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Supply-paced eligibility: aligning clinical policy and supply chains during HIV treatment transitions

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Abstract

Brazil's phased introduction of fixed-dose dolutegravir/lamivudine (DTG/3TC) illustrates a broader challenge in HIV programmes: how to expand access to new treatment technologies while procurement, inventory and distribution capacity are still adjusting. This Viewpoint proposes the concept of supply-paced eligibility to describe the deliberate sequencing of eligibility expansion so that clinical policy and supply systems can move together. Brazil progressively broadened eligibility for fixed-dose DTG/3TC from 2023 to 2025, while Ministry of Health data show rapid growth in national consumption during the transition. We argue that eligibility thresholds may serve not only clinical prioritization but also a temporary supply-management function. Such use should be explicit, measurable and time-limited, supported by demand forecasting, safety-stock planning for legacy and replacement presentations, and predefined indicators of supply readiness. Equity monitoring should accompany each phase of expansion to avoid reproducing disparities in access. Brazil's experience suggests that eligibility decisions, procurement planning and equity monitoring should be considered together when HIV programmes introduce new technologies.

Keywords: Anti-Retroviral Agents; Drug Combinations; Pharmaceutical Services; Health Policy; National Health Programs; HIV Infections.

HIV treatment transitions are rarely only clinical. Guidance can change through a technical act, while procurement cycles, stock turnover and redistribution take longer to adjust. When a new formulation becomes available, programmes therefore face two linked questions: who should receive it, and how quickly can eligibility expand without destabilizing supply? We use the term supply-paced eligibility to describe the deliberate sequencing of eligibility expansion so that clinical policy, procurement, inventory and distribution capacity can move together.

Brazil's introduction of fixed-dose dolutegravir/lamivudine (DTG/3TC) illustrates a broader challenge for HIV programmes: how to expand access to new treatment technologies while procurement and distribution capacity are still adjusting. Distribution began in December 2023 for people aged 50 years or older who were already receiving the two components separately. Subsequent notes progressively broadened access [1–6]. The age threshold moved from 50 to 40 and then to 35 years, while additional groups became eligible (Table 1). The Ministry prioritized groups for comorbidity prevalence, prolonged tenofovir use, polypharmacy and the availability of both fixed-dose and separate presentations [3]. In 2025, it explicitly linked gradual expansion to equity under logistical limits on acquisition and distribution [6]. About 160,000 of approximately 200,000 people receiving DTG plus 3TC dual therapy met the criteria for the fixed-dose formulation [6].

Eligibility criteria can have a second function. A threshold can identify clinical priority, but it can also regulate how quickly new demand reaches the supply system; the technical notes invoke both considerations. Age-based prioritization was central to COVID-19 vaccine allocation when supply was limited [7]. In HIV treatment transitions, however, the supply function is seldom distinguished from the clinical one. Making that function explicit does not mean allowing logistics to override clinical evidence. It means that, when supply constraints affect access, those constraints should be stated, temporary and measurable.

People receiving dual therapy who remained outside the fixed-dose criteria continued to receive the same drugs as separate tablets—three tablets each day rather than one—so the phased expansion changed the presentation, not the regimen [1,6]. The programme had to manage two stock trajectories: use of the legacy presentations needed to fall as use of the replacement increased. Guidance on antiretroviral transitions recommends phasing precisely to avoid shortages of the new product or excess stocks of the old one [8,9]. South Africa faced the same concern during its transition to tenofovir/lamivudine/dolutegravir, where avoiding both stock-outs and wastage was an explicit objective [10].

SICLOM consumption data show the transition's scale. The Ministry supplied monthly data from the Medication Logistics Control System (SICLOM) for fixed-dose DTG/3TC by federative unit from January 2024 through July 2026 [11]. National consumption was 24.8 million tablets in 2024 and 57.1 million in 2025. Consumption from January to July 2026 was 1.9 times that recorded over the same months of 2025, while monthly volume increased from 63,305 tablets in January 2024 to 8,458,059 in July 2026. These figures count tablets, not people, and they cannot establish that particular eligibility changes caused the increase. What they do show is how rapidly the volume handled by the supply system can grow during a transition.

Demand forecasting should be considered when eligibility policy is designed, rather than only after a decision has been made. Brazil procures antiretrovirals centrally, but demand emerges across clinical encounters and dispensing units. Before lowering an eligibility threshold, a programme can estimate how many additional people will become eligible, likely uptake, where demand will occur, replenishment lead times, the safety stock required for the new presentation and the rate at which legacy stock can be drawn down.

The Integrated HIV Care Monitoring Panel publishes anonymized, downloadable data and reports the number of people using combined dolutegravir and lamivudine by year and federative unit. SICLOM, in turn, records product consumption by federative unit [11,12]. Used together prospectively, these sources could support scenario-based estimates before eligibility is expanded and help make clear whether a threshold is driven by clinical evidence, supply constraints or a combination of the two.

Phased access also raises an equity question. An equitable intention does not guarantee an equitable result. Across Latin America and the Caribbean, access to dolutegravir-based regimens has differed by sex, particularly among women of reproductive age, even after treatment guidance changed [13]. If supply-paced eligibility is used, equity monitoring should therefore be specified in advance. Programmes should publish disaggregated indicators of uptake and dispensing, including by sex and, where feasible, race or ethnicity, region and other dimensions relevant to the setting.

Discussions of pharmaceutical sovereignty and dolutegravir access in Latin America have emphasized affordable supply and regional production capacity [14]. A related question is how access should expand while supply is still constrained. Long-acting pre-exposure prophylaxis is already being introduced under limited supply, and frameworks have been proposed to guide distribution without relying on restrictive risk-based eligibility [15]. Future HIV treatment and prevention technologies may produce similar periods in which clinical ambition advances faster than supply. In those circumstances, eligibility can serve as a temporary bridge to wider access, but only if its supply-related function is made explicit.

Four principles follow from this approach. First, programmes should distinguish clinical eligibility from supply-paced eligibility and say clearly when both are operating. Second, expansion should be preceded by forecasts of the additional eligible population and expected uptake, alongside separate safety-stock planning for legacy and replacement presentations. Third, further expansion should be tied to explicit and reviewable indicators of supply readiness rather than to administrative thresholds with no clear endpoint. Fourth, equity should be monitored throughout the transition so that managing the pace of demand does not reproduce existing disparities.

Eligibility cannot substitute indefinitely for adequate procurement. When it is explicit, measurable and temporary, however, supply-paced eligibility can help align clinical policy with procurement and inventory while keeping broader access as the endpoint. Brazil's DTG/3TC transition shows why eligibility decisions, demand forecasting and equity monitoring should be considered together when HIV programmes introduce new technologies.

Table 1. Key policy milestones in phased fixed-dose lamivudine 300 mg/dolutegravir 50 mg eligibility in Brazil, 2023–2025

Act	Date	Main policy signal
Technical Note 35/2024	28 Feb 2024	Documented that distribution had begun in Dec 2023 under Technical Note 365/2023 for people aged ≥ 50 years already receiving the separate components (dual therapy prescribed by 30 Nov 2023); clarified dispensing and revoked Technical Note 365/2023.
Technical Note 87/2024	20 Mar 2024	Lowered the age threshold to ≥ 40 years and updated the relevant prescription cut-off.
Technical Note 208/2024	6 Sep 2024	Set the threshold at ≥ 40 years for dual therapy started by 1 Sep 2024; added people aged ≥ 40 years on tenofovir/lamivudine/efavirenz and selected adolescents; revoked Technical Note 87/2024.
Technical Note 214/2024	16 Sep 2024	Rectified item 3.3 of Technical Note 208/2024 (dispensing of the fixed-dose combination against prescriptions for the separate tablets).
Technical Note 91/2025	17 Apr 2025	Removed the prescription cut-off for the ≥ 40 -year group, updated additional eligibility

		provisions and revoked Technical Note 214/2024.
Technical Note 200/2025	8 Sep 2025	Lowered the age threshold to ≥ 35 years and updated provisions for selected drug interactions.

Declarations

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

Diego Agostinho Calixto: Conceptualization; Data curation; Formal analysis; Investigation; Methodology; Writing – original draft; Writing – review & editing. Lilian Segnini Rodrigues: Conceptualization; Methodology; Supervision; Validation; Writing – review & editing. Both authors read and approved the final manuscript.

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Declaração de disponibilidade de dados de pesquisa

Os dados de pesquisa que sustentam este manuscrito são dados agregados de consumo de DTG/3TC registrados no SICLOM. Os arquivos mensais de janeiro de 2024 a julho de 2026 foram fornecidos pelo Ministério da Saúde do Brasil em resposta ao pedido de acesso à informação NUP 25072.057674/2026-19 e são depositados como dados de pesquisa desta submissão ao SciELO Preprints. Os atos ministeriais citados são de acesso público, e o Painel Integrado de Monitoramento do Cuidado do HIV disponibiliza dados públicos anonimizados de monitoramento clínico. Não foram utilizados microdados individualizados nem dados que permitam a identificação de pessoas.

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O OpenAI ChatGPT (GPT-5.6 Sol) foi utilizado exclusivamente para revisão ortográfica, gramatical e sintática do manuscrito. Os autores revisaram e aprovaram todas as alterações e assumem integral responsabilidade pelo conteúdo. Nenhuma ferramenta de Inteligência Artificial foi utilizada para geração ou análise de dados.

Ethics statement

This manuscript is based on policy documents, public anonymized monitoring data and aggregated administrative consumption data. It involves no direct interaction with human participants and no identifiable individual-level data.

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