո
2. Այո, բայց ֆիզարձակուրդում եմ
3. Ոչ
4. Տանն եմ աշխատում
5. Սեզոնային աշխատող եմ կամ հողագործ
6. ՈՒսանող եմ
7. Թոշակառու եմ

8. Այլ *(նշեք)*_____

C4. Միջին հաշվով, որքա՞ն են կազմում Ձեր ընտանիքի ամսական ծախսերը:

1. ☐ Մինչև 100,000 ՀՀ դրամ
2. ☐ 101,000-ից 200,000 ՀՀ դրամ
3. ☐ 201,000-ից 300,000 ՀՀ դրամ
4. ☐ 301,000-ից 400,000 ՀՀ դրամ
5. ☐ 401,000 ՀՀ դրամից ավել
6. ☐ Չգիտեմ/Չեմ ցանկանում պատասխանել

Appendix 4: Consent Form (English version)

INFORMED VERBAL CONSENT FORM

Good morning/afternoon, my name is (NAME OF THE INTERVIEWER), I am calling you on behalf of the Avedisian Onanian Center for Health Services Research and Development of the American University of Armenia, which, in collaboration with the Ministry of Health of Armenia is conducting a study to assess the patient experience with Hepatitis C treatment in Armenia. The aim of the study is improving the quality of medical services for the patients with Hepatitis C.

You are invited to participate in this study since you have received a Sofosbuvir/Daclatasvir therapy during 2020 and thus you have an experience of utilizing Hepatitis C treatment services in Armenia. Your name was provided by the Ministry of Health from the database of the patients with HCV. Please be informed that your name will not be mentioned anywhere. We are not going to put your name or your telephone number on the questionnaire. All the information given by you will stay confidential. Only the summary of the data from all 481 interviews will be presented in the final report of the study. Your participation in this study is voluntary. You may refuse to answer any question during the interview or stop the interview at any time without any negative consequences for you. There is no financial compensation or other personal benefits from participating in the study, but your sincere answers will help to better understand the situation with medical services for treatment of Hepatitis C in Armenia and to develop recommendations to improve their quality and effectiveness. The expected duration of the interview will be approximately 15 to 20 minutes.

If you have any questions or concerns regarding this study, you can contact Dr. Varduhi Petrosyan, the principal investigator of this study, via email, vpetrosi@aua.am, or by phone (060) 61 25 92. If you feel that your rights have been violated or that you have been hurt by

being selected to participate in this study, you can contact the Human Protections Administrator of the American University of Armenia Varduhi Hayrumyan via email:vhayrumyan@aua.am, or by phone (060) 61 25 61.

Do you agree to participate? Thank you! Now we will proceed to the questions.

Appendix 5: Consent Form (Armenian version)

Իրազեկ համաձայնության ձև

Բարև Ձեզ, իմ անունը (ՀԱՐՑԱԶՐՈՒՑԱՎԱՐԻ ԱՆՈՒՆԸ) է, ես զանգում եմ Ձեզ Հայաստանի ամերիկյան համալսարանի Ավետիսեան-Օնանեան առողջապահական ծառայությունների հետազոտման և զարգացման կենտրոնի անունից, որը, Հայաստանի առողջապահության նախարարության հետ համատեղ իրականացնում է հետազոտություն՝ գնահատելու համար Հայաստանում հեպատիտ C-ի բուժման հետ կապված պացիենտների փորձը: Այս հետազոտության նպատակը հեպատիտ C-ի բուժման ծառայությունների որակի բարելավումն է:

Դուք ընդգրկված եք այս հետազոտության մեջ, քանի որ Դուք 2020 թվականի ընթացքում ստացել եք բուժման կուրս Սոֆոսբուվիր/Դակլատասվիր դեղորայքով, հետևաբար Դուք ունեք Հայաստանում հեպատիտ C-ի բուժման ծառայություններից օգտվելու փորձ: Ձեր անունը տրամադրվել է առողջապահության նախարարության կողմից՝ հեպատիտ C-ով պացիենտների տվյալների շտեմարանից: Տեղեկացնում եմ, որ Ձեր անունը որևէ տեղ չի հիշատակվելու: Ոչ Ձեր անունը, ոչ էլ հեռախոսահամարը հարցաթերթիկում չեն նշվելու: Ձեր կողմից տրամադրված տեղեկատվությունը կմնա գաղտնի: Միայն բոլոր 481 հարցազրույցներից ստացված ամփոփ տեղեկատվությունը կներկայացվի հետազոտության վերջնական հաշվետվության մեջ: Ձեր մասնակցությունը այս ուսումնասիրությանը կամավոր է: Դուք կարող եք ցանկացած պահի հրաժարվել որևէ հարցի պատասխանել կամ կարող եք ընդհատել հարցազրույցը և դա չի ունենա որևէ բացասական հետևանք Ձեզ համար: Հետազոտությանը մասնակցելու համար որևէ ֆինանսական փոխհատուցում կամ այլ անձնական շահ նախատեսված չէ, բայց Ձեր անկեղծ պատասխանները կօգնեն ավելի լավ հասկանալ Հայաստանում հեպատիտ C-ի բուժման հետ կապված բուժօգնության ծառայությունների իրավիճակը և մշակել

առաջարկներ դրանց որակը և արդյունավետությունը բարելավելու ուղղությամբ:

Հարցազրույցի ակնկալվող տևողությունը կկազմի 15-ից 20 րոպե:

Եթե Դուք ունեք այս հետազոտության հետ կապված հարցեր կամ մտահոգություններ, կարող եք դիմել հետազոտության ղեկավար Վարդուհի Պետրոսյանին՝ vpetrosi@aua.am էլեկտրոնային փոստի հասցեով կամ (060) 61 25 92 հեռախոսահամարով: Եթե Դուք համարում եք, որ այս հետազոտությանը մասնակցելու համար Ձեզ ընտրելիս Ձեր իրավունքները ոտնահարվել են կամ Ձեզ վնաս է հասցվել, ապա Դուք կարող եք կապվել Հայաստանի ամերիկյան համալսարանի Էթիկայի հանձնաժողովի համակարգող Վարդուհի Հայրումյանին՝ vhayrumyan@aua.am էլեկտրոնային փոստի հասցեով կամ (060) 61 25 61 հեռախոսահամարով:

Դուք համաձա՞յն եք մասնակցել: Ծնորհակալություն: Այժմ մենք կանցնենք հարցերին:

Appendix 6: Telephone Script (English version)

Telephone Script

For Conducting an Interview on Assessment of Patients' Experience with Hepatitis C Treatment in Armenia

Overview

This telephone interview script is provided to assist interviewers while attempting to reach the patient. The script refers to the informed consent form for explaining the purpose of the survey and confirms necessary information about the patient. Interviewers must not conduct the survey with a proxy, but only with the patient himself/herself.

General Interviewing Instructions

- The telephone introduction script and the questions must be read verbatim
- Practice pronouncing the patient's name before initiating the call
- All text that appears in lowercase letters must be read out loud
- Text in UPPERCASE letters must not be read out loud
- All questions and all answer categories must be read exactly as they are worded
- During the survey, the use of **neutral** acknowledgment words such as the following is permitted:
    - Thank you
    - Alright, or Okay
    - I understand, or I see
    - Yes, Madam, or Yes, Sir

- Read the scripts from the interviewer copy to avoid reciting the survey from memory, which can lead to unnecessary errors
- Adjust the pace of the survey interview to be conducive to the needs of the respondent
- No changes are permitted to the order of the questions
- Text that is underlined must be emphasized
- Characters in < > brackets must not be read
- "Don't know / No answer" is a valid response option; however, this option must not be read out loud to the respondent. This response option allows the telephone interviewer to go to the next question if a patient is unable to provide a response for a given question (or refuses to provide a response).

INITIATING CONTACT

START Hello, may I please speak to [SAMPLED PATIENT NAME]?

<1> YES [GO TO INTRO]

<2> NO [REFUSAL]

<3> NO, NOT AVAILABLE RIGHT NOW [SET CALLBACK]

IF ASKED WHO IS CALLING:

This is [INTERVIEWER NAME] calling from [NAME OF THE ORGANIZATION CONDUCTING THE SURVEY]. We are conducting a health survey. Is [SAMPLED PATIENT NAME] available?

IF ASKED WHETHER PERSON CAN SERVE AS PROXY FOR SAMPLED PATIENT:

Sorry, but for this survey, we need to speak directly to [SAMPLED PATIENT NAME]. Is [SAMPLED PATIENT NAME] available?

IF THE SAMPLED PATIENT IS NOT AVAILABLE:

Can you tell me a convenient time to call back to speak with (him/her)?

IF THE SAMPLED PATIENT SAYS THIS IS NOT A GOOD TIME:

If you don't have the time now, when is a more convenient time to call you back?

IF SOMEONE OTHER THAN THE SAMPLED PATIENT ANSWERS THE PHONE RECONFIRM THAT YOU ARE SPEAKING WITH THE SAMPLED PATIENT WHEN HE OR SHE PICKS UP.

CALL BACK TO COMPLETE A PREVIOUSLY STARTED SURVEY

START: Hello, may I please speak to [SAMPLED PATIENT NAME]?

<1> YES [GO TO CONFIRM PATIENT]

<2> NO [REFUSAL]

<3> NO, NOT AVAILABLE RIGHT NOW [SET CALLBACK]

IF ASKED WHO IS CALLING: This is [INTERVIEWER NAME] calling from [NAME OF THE ORGANIZATION CONDUCTING THE SURVEY]. Is [SAMPLED PATIENT NAME] available to complete a survey that [HE/SHE] started at an earlier date?

CONFIRM PATIENT: This is [INTERVIEWER NAME] calling from [NAME OF THE ORGANIZATION CONDUCTING THE SURVEY]. I would like to confirm that I am speaking with [SAMPLED PATIENT NAME]. I am calling to continue the survey started on an earlier date. CONTINUE SURVEY WHERE PREVIOUSLY LEFT OFF.

INTRO

[READ THE INFORMED CONSENT FORM]

Do you agree to participate in the survey? It should take no more than 20 minutes to complete the interview.

<1> YES [GO TO START THE SURVEY]

<2> NO [REFUSAL: THANK THE RESPONDENT AND END THE CALL]

START THE SURVEY

[PROCEED WITH THE SURVEY QUESTIONNAIRE]

END: Those were all the questions I had. Thank you for your time. Have a good (day/evening).

Appendix 7: Telephone Script (Armenian version)

Հեռախոսային հարցազրույցի ուղեցույց

Հայաստանում հեպատիտ C-ի բուժման հետ կապված պացիենտների փորձի գնահատման համար

Ներածություն

Հեռախոսային հարցազրույցի այս ուղեցույցը տրամադրվում է պացիենտի հետ կապվելու նպատակով հարցազրուցավարին օգնելու համար: Ուղեցույցը հղում է անում իրազեկ համաձայնության ձևին՝ հետազոտության նպատակը պարզաբանելու համար, և հավաստում է պացիենտի մասին անհրաժեշտ տեղեկատվությունը: Հարցազուցավարը պետք է հարցազրույցը անցկացնի միայն պացիենտի, և ոչ թե որևէ այլ՝ նրան փոխարինող անձի հետ:

Հարցազրույցի վարման ընդհանուր ցուցումները

- Հարցազրույցի ներածական ուղեցույցը և հարցերը պետք է ընթերցվեն բառացիորեն
- Նախքան զանգելը փորձեք արտասանել պացիենտի անուն ազգանունը
- Փոքրատառերով գրված տեքստը պետք է ընթերցվի բարձրաձայն
- ՄԵԾԱՏԱՌԵՐՈՎ գրված տեքստը չպետք է ընթերցվի բարձրաձայն
- Բոլոր հարցերը և պատասխանների բոլոր տարբերակները պետք է ընթերցվեն ճիշտ այնպես, ինչպես նրանք ձևակերպված են
- Հարցման ընթացքում թույլ է տրվում օգտագործել նմանօրինակ չեզոք բառեր.
    - Շնորհակալություն / Շնորհակալ եմ
    - Լավ, կամ Շատ լավ
    - Հասկանում եմ, կամ Պարզ է
    - Այո, տիկին, կամ Այո, պարոն

- Կարդացեք տեքստը Ձեր օրինակից և խուսափեք այն հիշողությամբ վերարտադրելուց, ինչը կարող է հանգեցնել ավելորդ սխալների
- Հարցազրույցի տեմպը հարմարեցրեք պատասխանողի կարիքներին
- Հարցերի հերթականությունը չի կարող փոփոխվել
- Ընդգծված տեքստը պետք է շեշտադրվի
- < > փակագծերում նշվածը չպետք է ընթերցվի
- "Չգիտեմ / Պատասխան չունեմ"-ը պատասխանի հնարավոր տարբերակ է, սակայն այս տարբերակը չպետք է բարձրաձայն ընթերցվի պատասխանողի համար: Պատասխանի այս տարբերակը թույլ է տալիս հարցազրուցավարին անցնել հաջորդ հարցին, եթե պացիենտը չի կարողանում տվյալ հարցի համար որևէ պատասխանի տարբերակ տալ (կամ հրաժարվում է պատասխանելուց):

ՍԿԶԲՆԱԿԱՆ ԿՈՆՏԱԿՏԸ

ՍԿԻԶԲ Բարև Ձեզ, կարո՞ղ եմ ես խոսել [ԸՆՏՐՎԱԾ ՊԱՑԻԵՆՏԻ ԱՆՈՒՆԸ] հետ:

<1> ԱՅՈ [ԱՆՑՆԵԼ ՆԵՐԿԱՅԱՑՄԱՆԸ]

<2> ՈՉ [ՄԵՐԺՈՒՄ]

<3> ՈՉ, ԱՅՍ ՊԱՀԻՆ ՆԱ ՀԱՍԱՆԵԼԻ ՉԷ [ՊԱՑՄԱՆԱՎՈՐՎԵՔ ՀԵՏ ՁԱՆԳԵԼՈՒ ՄԱՍԻՆ]

ԵԹԵ ՀԱՐՑՆՈՒՄ ԵՆ ՈՎ Է ՁԱՆԳՈՒՄ.

Ձեզ զանգահարում է [ՀԱՐՑԱԶՐՈՒՑԱՎԱՐԻ ԱՆՈՒՆԸ] [ՀԵՏԱԶՈՏՈՒԹՅՈՒՆԸ ԻՐԱԿԱՆԱՑՆՈՂ ԿԱԶՄԱԿԵՐՊՈՒԹՅԱՆ ԱՆՈՒՆԸ]-ից: Մենք իրականացնում ենք առողջապահական հարցում : [ԸՆՏՐՎԱԾ ՊԱՑԻԵՆՏԻ ԱՆՈՒՆԸ]-ի հետ կարո՞ղ եմ խոսել:

ԵԹԵ ՀԱՐՑՆՈՒՄ ԵՆ, ԹԵ ԿԱՐՈՂ ԵՆ ԱՐԴՅՈՔ ԻՐԵՆՔ ՊԱՏԱՍԽԱՆԵԼ ԸՆՏՐՎԱԾ ՊԱՑԻԵՆՏԻ ՓՈԽԱՐԵՆ.

Կներեք, բայց այս հարցման համար մենք պետք է խոսենք հենց [ԸՆՏՐՎԱԾ ՊԱՑԻԵՆՏԻ ԱՆՈՒՆԸ] հետ: Նա կարո՞ղ է մոտենալ հեռախոսին:

ԵԹԵ ԸՆՏՐՎԱԾ ՊԱՑԻԵՆՏԻ ՀԵՏ ՀՆԱՐԱՎՈՐ ՉԷ ԽՈՍԵԼ.

Կարո՞ղ եք Դուք ինձ ասել, թե որ հարմար ժամին կարող եմ հետ զանգել նրա հետ խոսելու համար:

ԵԹԵ ԸՆՏՐՎԱԾ ՊԱՑԻԵՆՏԸ ԱՍՈՒՄ Է, ԱՅԴ ՊԱՀԻՆ ՆՐԱՆ ՀԱՐՄԱՐ ՉԷ ԽՈՍԵԼ.

Եթե Դուք այս պահին ժամանակ չունեք, ե՞րբ կարող եմ Ձեր համար ավելի հարմար պահի հետ զանգել:

ԵԹԵ ՍԿԶԲՈՒՄ ԸՆՏՐՎԱԾ ՊԱՑԻԵՆՏԻՑ ԲԱՑԻ ՄԵԿ ՈՒՐԻՇՆ Է ՊԱՏԱՍԽԱՆՈՒՄ ՁԱՆԳԻՆ, ՎԵՐԱՀԱՍՏԱՏԵՔ ՈՐ ԴՈՒՔ ԽՈՍՈՒՄ ԵՔ ԸՆՏՐՎԱԾ ՊԱՑԻԵՆՏԻ ՀԵՏ, ԵՐԲ ՆԱ ԿՎԵՐՑՆԻ ՀԵՌԱԽՈՍԸ:

ՀԵՏ ՁԱՆԳ ԱՎԵԼԻ ՎԱՂ ՍԿՍԱԾ ՀԱՐՑԱՁՐՈՒՅՑԸ ԱՎԱՐՏԻՆ ՀԱՍՑՆԵԼՈՒ ՀԱՄԱՐ

ՍԿԻՁԲ. Բարև Ձեզ, կարո՞ղ եմ խոսել [ԸՆՏՐՎԱԾ ՊԱՑԻԵՆՏԻ ԱՆՈՒՆԸ]-ի հետ:

<1> ԱՅՈ [ԱՆՑԵՔ ՊԱՑԻԵՆՏԻ ՀԱՎԱՍՏՄԱՆԸ]

<2> ՈՉ [ՄԵՐԺՈՒՄ]

<3> ՈՉ, ԱՅՍ ՊԱՀԻՆ ՆԱ ՀԱՍԱՆԵԼԻ ՉԷ [ՊԱՅՄԱՆԱՎՈՐՎԵՔ ՀԵՏ ՁԱՆԳԵԼՈՒ ՄԱՍԻՆ]

ԵԹԵ ՀԱՐՑՆՈՒՄ ԵՆ, ԹԵ ՈՎ Է ՁԱՆԳՈՒՄ. Ձեզ զանգահարում է [ՀԱՐՑԱՁՐՈՒՅԱՎԱՐԻ ԱՆՈՒՆԸ] [ՀԵՏԱՁՈՏՈՒԹՅՈՒՆԸ ԻՐԱԿԱՆԱՑՆՈՂ ԿԱԶՄԱԿԵՐՊՈՒԹՅԱՆ ԱՆՈՒՆԸ]-ից: [ԸՆՏՐՎԱԾ ՊԱՑԻԵՆՏԻ ԱՆՈՒՆԸ] կարո՞ղ է ավարտին հասցնել ավելի վաղ սկսած հարցազրույցը:

ՊԱՑԻԵՆՏԻ ՀԱՎԱՍՏՈՒՄԸ. Ձեզ զանգահարում է [ՀԱՐՑԱԶՐՈՒՑԱՎԱՐԻ ԱՆՈՒՆԸ] [ՀԵՏԱԶՈՏՈՒԹՅՈՒՆԸ ԻՐԱԿԱՆԱՑՆՈՂ ԿԱԶՄԱԿԵՐՊՈՒԹՅԱՆ ԱՆՈՒՆԸ]-ից: Ես ցանկանում եմ հավաստիանալ, որ ես խոսում եմ [ԸՆՏՐՎԱԾ ՊԱՑԻԵՆՏԻ ԱՆՈՒՆԸ]-ի հետ: Ես զանգել եմ ավելի վաղ սկսած հարցազրույցը ավարտին հասցնելու համար: ՇԱՐՈՒՆԱԿԵՔ ՀԱՐՑԱԶՐՈՒՑԸ ՆԱԽԿԻՆՈՒՄ ԿԻՍԱՏ ԹՈՂԱԾ ԿԵՏԻՑ:

ՆԵՐԿԱՑԱՑՈՒՄ

[ԸՆԹԵՐՑԵՔ ԻՐԱՉԵԿ ՀԱՄԱՁԱՅՆՈՒԹՅԱՆ ՁԵՎԸ]

Դուք համաձա՞յն եք մասնակցել հարցմանը: Հարցազրույցի համար կպահանջվի ոչ ավել, քան 20 րոպե ժամանակ:

<1> ԱՅՈ [ԱՆՑՆԵԼ ՀԱՐՑՈՒՄԸ ՍԿՍԵԼՈՒՆ]

<2> ՈՉ [ՄԵՐԺՈՒՄ. ՇՆՈՐՀԱԿԱԼՈՒԹՅՈՒՆ ՀԱՅՏՆԵԼ ՊԱՏԱՍԽԱՆՈՂԻՆ ԵՎ ԱՎԱՐՏԵԼ ԶԱՆԳԸ]

ՍԿՍԵԼ ՀԱՐՑՈՒՄԸ

[ԱՆՑՆԵԼ ՀԱՐՑԱԹԵՐԹԻԿԻ ՀԱՐՑԵՐԸ ԸՆԹԵՐՑԵԼՈՒՆ]

ԱՎԱՐՏ. Ես այլ հարցեր չունեմ, շնորհակալություն Ձեր ժամանակի համար: Ցտեսություն:

Appendix 8: Journal Form

Journal Form

(to be filled for each sampled case)

Before each phone call, fill in the data obtained from HCV patients' database on the Sampled case in the table below.

Interviewer ID _____

	Telephone number (include area code)	Age (number of years completed at last birthday)	Gender (M/F)	Place of residence (check one)			Treatment course in weeks (12/24)	Health Care Provider (tick the appropriate boxes - V)			
				Yerevan	Other cities	Rural		Yerevan	Region	Public	Private
Sampled case											

At the end of each attempt/completed interview choose the result code from the list below and fill in the table.

	Result Code	Interview N (only in case of completed interview)	Notes
Attempt 1			
Attempt 2			
Attempt 3			

Result code

1. Completed interview	5. Call answered by a different person*
2. No such case (wrong name, wrong phone number)	6. Postponed interview*
3. Refusal	7. Incomplete interview*
4. Call not answered*	8. Other *(specify)*_____

** These result codes could require further attempts (up to 3).*

Appendix 9: Budget

Cost Category	Unit Cost (AMD)	Quantity (number of units)	Total Cost (AMD)
Labor Costs (monthly salaries of research team)			
Principal investigator / Program coordinator	400,000	15 months (part-time)	3,000,000
Data Collector / Data Analyst 1	300,000	15 months (part-time)	2,250,000
Data Collector / Data Analyst 2	300,000	15 months (part-time)	2,250,000
Telephone bills			
Mobile phone packages (one from each mobile phone operator, total of three)	5,000	12 months	180,000
			Office Supplies
Paper / Stationery	20,000		20,000
Final report printing	3,000 (per copy)	50 copies	150,000
Other Costs			
Administrative (overhead) costs, including transportation (5% of direct costs)	390,000		390,000
Final report presentation and dissemination workshop (renting of the venue, simultaneous translation, coffee breaks, etc.)	400,000	1	400,000
Total			**8,640,000**