

The Feasibility of Using Criteria to Identify Stable Patients on HAART: Johannesburg, South Africa

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ABSTRACT

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Background: With recent increases in eligibility criteria to a CD4 count <350, South Africa has begun to see rapid growth in the number of patients on highly-active antiretroviral therapy (ART). The expanding number of patients is creating a substantial burden on HIV treatment staff and contributing to long waiting times for patients. HIV clinics are exploring ways to reduce the overall number of visits patients need to reduce the burden on staff. We sought to use routinely collected data to determine whether a simple screening tool could identify stable patients that would not need to see a clinician during a scheduled medical visit.

Methods: The data for this analysis come from Themba Lethu, an HIV clinic in Johannesburg, South Africa that has more than 40,000 medical visits annually. Eligible visits were all visits after 6 months on ART. Stable medical visits were defined as having all of the following: stable or increasing CD4 count, undetectable viral load, stable weight, no new pregnancy or comorbidity, no regimen change within the last three months, and normal lab results for hemoglobin, ALT, and creatinine clearance. We identified stable visits from 1 January 2007 to 7 September 2011. We assessed the sensitivity and specificity of stable visits at predicting two indicators of disease progression or needing additional care: a) ART regimen change; and b) follow-up visits in < 3 weeks from previous visit.

Results: Patients were 65% female and a median of 37 years old at ART initiation. A total of 143,474 eligible medical visits were made by 14,315 patients. Nearly 34% of visits were classified as stable and 75% of all patients had at least one stable visit. The most common reason for a visit not being stable was a declining CD4 count 51,217 (36%). A small proportion of stable visits 1.4% (N=668) resulted in an ART regimen being changed and 6.1% (N=2,662) of visits were in < 3 weeks. Stable visits had a sensitivity of 91.0% (95% CI 90.3-91.6) and a specificity of 34.9% (34.7-35.2) at predicting ART therapy changes, and a sensitivity of 78.2% (77.5-78.9) and specificity of 35.1% (34.8-35.4) for predicting a follow-up visit interval of < 3 weeks.

Conclusions: Our criteria have the potential to reduce the number of medical visits while missing few visits in which changes in regimen or additional care would be needed. More research is needed to determine whether implementation of our method could reduce visits without compromising safety or loss to follow-up

BACKGROUND AND OBJECTIVES

Expanding HCT programs and increasing the CD4 cell count threshold for ART initiation have increased the number of ART eligible patients by 50% in South Africa. More than twice the current 1.4 million patients will be receiving ART therapy by 2016. This large and rapid increase in the number of patients receiving treatment will occur in an environment of limited human resource and health service capacity.

South Africa plans to manage the increasing population of ART patients, primarily through “task-shifting:” specifically, nurse initiated and managed ART care (NIMART). A complimentary approach for reducing the burden on health services is the identification of stable patients allowing the targeting of clinician visits to those most in need and reduce the number of clinical consultations.

To evaluate the feasibility and safety of employing such a strategy, we set out to determine the likely reduction in medical visits and ability of a screening tool to correctly identify “stable patients” at a large urban public-sector clinic in Johannesburg South Africa.

METHODS

Study Population

All “on-ART” patient clinic visits between January 1, 2007 and September 7, 2011 at Themba Lethu Clinic in Johannesburg, South Africa.

Exclusions

- Patients who initiated ART prior to April 2004
- Visits in the first 6 months after ART initiation

Data Source

Laboratory results (CD4 count, viral load, ALT, creatinine clearance and hemoglobin), clinical observations (weight, pregnancy status, co-morbid conditions) and pharmacy records are captured and stored in an electronic patient record, TherapyEdge-HIV™.

Criteria for Stable Patient Visits

We divided the medical visits into “stable” and “non-stable visits”

A medical visit was defined to be “stable” if the following criteria are met:

- CD4 count within 12 months \geq their previous CD4 count (within 6 months for patients with less than 12 months on ART)
- Undetectable HIV viral load (<400 copies/ml) within 12 months (within 6 months for patients with less than 12 months on ART)
- Weight change <5% since previous medical visit (within 6 months for all patients)
- Not newly pregnant
- No co-morbid conditions
- On current ART regimen \geq 3 months
- No lab values indicating a possible side effect or adverse event:
 - Haemoglobin <8g/dL (on zidovudine)
 - ALT >100 (on nevirapine)
 - Creatinine clearance < 50ml/min (on tenofovir)

“Non-stable” visits are the opposite of a “stable” visit.

Data Analysis

- We identified stable patients visits to estimate the reduction in clinical visits
- We compared our definition of non-stable patient visit against 3 measures of doctor behavior that likely indicated a need to see a clinician:
 1. change in antiretroviral regimen at a medical visit;
 2. follow-up medical visit that occurs in less than 14 or 28 days from the current visit, and;
 3. Two composite measures combining either change in antiretroviral regimen at a medical visit and/or a follow-up visit in less than 14 days and less than 28 days.
- We calculated sensitivities, specificities and exact 95% CI comparing non-stable visits to the “gold standard” of the doctor behavior.

RESULTS

Patient Population and Stable Visits

- A total of 14,054 patients were on ART for at least 6 months between January 1, 2007-September 7, 2011.
- These patients had 139,685 medical visits for an average of 9.9 medical visits (range 1-46).
- 47,098 (33.7%) of these were defined as stable.
- Three-quarters (10,513/14,054) of the patients had at least one stable patient visit.
- Patients with at least one stable visit
 - more likely to be female,
 - have been on ART for more than double the average time, and
 - have a higher WHO stage at initiation as compared to subjects with no stable visits

Frequency of Non-Stable Medical Visits by Individual Criterion

Non-Stable Criterion	Frequency of Visits	Prevalence of Visits, % (95% CI)
CD4 Decline	49,453	35.4 (35.2 - 35.7)
Detectable Viral Load	37,380	26.8 (26.5 – 27.0)
Unstable weight	25,914	18.6 (18.3 - 18.8)
Comorbid Condition	15,831	11.3 (11.2 - 11.5)
Recent Regimen Change	12,939	9.3 (9.1 - 9.4)
New Pregnancy	457	0.3 (0.3 - 0.4)
ART Problem	167	0.1 (0.1 - 0.1)

- Declining CD4 count (35.4%), detectable viral load (26.8%), gain or loss in weight greater than 5% (18.6%), co-morbid conditions (11.3%) and ARV therapy change in the past 3 months (9.3%) were the most common reasons for not being stable.
- New pregnancies (0.3%) and abnormal laboratory values (0.1%) were rare.

The table below compares different doctor behavior to a non-stable visit: ARV regimen change at the clinical visit; medical visits <28 and <14 days, and composite measures of time to next visit and/or ARV regimen change.

Sensitivity ranged from 78.3% to 91.4% and specificity ranged from 34.4% to 35.4% for non-stable visit criteria predicting these different measures of doctor behavior.

Sensitivity and Specificity of Non-Stable Visits

Gold Standard	Sensitivity, % (95% CI)	Specificity, % (95% CI)
ARV Change	91.4 (90.7 – 92.0)	35.1 (34.8 - 35.3)
Visit Less than 28 days	78.3 (77.5 – 79.0)	35.3 (35 - 35.5)
Visit Less than 14 days	80.9 (79.4 - 82.2)	34.4 (34.1 - 34.6)
ARV Change or Visit Less than 28 days	82.3 (81.7 - 82.9)	36.1 (35.8 - 36.3)
ARV Change or Visit Less than 14 days	88 (87.3 - 88.6)	35.4 (35.1 - 35.7)

CONCLUSIONS

The limited set of clinical and laboratory signs that defined non-stable patients showed high sensitivity (78.3% to 91.4%) and low specificity (34.4% to 48.5%). The high sensitivity indicates that use of these criteria would likely miss a small proportion of patients who needed a clinical visit, but the moderate specificity results in a limited effect on reducing the number of clinical visits. Nonetheless, even the lowest specificity of 34.4% would result in a reduction of over 1/3 of the clinical visits at this clinic, approximately 14,000 per year - a significant reduction in clinic congestion.

Our criteria have the potential to reduce the number of doctor visits while missing few visits in which changes in regimen or additional care would be needed. More research is needed to determine the extent to which implementation of this method could reduce visits without compromising safety or increasing loss to follow-up.

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