

Official Title: Information Visualizations to Facilitate HIV-related Patient-provider Communication in New York City (Info Viz: HIV-NYC)

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Protocol: Information visualizations to facilitate clinician-patient communication in HIV care in New York City: Info Viz HIV - NYC

Study Purpose and Rationale

Latinos are the largest and fastest growing minority group in the US,^{1,2} and they are disproportionately affected by HIV.³⁻⁶ In 2014, almost 25% of new cases of HIV infections were among Latinos although they only represent 17% of the US population.⁷ Additionally, Latinos have a faster rate of progression from HIV to AIDS, higher rates of HIV-related deaths, and marked delay in the diagnosis of infections.^{3,4,8} Approximately 42% of HIV diagnoses among Latinos in the US are in persons born abroad.⁹ In absolute numbers, new HIV diagnoses among foreign-born individuals in the US were the highest among Caribbean-born persons, which may partially be attributed to high rates of bidirectional travel.¹⁰⁻¹² It is, therefore, critical that HIV prevention and treatment activities incorporate factors associated with Latino immigrant and transnational groups.^{13,14} In Washington Heights, New York City, understanding these factors related with bi-directional travel to the Dominican Republic is warranted, as the Latino population of Washington Heights is largely comprised of Dominicans.¹⁵

Many factors contribute to the health disparities experienced by Latinos, of which low health literacy and literacy in general are potential contributors.¹⁶⁻¹⁹ Health literacy, or “the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions,”²⁰ is an established concern affecting vulnerable communities globally.²¹ Not surprisingly, Spanish-speaking, less educated, and/or foreign-born Latinos have lower health literacy than those born in the US.²⁰ Low health literacy can lead to worse health outcomes, less use of services, and poorer knowledge of illness.^{22,23} Also, patients with limited health literacy are likely to have low numeracy which affects interpretations of medication quantities, time between doses, and time between appointments, among other quantitative knowledge relating to effective management of HIV.^{24,25}

Infographics are emerging technologies to help teach complex health concepts to patients with low health literacy. When effectively designed, infographics (information visualizations) contain a depth and breadth of information and lead to improved understanding of concepts.²⁶⁻²⁸ By carefully selecting the design and included content, simple images can convey large amounts of information in a visually appealing and comprehensible way.²⁹⁻³¹ Methodically constructed infographics have been shown to improve communication about health behaviors and health risks and minimize comprehension differences between individuals with high and low health literacy.^{27,32} They can also help improve information exchange amidst culture and language differences by using images familiar to patients to explain complicated processes³³ as well as augment attention span and recall of learned material.^{31,34,35} Furthermore, rigorously designed and evaluated infographics can help mitigate health disparities by helping clinicians provide the information that people need for effective health management in an understandable way.^{27,28,33}

During preliminary studies, we developed a set of infographics designed to facilitate HIV-related clinician-patient communication during clinic visits (AAAR3300). Initial infographics were designed by persons living with HIV (PLWH) in the Dominican Republic and are now being tested for feasibility and usability amongst a cohort in the DR (AAAR9023). In this study, we propose to assess the feasibility of using the infographic intervention in a clinic that specializes in HIV care in Washington

Heights to improve clinical communication and subsequently, patient outcomes. Additionally, we will collect information about acculturation and bi-directional travel to more thoroughly assess how these factors relate to HIV infection among Hispanic/Latino populations living in the US.

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

Aim 1. Establish potential differences in clinic messaging and cultural perceptions of infographics in New York and refine infographics for cultural and clinical relevance to a New York based clinic setting

Aim 2. Explore the feasibility and usability of the infographics that were designed during preliminary studies to facilitate HIV-related communication at The Comprehensive Health Program of NewYork-Presbyterian/Columbia (NYP-CHP) in New York City.

Aim 3. Pilot test measures to assess treatment outcomes within patients who self-identify as Hispanic/Latino at a health care clinic in New York and estimate measurement parameters for future efficacy testing (means and standard deviations).

Aim 4. Measure level of acculturation and rates of bi-directional travel in this study population.

Aim 5. 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 will be conducted. The components of this study include:

- 1) One design session with health care providers at CHP-NYP
- 2) A single group pretest/posttest study design will be used to pilot test the infographic intervention
- 3) In-depth interviews with two stakeholders
 - a. Patient participants who receive the intervention
 - c. Members of the clinical team at CHP-NYP

An initial design session will be conducted to learn how to adapt infographics that were designed in the DR to be useful and relevant in a clinical setting in New York City. Changes will be incorporated into the designs and then the intervention will take place over the subsequent 8 months. During the intervention, patient participants will receive information using the infographics during study visits, which will take place after their normal visits to CHP-NYP. Baseline data will be collected from patient participants at enrollment and at 3- and 6-month follow up visits. In-depth interviews will be completed with a selection of patient participants to develop an explanatory model of HIV infection and HIV-related communication using infographics. Individual interviews will also be conducted with additional members of the CHP-NYP clinical team to explore factors related to intervention implementation.

Statistical Procedures

1) Design session with health care providers ($N \leq 10$)

The audio recording of the design session with health care providers will be transcribed and analyzed with conventional content analysis to extract key points and recommended changes to infographic designs (Aim 1).

2) Single group pretest-posttest study design ($N = 30$)

Descriptive statistics (means, standard deviations) will be calculated for all participant demographics. Responses to open-ended questions in baseline and follow up questionnaires will be grouped according to meaning and then, needed changes in infographic design or clinical processes will be determined (Aim 2). Scores on the acculturation scale will be calculated according to published recommendations (Aim 4).^{36,37} Mean scores and standard deviations will be calculated for each additional scale included in the follow up assessments and the change in mean scores between baseline and follow-up assessments determined (Aim 3). To take into account sex as a biological variable (NOT-OD-15-102), mean scores between male and female participants will be compared. Cronbach's alpha will be used to compare the reliability of measures with reported values and to support the assertion that these tools can be used within this population. Data collected will also be used to estimate parameters for use in determining effect sizes, which will be corrected for the bias inherent in small samples,³⁸ and reported as relative risks for categorical outcomes and as Cohen's D for continuous outcomes which will enable a more precise power calculation for subsequent study phases (Aim 3).

3.a.) Individual interviews with patient study participants ($N \leq 25$)

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.³⁹ Depending on when saturation is reached, up to 30 in-depth interviews will be conducted with participants who are enrolled in the study.

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.^{40,41}

Recruitment for in-depth interviews will continue until we have reached data saturation, when no new information is gleaned from the most recent interviews.⁴² Analysis of transcripts from in-depth interviews (Aim 5) 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. An iterative content analysis method will then be used to generate codes and extract meaning from each question.⁴³⁻⁴⁵ 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.⁴⁶

3.b.) Individual interviews with members of the clinic team ($N \leq 10$)

Audio recordings of these interviews will also be transcribed and main points regarding changes to the study and clinical utility of infographics in this setting will be extracted.

Privacy and Data Security

Provide a description of how the confidentiality of study data will be ensured, addressing concerns or protections that specifically relate to the data storage elements identified above (e.g. hard copy, electronic, system, and/or endpoint)

All data collected will be coded to ensure confidentiality. Data from baseline and follow up assessments will be collected in Columbia University's REDCap survey management system then downloaded and stored on Columbia University Servers. Audio recordings of intervention visits and in-depth interviews will be transcribed 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. Audio Recordings will be transcribed by a secure transcription service outside of Columbia. Audio recordings will be destroyed as soon as data analysis is complete and the associated manuscript is accepted for publication.

Provide a description of the protections in place to safeguard participants' privacy while information is being collected:

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.

Procedures

Samantha Stonbraker, a Columbia Researcher, will be responsible for overseeing all study related procedures, data analysis, and final dissemination.

Study Setting

All study activities will take place at The Comprehensive Health Program of NewYork-Presbyterian/Columbia (NYP-CHP). This is a Ryan White funded, bilingual, patient-centered medical home that emphasizes sexual health, hepatitis management, and HIV care. It primarily serves Upper Manhattan and the South Bronx where residents are disproportionately affected by HIV. NYP-CHP's large multidisciplinary team provides HIV care to a population of more than 2,300 children, adolescents, and adults through more than 16,000 visits per year.

Design Session

Members of the clinic team at NYP-CHP will be asked if they are interested in participating in the study. Interested participants will all meet and provide verbal informed consent to participate in the study. During the design session, each infographic ($n=15$) will be shown to the group and the necessary

changes that need to be made to each will be solicited. The session will be audio recorded and later transcribed for analysis.

Infographic intervention

Study team members who will administer the intervention will have a training regarding how guide patient education with infographics using the adherence counseling format that is used at CHP-NYP and will review principal components of intervention fidelity, including how to maintain it.^{47,48} During the intervention period, after normal clinic visits, study team members will guide education using the laminated, paper-based set of infographics developed in preliminary studies. Infographics will be available in both English and in Spanish and will provide a visual representation of the pertinent information to be included in clinical conversations. Intervention fidelity will be verified by audio recording up to one-half of total intervention visits with patient permission as is detailed in the informed consent document. Members of the study team will listen to audio recordings to confirm the other team member is using infographics during visits as specified in the intervention training, that both study team members are using them in the same way, and that they are delivering the intervention consistently across visits. Study team members will complete a second training session after the baseline visits to revisit main points that need to be addressed while administering the intervention and address any concerns that arise during the initial intervention visits. Patient participants will be asked about study team members use of infographics during follow up assessments.

Participant eligibility will be verified by clinic staff through electronic health records during team huddles that take place in the mornings on study days. A list of eligible participants will be provided to the health care providers who are seeing patients that day. The provider will then assess potential participant interest using the attached recruitment script and refer those who are interested in participating to an on-site study team member. That team member will then further introduce the study and then if a participant is interested, complete the informed consent process.

After completing informed consent, patient participants will complete a baseline assessment using REDcap on an encrypted tablet with the help of a study team member prior to intervention administration (Table 1). Patient participants will then receive the intervention during study visits, which will take place after participants' normally scheduled appointments at baseline, 3- and 6-month visits. They will complete a follow up assessment at their visits closest to 3- and 6-months following their baseline visit. Study team members will extract information from patient medical records (CD4 count, viral load, current ART etc.) at each data collection time point. Patient participants will receive reminder phone calls prior to each of their study visits using the attached reminder phone call script. Time intervals were selected as CD4 count and viral load may change as early as three months after ART initiation.⁴⁹⁻⁵¹ Study team members will time how long it takes to administer the intervention.

Following their six-month study visit, participants will be asked to participate in an in-depth interview. At the end of the study, additional members of the clinical team will be interviewed to assess feasibility of infographic use in this clinical setting.

Table 1. Summary of research activities			
Date(s)	Study point	Participants	Activities
July 2019	Design Session	<ul style="list-style-type: none"> • Members of clinical team 	<ul style="list-style-type: none"> • Two hour design session
September 2019	Study team member training	<ul style="list-style-type: none"> • Study team members 	<ul style="list-style-type: none"> • Two-hour training on how to use infographics
September/October 2019	Enrollment	<ul style="list-style-type: none"> • Patients • Study team 	<ul style="list-style-type: none"> • Health literacy assessment • Baseline assessment • Exposure to intervention • CD4 & viral load extracted
December 2019/January 2020	3-month visits	<ul style="list-style-type: none"> • Patients • Study team 	<ul style="list-style-type: none"> • Exposure to intervention • Follow up assessment • CD4 & viral load extracted
March/April 2020	6-month visits	<ul style="list-style-type: none"> • Patients • Study team 	<ul style="list-style-type: none"> • Exposure to intervention • Follow up assessment • CD4 & viral load extracted
March – May	In-depth interviews	<ul style="list-style-type: none"> • Patients 	<ul style="list-style-type: none"> • Follow up assessment • CD4 & viral load extracted
April/May	In-depth interviews	<ul style="list-style-type: none"> • Members of the clinical team 	<ul style="list-style-type: none"> • Individual interviews with team members

Measures

Outcome selection was guided by a conceptual model to theoretically guide communication studies.^{52,53} 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, satisfaction with care,⁵⁴ self-efficacy to manage HIV,⁵⁵ adherence,⁵⁶ health related quality of life,⁵⁷ and health status (self-reported status and CD4 count and viral load) will all be included in the baseline and follow up assessments.

Baseline assessments will collect demographic information, assess level of acculturation,³⁷ evaluate health literacy level,⁵⁸ and contain a measure for each outcome.

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.

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.⁵⁹ 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.

In-depth interviews with clinical care team. To learn more about how this intervention was accepted and feasible at the clinic as a whole, interviews will be conducted with additional members of the clinical care team. Participants will complete a semi-structured interview containing questions on the following aspects of feasibility: acceptability, demand, implementation, practicality, adaptation, integration, expansion, and limited-efficacy testing⁶⁰ and questions elucidating feedback on infographic design and suggestions regarding their effective incorporation into clinical visits. Each session will be audio recorded, later transcribed, and then analyzed to identify key features of the study that worked and what didn't work in order to better inform future efforts.

Recruitment and Consent

Describe plans for screening and/or determining eligibility of prospective subjects

Patient participant eligibility will be confirmed by staff at CHP-NYP through the EHR. A list of eligible participants will be provided to the health care providers seeing patients on study days. During clinic visits, providers will review the study with eligible participants using the recruitment script and if they show interest in the study, will refer potential participants to speak to a study team member who will provide more information about the study, complete the informed consent process, and administer the intervention.

Eligible design session participants are staff at CHP-NYP that are involved in any patient education activities. Eligible members of the clinical care team who will complete individual interviews will be anyone who was involved with, or had knowledge of, the intervention and its use at CHP-NYP. Design session participants and clinic care team members will be identified by members of the research team who are affiliated with CHP-NYP.

Participants from the design session may also participate as care team members who complete individual interviews.

Describe how participants will be recruited

Patient participants

Using the attached recruitment script, health care providers will introduce the study to eligible patient participants and if they are interested, the providers will refer them to speak with an on-site researcher immediately following their clinic appointment. The on-site researcher will further introduce the study to participants in their primary language (English or Spanish) and answer any questions the person has, then continue with informed consent if the individual indicates interest in study participation.

Health care provider participants

After being selected by CHP-NYP affiliated study team members, potential participants for the design session, and members of the clinical care team who will complete individual interviews will be recruited by the study team members who will provide more information about the study and enroll participants.

To avoid coercion, all potential participants will be reminded that their participation in this research is completely voluntary, that they don't have to participate if they don't want to, and that there will not be any adverse effects to them if they choose not to participate.

Describe how participants' written consent will be obtained

Written informed consent of patients will be completed by an on-site study team member in a private space. The process will begin with a succinct summary of the research study. The complete informed consent form will be read to participants and comprehension of procedures will be verified by short questions in the consent forms. Additionally, participants will be provided the opportunity to discuss any of the information and will be encouraged to ask questions prior to signing the form. They will then be asked to confirm that they were provided sufficient information about the study and then they will be asked to sign the form. A signed copy of the informed consent form will be stored in a locked file cabinet in a locked office in the School of Nursing. Participants will be given a copy of the informed consent form for their records.

Verbal informed consent will be obtained for the design session and for the individual interviews with members of the clinical team.

Research Aims and Abstracts

Research Question(s)/Hypothesis(es)

Research Question 1: What are some of the cultural and practical differences between the way health information is provided to persons living with HIV in a health care clinic in the United States vs. in the Dominican Republic?

Research Question 2: To what extent are the infographics designed during preliminary studies a feasible and useful method to facilitate HIV-related clinician-patient communication amongst Hispanic/Latino persons living with HIV in New York City?

Research Question 3: 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 4: What are PLWH's perceptions of HIV-related communication including infographic use during a clinical visit with a healthcare provider?

Scientific Abstract

Latinos are the largest and fastest growing minority group in the United States (US) and they are disproportionately affected by HIV. In 2014, almost 25% of new cases of HIV infections were among Latinos although they only represent 17% of the US population. Many factors contribute to the health disparities experienced by Latinos, of which low health literacy and literacy in general are potential contributors. Health literacy, or "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions," is

an established concern affecting vulnerable communities globally. Low health literacy can lead to worse health outcomes, less use of services, and poorer knowledge of illness. Not surprisingly, Spanish-speaking, less educated, and/or foreign-born Latinos have lower health literacy than those born in the US.

Infographics are technologies designed to help teach complex health concepts to patients with low health literacy. When effectively designed, infographics (information visualizations) contain a depth and breadth of information and lead to improved understanding of concepts. Additionally, infographics can also help improve information exchange amidst culture and language differences by using images familiar to patients to explain complicated processes as well as augment attention span and recall of learned material. During preliminary studies, we developed a set of infographics designed to facilitate HIV-related clinician-patient communication during clinic visits (AAAR3300). Initial infographics were designed by persons living with HIV (PLWH) in the Dominican Republic and are now being tested for feasibility and usability amongst a cohort in the DR (AAAR9023). In this study, we propose to assess the feasibility of using infographics to improve patient outcomes at a clinic that specializes in HIV care in Washington Heights. Additionally, we will collect information about acculturation and bi-directional travel to more thoroughly assess how these factors relate to HIV infection among Hispanic/Latino populations living in the US.

Lay Abstract

Latinos are the largest and fastest growing minority group in the United States (US). Unfortunately, they have higher rates of HIV than their peers in other ethnic groups. Many things lead to this health disparity. One potential cause is low health literacy and/or literacy in general. Health literacy, is defined as “the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.” It is a large concern that affects vulnerable communities globally. Low health literacy can lead to worse health outcomes, less use of services, and poorer knowledge of illness. Spanish-speaking, less educated, and/or Latinos not born in the US have lower health literacy than those born in the US.

Infographics are tools that can help teach complex topics to patients with low health literacy. Well-designed infographics are images that combine symbols and text that aid in education. They can also lead to improved understanding of concepts and can improve communication when there are culture and language differences. This has been shown to help people pay attention for longer amounts of time and remember more of what they learn. In early work, we developed a set of infographics to support HIV-related clinician-patient communication in a clinical setting (AAAR3300). These infographics were designed by persons living with HIV (PLWH) in the Dominican Republic and are now being tested to see if they are useful during clinic visits in the DR (AAAR9023). In this study, we propose to test these infographics to see if they can improve patient’s health in a US-based clinic that specializes in HIV care.

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 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 an appropriate mental health professional.

Potential Benefits

This study does not have any direct benefit to participants. However, participants are more likely to benefit from the health education provided 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. 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

Inclusion Criteria

Adults (≥ 18 years of age) living with HIV, who self-identify as Hispanic/Latino, are English or Spanish Speaking, a new patient or a patient with a detectable viral load and plan to receive care at the NYP-CHP during the study period will be eligible for inclusion.

Exclusion are current pregnancy or inability to provide informed consent.

Study population characteristics

Study participants will be adults (≥ 18 years of age) living with HIV, who self-identify as Hispanic/Latino, are English or Spanish Speaking, with a detectable viral load and plan to receive care at

the NYP-CHP during the study period. Participants are likely to be economically and educationally disadvantaged and non-English speaking.

Subject population justification

PLWH at NYP-CHP are likely to have lower levels of education and low health literacy and adherence to antiretroviral medications is a perpetual concern. 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 \$25 in the form of a paycard for each of their study visits (three visits total). Participants who participate in the in-depth interviews will also receive a \$25 pay card for that visit. Providers involved in the intervention will be provided refreshments the two trainings on how to administer the intervention as well as during the semi-structured interview that they will complete at the end of the study.

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