The HIV epidemic is growing faster in countries excluded from Gilead voluntary licenses

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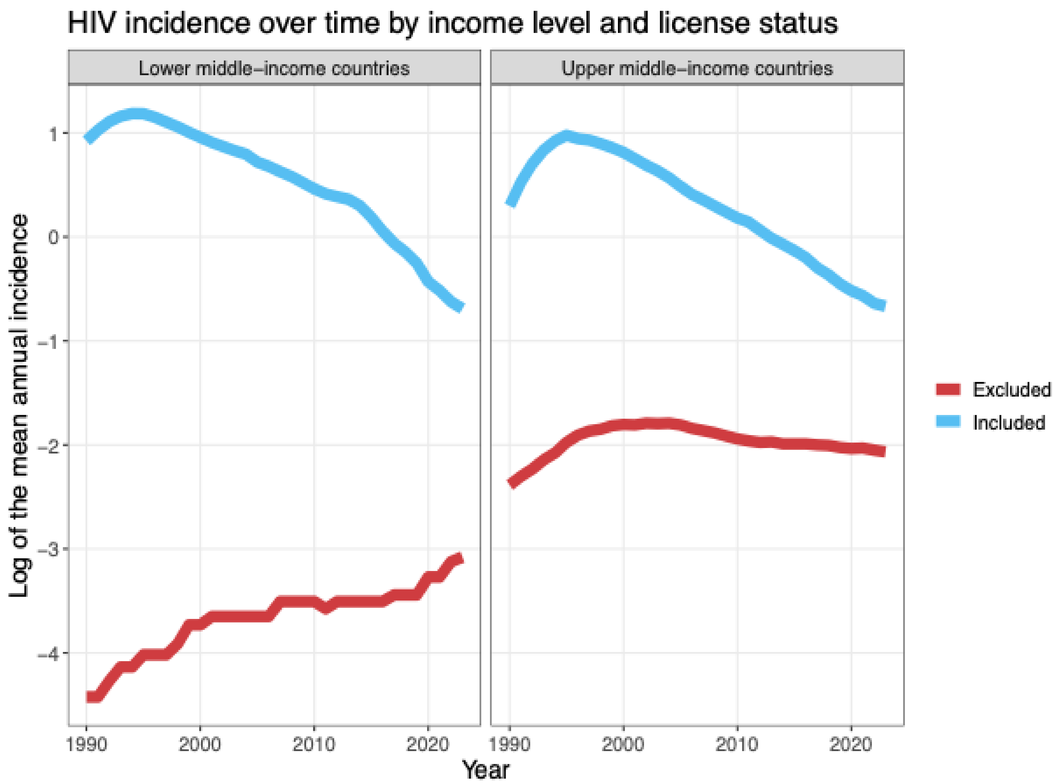
BACKGROUND

UNAIDS targets aim to reduce new HIV infections below 370,000 by 2025. However, the number of new HIV infections worldwide increased to 1.4 million in 2023. Pre-exposure prophylaxis (PrEP) is a crucial technology to prevent infection. Novel injectable forms of PrEP, cabotegravir and lenacapavir (LEN), have proven superior in efficacy to oral PrEP. Gilead have recently submitted a voluntary license (VL) for LEN including 120 LMICs and prioritising 18 initially. An existing Gilead VL for tenofovir alafenamide (TAF) includes 117 countries. VLs for HIV medications have previously been found to omit middle-income countries (MICs) with rapidly growing HIV epidemics in West Africa, South America and Asia. It is important that future VLs are empirically guided by infection rate.

METHODS

Epidemiological data were collected from the UNAIDS AIDSinfo 2023 database, which analyses country-level HIV data using the Spectrum model. We extracted epidemic size, annual HIV infections, change in incidence over time, HIV-related deaths, ART coverage, PrEP coverage and MTCT, for countries inside and outside the Gilead VL for TAF. Results were supplemented by PUBMED/EMBASE searches and national reports.

HIV epidemics have grown significantly faster in countries excluded from voluntary licenses



RESULTS

The TAF voluntary license covers an estimated 29,615,800 people living with HIV (PLHIV) in countries that constituted 808,900 new infections in 2023. Excluded MICs constitute 4,497,600 PLHIV and 288,189 new infections. Percentage change in new infections from 2010 to 2023 was +55.3% in excluded MICs vs -17.0% for nations included in the license. Incidence : prevalence ratio was 6.65 vs 4.56. Average rates of ART coverage were comparable (63.6% excluded vs 65.1% included).

CONCLUSIONS

Rate of new HIV infection is rising faster in countries excluded by the Gilead VL for TAF than in those included. With a VL now approved to enable access to LEN, it is crucial that change in rate of infection is recognised in the decision-making process to ensure health equity. Long-acting PrEP can be a turning point in the global HIV epidemic if access is based on need rather than historical precedent or inappropriate metrics.

ACKNOWLEDGEMENTS

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	Number of countries	Prevalence	New HIV acquisitions	Annual HIV epidemic growth	Change in new HIV infections 2010 to 2023 %	MTCT %
Global	119	39,900,000	1,300,000	+3.3%	-39%	10%
LIC included	24	7,249,200	202,500	+4.1%	-35%	19%
LMIC included	41	12,377,600	381,600	+4.7%	-9%	18%
LMIC excluded	6	76,900	10,700	+10.1	+157%	32%
UMIC included	28	9,972,300	223,500	+5.0%	-12%	12%
UMIC excluded	20	4,428,700	278,489	+5.9%	+22%	21%
Total included	93	29,615,800	808,900	+4.6%	-17%	17%
Total excluded	26	4,497,600	288,189	+6.7%	+55%	24%

