Factors associated to the control of viral load in HIV positive patients

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Artículos de Investigación

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Factores asociados con el control de la carga viral en pacientes con VIH

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Abstract: Objective: to evaluate factors associated with inadequate control of viral load in individuals with Human Immunodeficiency Virus (HIV) in the The Center for Assistance to Sexually Transmitted Infections/SIDA/Viral Hepatitis (CAP) of Itajubá, MG, Brazil. The acquired immunodeficiency syndrome remains a health challenge in Brazil. Therapeutic failures, characterized by detectable viral load, must have their causes evaluated. Among the most relevant reasons is the lack of adherence to treatment. **Materials and methods**: this is an observational, cross-sectional and documentary study of 261 medical records. The variables analyzed were socio-epidemiological characteristics and laboratory tests for viral load and CD4+ T lymphocytes, poor adherence in history or currently, duration of antiretroviral therapy (ART) use, depression and/or anxiety, use of illicit drugs, follow-up time at the CAP. **Results**: among the patients, 90.42% had an undetectable viral load and 64.37% had a CD4+ T count ≥500 in the last available test. Some characteristics were related to detectable viral load in the last exam: history of poor adherence during treatment (p<0,0001), inconsistent use of ART (p<0,0001) and use of illicit drugs (p=0,0155). Anxiety and/or depression were not statistically significant (p=0,3321). **Conclusion**: history of poor adherence, inconsistent use of ART and use of illicit drugs were associated with an increased risk of virologic failure. Early identification of groups at risk of poor adherence to treatment can support the development of intervention strategies in an transdisciplinary way to improve adherence and generate better results in the control of HIV infection.

Resumen: Objetivo: evaluar los factores asociados con el control inadecuado de la carga viral en individuos con virus de inmunodeficiencia humana (VIH) en el Centro de Asistencia para Infecciones de Transmisión Sexual/SIDA/Hepatitis Viral (CAP) de Itajubá, MG, Brazil. El síndrome de inmunodeficiencia adquirida sigue siendo un desafío para la salud en Brasil. Las fallas terapéuticas, caracterizadas por una carga viral detectable, deben tener sus causas evaluadas. Entre las razones más relevantes está la falta de adherencia al tratamiento. **Materiales y métodos**: estudio observacional, transversal y documental con 261 registros médicos. Las variables analizadas fueron características socioepidemiológicas y pruebas de laboratorio para carga viral y linfocitos T CD4+, pobre adherencia en la historia o en la actualidad, duración del uso de terapia antirretroviral (ARTE), depresión. y/o ansiedad, uso de drogas ilícitas, tiempo de seguimiento en el CAP. **Resultados**: de los pacientes, el 90.42% tenía una carga viral indetectable y el 64.37% tenía un recuento de CD4 + T ≥500 en la última prueba disponible. Fueron evidenciadas características relacionadas con la carga viral detectable en el último examen: antecedentes de mala adherencia durante el tratamiento ($p < 0,0001$), uso inestable de ARTE ($p < 0,0001$) y uso de drogas ilícitas ($p = 0,0155$). La ansiedad y / o depresión no fue estadísticamente significativa ($p = 0.3321$). **Conclusión**: el historial de adherencia deficiente, el uso inconsistente de ART y el uso de drogas ilícitas se asociaron con un mayor riesgo de falla virológica. La identificación de grupos en riesgo de mala adherencia al tratamiento puede ayudar a desarrollar estrategias de intervención de manera temprana y entre disciplinas para mejorar la adherencia y generar mejores resultados en el control de la infección por VIH.

Palabras clave: infecciones por VIH, VIH, medicamentos contra el VIH, carga viral, linfocitos T, seroprevalencia del VIH.

Introduction

The acquired immunodeficiency syndrome (AIDS) is caused by the human immunodeficiency virus (HIV) whose transmission occurs through sexual, parenteral (blood products, injectable drugs), vertical (pregnancy, childbirth or breastfeeding) and occupational transmission (work accidents with needlestick instruments contaminated with infected patients blood). This disease is characterized by a reduction in the CD4+ T lymphocyte count, which makes patients more vulnerable to opportunistic infections resulting from changes in the immune response [1,2]. Low and middle-income countries have been the most affected by the epidemic [3]. In Brazil, 966.058 HIV cases were identified from 1980 to June 2019 [4]. In 2018, according to the Joint United Nations Program on HIV/AIDS (UNAIDS) [5], Brazil had around 53.000 new HIV cases, with 15.000 deaths related to the disease.

The development of antiretroviral therapy (ART) has provided improvements in the prognosis of individuals infected with HIV, with a decrease in hospital admissions and the occurrence of opportunistic complications associated with HIV/AIDS. Resulting in an increase in the expectation and quality of life of these individuals [6, 7]. The ART leads to the undetected viral load and consequent immune recovery. Other benefits of this therapy are the reduction of the chronic inflammatory process caused by the presence of the infectious agent and decreased risk of virus transmission [8]. However, studies [6,7,8,9,10] indicate that in order to achieve such treatment success, regular use of therapy

is necessary. Its inconsistent use may result in the emergence of viral resistant strains to the available drugs. According to Gir et al. [11], there is a significant relation between lack of adherence and the viral load response. Therefore, control of viral load is necessary to identify therapeutic failures and research their causes, including lack of adherence [10].

UNAIDS [12,13,14] demonstrates the importance of the new set of goals that need to be achieved by 2020, to contribute to the end of the AIDS epidemic. The 90-90-90 strategy is one of them: 90% of all people living with HIV are diagnosed; 90% of diagnosed people receive antiretroviral therapy; and 90% of people receiving treatment have an undetectable viral load and can no longer transmit the virus. When this threefold goal is reached, at least 73% of all people living with HIV in the world will have viral suppression - a higher number than the current estimates [12,13,14].

Although progress has been made, the disease remains a critical public health issue due to the lack of prevention, early detection, monitoring of the patient's health conditions and adherence to treatment [9, 10]. In 2018, 37,9 million people lived with the virus in the world and only 20 million had suppressed viral load [5]. Adherence is the responsibility of both the patient and the health team, who must have clear explanations for the patient to agree with the recommended prescription, as it demands changes in behavior, side effects and lifetime use of this treatment from its users [15, 16].

Knowledge of the regional reality is important for the health team to be able to establish new strategies [17]. The control of viral load can help in this regard, by recognizing which groups are most vulnerable to therapeutic failures.

The Center for Assistance to Sexually Transmitted Infections/AIDS/ Viral Hepatitis (CAP) is the only service center in the city to do follow-up and distribute medicaments to individuals with HIV. With a team formed by a doctor, a nurse, a psychologist, two nursing technicians and a pharmacist, who maintains good contact with their patients and controls the use of ART by pharmacy data. It is noted that data are available on the socio-epidemiological profile of patients in the CAP of Itajubá, Minas Gerais (MG), Brazil, but there is a lack of organization and systematization of data regarding the patients' virological load and factors associated with inadequate viral suppression.

Therefore, this study objectives are to evaluate factors associated with inadequate control of viral load in individuals with HIV in the CAP of Itajubá, MG, Brazil.

Materials and methods

An observational, cross-sectional and documentary study was carried out at the CAP located in the city of Itajubá, MG, Brazil. The analysis was performed throught the analysis of all the medical records of patients infected with HIV/AIDS, the notification form of the national disease

notification system (SINAN) and control of drug withdrawal from the pharmacy in February 2019 at CAP who fulfilled the inclusion criteria, with a definitive sample of 261 medical records reported since the CAP was founded in 1993.

Population study

Itajubá is a Brazilian city located at the southern part of Minas Gerais with an estimated population of 96,869 inhabitants in 2019. Based on the latest data, it had a Human Development Index (HDI) of 0,777 (2010) and infant mortality of 11,49 deaths per thousand live births (2017) [18].

The CAP is responsible for caring patients infected with the HIV virus in Itajubá, MG, Brazil and region, and treatment of those who are being monitored in that location. People with HIV / AIDS in that region can choose any other center to be treated according to their decision, and CAP can be chosen by people from any other city. At the time of the data set collection (January to February 2019), patients from the following cities were treated at the CAP of Itajubá, MG, Brazil: Baependi, Brazópolis, Caxambu, Campos do Jordão, Conceição das Pedras, Consolação, Cristina, Delfim Moreira, Gonçalves, Guaratinguetá, Itajubá, Maria da Fé, Marmelópolis, Paraisópolis, Pedralva, Piranguçu, Piranguinho, Pouso Alegre, Santa Rita do Sapucaí, São José do Alegre, São Lourenço and Wenceslau Braz. Cities up to 110 kilometers away around Itajubá making up 663.022 inhabitants.

The inclusion and exclusion criteria

Medical records of patients with HIV / AIDS undergoing follow-up at the CAP in Itajubá, MG, Brazil, who started ART more than 8 weeks after the beginning of this study and who had more than one viral load test result were included in the research. The exclusion criteria were: medical records without a viral load test result before and after treatment, medical records of patients already transferred from the service or deceased, in a vertical transmission study without reagent conclusion for HIV and medical records of patients without HIV/AIDS until the beginning of this study.

Analyzed variables

The analyzed variables were: gender; age; skin color; education level; city of residence; sexual orientation informed in the notification form of SINAN; first and last results of tests for viral load and CD4 + T lymphocytes; history of poor adherence informed by the physician or the psychologist in the medical records; antiretroviral medication used when the data was collected, informed by the physician or the psychologist in the medical records or noticed by control of drug withdrawal from the pharmacy; ART use time; depression and / or anxiety if reported in the medical record as a diagnostic hypothesis; use of illicit drugs (recreational drugs, except alcohol and cigarettes, including inhaled, smoked or injected); and follow-up time in CAP.

The viral load quantification test (Real Time PCR – abbott Real Time HIV-1) is performed before the start of antiretroviral therapy and after a

period in which the therapy is considered effective. The undetected value is recommended as an effective form of treatment.

Statistical analysis

The data collected during the research were filed and systematized in the MS Office Standard Excel® 2013 program and later, statistically distributed in the form of tables and simple graphs, with absolute and relative frequency. After performing the descriptive statistical analysis (using the BioEstat 5.0 program), the Chi-Square test was performed by partition of the tests (using Yates correction for 2x2 tables), complementing with Residue Analysis, in order to determine the statistically significant variables. In addition, the binomial test was performed in the case of qualitative and dichotomous variables and the multiple logistic regression test, where the response of the dependent variable was considered assuming only two results, and the independent variables as categorical or dichotomous variables. The significance level was set at 0.05.

This study was approved by the Research Ethics Committee (CEP) of the Faculty of Medicine of Itajubá, MG, Brazil, with technical advice number as 3,065,121, respecting the resolution CNS 466/2012.

Results

Table 1 shows the socio-epidemiological profile of the 261 medical records analyzed. Some predominant aspects are highlighted in relation to these patients: most of the patients in the study were male, with a frequency of 176 (67.43%) individuals; the average age of the participants was 45 years (standard deviation of +/- 13), 190 (72.80%) concentrated in the range of 30-59 years; as for ethnicity 202 (77.39%) were caucasion; as the education time 165 (63.22%) showed more than 7 years of study; the highest percentage of patients in the study, 187 (71.65%) were from Itajubá, MG, Brazil; over sexual orientation, heterosexuals prevailed, with a frequency of 161 patients (61.69%). The follow-up time at the CAP of Itajubá, MG, Brazil, was organized in periods of 5 years, from 0 to ≥20 years. The majority, 88 (33.71%), of the patients started follow-up at the CAP of Itajubá, MG, Brazil, in the period of 0-4 years.

Table 2 shows the results of the first and last viral load tests performed on CAP patients in Itajubá, MG, Brazil. According to the Binomial test, it shows that there was a significant increase percentage between the first and last results of undetected viral load tests with 99% reliability. In the last available result, it was found that 90.42% of the patients had an undetected viral load.

Profile	% (Frequency)
Gender	
Female	32.56% (85)
Male	67.43% (176)
Age (years)	
0-29	13.79% (36)
30-59	72.80% (190)
60-89	13.40% (35)
Ethnicity	
Caucasion	77.39% (202)
Non caucasion	22.61% (59)
Education Time	
More than 7 years	63.22% (165)
Less than 7 years	21.07% (55)
Uninformed	15.71% (41)
City of Residence	
Itajubá	71.65% (187)
Immediate Geographic Region of Itajubá (except Itajubá)	20.31% (53)
Others	8.04% (21)
Sexual Orientation	
Bisexual	4.98% (13)
Heterosexual	61.69% (161)
Homosexual	28.35% (74)
Uninformed	4.98% (13)
Follow-up time (in years)	
0-4	33.71% (88)
5-9	16.09% (42)
10-14	21.46% (56)
15-19	22.22% (58)
= 20	6.51% (17)
Grand total	100.00% (261)

Table 1
Socio-epidemiological profile of CAP patients in Itajubá, Minas Gerais, Brazil
author's elaboration.

Viral load	First tests % (Frequency)	Last tests % (Frequency)	P value
Detected	82.38% (215)	9.58% (25)	<0,0001
Undetected	17.62% (46)	90.42% (236)	
Grand Total	100.00% (261)	100.00% (261)	

Table 2
Results of the first and last available viral load tests
of CAP patients in Itajubá, Minas Gerais, Brazil
author's elaboration

For the analysis presented in Table 3, the Chi Square test: partition was used, which showed a significant difference (p <0,0001) with 99% reliability between the first and last CD4 + T lymphocyte count tests. According to the test of Residue it was found that there was a significant drop in T CD4 + lymphocyte counts <350, and a significant increase in T CD4 + lymphocyte counts ≥500. Thus, there was no significant difference between the first and last CD4 + T lymphocyte count results in the 350-499 range. In the latest available results, it was found that 64.37% of the patients had CD4 + T ≥500.

The study found 46 patients (17.62%) with the first viral load test with an undetectable result. This is because some patients were transferred from other services already using ART and, consequently, presenting an undetectable viral load. Others, in the other hand, had their start of treatment records lost due to a flood in the CAP of Itajubá, Minas Gerais, Brazil, in 2000 and their available tests already had an undetectable viral load after this issue the medical records began to be made on informatic natter.

CD4+ T lymphocytes	First tests % (Frequency)	Last tests % (Frequency)	P value
<200	30.65% (80)	6.51% (17)	
200-349	17.62% (46)	9.58% (25)	
350-499	18.77% (49)	18.01% (47)	<0.0001
=500	31.42% (82)	64.37% (168)	
Uninformed	1.53% (4)	1.53% (4)	
Grand Total	100.00% (261)	100.00%	

Table 3
Results of the first and last available tests for CD4 + T lymphocytes from CAP patients in Itajubá, Minas Gerais, Brazil
author's elaboration.

Table 4 shows the last test performed for CD4 + T lymphocytes with the last test performed for patients' viral load, showing high significance (p=0,0002) of the analysis between CD4 + T lymphocytes and last viral load tests by the Chi Square test. Residue analysis showed significance (p<0,01) in the extreme values of CD4 + T lymphocytes with the values of viral load test. There was a greater chance of patients with undetectable viral load having CD4 + T lymphocytes ≥500 in the last exam, in addition to a higher chance of patients with detectable viral load having CD4 + T lymphocytes <200 in the last exam. The intermediate values (200-349 and 350-499) did not reveal significance.

In table 5, a higher detectable viral load rate was observed by the Chi Square test with Yates correction among individuals who had a history of poor adherence during treatment, around 20% had detectable viral load. Among individuals who never reported poor adherence during treatment, the detectable viral load rate was minimal, around 2% of patients. There was a relation between a history of poor adherence during treatment and a detectable viral load with a significance of p<0.0001.

CD4+ T lymphocytes	First tests % (Frequency)	Last tests % (Frequency)	P value
<200	30.65% (80)	6.51% (17)	
200-349	17.62% (46)	9.58% (25)	
350-499	18.77% (49)	18.01% (47)	<0.0001
=500	31.42% (82)	64.37% (168)	
Uninformed	1.53% (4)	1.53% (4)	
Grand Total	100.00% (261)	100.00%	

Table 4
Association between the last CD4 + T lymphocyte test and the last viral load test
author's elaboration.

Individuals who intermittently taken ART verified in reports in the medical record had a higher number of detectable viral loads; and individuals who taken ART correctly had a higher number of undetectable viral loads, with a significant relation using the Chi Square test with Residue Analysis (p<0.0001). For individuals who were not taking ART at the time of data collection, according to the pharmacy control, there was no significant result with the detected viral load. This fact must have been related to a small percentage of individuals in this group (1.14%).

Regarding individuals who had anxiety and / or depression reported in the medical record as a diagnostic hypothesis, there was no significant relation with the result of viral load by the Chi Square test with Yates correction (Table 5).

The patients using illicit drugs by chi-square test with Yates correction (Table 5) were p=0.0155, which shows significance with the use of illicit drugs and detectable viral load. According to the simple logistic regression test, it was found that there is a significant relationship between illicit drug use and viral load, in which illicit drug use increases the chance of detection of viral load by approximately 3 times (p=0.038). Determining the chance of detection of the viral load in a patient who uses illicit drug is approximately 21%.

Associated factors	Detected viral load % (Frequency)	Undetected viral load % (Frequency)	P value
History of poor adherence during treatment			
Yes	19.27% (21)	80.73% (88)	<0.0001*
No	2.10% (3)	97.90% (140)	
Uninformed	11.11% (1)	88.89% (8)	
Use of ART			
Yes	7.29% (18)	92.71% (229)	<0.0001*
No	33.33% (1)	66.67% (2)	
Inconsistant use	54.55% (6)	45.45% (5)	
Depression and / or Anxiety			
Yes	7.69% (3)	92.31% (36)	0.3321
No	9.91% (22)	90.09% (200)	
Use of Illicit Drugs			
Yes	20.69% (6)	79.31% (23)	0.0155*
No	8.19% (19)	91.81% (213)	
Grand Total	9.58% (25)	90.42% (236)	100.00%(261)

Table 5

Association between the last viral load test and the following topics: history of poor adherence; ART use on data collect date; depression and / or anxiety reported in medical records and use of illicit drugs

author's elaboration.

According to the multiple logistic regression test, it was verified by verisimilitude that the last detectable viral load result is significantly related to the history of poor adherence and the constant use of ART informed by the physician or the psychologist in the medical records or noticed by control of drug withdrawal from the pharmacy on data collect date. Where it was observed by the Odds ratio, that having poor ART adherence at some period of treatment increases the chance of detecting viral load in the last exam by approximately 8.65 (CI 95% = 2.44 - 30.75),

and that the intermittent use of ART also increases by 5.11 (CI 95% = 2.68 - 9.72) the chance of viral load detection (p<0,0001)

Discussion

The present study had similar data to the 2019 HIV / AIDS epidemiological bulletin [4], in relation to the gender of the participants, the first reveals a ratio of 2,07 cases of HIV in men to 1 case in women, and the second reveals 2.6 cases in men to 1 case in women. These data differ from those presented by UNAIDS [19] in 2016, which demonstrated that approximately 50% of infected people in the world are women and that the relation between genders has been decreasing with time due to the transition of the epidemiological profile. The possible explanation stems from the fact that the data in the 2019 epidemiological bulletin [4] refer to southeastern Brazil, while UNAIDS [19] data covers the entire world, including African countries, in which the epidemiological pattern of infection prevalence among heterosexuals is known to differ from that it is observed in other areas, such as the Americas and Europe, in which there is a predominance of infection among men who have sex with men and drug users [20, 21].

The age range of the patients in the present study was similar to the studies by Soares et al [2] and Soares et al [22], with a concentration of participants between 30-59 years of age, and according to Gómez-Hernández et al [23] with the average age of the participants around 45 years. Regarding sexual orientation, the majority were heterosexuals (61.69%), according to Soares et al (80.36%)[2].

Several studies [2, 8, 16, 24, 25] have shown a higher rate of HIV positive cases in individuals with less education. In the present study, on the other hand, 63.22% of the patients had more than 7 years of schooling. Such mismatch is possibly because Itajubá, MG, Brazil, is a city with a high schooling rate, 98.1% in children aged 6 to 14 years old, as demonstrated by the Brazilian Institute of Geography and Statistics (IBGE) [18]. The educational level of individuals with HIV positive virus has been largely related as an indicator of the socioeconomic level of this population [2, 8, 16, 24, 25].

The viral load test optimizes the treatment outcomes and reduces its cost, as it identifies the therapeutic failure and patients who are having difficulty adhering to the prescribed regimens [12]. The data from the present study show that during the follow-up at the CAP of Itajubá, MG, Brazil, there was a significant increase in the number of participants with an undetectable viral load: in the first result 17.62% and, in the second, 90.42% had viral suppression. This rate is higher than the average rate found in Latin America and the Caribbean, around 66%, and in other Brazilian services [4, 11, 12,13,14], which ranged from 43 to 62%.

The CD4 + T cells test is a prognostic marker of great importance and the higher its count, the lower the morbidity related to AIDS [24]. The proportion of patients with CD4 + T lymphocyte count>500cells/mm3 in the present study more than doubled when comparing the first and last

available exams, from 31.42% to 64.37%. This CD4 + T lymphocyte value (64.37%>500cells/mm3 and 82.38%>350cells/mm3) was higher than that evidenced in the study by Gir et al [11] (20.1%>500cells/mm3) and similar to that of Soares et al [26] (78.2%> 350cells/mm3).

Analyzes of CD4 + T lymphocyte numbers revealed that patients with undetectable viral load (indirect adherence factor) focused on the result >500 CD4 + T lymphocytes (-4.18), a range that represents a good immune response. They also revealed that patients with detectable viral load (indirect factor of poor adherence) concentrated on the result <200 of CD4 + T lymphocytes (2.86), a value that represents severe immunodeficiency, a fact also reported in the study by Seidl et al [16].

It was also observed that having a history of poor adherence during ART treatment increases, by the odds ratio test, the chance of having virological failure by approximately 8.65. This is similar to the study by Seidl et al [16], which suggests that people with a history of previous failures in ART treatment may be more likely to interrupt again or adhere to unsatisfactory levels.

The study by Tucker apud Calvetti et al [27] revealed that people with depression, anxiety or generalized panic were approximately twice as non-adherent as those without a psychological disorder. In the present study, there was no significant relation between virologic failure, depression and / or anxiety (p=0.3321). This can be related to the fact that the two conditions were assessed together (depression and anxiety) and possibly had different impacts on adherence to therapy, as well as deficiencies in the records of patients' records on the mental health of patients.

The present study reveals, in the logistic regression analysis, an increase of approximately 3 times the chance of a drug user patient having a detectable viral load. A similar fact was observed in the study by Schilkowsky et al [28], in which a positive association was observed between failures in drug treatment and use of illicit drugs, with a 1.8-fold increase in the chances of abandonment when compared to control. It is important that the health team, when classifying the risks of each patient, can address the individuality and offer support and treatment to the patient, as mentioned by Bonolo et al [10] in their study, in which, before the drug treatment of HIV, recommends the treatment of support for users of illicit drugs.

Among the limitations of the present study, we highlight patients who did not fit the inclusion criteria due to loss of follow-up or the change of location for follow-up, and thus did not have their medical records analyzed. This fact may predispose the viral loads of the most adherent patients to be evaluated, limiting the results. Another limiting factor is that the analysis was performed only by medical records, which depend on the reader's interpretation and allow only access to information deemed necessary by the physician who filled it in at that moment. In addition, due to the flood and the consequent loss of part of the medical records before 2000, some previous information could not be evaluated. As for depression and anxiety, it was only possible to have access to the

diagnostic hypothesis reported in the medical record, not being possible to use any validated instruments to acess those conditions.

The diagnosis of patients with CD4 + T lymphocytes <350cel/mm3 may indicate a late diagnosis. In the first available result of CD4 + T lymphocytes in the present study, 48.27% of the patients had a count below 350. This result can be confused as a study limitation, since the present study is ecological and does not evaluate the historical evolution, being necessary other studies to elucidate this result. Other suggestions for further studies: analysis of medical records of patients who died and of patients with loss of follow-up, to help characterize the other version of the CAP patients in Itajubá, MG, Brazil, that was not evaluated in this study. Research is also suggested with an emphasis on HIV patients who have not been diagnosed, or who are diagnosed but are not on ART, to clarify the goal 90-90-90 in Itajubá, MG, Brazil.

Conclusion

In conclusion, the present study showed 90.42% of patients presented viral suppression in the CAP of Itajubá, MG, Brazil, factors such as history of poor adherence during treatment, inconsistent use of ART and use of illicit drugs at the time of collection were related to detectable viral load in the last exam. Anxiety and / or depression were not related to the detectable viral load, a fact that may be a consequence of the two conditions having been assessed together or to deficiencies in the records on mental health in the collected material. The identification of groups at risk of poor adherence to treatment with ART can provide support for the development of intervention strategies in an early and transdisciplinary way, with the potential to improve adherence and generate better results in the control of HIV infection.

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