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Original Research Article

IMPACT OF COVID-19 PANDEMIC ON OPERATIONAL PARAMETERS OF TUBERCULOSIS CONTROL IN HAPUR DISTRICT OF UP, INDIA – A RETROSPECTIVE COHORT STUDY

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Abstract

Background: Delayed case presentations and delays in diagnosis and treatment after initial presentation are significant issues contributing to the high burden and transmission of tuberculosis (TB). During the COVID-19 pandemic, restrictions on movement and the diversion of healthcare workers exacerbated these delays, jeopardising the progress made in tuberculosis control programs worldwide. This study aims to estimate the impact of the pandemic on specific operational parameters of the National Tuberculosis Elimination Programme (NTEP), such as delay in enrolment, diagnosis, treatment, contact tracing, and follow-up, in the Hapur district of India. **Materials and Methods:** This retrospective cohort study utilised secondary data from the 'Nikshay' portal of NTEP. Patients enrolled during the intra-COVID period (April-September 2020) were compared with those enrolled during the pre-COVID period (April-September 2018) regarding various operational parameters. Statistical significance was established at $p < 0.05$ for all analyses. **Result:** During the intra-COVID period, we observed an initial 14.6% decline in diagnoses on enrolment day; however, within a week, 91.8% of the cases were successfully diagnosed, surpassing pre-COVID performance (89.1%). A greater proportion (44%) of patients began antitubercular therapy early during the intra-COVID period. Furthermore, the delay in 'enrolment within a week' improved by about 10%, and there was a noticeable increase in contact tracing of affected cases (46%) and follow-up of treated cases beginning during the intra-COVID period. Procurement of patients' bank details also improved by 6% during the pandemic. **Conclusion:** Our findings indicate that most operational parameters of the anti-tuberculosis campaign in the Hapur district not only remained adequate but also showed improvement during the pandemic.

INTRODUCTION

The recent COVID-19 pandemic was controlled to a large extent due to various interventions such as lockdowns, social distancing, quarantine, etc.[1] While these strategies successfully mitigate the pandemic's effects, routine healthcare services were disrupted to a large extent worldwide. One health service that is anticipated to be affected in low and middle-income countries such as India is the National Tuberculosis Elimination Program (NTEP). Tuberculosis (TB) is a preventable and usually curable disease and most people who develop TB can be cured with a timely diagnosis and correct treatment. Yet, it is the leading cause of death.[2,3]

Delayed case presentation is a major problem contributing to the high burden and transmission of TB in developing countries. One multi-country study by the World Health Organisation (WHO) found that the time from developing symptoms until treatment varied from 46 to 127 days.[4] The delay may be attributed to patient factors where the patient visits the healthcare facility 2 weeks or more after the onset of symptoms or to the healthcare system if the patient is not diagnosed and treated at the time of the first visit. Any delay may worsen the disease increasing the disease morbidity, aggravating the disease transmission in the community, contributing to drug resistance, and ultimately the risk of death.[3]

India still harbours about 26% of the world's TB burden,[2,5] owing to its large population base, despite making remarkable progress in diagnosing new cases of TB. Reducing the TB burden is a part of the United Nation's Sustainable Development Goals (SDG) 2030.[5,6] To meet this global goal India has a National Strategic Plan for Elimination of Tuberculosis (NSP 2017-25).[7,8] Some new activities were undertaken to break the chain of transmission. These included contact tracing to minimise secondary transmission and stringent follow-up of the treated patients to detect recurrence early. TB is known to be associated with low nutritional status for which the 'Nikshay Poshan' scheme,[9] was launched to provide direct cash benefit transfers to patient's bank accounts.[7] In India, all activities undertaken in pursuance of the End TB Strategy are orchestrated through the National Tuberculosis Elimination Programme and are handled through 'Nikshay' a web-based Health Management Information System (HMIS).

During the COVID pandemic, many authors speculated that many factors such as patient delay, disruptions in health facility services, and shortage of manpower, would have an unfavourable effect on TB treatment outcomes and program functioning, however, no study was conducted in the district of Hapur, India. Thus, this study was conducted to estimate the impact of the pandemic on various services under NTEP. It also proposes new parameters and categories, more suitable to conclude from 'Nikshay' data for programmatic evaluation and monitoring.

MATERIALS AND METHODS

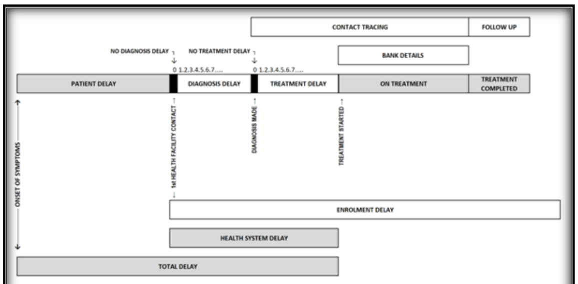

Figure 1 Time line of various types of delays & services. Greyed ones are not subject of this study

This retrospective cohort study was performed on data derived from the 'Nikshay' portal available from the nodal point for TB services i.e., District Tuberculosis Centre, Hapur. Detailed methodology is published elsewhere.[10] In brief, TB cases registered from April to September 2020 (intra-COVID period) were considered an "Exposed Cohort" and those registered from April to September 2018 (pre-COVID period) were considered a "Non-Exposed Cohort" in this study. The study duration of six months was further divided into two quarters Q2 (April to June) and Q3 (July to Sept), based on intensity of interruption of healthcare services.[11] All presumptive TB cases enrolled during Q2 and Q3 of 2018 and 2020 (3086) were included in this study while duplicate entries (16) were omitted. The Institutional Ethics Committee of GS Medical College & Hospital approved the research proposal.

The definitions adopted in the WHO document were suitably adapted to derive inferences.[4] The Nikshay portal automatically records the 'Enrollment date' whenever a new patient is registered on the presumption of suffering from TB. Two parameters of 'Health care system delay' chosen were: ***Diagnosis delay:*** Time taken for making diagnosis following enrolment on the web portal. ***Treatment delay:*** Time taken to start treatment once the diagnosis is made.

The 'Nikshay' does not record the 'date of onset of symptoms' so the calculation of 'Patient delay' was not feasible. Going through the records, we found that many cases were diagnosed before being enrolled. This may have happened in health facilities where patients are registered and treated but the records are maintained manually. The cases were later entered into 'Nikshay' to generate a Nikshay ID. In ideal situations, the generation of Nikshay ID should precede diagnosis and treatment but, in a patient-centric approach, diagnosis and treatment cannot be withheld for the want of Nikshay ID. The practical approach adopted in such cases is to generate a Nikshay ID as early as possible with the availability of spare time, a computer operator, or an internet connection. The period between the date of diagnosis and the date of enrolment should be minimised. This interval is referred to as '***Enrolment Delay***' in this paper.

To evaluate delays in our patients, we utilised three timeline subcategories. Our decision was based on the observation that the median delay, commonly used in other studies was often less sensitive and frequently produced similar results across both study periods. This Subcategorization also offers greater operational utility for assessing the elimination program.

We dichotomised our patients into subgroups based on median age (30). gender, site of infection, whether microbiologically confirmed or not, whether new patient or retreatment case, whether diagnosed with microbiological (Ziehl-Neelsen staining/culture/ molecular) methods or otherwise and service sector of enrolling health facility formed other categories to estimate the effect on all these time delay-based operational parameters.

In this paper, we have analysed these parameters to compare the performance of the NTEP program during pre-COVID and intra-COVID periods. We also compared the impact of the pandemic on 'contact tracing', 'follow up', and patient bank details collection. Results were analysed using Statistical Package for Social Science (SPSS) version 26. In all analyses, statistical significance was set at $p < 0.05$.

RESULTS

Of 3070 patients under study, males formed 52% of the cohort in the intra-COVID period and 54.9% in the pre-COVID period. The median age of the study participants was 31 years (IQR 22-48) in pre-COVID and 30 years (IQR 22-48) in the intra-COVID period. The proportion of males and females, and the age distribution were comparable during the two study periods. [Table 1]

Only 2782 (90.5%) patients were diagnosed with tuberculosis using appropriate i.e., clinical/radiological/laboratory diagnostics criteria. Of these 2736 (98.3%) were provided treatment. [Figure 2]

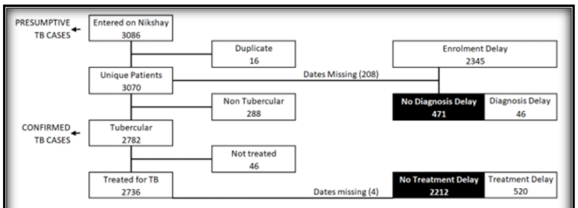

Figure 2 Flowchart illustrating the study population, highlighting various delays

- Enrolment delay: Patients diagnosed before being enrolled • Diagnosis delay: Patients diagnosed anyday after the day of enrollment
- Treatment delay: Treatment began anyday after the day of diagnosis

Diagnosis Delay: We found that cases diagnosed on the day of enrolment were 68.1% during the intra-COVID period compared to 82.6% during the pre-COVID period. The difference was significant (p=0.001). However, significantly more patients were diagnosed in the next six days during the intra-COVID period than in the pre-COVID period ($p < 0.05$). As a result, the patients diagnosed during one week were not significantly different between the two periods. [Table 2]. Overall, the diagnosis delay was less during the pre-COVID period than during the intra-COVID period ($p < 0.001$).

Upon exploring the predictors determining the diagnosis delay we found that the diagnosis delay had increased among both the age categories, and both genders, irrespective of the site of infection, whether microbiologically confirmed or not, in both private and public sector health facilities, in new as well as retreatment cases during the intra-COVID period. However, the increase was not significant in extrapulmonary cases, being treated in a private facility and in cases that were not microbiologically confirmed. [Table 3]

Treatment Delay: In our patients, the treatment was initiated on the day of diagnosis among 44.0% of patients during the intra-COVID period whereas during the pre-COVID period, this happened in 37.8%. The difference was significant ($p<0.05$). A significantly lesser number of patients were, however, put on treatment during the next six days ($p<0.05$). By the end of one week, there remained no significant difference between the two study periods ($p> 0.05$) [Table 2]

When treatment delay was compared between public and private health facilities, the performance of public facilities remained unchanged ($p> 0.05$) but the performance of private health facilities improved ($p < 0.05$). Significant improvement was seen in both the age categories and genders. Though the improvement was statistically significant in patients with pulmonary tuberculosis and new cases, the improvement in patients with extrapulmonary tuberculosis and retreatment cases was not significant. Treatment delay improved during the intra-COVID period irrespective of mode of diagnosis. [Table 3]

Enrolment Delay: Patients diagnosed before enrolling on 'Nikshay' (n=2345) are considered to have an enrolment delay. During the pre-COVID period, 91.7% of patients had an enrolment delay while during the intra-COVID period, only 52.8% had it. In 208 (2.1%) date of diagnosis was missing.

There was a significant increase in enrolment delay among persons below 30 years of age and among females ($p < 0.05$). Additionally, delay in duration of enrollment improved among patients diagnosed with pulmonary tuberculosis, both new and retreatment cases, microbiologically confirmed, and in those cases opting for public sector facilities for enrolment [Table 3].

Contact Tracing: Whereas in 2018, contact tracing was done in 183 (10%) patients, it was done in 679 (56%) in 2020. The observed difference was significant ($p<0.05$). [Table 2]

Follow-up: No patient was followed up during the pre-COVID period, 98 (8%) were followed up during the Intra-COVID period. The difference was significant ($p<0.05$). [Table-2]

Bank details: Procurement of Bank details increased from 61% in the pre-COVID period to 67% during the Intra-COVID period ($p<0.05$). [Table 2]

Table 1: Demographic and other characteristics of the study population.

Characteristics	Notified TB Cases (N = 3070) %	Pre-COVID-19 (Apr-Sep 2018) (N = 1859) %	Intra-COVID-19 (Apr-Sep 2020) (N = 1211) %	p-Value
Age, years	***3070***	***1859***	***1211***	
≤ 30	1539 (50.1)	927 (49.9)	612 (50.5)	P = 0.745
> 30	1531 (49.9)	932 (50.1)	599 (49.5)	P = 0.745
Gender	***3070***	***1859***	***1211***	
Male	1651 (53.8)	1021 (54.9)	630 (52.0)	p = 0.115
Female	1417 (46.2)	838 (45.1)	579 (47.8)	p = 0.142
Transgender	2 (0.1)	0 (0.0)	2 (0.2)	p = 0.054
Site of Infection	***3070***	***1859***	***1211***	
Pulmonary	1914 (62.3)	1192 (64.1)	722 (59.6)	**p = 0.012**
Extrapulmonary	792 (25.8)	518 (27.9)	274 (22.6)	**p = 0.001**

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Information missing	364 (11.9)	149 (8.0)	215 (17.8)	**p = 0.001**
Type of infection	***3070***	***1859***	***1211***	
Newly diagnosed	2523 (82.2)	1615 (86.9)	908 (75.0)	**p < 0.001**
Retreatment	245 (8.0)	175 (9.4)	70 (5.8)	**p < 0.001**
PMDT	75 (2.4)	40 (2.2)	35 (2.9)	p = 0.223
Information missing	227 (7.4)	29 (1.6)	198 (16.4)	**p < 0.001**
Mode of diagnosis	***3070***	***1859***	***1211***	
Microbiologically confirmed *	1491 (48.6)	913 (49.1)	578 (47.7)	p = 0.448
Clinical diagnosis	1579 (51.4)	946 (50.9)	633 (52.3)	p = 0.448
Enrolling Health Facility	***3070***	***1859***	***1211***	
Public	2453 (79.9)	1513 (81.4)	940 (77.6)	**p = 0.010**
Private	617 (20.1)	346 (18.6)	271 (22.4)	**p = 0.010**
Current Facility	***3070***	***1859***	***1211***	
Public	2533 (82.5)	1547 (83.2)	986 (81.4)	P = 0.199
Private	537 (17.5)	312 (16.8)	225 (18.6)	P = 0.199

* Microbiologically confirmed = Positive on ZN staining/culture / molecular tests

Table 2: Operational parameters during pre-COVID and intra-COVID periods

Characteristics	**Notified TB Cases (N = 3070) %**	**Pre-COVID-19 (Apr-Sep 2018) (N = 1859) %**	**Intra-COVID-19 (Apr-Sep 2020) (N = 1211) %**	**p-Value**
Follow Up	***3070***	***1859***	***1211***	
Yes	98 (3.2)	0 (0.0)	98 (8.0)	**p < 0.001**
No	2972(96.8)	1859 (100.0)	1113 (92.0)	**p < 0.001**
Contact Tracing	***3070***	***1859***	***1211***	
Yes	862 (28.1)	183 (10.0)	679 (56.0)	**p < 0.001**
No	2208 (71.9)	1676 (90.0)	532 (44.0)	**p < 0.001**
Bank Details	***3070***	***1859***	***1211***	
Yes	1945 (63.4)	1130 (61.0)	815 (67.0)	**p < 0.001**
No	1125 (36.6)	729 (39.0)	396 (33.0)	**p < 0.001**
Enrolment Delay	***2345***	***1705***	***640***	
Within a week	922 (39.3)	626 (36.7)	296 (46.3)	**p < 0.001**
1-2 weeks	485 (20.7)	382 (22.4)	103 (16.1)	**p < 0.001**
More than two weeks	938 (40.0)	697(40.9)	241 (37.7)	p = 0.159
Diagnosis Delay	***517***	***138***	***379***	
No delay (a)	372 (72.0)	114 (82.6)	258 (68.1)	**p = 0.001**
1 - 6 Day (b)	99 (19.1)	9 (6.5)	90 (23.7)	**p < 0.001**
Within 1 week (a+b)	471 (91.1)	123 (89.1)	348 (91.8)	p = 0.341
More than one week	46 (8.9)	15 (10.9)	31 (8.2)	p = 0.341
Treatment Delay	***2732***	***1736***	***996***	
No delay (a)	1095 (40.1)	657 (37.8)	438 (44.0)	**p = 0.001**
1 - 6 Day (b)	1117 (40.9)	743 (42.8)	374 (37.6)	**p = 0.007**
Within 1 week (a+b)	2212 (81.0)	1400 (80.6)	812 (81.5)	p = 0.564
More than one week	520 (19.0)	336 (19.4)	184 (18.5)	p = 0.564

Table 3: Effect of COVID-19 pandemic on various operational delays

Type of delay	**Enrolment Delay**		**Diagnosis Delay**		**Treatment Delay**	
Age category	*≤ 30*	*> 30*	*≤ 30*	*> 30*	*≤ 30*	*> 30*
	⇩ **P < 0.0001**	↑ **P < 0.0001**	⇩ **P = 0.0108**	⇩ **P = 0.0051**	↑ **P < 0.0001**	↑ **P < 0.0001**
Gender	*Male*	*Female*	*Male*	*Female*	*Male*	*Female*
	↑ **P < 0.0001**	⇩ **P < 0.0001**	⇩ **P = 0.0145**	⇩ **P = 0.0007**	↑ **P < 0.0001**	↑ **P < 0.0001**
Site of infection	*Pulmonary*	*Ext. Pulm.*	*Pulmonary*	*Ext. Pulm.*	*Pulmonary*	*Ext. Pulm.*
	↑ **P < 0.0001**	⇩ P = 0.1540	⇩ **P = 0.0003**	⇩ P = 0.4093	↑ **P = 0.0031**	↑ P = 0773
Type of patient	*New*	*Retreatment*	*New*	*Retreatment*	*New*	*Retreatment*
	↑ **P < 0.0001**	↑ **P < 0.0324**	⇩ **P = 0.0009**	⇩ **P = 0.0180**	↑ **P = 0.0052**	↑ P = 0.8025
Microbiologically confirmed	*Yes*	*No*	*Yes*	*No*	*Yes*	*No*
	↑ **P < 0.0001**	⇩ **P < 0.0001**	⇩ **P = 0.0002**	⇩ P = 0.6491	↑ **P = 0.0002**	↑ **P < 0.0001**
Service sector	*Private*	*Public*	*Private*	*Public*	*Private*	*Public*
	↑ P = 0.5045	↑ **P < 0.0001**	⇩ p = 0.0887	⇩ **P = 0.0001**	↑ **P = 0.0205**	↑ P = 0.2579

● Upward arrow (↑) represents improvement in delay, Downward arrow (⇩) represents worsening in delay
●Ext. Pulm. = Extra Pulmonary ●Microbiologically confirmed = Positive on ZN staining/culture/molecular tests

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DISCUSSION

We conducted a retrospective cohort study to compare the operational parameters of the National Tuberculosis Elimination Program during two periods: pre-COVID (2018) and intra-COVID (2020). Our findings revealed that during the intra-COVID period, there was an initial decline in diagnoses, with nearly three out of ten cases not being diagnosed on the day of enrollment. However, within just one week, the program's performance improved significantly, with over 90% of cases being diagnosed successfully. The program also showed positive results in terms of treatment allocation for diagnosed cases. During the intra-COVID period, a larger proportion of the population started antitubercular therapy earlier than before. It was observed that most of the study population was diagnosed first and then subsequently enrolled in the 'Nikshay' portal, which indicates a general delay in enrollment. However, improvements in enrollment timelines were noted during the intra-COVID period. Furthermore, there was a significant increase in the contact tracing of affected cases during this time.

Diagnosis Delay: The methods for estimating the delay in diagnosing patients with tuberculosis vary across the literature. Purohit et al,[12] reported a median diagnosis delay of 8 weeks in a study conducted from 2004 to 2012. In contrast, Chandra et al. reported a median delay of 32.5 days in Ballabgarh.[13] One systematic review found a median delay of 31.0 days (Interquartile Range (IQR): 24.5-35.4) across 23 studies from India.[14] A more recent study from China reported a median diagnosis delay of 8 days (IQR: 0–18).[15]

In the Chinese study, 35.2% of patients experienced delays of more than 14 days.[15] Sumana M. et al. reported in a study conducted in 2008 that the diagnosis delay exceeded 15 days for 43.8% of patients. In our study, however, we found that the delay was more than one week for only 10.9% of patients in 2018 and 8.2% in 2020, indicating a significant improvement compared to the findings of 2008.[3]

More recently, Gandhi et al. found a median diagnosis delay increased by 33 days when comparing the pre-COVID and post-COVID periods.[11] In our study, we observed a mean decrease in delay of 4.0 days ($p = 0.0029$).

In the best-performing tuberculosis control programme, the patient should be diagnosed and treatment should begin on the day of the first visit.[16] Many authorities have stressed the need to diagnose on the day of first contact with the health care system. During the pandemic, tuberculosis control services were hampered and it was observed that case detection and diagnosis were delayed in many studies conducted in low and middle-income countries.[17] However in our study population, after a decline in diagnosis on enrolment day, more patients were diagnosed during the next six days during the intra-COVID period compared to the pre-COVID period. This points out that the diagnostic service was available but was not accessible due to ongoing restrictions on movements. For the same reason, the difference between the two periods was insignificant ($p < 0.05$) by the end of one week.

Treatment Delay: Sumana M. et al. found that after one week, 10.1% of cases remained untreated.[3] In our patient cohort, the percentage of untreated cases after one week of diagnosis was 18.5% in 2020, compared to 19.4% in 2018, indicating a slight improvement.

The mean treatment delay varied between 2 to 6 days across different studies.[11,13,14] Our study found the mean treatment delay to be 5.3 days (± 20.2), comparable to what has been reported in the literature. Very few studies have examined the differences between the pre-COVID and post-COVID periods. Among those that did, Gandhi et al. found the treatment delay increased by 6 days, while our research found a statistically insignificant decrease of 0.7 days.

In the population of Hapur district, during the intra-COVID period, a significantly higher proportion of patients with tuberculosis began their treatment on the day of diagnosis. This reflects the commitment of the healthcare workers involved in the NTEP program to ensure the continuation of services while handling the burden of a pandemic.

The improved performance of private healthcare facilities in reducing treatment delays in our population explains why the general population prefers to seek private healthcare services. This preference is attributed to easier accessibility and quicker treatment delivery, even though many studies report higher out-of-pocket expenditures and diagnosis delays.[3,13]

Treatment delays improved for new and pulmonary cases during the intra-COVID period, but not for retreatment or extrapulmonary cases. This may be due to the similar clinical presentations of these cases and COVID-19, which likely prompted patients to seek diagnosis and treatment more promptly. Once diagnosed, no significant differences were found in treatment delays between different age groups and genders.

Enrolment Delay: We could not find any literature on ‘Enrolment delay’. This exists when a patient visits a health establishment and is diagnosed but Nikshay ID is not generated before diagnosis. Ideally, Nikshay ID should be generated for all presumptive cases first and then diagnosis tests should be performed. Non-availability of computer operators is the most common reason. Attempts have been made to address it. Whereas in the pre-COVID period, 91.7% of patients were diagnosed before being enrolled, this was reduced to 52.8% during the intra-COVID period, showing better performance during the intra-COVID period.

Other operational indicators also showed improvement during the intra-COVID period compared to the pre-COVID period. These were an

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increase in the follow-up of TB patients, contact tracing, and procurement of bank details for direct benefit transfer.[18] In a similar study on 'Nikshay' data in east India, 4% more households were screened during the intra-COVID period despite a 30% reduction in registrations.[19] Follow-up of TB patients which did not exist in the pre-COVID period, made a beginning in the intra-COVID period but was still abysmally low at 8%.

Improvement in all these parameters despite resource crunch and non-availability of extra healthcare personnel, demonstrates political commitment, better leadership of the program managers, time management, and dedication of the field healthcare workers towards implementing the NTEP program. In addition, as India strives to meet the global targets of the TB program, these favourable outcomes also demonstrate a minimal interruption in the supply of medicine and laboratory consumables. Nonetheless, we acknowledge that these results could also have been attributed to an overall reduction of the burden of the cases during the intra-COVID period.

CONCLUSION

Our findings indicate that the anti-tuberculosis campaign in the Hapur district not only remained adequate but also showed improvement during the pandemic as judged by a few operational parameters used in the study. We believe that, due to the strong political will, local administrative commitment, dedicated healthcare workers, laboratory services, and paramedical staff, it is possible to sustain a resilient TB care cascade under the National Tuberculosis Elimination Programme (NTEP), even in the face of a pandemic. These efforts when replicated at a larger level can accelerate the progress to achieve the global objective of elimination of tuberculosis. Additionally, we also conclude that there is a need to create awareness among healthcare personnel entrusted with the task of reporting TB cases to generate a 'Nikshay' ID before carrying out diagnostic tests or treatment.

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