Protocol: Information visualizations to facilitate clinician-patient communication in HIV care: Info Viz HIV

Outline of organizational structure of the multicenter protocol

All recruitment, enrollment, and data collection will take place at Clínica de Familia La Romana, in the Dominican Republic. Samantha Stonbraker, a postdoctoral fellow at Columbia University and co-investigator on this study, will be on-site throughout the course of the study and will be responsible for all administrative duties, subject/data/and site monitoring, and will also facilitate communications and lead all data analysis. Clínica de Familia is in the process of obtaining and FWA number. Once it is obtained, it will be provided to the IRB prior to any study activities beginning.

Samantha Stonbraker, a postdoctoral fellow at Columbia University and co-investigator on this study, will be responsible for reviewing and reporting all adverse events. She will be responsible for training any local study team members to identify and report any adverse events.

Samantha Stonbraker will be in charge of maintaining records of all IRB/ethics committee review and approval of all protocol and consent forms for all collaborating sites for the duration of the study. She will apply for a renewal at least 60 days prior to the end of the approval period at CUMC's IRB. CONABIOS, the ethical review board in the Dominican Republic, does not require renewals for approved protocols.

Samantha Stonbraker will be responsible for all administrative duties, subject/data/site monitoring, facilitating communication, and data analysis. She is working on this study as part of an NIH funded career development award and will be monitored closely by her mentoring team who are all indicated as co-investigators on this study.

Provide a description of the responsibilities of the *coordinating center* / *lead institution* with regard to communication and training of research personnel across sites:

Samantha Stonbraker, a postdoctoral fellow at Columbia University, will be the point person for communication with Columbia University. She has already received training in the protection of human research subjects.

Samantha Stonbraker will also be in charge of training any local staff to ensure accurate and consistent instrument training and data management across sites. She will also oversee all study procedures at Clínica de Familia La Romana. All data will be entered into encrypted tablets into Columbia University's REDCap Survey Management Software. No special equipment is needed for data transfer.

Samantha Stonbraker will meet individually with any local study team members daily at the beginning of the study to ensure that all procedures are being carried out correctly, that the study protocol is well understood, and that everything is completed in a confidential and ethically appropriate way.

Provide a plan to ensure that collaborating sites do not begin any research-related activity until IRB approval has been granted for the conduct of research at that site:

Samantha Stonbraker will be responsible of overseeing all research activities at Clinica de Familia La Romana and will not begin data collection until all IRB approvals have been obtained.

Provide a description of the transmission of data to the data coordinating center:

All study data will be stored on an encrypted password protected Columbia University Computer and will be on Columbia University Servers. Data will be collected on an encrypted tablet into Columbia University's REDCap Survey Management Software. No data will be stored on the tablets. Any data that needs to go back and forth between CUMC and the DR will be saved in these servers as Samantha Stonbraker will have access to them both in the Dominican Republic and on the CUMC campus. Samantha Stonbraker will review all data for completeness as it is being collected and will be responsible for obtaining any missing data and correcting any errors that she finds. All participant information will be stored on Columbia University servers that Samantha Stonbraker will be able to access both from the study site in the Dominican Republic and from the CUMC campus. If any data needs to be transmitted beyond the servers, it will be de-identified and shared through secure Columbia University email accounts.

Specify how and where the data will be analyzed and who is responsible for the analysis(es):

Data will be analyzed using the methods that are detailed in the procedures section. Samantha Stonbraker will be responsible for data analysis. She consistently travels back and forth between the Dominican Republic and the CUMC campus so data analysis will take place in both sites.

Study Purpose and Rationale

The Caribbean has among the highest HIV prevalence in the world.[1,2] Regionally, the majority of HIV/AIDS cases are located on the island of Hispaniola, comprised of the Dominican Republic (DR) and Haiti.[3] Due to a large international response and widespread availability of antiretroviral therapy (ART), in recent years the incidence of HIV in the DR has declined and prevalence hovers around 1% in the general population.[2,4] The effective and long-term management of this condition depends on infected individuals being able to acquire ART and apply the learned information and self-management skills that lead to optimal adherence.

HIV-related disparities exist in developing countries, such as the DR, where minority groups and/or those with low socioeconomic status experience higher disease burdens and worse health outcomes than those with higher socioeconomic status.[1,3,5,6] These disparities may be exacerbated when individuals are unable to understand the health information,[7,8] as low health literacy has been associated with worse health outcomes, less use of healthcare services, poorer knowledge of illness, and worse self-management.[9-11] The effective management of HIV requires patients to acquire, comprehend, and use large amounts of complex information, including how to manage variations in health status, medications and their side effects, nutrition and exercise needs, and healthy coping. [12-14] Health care providers can help patients understand pertinent health information by offering it in targeted, culturally-, language-, and literacy-appropriate ways.[15]

One such strategy is to use infographics to assist communication through visual representations of information.[16,17] Participatory design of infographics supports presentation of information in a culturally appropriate and visually appealing format which can improve information understanding, health behaviors, attention span, and ability to recall information.[17-19] It is critical to develop and test methods to improve the way health information is delivered to patients in these clinical contexts so patients, including those with low health literacy, can acquire and comprehend the information needed to improve self-management behavior and treatment outcomes.[15,20]

Preliminary studies (T32 NR013454) showed many persons living with HIV (PLWH) attending Clínica de Familia La Romana do not fully comprehend and use the health information they receive through current modalities.[21,22] In response, culturally relevant, evidence-based infographics to improve information delivery during clinical visits were developed (T32 NR007969) with a participatory design methodology (manuscript under review).[19] The next phase of this study is to rigorously assess if using these infographics is a feasible, acceptable, and efficacious method to enhance HIV-related clinician-patient communication and lead to improved patient outcomes. Additionally, a thorough exploration into the cultural factors of patient-provider communication in the Dominican Republic that can influence infographic use for clinician-patient communication in a clinical setting is warranted.

The purpose of this study is, therefore, to complete the following research aims:

Aim 1. Explore the usability of infographics (designed during preliminary studies) to facilitate HIV-related clinician-patient communication and to assess their feasibility using established guidelines.[23]
Aim 2. Pilot test measures to assess treatment outcomes within this population and estimate measurement parameters for future efficacy testing (means and standard deviations).
Aim 3. Measure the effect of infographic use on PLWH's treatment outcomes at three-, six- and nine-month intervals following initial exposure to the intervention.
Aim 4. Generate an explanatory model of HIV infection among patients in this clinical context and explore how it may be used to guide HIV-related communication using infographics.

Study Design

To complete the study aims, a mixed methods study that includes a single group pretest posttest study design will be used to pilot test the infographic intervention. In-depth interviews will be completed with a selection of participants to explore participant perceptions of HIV-related communication using infographics. Data will be collected from participants through baseline (at enrollment) and follow up assessments (at 3-, 6-, and 9-month follow up visits). Follow up interviews will be conducted with the providers involved in the intervention to ascertain their perspectives on the clinical utility of infographics. Participant's most recent CD4 count and viral loads will be collected from participants' medical records at each study visit.

Quantitative Data Analysis

See Statistical Procedures Attachment.

Qualitative Data Analysis

We will conduct semi-structured individual interviews using an iterative interview guide (see attached interview guide) developed following the recommendations of Kallio 2016 which includes 1) internal testing by the research team; 2) expert assessment by specialists outside the research team; and 3)

field-testing with the potential study participants.[31] The guide includes open-ended questions and probes designed to generate an explanatory model of participants' experience living with HIV and communicating about it in a clinical setting.[32,33] Recruitment for in-depth interviews will continue until we have reached data saturation, when no new information is gleaned from the most recent interviews.[34] Analysis of transcripts from in-depth interviews (Aim 4) will be guided by a qualitative descriptive (QD) methodology and will include conventional QD content analysis methods such as inductive line-by-line latent coding. Recognizing that the researcher is the instrument in QD methods, only one researcher will conduct all interviews. An iterative content analysis method will then be used to generate codes and extract meaning from each question.[35-37] A coding guide will be developed by one member of the research team after initial review of a subset of transcripts. Other team members will then review and refine the coding guide. Then, two members of the research team will code each transcript and discrepancies will be resolved by discussion until consensus is achieved. Analyses will be conducted in Spanish then translated to English for final dissemination. NVivo will be used to support data management and Gioia's methodology to ensure rigor in qualitative research will be followed.[38] A summary of the findings will be shared with a subset of participants (selected through purposive sampling) to determine if the findings resonate with them ("member check"). Any changes suggested will be made and the findings will be finalized.

Privacy and Data Security

All data collected will be coded to ensure confidentiality. Data from baseline and follow up assessments will be collected in Columbia University's REDCap online survey management system then downloaded and stored on Columbia University Servers. Audio recordings of intervention visits and in-depth interviews will also be coded then saved on Columbia University Servers. Only members of the research team will have access to the list that matches codes with participants. That list will be stored in password protected Columbia University Servers.

Data will be collected in a private interview setting to maintain participant comfort and confidentiality. All collected data will be coded. Only the study team will have access to the file which can link participants to their study data. It will be password protected on Columbia University Servers.

Audio Recordings will be transcribed by a secure transcription service outside of Columbia after a data use agreement has been signed.

Procedures

Columbia University researcher, Samantha Stonbraker, will be in charge of completing and overseeing all study procedures in collaboration with local study team members.

Study Setting

All study activities will take place at Clínica de Familia La Romana, which is a non-profit health center in the Dominican Republic licensed by the Dominican Ministry of Health that specializes in the education, diagnosis, treatment, and management of sexually transmitted infections, including HIV. More than 40 interdisciplinary professionals offer free care, treatment, and support to over 2,000 persons living with HIV during more than 17,000 visits annually.[39]

Intervention

Interventionists (N=2), will be physicians with two or more years of experience providing care to adults living with HIV at the Clinic. They will initially attend a training to guide patient education with infographics in a clinical setting, and will receive coaching on intervention fidelity, including how to maintain it.[40,41] During the intervention, in normal clinic visits, interventionists will guide education using the paper-based set of infographics developed in preliminary studies. Infographics will provide a visual representation of the pertinent information to be included. Paper versions of the infographics to

be used during the intervention will be kept in participants' medical records to enable easy access during visits, prevent providers from accessing them with non-study participants, and enable providers to mark graphics while teaching. Intervention fidelity will be verified by audio recording one-half of total intervention visits with equal numbers of visits over the three time points and an equal number of recorded visits with each interventionist with patient permission as is detailed in the informed consent document. Members of the study team will listen to audio recordings to confirm interventionists are using infographics during visits as specified in the intervention training, that both providers are using them in the same way, and that they are delivering the intervention consistently across visits. Additionally, participants will be asked about provider's infographic use during follow up assessments.

Participant eligibility will be verified in the medical records of patient's scheduled appointments at the beginning of each day. Eligible participants will then be recruited by the receptionist when they present to the Clinic for their regular clinic visit and referred to speak to an on-site researcher who will further introduce the study (see attached recruitment script) and then if a participant is interested, complete the informed consent process. After completing the informed consent process, participants will complete a baseline assessment using REDCap software with the help of a study team member prior to their visit (Table 1). Participants will then receive the intervention during the enrollment visit and at three and six-month visits and complete the follow up assessment at each of these time. Time intervals were selected as CD4 count and viral load may change as early as three months after ART initiation.[42-44] Interventionists will time visits and no extra time will be allowed for study visits. Following their six-month study visit, participants will be asked to participant in in-depth interviews. At the nine-month study visit, participants will complete a follow up assessment to assess ability to recall information from infographics over time. At the end of the study, the interventionists will be interviewed to assess feasiblity of infographic use in a clinical setting.

Measures

Outcome selection was guided by a conceptual model to theoretically guide communication studies.[45,46] This model illustrates pathways through which clinician-patient communication may influence health outcomes in the short (proximal), medium (intermediate), and long-term. Primary outcomes of CD4 count and viral load will be collected from patient medical records at each study visit. Measures of information recall/comprehension, engagement with clinician[47], satisfaction with care,[48] self-efficacy to manage HIV,[49] adherence,[50] health related quality of life,[51] and health status (self-reported status and CD4 count and viral load) will all be included in the baseline and follow up assessments.

Table 1. Research activity at each time point

Time point	Activity
Enrollment	• Health literacy assessment • Baseline assessment • Exposure to intervention
3 months	• Exposure to intervention • Follow-up assessment
6 months	• Exposure to intervention • Follow-up assessment
9 months	• Follow up assessment
Study end	• Follow-up interview for health care providers

Note: In-depth interviews will take place after participant's 6 month visits

Baseline assessments will collect demographic information, evaluate health literacy level,[52] and contain the instruments to assess outcome measures.

Follow up assessments for PLWH will include the outcome measures as well as open-ended questions exploring the usability of infographics, satisfaction with designs and recommendations for improvement. Open-ended questions regarding interventionists' communication strategies and intervention delivery will be included to assess providers' communication variability. Participants' responses to open-ended questions on the follow up assessments will be audio-recorded with participants' permission and then transcribed to enable more effective analysis.

Follow up interview for health care providers. Interventionists will complete a semi-structured interview containing questions on the following aspects of feasibility: acceptability, demand, implementation, practicality, adaptation, integration, expansion, and limited-efficacy testing[23] and

questions elucidating feedback on infographic design and suggestions regarding their effective incorporation into clinical visits.

In-depth interviews with PLWH. To describe PLWH's perceptions of HIV-related communication in a clinical setting and how it may be influenced by infographic use, directed content analysis guided by McGuire's Classic Input-Output Framework for Constructing Persuasive Messages will be used.[53] In-depth interviews will be conducted using a semi-structured interview guide in a private setting by a study team member and will be audio-recorded and transcribed.

Recruitment and Consent

Describe how participants will be recruited
At the beginning of each recruitment day, participant's eligibility will be verified in the medical records of patients who have appointments scheduled for that day. The receptionists will then refer eligible participants to speak with an on-site researcher when they present to the Clinic for their regular clinic visit. The on-site researcher will further introduce the study using the recruitment script, answer any questions the person has, and continue with informed consent if the individual indicates interest in study participation.

Describe how participants' written consent will be obtained
Informed consent will be completed by an on-site study team member in a private space. The complete informed consent form will be read to participants, comprehension of procedures will be verified by short questions in the consent forms, and participants will be encouraged to ask questions prior to signing the form. A signed copy of the informed consent form will be stored in a locked file cabinet in a locked office in the Clinic. Participants will be given a copy of the informed consent form for their records.

Research Aims and Abstracts

Research Question(s)

Research Question 1: To what extent are the infographics designed during preliminary studies a feasible and useful method to facilitate HIV-related clinician-patient communication?

Research Question 2: How efficacious are these measures (described in the procedures section) to assess treatment outcomes among this population and what are their measurement parameters (means and standard deviations) in this population?

Research Question 3: How much does infographic use during clinic visits influence PLWH's treatment outcomes at three-, six- and nine-month intervals following initial exposure to the intervention?

Research Question 4: What are PLWH's perceptions of HIV-related communication including infographic use during a clinical visit with a healthcare provider?

Scientific Abstract
The Caribbean has among the highest HIV prevalence in the world. Regionally, the majority of HIV/AIDS cases are located on the island of Hispaniola, comprised of the Dominican Republic (DR) and Haiti. Due to a large international response and widespread availability of antiretroviral therapy (ART), in recent years the incidence of HIV in the DR has declined and prevalence hovers around 1% in the general population. The effective and long-term management of this complex chronic condition depends on infected individuals being able to acquire ART and apply the learned information and self-management skills that lead to optimal adherence. Unfortunately, in developing countries, such as the

DR, various disparities (economic, educational, social) may make it more difficult for individuals to acquire and understand the health information needed for effective self-management. Health care providers in these settings can help patients understand pertinent health information by offering it in targeted, culturally-, and literacy-appropriate ways, such as by using visual representations of information e.g. infographics. Participatory design of infographics supports presentation of information in a culturally appropriate and visually appealing format which can improve information understanding, health behaviors, attention span, and ability to recall information. In preliminary studies, a set of infographics was developed using a participatory design method. This next study phase is to rigorously assess if using these infographics is a feasible, acceptable, and efficacious method to enhance HIV-related clinician-patient communication and lead to improved patient outcomes. Additionally, an understanding of the cultural factors that may influence clinician-patient communication using infographics in a clinical setting will provide valuable information regarding how to improve clinical communication with this population.

Lay Abstract

The Caribbean region has high rates of HIV. The majority of these are found on Hispaniola, an island made of the Dominican Republic (DR) and Haiti. Due to a large international response and availability of treatment, the number of new HIV infections in the DR has gone down and about 1% of the general population is living with HIV. The effective management of this condition depends on those living with HIV being able to access treatment and apply the information and skills that improve adherence. Unfortunately, in developing countries such as the DR, many things make it more difficult for individuals to get and use this information. Health care providers can help patients understand health information by offering it in targeted, culturally-, and literacy-appropriate ways, such as by using images that contain information e.g. infographics. When well designed, infographics can support communication in culturally friendly and visually appealing ways. This can improve understanding, health behaviors, attention span, and ability to remember information. In earlier studies, a set of infographics was developed from input from patients and providers. This next study phase is to test if these infographics are a useful method to improve communication and lead to better health for patients. Additionally, understanding the cultural factors that change clinician-patient communication using infographics in a clinical setting will provide valuable information as to how to improve clinical communication with this population.

Risks, Benefits, and Monitoring

Potential Risks

One potential risk to participants directly related to their participation in this protocol is possible loss of confidentiality. However, all of the data safety and monitoring procedures in this protocol will be strictly adhered to in order to avoid any loss of confidentiality. An additional risk is that participants might feel uncomfortable if they are unable to answer some of the questions in the surveys. Prior to beginning data collection, all participants will be reminded they do not have to answer any question that makes them feel uncomfortable and that they may withdraw from the study at any point without any consequences whatsoever. During the study visits, a study team member will also be available in order to provide any help that does not lead participants to the correct answer. During in-depth interviews participants may feel discomfort discussing their HIV status. Prior to interviews, participants will be reminded that they do not have to answer any question that makes them feel uncomfortable and that they are free to leave the interview at any time without any consequences whatsoever.

Additionally, all study team members will be trained to identify signs of suicidal ideation and depression. Should they notice any of these signs while they are completing a study visit, or if participants are showing signs of discomfort, the study visit will be stopped immediately and the participant will be referred to speak to the on-site psychologist.

Potential Benefits

This study does not have any direct benefit to participants. However, participants are more likely to benefit from the health education provided through their visits because of the intervention. Additionally, by participating in this research, they will be able to actively contribute to improving the health care services that they and their peers receive.

Alternatives

This study does not present greater than minimal risks to participants. However, an alternative is to not participate in this research.

Data and Safety Monitoring

The safety of this study's data will be regularly monitored by the study team. Any breaches of the study protocol will be submitted to the IRB immediately.

Subjects

Study population characteristics

This study will enroll adult (≥ 18 years of age) patients at Clínica de Familia La Romana who are living with HIV, have detectable viral loads, and are planning to receive care at the clinic for the next year. Participants are likely to be economically and educationally disadvantaged and non-English speaking.

Subject population justification

PLWH at Clínica de Familia La Romana have low levels of education and low health literacy [22,30] and adherence to antiretroviral medications is a perpetual concern.[54] Although a vulnerable population because they are living with a stigmatized health condition and are economically and educationally disadvantaged, their participation in this research is justified because it enables them to help design a tool and intervention that may help them to better manage their condition and improve the clinic services that they and their peers receive. Furthermore, if the target population of interventions is not included in the research design and evaluation phases, interventions may be ineffective and misguided.

Describe and justify reimbursement/compensation

Participants will receive money for transportation ($3) to each of their study visits (four visits total). Participants who participate in the in-depth interviews will also receive $3 for that visit. Providers involved in the intervention will be provided a small incentive ($50) for completing the training on how to administer the intervention and a small incentive ($50) following the semi-structured interview that they will complete at the end of the study.

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