



Why are HIV-infected people not started on antiretroviral therapy? A mixed-methods study from Gujarat, India

S. Chawla,¹ K. Shringarpure,² B. Modi,³ R. Sharma,⁴ B. B. Rewari,⁵ A. N. Shah,⁶ P. B. Verma,^{1,3} A. R. Dongre,⁷ A. M. V. Kumar^{8,9}

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Setting: Five purposively selected antiretroviral therapy (ART) centres in Gujarat, India.

Objectives: To assess the proportion of ART-eligible people living with the human immunodeficiency virus (PLHIV) who were not initiated on ART within 2 months of being recorded as eligible, to identify factors associated with non-initiation and to explore reasons from the provider's perspective.

Design: We used a mixed-methods design (triangulation) of 1) a quantitative phase involving record reviews and cohort analysis (Poisson regression) of PLHIV registered during April 2014–March 2015, and 2) a qualitative phase involving one-to-one interviews with 25 providers.

Results: Of 2079 ART-eligible PLHIV, 339 (16%) were not started on ART within 2 months. PLHIV with CD4 counts of <350 cells/μl and patients who were labourers, hospitalised, bedridden or registered with certain ART centres were more likely not to be initiated on ART. Qualitative results were categorised into two broad themes: government health system- and patient-related challenges, which validated and complemented the quantitative findings.

Conclusion: Several patient subgroups at greater risk of ART non-initiation were identified, along with reasons for risk; this has important programme implications for achieving the UNAIDS 90–90–90 goal, and particularly the second 90 component of having 90% of diagnosed PLHIV start ART.

In 2015 an estimated 36.7 million people globally were living with the human immunodeficiency virus (PLHIV), with 1.1 million deaths. As of December 2015, 17 million PLHIV were accessing antiretroviral therapy (ART).¹ Despite these achievements, significant gaps remain in the uptake of ART, with only about half of estimated PLHIV receiving treatment in 2015.¹

Studies from sub-Saharan Africa and Asia have reported high rates of attrition between HIV diagnosis and ART initiation.^{2–4} Previously published studies from India have confirmed these findings: about 20–26% of diagnosed PLHIV are lost before being registered at the ART centres, while 40–80% of ART-ineligible PLHIV are lost after registration at ART centres during pre-ART care.^{5–9} There is no published evidence in India as to what proportion of ART-eligible PLHIV are lost before initiating ART. Analysis of routinely reported aggregate data from the National AIDS (acquired immune-deficiency syndrome) Control Programme (NACP) in the state of Gujarat, India,

indicates that the gap between the number of people eligible for ART initiation and the number actually initiated on ART was approximately 12% in 2014–2015.¹⁰

Having all PLHIV assessed for ART eligibility and initiated on ART is a global priority, and central to achieving the bold new UNAIDS (Joint United Nations Programme on HIV/AIDS) 90–90–90 vision of diagnosing 90% of the estimated PLHIV, treating 90% of those diagnosed and achieving viral suppression in 90% of those treated.¹¹ Achieving this target is crucial if we are to end the HIV/AIDS epidemic by 2030, as envisaged in the United Nations Sustainable Development Goals.¹² In this context, quantifying the gap between registration at ART centres and ART initiation and knowing the reasons for this gap are very important for the NACP.

There is limited evidence on factors influencing pre-ART attrition in India. A systematic review, mostly of studies from the African region and one qualitative study from Ethiopia, revealed multiple barriers for ART initiation which include costs, long distances to ART centres, stigma and fear of disclosure.^{13,14} These factors tend to be context-specific, however, and there are challenges in generalising them to the national situation in India. While previous publications from India have quantitatively assessed the factors associated with pre-ART attrition among ART-ineligible PLHIV,^{5–8} they have not provided insights into the reasons for attrition, which require qualitative study.^{6,7}

We therefore aimed to quantify, among PLHIV enrolled for care in two districts of Gujarat, the gap between being recorded as eligible for ART and initiation on ART within 2 months of eligibility, and to assess the factors (both quantitatively and qualitatively) associated with non-initiation. The specific objectives were 1) to determine the number (proportion) not started on ART within 2 months among PLHIV eligible for ART at enrolment; 2) to assess the demographic and clinical factors associated with non-initiation of ART; and 3) to understand the perceived reasons for non-initiation of ART and explore suggestions for addressing non-initiation from the perspective of the providers.

MATERIAL AND METHODS

Study design

This was a mixed-methods design (triangulation), with a quantitative phase (cohort analysis using secondary data extracted from patient records) and a

AFFILIATIONS

- 1 Gujarat State AIDS Control Society, Health and Family Welfare Department, Government of Gujarat, Ahmedabad, India
- 2 Department of Community Medicine, Government Medical College and SSG Hospital, Vadodara, India
- 3 Department of Community Medicine, Gujarat Medical Education and Research Society (GMERS) Medical College, Gandhinagar, India
- 4 Department of Community Medicine, GMERS Medical College, Sola, Ahmedabad, India
- 5 World Health Organization India Country Office, New Delhi, India
- 6 Department of Medicine, BJ Medical College and Civil Hospital, Ahmedabad, India
- 7 Department of Community Medicine, Sri Manakula Vinayagar Medical College and Hospital, Puducherry, India
- 8 International Union Against Tuberculosis and Lung Disease (The Union), South-East Asia Office, New Delhi, India
- 9 The Union, Paris, France

CORRESPONDENCE

Sudhir Chawla
E 304 Parshwanath Metrocity, near H.B. Kapadiya School
T P 44
Opposite Golden Villa Chandkheda, Ahmedabad 382 424
India
e-mail: drsudhirchawla74@gmail.com

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qualitative phase (a descriptive study involving one-to-one interviews).¹⁵

Study setting

Gujarat, a state in western India that is divided into 33 districts, has an estimated 0.17 million PLHIV, with an estimated adult HIV prevalence of 0.42% (0.33–0.50).¹⁶ As of 31 March 2015, there were 30 ART centres in Gujarat. This study was undertaken in five ART centres in two districts of Gujarat: three ART centres (Civil Hospital Ahmedabad, Sola Civil Hospital and V. S. Hospital) in Ahmedabad district (population 5.5 million) and two ART centres (SSG Hospital and Gotri Hospital) in Vadodara district (population 4.1 million). These five centres were purposively selected based on a preliminary analysis of aggregate programme data that showed that these centres had higher rates of ART non-initiation (within 2 months of eligibility) compared to the state average (~12%),¹⁰ two of which also had the highest rates of ART non-initiation (20–24%). All five ART centres are located in Medical College Hospitals and are managed by a multi-disciplinary team of physicians, nurses, counsellors, pharmacists, data managers and care coordinators.

National AIDS Control Programme guidelines

Patients diagnosed with HIV infection at integrated counselling and testing centres (ICTC) are referred to the ART centre of their choice for follow-up and management. At the ART centre, patients are registered for care, assessed for ART eligibility and started on ART as per NACO guidelines.⁷ All patients receive on average 2–3 sessions of ART preparedness counselling while undergoing clinical and laboratory screening. The counsellor provides detailed information so that the patient can understand the life-long nature of treatment, the drugs used and their adverse effects, and the need for strict adherence to treatment. Only when the counsellor certifies ‘treatment preparedness’ is the patient initiated on ART by the medical officer; this process usually takes approximately 7 days.¹⁸

All asymptomatic HIV-positive patients at WHO clinical stage 1 or 2 with a CD4 count <350 cells/μl are considered eligible for ART, while ART initiation is recommended irrespective of CD4 count in patients with WHO clinical stage 3 or 4, all those co-infected with TB, hepatitis co-infected patients with severe liver disease, all HIV-positive pregnant women and all HIV-positive children aged <5 years.¹⁹

While most PLHIV seek care in public sector ART centres, some seek care in the private sector, which is largely unregulated. The District AIDS Prevention and Control Unit (DAPCU) is the district level monitoring agency for NACP, which consists of a district AIDS control officer supported by a team of five, inclusive of the district supervisor and monitoring and evaluation officer. All care and support services for PLHIV are provided under one umbrella, the care and support centres (CSC). The CSC team comprises a project coordinator, a counsellor, a peer counsellor, and outreach workers, who provide counselling, outreach, referral and linkages, training in home-based care, life skill education, advocacy and support group meeting services.

Information on all the clients enrolled at the ART centre is captured in standardised NACO paper-based tools (patient treatment cards, also referred to as ‘white cards’ and registers), and is also captured in an electronic database.

Study population and study period

Quantitative study

A comprehensive sample of all ART-naïve PLHIV newly registered for care from 1 April 2014 to 31 March 2015 found to be eligible for ART at five selected ART centres of Gujarat were included in the study. PLHIV who were transferred in for care from other centres, and those who were not eligible for ART at enrolment but became eligible later, were excluded.

Qualitative study

For the quantitative aspect of the study, interviews were conducted with health care providers. Programme staff and research team members completed a brain-storming exercise to select a variety of key informants (providers). Key informants who were assumed to be knowledgeable (aware) about PLHIV care due to their direct and prolonged work experience, and who were articulate and willing to participate, were purposively selected for one-to-one interviews to explore the challenges encountered and suggestion solutions in patient care. The sample size was guided by the saturation of findings. The data were collected between October 2015 and January 2016.

Data collection and analysis

Quantitative study

Variables for quantitative analysis were extracted from the already existing electronic patient database maintained at each ART centre by the data manager in an MS Excel database (Microsoft Corp, Redmond, WA, USA) and analysed using EpiData analysis software v. 2.2.2.183 (EpiData Association, Odense, Denmark).

The variables included sociodemographic and clinical characteristics such as age, sex, occupation, education, caste, baseline WHO clinical stage,¹⁷ baseline CD4 count, presence of opportunistic infections and baseline functional status (graded as working, ambulatory and bedridden).¹⁷ The outcome variable was ‘ART non-initiation’ within 2 months of enrolment for HIV care at an ART centre. The 2-month cut-off for ART initiation was chosen based on national guidelines and a citizen charter, and not upon clinical or epidemiological criteria,²⁰ which included death, loss to follow-up and those ‘still in pre-ART care at 2 months’. Although some patients still in pre-ART care were started on ART after 2 months, they were considered as ‘not initiated on ART’ for the purpose of this analysis.

Relative risks (RR) and 95% confidence intervals (CI) were used as measures of association. All the variables were entered into a multivariable model (Poisson regression) in line with the exploratory approach to analysis, and adjusted RRs were computed. Regression analysis was performed in STATA software (v. 12.1, StataCorp, College Town, TX, USA). Variables with a *P* value ≤ 0.05 as computed using likelihood ratio tests were considered statistically significant.

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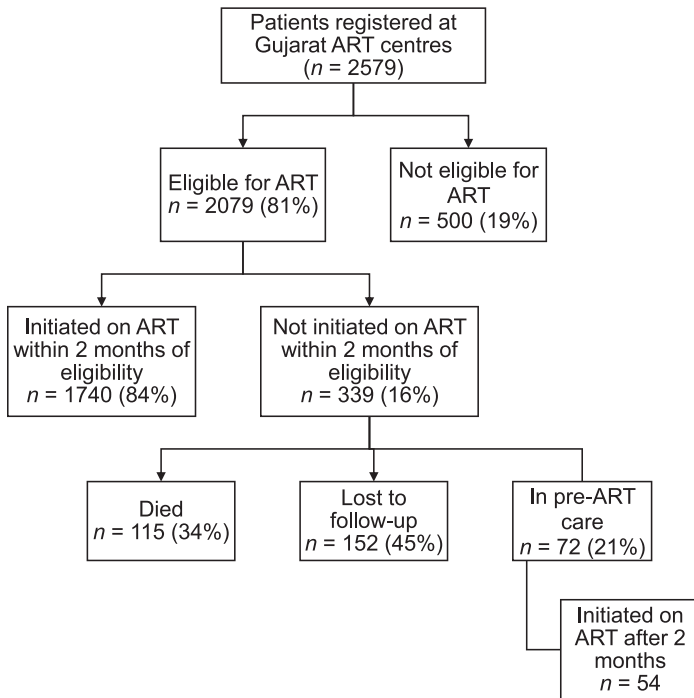


FIGURE 1 Flowchart depicting the cascade of care and outcomes among PLHIV eligible at enrolment in five selected ART centres of Gujarat, India, 2014–2015. ART = antiretroviral therapy; PLHIV = people living with the human immunodeficiency virus.

Qualitative study

Investigators trained in qualitative research methods interviewed the participants (interview guide in Appendix 1). If participants gave their consent, interviews were audio-recorded. If not, notes were taken. Each interview took approximately 15–20 minutes. Participant validation was undertaken after each interview by summarising the key findings to the participants. Transcription was performed on the same day as the interview to strengthen the completeness and accuracy of information. We performed descriptive content analysis. Coding was performed using Atlas.ti 7.5 software (Atlas.ti Scientific Software Development, Berlin, Germany). The categorisation of codes and the generation of themes from the categories were performed manually.²¹ The findings were reviewed by KS and by ARD and AMVK to reduce subjective bias and to increase interpretive credibility. Any disagreements among the authors were resolved by discussion.²² We followed the Consolidated criteria for reporting qualitative research (COREQ) for reporting the study.²³

Ethics approval

Ethics approval was obtained from the Institutional Ethics Committee of the BJ Medical College and Civil Hospital, Ahmedabad, Gujarat, India, and the Ethics Advisory Group of the International Union Against Tuberculosis and Lung Disease, Paris, France. Informed consent was obtained from all the participants who were interviewed. To maintain confidentiality, the names of the ART centres were not reported in the analysis.

RESULTS

Quantitative

A total of 2079 PLHIV were found eligible for ART at the time of enrolment at the five ART centres during the study period. The

median time to ART initiation was 7 days, with an interquartile range (IQR) of 4–16 days. Of the 2079 PLHIV eligible for ART, 339 (16%) were not started on ART within 2 months of registration. Of these, 115 (34%) died, 152 (45%) were lost to follow-up and 72 (21%) were still in pre-ART care at 2 months of enrolment (Figure 1). Of the latter group, 54 were started on ART after 2 months and 18 were still in pre-ART care as of 31 May 2015 (the date of data extraction).

Sociodemographic and clinical characteristics

The mean (standard deviation) age of the participants was 36 (± 13) years and about two thirds were males. The majority of the participants were married. About one third of PLHIV were illiterate, a quarter were daily-wage labourers and two thirds belonged to socio-economically marginalised and vulnerable groups (referred to as scheduled castes, scheduled tribes and other backward classes by the Indian constitution).²⁴ The median CD4 count was 183 cells/ μ l (IQR 91–297), and 28% were WHO clinical stage 3 or 4. The proportion not initiated on ART varied between 10% and 21% across the ART centres. While most participants were working or ambulatory, about 12% were severely ill and bedridden. The median CD4 cell count among those who were started on ART (191 cells/ μ l, IQR 95–307) was higher than among those who were not (143 cells/ μ l, IQR 62–267 overall; 55 cells/ μ l, IQR 25–132 among patients who died; 207 cells/ μ l, IQR 116–284 among patients lost to follow-up). Among the 18 patients who remained in pre-ART care as of 31 May 2015, the median CD4 count was 958 cells/ μ l (IQR 231–2435) (Table 1).

Factors associated with non-initiation of ART

On adjusted analysis, PLHIV with CD4 counts < 350 cells/ μ l, who were labourers, hospitalised, bedridden or registered at certain ART centres were more likely not to be initiated on ART (Table 2).

Qualitative

Twenty-five health care providers (13 male and 12 female) directly involved in the care of PLHIV were purposively sampled and interviewed in person. These included 5 staff nurses, 4 doctors, 1 community care coordinator, 11 counsellors, 1 monitoring and evaluation officer, 2 programme coordinators and 1 district supervisor from all five ART centres, co-located HIV testing centres, care and support centres and a district AIDS prevention and control unit.

Challenges in ART initiation and suggestions for improvement from the providers' point of view

The challenges in the initiation of ART as perceived by the providers were coded under 35 codes organised into 10 categories. These 10 categories were grouped into two broad themes: 1) government health system-related challenges, and 2) patient-related challenges. These are listed in Table 3 and briefly described below. Suggestions on how to improve ART uptake were coded under 29 codes and organised into six categories. These are presented in Table 4 and discussed later. All the themes and the categories are depicted in Figure 2.

Theme 1: Government health system-related challenges

The respondents identified the following factors as key barriers to ART initiation: long queues and increased waiting times for laboratory investigations, overburdened staff in centres with high patient loads, inadequate remuneration, delays in salary payment leading to a lack of job satisfaction and indifferent behaviour toward the patients, frequently changing programme guidelines on ART eligibility, and occasional shortages in supplies of anti-retro-

TABLE 1 Sociodemographic and clinical characteristics of ART-eligible PLHIV enrolled in five ART centres, Gujarat, India, 2014–2015

| Variable | Total ART eligible n (%) | Started on ART n (%) | Not started on ART n (%) |
|-------------------------|-----------------------------|-------------------------|--------------------------------|
| Total | 2079 | 1740 | 339 |
| Age, years | | | |
| 0–14 | 90 (4) | 71 (4) | 19 (6) |
| 15–44 | 1389 (67) | 1175 (68) | 214 (63) |
| 45–64 | 548 (26) | 450 (26) | 98 (29) |
| ≥65 | 52 (3) | 44 (2) | 8 (2) |
| Sex | | | |
| Male | 1371 (66) | 1129 (65) | 242 (72) |
| Female | 698 (33) | 602 (34) | 96 (28) |
| Transgender | 10 (1) | 9 (1) | 1 (0) |
| Caste | | | |
| General | 646 (31) | 566 (32) | 80 (24) |
| SC | 349 (17) | 288 (17) | 61 (18) |
| ST | 172 (8) | 130 (8) | 42 (12) |
| OBC | 796 (38) | 661 (38) | 135 (40) |
| Unknown | 116 (6) | 95 (5) | 21 (6) |
| Hospital admission | | | |
| Outdoor | 1654 (80) | 1428 (82) | 226 (67) |
| Indoor | 425 (20) | 312 (18) | 113 (33) |
| Education | | | |
| Illiterate | 648 (31) | 521 (30) | 127 (37) |
| Primary | 625 (30) | 528 (30) | 97 (29) |
| Secondary | 696 (34) | 596 (34) | 100 (30) |
| College | 110 (5) | 95 (6) | 15 (4) |
| Occupation | | | |
| Labourer | 567 (27) | 443 (26) | 124 (37) |
| Other | 1512 (73) | 1297 (74) | 215 (63) |
| Marital status | | | |
| Never married | 392 (19) | 312 (18) | 80 (24) |
| Married/ cohabiting | 1377 (66) | 1176 (68) | 201 (60) |
| Divorced/ widowed | 310 (15) | 252 (14) | 58 (17) |
| WHO stage | | | |
| 1 | 606 (29) | 532 (30) | 74 (22) |
| 2 | 767 (37) | 639 (37) | 128 (38) |
| 3 | 361 (17) | 291 (17) | 70 (20) |
| 4 | 345 (17) | 278 (16) | 67 (20) |
| Functional status | | | |
| Working/ ambulatory | 1796 (86) | 1559 (90) | 237 (70) |
| Bedridden | 283 (14) | 181 (10) | 102 (30) |
| OI | | | |
| Present | 647 (31) | 524 (30) | 123 (36) |
| Absent | 1301 (63) | 1113 (64) | 188 (56) |
| Unknown | 131 (6) | 103 (6) | 28 (8) |
| CD4 count (cells/μl) | | | |
| <350 | 1713 (82) | 1421(82) | 292 (86) |
| >350 | 350 (17) | 314 (18) | 36 (11) |
| Unknown | 16 (1) | 5 (0) | 11 (3) |
| ART centre | | | |
| ARTC1 | 758 (37) | 647 (37) | 111 (33) |
| ARTC2 | 69 (3) | 55 (3) | 14 (4) |
| ARTC3 | 267 (13) | 212 (12) | 55 (16) |
| ARTC4 | 589 (28) | 470 (27) | 119 (35) |
| ARTC5 | 396 (19) | 356 (21) | 40 (12) |

ART = antiretroviral therapy; PLHIV = people living with the human immunodeficiency virus; SC = scheduled caste; ST = scheduled tribe; OBC = other backward class; WHO = World Health Organization; OI = opportunistic infection.

viral drugs. Providers felt that these might be the reason for patients' loss of faith in government health facilities and preference for seeking care in the private sector.

Respondents felt that the main reason for the lack of knowledge among patients about the importance of timely ART initiation was ineffective counselling. Among bed-ridden and hospitalised patients, it is the care givers who interact with the ART staff and they do not always pass the information on to the patients. Patients thus continue to remain unaware of their HIV status and the need for life-long ART.

In Gujarat, the cost of patients' travel to the ART centre is expected to be reimbursed under the Jatan Project, a state government scheme for travel reimbursement for PLHIV visiting ART centres. Due to irregularities in travel cost reimbursements, however, financially poor patients found it difficult to adhere to the ART centre appointments.

Theme 2: Patient-related challenges

According to the health care providers, some patients perceived themselves as being healthy and were in denial about the existence of the HIV infection or the need for ART, while others reported fears related to HIV, disclosure to family members and resulting stigma and discrimination, and the adverse effects of ART and other medicines for co-infections. The providers suggested that the counsellors should discuss and clarify these fears and misconceptions with the PLHIV.

The patients' preference for private health sector and other systems of medicine was cited as another reason for non-initiation of ART. While some severely sick patients from rural areas sought treatment from traditional faith healers or ayurvedic healers (the traditional Indian system of medicine), others, especially wealthy patients, preferred to go to private providers to keep their HIV status confidential. The providers felt that patients tended to avoid government health facilities due to the long queues, fear of disclosure and unfriendly staff behaviour.

Household responsibilities, the non-availability of care givers, frequent job-related travel, travelling for social events and the non-reimbursement of indirect costs by the Jatan Project were cited as other reasons for ART non-initiation. According to the providers, many patients who were diagnosed late and reached the ART centre with severe illness (including those bedridden at home) died before the initiation of ART. Providers also felt that migrants tended not to comply with appointments and returned to their native places without leaving accurate contact details with the ART centre staff. While these patients might be enrolled with other ART centres, this information is not communicated between centres, and such cases are recorded as 'lost to follow-up'.

DISCUSSION

This is to our knowledge the first study from India to quantify non-initiation of ART among ART-eligible PLHIV and provide insights into possible reasons. About one in six PLHIV were not initiated on ART within 2 months despite being eligible; of these, about 80% died or were lost to follow-up. Of those who were receiving pre-ART care at 2 months, the vast majority were started on ART after 2 months. A small minority continued to remain in pre-ART care, possibly because they were relatively healthier. ART non-initiation varied across ART centres, and was more likely to occur among in-patients, bedridden patients, daily wage labourers and those with advanced immune deficiency.

TABLE 2 Sociodemographic and clinical characteristics associated with non-initiation of ART among ART-eligible PLHIV enrolled in five ART centres, Gujarat, India, 2014–2015

| Variable | Total ART eligible <i>n</i> | Not initiated on ART <i>n</i> (%) | Crude RR (95%CI) | <i>P</i> value | aRR (95%CI) | <i>P</i> value |
|----------------------|--------------------------------|--------------------------------------|------------------|----------------|---------------|----------------|
| Total | 2079 | 339 (16) | | | | |
| Age, years | | | | 0.35 | | 0.52 |
| 0–14 | 90 | 19 (21) | 1.4 (0.9–2.1) | | 1.6 (0.9–3.0) | |
| 15–44 | 1389 | 214 (15) | 1.0 | | 1.0 | |
| 45–64 | 548 | 98 (18) | 1.2 (0.9–1.4) | | 1.0 (0.8–1.4) | |
| ≥65 | 52 | 8 (15) | 1.0 (0.5–1.9) | | 0.9 (0.4–2.0) | |
| Sex | | | | 0.06 | | 0.75 |
| Male | 1371 | 242 (18) | 1.3 (1.0–1.6) | | 1.1 (0.8–1.5) | |
| Female | 698 | 96 (14) | 1.0 | | 1.0 | |
| Transgender | 10 | 1 (10) | 0.7 (0.1–4.7) | | 0.9 (0.1–6.8) | |
| Caste | | | | 0.003 | | 0.12 |
| General | 646 | 80 (12) | 1.0 | | 1.0 | |
| SC | 349 | 61 (18) | 1.4 (1.0–1.9) | | 1.3 (0.9–1.9) | |
| ST | 172 | 42 (24) | 2.0 (1.4–2.8) | | 1.6 (1.1–2.4) | |
| OBC | 796 | 135 (17) | 1.4 (1.1–1.8) | | 1.2 (0.9–1.6) | |
| Hospital admission | | | | 0.0001 | | 0.08 |
| Outdoor | 1654 | 226 (14) | 1.0 | | 1.0 | |
| Indoor | 425 | 113 (27) | 2.0 (1.6–2.4) | | 1.3 (0.9–1.8) | |
| Education | | | | 0.05 | | 0.78 |
| Illiterate | 648 | 127 (20) | 1.4 (0.9–2.4) | | 1.0 | |
| Primary | 625 | 97 (16) | 1.1 (0.7–1.9) | | 0.9 (0.6–1.2) | |
| Secondary | 696 | 100 (14) | 1.1 (0.6–1.7) | | 0.9 (0.6–1.2) | |
| College | 110 | 15 (14) | 1.0 | | 1.0 (0.5–1.8) | |
| Occupation | | | | 0.0001 | | 0.01 |
| Labourer | 567 | 124 (22) | 1.5 (1.3–1.9) | | 1.4 (1.1–1.8) | |
| Other | 1512 | 215 (14) | 1.0 | | 1.0 | |
| Marital status | | | | 0.01 | | 0.20 |
| Never married | 392 | 80 (20) | 1.4 (1.1–1.8) | | 1.3 (0.9–1.8) | |
| Married/cohabiting | 1377 | 201 (15) | 1.0 | | 1.0 | |
| Divorced/widowed | 310 | 58 (19) | 1.3 (1.0–1.7) | | 1.2 (0.8–1.6) | |
| WHO stage | | | | 0.007 | | 0.24 |
| 1 and 2 | 1373 | 202 (15) | 1.0 | | 1.0 | |
| 3 and 4 | 706 | 137 (19) | 1.3 (1.1–1.6) | | 0.6 (0.4–1.1) | |
| Functional status | | | | 0.0001 | | 0.001 |
| Working/ambulatory | 1796 | 237 (13) | 1.0 | | 1.0 | |
| Bedridden | 283 | 102 (36) | 2.7 (2.3–3.3) | | 2.4 (1.7–3.3) | |
| OI | | | | 0.01 | | 0.21 |
| Present | 647 | 123 (19) | 1.3 (1.1–1.6) | | 1.6 (0.9–2.8) | |
| Absent | 1301 | 188 (15) | 1.0 | | 1.0 | |
| CD4 count (cells/μl) | | | | 0.002 | | 0.04 |
| <350 | 1713 | 292 (17) | 1.7 (1.2–2.3) | | 1.5 (1.0–2.3) | |
| >350 | 350 | 36 (10) | 1.0 | | 1.0 | |
| ART centre | | | | 0.0001 | | 0.004 |
| ARTC1 | 758 | 111 (15) | 1.5 (1.0–2.0) | | 1.6 (1.1–2.4) | |
| ARTC2 | 69 | 14 (20) | 2.0 (1.2–3.5) | | 2.0 (1.0–3.9) | |
| ARTC3 | 267 | 55 (21) | 2.0 (1.4–3.0) | | 2.4 (1.4–4.0) | |
| ARTC4 | 589 | 119 (20) | 2.0 (1.4–2.8) | | 2.0 (1.3–2.9) | |
| ARTC5 | 396 | 40 (10) | 1.0 | | 1.0 | |

ART = antiretroviral therapy; PLHIV = people living with the human immunodeficiency virus; RR = relative risk; aRR = adjusted relative risk; CI = confidence interval; SC = scheduled caste; ST = scheduled tribe; OBC = other backward class; WHO = World Health Organization; OI = opportunistic infection.

The findings of our study are strikingly similar to those conducted elsewhere, mainly in Africa. Studies from Kenya, Malawi, South Africa and Uganda^{25–28} reported an 18–26% gap in ART initiation, of whom up to 39% were non-traceable and approximately 34% had died. Another systematic review summarising patient and programmatic factors associated with linkage to ART

care identified transport costs, distance, stigma and fear of disclosure as the main reasons for not initiating ART, followed by staff shortages, long waiting times, fear of medication side effects, male sex, younger age and the need to take time off from work. All of these elements have also been identified as contributing factors in our study.^{8,9,13,14}

TABLE 3 Challenges in ART initiation from providers' point of view in five selected ART centres of Gujarat, India, 2014–2015

| Category | Subcategory | Verbatim quotes |
|---|--|--|
| Theme 1: Government health system-related challenges | | |
| Health facility-related challenges | High patient load | At the time of enrolment, multiple laboratory investigations have to be done for which patients have to visit many places in the hospital, due to long queues at these places or due to their sick condition, they drop out [Counsellor 1, male, age 37 years] |
| | Long queues and waiting times for investigations, especially USG | |
| | Lack of coordination between the different departments within the hospital and ART centre | Sometimes patients have to undergo USG or X-ray for confirmation of tuberculosis or other opportunistic infections, but due to long waiting period of 2–3 months for USG, the decision about eligibility gets delayed [Counsellor 1, male, age 37 years] |
| | | They are tired of various referrals in hospital for various investigations [SMO 15, male, age 35 years] |
| | | For various opportunistic infections client have to approach concerned OPDs as per referral so he/she is exhausted [Counsellor 25, male, age 28 years] |
| Programme-related challenges | Frequently changing guidelines for initiating ART | Once upon a time, due to shortage of ART, we were not able to initiate ART in new patients [Counsellor 2, female, age 36 years] |
| | Occasional shortages in supplies of antiretroviral drugs | |
| Staff-related challenges | Overburdened staff | Counselling should not be affected by delay in salary payment, but it does affect us. After all, we are also human beings [Counsellor 3, male, age 29 years] |
| | Inadequate remuneration, delays in salary payment, leading to lack of job satisfaction | |
| | Frequent change in job postings from heavily crowded on-ART care services to less crowded pre-ART care services and vice versa | |
| | Indifferent behaviour by health care staff towards patients | |
| Counselling-related challenges | Inadequate information given to patient during counselling | Patients referred from ICTC, expects immediate initiation of ART. However, assessment for eligibility and preparedness counselling may take 2–3 visits to the counsellor. Patients tend to drop out during this phase [Counsellor 1, male, age 36 years] |
| | Unrealistic expectations on the part of the patient leading to disappointment with government staff and non-initiation of ART | |
| | Lack of knowledge regarding the importance of timely ART initiation and harms of non-initiation among PLHIV, especially among admitted patients | At the time of discharge, patient feels that his medical treatment is completed and does not come for follow-up visits [Counsellor 1, male, age 36 years] |
| Travel and finance-related challenges | Irregularities in travel cost reimbursement (in Gujarat, patients' travel expenditures to ART centre are expected to be reimbursed under the Jatan Project, a state government scheme for travel reimbursement of PLHIV visiting ART centres) | As the travel reimbursement under Jatan project is not regular, patients think that we are misguiding them for the same [Counsellor 1, male, age 36 years] |
| | | Problem of reimbursement of travel allowance under Jatan project as it is sometimes not reimbursed [CCC 1, Female, 37 years] |
| Theme 2: Patient-related challenges | | |
| Fears and misconceptions | Perceived healthy status Fears related to HIV Fear of disclosure to family members Stigma and discrimination Fear of adverse effects of ART and other medicines | Some patients say: As I do not have any problem, do I need any medication? [District supervisor 1, male, age 36 years] |
| | | Very big disease! [Staff nurse, 1, female, age 34 years] |
| | | Taking two medicines together will be hot for me [Counsellor 4, male, age 30 years] |
| | | Some patients have inherent stigma related to daily need of taking medicine in the presence of others [Counsellor 4, male, age 30 years] |
| | | Severely ill patients from rural area approach supernatural powers such as saints and tantric faith healers [Counsellor 5, female, age 28 years] |
| Health care-seeking behaviour | Faith in traditional faith healers Belief in Ayurveda (Indian system of medicine) Faith in private providers due to their reassurance of cure from the disease Patients financially better off prefer private providers Avoiding government facility due to long queues or fear of disclosure or poor support from the staff | If client is from upper middle class or middle class then he prefers private hospitals [MO 1, male, age 40 years] |
| | | Because of fear of disclosure, they did not turn up [Counsellor 1, male, age 37 years] |
| Personal, social and financial problems | Household responsibilities Non-availability of caregivers Frequent job-related travel Travelling for social events Non-reimbursement of indirect costs by the Jatan Project | Female patients not able to spare time due to responsibility of household work [Counsellor 2, female, age 36 years] |
| | | There are some truck drivers whose post-test counselling is done, but when contacted to come for treatment, they say that they are out of station due to job and will contact once they return, but never do so [District supervisor 1, male, 36 years] |
| | | |
| | | |
| Severe clinical conditions | Poor general clinical condition Late detection of HIV status | Those who are seriously ill prefer to go to their village for their last days [Counsellor 2, female, age 36 years] |
| | | |
| Migration | Migrants tend to be lost to follow-up, not having valid proof of address, difficult to track | Migrant patients not able to provide valid proof of Gujarat address [Counsellor 4, male, age 30 years] On tracking, we came to know that patient returned to native place [District supervisor, 1, male, age 36 years] |

ART = antiretroviral therapy; SMO = senior medical officer; OPD = out-patient department; CCC = community care coordinator; MO = medical officer; ICTC = integrated counselling and testing centres; PLHIV = people living with the human immunodeficiency virus.

TABLE 4 Suggestions to improve ART initiation from the providers' point of view in five selected ART centres of Gujarat, India, 2014–2015

| Category | Sub-category | Verbatim quotes |
|---|---|---|
| Theme 1: Government health system-related suggestions | | |
| Health facility-related suggestions | Infrastructural expansion of ART centres Expansion of links between ART centre facilities Blood sample collection at ARTC and ICTC Priority appointment for USG Closely scheduled appointments Strengthen inter-departmental linkage and referral | To manage patient load at ART centre, every ICTC may be converted to link ART centre [Counsellor 6, male, age 32 years] |
| Staff-related suggestions | Regular workshops to improve communication skills of health care workers Regularise monthly remunerations and annual increments Appoint additional staff as per workload Adopt methods to improve job satisfaction among staff Change in rotation policy of counsellors from pre-ART to on-ART care | To avoid misconceptions, sensitisation and awareness workshops must be organised [Counsellor 7, female, age 40 years] One counsellor can be fixed for follow-up of pre-ART patient care and during the duty rotation in on-ART care, the documentation related work can be done by another counsellor [Counsellor 2, female, age 36 years] |
| Counselling-related suggestions | Strengthen post-test counselling at ICTC Strengthen preparedness counselling at ARTC | Counsellors' skills to be improved for counselling on acceptance of HIV; proper counselling need to happen at ICTC [Counsellor 6, male, age 32 years] |
| Travel and finance-related suggestions | Regularise travel reimbursement under state government Jatan Project | Travel reimbursement under Jatan project, must be regularised [Counsellor 1, male, 37 years] |
| Theme 2: Patient-related suggestions | | |
| Fears and misconceptions | Counselling services of ICTC and ARTC to be strengthened and should be sensitive to the fears and misconceptions of PLHIV | Fear of status disclosure may not be a reason for all patients [Counsellor 6, male, 32 years] |
| Personal, social and financial problems | ART dispensing on hospital holidays Linkage of PLHIV to social welfare schemes | ART dispensing needs to be started on hospital holidays especially for those who are not able to come on regular days due to any reason [Counsellor 2, female, 36 years]. |
| Severe clinical conditions | Complete clinical work-up of patients Fast tracking while seeking care in hospital Early diagnosis of tuberculosis Priority appointments for sick patients Instituting helpline number for emergency | A circular may be sent from hospital to all departments that HIV patients need to be fast tracked, so that they need not wait in queues [Counsellor 6, male, 32 years] If dates are given for USG within 7 days of request, it will reduce the problem [Counsellor, 4, Male, 30 years] |
| Migration | Home address verification e-tracking across the ART centres Telephone tracking Mobile phone reminders to PLHIV Strengthening of Vihaan project provision of outreach worker at ART centre Migrant policy | If one ORW given for every 500 patients at the ART centre, then home visit may be planned by ART centre for migrant patients address verification [Counsellor 6, male, 32 years] There should be some policy to get feedback about interdistrict/state LTFU tracking activities [Counsellor 1, Male, 37 years] |

ART = antiretroviral therapy; ICTC = integrated counselling and testing centres; ARTC = ART centres; USG = ultrasonography; PLHIV = people living with the human immunodeficiency virus; ORW = outreach worker; LTFU = loss to follow-up.

There were several strengths to this study. First, the mixed-methods research design helped in providing a complete picture of the magnitude, causes and possible solutions to the problem of non-initiation of ART among ART-eligible PLHIV. The quantitative and qualitative components of the study each mutually validated and complemented the findings of the other component. Second, as the study was conducted under routine programmatic settings, the findings reflect the ground reality and provide actionable information for programme managers. Third, the study used high quality data from a large sample size with very few missing values. A large number of providers were interviewed and saturation was achieved.

There were some limitations. As the study was conducted in five selected ART centres, all of which were based in medical college hospitals, caution is required before extrapolating the findings to other ART centres based at secondary care level. While several possible reasons for non-initiation of ART were identified, the relative significance of these reasons in quantitative terms was not assessed. This needs further investigation using quantitative survey methods. The findings from the qualitative component of this study should be helpful in feeding into the questionnaire for such a survey.

Programme implications

The study has many programme implications. First, ineffective post-test counselling at the ICTCs was one of the key factors attributed to the non-initiation of ART. This needs attention. The insights found in this study are around patient fears and misconceptions, and the preference for private providers and unqualified providers should be used to prepare a counselling guide used for training. This will help to customise counselling to the unique needs and circumstances of the patients and prevent the risk of non-initiation of ART.

The time spent with the patient during counselling was related to patient load and to staff shortages. Two strategies were suggested to address this issue, one to reduce the patient load and another to increase the staff strength. The suggestion to expand and establish links between ART centres in all ICTCs is excellent, as this would shift clinically stable patients on ART from the main ART centres and reduce congestion. This would provide more time per patient for the staff at the main ART centres, who could focus on more complex and clinically challenging cases and ensure that all PLHIV are started on ART.

Second, the study identified several patient subgroups at higher risk for ART non-initiation. These subgroups should re-

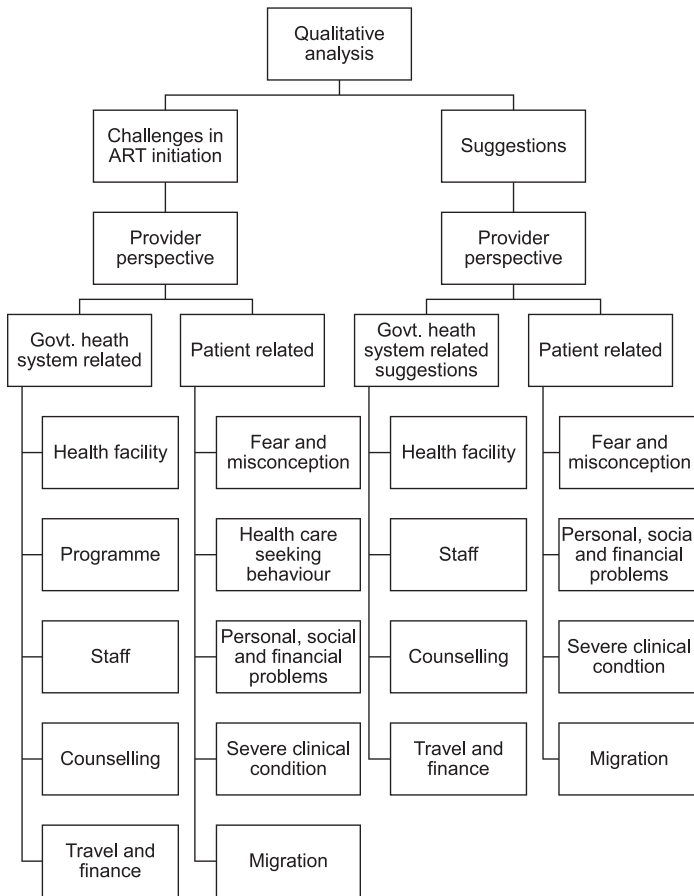


FIGURE 2 Challenges in ART initiation and suggested solutions in five selected ART centres of Gujarat, India, 2014–2015. Govt. = government; ART = antiretroviral therapy.

ceive prioritised attention from ART centre staff, who should spend more time with such patients during counselling and provide more frequent follow-up by outreach workers.

Third, there were several suggestions to improve health service delivery, which include prioritising PLHIV for all investigations, especially ultrasonography, single-window blood sample collection at ART centres, improving coordination among the different departments of the hospital and the ART centre, escorting patients wherever required, and fast-tracking them for services within the hospital and enhanced tracking and monitoring. These interventions would likely reduce delays in ART initiation and save lives.

Fourth, poor staff behaviour was another reason for patients' preference for seeking care in the private sector, often through unqualified providers, which could be hazardous. This could partly be addressed by training staff in 'soft' skills, including effective communication. Poor staff behaviour may also, however, be a reflection of a lack of job satisfaction, which in turn is related to the irregular payment of salaries and annual increments. These issues need to be urgently addressed.

Finally, most patients who were not initiated on ART either died or were lost to follow-up, and had significantly lower CD4 counts compared to patients started on ART. This indicates that PLHIV are accessing care at advanced stages of immune deficiency. To prevent this and to diagnose HIV early, HIV testing needs to be decentralised to health sub-centres in the public

health system, and provider-initiated HIV testing needs to be expanded to include presumptive TB patients, all in-patients and partners of PLHIV. The WHO 2016 guidelines recommend that all diagnosed PLHIV should be started on ART irrespective of CD4 count.²⁹ Programmatic data from several countries offering earlier ART have shown significant increases in ART uptake and linkage to care, reduction in the time between HIV diagnosis and ART initiation regardless of baseline CD4 cell count, and an increase in the median CD4 value at ART initiation.^{29–32} The NACP in India should consider implementing this recommendation as soon as possible if we are to achieve the 90–90–90 targets and end the HIV epidemic by 2030.^{11,12} These goals cannot be achieved without integrating HIV care and support into the general health system and making HIV care the responsibility of all health care providers.

In conclusion, about 16% of ART-eligible PLHIV were not started on ART in five selected ART centres of Gujarat, and most of these died or were lost to follow-up. Several patient sub-groups at higher risk of ART non-initiation and reasons for non-initiation of ART from the provider perspective were identified in this study. These findings have important programme implications.

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APPENDIX

Key informant interview: interview guide

Name of the participant:

Designation:

Date of interview:

Interview start/end time:

Name of the interviewer:

After a brief introduction to the participant regarding the purpose of the interview, the interviewer will obtain written informed consent for the interview. Written informed consent will also be requested for audio recording.

- 1 What are the challenges at programme level for initiation of ART? [probe... guidelines, logistics, manpower, referral and linkages, investigation, etc.]
- 2 What are the suggested solutions for these problems? [probe ... any ideas can be given]
- 3 What are the patient related problems in early initiation of ART? [probe ... time, work, money, distance, etc.]
- 4 What are the suggested solutions for the same? [probe...any ideas can be given]
- 5 Anything else you want to share with me? [your experiences]

Investigator will complete the interview by acknowledging the time spared by the participant from his/her busy schedule. He/she will also give a summary of the notes taken and confirm the same from the participant.

Patient interview: interview guide

Date of interview:

Place of interview:

Interview start/end time:

Name of the interviewer:

After a brief introduction to the participant regarding the purpose of the interview, the interviewer will obtain written informed consent for the interview. Written informed consent will also be requested for audio recording. Based on the basic information available in the patient's treatment card, we will probe specific issues related to the patient.

- 1 How is your treatment going on? [probe ... source, regularity, problems]
- 2 What are the challenges/problems you are taking/facing while getting treatment from us? [probe ... example, social, work, time, money]
- 3 Is there anything we can do to help you start treatment? [probe ... your suggestion]
- 4 Anything else you want to share with me? [your experience]

Investigator will complete the interview by acknowledging the time spared by the participant from his/her busy schedule. He/she will also give a summary of the notes taken and confirm the same from the participant.

Contexte : Cinq centres du TAR (traitement antirétroviral) sélectionnés dans ce but dans l'état de Gujarat, Inde.

Objectifs : Evaluer la proportion de personnes vivant avec le virus de l'immunodéficience humaine (PVVIH) éligibles pour le TAR non mis sous TAR dans les 2 mois de leur éligibilité, identifier les facteurs associés à la non initiation et explorer les raisons vues par les prestataires de soins.

Schéma : Nous avons eu recours à un mélange de méthodes (triangulation) : 1) une phase quantitative impliquant une revue des dossiers et une analyse de la cohorte (régression de Poisson) des PVVIH enregistrés entre avril 2014 et mars 2015, et 2) une phase qualitative impliquant des entretiens individuels avec 25 prestataires de soins.

Résultats : Sur 2079 PVVIH éligibles au TAR, 339 (16%) n'ont pas été

mis sous traitement dans les 2 mois. Les PVVIH ayant un taux de CD4 <350 cellules/ μ l, les patients qui étaient des travailleurs journaliers, hospitalisés, alités ou suivis par certains centres du TAR ont été plus susceptibles de ne pas être mis sous TAR. Les résultats qualitatifs ont été classés en deux vastes catégories : système de santé du gouvernement et défis liés aux patients ; ceux-ci ont validé et complété les résultats quantitatifs.

Conclusion : Plusieurs sous-groupes de patients ayant un risque plus élevé de non mise en route du TAR et les raisons de ce problème ont été identifiés ; ceci pourrait avoir des implications importantes pour le programme dans l'atteinte de l'objectif 90–90–90, surtout en ce qui concerne le deuxième 90, qui consiste à débiter le TAR chez 90% des PVVIH diagnostiqués.

Marco de referencia: Cinco centros de suministro del tratamiento antirretrovírico (TAR) de Gujarat en la India, escogidos por muestreo dirigido.

Objetivos: Evaluar la proporción de personas positivas frente al virus de la inmunodeficiencia humana (PPVIH) aptas para recibir el TAR, que no habían iniciado el tratamiento 2 meses después de haberse considerado idóneas; determinar los factores asociados con la falta de iniciación del TAR; y analizar las razones desde la perspectiva de los profesionales de salud.

Método: Se utilizó un diseño de métodos mixtos (triangulación), con una fase cuantitativa de análisis de las historias clínicas y de cohortes de PPVIH registradas de abril del 2014 a marzo del 2015 y una fase cualitativa con entrevistas personales a 25 profesionales de salud.

Resultados: De las 2079 PPVIH aptas para recibir el TAR, 339 no lo

habían iniciado en un lapso de 2 meses (16%). La probabilidad de no iniciar el TAR fue mayor en las PPVIH con cifras de linfocitos CD4 <350 células/ μ l, los pacientes que eran obreros, estaban hospitalizados, encamados o que acudían a determinados centros de suministro de TAR. Los resultados se clasificaron en dos amplias categorías, a saber: problemas relacionados con el sistema público de salud o atribuibles a los pacientes, con lo cual se validaron y complementaron los resultados cuantitativos.

Conclusión: Varios subgrupos de pacientes presentaron un mayor riesgo de no iniciar el TAR y se determinaron las razones del riesgo; los resultados pueden tener repercusiones importantes en el programa y favorecer el progreso hacia el cumplimiento del triple objetivo 90–90–90, sobre todo de su segundo componente, según el cual el 90% de las PPVIH debe iniciar el TAR.