

An intervention for the implementation of clinical monitoring in specialized care services to people living with HIV/AIDS

Intervenção para a implementação do monitoramento clínico em serviços especializados de atenção às pessoas vivendo com HIV/aids

Intervención para la implementación del monitoreo clínico en servicios especializados de atención a personas afectadas por el VIH/SIDA

Ana Paula Loch ¹
Joselita Maria de Magalhães Caraciolo ¹
Simone Queiroz Rocha ¹
Mylva Fonsi ¹
Rosa de Alencar Souza ¹
Maria Clara Gianna ¹
Alexandre Gonçalves ¹
Artur Olhovetchi Kalichman ¹

doi: 10.1590/0102-311X00136219

Abstract

The clinical monitoring of people living with HIV/AIDS (PLWHA) contributes to identifying and managing cases of individuals who have not begun treatment (gap), those experiencing treatment failure or who have abandoned treatment. This article sought to present and discuss the development of a methodology to implement the clinical monitoring of PLWHA in the services of the Brazilian Unified National Health System (SUS). The methodology used since 2014 by the CRT-STI/AIDS-Coordination of the STI/AIDS Program, São Paulo State, Brazil, was re-structured in three meetings between June and August 2018. The new methodology retained the axes of presentation of number of users in treatment failure, gap or abandonment in the participant services, as well as the discussion of individual, social and programmatic vulnerabilities. A new axis was added which directs the discussion of the possibilities of reorganizing service care flows and management practices. Additionally, the intervention started to be carried out in health services, with the participation of a higher number of professionals from the multi-professional team, discussion of cases, workflows and processes, and regional meetings to exchange clinical monitoring experiences between services. The re-structuring of the methodology contributed to a reduction in treatment gap, a reorganization of care flows and the inclusion of clinical monitoring as a management tool in services specialized in providing care to PLWHA. This methodology can be implemented by other state programs, municipalities and services, since all have access to the same information sources used in this intervention.

Process Assessment (Health Care); Treatment Adherence; Unified Health System; HIV; Implementation Science

Correspondence

A. P. Loch
Centro de Referência e Treinamento DST/AIDS-SP-
Coordenação do Programa Estadual de IST/AIDS.
Rua Santa Cruz 81, São Paulo, SP 04121-000, Brasil.
anapaulaloch@gmail.com

¹ Centro de Referência e Treinamento DST/AIDS-SP-
Coordenação do Programa Estadual de IST/AIDS, São Paulo,
Brasil.



Introduction

Since 2014, the Joint United Nations Programme on HIV/AIDS (UNAIDS) proposed an ambitious goal to propel the world response toward the end of the AIDS epidemic, known as the 90-90-90 goal. This goal is supported by mathematical models that suggest that diagnosing 90% of individuals infected with HIV, treating 90% of diagnosed individuals and suppressing the viral load of 90% of individuals in treatment until 2020 will lead to the end of the AIDS epidemic by 2030 ¹.

The concept of treatment as prevention, which underlies the 90-90-90 goal, is supported by the fact that people living with HIV and AIDS (PLWHA) who are in treatment and whose viral load is undetectable cannot transmit the virus. This proposal has a large potential impact on the increase in the efficacy of epidemic control policies and has enormous benefits, both from the individual standpoint and from a public health perspective ².

The recognition of the importance of antiretroviral therapy (ART) for the prevention of transmission, reduction of morbimortality and improvement of PLWHA's quality of life brings organizational and programmatic challenges of different kinds to public health services. The monitoring of the many stages of care for PLWHA and the development of intervention strategies to guarantee timely access and the maintenance of treatment adherence are at the heart of these challenges and are crucial to improving the Brazilian response to the epidemic ¹.

A signatory of the 90-90-90 strategy, Brazil monitors its progress with regard to this strategy annually, identifying gaps in the stages of the continuous HIV care which require intervention and subsidizing decision-making and planning of programmatic actions ².

The clinical HIV monitoring report showed an important increase in the number of individuals who are diagnosed (from 69% to 84%), linked (from 66% to 79%), retained (from 55% to 69%), in treatment (from 44% to 63%) and with a suppressed viral load (from 38% to 58%) from 2012 to 2017 in Brazil. After recommendations of ART use were broadened in 2013, including the offer of early treatment, the number of users in treatment increased from 48% in 2013 to 63% in 2017. Among users who had been in treatment for more than six months, 91.78% had reached viral suppression (viral load < 1,000 copies/mL) in 2017 ³.

To aid services in the identification and management of care of PLWHA who have not initiated treatment, who have detectable viral load six months after starting treatment or who have abandoned treatment, in 2013, the Brazilian Ministry of Health developed the Clinical Monitoring System (SIMC, in Portuguese; <https://simc.aids.gov.br>) which provides four reports to services, three of which are the focus of the intervention described in this article.

The first report is the list of users in treatment gap, that is, who never received antiretrovirals. These users are those identified by the Laboratory Exam Control System (SISCEL, in Portuguese) as having undergone a viral load and/or CD4 lymphocytes quantification exam, but have never been registered in the Logistical Medication Control System (SICLOM, in Portuguese). The Ministry of Health estimated that 10,296 users were in treatment gap in the State of São Paulo in May 2019, representing 5.48% of all PLWHA in the state. Of these, 9,151 (88.9%) had been identified by SIMC, but not analyzed by the services (SIMC. <https://simc.aids.gov.br/index.php#>, accessed on 08/May/2019).

The second report informs services, since late 2017, of the users identified in SISCEL as having the last detectable viral load in an exam performed six months after beginning ART, as identified in SICLOM (SIMC. <https://simc.aids.gov.br/index.php#>, accessed on 10/Nov/2017). It is estimated that 8,929 individuals (5.95% of all those in treatment in the state) were in treatment failure in São Paulo in June 2019 (SIMC. <https://simc.aids.gov.br/index.php#>, accessed on 08/May/2019).

The third report lists the PLWHA who have abandoned treatment, identified as the users with a medication dispensation delay exceeding 100 days. This report was made available by SIMC in December 2019. Previously, it was issued only by SICLOM, only accessed by the services' pharmacies. The Ministry of Health estimates that 27,611 users had abandoned treatment in São Paulo (15.5% of users who started ART in the state) in June 2019. Since December 2019, the SIMC also began to issue a report identifying pregnant individuals with a detectable viral load, in order to eliminate the vertical transmission of HIV.

Use of these reports contributes to identifying programmatic failures and searching for users who require more intensive care from services at the different stages of the care continuum. Realizing the

importance of SIMC for managing care, between 2014 and 2016, the Reference and Training Center on STI/AIDS-SP-Coordination of the State STI/AIDS Program (CRT-DST/AIDS, in Portuguese) carried out nine events training professionals to use the system, with the main focus on services that concentrated 70% of the treatment gap cases in São Paulo in 2013. Despite an initial movement of clinical monitoring in services that received training, the gap evolution reports showed the need for efforts to accelerate its reduction.

In order to improve the system's implementation, stimulate the continuous monitoring of PLWHA in specialized services, reduce treatment gap and the number of users in treatment failure and abandonment, the CRT-DST/AIDS, with support from the Ministry of Health and the Pan American Health Organization (PAHO), re-structured the intervention carried out between 2014 and 2016 and trained professionals from 21 services from four health regions in the State of São Paulo to use SIMC between 2018 and 2019 (over a six month period). This article seeks to present and discuss the development of the methodology used in the intervention for improving the clinical monitoring of PLWHA. We emphasize that the focus of this study is the evaluation of strategies for implementing work tools and processes geared toward improving clinical monitoring in these services. As such, we will also present some comparative results generated based on reports produced by SIMC before and during the interventions carried out in 2018/2019.

Methodology

Intervention re-structuring process

The intervention carried out between 2014 and 2016 lasted eight hours and was carried out in the state capital and some smaller cities in the State of São Paulo, bringing together the multi-professional team, managers, municipal STI/AIDS programs and epidemiological surveillance of the specialized care services (SAE, in Portuguese).

The axes that guided this first intervention were focused on the presentation and discussion were: (a) the incidence of, and mortality from, AIDS in the State of São Paulo and the regions that are the focus of the intervention; (b) the individual, programmatic and social vulnerabilities that impact the stages of care for PLWHA; and (c) the data found in each of the SIMC reports, correlated with the goals established by the state and national STI/AIDS Programs. After this, access logins were created for the services and there was an initial movement of monitoring the treatment gap report, however, services did not make monitoring part of their routines. In November 2017, for example, 82.24% (8,656 of 10,525) users in treatment gap were still awaiting analysis by the services (SIMC. <https://simc.aids.gov.br/index.php#>, accessed on 10/Nov/2017).

The re-structuring of the intervention was defined in three meetings carried out between June and August 2018. The new proposal was structured taking into account the premises already used in 2014 and a fourth principle originating in Implementation Science 4: (i) the availability of a clinical monitoring system for identifying users in treatment gap, failure or abandonment and its low implementation in practice (SIMC. <https://simc.aids.gov.br/index.php#>, accessed on 08/May/2019); (ii) the immediate benefits which could result from use of the system due to the insertion/reinsertion of users into treatment and the intensification of adherence¹; (iii) the potential for improving services' care processes and management activities after the implementation of SIMC as a management tool; and (iv) the need to consider services' local context for the implementation of new interventions, in this case, the clinical monitoring through SIMC and SICLOM, based on the involvement of health professionals, evaluation of available resources for the re-engagement of users in care after their identification in the systems mentioned above⁵.

Box 1 compares the guiding axes and the intervention methodology carried out in 2018/2019 with the 2014 intervention. The presentation of the number of users in treatment gap, failure and abandonment, as well as the discussion of individual, social and programmatic vulnerabilities remained in 2018/2019. To these was added the axis that seeks to encourage discussion between health service professionals regarding the care and management flows that can improve the quality of the care offered to users⁶.

Box 1

Comparison of the structures of Clinical Monitoring System (SIMC) implementation interventions carried out in the State of São Paulo, Brazil, in 2014 and 2018/2019.

	2014	2018/2019
GUIDING AXES	Mortality from AIDS in the State of São Paulo and according to health region, when available, and incidence in the State of São Paulo.	Excluded.
	Presentation of the number of patients with detectable viral loads, in treatment gap and who had abandoned treatment in the participating services and targets of the State Program for reducing these numbers.	Presentation of the number of patients with detectable viral loads, in treatment gap and who had abandoned treatment in the participating services.
	Individual, social and programmatic vulnerabilities that impact the care continuum for patients with HIV.	Individual, social and programmatic vulnerabilities that impact the care continuum for patients with HIV.
	-	Possibility of re/organizing care flows and management practices based on cases identified in SIMC.
METHODOLOGY	Presentation and exercises in SIMC in a computer room in a location not belonging to the health service.	SIMC presentation and training on a previously-scheduled date at the health service.
	Participation of the manager and all professionals who had the availability to leave the service.	Participation of the manager and all the professionals who were available at the service on the training day.
	Involvement of professionals from different services in the same training.	Involvement only of professionals from the same service in trainings designed for each individual service.
	Limited training and monitoring from a distance.	In-person monitoring with exchanges of experiences between services from the same health region.
	-	In loco discussion of cases identified in SIMC, supported by information from the chart and from the Laudo and SICLOM systems (which have laboratory and antiretroviral dispensation information, respectively).
	-	In loco discussion and review of care and management flows based on cases identified in SIMC, with the goal of improving the quality of care.
	-	In loco discussion with the goal of implementing clinical monitoring, considering the work processes in place in the services.

SICLOM: Logistical Medication Control System.

There are four main methodological changes, presented in Box 1: (i) the technical training for using the system and the in loco clinical monitoring in each specialized service, with the support of information from medical charts, SISCEL and SICLOM; (ii) the use of case discussion technology as a trigger for restructuring care and management flows during technical visits; (iii) the active participation of professionals from the services' multi-professional teams in the clinical monitoring; and (iv) the occurrence of encounters for sharing clinical monitoring experiences between services from the same health region.

Direction of the re-structured intervention

In 2018, the specialized services and municipal STI/AIDS coordinators were brought closer together through a meeting called to present the proposed intervention for improving clinical monitoring. The meetings were held in the health regions' headquarters, with the epidemiological surveillance groups' STI/AIDS Interlocution participating both in issuing the invitations and organizing the space. In this

meeting, the SIMC was presented, emphasizing its importance for identifying users with difficulties in the different stages of the care continuum. Technical visits for clinical monitoring training in the health services were also scheduled.

The intervention's logical model is presented in Box 2. The purpose of the intervention is the reduction of the number of users included in the three reports and the discussion and qualification of the care and management processes, based on the cases identified in SIMC and SICLOM.

The trainings for the implementation of clinical monitoring were carried out in loco in the health services, with the participation of professionals from the services' multi-professional teams. At the beginning of the training in each service, access logins were created and, after the reports available on the system were issued, at least three cases from the treatment gap report, three cases from the treatment failure report and three cases of treatment abandonment were discussed with the team. During discussions, information was extracted from medical charts in order to evaluate conducts and the existence of individual, social and programmatic vulnerabilities that could explain the user's identification in the reports; from SISCEL, such as the history of CD4, viral load and genotype exams, to determine when the first CD4 and viral load exams were carried out, the frequency with which they were carried out, since when the user had a detectable viral load and if there was a genotype history for the assessment of treatment failure; and from SICLOM, to evaluate the frequency with which users collected their medications in cases of treatment failure and abandonment.

Box 2

Logical model of the intervention for improving clinical monitoring in the State of São Paulo, Brazil.

Users identified in SIMC	Purpose of the intervention	Discussion-triggering questions during training
Diagnosed users in treatment gap.	To identify and reduce the number of diagnosed users not on treatment and to promote a discussion of the care flow between the stages diagnosis, linking, retention and treatment.	How is the user's care flow diagnosed in the service? How are referrals to the network handled? What is the average time between diagnosis and viral load and CD4 exams? And between the exams and the first medical appointment? Does the service offer any appointments for clarifying doubts and clinical evaluation before the first medical appointment? Do all team members understand the importance of beginning ART?
Users on ART for more than six months with a detectable viral load.	To identify and reduce the number of users in treatment failure through identification, discussion and implementation of care actions that seek to improve treatment adherence and to identify users with viral resistance to ART using genotyping exams and to switch treatment.	Does the service monitor in any way the doses dispensed by the pharmacy? Do the members of the multi-professional team have any mechanism with which to warn the medical staff regarding the need to assess adherence and request geotyping? Does the service carry out any activity to improve treatment adherence, such as appointments with professionals from the multi-professional team?
Users who abandoned ART.	To identify and reduce the number of users with a antiretroviral dispensation delay greater than 100 days. To discuss the care flow for contacting and re-engaging users who have abandoned treatment.	Does the service offer any appointment to verify the adequacy of ART in the user's routine after they begin treatment? Does the service have any established flow to search for users who have abandoned treatment? Does the service carry out any differentiated monitoring activity for users with a history of abandonment? Does the service seek to identify the reasons for ART and follow-up abandonment and does it trigger actions by the multi-professional team with a focus on adherence and retention in care?

ART: antiretroviral therapy; SIMC: Clinical Monitoring System.

During training, some triggering questions were presented after the reports were extracted from the system, in order to promote the teams' reflection regarding the work processes in place in the service and the possibilities of altering these processes in order to guarantee better care quality and the long-term reduction of the number of cases in the reports. Answers to these questions were not recorded, as they were only intended to promote discussion between team professionals.

After the training, in approximately 60 days, service professionals presented their evolution in clinical monitoring in meetings held at the health region headquarters. These in-person meetings involved only the health services from the same health region. In these meetings, the services presented an analysis of the situation of users identified in the reports, changes in care and management processes carried out in the services in order to implement clinical monitoring and improve quality of care, as well as the difficulties and challenges faced in this work.

Characterization of the services of the STI/AIDS care network and the services that participated in the intervention

The 645 municipalities of the State of São Paulo are grouped into 63 Health Regions, only two of which do not have specialized reference services for PLWHA. The intervention was carried out in 21 specialized services belonging to four priority regions in the State of São Paulo.

Table 1 describes the set of services that comprise the network of specialized STI/AIDS care in the State of São Paulo and characterizes the services of regions 1 through 4 which agreed to participate in the intervention, as well as a comparison group of services from regions 5 through 8 which did not receive the intervention. Table 1 presents the managing institutions, type of service and size of service in terms of the number of users in treatment. In the three groups, service management falls predominantly to the municipal health secretariat and most outpatient services specialize on users with HIV/AIDS, STI and viral hepatitis. This table also presents the treatment gap, failure and abandonment of each group at the beginning of the intervention.

The data used to characterize the services were collected in 2016 through the QualiAids survey, which assesses the quality of care to PLWHA ⁷, covering the totality of existing services. Since then, there have been no significant changes to their composition. The proportions of users in treatment gap, failure and abandonment were calculated using the number of users in ART and abandonment extracted from SICLOM, while the number of users in treatment gap and failure were extracted from SIMC. Our calculations considered the formulas used by the Ministry of Health for the follow-up of the implementation of clinical monitoring in the states:

$$\% \text{ of treatment gap} = \frac{\text{number of PLWHA in treatment gap}}{\text{Diagnosed PLWHA}} \times 100$$

where the number of diagnosed PLWHA is the sum of number of PLWHA in ART + number of PLWHA in treatment gap + number of PLWHA in abandonment.

$$\% \text{ of treatment failure} = \frac{\text{number of PLWHA on ART with detectable viral load}}{\text{number of PLWHA on ART}} \times 100$$

$$\% \text{ of treatment abandonment} = \frac{\text{number of PLWHA in abandonment}}{\text{number of PLWHA who initiated ART at some point}} \times 100$$

where the number of PLWHA who initiated ART at some point is the sum of number of PLWHA in abandonment + number of PLWHA on ART.

Monitoring and evaluation of results

We monitored the services' evolution before, during and after the intervention based on the calculation of the proportions of each service in the reports available in SIMC and information reported by health professionals in the in-person meetings.

The proportions of users in each of the reports obtained by the services that participated in the intervention were compared to the proportions of service groups belonging to the other four prior-

Table 1

Characteristics of the Specialized Care services in the State of São Paulo, Brazil, of the services participating in the intervention and the comparison group.

Characteristics	Set of services in the State of São Paulo		Regions 1-4 (with intervention)		Regions 5-8 (without intervention)	
	n	%	n	%	n	%
Managing institution						
Municipal Health Secretariat	166	84.8	20	95.2	15	83.3
State Health Secretariat	12	6.1	-	-	-	-
University	9	4.6	-	-	2	11.1
Ministry of Health	3	1.5	-	-	-	-
Inter-municipal Consortium	2	1.0	1	4.8	-	-
Others	4	2.0	-	-	1	5.6
Type of service						
Outpatient service that exclusively provides care to users with HIV/AIDS, STI and viral hepatitis	82	41.8	12	57.1	8	44.4
Outpatient service specialized in infectious diseases	44	22.4	5	23.8	5	27.8
Specialized outpatient service inserted into a primary care unit	17	8.7	-	-	1	5.6
Primary care service that provides care to people living with HIV	15	7.7	-	-	-	-
Outpatient service that offers care in multiple specialties	15	7.7	2	9.5	-	-
Others	23	11.7	2	9.5	4	22.2
Service size (users) *						
< 100 **	40	20.4	7	33.3	13	72.2
> 100 e < 500 ***	70	35.7	5	23.8	2	11.1
≥ 500 #	76	38.8	9	42.9	3	16.7
Users per report ##						
Treatment gap	9,795 (d = 184,964)	5.3	1,218 (d = 24,735)	4.9	632 (d = 14,542)	4.3
Treatment failure	11,762 (d = 144,401)	8.1	1,597 (d = 21,135)	7.6	770 (d = 12,163)	6.3
ART abandonment	30,768 (d = 175,169)	17.6	2,382 (d = 23,517)	10.1	1,747 (d = 13,910)	12.6

d: denominator.

* 10 (5.1%) services did not report the number of users to which they provide care;

** Provide care to a total of 2,490 users (2.6% of the total in the State of São Paulo);

*** Provide care to a total of 19,399 users (20.2% of the total in the State of São Paulo);

Provide care to a total of 74,277 users (77.2% of the total in the State of São Paulo);

The proportions referring to the State of São Paulo were calculated with data from June/2018, reported by the Ministry of Health in a monitoring meeting. The proportions referring to the health regions were calculated with data from August/2018 extracted from the Clinical Monitoring System (SIMC) and the Logistical Medication Control System (SICLOM).

Source: Qualiaids (2016), SIMC (2018), and SICLOM (2018).

ity health regions in the State of São Paulo. These four regions were chosen because they had similar proportions of treatment gap, failure and abandonment to the regions involved in the intervention.

The changes in care and management processes were reported by the services during the experience-sharing meetings and were presented taking into consideration the service's size and the type of change: care or management.

Results

Twenty-one services (91.3%) from four health regions took part in the intervention for the implementation of clinical monitoring between September 2018 and February 2019. Of these, six services had participated in the trainings carried out between 2014 and 2016.

The evolution of the set of services in the monitoring of treatment gap and failure can be seen in Figure 1. There was a reduction in the proportion of treatment gap in all participating regions, when compared to the proportion of the group without intervention. The group that did not participate in the intervention had a proportion of 4.3% of treatment gap in the beginning of the process and a 4.8% proportion at the end of the intervention. All regions that participated in the intervention had a treatment gap proportion under 4% in January 2019, including Region 2, which had a proportion of 5.7% in the beginning of the process and 6% in the second month of the intervention (Figure 1).

There was a reduction in the proportion of users in treatment failure in all health regions, especially in December. Part of this reduction is due to an improvement of linkages between databases provided by the Department of Chronic Conditions and Sexually Transmitted Infections, Ministry of Health (DCCI/MS, in Portuguese) informed in a meeting for the three-month monitoring of results in the State of São Paulo. We should also consider that the intervention's impact on the proportion of treatment failure is not as immediate as the impact on treatment gap because the Clinical Protocol and Therapeutic Guidelines on HIV Infection Management in Adults (PCDT, in Portuguese) establishes that viral load exams be performed every six months (Figure 1).

Impacts on the general care flow and technical management of the work in the services that participated in the intervention

During the technical visit, services identified one professional responsible for extracting the reports from the system. In most cases, it was a professional from the multi-professional team who was not a doctor, including nurses, social workers, pharmacists, psychologists and nursing technicians.

In the discussions, participants also sought to identify which work processes could be revised and improved in the services' care and management routine in order to start new users on ART, facilitate access to ART, re-engage users in the service and improve adherence. Box 3 shows examples of care and management processes that were re-organized based on these discussions and reported on the experience-sharing meetings.

Among the care processes, there were changes that facilitated access to follow-up control exams and to antiretroviral medication through partnerships between specialized services and other services from the care network. Appointments with nurses and pharmacists were also inserted into the care flow, in order to improve the link of newly-diagnosed users who were awaiting the first medical appointment and adherence to treatment for newly-diagnosed users who are prescribed ART.

Services also implemented activities to monitor users with difficulty adhering to treatment and to follow-up, such as: monitoring collection of antiretroviral medication, signaling delayed dispensation in users' charts and the search for users who miss medical appointments or exams.

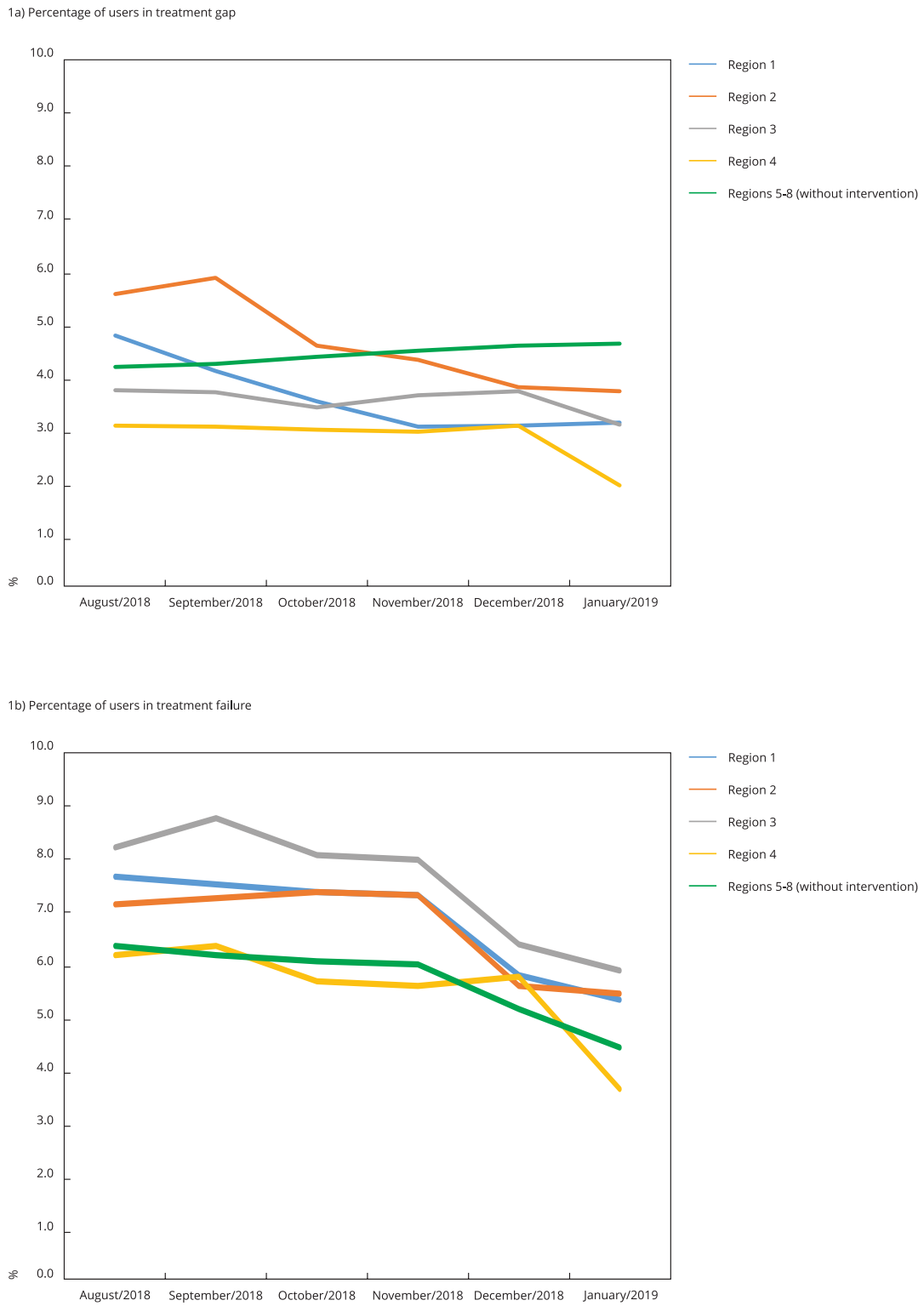
Within the management processes, the reports identified in SIMC guided case discussions in weekly team meetings. There were also actions that seek tariff exemption in public transportation for users, in order to guarantee access to services. Services re-evaluated the flow of benefit offers for users in municipalities that had already established this exemption and there was a movement toward tariff exemptions in municipalities that did not guarantee this possibility.

One of the small-size services was unable to extract reports from SIMC because the viral load and CD4 exams were performed in a private lab that did not report results in SISCEL. Because of this, CRT-DST/AIDS issued a directive to the municipal health secretary reinforcing the importance of using a reference laboratory from the public network and, consequently, SISCEL. The exams started to be performed by the network laboratory and the service gained access to the SIMC reports.

The services reported some difficulties in carrying out the monitoring. These were: out-of-date user registries, reduced technical and management team, resistance to incorporating new proposals to services' work processes, duplicated records in the SISCEL and SICLOM systems, the need to maintain efforts for monitoring, the team's heterogeneous understanding of the importance of clini-

Figure 1

Proportions of users in treatment gap and failure before, during and after the intervention, according to health region.



Source: Clinical Monitoring System – SIMC (2018-2019).

Box 3

Reorganized processes in the general care flow and technical work management reported by the health services in the experience-sharing meeting.

Service size	Changes in the care (C) or management (M) flow	Purpose of the change
SMALL	C – Analysis of the regularity of medication dispensation in SICLOM and identification of treatment failure in SIMC, followed by signaling non-adherence through a color scheme in the physical chart *.	To guarantee the identification of users with poor adherence by the multi-professional team in the service's care process routines for decision-making (e.g., confirmation viral load exam, genotyping request, strategies for improving adherence, etc.).
	M – Making 1 hour per week available for each member of the multi-professional team to revise and study the PCDT.	To ensure a homogeneous understanding, by the entire health team, of clinical practices established in PCDT.
	C – Creation of an agreement with the reference laboratory establishing new days to receive viral load and CD4 samples, increasing collection from once a month to every 15 days.	To offer users more dates on which to undergo viral load and CD4 exams, so as to avoid long intervals between exams and delays in confirmation of treatment failure, as well as to optimize evaluation of users who have abandoned treatment and follow-up.
	M – Implementation of exams in the public network's reference laboratory which had previously been carried out in a private lab.	To guarantee the centralization of information related to PWLHA's exams in SISCEL. To reduce costs related to exams in the municipality.
MEDIUM	C – Introduction of an appointment with the pharmacist after 15 days for all users beginning ART.	To offer pharmaceutical care with information and answers to questions related to treatment (among them, dosage, medication interactions and adverse events) and to support treatment adherence.
	M – Search for users who have missed medical appointments by the specialized service or in partnership with primary care for uses in the municipality.	To identify early users who need to schedule a new appointment, in order to guarantee the continuity of care.
	M – Sending medication to primary care in specific cases in which the user does not have sufficient resources to get to the specialized service.	To guarantee access to medication to socially vulnerable users.
LARGE	C – Introduction of appointments with nurses during the process of linking recently-diagnosed users to the service.	To support or promote recently-diagnosed users' link to the service in the first six months following diagnosis, guaranteeing the assessment of risks and vulnerabilities in the interval between diagnosis and linking.
	M – Use of treatment gap and failure reports as guides for case discussions in weekly team meetings.	To support the discussion of cases identified in SIMC in meetings in which the multi-professional team participates systematically.
	M – Carrying out weekly team meetings to discuss cases identified in the SIMC.	To guarantee that all cases identified in SIMC be discussed in a timely manner without clinical harm to the user.
	C – Search for users who miss CD4 and viral load exams.	To identify users who require new appointments for exams to guarantee continuity, monitoring and the early identification of treatment failure.

ART: antiretroviral therapy; PCDT: Clinical Protocol and Therapeutic Guidelines; PLWHA: people living with HIV/AIDS; SICLOM: Logistical Medication Control System; SIMC: Clinical Monitoring System; SISCEL: Laboratory Exam Control System.

* Also reported by a large service.

Source: meetings for sharing clinical monitoring experiences.

cal monitoring, little communication between services' team professionals and the lack of material resources, such as computers and phone lines.

Despite these difficulties, Figure 1 shows a reduction in the number of users in treatment gap found in the reports and of the proportion of non-monitored users, suggesting the implementation of a culture of clinical monitoring in the participating services since the beginning of the intervention.

At the beginning of the intervention, the set of services included in the process had 1,367 users in the treatment gap report and, of these, 1,127 (82.44%) awaiting analysis. In July 2019, these services had 777 users in treatment gap, of which 524 (67.43%) were awaiting analysis. That is, there was a 56.8% reduction in the number of patients in treatment gap and a 45.6% reduction of non-monitored cases/cases awaiting analysis. There were 1,648 users in treatment failure at the beginning of the intervention and, in July 2019, there were 860, a 52% reduction in the set of services in all four regions.

Discussion

This intervention model is an effective methodology to improve the clinical monitoring of PLWHA and is reproducible by other services that follow these individuals in the country, since all have access to SIMC and to the delayed ART dispensation report generated by SICLOM. It is worth noting that the systematic monitoring of users through data available on charts and clinical data originating in information systems is a globally-recommended strategy to increase service retention, ART adherence and viral suppression ⁶.

The intervention contributed to reducing the number of users “lost” between the stages of linking and treatment through the treatment gap report and between treatment and viral suppression through the treatment failure report.

At the systematic level of evaluation and monitoring, programs and services use the stages of care as a parameter for constructing epidemiological models (care continuum cascades) which present the linear and uni-directional distribution of users of a certain set (country, state, municipality, service, among others) in each of the stages, with the final purpose of identifying the gaps that require intervention between the different stages ². At the care management level, these stages become a series of care and management actions, put into practice based on technologies that seek the individual’s integral care. Organizational arrangements that broaden care, such as welcoming users, case discussions in the multi-professional teams and the formulation of a singular therapeutic project are examples of technologies that seek the organization of care and must consider the specificities and singularities of each user ^{8,9}. The individual management of care is necessary for users who, in real life, do not experience the care continuum in such a simplified, linear manner. These individuals may leave the care continuum for some time and then return (e.g., users who abandon treatment) ¹⁰.

The intervention contributed to the analysis of the cases found in the reports and to the flow revision for the incorporation of these technologies of individual care into the services. Care and management processes were revised based on the identification of care failures observed during technical visits, among them: (a) the long interval between diagnosis and the first medical appointment; (b) the low notoriety of users not in treatment; (c) the lack of defined flows for identifying and approaching users who missed a medical appointment, or who are in treatment failure; (d) the insufficiency of work shared with other instances (Primary Care or Psychosocial Care Centers) in the care for PLWHA. We emphasize that not all services reported changes in processes, a fact that may be due to the previous organization of well-defined care and management flows or to the lack of human resources, reported by services as a challenge to this work.

A factor that facilitated the intervention was the alignment between the goals of the intervention and the #5 Strategy of the 2017-2020 Strategic Plan of the São Paulo STI/AIDS Program. This strategy establishes the broadening of retention, antiretroviral treatment and viral suppression in PLWHA and the strategy’s indicators are the percentage of treatment gap and reduction in the percentage of PLWHA in treatment with treatment failure ¹¹.

We should further note that the services that participated in the intervention are located in the four health regions that are part of the QualiRede intervention for the improvement of the HIV, congenital syphilis and hepatitis C care continuum ¹². At the end of the QualiRede intervention, regional care network qualification plans were developed, with goals related to clinical monitoring ¹³, and this certainly contributed to the participation of nearly 100% of the services from the four health regions in the intervention described in this article.

Some barriers also accompanied the development of the intervention. The lack of previous experience using the SIMC and the lack of human resources, the latter pointed out by all services, led to

the need to introduce clinical monitoring more slowly in the services. For these reasons, the intervention prioritized the analysis of cases available in SIMC (treatment gap and failure), leaving the ART abandonment cases for a different moment. Thus, we must consider, for the next intervention, the need to extend the intervention to 12 months, with meetings in the health region headquarters every three months.

Limitations

The intervention established that the services would carry out a search of users identified in all three reports (treatment gap, failure and abandonment). However, the lack of human resources available for this work led the services to prioritize, in the six months when the intervention took place, cases of treatment gap and failure, leaving the clinical monitoring of ART abandonment to a later time, to be carried out between 2019 and 2020.

We must consider that we do not know precisely what proportion of the cases included in these reports are duplicated, either within one system or between different systems, how many are unregistered deaths and other factors that may lead to an overestimation of the numbers. Likewise, the reduction found during the intervention may be overestimated due to the correction of these inconsistencies. However, it is worth remembering that the responsibility for monitoring, identifying duplicates and requesting corrections of records to the Ministry of Health falls to the services.

The identification of people on ART carried out by the DCCI/MS, as well as the inactivation of a record in SICLOM, the recording of deaths in SISCEL or SICLOM and the monitoring of deaths in SIMC, carried out by other instances, such as epidemiological surveillance or other network services, may also overestimate the reduction of users in treatment gap or failure identified in the services as a result of the intervention.

Another important point when analyzing these findings is the fact that reports are dynamic, including new users every month. That is, newer lists may include users whose diagnosis and/or first viral load exam occurred after the first report was issued and who, therefore, were not included in the treatment gap count at the beginning of the intervention, or, further, users whose viral load was detectable the previous month, leading to an underestimation in the findings.

It is worth noting that the period in which results were followed and compared may be considered short and limit the conclusions regarding the intervention, especially with regard to the long-term sustainability of clinical monitoring practices. Despite all these considerations, there was an important reduction in the number of users awaiting analysis and in treatment failure in the 21 services that participated in the intervention, which suggests that a culture of clinical monitoring was implemented in the services.

Perspectives

Based on the results of this intervention for the implementation of clinical monitoring and improvement of the care provided to PLWHA, the CRT-STD/AIDS decided to expand this work to 30 other services from nine other health regions between 2019 and 2020. In this new intervention phase, the suggestion made by the services to expand the intervention time will be taken into account and the services will be followed over one year, enabling a monitoring and exchange of experiences in clinical monitoring for a longer period. We hope that this change will propitiate the work of identifying and searching for users from all three reports.

Conclusion

The re-structuring of the intervention, considering the case discussion in the health services and the exchange of experiences between services, contributed to the implementation of clinical monitoring in services that follow PLWHA. The new intervention also contributed to the reorganization of general care and management flows, which seek to improve the quality of the care provided. The changes in process took place according to each service's individual needs.

The participation of professionals from the multi-professional teams, as well as the use of real cases from the services for the discussion, including information from charts, history of viral load exams and history of medication dispensation, seem to be predictive factors for the implementation of clinical monitoring. Still, the lack of human resources for the monitoring was reporting by all services involved as is a challenge that must be overcome.

Contributors

All authors contributed to all stages of producing the article.

Additional informations

ORCID: Ana Paula Loch (0000-0002-1725-4213); Joselita Maria de Magalhães Caraciolo (0000-0001-9170-0982); Simone Queiroz Rocha (0000-0002-9689-5149); Mylva Fonsi (0000-0002-9242-4630); Rosa de Alencar Souza (0000-0002-7930-0203); Maria Clara Gianna (0000-0002-4685-9596); Alexandre Gonçalves (0000-0001-7753-6549); Artur Olhovetchi Kalichman (0000-0002-8912-6042).

Acknowledgments

We would like to thank the Brazilian Ministry of Health and the Pan American Health Organization for making it possible to hire a supporter for the re-structuring and the development of the intervention. We would also like to thank all the professionals from the services that participated in the intervention for believing in clinical monitoring as a tool for managing individual care.

References

1. Programa Conjunto das Nações Unidas sobre HIV/AIDS. 90-90-90. Uma meta ambiciosa de tratamento para contribuir para o fim da epidemia de AIDS. Geneva: Programa Conjunto das Nações Unidas sobre HIV/AIDS; 2015.
2. Cohen MS, Chen YQ, McCauley M, Gamble T, Hosseinipour MC, Kumarasamy N, et al. Antiretroviral therapy for the prevention of HIV-1 transmission. *N Engl J Med* 2016; 375:830-9.
3. Departamento de Vigilância, Prevenção e Controle das Infecções Sexualmente Transmissíveis, do HIV/AIDS e das Hepatites Virais, Secretaria de Vigilância em Saúde, Ministério da Saúde. Relatório de monitoramento clínico do HIV. Brasília: Ministério da Saúde; 2018.
4. Bauer MS, Damschroder L, Hagedorn H, Smith J, Kilbourne AM. An introduction to implementation science for the non-specialist. *BMC Psychol* 2015; 3:32.
5. Theobald S, Brandes N, Gyapong M, El-Saharty S, Proctor E, Diaz T, et al. Implementation research: new imperatives and opportunities in global health. *Health Policy* 2018; 392:2214-28.
6. International Advisory Panel on HIV Care Continuum Optimization. IAPAC guidelines for optimizing the HIV care continuum for adults and adolescents. *J Int Assoc Provid AIDS Care* 2015; 14 Suppl 1:S3-34.

7. Nemes MIB, Castanheira ERL, Loch AP, Santos MA, Alves AM, Melchior R, et al. Avaliação de serviços de saúde: a experiência do QualiAids. Porto Alegre: Rede Unida; 2016.
8. Centro de Referência e Treinamento em DST/AIDS, Coordenadoria de Controle de Doenças, Secretaria de Estado da Saúde. Diretrizes para implementação da rede de cuidados em IST/HIV/AIDS. Manual de gestão da rede e dos serviços de saúde. São Paulo: Secretaria de Estado da Saúde de São Paulo; 2017.
9. Secretaria Municipal da Saúde de São Paulo. Programa Municipal de DST/AIDS. Linha de cuidados de IST/AIDS. São Paulo: Secretaria Municipal da Saúde de São Paulo; 2018.
10. Kay ES, Batey S, Mugavero MJ. The HIV treatment cascade and care continuum: updates, goals, and recommendations for the future. *AIDS Res Ther* 2016; 13:35.
11. Cervantes VA, Dantas JCO, Vilela MC, Caraciolo JMM, Tancredi MV. Planejamento estratégico do Programa Estadual de IST/AIDS SP 2017-2020. São Paulo: Programa Estadual de IST/AIDS; 2017.
12. Nemes MIB, Castanheira EL, Alves AM, Adania C, Loch AP, Monroe AA, et al. A intervenção QualiRede: melhoria do desempenho do contínuo do cuidado em HIV, sífilis congênita e hepatite C em regiões de saúde. *Rev Bras Epidemiol* 2019; 22 Suppl 1:e190010.
13. Nemes MIB, Nemes Filho A, Alves AM, Loch AP, Adania C, da Silva FL, et al. Projeto QualiRede – Qualificação da Rede de Cuidados em IST, HIV/AIDS e Hepatites Virais. Planos regionais de qualificação da rede de cuidados em IST, HIV/AIDS e hepatites virais das regiões do Alto Tietê, Grande ABC, Registro e Baixada Santista. São Paulo; 2017. <https://www.qualirede.org/planos-regionais> (accessed on 27/Jun/2019).

Resumo

O monitoramento clínico de pessoas vivendo com HIV/aids (PVHA) contribui para a identificação e gestão de caso das pessoas sem início de tratamento (gap), em falha terapêutica e em abandono de tratamento. O objetivo deste artigo é apresentar e discutir o desenvolvimento de uma metodologia para a implementação do monitoramento clínico das PVHA em serviços do Sistema Único de Saúde (SUS). A metodologia utilizada desde 2014 pelo Centro de Referência e Treinamento DST/AIDS-SP-Coordenação do Programa Estadual de IST/AIDS do Estado de São Paulo, Brasil, foi reestruturada em três reuniões, no período de junho a agosto de 2018. Foram mantidos os eixos de apresentação do número de usuários com falha terapêutica, em gap e em abandono de tratamento nos serviços participantes, e a discussão de vulnerabilidades individuais, sociais e programáticas. Foi adicionado um novo eixo que direciona a discussão das possibilidades de reorganização de fluxos assistenciais e práticas gerenciais do serviço. Adicionalmente, a intervenção passou a ser feita nos serviços de saúde, com a participação de um número maior de profissionais da equipe multiprofissional, discussão de casos, fluxos e processos de trabalho e encontros regionais para a troca de experiências em monitoramento clínico entre os serviços. A reestruturação da metodologia contribuiu para a diminuição do gap de tratamento, reorganização de fluxos assistenciais e inclusão do monitoramento clínico como ferramenta de gestão nos serviços de assistência especializada às PVHA. Essa metodologia pode ser implementada por outros programas estaduais, municípios e serviços, uma vez que todos têm acesso às mesmas fontes de informação usadas nesta intervenção.

Avaliação de Processos (Cuidados de Saúde); Adesão ao Tratamento; Sistema Único de Saúde; HIV; Ciência da Implementação

Resumen

El monitoreo clínico de personas afectadas por el VIH/SIDA (PVHA) contribuye a la identificación y gestión de caso de personas sin inicio de tratamiento (gap), con fallos en la parte terapéutica y abandono del tratamiento. El objetivo de este artículo es presentar y discutir el desarrollo de una metodología para la implementación del monitoreo clínico de las PVHA en servicios del Sistema Único de Salud (SUS). La metodología utilizada desde 2014 por el CRT-ETS/SIDA-Coordinación del Programa Estatal de ETS/SIDA del Estado de São Paulo, Brasil, fue reestructurada en tres reuniones, durante el período de junio a agosto de 2018. Se mantuvieron los ejes de presentación del número de usuarios con fallos en la parte terapéutica, gap y con abandono de tratamiento en los servicios participantes estudiados, así como la discusión de vulnerabilidades individuales, sociales y programáticas. Se añadió un nuevo eje que vertebra la discusión sobre las posibilidades de reorganización de los flujos asistenciales y prácticas de gestión del servicio. Asimismo, la intervención pasó a realizarse en los servicios de salud, con la participación de un mayor número de profesionales del equipo multiprofesional, discusión de casos, flujos y procesos de trabajo, así como encuentros regionales para el intercambio de experiencias en el monitoreo clínico entre los servicios. La reestructuración de la metodología contribuyó a la disminución del gap en el tratamiento, la reorganización de flujos asistenciales, así como la inclusión del monitoreo clínico como herramienta de gestión en los servicios de asistencia especializada a las PVHA. Esta metodología puede ser implementada en otros programas estatales, municipios y servicios, ya que todos tienen acceso a las mismas fuentes de información usadas en esta intervención.

Evaluación de Proceso (Atención de Salud); Adherencia al Tratamiento; Sistema Único de Salud; VIH; Ciencia de la Implementación

Submitted on 17/Jul/2019

Final version resubmitted on 21/Feb/2020

Approved on 12/Mar/2020