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Original article

Uptake and impact of COVID-19 vaccination among HIV key populations: a cohort study from Tamil Nadu, India

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Abstract

Objective: Human Immunodeficiency Virus (HIV) Key Populations (KPs) include Female Sex Workers (FSWs), men who have sex with men (MSM), transgender (TG), and transsexual (TS) persons. This study assessed coronavirus disease 2019 (COVID-19) vaccine uptake among KPs for HIV in India, adverse events following immunization (AEFI), and breakthrough infections among the vaccinated.

Materials and Methods: This retrospective cohort study was conducted among 421 KPs enrolled in 41 Targeted Intervention (TI) clusters in 31 districts of the Tamil Nadu State Acquired Immunodeficiency Syndrome (AIDS) Control Society (TANSACS), India, from June to September 2022. A semi-structured, bilingual (English and Tamil), interviewer-administered questionnaire was used to collect data on socio-demographic characteristics, vaccination status, AEFIs, and breakthrough infections among the KPs under the TIs.

Results: Among the KPs, 45.4% were FSWs, 37.1% were MSM, 16.2% were TG, and 1.4% were TS persons. Among them, 4.3% had HIV, and 2.9% had syphilis or other sexually transmitted infections (STIs). The COVID-19 vaccine uptake rate was 96%. Among the KPs, TG/TS persons had the highest vaccine uptake (98.6%), followed by FSWs (96.3%) and MSM (94.2%). AEFIs were reported by 85.4% of the participants. HIV positive status was significantly associated with the incidence of AEFI. The breakthrough infection rate was 5.4% among the vaccinated participants.

Conclusion: The COVID-19 vaccine uptake among HIV KPs was high in Tamil Nadu. AEFIs and breakthrough infections among COVID-19 vaccinated HIV KPs may be low, with mild AEFIs.

Key words: human immunodeficiency virus (HIV), coronavirus disease 2019 (COVID-19) vaccine, transgenders, female sex workers, India

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Introduction

Vaccination is recommended as an effective way to manage the coronavirus disease 2019 (COVID-19) pandemic. Multiple COVID-19 vaccines have been introduced worldwide, with varying efficacies and effectiveness against the novel virus. Globally, it has been estimated that 14.4 million deaths have been averted because of COVID-19 vaccines[1]. While these vaccines are recommended for adults as well as pediatric age groups, the safety profiles of the vaccines, both short- and long-term, are under study. As data emerges, the recommendations are being modified accordingly. In India, the Human Immunodeficiency Virus (HIV) Key Populations (KPs) comprise female sex workers (FSWs), men who have sex with men (MSM), transgender (TG) and transsexual (TS) persons[2]. Their status as marginalized population, impacts their accessibility and availability of social and healthcare services[3–5]. The COVID-19 pandemic has affected all populations worldwide, with already marginalized sections being the most affected groups. Within KPs, TG and MSM adults are further marginalized as sexual minorities due to the taboos associated with practices in

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countries like India[3, 6]. Considering the high risk of severity of COVID-19 infections[7], vaccine coverage for them is essential. When COVID-19 vaccination was introduced, HIV KPs might have had trust issues towards the vaccine and the health system providing it, from a historical perspective. The combination of higher susceptibility to minority stressors and disproportionate psychological and financial burdens among sexual and gender minority (SGM) populations may reduce the adoption of COVID-19 vaccination and further exacerbate health disparities[8, 9]. The majority of trans-adults expressed their willingness to receive COVID-19; however, barriers in accessing such vaccinations have also been highlighted[5]. Hence, it is of vital importance that vaccine uptake among these populations is studied in order to identify the determinants and potential gaps in service provision and coverage. Studies assessing or including these marginalized groups for their behavior towards COVID-19 vaccines and their determinants are limited[6]. McNaghten *et al.* reported an 85.4% uptake of ≥1 COVID-19 vaccine dose among gay or lesbian adults, which was higher than that of heterosexual adults in the United States of America (USA) until October 2021. They also reported a 75.7% uptake among transgender adults[10]. Low *et al.* reported a similar vaccine uptake of 81% among adults who identified as lesbian, gay, bisexual, transgender, queer, and other sexual identities (LGBTQ+) in New York city[11]. Another study conducted in USA in early 2021 reported a moderately high acceptance of COVID-19 vaccine among sexual/gender minority men and TG women[9]. MSM who were HIV-positive from China were found to have a very low uptake of 8.7%, mainly due to concerns about side effects and fear of HIV-positive status disclosure[12]. India, the country with the second largest HIV epidemic, has an estimated 2.35 million people living with HIV (PLHIV)[13]. Although studies on vaccine uptake rates in the general population have been conducted in India, no studies have been conducted on HIV KPs.

Hence, we conducted the following study to assess COVID-19 vaccine uptake among KPs for HIV from India and to determine adverse events following immunization (AEFIs) and breakthrough infections.

Materials and Methods

Study design: Retrospective cohort study.

Study population: KPs enrolled in the Tamil Nadu State Acquired Immunodeficiency Syndrome (AIDS) Control Society (TANSACS). The KPs were TG, TS, MSM, and FSWs. KPs aged <18 years and those who did not provide written informed consent were excluded.

Study period: June–September 2022

Study setting: Tamil Nadu, India. Tamil Nadu has a population of 6.8 crores. The state is divided into 38 administrative districts. There were approximately 83,681 KPs in the 85 Targeted Intervention (TI) clusters of TANSACS across these 38 districts. Among the KPs, 45,367 FSWs, 5,607 transgender individuals, and 32,310 MSM are registered. The KPs avail services from the Integrated counselling and testing centers (ICTCs), and Anti-retro viral therapy (ART) centers. They receive TIs through outreach services and non-governmental organizations (NGOs).

Sample size, sampling technique & data collection: As data on vaccine uptake among the KPs were not available for the said population, the study was conducted to include a maximum sample size, with the assumption of 50% uptake among the KPs and a 10% relative error, including a 10% non-response rate, which ascertained a sample size of 440.

Among the 85 TIs, 41 clusters from 31 districts expressed willingness to participate in the study. Ten KP from each cluster were included through consecutive sampling. The largest cluster among these 41 clusters enrolled 20 participants. A semi-structured, bilingual (English and Tamil), interviewer-administered questionnaire was used to collect data on socio-demographic characteristics, vaccination status, AEFI, and breakthrough infections among the KPs under the TIs. Breakthrough infections were probed according to definitions in the literature (infections 21 days after 1st dose, and 14 days after the 2nd dose)[14]. Covishield and Covaxin are administered under the Tamil Nadu public health delivery system. Covaxin contains inactivated SARS-CoV-2 viral particles. The virus has been modified to prevent replication. The vaccine is mainly composed of inactivated SARS-CoV-2 antigen (strain NIV-2020-770), aluminum hydroxide gel as an adjuvant, TLR 7/8 agonist (imidazoquinolinone), TM 2-phenoxyethanol, and phosphate buffer saline[15]. Covishield is a nonreplicating adenovirus vector vaccine that contains the recombinant spike protein of the SARS-CoV-2 virus[16]. Both the vaccines are administered at doses of 0.5 mL.

Statistical analysis

Data analysis was performed using the Statistical Package for Social Sciences version v26.0. COVID-19 vaccine uptake, AEFIs, and breakthrough infections were reported in proportions. Univariate analysis was conducted to test the associations between sociodemographic factors and vaccine uptake, AEFIs, and breakthrough infections. The odds ratios (OR) with 95% confidence intervals (CI) were calculated. An adjusted analysis was conducted using logistic regression. Factors with a *P*-value of <0.1 in univariate analysis were included in the adjusted analysis. A *P*-value of <0.05 was considered statistically significant.

Results

A total of 421 participants completed the survey, with a response rate of 95.68%. The sociodemographic profile of the study participants are presented in Tables 1 and 2.

Table 1 Socio-demographic profile of the study participants (N=421)

Participant characteristics	Frequency	%
Age (years)		
≤20	15	3.6
21–30	158	37.5
31–40	216	51.3
41–50	26	6.2
>50	6	1.4
Education		
Illiterate	11	2.6
Primary	330	78.4
High school	37	8.8
Higher secondary	15	3.6
Diploma holder	12	2.9
Graduate and above	16	3.8
Gender		
Male	156	37.1
Female	191	45.4
TG	74	17.6
Occupation		
Yes	322	76.5
No	99	23.5
Below poverty line (N=411)		
Yes	31	7.5
No	380	92.5
Typology		
FSW	191	45.4
MSM	156	37.1
TG	68	16.2
TS	6	1.4
Marital status		
Married	244	58
Unmarried	173	41.1
Widowed	4	1

FSW: female sex workers; MSM: men who have sex with men; TG: transgenders; TS: trans-sexual.

Table 2 Socio-demographic profile of the study participants (N=421)

Participant characteristics	Frequency	%
Place		
Resident of same district	369	87.6
Resident of other district	44	10.5
Tobacco		
Yes	97	23
No	324	77
Alcohol		
Yes	168	39.9
No	253	60.1
Comorbidities		
HIV	18	4.3
Syphilis	7	1.7
Diabetes	11	2.6
STI	5	1.2
Others	5	1.2
History of COVID-19 infection		
Yes	82	19.5
No	339	80.5
Severity of COVID-19		
Mild	48	11.4
Moderate	22	5.2
Severe	12	2.9

COVID-19: coronavirus disease 2019; HIV: human immunodeficiency virus; STI: sexually transmitted infection.

Regarding KP type, 45.4% were FSWs, 37.1% were MSM, 16.2% were TGs, and 1.4% were TS. Among the 12.4% who reported co-morbidities, 4.3% had HIV, and 2.9% had syphilis or other sexually transmitted infections (STIs). Most study participants were females (45.4%), aged 31–40 years (51.3%), had primary school education (78.4%), employed (76.5%), belonged to above poverty line (92.5%), and married (58%). Among the KP, 19.5% had a history of COVID-19 infection before vaccination.

The COVID-19 vaccine uptake among KPs with HIV was 94.4%. The majority of the vaccinees had received the Covishield vaccine (75.5%), while 24.5% had received Covaxin. Among the KPs, TG/TS showed the highest uptake of COVID-19 vaccine (98.6%), followed by FSW (96.3%) and MSM (94.2%). Univariate analysis revealed a significant association between poverty, marital status, and COVID-19 vaccine uptake, whereas after adjusted analysis, only marital status was significantly associated with vaccine uptake (Table 3).

Majority of the study participants had completed the two-dose schedule (90.1%). AEFIs were reported among 85.4% of the participants after COVID-19 vaccination (after one or more doses). Fever (49.5%) and myalgia (48.8%) were the most commonly reported AEFIs. However, none of them had any serious AEFIs. HIV-positive status was significantly associated with the incidence of AEFI due to COVID-19 vaccinations (Table 4).

Breakthrough infection rate was 5.4% among the vaccinated participants. Majority of breakthrough infections were mild (90.9%), while one patient had a severe infection requiring mechanical ventilation. None of the factors showed a significant association with breakthrough infections (Table 5).

Discussion

This study is the first from India to assess COVID-19 vaccine uptake among HIV KPs and its subsequent impact

Table 3 Association between socio-demographic characteristics and COVID-19 vaccine uptake (N=421)

Variable		COVID-19 vaccination status yes		COVID-19 vaccination status no		*P*-value	Odds ratio (95% CI)
		Frequency	%	Frequency	%		
Age (years)	≤30	166	96	7	4	0.994	0.996 (0.372–2.671)
	>30	238	96	10	4		Reference
Gender	Male	147	94.2	9	5.8		Reference
	Female	184	96.3	7	3.7	0.159	0.469 (0.556–35.953)
	TG	73	98.6	1	1.4	0.343	2.777 (0.336–22.970)
Education	Till high School	361	95.5	17	4.5	0.238	–
	Above high school	43	100	0	0		–
Below poverty line		27	87.1	4	12.9	0.025*	0.220 (0.066–0.729)
Work status	Working	312	96.9	10	3.1	0.080	2.374 (0.879–6.411)
	Not working	92	92.9	7	7.1		Reference
Typology	FSW	184	96.3	7	3.7	–	Reference
	MSM	147	94.2	9	5.8	0.343	2.777 (0.336–22.970)
	TG/TS	73	98.6	1	1.4	0.159	4.469 (0.556–35.953)
Marital status	Married	229	93.9	15	6.1	**0.011****	0.179 (0.040–0.791)
	Unmarried	171	98.8	2	1.2		Reference
Place of residence	Same district	354	95.9	15	4.1	0.700	1.124 (0.248–5.086)
	Other district	42	95.5	2	4.5		Reference
Consumes tobacco		90	92.8	7	7.2	0.070	0.409 (0.152–1.106)
Consumes alcohol		158	94	10	6	0.104	0.450 (0.168–1.206)
Comorbidities		50	96.2	2	3.8	1.000	1.059 (0.235–4.771)
HIV		17	94.4	1	5.6	0.531	0.703 (0.088–5.614)
Syphilis		7	100	0	0	1.000	–
Diabetes		10	90.9	1	9.1	0.368	0.406 (0.049–3.368)

*Not significant in adjusted analysis. **Significant after Adjusting for below poverty line status, occupation, marital status & tobacco consumption. COVID-19: coronavirus disease 2019; CI: confidence interval; FSW: female sex workers; HIV: human immunodeficiency virus; MSM: men who have sex with men; TG: transgenders; TS: trans-sexual.

on them. The COVID-19 vaccine uptake among KPs for HIV was 96%. Among the KPs, TG/TS showed the highest uptake (98.6%), followed by FSW (96.3%) and MSM (94.2%). The vaccine coverage in our study was higher than that in the USA, which reported 85.4% uptake among gay/lesbian adults and 75.7% uptake among TG adults[10]. Low *et al.* reported that 81% of LGBTQ+ participants received one or more doses of COVID-19 vaccine in New York city[11]. Studies from Australia reported a lower coverage of 28%–57.2% among gay and bisexual men[17, 18]. The differential coverage may be due to the period of the studies, which had a gap of at least one year. This difference might also be due to racial differences, as it has been reported that SGM populations of Asian origin are more likely to accept COVID-19 vaccines than their white counterparts[9]. Zheng *et al.* reported a COVID-19 vaccine uptake of 8.7% among HIV-positive MSM from mainland China during the early days of COVID-19 vaccinations in 2021[12]. Our study participants reported higher vaccine uptake than the general Indian population. Among the general population aged 45+ years in Tamil Nadu, a vaccination rate of 64% was reported between June–September 2021[19]. Among the general population in other parts of India, Arora *et al.* and Dhumal *et al.* reported that the uptake was 54.6% and 82.1%, respectively[20, 21], whereas Gandhi *et al.* reported an uptake rate of 66.8% among pregnant women in Northern India[22]. However, the time interval between the present study and these studies was one year[19–21].

In our study, marital status was significantly associated with vaccine uptake. The spouses of married KPs might have had a positive motivation to take the vaccination, resulting in a significantly higher uptake than among unmarried persons. It has been reported that majority of couples share common health behaviors that influence each other, such as COVID-19 vaccine uptake[23]. The presence of children in families of married KPs might also have positively influenced their COVID-19 vaccine uptake. Low *et al.* reported a significant association between low vaccine uptake and income levels below $50,000, whereas Holt *et al.* reported lower willingness among those who lost their

Table 4 Association between socio-demographic characteristics and AEFIs among vaccinated population (N=404)

Variable		AEFI with COVID-19 vaccine Yes		AEFI with COVID-19 vaccine No		*P*-value	Odds ratio (95% CI)
		Frequency	%	Frequency	%		
Age (years)	≤30	148	89.2	18	10.8	0.074	1.711 (0.945–3.099)
	>30	197	82.8	41	17.2		Reference
Gender	Male	127	86.4	20	13.6		Reference
	Female	161	87.5	23	12.5	0.120	0.561 (0.271–1.162)
	TG	57	78.1	16	21.9	0.061	0.509 (0.251–1.031)
Education	Till high school	305	84.5	56	15.5	0.128	0.408 (0.122–1.366)
	Above high school	40	93	3	7		Reference
Below poverty line		22	81.5	5	18.5	0.503	0.708 (0.257–1.953)
Occupation	Working	272	87.2	40	12.8	0.062	1.770 (0.967–3.238)
	Not working	73	79.3	19	20.7		Reference
Typology	FSW	161	87.5	23	12.5		Reference
	MSM	127	86.4	20	13.6	0.061	0.509 (0.251–1.031)
	TG/TS	57	78.1	16	21.9	0.120	0.561 (0.271–1.162)
Marital status	Married	197	86	32	14	0.612	1.154 (0.662–2.012))
	Unmarried	144	84.2	27	15.8		Reference
Place of residence	Same district	305	86.2	49	13.8	0.086	1.945 (0.899–4.207)
	Other district	32	76.2	10	23.8		Reference
Consumes tobacco		82	91.1	8	8.9	0.082	1.988 (0.906–4.360)
Consumes alcohol		138	87.3	20	12.7	0.375	1.3 (0.728–2.323)
Any comorbidities		39	78	11	22	0.114	0.556 (0.267–1.160)
HIV		11	64.7	6	35.3	**0.014***	3.437 (1.220–9.687)
Syphilis		6	85.7	1	14.3	1.000	1.027 (0.121–8.684)
Diabetes		7	70	3	30	0.167	0.387 (0.097–1.539)

*Significant after adjusting for age, occupation, tobacco consumption & place of residence. AEFI: adverse events following immunization, COVID-19: coronavirus disease 2019, CI: confidence interval, FSW: female sex workers, HIV: human immunodeficiency virus, MSM: men who have sex with men, TG: transgenders, TS: trans-sexual.

income[11, 17]. This signifies the role of the financial situation in vaccine uptake among SGM.

In the index study, AEFIs were reported in 85.4% of the participants after COVID-19 vaccination (after one or more doses). Fever (49.5%) and myalgia (48.8%) were the most commonly reported AEFIs. HIV-positive KPs were significantly associated with a higher incidence of AEFI associated with COVID-19 vaccines. In contrast, studies from the United Kingdom and China reported no significant differences in AEFIs between HIV-positive and HIV-negative study populations[24, 25]. Zou *et al.* reported that most PLHIV had a suppressed viral load and a cluster of differentiation 4 (CD4) count of >350 cells per μL[25], and the patients included in Frater *et al.* had a CD4 count of >350 cells per μL[24]. However, data on the viral load and CD4 count of PLHIV were not available in the index study. The HIV control status might affect the incidence of AEFIs in PLHIV. However, studies on the safety of the COVID-19 vaccines in uncontrolled PLHIV are not available[26]. None of the KPs or PLHIV in the current study had any serious AEFIs, indicating that the COVID-19 vaccines in India might be safe for this population. Previous studies have reported no serious AEFIs among PLHIV[24, 25]. A prospective cohort study from Northern India reported a 28-day AEFIs rate ranging from 70.9% to 76.5% among women, which was lower than the AEFI rates reported among the KPs in the present study[22].

The breakthrough infection rate was 5.4% among vaccinated participants, which is similar to the rate reported by Dhumal *et al.* for the general population in India (5.6%)[21]. Arora *et al.* reported a higher rate (7.91%) among the general population[20]. The majority of breakthrough infections were mild (90.9%), while one patient in the present study had a severe infection requiring mechanical ventilation. Arora et al. reported a higher severity in the Indian general population following vaccination[20]. The lower proportion of breakthrough infections as well as the severity of the infections in our study participants might be due to 90.1% of them being fully vaccinated with two doses, while the majority of them in Arora et al. might have taken only one dose. Female sex and the absence of previous COVID-19 infection were

Table 5 Association between socio-demographic characteristics and COVID-19 breakthrough infections (N=404)

Variable		Breakthrough Infection Yes		Breakthrough Infection No		*P*-value	Odds ratio (95% CI)
		Frequency	%	Frequency	%		
Age (years)	≤30	9	5.4	157	94.6	0.986	0.992 (0.414–2.378)
	>30	13	5.5	225	94.5		Reference
Gender	Male	10	6.8	137	93.2		Reference
	Female	9	4.9	175	95.1	0.430	0.587 (0.157–2.202)
	TG	3	4.1	70	95.9	0.789	0.833 (0.219–3.169)
Below poverty line		2	7.4	25	92.6	0.646	1.469 (0.324–6.668)
Occupation	Working	18	5.8	294	94.2	0.795	1.347 (0.444–4.084)
	Not working	4	4.3	88	95.7		Reference
Typology	FSW	9	4.9	175	95.1		Reference
	MSM	10	6.8	137	93.2	0.789	0.833 (0.219–3.169)
	TG/TS	3	4.1	70	95.9	0.430	0.587 (0.157–2.202)
Marital status	Married	12	5.2	217	94.8	0.792	0.890 (0.375–2.112)
	Unmarried	10	5.8	161	94.2		Reference
Place of residence	Same district	17	4.8	337	95.2	0.057	0.373 (0.130–1.070)
	Other district	5	11.9	37	88.1		Reference
Consumes tobacco		5	5.6	85	94.4	0.958	1.028 (0.368–2.867)
Consumes alcohol		10	6.3	148	93.7	0.531	1.318 (0.555–3.126)
Comorbidities		4	8	46	92	0.334	1.636 (0.526–5.007)
HIV		2	11.8	15	88.2	0.235	2.447 (0.523–11.441)
Syphilis		2	28.6	5	71.4	0.050	7.540 (1.377–41.289)
Diabetes		0	0	10	100	1.000	–
COVID-19 infection before vaccination		5	6.3	74	93.7	0.700	1.224 (0.438–3.425)

COVID-19: coronavirus disease 2019; CI: confidence interval; FSW: female sex workers; HIV: human immunodeficiency virus; MSM: men who have sex with men; TG: transgenders; TS: trans-sexual.

reported as risk factors for breakthrough infections in the general population of India[21], whereas none were found in our study. Ghosh *et al.* in a larger cohort of 1.59 million health care workers (HCWs) and frontline workers (FLWs) reported a vaccine effectiveness of 91.8–94.9%[16].

The disproportionate risk and severity for COVID-19 among TGs[27], can be addressed by maintaining a high coverage of vaccination in the Indian setting.

This study is the first to be conducted among FSWs, TG/TS, and MSM populations in India. The sampling framework included one of the largest states of India, with participants from different districts of the state, to improve representation and generalizability. However, the present study has some limitations. Data on the exact date of vaccination were not available; hence, the time of the incidence of breakthrough infections following vaccination could not be assessed. Owing to the retrospective and self-reported nature of this study, recall bias in the responses may have occurred. Selection bias owing to the convenience sampling of the study participants who had access to TI during the data collection period was present.

Conclusion

Overall, COVID-19 vaccine uptake among HIV KPs is high in Tamil Nadu. AEFIs and breakthrough infections among COVID-19 vaccinated HIV KPs may be low, with all AEFIs being mild. High vaccination coverage must be sustained among KPs. Further studies must be conducted to explore the factors that facilitate high vaccine uptake in this population. Further multi-centric (involving other states) prospective cohort studies with adequate power should be conducted to improve the validity of our findings.

Data sharing statement: Documents containing all data have been made available in the manuscript. Anonymized raw data will be shared based on specific and reasonable requests made to the authors.

Ethics: Ethical approval for this study was obtained from the Institute Ethics Committee of the Government Medical College, Dindigul (Ref no.001316). Approval from the Research Review Committee of TANSACS for conducting the study was also obtained. Written informed consent was

obtained from all participants after ensuring confidentiality.

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