Section: Medicine

Original Research Article

ASSOCIATION BETWEEN DURATION OF ANTIRETROVIRAL THERAPY EXPOSURE AND DECLINE IN KIDNEY FUNCTION AMONG PEOPLE LIVING WITH HIV: A LONGITUDINAL OBSERVATIONAL STUDY

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ABSTRACT

Background: Long-term antiretroviral therapy (ART) may influence kidney function among people living with HIV. This study assessed the association between duration of ART exposure and decline in renal function.

Materials and Methods: This hospital-based longitudinal observational study included 60 people living with HIV receiving ART. Participants were classified into <2 years, 2–5 years and >5 years of ART exposure, with 20 patients in each group. Kidney function was assessed using serum creatinine and estimated glomerular filtration rate (eGFR). Changes in eGFR were compared across the groups. Correlation and regression analyses were used to assess the association between ART duration and annual eGFR change.

Results: The mean age was 39.77 ± 7.69 years and 43 (71.7%) participants were male. Mean eGFR declined from 113.33 ± 9.27 to 102.41 ± 14.80 mL/min/1.73 m² ($p<0.001$). The absolute eGFR change was −2.34 ± 1.09, −7.78 ± 2.86 and −22.66 ± 11.78 mL/min/1.73 m² in the <2-year, 2–5-year and >5-year groups respectively ($p<0.001$). Four patients had a decline of at least 25% and all were in the >5-year group ($p=0.014$). Each additional year of ART was associated with greater annual eGFR decline after adjustment (β=−0.26, 95% CI −0.33 to −0.20; $p<0.001$). Tenofovir-based ART was also associated with greater decline (β=−0.90, 95% CI −1.28 to −0.52; $p<0.001$).

Conclusion: Longer ART exposure was associated with greater decline in kidney function. Regular monitoring of renal function is required during long-term ART, particularly among patients receiving tenofovir.

Keywords: Antiretroviral therapy; estimated glomerular filtration rate; HIV; kidney function; renal impairment; tenofovir.

INTRODUCTION

Antiretroviral therapy (ART) has markedly improved survival and quality of life among people living with HIV. As treatment is continued lifelong, long-term non-communicable complications have become an important part of HIV care.[1] Renal dysfunction is one such complication. It may remain asymptomatic during the early stage and can progress without regular monitoring.[2]

Kidney dysfunction in people living with HIV has a multifactorial origin. HIV-related renal disease, chronic inflammation, opportunistic infections and hepatitis coinfection may affect renal function. Increasing age, hypertension, diabetes and exposure to nephrotoxic drugs can further increase the risk.[3] ART may protect the kidneys through viral suppression and immune recovery. However, prolonged exposure to some antiretroviral drugs may also produce glomerular or tubular injury.[4]

Tenofovir disoproxil fumarate is widely used as part of ART. It is mainly eliminated through the kidneys and may cause proximal tubular toxicity in susceptible patients. The risk may be influenced by

cumulative exposure, baseline renal function, increasing age and concomitant use of other nephrotoxic drugs.[5] Renal changes may occur even in patients without clinically evident chronic kidney disease. A gradual decline in estimated glomerular filtration rate (eGFR) may provide an early indication of renal involvement.[6]

The effect of ART duration on renal function is not uniform. Some patients show improvement after ART initiation due to control of HIV infection. Others may develop a gradual decline during prolonged treatment. Differences in ART regimen, duration of exposure, baseline eGFR and associated comorbidities may contribute to this variation.[7] Assessment based only on a single serum creatinine value may not identify the pattern of renal change over time.

Longitudinal evaluation of serum creatinine and eGFR can provide a better understanding of renal changes during ART. It may also help identify patients requiring closer monitoring or modification of treatment. Data regarding the association between total duration of ART exposure and progressive decline in kidney function remain limited in routine clinical settings. The present study was undertaken to assess the association between duration of ART exposure and decline in kidney function over time among 60 people living with HIV.

MATERIALS AND METHODS

Study Design and Setting: This longitudinal observational study was conducted in the Department of Medicine at a tertiary care centre.The study included people living with HIV who were receiving ART and attending the ART centre.

Study Population: A total of 60 people living with HIV receiving ART were included. Participants were selected according to the predefined eligibility criteria. Clinical records and laboratory reports were reviewed to assess changes in kidney function during ART.

Inclusion Criteria

- People living with HIV aged 18 years or above.
- Patients receiving ART for at least six months.
- Patients with documented duration and regimen of ART.
- Availability of baseline and at least one follow-up serum creatinine value.
- Availability of the required clinical and laboratory records.

Exclusion Criteria

- Previously diagnosed chronic kidney disease before initiation of ART.
- Acute kidney injury at the time of baseline assessment.
- Pregnancy.
- Current opportunistic infection or severe acute illness affecting kidney function.
- Known structural renal disease.
- Incomplete ART or renal function records.
- Current use of nephrotoxic drugs unrelated to ART.

Data Collection: Data were collected using a structured data collection form. Demographic details included age and sex. Clinical variables included duration of HIV infection, duration of ART, current ART regimen, history of regimen change and associated comorbidities. Information regarding hypertension, diabetes mellitus, hepatitis B or C coinfection and exposure to other nephrotoxic drugs was recorded.

Laboratory variables included serum creatinine, blood urea, CD4 count and HIV viral load where available. Serum creatinine values recorded at baseline and subsequent follow-up visits were collected. The timing and number of renal function assessments were documented for each participant.

Assessment of ART Exposure: ART exposure was calculated from the documented date of ART initiation to the most recent renal function assessment. Total duration was recorded in months and years. Participants were classified according to duration of ART exposure as follows:

- Group I: less than 2 years
- Group II: 2–5 years
- Group III: more than 5 years

The ART regimen was classified as tenofovir-based or non-tenofovir-based. Previous exposure to tenofovir and any documented change in regimen were also recorded.

Assessment of Kidney Function: Kidney function was assessed using serum creatinine and estimated glomerular filtration rate (eGFR). The eGFR was calculated using the Chronic Kidney Disease Epidemiology Collaboration equation. Values were expressed as mL/min/1.73 m².

The change in kidney function was calculated as:

Annual rate of change was calculated as: A negative value indicated a decline in kidney function. A decline of at least 25% from the baseline eGFR was considered clinically relevant. Kidney dysfunction was defined as an eGFR below 60 mL/min/1.73 m² on two measurements separated by at least three months.

Outcome Measures: The primary outcome was the change in eGFR from baseline to the latest available follow-up according to duration of ART exposure.

Secondary outcomes included:

- Annual rate of eGFR decline.
- Proportion of patients with at least 25% decline in eGFR.
- Frequency of eGFR below 60 mL/min/1.73 m².
- Comparison of renal function between ART-duration groups.
- Comparison between tenofovir-based and non-tenofovir-based regimens.
- Clinical factors associated with decline in kidney function.

Statistical Analysis: Data were analysed using IBM SPSS Statistics version 32.0. Continuous variables were expressed as mean ± standard deviation or median with interquartile range. Categorical

variables were presented as frequency and percentage. Baseline and follow-up eGFR were compared using the paired t-test or Wilcoxon signed-rank test. Differences among ART-duration groups were assessed using ANOVA or the Kruskal–Wallis test. Correlation and regression analyses were used to evaluate the association between ART duration and change in eGFR. A p-value <0.05 was considered statistically significant.

Ethical Considerations: The study was conducted after approval from the Institutional Ethics Committee of the institution. Patient information was kept confidential. For a retrospective record-based study, waiver of informed consent was obtained from the Ethics Committee. If participants were assessed prospectively, written informed consent was obtained before enrolment.

RESULTS

Table 1: Baseline characteristics according to ART duration

Variable	Total (n=60)	<2 years (n=20)	2–5 years (n=20)	>5 years (n=20)	p-value
Age, years	39.77 ± 7.69	37.75 ± 7.36	38.65 ± 6.61	42.90 ± 8.37	0.076
Age >50 years	4 (6.7%)	0	1 (5.0%)	3 (15.0%)	0.153
Male sex	43 (71.7%)	15 (75.0%)	12 (60.0%)	16 (80.0%)	0.344
BMI, kg/m²	23.31 ± 2.26	23.69 ± 2.29	23.07 ± 2.55	23.16 ± 1.96	0.655
Systolic BP, mmHg	116.55 ± 10.27	114.90 ± 10.69	115.80 ± 9.39	118.95 ± 10.75	0.431
Diastolic BP, mmHg	72.95 ± 6.99	71.15 ± 7.22	73.50 ± 7.21	74.20 ± 6.49	0.358
Hypertension	11 (18.3%)	3 (15.0%)	4 (20.0%)	4 (20.0%)	0.895
Diabetes mellitus	3 (5.0%)	1 (5.0%)	0	2 (10.0%)	0.349
Current smoking	16 (26.7%)	6 (30.0%)	7 (35.0%)	3 (15.0%)	0.330
Hepatitis B coinfection	4 (6.7%)	0	1 (5.0%)	3 (15.0%)	0.153
Hepatitis C coinfection	1 (1.7%)	1 (5.0%)	0	0	0.362

The study included 60 participants with 20 patients in each ART-duration group. The mean age was 39.77 ± 7.69 years and 43 (71.7%) participants were male. Hypertension was present in 11 (18.3%) and diabetes in three (5.0%) patients. Baseline demographic and clinical characteristics were comparable across the groups.

Table 2: HIV and ART profile

Variable	Total (n=60)	<2 years (n=20)	2–5 years (n=20)	>5 years (n=20)	p-value
Duration of ART, years	4.04 ± 2.68	1.41 ± 0.26	3.37 ± 0.60	7.35 ± 1.58	<0.001
Current CD4 count, cells/mm³	512.53 ± 141.11	404.40 ± 104.77	506.65 ± 102.49	626.55 ± 119.66	<0.001
CD4 count <200 cells/mm³	0	0	0	0	1.000
Viral load suppressed	49 (81.7%)	15 (75.0%)	17 (85.0%)	17 (85.0%)	0.641
Tenofovir-based regimen	44 (73.3%)	18 (90.0%)	16 (80.0%)	10 (50.0%)	0.012
Dolutegravir-based regimen	40 (66.7%)	19 (95.0%)	13 (65.0%)	8 (40.0%)	0.001
Previous ART regimen change	11 (18.3%)	2 (10.0%)	2 (10.0%)	7 (35.0%)	0.062
History of opportunistic infection	17 (28.3%)	6 (30.0%)	6 (30.0%)	5 (25.0%)	0.921
Cotrimoxazole use	13 (21.7%)	7 (35.0%)	4 (20.0%)	2 (10.0%)	0.155

The mean ART duration was 4.04 ± 2.68 years. Mean CD4 count increased from 404.40 ± 104.77 cells/mm³ in the <2-year group to 626.55 ± 119.66 cells/mm³ in the >5-year group (p<0.001). Viral suppression was present in 49 (81.7%) participants. Tenofovir-based ART was used by 44 (73.3%) patients and its use differed across the duration groups (p=0.012)

Table 3: Change in renal parameters during ART

Renal parameter	Baseline	Latest follow-up	Mean change	p-value
Serum creatinine, mg/dL	0.79 ± 0.07	0.89 ± 0.13	0.10 ± 0.10	<0.001
Blood urea, mg/dL	23.68 ± 2.95	25.92 ± 3.98	2.24 ± 3.01	<0.001
eGFR, mL/min/1.73 m²	113.33 ± 9.27	102.41 ± 14.80	−10.93 ± 11.08	<0.001
Serum sodium, mEq/L	138.33 ± 2.34	138.26 ± 2.75	−0.07 ± 1.35	0.704
Serum potassium, mEq/L	4.17 ± 0.23	4.22 ± 0.32	0.05 ± 0.18	0.024
Serum phosphate, mg/dL	3.54 ± 0.36	3.44 ± 0.38	−0.09 ± 0.14	<0.001

Mean serum creatinine increased from 0.79 ± 0.07 to 0.89 ± 0.13 mg/dL (p<0.001). Blood urea increased from 23.68 ± 2.95 to 25.92 ± 3.98 mg/dL (p<0.001). Mean eGFR declined from 113.33 ± 9.27 to 102.41 ± 14.80 mL/min/1.73 m², with a mean reduction of 10.93 ± 11.08 mL/min/1.73 m² (p<0.001). Serum phosphate also showed a small decline from 3.54 ± 0.36 to 3.44 ± 0.38 mg/dL (p<0.001)

Table 4: Renal outcomes according to ART duration

Renal outcome	<2 years (n=20)	2–5 years (n=20)	>5 years (n=20)	p-value
Baseline eGFR, mL/min/1.73 m²	111.91 ± 7.89	117.12 ± 8.53	110.99 ± 10.43	0.077
Follow-up eGFR, mL/min/1.73 m²	109.57 ± 7.64	109.33 ± 8.46	88.33 ± 15.38	<0.001

Absolute change in eGFR	−2.34 ± 1.09	−7.78 ± 2.86	−22.66 ± 11.78	<0.001
Annual eGFR change	−1.67 ± 0.72	−2.29 ± 0.63	−2.97 ± 0.97	<0.001
Any decline in eGFR	20 (100.0%)	20 (100.0%)	20 (100.0%)	1.000
≥25% decline from baseline	0	0	4 (20.0%)	0.014
Follow-up eGFR <60 mL/min/1.73 m²	0	0	1 (5.0%)	0.362
Urine protein positive	3 (15.0%)	3 (15.0%)	0	0.189

The reduction in eGFR increased with ART duration. Mean absolute change was −2.34 ± 1.09 mL/min/1.73 m² in the <2-year group, −7.78 ± 2.86 mL/min/1.73 m² in the 2–5-year group and −22.66 ± 11.78 mL/min/1.73 m² in the >5-year group (p<0.001). The corresponding annual changes were −1.67 ± 0.72, −2.29 ± 0.63 and −2.97 ± 0.97 mL/min/1.73 m² per year (p<0.001). Four patients had a decline of at least 25% and all belonged to the >5-year group (p=0.014)

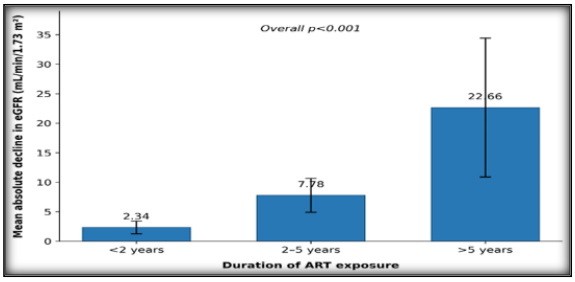

Figure 1: Mean absolute decline in eGFR according to duration of ART exposure. Error bars represent standard deviation.

Table 5: Factors associated with annual change in eGFR

Variable	Unadjusted β (95% CI)	p-value	Adjusted β (95% CI)	p-value
ART duration, per year	−0.23 (−0.30 to −0.16)	<0.001	−0.26 (−0.33 to −0.20)	<0.001
Age, per year	−0.04 (−0.07 to −0.01)	0.011	−0.02 (−0.04 to 0.00)	0.066
Baseline eGFR	−0.01 (−0.03 to 0.02)	0.580	−0.02 (−0.04 to 0.00)	0.054
Tenofovir-based regimen	−0.29 (−0.83 to 0.24)	0.288	−0.90 (−1.28 to −0.52)	<0.001
Hypertension	−1.17 (−1.71 to −0.63)	<0.001	—	—
Diabetes mellitus	−0.76 (−1.84 to 0.33)	0.176	—	—
Current CD4 count, per 100 cells	−0.33 (−0.48 to −0.19)	<0.001	—	—

Each additional year of ART exposure was associated with a greater annual decline in eGFR in the adjusted analysis (β=−0.26, 95% CI −0.33 to −0.20; p<0.001). Tenofovir-based ART was also associated with a greater annual decline (β=−0.90, 95% CI −1.28 to −0.52; p<0.001). Age and baseline eGFR were not statistically significant after adjustment. The adjusted model explained 61.1% of the variation in annual eGFR change.

DISCUSSION

The present study assessed the relationship between duration of ART exposure and change in kidney function among people living with HIV. The main finding was a greater decline in eGFR among patients with longer ART exposure. Serum creatinine and blood urea increased during follow-up while eGFR and serum phosphate decreased. ART duration and tenofovir-based treatment remained associated with annual eGFR decline after adjustment. However, clinically advanced kidney dysfunction was uncommon.

As shown in [Table 1], the mean age of the study population was 39.77 ± 7.69 years and 71.7% were male. Age, sex, BMI, blood pressure and major comorbidities were comparable across the ART-duration groups. This reduces the possibility that the observed differences in kidney function were entirely due to unequal baseline characteristics. However, patients in the >5-year group were numerically older. Age-related reduction in renal reserve may have contributed partly to the lower follow-up eGFR in this group. Hypertension was present in 18.3% and diabetes in 5.0% of participants. These conditions were not significantly different between the groups but remain clinically important because even mild cardiometabolic burden may accelerate renal decline in people living with HIV. Gao et al. reported that older age, diabetes, hypertension and changing clinical characteristics during follow-up influenced the development of CKD among people with HIV.[15] Chadwick et al. also found that long-term renal progression was influenced by both HIV-related and conventional renal risk factors.[16]

[Table 2] shows the HIV and ART profile. Mean CD4 count increased from 404.40 ± 104.77 cells/mm³ in patients with less than two years of ART to 626.55 ± 119.66 cells/mm³ in those exposed for more than five years. This probably represents continued immune recovery among patients who remained adherent to treatment. Viral suppression was present in 81.7% of the study population and was comparable across the groups. Long-term ART can produce sustained viral control and gradual improvement in immune status, although complete immune recovery may not occur in every patient. Wang et al. observed progressive immune recovery with increasing ART duration in a longitudinal study. The probability of CD4/CD8 ratio normalisation increased over time following treatment initiation.[8]

Tenofovir-based ART was used by 73.3% of the participants. Its use decreased from 90.0% in the <2-year group to 50.0% in the >5-year group. Dolutegravir use showed a similar reduction across the duration groups. This distribution may reflect changes in national treatment protocols, previous regimen modification or replacement of tenofovir

following clinical or laboratory concerns. The greater frequency of regimen change in the >5-year group also supports this explanation, although the difference did not reach statistical significance. Treatment history should be considered while interpreting cumulative ART exposure because current regimen alone may not represent earlier drug exposure.

[Table 3] demonstrates a significant change in the renal parameters during ART. Mean serum creatinine increased from 0.79 ± 0.07 to 0.89 ± 0.13 mg/dL and blood urea increased from 23.68 ± 2.95 to 25.92 ± 3.98 mg/dL. Mean eGFR declined by 10.93 ± 11.08 mL/min/1.73 m². These changes were statistically significant. The absolute creatinine values remained within the usual clinical range in most patients. This suggests that a gradual fall in filtration may occur before serum creatinine becomes clearly abnormal. Serial eGFR assessment may therefore be more informative than interpretation of a single creatinine value.

Cumulative exposure to selected antiretroviral drugs has previously been associated with renal impairment. The D:A:D study showed that increasing exposure to tenofovir, atazanavir and lopinavir/ritonavir was associated with a higher risk of renal impairment among patients who initially had normal renal function.[9] In a later prospective international analysis, cumulative exposure to tenofovir and some boosted protease inhibitors was associated with incident CKD.[10] These findings support assessment of the full treatment history rather than only the current ART regimen.

The reduction in serum phosphate from 3.54 ± 0.36 to 3.44 ± 0.38 mg/dL was small but statistically significant. Tenofovir can affect proximal tubular handling of phosphate. A minor reduction in serum phosphate may occur before overt Fanconi syndrome or marked reduction in eGFR. However, serum phosphate alone is not specific for tenofovir-related tubular injury. Dietary intake, vitamin D status and other metabolic factors may also influence it. Chadwick et al. found increased tubular proteinuria and asymptomatic tubular dysfunction among patients exposed to tenofovir in Ghana.[14] Urine glucose in the presence of normal blood glucose, urine protein, serum phosphate and fractional phosphate excretion would provide a more complete assessment of proximal tubular function.

Serum sodium did not change significantly, while potassium showed a small increase of 0.05 mEq/L. The potassium difference is unlikely to be clinically important because both measurements remained within the normal range. Statistical significance in a laboratory parameter should not automatically be considered clinically meaningful. The major renal finding in [Table 3] remains the decline in eGFR rather than the small electrolyte changes.

[Table 4] shows a clear gradient in renal decline across ART-duration groups. The mean absolute eGFR change was −2.34 ± 1.09 mL/min/1.73 m² in the <2-year group, −7.78 ± 2.86 mL/min/1.73 m² in the 2–5-year group and −22.66 ± 11.78 mL/min/1.73 m² in the >5-year group. The annual decline also increased from −1.67 ± 0.72 to −2.97 ± 0.97 mL/min/1.73 m² per year. The comparable baseline eGFR values and the marked difference in follow-up eGFR suggest that longer exposure was associated with greater accumulated renal loss.

Indian evidence has also raised concern regarding renal impairment during tenofovir exposure. Pujari et al. reported a higher risk of renal impairment among tenofovir-treated patients in Western India compared with a United Kingdom population.[11] Asian patients may have additional susceptibility related to lower body weight, comorbidities and differences in treatment monitoring. Suzuki et al. followed treatment-naïve Asian patients for up to 12 years and found that tenofovir exposure was associated with incident CKD and a faster eGFR reduction.[12] A regional Asia-Pacific analysis by Tanuma et al. similarly identified renal dysfunction during tenofovir use, with older age, lower body weight and lower baseline eGFR contributing to risk.[13]

A decline of at least 25% from baseline occurred in four patients and all were in the >5-year group. This supports a possible cumulative effect. However, only one participant developed an eGFR below 60 mL/min/1.73 m². The findings mainly represent early or moderate renal decline rather than established advanced CKD. The absence of a large number of CKD events may be related to the relatively young age, preserved baseline eGFR and low frequency of diabetes. It may also reflect regimen modification when renal deterioration was detected.

Not all published studies have demonstrated marked tenofovir nephrotoxicity. Salome et al. found no significant difference in renal function between Ugandan adults receiving tenofovir and non-tenofovir regimens despite long-term treatment.[17] Differences in baseline renal risk, duration of follow-up, body weight, treatment selection and definition of renal dysfunction may explain the inconsistent findings. Clinicians may also preferentially avoid or discontinue tenofovir in patients with renal risk. This may underestimate its association with renal decline in observational studies.

[Table 5] presents the factors associated with annual eGFR change. Each additional year of ART exposure was associated with an adjusted reduction of 0.26 mL/min/1.73 m² per year. Tenofovir-based treatment was independently associated with a further annual reduction of 0.90 mL/min/1.73 m². The findings remained significant after adjustment for age and baseline eGFR. They suggest that duration of treatment and type of ART regimen may both contribute to renal decline.

The association with ART duration should not be interpreted as proof that ART itself causes progressive renal damage. Duration of ART is also related to duration of HIV infection, increasing age, previous exposure to different regimens and cumulative burden of comorbidities. ART provides major renal benefits by suppressing viral replication

and reducing HIV-associated renal injury. The observed decline probably represents a balance between the protective effect of viral suppression and the effects of ageing, comorbidities and exposure to potentially nephrotoxic drugs.

Age was associated with annual eGFR decline in the unadjusted analysis but did not remain statistically significant after adjustment. Baseline eGFR also approached significance. These results should be interpreted cautiously because the study included only 60 patients. The adjusted model explained 61.1% of variation in annual eGFR change, but this may be optimistic in a small sample. The model should remain exploratory and should not be described as establishing independent predictors. Larger longitudinal studies have shown that renal risk changes over time and depends on both baseline and time-updated clinical factors.[15] Long-term data from Ghana also indicate that kidney function may follow different patterns, including improvement after ART initiation followed by later decline.[16]

The present findings support regular monitoring of serum creatinine and eGFR in patients receiving long-term ART. Monitoring may be particularly important in patients with more than five years of exposure, tenofovir use, older age, hypertension, diabetes or lower baseline eGFR. Urinalysis and serum phosphate can be added when proximal tubular injury is suspected. A progressive fall in eGFR should lead to review of the ART regimen, concomitant nephrotoxic drugs and other reversible causes.

This study has some limitations. The sample size was small and only a few patients developed clinically significant renal dysfunction. Serum creatinine-based eGFR can be influenced by age, muscle mass and nutritional status. Proteinuria and detailed tubular markers were not available for all patients.

Despite these limitations, the study demonstrates a graded decline in kidney function with increasing ART duration. The findings highlight that normal serum creatinine does not exclude early renal deterioration. Regular assessment of eGFR and individual renal risk remains important during long-term HIV treatment.

CONCLUSION

Longer ART exposure was associated with a greater decline in kidney function among people living with HIV. The reduction in eGFR was highest after more than five years of treatment. Tenofovir-based ART was also associated with greater annual eGFR decline. Regular monitoring of serum creatinine and eGFR is required during long-term ART, particularly among patients receiving tenofovir.

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