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HEALTHCARE PERFORMANCE USING SIX SIGMA: MULTIVARIATE CAPABILITY AND PROCESS VARIABILITY IN A HIGH-COST CARE PROGRAM

DESEMPEÑO ASISTENCIAL MEDIANTE SEIS SIGMA: CAPACIDAD MULTIVARIABLE Y VARIABILIDAD DE PROCESOS EN UN PROGRAMA DE ALTO COSTO

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Abstract

This study evaluated healthcare performance, multivariate capability, and temporal process variability in a Colombian high-cost care program for people with HIV from 2021 to 2023 using Six Sigma metrics. A quantitative, observational, longitudinal analysis was conducted using 2,763 care records reported to the Colombian High-Cost Account. Four clinical-operational processes were examined: antiretroviral treatment adherence, viral load undetectability, early case detection, and CD4 lymphocyte control. Defects per million opportunities (DPMO), sigma level (Z), and yield (Y) were calculated for each period; the Global Performance Index (GPI) available in the analytical dataset was used as a complementary multivariate measure. The three-year mean yield was 84.3% for adherence, 71.0% for viral load undetectability, 52.3% for early detection, and 78.0% for CD4 control. Adherence had the highest performance, although it fell to 69% in December 2023. Viral load undetectability reached its lowest performance in October 2023 (Y = 52%; Z = 2.48; DPMO = 159,204). CD4 control showed the largest annual decline, from 89.9% in 2021 to 65.7% in 2023, with its minimum also occurring in October 2023 (Y = 49%; Z = 2.44). Early detection remained close to 52%, despite reaching 73% in December 2023. The GPI decreased from 0.36 to 0.33. Six Sigma metrics identified differences in performance across processes and periods of greater variability. These findings support longitudinal monitoring based on DPMO, Z, and Y, whereas the multivariate component should remain descriptive until the complete GPI algorithm is available.

Keywords: Six Sigma; Quality Management; Quality Indicators, Health Care; Quality Improvement.

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Resumen

El objetivo fue evaluar el desempeño asistencial, la capacidad multivariable y la variabilidad temporal de los procesos de un programa colombiano de alto costo para la atención de personas con VIH entre 2021 y 2023 mediante métricas Seis Sigma. Se realizó un estudio cuantitativo, observacional y longitudinal con 2.763 registros de atención reportados a la Cuenta de Alto Costo. Se analizaron cuatro procesos clínico-operativos: adherencia al tratamiento antirretroviral, indetectabilidad de la carga viral, captación temprana y control de linfocitos CD4. Para cada periodo se calcularon defectos por millón de oportunidades (DPMO), nivel sigma (Z) y rendimiento (Y); como medida complementaria de comportamiento multivariable se utilizó el Índice Global de Desempeño (IDG) disponible en la base analítica. El rendimiento promedio trienal fue 84,3% para adherencia, 71,0% para indetectabilidad, 52,3% para captación temprana y 78,0% para CD4. La adherencia fue el proceso con mayor rendimiento, aunque cayó a 69% en diciembre de 2023. La indetectabilidad alcanzó su menor desempeño en octubre de 2023 (Y = 52%; Z = 2,48; DPMO = 159.204). El control de CD4 mostró el deterioro anual más marcado, al pasar de 89,9% en 2021 a 65,7% en 2023; su mínimo también ocurrió en octubre de 2023 (Y = 49%; Z = 2,44). La captación temprana permaneció alrededor de 52%, pese a alcanzar 73% en diciembre de 2023. El IDG descendió de 0,36 a 0,33. Las métricas Seis Sigma permitieron identificar diferencias de desempeño entre procesos y localizar periodos de mayor variabilidad. Los resultados respaldan un monitoreo longitudinal basado en DPMO, Z y Y, mientras que la interpretación del componente multivariable debe mantenerse descriptiva hasta disponer del algoritmo completo del IDG.

Palabras clave: Seis Sigma; Gestión de la Calidad; Indicadores de Calidad, Cuidado de la Salud; Mejoramiento de la Calidad.

Introduction

High-cost programs concentrate care processes that require clinical continuity, timely diagnosis, therapeutic follow-up, and the capacity to sustain results over time. In the care of people with HIV, these requirements are expressed in adherence to antiretroviral treatment, viral suppression, timely enrollment, and immunological follow-up. In Colombia, the High-Cost Account consolidates information for monitoring this population, while the HIV/AIDS Response Plan 2022-2025 and international recommendations guide care toward timely diagnosis, effective treatment, and continuity of care (High-Cost Account, 2021; Ministry of Health and Social Protection, 2022; World Health Organization [WHO], 2021). These goals are related to Sustainable Development Goal 3.3 and to international commitments to end the epidemic as a public health threat, the fulfillment of which is still uneven between regions and health systems (UN Colombia, n.d.; Joint United Nations Programme on HIV/AIDS [UNAIDS], 2022, 2024).

The clinical relevance of these processes is well established. Early initiation of antiretroviral therapy reduces serious AIDS-related and non-AIDS-related events (INSIGHT START Study Group, 2015), and sustained viral suppression effectively eliminates sexual transmission of the virus, a principle summarized in the adage undetectable = untransmittable (Eisinger et al., 2019). Furthermore, adherence is a direct determinant of virological success: from the first studies with protease inhibitors, it was observed that small reductions in the proportion of doses taken were associated with substantially higher rates of virological failure (Paterson et al., 2000). Therefore, the care cascade model proposed by Gardner et al. (2011) showed that the cumulative losses between diagnosis, linkage, retention, treatment, and viral suppression explain why only a small fraction of people living with HIV achieve optimal outcomes. In the Colombian context, cohort studies have documented the association between regimen changes, adherence and virological

failure (Gómez Hernández et al., 2020), as well as the influence of clinical and social factors on adherence (Urrutia Valdés et al., 2025).

Immunological monitoring retains its own place within this chain of processes. Although viral load is the standard for monitoring treatment response, CD4 lymphocyte count remains necessary to identify advanced disease, determine prophylaxis, and guide differentiated care (Ford et al., 2017; WHO, 2017). Consequently, the quality of an HIV program is not reducible to a single outcome, but rather depends on the articulation of structure, process, and outcome in the sense proposed by Donabedian (1988), and on attributes such as effectiveness, timeliness, and continuity, as noted by the Institute of Medicine (2001).

Healthcare performance is often described using adherence rates, viral suppression, or immune recovery. These indicators are clinically useful, but aggregated values can mask monthly fluctuations, defect concentrations, and episodes of operational deterioration. Six Sigma offers a complementary perspective by quantifying defects per million opportunities, throughput, and distance from an expected quality level, allowing for the comparison of processes and periods using a common metric (Harry and Schroeder, 2000; Linderman et al., 2003; Pyzdek and Keller, 2018). Its integration into the healthcare sector has been described in reviews that identify applications in emergency services, surgery, laboratories, pharmacies, and administrative processes (DelliFraine et al., 2010; Mason et al., 2015; Taner et al., 2007). More recent systematic reviews confirm benefits in reducing errors, waiting times, and costs, although they note methodological heterogeneity and a lack of evaluation of the sustainability of the results (Antony et al., 2018; McDermott et al., 2022; Niñerola et al., 2020). Hospital studies in Latin America and the Middle East have also shown their usefulness in identifying variability and guiding improvement actions (Cerdá Suárez et al., 2018; Kobo-Greenhut et al., 2021; Pérez Pulido et al., 2018).

In antiretroviral programs, quality improvement initiatives have been associated with increases in treatment coverage, adherence, and viral suppression, although with variable effects and mostly observational designs (Hargreaves et al., 2019). This evidence suggests that systematically measuring process performance is a prerequisite for targeted intervention, and that tools such as statistical process control allow us to distinguish between system-specific variation and variation attributable to special causes (Benneyan et al., 2003; Thor et al., 2007).

Process analysis can be expanded through multivariate approaches that integrate several service dimensions into a single, comprehensive view. Capability indices based on principal components (Wang and Chen, 1998) and multivariate control charts such as Hotelling's T^2 (Montgomery, 2020) were developed for processes in which several quality characteristics must be met simultaneously. Following this line of thought, Fontalvo-Herrera et al. (2022) proposed a procedure that combines Six Sigma metrics, Hotelling's T^2 chart, and a principal component-based capability indicator to evaluate the performance of service processes. This approach is particularly relevant in a high-cost program because its components do not necessarily evolve in parallel: favorable adherence performance may coexist with lower viral suppression, insufficient early uptake, or impaired immune control. Therefore, program capability should not be inferred from a single percentage but rather examined based on the overall performance pattern and its temporal variability.

In the reviewed literature, the longitudinal application of Six Sigma metrics and a multivariate measure to care processes in a high-cost Colombian program for people living with HIV remains poorly documented; healthcare applications of Six Sigma in the country have focused primarily on perceived quality or specific hospital services (Pérez Pulido et al., 2018). Monthly and annual evaluations can complement aggregated indicators, identify periods of low performance, and distinguish processes with different trajectories. Consequently, the objective was

to evaluate care performance using Six Sigma, characterize the temporal variability of four clinical-operational processes, and describe the behavior of the available multivariate indicator in a high-cost program in Colombia between 2021 and 2023.

Methodology

A quantitative, observational, longitudinal study was conducted based on routine care records from a high-cost Colombian program for people living with HIV. The unit of analysis was the monthly record used to calculate process indicators. The available dataset comprised 2,763 records between January 2021 and December 2023, distributed as follows: 886 records in 2021, 944 in 2022, and 933 in 2023. The information came from institutional records reported to the High-Cost Account, the entity that standardizes the reporting of people living with HIV treated in the Colombian health system (High-Cost Account, 2021). The design aimed to compare the performance of different processes and describe their variability over 36 months, without attributing causality to the observed fluctuations.

Records with sufficient information to calculate the metrics for the four dimensions evaluated were included. Records with inconsistencies or missing data for the variables required for calculation were excluded according to the cleaning procedure documented in the source database. The number of excluded records and a description of imputation are not available; therefore, the analysis was limited to complete records.

Four clinical-operational processes were evaluated, selected for their correspondence with the critical moments in the HIV care cascade (Gardner et al., 2011; WHO, 2021): adherence to antiretroviral treatment, defined as compliance with the recorded therapeutic process (Paterson et al., 2000); viral load undetectability, as achievement of the viral suppression criterion used by the program (Eisinger et al., 2019); early detection, as timely identification and linkage of cases (INSIGHT START Study Group, 2015); and CD4 lymphocyte monitoring, as compliance with the established criterion for immunological follow-up (Ford et al., 2017). For each process and month, three operational quantities were used: U, number of units evaluated; O, number of opportunities per unit; and N, number of defects observed.

Six Sigma performance was estimated using three metrics. Defects per million opportunities (DPMO) were calculated as $DPMO = N/(U \times O) \times 1{,}000{,}000$. The sigma level was estimated using $Z = \Phi^{-1}(1 - DPMO/1{,}000{,}000) + 1.5$, where Φ^{-1} corresponds to the inverse function of the standard normal distribution and the term 1.5 represents the conventional long-term shift of the process mean (Harry and Schroeder, 2000; Pyzdek and Keller, 2018). Yield was calculated as $Y = (1 - N/U) \times 100$. Together, DPMO, Z, and Y were used to describe defect frequency, relative performance, and temporal variability for each process. These expressions reproduce the values recorded in the analytical tables of the study and are consistent with the measurement logic used in Six Sigma health applications (Antony et al., 2018; Niñerola et al., 2020; Taner et al., 2007).

The multivariate approach was complemented by the annual Global Performance Index (GPI) calculated in the original analytical set, constructed using the logic of principal component-based capability indicators (Fontalvo-Herrera et al., 2022; Wang and Chen, 1998). The available documentation did not specify a complete weighting equation that would allow for the independent reproduction of this index; therefore, it was used only as a descriptive measure to compare the overall performance between 2021 and 2023, and not as a universal capability threshold. The analysis summarized annual returns, extreme monthly values, the GPI trajectory, and the temporal evolution of the four processes. No significance tests or causal models were performed to explain the observed variations.

The study used aggregated secondary information, without personal identifiers, and was therefore considered a risk-free investigation according to Colombian regulations for health research.

Results

Clinical performance showed differences between processes and significant temporal variability over the 36 months. Adherence to antiretroviral treatment had the highest three-year performance (84.3%), followed by CD4 control (78.0%) and viral load undetectability (71.0%). Early recruitment had the lowest average performance (52.3%). In the year-on-year evolution, adherence decreased from 87.0% in 2021 to 80.2% in 2022 and recovered to 85.9% in 2023. Undetectability improved from 68.6% to 75.2% between 2021 and 2022, but returned to 69.0% in 2023. Early detection remained practically stable at around 52%, while CD4 control decreased from 89.9% in 2021 to 78.3% in 2022 and 65.7% in 2023.

Table 1. *Annual performance of healthcare processes, 2021-2023*

Dimension	2021 (%)	2022 (%)	2023 (%)	Average (%)
Adherence to antiretroviral treatment	87.0	80.2	85.9	84.3
Undetectable viral load	68.6	75.2	69.0	71.0
Early detection	51.6	52.1	52.8	52.3
CD4 lymphocytes	89.9	78.3	65.7	78.0

Note: The average corresponds to the average performance for the period 2021-2023. The values were calculated from the monthly observations recorded in the analytical database.

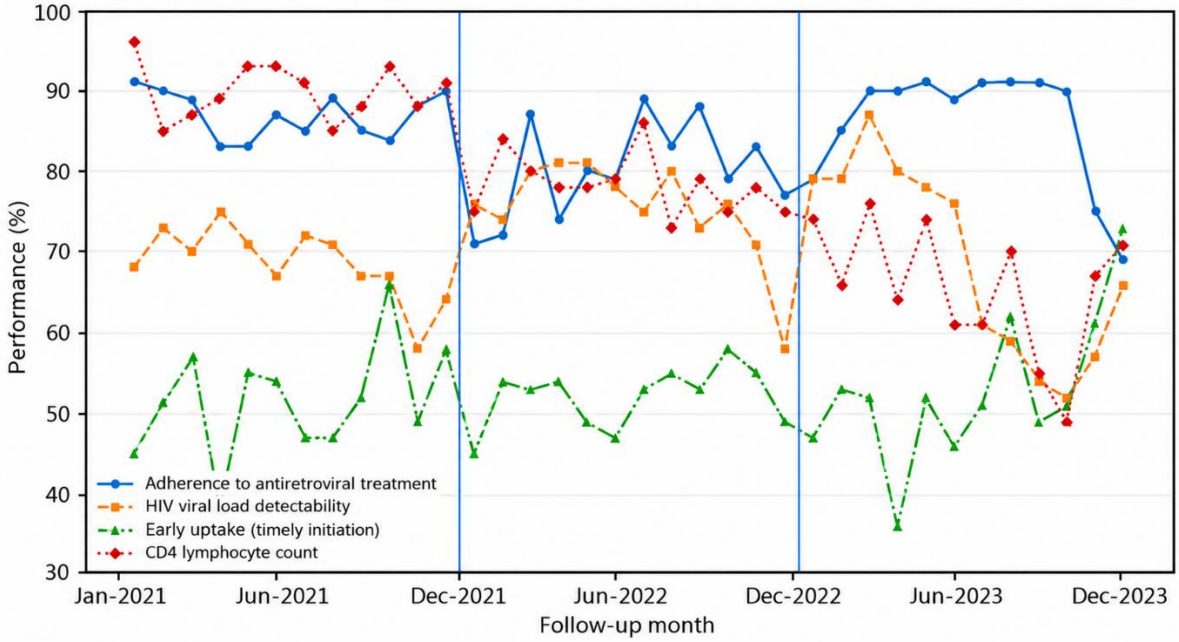
Monthly variability was not evenly distributed across the processes. In adherence, the lowest value occurred in December 2023 (Y = 69%; Z = 2.92; DPMO = 76,613). In viral load undetectability, the lowest was observed in October 2023 (Y = 52%; Z = 2.48; DPMO = 159,204). Early detection reached its lowest performance in April 2023 (36%; Z = 2.48; DPMO = 161,017), although it ended the year at 73% in December. The most pronounced decline in CD4 control was recorded in October 2023, with Y = 49%, Z = 2.44, and DPMO = 169,154. These extremes show that the annual average alone does not describe the magnitude or temporal location of the episodes of poor performance.

Table 2. *Periods of greatest deterioration in Six Sigma performance by process*

Dimension	Period	AND (%)	Z	DPMO
Adherence to antiretroviral treatment	December 2023	69	2.92	76,613
Undetectable viral load	October 2023	52	2.48	159.204
Early detection	April 2023	36	2.48	161.017
CD4 lymphocytes	October 2023	49	2.44	169.154

Note. The period of lowest performance was defined by the minimum monthly value of Y within each dimension.

Figure 1. *Monthly variability of performance (Y) of care processes, 2021-2023*



Note: Vertical lines separate the years. Data is taken from the monthly tables of the study.

The multivariate component also showed an unfavorable change over the period. The IDG decreased from 0.36 in 2021 to 0.35 in 2022 and 0.33 in 2023, averaging 0.35. This trend was consistent with the deterioration observed in some processes during 2023; however, because the complete algorithm for constructing the index was not documented in the source version, the values were used only for internal time-series comparisons and not for ranking the program's capability against an external standard.

Table 3. *Global Performance Index (GPI), 2021-2023*

Year	IDG
2021	0.36
2022	0.35
2023	0.33
Average	0.35

Discussion

The main finding is that the high-cost program's performance was not uniform: each process exhibited a distinct profile, and the magnitude of the fluctuations changed over the 36 months. Adherence maintained the highest average performance, although it registered a temporary drop at the end of 2023. Early detection remained the lowest-performing process. CD4 control showed the most marked annual decline, falling from 89.9% to 65.7%, while undetectability lost the improvement observed during 2022 in 2023. The IDG decreased from 0.36 to 0.33. Taken together, these results support an interpretation of the program based simultaneously on performance, variability, and multivariate behavior, rather than relying on a single aggregate average, consistent

with the multidimensional conception of healthcare quality (Donabedian, 1988; Institute of Medicine, 2001).

The contribution of Six Sigma in this analysis lies in transforming clinical outcomes into comparable process metrics. DPMO quantified the frequency of defects relative to the opportunities assessed; Z allowed performance to be expressed on a common sigma scale; and Y showed the percentage of units without the defined defect for each process. This combination made it possible to pinpoint specific months of decline that might otherwise be masked by annual averages. The healthcare literature has described this utility of Six Sigma for evaluating variability and guiding the improvement of clinical and administrative processes (Cerdá Suárez et al., 2018; Kobo-Greenhut et al., 2021; McDermott et al., 2022; Niñerola et al., 2020). The observed sigma levels, which ranged approximately from 2.4 to 3.7, fall within the range described in the literature as typical for non-standardized healthcare processes and are far from the 6σ benchmark characteristic of industrial settings (Linderman et al., 2003; Taner et al., 2007). However, a low Z-value does not, in itself, demonstrate that a process is statistically out of control; such a conclusion would require specific statistical control tools, such as control charts with limits estimated from the process (Benneyan et al., 2003; Mohammed et al., 2008).

Clinical analysis of the metrics shows that relatively high adherence performance does not guarantee equivalent performance in other processes. The lower undetectability rate and the decline in CD4 counts during 2023 indicate that care dimensions should be monitored separately. This disconnect is consistent with evidence showing that recorded adherence only partially explains the virological response, which also depends on regimen changes, clinical factors, and social conditions (Gómez Hernández et al., 2020; Urrutia Valdés et al., 2025). International HIV response goals prioritize diagnosis, treatment, and sustained viral suppression (WHO, 2021; UNAIDS, 2022, 2024). However, the Six Sigma indicators used here are not equivalent to the population-based 95-95-95 targets and should not be interpreted as measuring the national cascade. Their usefulness lies in describing the program's internal functioning and highlighting periods that require operational review.

The decline in CD4 count monitoring warrants particular attention. Although the use of CD4 counts to determine treatment initiation became less relevant after the recommendation to treat all diagnosed individuals, this marker remains essential for detecting advanced disease, indicating prophylaxis against opportunistic infections, and triaging individuals for differentiated care models (Ford et al., 2017; WHO, 2017). A sustained drop in adherence to this monitoring could reduce the program's ability to identify individuals at higher clinical risk in a timely manner, making it a priority for operational review.

The deterioration observed during some months of 2023 does not allow us to attribute causality to administrative factors, medication availability, contractual changes, or modifications to treatment regimens, because these variables were not part of the analytical basis. Explanations related to administrative cycles are therefore considered hypotheses for future studies. Linking process metrics with information on antiretroviral dispensing, appointments, regimen changes, virological results, and treatment discontinuation events would allow for the direct evaluation of these potential explanations, as recommended by reviews on quality improvement in antiretroviral programs (Hargreaves et al., 2019).

Early detection showed a particular trajectory within the set of processes. Its annual performance remained around 52%, but reached 73% in December 2023 after several months with lower values. This one-off increase does not allow us to conclude a sustained improvement, although it highlights the importance of analyzing monthly variability. From the perspective of statistical process control, monitoring by periods allows us to differentiate transient changes from

stable trends and prevents an annual average from masking episodes of improvement or decline (Montgomery, 2020; Thor et al., 2007). The relevance of this process is clinical and not just operational: late diagnosis and treatment initiation are associated with higher morbidity and persistent transmission (Eisinger et al., 2019; INSIGHT START Study Group, 2015).

The study has limitations that affect the interpretation of the program's capacity. Only one high-cost program was analyzed, and routine records were used, thus limiting generalizability to other institutions. The available dataset did not allow for the inclusion of individual covariates, adjustment for clinical complexity, or the identification of the causes of temporal changes. Furthermore, the exact number of excluded records and a complete equation for reproducing the IDG were not documented; consequently, the multivariate component was interpreted descriptively. The absence of control charts prevents the formal establishment of the statistical stability of the processes (Mohammed et al., 2008). Additionally, the assumption of a 1.5σ shift incorporated into the Z calculation is an industry convention whose validity in healthcare processes has been questioned; therefore, sigma levels should be interpreted comparatively, not absolutely (Antony et al., 2018; DelliFraine et al., 2010). As a strength, 36 months of observation were preserved and the same set of Six Sigma metrics was applied to four clinical-operational processes, allowing for consistent longitudinal comparisons within the program.

For managing a high-cost program, the results support a surveillance system that combines clinical indicators with Six Sigma metrics and a reproducible multivariate measure. Analytical priority should focus on processes with lower performance or greater temporal deterioration, particularly early detection, CD4 count monitoring, and months with lower undetectability rates. Subsequent studies should expand the analysis to multiple programs, fully document the multivariate algorithm, for example, using capability indices based on principal components (Fontalvo-Herrera et al., 2022; Wang and Chen, 1998), incorporate variables related to access, dispensing, adherence, treatment regimen, and timeliness of care, and add statistical process control tools, including Hotelling's multivariate T^2 charts, to differentiate common variation from special variation (Benneyan et al., 2003; Montgomery, 2020).

Conclusion

Between 2021 and 2023, the high-cost program exhibited heterogeneous healthcare performance and process variability that was not visible through a single aggregate indicator. Treatment adherence maintained the highest average performance; early detection remained the lowest-performing process; CD4 count monitoring showed the most marked annual decline; and viral load undetectability showed a significant reduction during 2023, reaching its lowest point in October. The IDG decreased from 0.36 to 0.33, although its interpretation should be limited to internal comparisons until its algorithm is fully documented. The combined application of DPMO, sigma level, and performance made it possible to identify periods of greater decline and compare the behavior of clinical-operational processes using a homogeneous metric. Thus, Six Sigma provides a useful framework for the longitudinal monitoring of healthcare performance; the formal estimation of multivariate capability and statistical stability will require, in subsequent studies, a reproducible index and specific process control tools.

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