Short Communication

Operational research principles for a routine service process for monitoring the human immunodeficiency virus/ acquired immunodeficiency syndrome treatment cascade: data from a cohort in Brazil

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Abstract

Introduction: Bottlenecks still exist during human immunodeficiency virus care that may delay the achievement of better outcomes. **Methods:** We established a monitoring system to trace patients throughout the human immunodeficiency virus/ acquired immunodeficiency syndrome care process in Juiz de Fora, Brazil, to identify potential bottlenecks. **Results:** Among 250 patients, 17.6% abandoned follow-up. Our monitoring system tracked 86.4% of patients through the medication logistics control system and 2.3% through the mortality information system. Two percent of patients were not located by our monitoring system. **Conclusions:** A pathway care process contributes to a better understanding of the barriers to the treatment cascade.

Keywords: Human immunodeficiency virus. Acquired immunodeficiency syndrome. Operational research in health.

Brazil occupies a prominent position on the world stage in the fight against the acquired immunodeficiency syndrome (AIDS) epidemic[1]. One reason for its success is the universal access to antiretroviral therapy (ART), which accords with the principles of the country's health policy[2]. The initial impact of ART on human immunodeficiency virus (HIV)/AIDS patient survival has been documented in the literature[3].

However, despite these advances, Brazil's mortality rates have plateaued since 2005[4], which may be related to barriers to universal access to ART. High dropout rates have been described in the worldwide literature, which may be related to many factors, such as the infrastructure, personnel, and social problems[5,6]. In Brazil, dropout incidences of up to 26.5 per 100 person-years are observed[7,8], and this is probably one of the barriers to the country's development of HIV care. Retention in care is associated with a better prognosis and is recognized as a marker of quality of care[9].

Knowing that there are barriers to excellence of care, and that ART not only preserves the health of people with HIV but also lowers their risk of transmitting HIV to others[10], quality indicators based on the HIV care-continuum are crucial for identifying bottlenecks in the defined pathways of the process. Information about the role of the treatment cascade collected from well-defined pathways of care has contributed to a better understanding of the bottlenecks and decision-making process, which may influence strategies for directing action and redefining the care process[11]. To improve the HIV/AIDS care process, we aimed to establish a monitoring strategy of the pathway care process in order to identify steps sensitive to verification and assessment and to work toward more effective care.

The current study was an observational prospective cohort study of patients from the regional referral HIV/AIDS clinic in the City of Juiz de Fora, Minas Gerais State, in the Southeast region of Brazil. A convenience sample of patients with HIV older than 18 years and receiving ART who attended the clinic for scheduled medical appointments during July and August 2011 was selected. The inclusion criteria were that patients were being followed up at the outpatient clinic, attending medical appointments on the date of the recruitment, and consenting to participate.

The sample was followed for 9 months. A model was designed to monitor the distribution of dropouts, which is evidence of the critical points in the local care pathway, in order to detect bottlenecks in the care of patients that already have medical appointments. The monitoring model was based on the local treatment pathway and took into account the Brazilian protocol for HIV/AIDS therapy. It utilized locally available databases and information systems − the SICLOM (an information system for ART medicine delivery), SIH (an information system for hospitalization), and SIM (a mortality information system)−in order to collect data about the routine care.

Patients who did not return for scheduled medical appointments within 90 days after the 60-month follow-up were considered dropouts. These patients were systematically searched for in the databases and information systems. The SPSS (Statistical Package fot the Social Sciences) Statistics for Windows software (v. 17.0; SPSS Inc., Chicago, USA) was used to characterize the cohort and investigate the association between the variables and patient dropout. Descriptive analysis was performed using frequency tables for categorical variables and measurements of central tendency for numeric variables (i.e., median and interquartile range). For the univariate analysis, the variables were categorized and statistical analysis was conducted using relative risk (RR) with 95% confidence intervals (CI).

The cohort included 250 patients receiving ART who attended scheduled medical appointments during July and August 2011. These patients had a median age of 43 years and 132 (52.8%) were male. Patients were receiving ART for a median of 5 years; 144 (59.3%) patients had a CD4 cell count less than or equal to 500 cells/mm³ and 93 (38%) patients had a detectable viral load at the last test prior to the interview. The patients' demographic and clinical epidemiological characteristics are presented in **Table 1**.

Forty-four (17.6%) patients were considered dropouts. Thirty-eight (86.4%) patients' records were found in the SICLOM and one (2.3%) record was found in the SIM. Five (2%) records were not located in either database **(Figure 1)**. None of the patients' records were found in the hospital's SIH.

Younger age, longer time since admission, and being seen by a specific physician were potential risk factors for outpatient dropout. Younger patients (≤ 43 vs. > 43 years) (RR: 2.08; 95% CI: 1.2–3.7) and patients with longer admission to the service (> 7 vs. ≤ 7 years) (RR: 1.96; 95% CI: 1.1–3.4) were more likely to dropout. Patients assisted by physician B (RR: 0.13; 95% CI: 0.0–0.9), C (RR: 0.35; 95% CI: 0.2–0.8), or D (RR: 0.16; 95% CI: 0.1–0.5) were less likely to dropout compared with patients assisted by physician E **(Table 2)**.

The estimated patient dropout of 17.6% combined with the identification of many of these patients in the SICLOM (86.4%) indicates the need for a better understanding of the care process for HIV/AIDS, which would enable this cohort to receive one of the first steps of this optimization. From observing the health information systems and the data collection using standardized instruments, the unique flow of patient inclusion

was developed whereby patient dropouts could be identified. The aim was to use independent and standardized instruments that will continue to be useful as a routine service tool for the detection of patient dropouts, and that will serve as an additional tool for improvement and contribute to a better understanding of the bottlenecks in the treatment cascade, which may influence strategies for directing action and resetting care processes.

Operational research is based on the identification of what hinders the efficient operation of a program. It is possible to identify these challenges by monitoring the process, and solutions are aimed at supporting decision-making, being practically relevant to improving the provision of healthcare, and ensuring that investment is properly used[11,12]. Regarding HIV/AIDS, the successful implementation of a sustainable delivery of AIDS treatment and prevention services worldwide is crucial, which is acknowledged by the World Health Organization as one of the five pillars of its AIDS treatment strategy. This allows providers and policymakers to *learn by doing*, ultimately contributing to the improvement of care and HIV-related outcomes[10]. The solution, however, is not to apply it once, but to see it as an ongoing and dynamic process in which constant monitoring is urgent in different contexts. As such, identifying ways to make things feasible after the end of the study was a major concern. As in plan-do-study-act cycles, there must be an iterative testing of changes to improve the quality of the systems[13].

Despite the large variability in estimated outpatient dropout rates worldwide, the observed cumulative incidence of 17.6% in Brazil within 90 days after the sixth month of the last visit is high when contrasted to the Ministry of Health's definition; within this period, all patients should have returned for scheduled medical appointments. The identification of potential risks for outpatient dropout among younger patients, patients with longer admission in the service, or those seen by a specific physician in the univariate analysis highlight the need for local practices targeted at these issues. After identifying this process failure, new strategies are required for a better quality of patient care. However, they should be regarded as, and included in, a process, and not used in isolation.

In addition to providing counseling, the outpatient follow-up is primarily based on patient monitoring, because immunological and virological failure may present asymptomatically and some adverse effects of ART can be assessed only through laboratory testing; thus, dropout may contribute to higher rates of virological failure and increased morbidity and mortality[15]. The benefits of monitoring, however, include not only the patient's health at the individual level, but also benefits in the context of public health related to increased survival[15] and decreased transmission of the virus from suppressing viral loads[14,15].

Differently from what was expected (i.e., that supposed outpatient dropouts could be detected in the mortality or hospitalization records[6]), the vast majority (86.4%) of the dropouts' patient records was found in the SICLOM. Even though locating the patients in the SICLOM suggests adherence to ART, the efficiency of the service could not be confirmed because a detectable viral load was observed in 44.7% of these

TABLE 1

Characteristics of the 250 patients included in the cohort.

Characteristics	Number or median	Percentage or IQR
Gender		
male	132/250	52.8
female	118/250	47.2
Age (years)		
≤ 43	127/250	50.8
> 43	123/250	49.2
Schooling		
never studied	4/250	1.6
basic education	155/250	62.0
school	65/250	26.0
technical education or superior	26/250	10.4
Time since admission (years)		
≤ 7	144/250	57.6
> 7	106/250	42.4
median	7	3–10
Time of receiving ART (years)		
≤ 5	131/242	54.1
> 5	111/242	45.9
median	5	2–9
missing data	8/250	3.2
CD4 cell count pre-interview		
≤ 500 cells/mm³	144/243	59.3
> 500 cells/mm³	99/243	40.7
median	440	276–609
missing data	7/250	2.8
Time from CD4 to interview* (months)		
≤ 6.44	123/243	50.6
> 6.44	120/243	49.4
median	6.44	3.25–10.61
Viral load pre-interview		
≤ 50 cps/ml (undetectable)	152/245	62.0
> 50 cps/ml (detectable)	93/245	38.0
median	1.7 log 10	1.7–2.7
missing data	5/250	2.0
Time from CV to interview* (months)		
≤ 5.85	123/245	50.2
> 5.85	122/245	49.8
median	5.85	3.12–10.17
missing data	5/250	2.0
Drug abuse		
past	73/250	29.2
current	17/250	6.8
Transportation		
bus (rental or not)	211/250	84.4
own vehicle/walking	39/250	15.6
Attending physician		
A	22/250	8.8
B	23/250	9.2
C	67/250	26.8
D	56/250	22.4
E	82/250	32.8

IQR: interquartile range; **ART:** antiretroviral therapy; **CD4:** CD4 count cell; **CV:** viral load; **cps:** copies. *Time between being examined and interviewed.
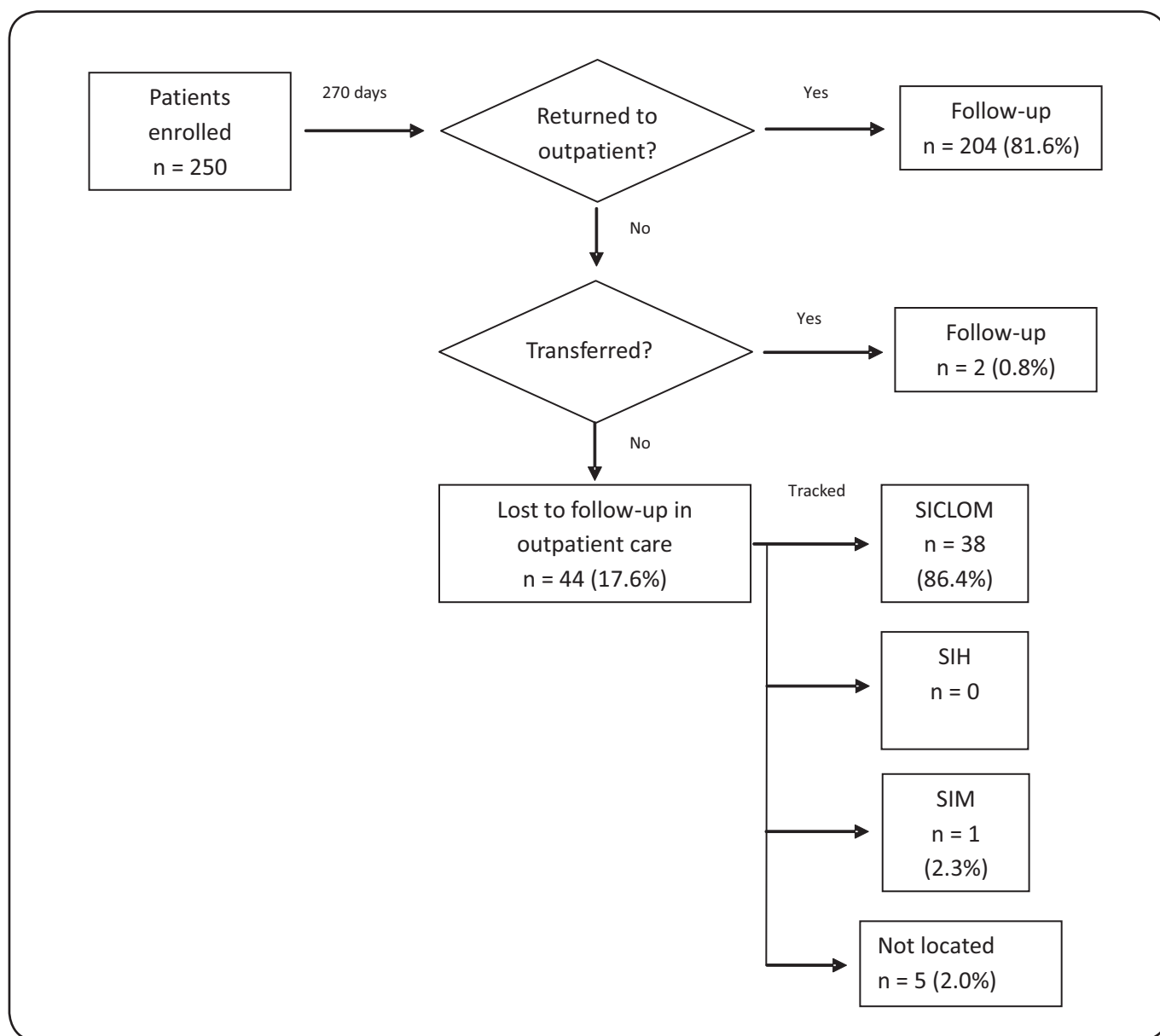
FIGURE 1 - Pathway of the continuity of the care process. **SICLOM:** Information System for antiretroviral therapy; **SIH:** Information System for Hospitalization; **SIM:** Mortality Information System.

individuals who had been using ART for a median of 5 years. As such, an unfavorable outcome in the morbidity and mortality of HIV-infected patients, even in those receiving ART, may be related to outpatient dropout rates. Patients in this cohort did not undergo tests to quantify their viral load or CD4 cell counts for a median of 5.8 and 6.4 months respectively, despite the recommendation that these tests should be conducted three times per year.

The identification of most of the dropouts' patient records in the SICLOM, which was allied with the identification by univariate analysis of the increased dropout risk among patients admitted to the service 7 years or more beforehand, may be related to the saturation of the service. Due to increasing survival, there are more patients in follow-up, and coupled with inadequate public health resourcing that prioritizes recently

diagnosed individuals, it is clear that there is a need for larger surveys for better understanding and targeted interventions to expand the service. The conclusion about the saturation of the service as a probable bottleneck in the care process and the importance of tracking patients is related to the organizational design of how assistance is provided, with observation of the different information systems and inclusion in the pathway. Further understanding of the extent of this problem will help with designing targeted interventions. The Brazilian health system recommends a coordinated approach involving both specialized and primary care for the HIV patient follow-up. This, however, could not be assessed in the present study. We therefore highlight the complexity of the healthcare network, along with the essential aid of management tools for its rational guidance.

TABLE 2

Univariate analysis of factors associated with outpatient dropout.

Characteristics	Outpatient dropout		RR (95% CI)
	yes	no	
Gender			
male	20/132 (15.2)	112/132 (84.8)	0.74 (0.4–1.3)
female	24/118 (20.3)	94/118 (79.7)	1
Age (years)			
≤ 43	30/127 (23.6)	97/127 (76.4)	2.08 (1.2–3.7)
> 43	14/123 (11.4)	109/123 (88.6)	1
Years of education (years)			
≤ 8	28/160 (17.5)	132/160 (82.5)	0.98 (0.6–1.7)
> 8	16/90 (17.8)	74/90 (82.2)	1
Time since admission (years)			
≤ 7	18/144 (12.5)	126/144 (87.5)	1
> 7	26/106 (24.5)	80/106 (75.5)	1.96 (1.1–3.4)
Time of receiving ART (years)			
≤ 5	21/131 (16.0)	110/131 (84.0)	1
> 5	23/111 (20.7)	88/111 (79.3)	1.29 (0.8–2.2)
CD4 cell count pre-interview			
≤ 500 cells/mm³	27/144 (18.8)	117/144 (81.2)	1.24 (0.7–2.2)
> 500 cells/mm³	15/99 (15.2)	84/99 (84.8)	1
Time from CD4 to interview[*](months)			
≤ 6.44	25/123 (20.3)	98/123 (79.7)	1
> 6.44	17/120 (14.2)	103/120 (85.8)	0.70 (0.4–1.2)
Viral load pre-interview			
≤ 50 cps/ml (undetectable)	22/152 (14.5)	130/152 (85.5)	1
> 50 cps/ml (detectable)	21/93 (22.6)	72/93 (77.4)	1.56 (0.9–2.7)
Time from CV to interview[*] (months)			
≤ 5.85	25/123 (20.3)	98/123 (79.7)	1
> 5.85	18/122 (14.8)	104/122 (85.2)	0.73 (0.4–1.3)
Drug abuse			
past	16/73 (21.9)	57/73 (78.1)	1.39 (0.8–2.4)
current	28/177 (15.8)	149/177 (84.2)	1
Transportation			
bus (rental or not)	40/211 (19.0)	171/211 (81.0)	1.85 (0.7–4.9)
own vehicle/walking	4/39 (10.3)	35/39 (89.7)	1
Attending physician			
A	4/22 (18.2)	18/22 (81.8)	0.53 (0.2–1.4)
B	1/23 (4.3)	22/23 (95.7)	0.13 (0.0–0.9)
C	8/67 (11.9)	59/67 (88.1)	0.35 (0.2–0.8)
D	3/56 (5.4)	53/56 (94.6)	0.16 (0.1–0.5)
E	28/82 (34.1)	54/82 (65.9)	1

RR: relative risk; **CI:** confidence interval; **ART:** antiretroviral therapy; **CD4:** CD4 count cell; **CV:** viral load; **cps:** copies. [*]Time between being examined and interviewed.

A meta-analysis that tracked patients lost to follow-up estimated a mortality of 40% among these patients in different African countries[6]. Using an algorithm of linkage databases in Brazil, one study that evaluated the outcome of the apparent dropout patients through the SIM identified the death of 23.9% of these patients[7]. Despite the probable mortality, in this analysis only one (2.3%) patient was located through the SIM, while the SIH did not identify any patients in the cohort. Although the absence of hospitalizations and small number of deaths during monitoring indicate a better prognosis, there were still bottlenecks to care that possibly had a continuous impact throughout the care process and, consequently, affected these patients' clinical improvement.

An investigation that does not influence policy decisions and practice is a waste; thus, it is relevant that operational research be recognized as a method for obtaining results in services. The main setbacks for its practical application may relate to the lack of knowledge about the necessary steps, and the difficulty of implementation and dissemination of the results, while team engagement (both managers and assistants) is a key feature in the planning, development of issues, and data analysis[12]. The routine collection of data will often be seen as hard work for the care team; however, the analysis of routinely collected data in the service will increase the reliability and accuracy of information, making the results more valid[12,13]. After results are measured and questions raised by the team are answered, it is probable that new questions will arise, characterizing the process as continuous and dynamic. The routine and systematic collection of data is a fundamental step when inserted into a pathway, and it enables the analysis of the quality of care, improvement in efficiency, and strengthening of health systems. The efficiency of care in terms of the quality of health, however, should not be based on differing goals, but on unique and patient-centered goals.

Ethical considerations

The study followed the Declaration of Helsinki's principles and was approved by the ethics committee of the Universidade Federal Fluminense Medical School/Antonio Pedro University Hospital (CEPCMM/HUAPNo.220/05).

Conflict of interest

The authors declare that there is no conflict of interest.

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