

RESEARCH ARTICLE

# Quality assessment of data for decentralised antiretroviral therapy referrals and laboratory results in the South African national electronic HIV management register TIER.Net

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**Citation:** Naidu L, van der Molen J, Jugathpal V, Sookrajh Y, Khubone T, Hobe L, et al. (2026) Quality assessment of data for decentralised antiretroviral therapy referrals and laboratory results in the South African national electronic HIV management register TIER.Net. PLOS Glob Public Health 6(3): e0005534. <https://doi.org/10.1371/journal.pgph.0005534>

**Editor:** Andrés F. Henao-Martínez, University of Colorado Anschutz Medical Campus: University of Colorado - Anschutz Medical Campus, UNITED STATES OF AMERICA

**Received:** November 6, 2025

**Accepted:** February 23, 2026

**Published:** March 16, 2026

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**Data availability statement:** The data used for this analysis cannot be shared publicly because of legal and ethical requirements regarding

## Abstract

Three Interlinked Electronic Register (TIER.Net) is South Africa’s national electronic HIV patient database, used to monitor antiretroviral therapy (ART) delivery and laboratory results. However, few published evaluations have quantified TIER.Net data quality relative to national sources. We aimed to evaluate how well decentralised ART referral and laboratory result data are captured in TIER.Net. We conducted a retrospective analysis comparing TIER.Net to national electronic health systems. For decentralised ART, we used de-identified data from 56 clinics in eThekweni (2020–2023) and compared the annual number of TIER.Net decentralised ART referrals to ART prescriptions in the Synchronised National Communication in Health (SynCH) database. For laboratory data, we used de-identified records from 103 clinics in KwaZulu-Natal (2015–2022) and compared the annual number of TIER.Net viral load (VL) and CD4 tests with the number in National Health Laboratory Service (NHLS). The proportion of SynCH decentralised ART prescriptions and NHLS VL and CD4 counts captured in TIER.Net were calculated by clinic, and trends were assessed using linear mixed-effects models (LMMs). The median proportion of SynCH decentralised ART prescriptions captured in TIER.Net was 104.4% (IQR: 99.9-115.1%) in 2020 and 102.4% (IQR: 100.5-104.5%) in 2023. The LMM estimated an annual decrease of 2.8% (95% CI: -5.2;-0.5%). The median proportion of NHLS VLs captured in TIER.Net was 85.7% (IQR: 70.0-97.9%) in 2015 and 99.1% (IQR: 94.5-102.5%) in 2022. The LMM estimated an annual increase of 1.8% (95% CI: 1.2;

use of routinely collected clinical data in South Africa and because they are owned by the KwaZulu-Natal Provincial Department of Health. The TIER.Net data can be requested from the KwaZulu-Natal Provincial Department of Health through the Epidemiology, Health Research and Knowledge Management email address, [hrkm@kznhealth.gov.za](mailto:hrkm@kznhealth.gov.za). The SyNCH data can be requested through the Health Systems Trust email address, [hst@hst.org.za](mailto:hst@hst.org.za). NHLS data can be requested through the Academic Affairs and Research Management System (AARMS) website (<https://aarms.nhls.ac.za/Public/Default.aspx>). The analysis code is available on request from the first author.

**Funding:** This work was supported, in whole or in part, by the Gates Foundation (INV-073793). The conclusions and opinions expressed in this work are those of the authors alone and shall not be attributed to the Foundation. Under the grant conditions of the Gates Foundation, a Creative Commons Attribution 4.0 Generic License has already been assigned to the Author Accepted Manuscript version that might arise from this submission. JAB is funded by the Swiss National Science Foundation (P500PM\_221966, to JAB). JD, Academic Clinical Lecturer (CL-2022-13-005), is funded by the UK National Institute of Health and Social Care Research (NIHR). The views expressed in this publication are those of the authors and not necessarily those of the NIHR, the National Health Service, or the UK Department of Health and Social Care. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

**Competing interests:** The authors have declared that no competing interests exist.

**Abbreviations:** ART, Antiretroviral therapy; CCMDD, Centralized Chronic Medicines Dispensing and Distribution; HIV, human immunodeficiency virus; IQR, Interquartile range; NHLS, National Health Laboratory Service; SyNCH, Synchronised National Communication in Health; TIER.Net, Three Interlinked Electronic Register; VL, Viral load.

2.3%). The median proportion of NHLS CD4s captured in TIER.Net was 74.3% (IQR: 63.9-85.4%) in 2015 and 80.1% (IQR: 68.4-89.1%) in 2022. The LMM estimated no statistically significant trend over time (-0.09%, 95% CI: -0.9;0.7). Reassuringly, capture of TIER.Net for decentralised ART and VL data has improved to near 100%, but CD4 count capture remains sub-optimal, highlighting strengths and limitations of conducting analyses with this critical HIV programme database.

## Introduction

The Three Interlinked Electronic Register (TIER.Net) is a paper-to-digital electronic register used to record demographic and clinical data for individuals receiving antiretroviral therapy (ART) in the South African public sector [1]. TIER.Net data capturers use paper-based medical records to manually enter data on decentralised ART delivery through the Centralized Chronic Medicines Dispensing and Distribution (CCMDD) programme and laboratory test results including viral load (VL) and CD4 counts. Data from TIER.Net is collated at clinic, district, provincial, and national levels to support the evaluation of the HIV programme and to support clinical management and policy decisions [1–3]. However, few published evaluations have quantified the quality of TIER.Net data relative to other national data sources that record CCMDD ART prescriptions, VL and CD4 count tests.

In South Africa, decentralised ART delivery for clinically stable people living with HIV has expanded rapidly through the CCMDD programme, which enables patients to collect their medicines from designated pick-up points outside of healthcare facilities [4]. By 2024, over 5.3 million patients had been registered on the CCMDD programme with approximately 2.9 million patients actively collecting ART through the programme [5]. For patients receiving an ART prescription through CCMDD, the corresponding clinic visit should be manually recorded in TIER.Net as a CCMDD referral. Accurate capture of these referrals in TIER.Net is critical to ensure that patients collecting ART outside of the clinic are not erroneously classified as lost to follow-up. CCMDD prescriptions, including ART prescriptions, are processed through the Synchronised National Communication in Health (SyNCH) [6,7]. Therefore, comparison of SyNCH data and TIER.Net data can affirm the completeness and reliability of CCMDD referral records within TIER.Net.

The National Health Laboratory Service (NHLS) conducts all public sector VL and CD4 count testing and has a national repository for laboratory data from the public sector [8]. Therefore, comparison of NHLS and TIER.Net data can affirm the reliability of VL and CD4 count records captured within TIER.Net.

Understanding the quality of data within TIER.Net is increasingly critical as South Africa scales up differentiated service delivery models such as the CCMDD programme. With rising patient enrolment in CCMDD and a growing emphasis on client-centred care amidst funding constraints, accurate and reliable data is essential for monitoring programme performance and informing policy decisions. TIER.Net provides a comprehensive dataset, including sociodemographic, clinical, and laboratory

variables necessary for robust evaluations of CCMDD's impact on treatment outcomes [4,9]. Key indicators such as VL, which reflects the final "95" in the UNAIDS 95-95-95 targets [10], and CD4 count, used to classify AIDS progression and advanced HIV disease (AHD) [11], are central to programmatic assessments. Furthermore, TIER.Net data has supported numerous peer-reviewed publications evaluating various aspects of the national HIV response [3,12–14]. A deeper understanding of the completeness and reliability of this data will help identify and mitigate potential biases in current and future analyses.

We aimed to assess the quality of data captured in TIER.Net by comparing the total number of CCMDD referrals in TIER.Net with the corresponding CCMDD ART prescriptions fulfilled in the SyNCH database, as well as the total number of VL and CD4 tests recorded in TIER.Net with the corresponding results in the NHLS database.

## Methods

### Study design and setting

We conducted a retrospective analysis using de-identified, routinely collected data from the KwaZulu-Natal province, South Africa. To compare decentralised ART referral data, we included clinic-level TIER.Net and SyNCH data from 56 public clinics in the eThekweni Municipality. To compare VL and CD4 count data, we used clinic-level TIER.Net and NHLS data from 103 clinics managed by eThekweni Municipality (53 clinics), uMgungudlovu District (37 clinics) and uMkhanyakude District (13 clinics).

In 2022, KwaZulu-Natal was among the provinces with the highest HIV prevalence (16.0%) [15]. The CCMDD programme was initially introduced in KwaZulu-Natal to support ART roll-out [12]. The programme contracts pharmacy service providers to dispense and deliver ART and noncommunicable disease medicine parcels at pick-up points, including external pick-up points (private sector community pharmacies or general practitioners), adherence clubs, and internal pick-up points within the clinic that allow for ART collection without a nurse consultation [7]. The standard prescription length is 6-months, however, 12-month prescriptions were permitted from May 2020 to September 2021 in response to the COVID-19 pandemic [9].

Based on the national ART guidelines applicable during the time of this analysis, HIV VL testing was advised at six and twelve months after starting ART, and then annually, with viraemia triggering adherence counselling and repeat VL testing after three months [16]. In South Africa, the 'Universal Test and Treat' (UTT) strategy was rolled out in May 2016 which advises ART initiation to individuals who test positive for HIV irrespective of their CD4 count and clinical staging [17]. CD4 cell count testing is advised at and 10 months after ART initiation, upon re-initiation after disengagement from care, detection of viraemia, or clinical indication, and six-monthly while viraemic or as long as the previous CD4 cell count was  $\leq 200$  cells/ $\mu$ L [16]. CD4 counts are a crucial predictor of disease progression, particularly for AHD [11].

### Participants

We included all people living with HIV receiving ART through the CCMDD programme at participating clinics in eThekweni Municipality between 1 January 2020 and 31 December 2023, and all HIV VL and CD4 test results recorded in TIER.Net and the NHLS data warehouse from participating clinics between 1 January 2015 and 31 December 2022.

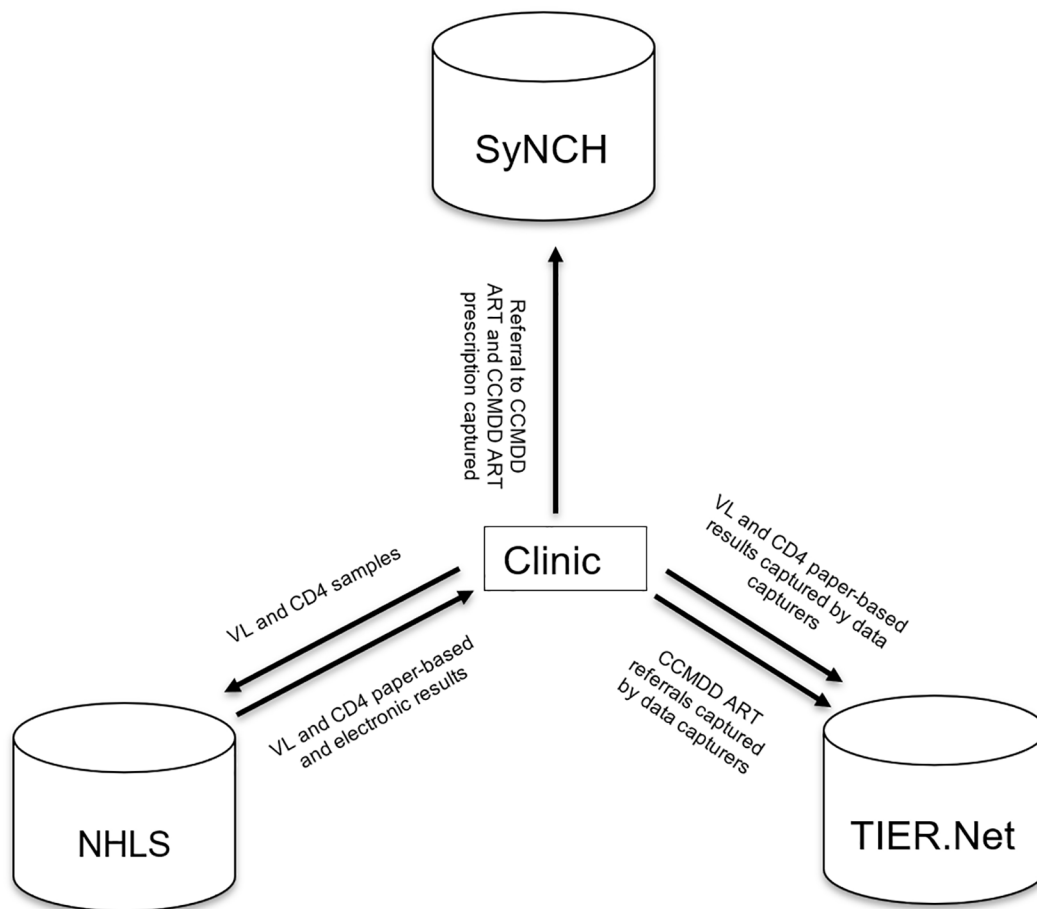
### Data sources and data management

TIER.Net, NHLS and SyNCH data were accessed on 19 March 2024, 30 Jan 2025 and 29 May 2025, respectively. TIER.Net and NHLS included individual de-identified patient level data, while SyNCH included aggregated clinic-level data. Duplicated tests were removed from the TIER.Net and NHLS dataset if an individual had more than one test recorded on the same day. SyNCH data was not at an individual level; therefore, duplicate prescriptions, if any, could not be removed. TIER.Net CCMDD ART referrals and SyNCH CCMDD ART prescriptions were categorised by pick-up point (external,

internal and adherence club) by year and totalled to the clinic-level by year. TIER.Net and NHLS VL and CD4 count tests were totalled by thresholds by year and totalled to clinic-level by year. There was 1 clinic that does not have year values for laboratory tests in 2015, therefore only laboratory test values for 2016–2022 were included in the model (Fig 1).

### Variables

For the CCMDD analysis, the primary endpoint was the proportion of SyNCH CCMDD ART prescriptions captured in TIER.Net per year. The secondary endpoints were the proportion of SyNCH CCMDD ART prescriptions captured in TIER.Net per year by pick-up point (external, internal and adherence club). For the laboratory analysis, the primary endpoints were the proportion of NHLS VL and CD4 cell count results captured in TIER.Net per year. Categorical laboratory test variables were created from absolute numbers of the VL and CD4 results received from NHLS and TIER.Net. The secondary endpoints were proportion of NHLS VL and CD4 cell count results in TIER.Net per year by threshold (VL: <50, between 50 and 1000, and ≥ 1000 copies/mL; CD4: <200 and ≥ 200 cells/μL). Clinic size was measured annually and defined as the number of individuals who visited the clinic at least once in a year.



**Fig 1. Flow-chart showing flow of data between different sources and the clinic.** ART: antiretroviral therapy; CCMDD: Centralized Chronic Medicines Dispensing and Distribution; National Health Laboratory Service (NHLS); SyNCH: Synchronised National Communication in Health; TIER.Net: Three Interlinked Electronic Register; VL: Viral Load.

<https://doi.org/10.1371/journal.pgph.0005534.g001>

## Statistical analysis

To describe the clinics used in the analysis, the median and interquartile range (IQR) clinic size was illustrated by year and district. We created figures showing yearly totals of SyNCH CCMDD ART prescriptions and TIER.Net CCMDD ART referral visits overall and by pick-up point. We also created figures showing yearly totals of NHLS and TIER.Net VL and CD4 counts overall and by threshold. We divided the total number of TIER.Net CCMDD ART referrals by the corresponding total number of SyNCH CCMDD ART prescriptions to obtain proportions by clinic, and similarly we divided the total number of VL and CD4 count results in TIER.Net by the corresponding numbers in NHLS to obtain proportions by clinic. We calculated and plotted the median and IQR of the clinic-level proportions per year. The means and standard deviations of the clinic-level proportions were calculated per year and if a clinic had a value more than 3 standard deviations above or below the mean in any year, the clinic was excluded from all years and defined as an outlier. Since NHLS and SyNCH are considered the gold standard, clinic-level proportions exceeding 100% reflect over-capture in TIER.Net. The decrease in an over-captured clinic-level proportion with time would indicate improved concordance with the reference system. Linear mixed models (LMM) were used to analyse clinic-level proportions for the three outcomes (CCMDD prescriptions, VL and CD4 counts), with fixed effects for year (continuous) and district, clinic-specific intercepts and clinic-specific slopes for year. For the laboratory outcomes, we conducted a sensitivity analysis to investigate whether trends over time differed by district. Specifically, we used a likelihood ratio test to assess whether the inclusion of an interaction term between year and district improved model fit. Data was analysed using R version 4.1.1.

## Ethical approval

This work was approved by University of KwaZulu-Natal Biomedical Research Ethics Committee (BE646/17), the KwaZulu-Natal Department of Health's Provincial Health Research Ethics Committee (KZ\_201807\_021), NHLS (PR2346201) and the eThekweni Municipality Health Unit, with a waiver for informed consent for analysis of de-identified, routinely collected data.

## Feedback of results

As part of our collaboration with public sector healthcare providers, we fed back results through presentations to the eThekweni Municipality Health Unit Executive, the Kwazulu-Natal Provincial Department of Health HIV and AIDS, Sexually Transmitted Infections, and Tuberculosis team, and to all eThekweni Municipality facility managers through a specially arranged meeting to improve data entry practices at the source.

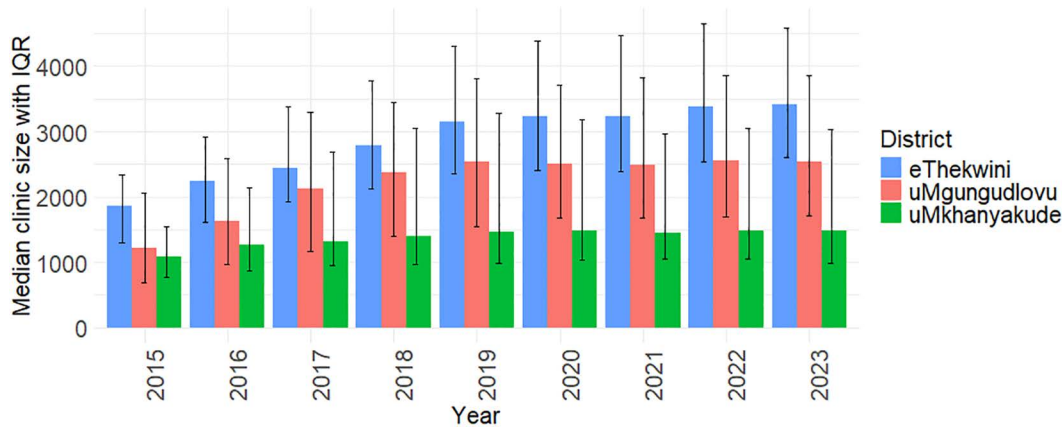
## Results

### Description of included clinics

We included 58 clinics (51 clinics contributing to the CCMDD and VL and CD4 dataset, 5 clinics contributing to the CCMDD dataset only and 2 clinics contributing to the VL and CD4 dataset only) in eThekweni, with a median size of 1862 in 2015 and 3412 in 2023, 37 clinics from uMgungudlovu with a median size of 1214 in 2015 and 2531 in 2023, and 13 clinics in uMkhanyakude, with a median size of 1083 in 2015 and 1488 in 2023. (Fig 2). We excluded 4 clinics due to outlying CCMDD or lab data.

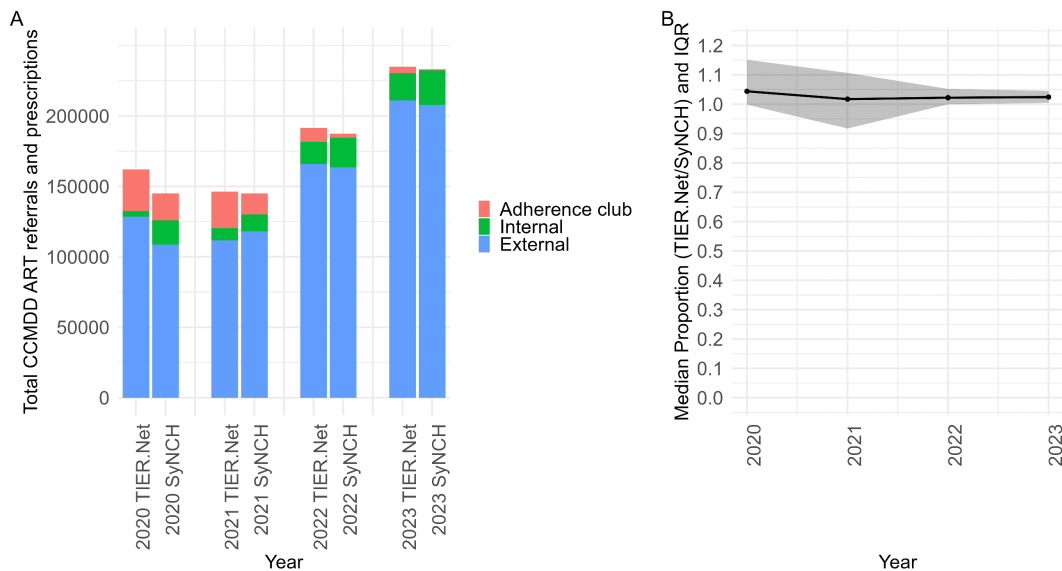
### CCMDD data

Between 2020–2023, there were 741,211 CCMDD referral visits in TIER.Net and 715,063 ART CCMDD prescriptions in SyNCH. CCMDD referral visits in TIER.Net increased from 162,818 in 2020 to 238,182 in 2023 while ART CCMDD prescriptions in SyNCH increased from 147,281 in 2020 to 233,214 in 2023 (Fig 3A). In 2020, the median (IQR) clinic-level proportion of total ART CCMDD prescriptions in SyNCH captured in TIER.Net as CCMDD referral visits was 104.40%



**Fig 2. Median clinic size by district and year, with bars indicating interquartile ranges (IQRs).**

<https://doi.org/10.1371/journal.pgph.0005534.g002>



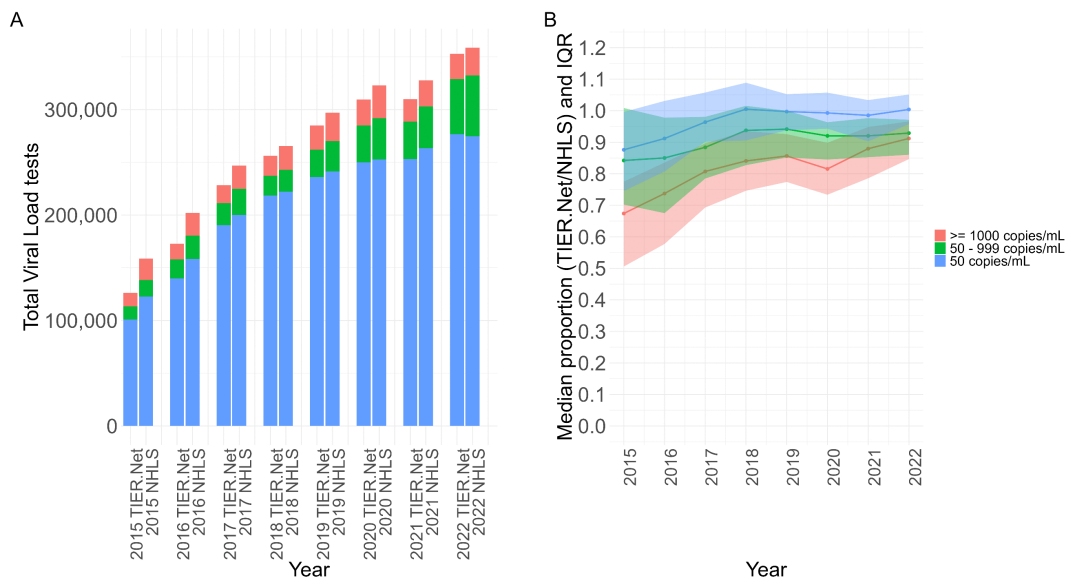
**Fig 3. (A) Total number of CCMD ART referrals (TIER.Net) and prescriptions (SyNCH) by pick-up point type and year. (B) Median clinic-level proportion of CCMD prescriptions with recorded CCMD referrals (TIER.Net/SyNCH) by year, with shading indicating the IQR.** ART: antiretroviral therapy; CCMD: Centralized Chronic Medicines Dispensing and Distribution; IQR: interquartile range; SyNCH: Synchronised National Communication in Health; TIER.Net: Three Interlinked Electronic Register.

<https://doi.org/10.1371/journal.pgph.0005534.g003>

(99.85 to 115.13%), which decreased to 102.44% (100.45 to 104.54%) (Fig 3B) by 2023. The LMM estimated an annual decrease of 2.84% (95% CI: -5.18 to -0.50%) in the proportion of SyNCH CCMD ART prescriptions captured in TIER.Net.

### Laboratory data (VL and CD4 count)

Between 2015–2022, there were 2,040,962 VL tests in TIER.Net and 2,179,870 VL tests conducted by NHLS. TIER.Net VL tests increased from 126,205 in 2015 to 352,833 in 2022 while NHLS VL tests increased from 158,648 in 2015 to 358,741 in 2022 (Fig 4A). In 2015, the median (IQR) clinic-level proportion of NHLS VLs captured in TIER.Net was



**Fig 4. (A) Total number of viral load tests recorded in TIER.Net and NHLS for each threshold by year. (B) Median clinic-level proportion of VLs (TIER.Net/NHLS) with IQR shading for each threshold by year.** IQR: interquartile range; National Health Laboratory Service (NHLS); TIER.Net: Three Interlinked Electronic Register.

<https://doi.org/10.1371/journal.pgph.0005534.g004>

87.60% (74.52 to 99.60%) for VLs < 50 copies/mL, 84.21% (70.23 to 100.85%) for VLs 50–999 copies/mL, 67.40% (50.58 to 77.50%) for VLs ≥ 1000 copies/mL, and 85.70% (69.97 to 97.85%) overall. By 2022, these had increased to 100.40% (95.75 to 105.14%) for VLs < 50 copies/mL, 92.90% (86.04 to 97.13%) for VLs 50–999 copies/mL, 91.19% (84.65 to 96.58%) for VLs ≥ 1000 copies/mL, and 99.05% (94.53 to 102.53%) overall (Fig 4B). The LMM estimated an annual increase of 1.77% (95% CI: 1.22 to 2.32%) in the proportion of NHLS VLs captured in TIER.Net. In the sensitivity analysis, the model with an interaction of year and district did not improve model fit.

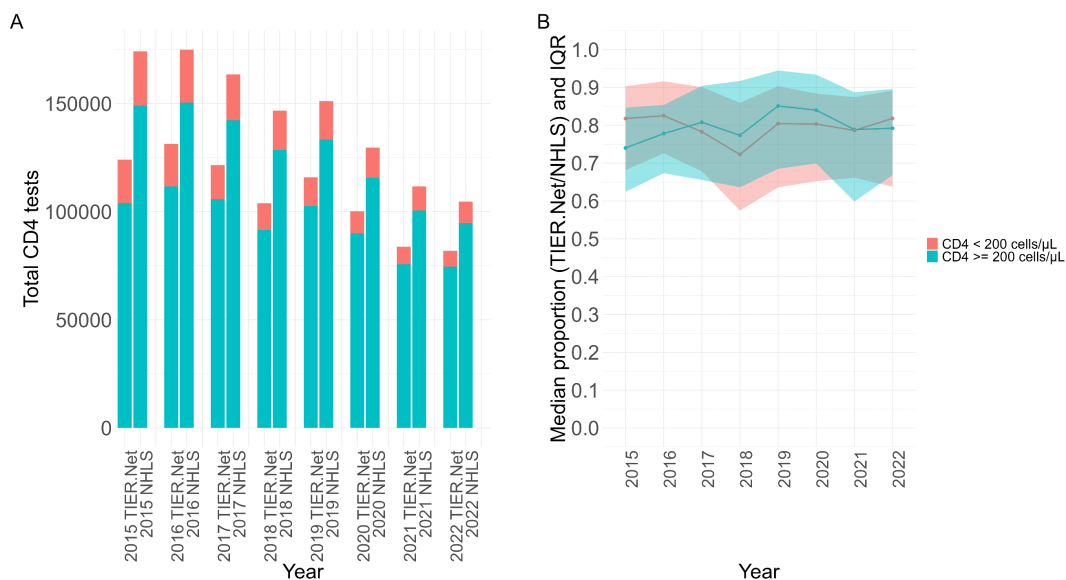
Between 2015–2022, there were 862,813 CD4 tests in TIER.Net and 1,156,822 CD4 tests conducted by NHLS. TIER.Net CD4 tests decreased from 124,077 in 2015 to 81,886 in 2022 while NHLS CD4 tests decreased from 174,214 in 2015 to 104,751 in 2022 (Fig 5A). In 2015, the median (IQR) proportion of NHLS CD4 tests captured in TIER.Net for clinics was 74.03% (62.44 to 84.66%) for CD4 ≥ 200 cells/μL, 81.80% (IQR 68.17 to 90.33%) for CD4 < 200 cells/μL and 74.31% (63.91 to 85.35%) in total. In 2022, the median (IQR) proportion of NHLS CD4 tests captured in TIER.Net for clinics was 79.21% (66.84 to 89.59%) for CD4 ≥ 200 cells/μL, 81.81% (63.80 to 89.14%) for CD4 < 200 cells/μL and 80.11% (68.40 to 89.13%) for total CD4 tests (Fig 5B). There was insufficient evidence from the LMM to suggest that data capturing had changed over time (annual change: -0.09% [95% CI: -0.91% to 0.72%]).

In the sensitivity analysis, the LMM estimated an annual decrease of 1.21% (95% CI: -2.32 to -0.11%) in NHLS CD4 results captured in TIER.Net in eThekweni. The annual increases observed in uMgungundlovu (0.96%; 95% CI: -0.23% to 1.79%) and uMkhanyakude (1.46%; 95% CI: -0.15% to 2.78%) were not statistically significant.

## Discussion

We examined the completeness of CCMDD referrals, VL and CD4 count data captured in TIER.Net compared to SyNCH and NHLS over multiple years. Our findings showed that data capture of CCMDD referrals and VLs improved over time, whereas CD4 data capture remained sub-optimal.

TIER.Net CCMDD ART referrals were over-captured in comparison to SyNCH CCMDD ART prescriptions, however this proportion decreased with time showing improved data concordance. Over capture could have occurred if data



**Fig 5. (A) Total CD4 tests from TIER.Net and NHLS for each threshold by year and (B) median proportion (TIER.Net/NHLS) with IQR shading for each threshold for clinics by year. IQR:** interquartile range; National Health Laboratory Service (NHLS); TIER.Net: Three Interlinked Electronic Register.

<https://doi.org/10.1371/journal.pgph.0005534.g005>

capturers incorrectly captured ART collection at clubs or pick-up points as a clinic visit in TIER.Net, although this should not have occurred with adequate training. For VL, we found that TIER.Net VL results were under-captured in comparison to NHLS VL results, although the degree of under-capture improved over time. When disaggregating data by VL threshold, we noted that VL < 50 copies/mL had the highest median proportion of NHLS VL captured in TIER.Net, followed by 50–999 copies/mL and then VL ≥ 1000 copies/mL, although IQRs overlapped for most years. The VL tests included in the VL ≥ 1000 copies/mL threshold likely included more repeat VLs which appear out of the annual VL date, and for this reason may be considered lower priority for data capture. Lastly, our analysis showed that TIER.Net CD4 count results were under-captured in comparison to NHLS CD4 count results, and that the degree of under-capture was similar across the CD4 thresholds, CD4 < 200 cells/μL and CD4 ≥ 200 cells/μL.

While CD4 count is a crucial indicator of AHD, there may be less of an emphasis on CD4 counts post-UTT. Prior to the implementation of UTT, a CD4 count was required at HIV diagnosis to determine eligibility for ART. With the introduction of UTT, CD4-based eligibility was removed and, in many settings, CD4 testing was subsequently de-prioritised. Clinical focus shifted toward VL monitoring as the primary measure of ART effectiveness [18]. South African guidelines reflect this change with routine VL testing being recommended annually, whereas CD4 testing is only advised at ART initiation and again after 10 months [16]. Consequently, clinicians prioritise VL monitoring, and this emphasis is likely mirrored in data capture patterns, where annual VL results are increasingly used for programmatic evaluation and patient monitoring.

There are few other published studies assessing data quality in TIER.Net compared to national electronic information systems on a large scale, and none looking at the quality of decentralised ART delivery data. Our findings on CD4 count data align with earlier research examining first CD4 counts in TIER.Net and NHLS separately between 2004 and 2018 [19]. This study found that fewer first CD4 counts were recorded in TIER.Net compared to NHLS. After UTT implementation, the number of individuals with a first CD4 count declined in TIER.Net and NHLS, however, the decline in NHLS was lower than the decline in TIER.Net. It was suggested that this decline may reflect increased underreporting of laboratory data in TIER.Net [19].

Previous analyses based on comparison to verified records have noted further limitations in the data quality of TIER.Net. A study evaluating the accuracy of patient treatment outcomes (still in care, transferred out, LTFU and deceased) recorded in TIER.Net through comparison with verified records with ART start dates between 2014–2017, found that 36% of TIER.Net patient outcomes were misclassified with first CD4 counts amongst other indicators associated with misclassification [20]. Another assessment of TIER.Net data quality used 277 records from October 2018 to December 2019 for HIV and tuberculosis (TB) from three South African districts highlighted areas of improvement for data completeness in TIER.Net [21].

Our study offers a novel contribution by evaluating the completeness of TIER.Net data through comparison with SyNCH for CCMDD data and NHLS for VL and CD4 count data using more recent data. This analysis spans multiple programmatic areas and uses two national-level reference systems to assess data quality across several clinics. The integrated approach provides an understanding of the reliability of routine health information systems used in South Africa's HIV programme and highlights specific areas where data capture can be strengthened. The limitations of the study were that we included all CD4 count tests, instead of focusing specifically on the first CD4 count at ART initiation which is of higher clinical priority, and we had not performed patient-level linkage between TIER.Net and the national reference systems. Additionally, ART regimen information was not available for validation between TIER.Net and SyNCH. Furthermore, under-captured results (VL and CD4 count) in TIER.Net did not confirm if these results were reviewed and intervened at a patient-level by the clinical team.

Strengthening data quality is essential for accurate monitoring of the HIV programme on a national level. TIER.Net is observed to be increasingly reliable for CCMDD and VL data over time, however CD4 counts are under-represented. CD4 counts remain the best indicator of AHD and the implication of under-capturing of CD4 counts, especially  $<200$  cells/ $\mu$ L is that cases of AHD may continue undetected based on TIER.Net data. This gap in data used for monitoring the effectiveness of the HIV programme may underestimate the burden of AHD in KwaZulu-Natal. Addressing these data gaps is not only a technical requirement but a strategic priority for improving HIV programme outcomes. Accurate identification of areas with a high burden of AHD cases enables improved resource allocation thus supporting timely clinical intervention which is essential for reducing morbidity and mortality. Strengthening CD4 data capture would also improve the reliability of national HIV surveillance and support evidence-based decision-making for programme planning and policy development. Reviewing data workflows to identify opportunities to improve health information systems is crucial, and specific scalable recommendations could include automated integration of NHLS laboratory results with clinical information in TIER.Net, accelerating the planned introduction of a unique patient identifier across all platforms to improve linkage of records, and developing and rolling out newer integrated electronic health record systems [22].

In conclusion, our findings indicate progressive improvements in data capture for certain indicators, while highlighting areas requiring further attention. TIER.Net is sufficiently reliable to guide HIV programmes based on CCMDD and VL data. Further research is needed to quantify the accuracy of TIER.Net data following the changes in HIV programme funding in South Africa in 2025.

## Acknowledgments

We thank the eThekweni Municipality and uMgungundlovu District Municipality Health Units as well as the staff and patients at the participating healthcare facilities.

## Author contributions

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