Brief Report

Variation in subsequent viral load testing and outcomes by visit type patterns in the first year of the COVID-19 pandemic at a large academic medical center in North Carolina

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Abstract: While telehealth was widely used to provide human immunodeficiency virus (HIV) care during the coronavirus disease 2019 (COVID-19) pandemic, research evaluating viral suppression by visit type is conflicting. This study assessed variation in viral load (VL) testing and outcomes by visit type for routine HIV care visits among people living with HIV (PWH) at a large academic health center in central North Carolina (NC). Electronic health records (EHRs) data from the Duke University Infectious Disease (ID) Clinic in NC were extracted in aggregated form. Pearson's Chi-square (χ^2) tests were used to examine variation in VL testing and virologic suppression (VS) in 2022 by visit type patterns in the first year of the pandemic. Tipping point (TP) sensitivity analyses were conducted. EHR data from 1,835 PWH were included. Between March 16, 2020 and March 15, 2021, 53% of PWH received in-person HIV care only, 32% received a combination of telehealth and in-person care, and 15% received telehealth care only. About 20% of PWH did not have any VL test recorded in 2022. Among PWH with a VL test, 90% were virologically suppressed at all tests in 2022. Visit type was significantly associated with VL testing (P<0.001). The proportion of people who had no VL test in 2022 was larger among telehealth only users (31%) as compared to in-person only or PWH who received a combination (19% and 18%, respectively). VS in 2022 did not differ by visit type pattern in the first year of the pandemic (P=0.36) among PWH with a VL test in 2022. TP analyses identified that the proportion of unsuppressed VL tests among PWH without any VL test in 2022 would need to be multiplied by 2.1 to result in a statistically significant difference in VS by visit type (P=0.045). Our findings indicate that VL outcomes among telehealth users who had VL testing results documented in EHR at least one year later did not differ from in-person HIV care users. However, VL testing uptake was lower among telehealth only users suggesting the need for strategies such as remote VL testing to ensure regular VL testing among PWH who use telehealth HIV care.

Keywords: Human immunodeficiency virus care outcomes (HIV care outcomes); telehealth; electronic health records (EHRs); coronavirus disease 2019 (COVID-19); North Carolina (NC)

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Introduction

People living with human immunodeficiency virus (HIV) faced high levels of HIV care interruptions during the coronavirus disease 2019 (COVID-19) pandemic (1,2). Telehealth was rapidly implemented in most HIV clinics across the United States (US) to facilitate continuity of care (3). HIV care continuity is crucial to attain antiretroviral treatment (ART) benefits, such as decreased HIV-related co-morbidities and improved life expectancy for people living with HIV (PWH), and reduced transmission risk for people at risk of acquiring HIV (4-6).

As HIV treatment relies heavily on regular laboratory testing to monitor HIV progression and immune status, viral load (VL) and cluster of differentiation 4 (CD4) count testing uptake and outcomes were frequently used to describe the quality of telehealth HIV care. However, study findings remain conflicting. While some telehealth studies found that neither VL outcomes nor CD4 counts varied by visit type or pandemic *vs.* pre-pandemic time periods (7-12), Galaviz *et al.* found increased telehealth visit volumes to co-occur with lower rates of undetectable VLs (13). Other studies noticed increased odds of viral non-suppression during shelter-in-place orders (14,15), and after the initial COVID-19 wave (16), as compared to the pre-pandemic epoch. Widely varying approaches, data sources, sample sizes, and foci on specific populations (e.g., veteran or pediatric/adolescent populations) limit the generalizability of study results.

This study is one of the first to evaluate variation in VL testing and outcomes following variation in HIV care visit types in the first year of the COVID-19 pandemic at a large academic medical center in North Carolina (NC) serving a diverse population of PWH. Using data on all HIV care visits of the entire patient population served at a large HIV care provider in NC, our findings provide additional understanding of conflicting literature by assessing variation in subsequent VL testing and outcomes related to visit type patterns during the first year of the COVID-19 pandemic.

Methods

Design, setting, and data

We used a retrospective observational study design to evaluate variation in VL testing and outcomes by visit type in the first year of the COVID-19 pandemic among PWH. Electronic health records (EHRs) data from Duke University's Infectious Diseases (ID) Clinic in Durham, NC were used. The Duke ID clinic provides HIV care to a heterogeneous patient population of around 2,000 PWH. Study data comprise all visits of eligible patients, i.e., adult PWH cared for by the Duke ID clinic between March 16, 2020 to December 31, 2022. EHR data were extracted using Epic's SlicerDicer tool, a reporting tool within Epic EHR management software (17) in June 2023. Visit-level data were aggregated across patients by HIV care pattern and VL history. This manuscript is part of a larger study on telehealth and in-person care use during the COVID-19 pandemic, a detailed description of the data used in this study has been reported previously (18).

Ethical statement

The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). Researchers from Duke University and University of South Carolina collaborated to conduct this study and sought ethical approval for their research and collaboration at both institutions. The study protocol was determined to be exempt from review by the Institutional Review Boards (IRBs) of Duke University Health System (Pro00112920) and the University of South Carolina (Health Sciences South Carolina IRB; Pro00128577). The IRBs waived the requirement for informed consent.

Variables of interest

Visit type patterns were described as whether PWH

received (I) only in-person; (II) a combination of telehealth and in-person; or (III) only telehealth HIV care in the first year of the pandemic (i.e., between March 16, 2020 and March 15, 2021). March 16, 2020 was selected as beginning of the pandemic as that day marked a clear and sudden drop in in-person clinic visits at Duke's ID clinic. NC's stay at home order was enacted shortly thereafter on March 30, 2020. The key outcome variables of interest were VL testing in 2022 and viral suppression (VS) among people who had a test in 2022 as VL is the recommended clinical marker to monitor a patient's response to ART (19) and can be used to assess longer-term outcomes associated with telehealth. VL testing was categorized into two groups: (I) not having any VL test recorded in 2022 or (II) having at least one VL test recorded in 2022. VS was categorized into two groups: (I) VS at all tests in 2022 [<200 copies per milliliter blood (c/mL)] or (II) at least one VL test was unsuppressed in 2022 (≥200 c/mL).

Analysis

Differences in VL testing and VS by visit type patterns were assessed using Pearson's Chi-square (χ^2) tests.

Two different approaches of tipping point (TP) analysis were performed to explore the sensitivity of our results. TP analysis is an approach to analyze missing data under the assumption that missing data are related to unobserved variables and to identify the 'tipping point' at which differences in VS by visit type patterns become statistically significant (20,21). TP scenarios were generated to describe missing VL outcomes among PWH that had no VL test in 2022 (18–30.9% across visit type patterns).

The first approach of TP analysis explored the increasing proportion of PWH with at least one unsuppressed VL test among those without a VL test ("non-testers") keeping the treatment effect of visit types constant. The observed proportion of PWH with unsuppressed VL among those who had a VL test in 2022 ("tested") was used as the starting point (multiplier =1). Following recent studies reporting that people with unsuppressed VL were more likely to delay or miss VL tests (22,23), we incrementally increased the proportion of unsuppressed VL in our missing data from non-testers. The multipliers ranged from 1 to 4 increasing by 0.1 increments. For example, the multiplier 2.3 describes a scenario where the proportion of PWH with an unsuppressed VL test among non-testers is 2.3 times the proportion of PWH with at least one unsuppressed VL test among tested PWH.

For the second approach of TP analysis, the treatment effect for mixed visit types and telehealth only compared to in-person HIV care was calculated using the proportion ratio of unsuppressed VL tests. The treatment effect was incrementally decreased and tested the assumption that telehealth use (only and in combination) is inferior to in-person care. Telehealth only and mixed visit types were compared to in-person care separately by calculating the relative difference in treatment effects, which describes the probability of in-person care being more effective than telehealth or mixed visit types. TP scenarios were generated by incrementally adding 1-percentage point (pp) to the proportion of unsuppressed VL tests among non-testers using mixed visit types or telehealth only. The pp increase ranged from 0–20. The proportion of unsuppressed VL tests for in-person care remained constant at the VS rate among tested PWH. χ^2 tests were performed for each scenario. P values below 0.05 were considered statistically significant. Analyses were performed in StataSE version 18 (StataCorp, College Station, TX, USA).

Results

Among the 1,835 PWH who received HIV care at the Duke ID clinic in the first year of the COVID-19 pandemic, most patients were 50 years and older (63%), non-Hispanic Black (58%), male (74%), and living in a county different from the ID clinic location (65%; *Table 1*). About half (53%) received exclusively in-person HIV care, 32% PWH received a combination of telehealth and in-person HIV care, and 15% PWH received exclusively telehealth HIV care. About 20% of PWH did not have any VL test recorded in 2022, 72% of PWH were virologically suppressed at all tests in 2022, and 8% had at least one unsuppressed VL test. Among those who had at least one VL test documented in 2022 (n=1,461), 90% were virologically suppressed at all tests in 2022, and 10% had at least one unsuppressed VL test.

VL testing in 2022 varied significantly by visit type patterns in the first year of the pandemic (P<0.001; *Figure 1A*). The proportion of people who had no VL test recorded was higher among people who used telehealth only as compared to people who used in-person care only or a combination of telehealth and in-person HIV care (31% *vs.* 19% and 18%, respectively). We found no significant variation in VS by visit type among people who had at least one VL test in 2022 (*Figure 1B*).

Our first approach for the TP sensitivity analysis followed the assumption that VS is different among non-

Table 1 Characteristics of people living with HIV receiving care at Duke's Infectious Diseases Clinic between March 16, 2020 and March 15, 2021 (n=1,835)

Characteristics	People living with HIV, n (%)
Current age[†]	
18–49 years	684 (37.28)
50 years and older	1,151 (62.72)
Race and ethnicity	
Non-Hispanic White	539 (29.37)
Non-Hispanic Black	1,072 (58.42)
Other or unspecified	224 (12.21)
Legal sex	
Female	484 (26.38)
Male	1,349 (73.51)
Other	2 (0.11)
County of residence	
Clinic county	640 (34.88)
Other county	1,195 (65.12)
Visit type patterns[‡]	
Only in-person	970 (52.86)
Combination of telehealth and in-person	583 (31.77)
Only telehealth	282 (15.37)
VL history in 2022	
No viral load test	374 (20.38)
All <200 c/mL	1,317 (71.77)
At least one ≥200 c/mL	144 (7.85)
VL history in 2022 among patients with at least one VL test (n=1,461)	
All <200 c/mL	1,317 (90.14)
At least one ≥200 c/mL	144 (9.86)

[†], current age at the time of data extraction in June 2023; [‡], visit type patterns categorize all HIV care visits between March 16, 2020 and March 15, 2021. c/mL, copies per milliliter blood; HIV, human immunodeficiency virus; VL, viral load.

testers compared to tested PWH (*Figure 2*). We identified the following scenarios at which changes in VS by visit type patterns reached statistical significance: multiplying the proportion of PWH with at least one unsuppressed VL test among non-testers by a factor of 2.1 reached significance at α =0.05 with P=0.045. Multiplying the proportion of PWH with at least one unsuppressed VL test among non-testers by a factor of 2.8 reached statistical significance at α =0.01 with P=0.009.

The treatment effect (proportion ratio of unsuppressed VL tests) among tested PWH for mixed visit types *vs.* in-person only care was 1.14 indicating that PWH using mixed visit types were 1.14 times as likely to have an unsuppressed VL test than in-person only users. The treatment effect for telehealth only *vs.* in-person only care was 1.37. For our second approach for the TP sensitivity analysis, we incrementally decreased the effect of telehealth only (*Figure 3A*) and mixed visit types (*Figure 3B*). We identified that telehealth only reached significance at α =0.05 with a 3-pp increase in the proportion of unsuppressed VL tests among non-testers with P=0.04 (treatment effect: 1.70). Telehealth only reached significance at α =0.01 with a 7-pp increase in the proportion of unsuppressed VL tests among non-testers with P=0.007 (treatment effect: 2.14). Telehealth only reached significance at α =0.001 with a 13-pp increase in the proportion of unsuppressed VL tests among non-testers with P<0.001 (treatment effect: 2.81).

For mixed visit type use, TP analysis #2 showed that significance at α =0.05 was reached with an 11-pp increase in the proportion of unsuppressed VL tests among non-testers with P=0.043 (treatment effect: 2.36). Mixed visit types reached significance at α =0.01 with a 16-pp increase in the proportion of unsuppressed VL tests among non-testers with P=0.009 (treatment effect: 2.91).

Discussion

Telehealth HIV care was used by almost half (47%) of the PWH cared for by the Duke ID clinic between March 16, 2020 and March 15, 2021. We found that visit type patterns were significantly associated with VL testing uptake in 2022 but not VS among people with at least one VL test in 2022.

Among telehealth only users the proportion not having a VL test documented in 2022 was higher than among in-person care users and those using a combination of telehealth and in-person HIV care. While our data does not allow us to further examine the characteristics of telehealth only users, we hypothesize that the lack of VL testing may stem from two factors: the inability to draw blood during telehealth encounters and patients' transferring care to another clinic. Firstly, the lack of ability to draw blood during a telehealth encounter is an often-cited barrier to or disadvantage of telehealth (13,24-28). As demonstrated

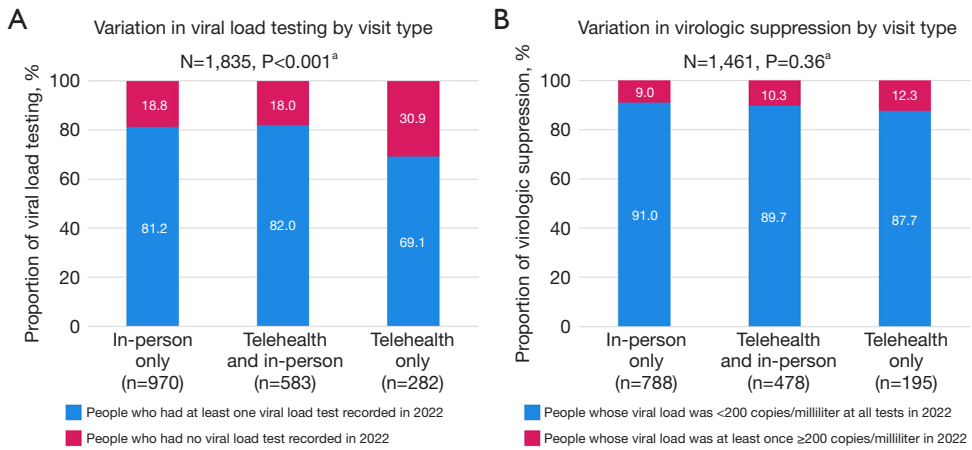

Figure 1 Systematic variation in viral load testing and virologic suppression in 2022 with patterns of HIV care visit types during the first year of the COVID-19 pandemic*. (A) Variation in viral load testing by visit type. (B) Variation in virologic suppression by visit type. [a], P values are calculated by Pearson's Chi-square test. *, March 16, 2020 through March 15, 2021. COVID-19, coronavirus disease 2019; HIV, human immunodeficiency virus.

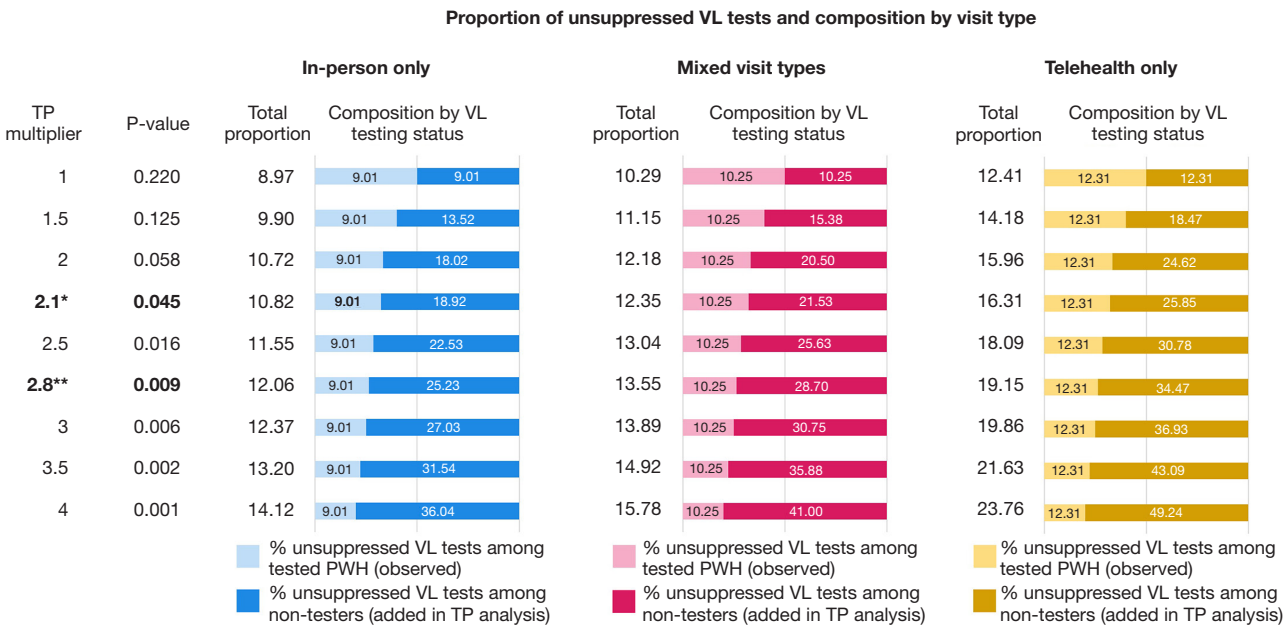

Figure 2 TP sensitivity analysis #1: Pearson's Chi-square test results and proportion of people with at least one unsuppressed VL test by TP multiplier and visit type. Tipping point scenarios incrementally increased the proportion of people with HIV with at least one unsuppressed VL test among those who had no VL test in 2022. Tipping point multipliers ranged from 1 to 4. Pearson's Chi-square tests were used to assess the variation in virologic suppression by visit type patterns for each tipping point scenario. *, statistical significance at α =0.05; **, statistical significance at α =0.01. HIV, human immunodeficiency virus; TP, tipping point; PWH, people living with HIV; VL, viral load.

in pilot studies (29,30), alternative laboratory monitoring strategies including home-based VL testing and monitoring may present a feasible option to guide the optimal integration of telehealth in HIV care, promote successful and equitable HIV care, and to overcome this disadvantage of telehealth HIV care. Secondly, our study population likely included people who moved and/or transferred care to another clinic during or after the pandemic. While we do not

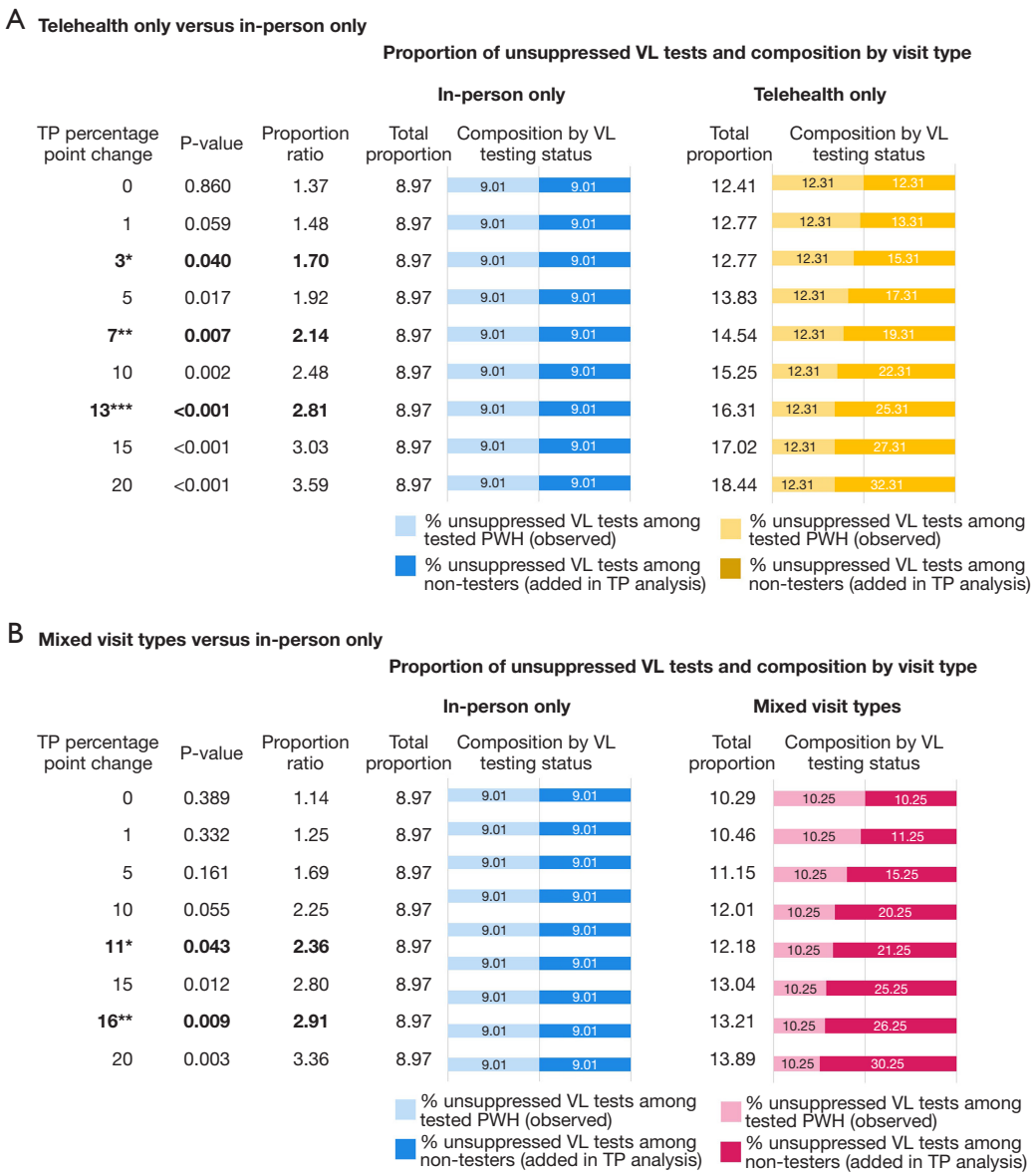

Figure 3 TP sensitivity analysis #2: Pearson's Chi-square test results and treatment effect of people with at least one unsuppressed VL test by TP percentage point increase and visit type. Tipping point scenarios incrementally increased the proportion of people with HIV with at least one unsuppressed VL test among telehealth and mixed visit type users who had no VL test in 2022. Percentage point increases ranged from 0 to 20. Pearson's Chi-square tests were used to assess the variation in virologic suppression comparing telehealth only *vs.* in-person only and mixed visit types *vs.* in-person only for each tipping point scenario. (A) Telehealth only versus in-person only. (B) Mixed visit types *vs.* in-person only. *, statistical significance at α =0.05; **, indicate statistical significance at α =0.01; ***, indicate statistical significance at α =0.001. HIV, human immunodeficiency virus; PWH, people living with HIV; TP, tipping point; VL, viral load.

have access to data to observe care engagement and outcomes of PWH who left our HIV clinic, clinic transfers can be associated with undesirable HIV care outcomes (31). Future research is needed to understand whether people who do not have a VL test documented in Duke's ID clinic EHR have discontinued their care or continued it elsewhere.

We found that 90% of PWH who had at least one VL test documented in 2022 at Duke's ID Clinic were virologically suppressed at all tests. Including all PWH in our study population, VS was reached by 72% of people

with HIV, which is 5 percentage-points above the rate of VS in NC (32). Finding that the proportions of PWH having at least one unsuppressed VL result in 2022 is not statistically significantly different across visit type patterns supports telehealth as a viable HIV care option that can lead to desirable HIV care outcomes as described by others (7-11,33,34). Nevertheless, reports of lower viral suppression rates among telehealth users in some studies and especially among people experiencing housing instability (13-16), merit serious consideration. Prudence requires continued monitoring of VL testing and sustained efforts to encourage antiretroviral medication adherence to maintain VS among telehealth users.

Borrowing the TP approach from clinical trial methodology, we were able to provide additional, important context information to evaluate telehealth in HIV care and its performance under "worse" circumstances as compared to the observed. Firstly, we were able to characterize those PWH who did not have a documented VL in 2022 and identify the 'tipping point proportion' of viral non-suppression that would result in a statistically significant difference of VL outcomes by visit type. While research shows that missed HIV care visits are associated with undesirable clinical outcomes (35), our findings identify a large TP at which the use of telehealth would be associated with undesirable outcomes as compared to in-person care supporting the robustness of our findings. The proportion of PWH with an unsuppressed VL among non-testers would have to be twice (or almost three times) as high as the proportion of PWH with an unsuppressed VL among testers to reach significance with a 95% (or 99%) confidence level. This large difference in the proportion of viral non-suppression necessary to result in worse outcomes associated with the use of telehealth may support the suitability of telehealth. Nevertheless, longitudinal studies following PWH in their HIV care treatment for a longer period are needed to assess VL outcomes over time among people who have missed HIV care and/or laboratory visits. Secondly, we were able to identify the change in treatment effectiveness of telehealth only or mixed visit types to reach statistically significant differences of VS by visit type. Our analyses showed that large TPs would be needed for significant results indicating that in-person care is more effective than telehealth or mixed visit types. This finding supports the robustness of our initial findings that there is no significant difference between visit types. For telehealth only, the relative difference in treatment effect would need to be almost twice (or more than three times) as large to reach significance with a 95% (or 99%) confidence level. For mixed visit types, the relative difference in treatment effect would need to be almost 10 times (or more than 13 times) larger to reach significance with a 95% (or 99%) confidence level. Identifying these large differences in treatment effect needed to reach statistical significance therefore supports the suitability of telehealth as an HIV care option with the potential to achieve desirable HIV care outcomes and ART benefits. However, these TP scenarios were artificially designed, and studies evaluating real world evidence are warranted to inform telehealth scale-up and promotion in HIV care.

Limitations

We note several limitations of this study. Firstly, we only included EHR data from one HIV care clinic in NC, which limits generalizability of our findings. Secondly, because this study used aggregated data multivariable analyses including other potential confounders of VL testing and outcomes could not be performed. Nevertheless, findings from this study warrant further individual-level and multi-variable analyses to immerse deeper into telehealth and HIV care disparities and explore causal relationships. Thirdly, in our study we use subsequent outcomes data measured in calendar year 2022 (≥1 year after visits occurred). While this may result in the inclusion of people moving or switching HIV care providers, it allows to focus on longer-term outcomes and prevents an overemphasis of short-term COVID-19 pandemic-related changes in VL testing and VS. Fourth, using Chi-squared tests, we tested for a difference of outcomes which does not allow any direct conclusions regarding non-inferiority of telehealth compared to telehealth. The small proportion of people using telehealth only care in our study may have prevented detecting significant differences. As mentioned above, a more detailed analysis of individual level data should investigate equivalence or non-inferiority of visit types.

Conclusions

We found a significant difference in VL testing but not in VL outcomes among telehealth users who had VL testing results at least one year later. By using TP analysis, we further identified that the proportion of PWH having unsuppressed VL tests would need to be more than twice as high among people who had no VL test as compared to people with VL tests to show statistically significantly

different VS rates by visit type. This finding supports the robustness of our finding that VL outcomes do not vary by visit type. Taken together, these data provide some support for telehealth as a viable HIV care option to achieve desirable HIV care outcomes at the individual and population level, with the caveat that in this analysis VL testing uptake was lower among telehealth only users. As VL testing is crucial to monitor treatment success, strategies such as remote VL testing at home or through a local laboratory could help to ensure regular VL testing among PWH who use telehealth HIV care.

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Footnote

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). Researchers from Duke University and University of South Carolina collaborated to conduct this study and sought ethical approval for their research and collaboration at both institutions. The study protocol was determined to be exempt from review by the Institutional Review Boards (IRBs) of Duke University Health System (Pro00112920) and the University of South Carolina (Health Sciences South Carolina IRB; Pro00128577). The IRBs waived the requirement for informed consent.

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