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The Social, Mental, and Physical Health Impacts of the COVID-19 Pandemic on People With HIV: Protocol of an Observational International Multisite Study

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Abstract

As the COVID-19 pandemic spread across the world, immunocompromised individuals such as people with HIV (PWH) may have faced a disproportionate impact on their health and HIV outcomes, both from COVID-19 and from the strategies enacted to contain it. Based on the SPIRIT guidelines, we describe the protocol for an international multisite observational study being conducted by The International Nursing Network for HIV Research, with the Coordinating Center based at the University of California, San Francisco (UCSF) School of Nursing. Site Principal Investigators implement a standardized protocol to recruit PWH to complete the study online or in-person. Questions address demographics; HIV continuum of care indicators; mental and social health; COVID-19 and vaccination knowledge, attitudes, behaviors, and fears; and overall outcomes. Results of this study will contribute to knowledge that can inform responses to future public health crises to minimize their impacts on vulnerable populations such as PWH.

Key words: COVID-19, international, observational, people with HIV, SPIRIT checklist, STROBE checklist, study protocol

All authors are members of the International Nursing Network for HIV Research.

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Background and Rationale

Because a new virus that could result in acute respiratory illness and death became a global pandemic in 2020, measures were instigated to mitigate transmission. With the identification of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and 2019 novel coronavirus (COVID-19), researchers quickly identified epidemiological patterns of morbidity and mortality as well as approaches to treatment that could decrease fatality (Matta et al., 2020). Individuals with the highest risk for COVID-19 and resulting morbidity and mortality include those who are immunocompromised; have comorbidities such as hypertension, obesity, and heart disease; and experience inequities related to social determinants of health (e.g., aging, chronic illness, poverty, and lack of housing; Abrams & Szefler, 2020; Dong et al., 2021; Kompaniyets et al., 2021; Sanyaolu et al., 2020). In turn, COVID-19 posed concern for people with HIV (PWH) because of their immunocompromised status. As the knowledge of COVID-19 increases, there is a need to learn more about the impact of COVID-19 on the HIV Care Continuum (2023) and the experience of PWH across the globe during and after the pandemic. To better understand the impact of COVID-19 on PWH, the socio-ecological model of HIV care and engagement guided development of this study protocol (Baral et al., 2013; Messer et al., 2013; Phillips & Blais, 2015; Sallis & Owen, 2015; Sterrett-Hong et al., 2023). A socio-ecological approach facilitates exploration of factors influencing health from multiple social systems levels (Figure 1). This approach is consistent with previous studies conducted by and the philosophical underpinnings of the International Nursing Network for HIV Research (Corless et al., 2017; Dawson Rose et al., 2014; Phillips et al., 2013; Sullivan et al., 2017; Wang et al., 2022; Webel et al., 2019).

Globally, many PWH experience symptoms of poor physical, mental, and social health (Marziali et al., 2019; Rubin & Maki, 2019; Shah et al., 2018), all of which may be exacerbated by both the COVID-19 pandemic and the efforts to mitigate its impact, including shelter-in-place/lock-down mandates and social distancing. Compared with the general population, older PWH in Spain were found to have a higher prevalence of frailty and functional impairment, which can lead to poor physical health (Brañas et al., 2017). PWH around the world engage in less physical activity compared with people without HIV infection (Erlandson, 2020; Vancampfort et al., 2018). Furthermore, studies in Spain and Italy found that the COVID-19 pandemic negatively affected physical activity, likely because of shelter-in-place and closure of gyms and exercise facilities (Castañeda-Babarro et al., 2020; Zaccagni et al., 2021).

Before the pandemic, research indicated that coping with HIV can be accompanied by numerous social and emotional stressors (Harris et al., 2020; Heywood & Lyons, 2016; Mao et al., 2018). These factors negatively affect health-related quality of life, a construct that is essential in HIV because it encompasses multiple aspects of health, from physical to mental to social (Fayers & Machin, 2015). According to the Coronavirus Health and Impact Survey, a range of negative mental health outcomes have been shown in previous epidemics, with symptoms including anxiety, stress, loneliness, depression, lack of social support, post-traumatic stress disorder, and sleep disturbances (Nikolaidis et al., 2021). These findings suggest that the disruptions to everyday life and the lingering uncertainty of living with the threats of the COVID-19 pandemic may be associated with an increase in symptomatology and a decrease in quality of life in different groups of individuals across the globe.

In addition to COVID-19's impact on symptoms and health, pandemic mitigation efforts could interrupt the HIV care continuum by decreasing access to HIV testing, health care, and access and adherence to HIV antiretroviral medications globally (Jiang et al., 2020; Santos et al., 2021). An early study found that PWH living in Ohio and North Carolina (USA) reported that HIV medication adherence was a priority during the pandemic and that taking their ARVs aided with maintaining a strong immune system and assisted them with fighting COVID-19 (Horvat Davey et al., 2023). Among a cohort of PWH in Atlanta, Georgia (USA), HIV medication adherence was not negatively affected by COVID-19 (Kalichman et al., 2020), whereas a study in Los Angeles, California (USA) documented significantly reduced antiretroviral therapy (ART) medication adherence in a study among PWH (Bogart et al., 2021). Data from Uganda indicate a negative impact of COVID-19 on both access to care and medication adherence (Linnemayr et al., 2021). The varying experiences of medication adherence in PWH should be further assessed, particularly by geographic region.

Although PWH were at great risk of severe COVID-19 disease, actual incidence was lower in this population in San Francisco, California (USA; Spinelli et al., 2021). At the same time, however, HIV suppression was negatively affected by the pandemic, particularly among unhoused individuals in San Francisco, California (USA; Spinelli et al., 2020). In a systematic review (Meyer et al., 2023), the investigators found that the pandemic's impacts in the United States included missed HIV care visits, cancelled

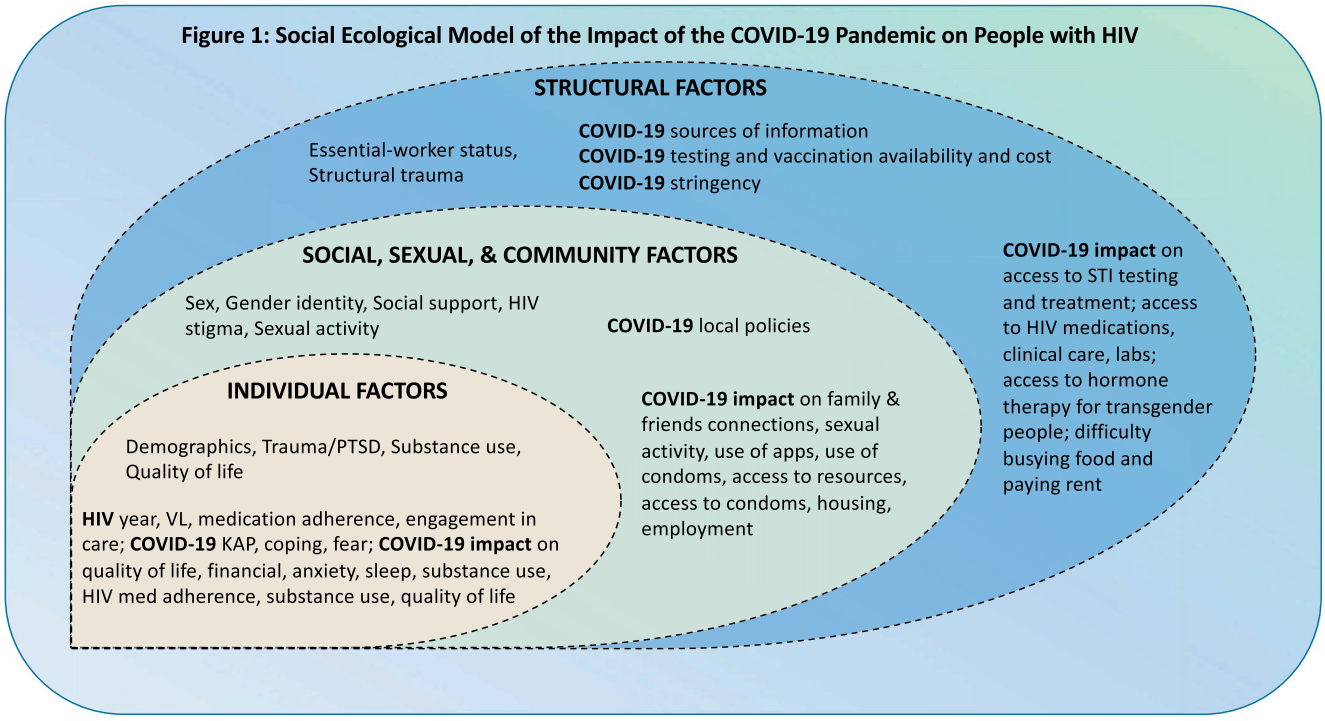

Figure 1. Social ecological model of the impact of the COVID-19 pandemic on people with HIV (Phillips & Blais, 2015). This figure is available in color online www.janacnet.org.

appointments, and difficulty accessing behavioral health services and ART, but also reported that telehealth facilitated completion of visits for some individuals, including Black clients, women, and populations that were historically hard to reach. An international study of men who have sex with men (primarily in Brazil, France, Mexico, Taiwan, and Russia) found that the impact of COVID-19 disproportionately affected PWH, racial and ethnic minority groups, and economically disadvantaged individuals (Santos et al., 2021).

Objectives

Although some initial research has examined the effects of COVID-19 on the physical and mental health of PWH in certain locations, there is a lack of large-scale nursing-focused international data on the impact of the disease and its mitigation efforts on PWH. To address this gap, a prospective multisite international observational study to examine the impact of COVID-19 on PWH was developed by the International Nursing Network for HIV Research ("The Network"). Led by the Coordinating Center at the University of California, San Francisco (UCSF) School of Nursing, The Network designed a standard protocol for use at sites across the United States and globally. The overarching goal of this study was to examine the impact of the COVID-19 pandemic and the strategies and policies used to mitigate its spread on the lives of PWH around the world. Specifically, the objectives of this study are (a) to describe the impact of COVID-19 across the HIV Care Continuum (2023) (i.e., access to and engagement in HIV care and HIV medication adherence) and examine HIV and other physical, social, and mental health symptoms; (b) to identify barriers to COVID-19 testing, care, and vaccination among PWH; and (c) to examine COVID-19 vaccine hesitancy among PWH. The purpose of this article was to share an international multisite study protocol that could be rapidly implemented in future public health emergencies for planning and response, in general, and to ensure that the needs of PWH are addressed.

Methods

This is the eighth multisite international study of the International Nursing Network for HIV Research (Holzemer, 2007; Reyes et al., 2021). We have used elements of the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines (Schulz & Grimes, 2013) and the STROBE guidelines (von Elm et al., 2014) to describe the protocol. Administrative Information is described in Table 1.

Coordinating Center

The UCSF School of Nursing serves as the Coordinating Center for the overall study (Holzemer, 2007). The Coordinating Center (CC) is made up of two study PIs, a data manager, and research assistants. The study PIs drafted the initial conceptualization of the study, recruited participating sites, and coordinated input from all sites to finalize the protocol. The CC obtained overall Institutional Review Board (IRB) approval; managed Memoranda of Understanding (MOUs) and Data Use Agreements (DUAs) for all participating sites to facilitate sharing data for the purpose of creating a single unified dataset; and coordinated regular meetings and communications with all sites. In addition, the CC designs and maintains data management systems, produces a final compiled dataset, and serves as the repository for the dataset. Each site principal investigator (PI) is responsible for ensuring compliance with local ethical guidance, and with the standardized protocol, including options for consent, recruitment, and data collection. In addition, each site PI is responsible for submission of data to the CC.

Ethical Approval and Data Sharing

The UCSF School of Nursing received approval from the UCSF Human Research Protection Program's IRB both to serve as Coordinating Center and to serve as a data collection site. Based on this approved protocol, each Site PI then received IRB/ethical approval from their own institution to conduct the study (Appendix 1, Supplemental Digital Content 1, http://links.lww.com/JNC/A44). The protocol will not be modified.

Participant Recruitment and Inclusion Criteria

The study is being conducted primarily through academic sites in the United States (Boston, Cleveland, Houston, New York, San Francisco, and San Juan) and around the world (Botswana, Canada, China, Colombia, Hong Kong, Kenya, Nigeria, South Africa, and Thailand; Appendix 1, Supplemental Digital Content 1, http://links.lww.com/JNC/A44).

The study uses a convenience sampling approach and is not an intervention study that is powered to detect differences between study groups; therefore, the sample size was determined based on practical considerations and the available resources. Target recruitment for each site is 100 participants. All participants are self-reported living with HIV and are at or above the age of consent in their location (21 years in Puerto Rico, 18 years in other locations). To reach a diverse population, recruitment is conducted through sites serving PWH, sexual and gender minority people, and resource poor people, among other groups often underrepresented in research.

Participants will be recruited in two main ways: online and/or in-person. Online recruitment consists of making posts on social media and on the websites of HIV and community organizations that serve PWH. People who are interested in participating in the study will be advised to call that site's researchers to be screened for eligibility. Telephone calls help researchers reduce the threat of "bots" or automated systems that may submit fake data to tamper with results and/or to gain additional financial incentives. Once an individual has been screened for eligibility and for not being a "bot," they are given the link to the online study or can make an appointment to meet with a researcher in-person.

In-person recruitment consists of various methods. Researchers post or distribute flyers about the study and contact information in waiting rooms and on bulletin boards at clinical and community sites. Researchers may also be present at support groups for PWH or in HIV clinic waiting rooms, with the approval of the organization's director, and approach individuals with information about the study. Health care providers may give flyers to clients, or individuals may be referred from other ongoing studies. People who are eligible and interested may self-administer the study through a tablet, a computer, or a paper booklet at that time; complete an interviewer-administered version of the study on-site or over the telephone; or may call the researchers to be screened and to self-administer the study at a convenient time.

Informed Consent

Informed consent procedures were approved by each individual IRB. The informed consent document was drafted in English and translated to Chinese, French, Setswana, Sotho, Spanish, Swahili, Tsonga, and Venda using a back-translation process with bilingual investigators and translators. The informed consent forms were then submitted to the IRB at each site and adjusted for each IRB's standards, requirements, and regulations. Informed consent of participants is accomplished in three ways. Individuals who choose to self-administer the study online go to the study link. The first page of the website consists of consent text, which includes information about study requirements, the voluntary nature of the study, and the ability to withdraw from the study at any time, as well as contact information in case the person would like to communicate with a researcher

Table 1. Administrative Issues

SPIRIT Item	
Title	The Social, Mental, and Physical Health Impacts of the COVID-19 Pandemic on People with HIV: Protocol of an Observational International Multisite Study
Trial registration	Not applicable
Protocol version	August 20, 2021. Version 1
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Table 1. (*continued*)

SPIRIT Item	
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Name and contact information for the trial sponsor	The International Nursing Network for HIV Research Dr. Yvette P. Cuca UCSF School of Nursing E-mail: Yvette.Cuca@ucsf.edu
Role of study sponsor and funders	The content of this protocol is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health, the Agency for Health care Research and Quality, or any other funding agency

Note. SPIRIT = Standard Protocol Items: Recommendations for Interventional Trials.

about any questions. Individuals read the consent form and provide consent by clicking "Yes" to the question "Do you consent to participate." Individuals who choose to complete the study in-person or later at a scheduled time over the telephone meet with a study researcher in a private location where the researcher reviews the entire consent form with the individual and answers any questions that the individual has. If the individual agrees to participate, they sign the consent form. Finally, at sites that have approval for a waiver of signed consent because of the minimal-risk nature of the study, the researcher meets with the individual in person, on the telephone, or via Zoom, describes the study using an information sheet with details about the study, answers any questions, then asks the individual whether they consent to participate in the study, and documents on an information sheet when the consent discussion took place. Participants may keep a copy of the information sheet. People who are interested in the study but who cannot read may participate through the interviewer-administered consent and survey completion methods.

Data Collection Methods

The study consists of a one-time survey that takes approximately 15–45 min depending on how it is administered. Participants can self-administer the study on paper or online through a Qualtrics study website that can be accessed from a computer, tablet, or smartphone. The first page of the study website consists of the informed consent information and agreement. After consenting to the research, participants are taken to the first page of the questionnaire. From there, they click through and respond to the questions. On the last page of the online survey is a link to a separate Qualtrics survey where they can leave their contact information (e.g., email address) to receive an electronic gift card in appreciation for their time. The contact information is decoupled from the survey, so that the survey remains anonymous.

The study may also be interviewer-administered by a member of the research team, either in-person or on the telephone. The researcher reads each question and the corresponding response options aloud. As the participant responds to each question, the researcher either enters the data directly into the Qualtrics study website or marks the responses on paper to be entered into the study database at a later time. At the end of the survey, the individual is given/mailed an incentive (gift card, telephone card, cash) in appreciation for their time. The value of incentives ranges from US$ 2.26 to US$ 25.00, depending on the site.

Translation

Because of the international nature of this study, all documentation (recruitment materials, consent materials, questionnaire, and response options) is translated into the local language of each site. Several sites, both within the United States and outside, serve individuals who speak Spanish, and so a team of site investigators worked together to create one set of Spanish documents to be used by all these sites. This team, led by researchers at the University of Puerto Rico, first identified which standardized instruments were already available and validated in Spanish, including measures that had already been translated for previous Network studies. For measures that were not already available in Spanish, the University of Puerto Rico and Universidad del Valle in Colombia teams each engaged in an iterative translation/back-translation process (Beaton et al., 2000). Both teams met to discuss and resolve any discrepancies. Afterward a team of multiple sites that were using the Spanish versions (Colombia, Puerto Rico, Texas, and New York) revised the questionnaires and made suggestions that were discussed and integrated to ensure cross-cultural equivalence (Beaton et al., 2000). The discussion across sites was essential to address cultural nuances at different sites. In some cases, this required the inclusion of multiple word options to meet the needs of varying Spanish dialects; for example, to translate "high school" into Spanish, the term "bachillerato" is used in Colombia, "escuela secundaria" in Peru, and "escuela superior" in Puerto Rico.

Site PIs at other international sites are responsible for translation of study documentation in their own languages. This process first consists of identifying validated translations of the standardized instruments. For instruments that do not have a validated translated version, a translation/back-translation and integration process is completed with the study team and expert translators. Study documentation was translated from English to Chinese, French, Setswana, Sotho, Spanish, Swahili, Tsonga, and Venda through translation/back-translation with experts to establish basic content validity. The online Qualtrics survey is available only in English, Spanish, and French. All study participants from any study site may complete the English version of the study online, which is particularly relevant for sites in Africa where many people speak English and their local language. At sites using other languages, data collection occurs mainly on paper because this is more common and accepted in those locales, and for this reason, the translated versions are not available online.

Responses to open-ended questions will be translated into English before analysis, in a process similar to the

one-step approach described by Scholz et al. (2022). At least two bilingual investigators from each site will work together to translate responses into English to reach consensus about the meaning of the response within the context of the site.

Data Management

In most cases, data will be collected through Qualtrics survey software, either through the web portal administered by the Coordinating Center or through a version of the study instrument that is exported by the CC, imported by the study site through their university's Qualtrics system, and then sent back to the CC post-data collection. The use of Qualtrics is not permitted in China, so the survey is administered through a locally approved online system, and then data will be transmitted to the CC.

The CC stores data on a secure server, and both computers and files are password restricted so that only the PIs and data manager have access. Participant contact information for incentives is not linked directly to responses and is destroyed once data collection is complete. The CC will merge data files from Qualtrics and Excel and will conduct initial cleaning and scoring. The compiled data set can then be shared securely with study sites such that site PIs can collaborate to analyze data and communicate results on outcomes of interest. The final dataset will be de-identified, and will be emailed via an encrypted system through which PIs outside of the CC must register with the CC. As per the study's Publication Policy (available on request), all site PIs fulfill authorship criteria. Site PIs submit manuscript concepts through a REDCap (Harris et al., 2009, 2019) system hosted by the CC. All manuscript proposals will be reviewed during regular study team meetings to ensure agreement with the concept and to establish authorship. A Data Monitoring Committee is not considered necessary because of the noninterventional nature of this study.

Measures

Demographics. This study uses a series of measures. Demographic measures include factors such as age; location and type of location (urban, rural, and suburban); Hispanic origin; African Origin; gender identity and sex assigned at birth; level of education; employment status (Cox et al., 2021); monthly income amount and currency, which can be converted based on the analysis (e.g., to U.S. dollars, to local poverty level); number of persons and children in the household; housing status; and whether the respondent is considered a COVID-19 essential worker where they live. Race for most sites is categorized as African American/Black/African, Asian, Native Hawaiian or other Pacific Islander, American Indian or Alaska Native, White/Anglo, Multiracial, or Other. In South Africa, race is categorized as African, White, Colored, or Indian; ethnicity is categorized as Venda, Northern Sotho, Tsonga, Ndebele, or Other. In Canada, ethnoracial group is categorized as Indigenous (First Nations; Inuit; Métis; Other); Latin American; East Asian; Indo-Caribbean; South Asian; Middle Eastern; South East Asian; White Canadian or White American; White European; Black Canadian or Black American; Black African; or Not listed or do not want to specify.

Sexual activity. Two questions ask whether the respondent has had sex in the past 3 months (with men, women, or both), and whether they had sex with anyone outside of their household and/or with someone other than a regular partner during the peak of COVID-19.

Social support. Level of social support will be measured using the four-item California Health Interview Study instrument (UCLA Center for Health Policy Research et al., 2011), based on the Medical Outcomes Study Social Support Survey instrument (Sherbourne & Stewart, 1991). This instrument queries "How often is someone available to:" "help with daily chores if you are sick," "get together with for relaxation," "understand your problems," and "love you and make you feel wanted." Responses range from 1 = "None of the time" to 5 = "All of the time," and one mean score is calculated. Higher scores indicate higher levels of social support. This instrument has previously been used among women living with HIV (Cuca et al., 2019). Studies have shown this survey correlates well with other social support measures and longer versions of the Medical Outcomes Study Social Support Survey (r = .80–.90), with test–retest reliability ranging from 0.69 to 0.88, and Cronbach's alpha ranging from 0.83 and 0.94 (Gjesfjeld et al., 2008; Higgins et al., 2015; Sherbourne & Hays, 1990).

Quality of life. This study uses the PROMIS-10 instrument, a 10-item measure to assess health-related physical, mental, and social health that is part of the larger NIH-supported Patient-Reported Outcomes Measurement Information System. The PROMIS-10 demonstrates strong convergent and discriminant validity and is a reliable instrument (Kasturi et al., 2018). The 29-item version of this instrument has previously been validated among people living with HIV (Schnall et al., 2017).

Substance use. The study uses the Alcohol Use Disorders Identification Test (AUDIT-C), a three-item screen to identify hazardous drinking and alcohol abuse and dependence (Bradley et al., 2003; Bush et al., 1998). The AUDIT-C is a practical and valid measure, shows internal consistency (Cronbach's α = 0.82–0.90), and good construct validity (Bush et al., 1998). Two items of the

Alcohol, Smoking, and Substance Involvement Test (ASSIST) were used to measure "ever use" of substances and "past three months" use of substances (Humeniuk et al., 2008; WHO ASSIST Working Group, 2002). The ASSIST demonstrates concurrent and discriminant validity, high internal consistency, and acceptable reliability for most substances (Hides et al., 2009; Humeniuk et al., 2008). Both the AUDIT-C and the ASSIST have previously been used among women living with HIV (Cuca et al., 2019; Dawson-Rose et al., 2017).

Trauma and Posttraumatic Stress Disorder. The 14-item Trauma History Screen was simplified to ask whether the respondent had ever experienced each potentially traumatic event (y/n; Prins et al., 2016). This instrument demonstrates reliability and construct validity and has previously been used among people living with HIV (Carlson et al., 2011; Cuca et al., 2019). The 5-item Primary Care PTSD Screen for DSM-5 (PC-PTSD-5) is used to measure the impact of trauma and to screen for potential post-traumatic stress disorder (PTSD). This instrument demonstrates content and face validity, and internal consistency (Cronbach's $\alpha = 0.87$), and has been used among people living with HIV (Kekibiina et al., 2021; Pence et al., 2007; Prins et al., 2016).

Year of HIV diagnosis. Various participant HIV characteristics are measured. Number of years living with HIV is calculated from this measure.

Engagement in HIV care. Participants are asked how many times they have seen their HIV primary care provider (doctor, nurse, nurse practitioner, or physician's assistant) in the past 12 months and what proportion of visits were in person versus virtual (telephone or video).

HIV medications and adherence. Participants are asked whether they are currently taking ARVs, have never taken them, or have taken them but stopped. Those who are currently taking ARVs are then asked two questions: "For the past [3 days/30 days] what percent of the time were you able to take your HIV medications exactly as prescribed," and entered a percentage on a scale from 0% to 100% (Lu et al., 2008; Walsh et al., 2002).

Viral load. Most recent viral load is recorded as undetectable (<50 copies/ml) or detectable. If detectable, the actual viral load is recorded.

HIV stigma. The study uses the Brief Measure of Stigma for HIV+ Youth, a 10-item measure that includes items about experiences and feelings related to how PWH are treated (Wright et al., 2007). The instrument, which demonstrates reliability, good internal consistency, and validity (Wright et al., 2007) is based on the 40-item HIV Stigma Scale (Berger et al., 2001) that has been used extensively among people living with HIV (Holzemer et al., 2009; Lodi et al., 2023; Montaño et al., 2020). The shorter 10-item version was selected to reduce respondent burden and also because it uses items directly from the original Berger scale. The original scale has been widely used and validated showing high internal consistency (Cronbach's $\alpha = 0.90$–0.96) and test–retest reliability ($r = .87$–$.92$; Berger et al., 2001; Holzemer et al., 2009).

The primary study outcomes are related to COVID-19 and to changes in various aspects of life because of the COVID-19 pandemic and mitigation strategies:

COVID-19 knowledge and information sources. Based on the Johns Hopkins University COVID Behaviors Dashboard (Babalola et al., 2021; Johns Hopkins University, n.d.), this survey includes three questions measuring knowledge about how COVID-19 is spread, symptoms of COVID-19, and knowledge about the term "physical distancing." An additional question asks about sources from which the participants received news and information about COVID-19 during the past week. The creation of the dashboard has been described in detail (Dong et al., 2021).

COVID-19 prevention behaviors. Items from the UCSF COVID-19 Citizen Science Study (Beatty et al., 2021) were used to measure how often the respondent wore a mask and observed physical distancing over the past week and "during the peak of COVID-19" in their locale. An additional question asks the extent to which the respondent has been able to carry out these prevention measures in their daily lives.

COVID-19 testing. Participants are asked whether they know where/how to get a COVID-19 test and whether they can afford the test if it is not free. They are asked about past tests, test results, and whether anyone close to them has tested positive or died from COVID-19.

COVID-19 vaccination. Participants are asked whether the COVID-19 vaccine is available where they live. They are then asked whether they have been vaccinated. If not, they are asked whether they plan to get vaccinated and, if not, their main reasons for choosing not to receive the vaccine. Among those who have been vaccinated, participants are asked which brand of vaccine they received and how many total vaccine shots they have received. An open-ended question asks whether they have any comments about the vaccination. All participants are then asked what factors influenced them to get the vaccine or not, with a set of responses modified from a similar question from the COVID-19 Citizen Science Study (Beatty et al., 2021).

Coping with COVID-19. This survey uses the All of Us Study COVID-19 Participant Experience (COPE) instrument, which asks participants to select all that apply from a list of strategies that they use "to cope with social distancing and isolation" (All of Us Study, n.d.; Schulkey et al., 2023).

Fear of COVID-19. This survey uses the Fear of COVID-19 Scale (Ahorsu et al., 2022), a 7-item instrument with a 5-point Likert-type response scale. Total scores range from 7 to 35, with higher scores indicating greater fear. This instrument has also been used among people living with HIV (Khumsaen & Peawnalaw, 2022). The scale had good internal consistency (Cronbach's α = 0.82) and test–retest reliability (r = 0.72). The scale also demonstrated convergent validity with measures of anxiety and depression (Ahorsu et al., 2022).

COVID-19 local policies. Participants are asked to identify local government restrictions designed to mitigate the spread of COVID-19, based on the COVID-19 Citizen Science Study (Beatty et al., 2021). We will access the Stringency Index, part of the Oxford COVID-19 Government Response Tracker, which calculated and compared the strictness of COVID-19 restriction by country or region over time (Hale et al., 2021).

Impact of COVID-19. The Center for Drug Use and HIV/HCV Research (CDUHR) hosted a website through GitHub for researchers to share COVID-19–related measurement items for vulnerable populations (CDUHR, 2020). The current survey uses a modified version of the Adolescent Trials Network (ATN) COVID Questionnaire Draft (Revised 4.2.20) posted on this site (ATN, 2020). Participants respond to the overall question "Compared to the time before COVID-19, please tell us if COVID-19 and the plans used to manage COVID-19 have impacted you," using a 5-point Likert-type scale of "highly decreased" to "highly increased" because of COVID-19. Seven items address general impacts (e.g., general quality of life, levels of anxiety, quality of sleep, feeling connected to family and friends, and access to resources and internet); four items address impacts on income (e.g., number of paid work hours, need to support others, difficulty buying food or paying rent); 12 items address activities and behaviors (e.g., number of sexual partners, opportunities to have sex, use of dating/hook-up apps, access to and use of condoms, access to STI testing or treatment, use of alcohol and drugs, and access to and adherence to hormones for individuals who are transgender); and four items address HIV (e.g., access and adherence to HIV meds, getting clinical care, and laboratory studies). An additional set of questions in the instrument asks more specifically about loss of jobs, insurance, and housing because of COVID-19. Three final items ask more specifically about access to HIV medications and care.

To gain a greater understanding of the impact of COVID-19 on PWH, a final open-ended question queries: "Is there anything you would like to share about your experience being HIV-positive during the COVID-19 pandemic?" Most of the COVID-19 measures are new and there is currently limited reliability and validity data published on them. We will report reliability and validity data on these measures. Data collection forms are available on request from the CC.

Planned Analyses

To address the first objective of the study—to describe the impact of COVID-19 across the HIV Care Continuum, and examine HIV and other physical, social, and mental health symptoms—we will perform descriptive analyses focused on variables of interest including ATN access to HIV medications, ATN adherence to HIV medications, ATN access to clinical care, viral load, PTSD symptoms, quality of life, HIV stigma, and substance use. To address the second objective—to identify barriers to COVID-19 testing, care and, vaccination among PWH—we will use descriptive analyses to summarize availability and cost of COVID-19 testing and vaccination, and receipt of vaccinations. To address the third objective—to examine COVID-19 vaccine hesitancy among PWH—we will utilize descriptive analyses to summarize reasons for and against getting a COVID-19 vaccination.

Additional analyses, as proposed through concept papers submitted through the CC REDCap system, will focus on other outcomes and will use appropriate additional analyses. Topics may include, for example, the impact of COVID-19 on sleep using linear models or linear regression, adjusted for social determinants of health; gender differences in HIV medication adherence during the COVID-19 pandemic; and impact of knowing someone who died on COVID-19 prevention behaviors. Power analyses will be conducted for each analysis. Analyses will take into consideration the potential of response pattern difference based on method of data collection.

Discussion

Because PWH are known to experience symptoms of poor physical, mental, and social health (Marziali et al., 2019; Rubin & Maki, 2019; Shah et al., 2018), it is essential to assess the impact of the COVID-19 pandemic and associated shelter-in-place/lock-down mandates as well as social distancing on these factors. We expect to observe negative impacts along the HIV care continuum (e.g., reduced engagement in care, reduced access and adherence to HIV medications, and unsuppressed viral load), and substantial negative mental and social health outcomes (fear of COVID-19, poor quality of life, poor social support, and PTSD symptoms). The study will examine differences in these outcomes and differences in

vaccine hesitancy by various factors such as location, COVID-19 knowledge, and local COVID-19 policies and their stringency. This study will generate rigorous data on the physical, mental, and social health experiences of PWH during the COVID-19 pandemic, and these data will inform recommendations for PWH during future public health crises.

Author Contributions

All authors on this paper meet the four criteria for authorship as identified by the International Committee of Medical Journal Editors (ICMJE); all authors have contributed to the conception and design of the study, drafted, or have been involved in revising this manuscript, reviewed the final version of this manuscript before submission, and agree to be accountable for all aspects of the work.

Specifically, using the CRediT taxonomy, the specific contributions of each author is as follows:

Conceptualization, Funding Acquisition, Investigation, Methodology, & Project Administration: Y.P. Cuca, C. Horvat Davey, I.B. Corless, J.C. Phillips, A.J. Sierra-Perez, S. Solís-Báez, E. Iwu, M. Sabone, M. Tshilidzi Mulaudzi, C. Murphey, S. Shaibu, W.-T. Chen, D. Santa Maria, R. Schnall, P. Palmieri, P. Apiruknapanond, T. Wang, T. De Jesús, E. Huang, J. Broussard, and C. Dawson-Rose; Writing—Original Draft: Y. Cuca and C. Dawson-Rose; Writing—Review & Editing: Y. Cuca, C. Horvat Davey, I.B. Corless, J.C. Phillips, T. De Jesús, and C. Dawson-Rose.

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Key Considerations

- People with HIV (PWH) and other chronic or complex health conditions may encounter challenges accessing medications and necessary health care services during large-scale public health responses to a pandemic or humanitarian disasters that require careful planning, collaboration, and coordination with nurses and other health care providers.
- Clinicians working with PWH should develop contingency plans with PWH and other people living with chronic or complex health conditions to ensure that continuity of care is maintained throughout pandemics or other humanitarian disasters and the responses.
- Clinicians working with PWH may need to advocate with policy makers to ensure that necessary steps are taken to limit disruptions to access to necessary medications and health care for PWH during the initial phases of pandemic response or in humanitarian disasters.

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