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# Tracking KP.2 SARS-CoV-2 Variant in India and the Clinical Profile of KP.2 Cases in Maharashtra, India

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## Abstract

Background: Following the emergence of the JN.1 SARS-CoV-2 variant, variants with key mutations in the spike protein, such as L455F, F456L, and R346T, were identified. In early January 2024, the KP.2 (JN.1.11.1.2) variant was first identified in clinical samples. Its increasing global prevalence has raised concerns over its transmission and clinical impact. The study investigates KP.2*'s (*indicates KP.2 and all its sub-lineages) spread and clinical severity in Maharashtra.

Methods: This study involved 5,173 Indian SARS-CoV-2 whole genome sequences with collection dates between November 1, 2023 and June 24, 2024. Lineage analysis of sequences was performed using Nextclade software (version 3.8.0). Telephonic interviews were conducted to confirm the demographic details and obtain clinical information on the KP.2* cases. The obtained data were recorded and analyzed using Microsoft® Excel (Microsoft Corporation, Redmond, WA).

Results: Among the 5,173 sequences analyzed, JN.1* appeared as the predominant lineage (65.96%, 3412/5173), followed by KP.2* (7.83%, 405/5173) and KP.1* (3.27%, 169/5173). In India, KP.2* was first detected on December 2, 2023, in Odisha. The majority of KP.2* sequences were from Maharashtra (248/405, 61.23%), followed by West Bengal (38/405, 9.38%), Gujarat (27/405, 6.67%), and Rajasthan (24/405, 5.93%). Maharashtra reported its first KP.2* sequences on January 24, 2024. The clinical study included 160 cases of the KP.2* variant from Maharashtra. Of these, 95.63% (153/160) presented with mild symptoms, such as fever (108/160, 67.50%), cold (87/160, 54.38%), cough (80/160, 50%), sore throat (44/160, 27.5%), body ache (43/160, 26.88%), and fatigue (42/160, 26.25%). About 33.13% (53/160) of the cases required institutional quarantine or hospitalization, with the rest managed at home. Among those hospitalized, 50.94% (27/53) received conservative treatment, while 49.06% (26/53) needed supplemental oxygen, steroids, or antiviral therapy. Regarding the vaccination status, 89.38% (143/160) of the cases had received at least one dose of the COVID-19 vaccine, whereas 10% (16/160) were unvaccinated, with the majority of the unvaccinated being children aged zero to nine years (7/16, 43.75%). The overall recovery rate for KP.2* cases was 99.38% (159/160), with only 0.62% (1/160) succumbing to the disease.

Conclusion: The KP.2 variant has become the dominant SARS-CoV-2 variant in India and Maharashtra. Despite the affected individuals experiencing mild symptoms, studies have shown lower neutralization titers and high infectivity due to FLiRT mutations, suggesting KP.2's potential rise to global dominance.

**Categories:** Epidemiology/Public Health, Internal Medicine, Infectious Disease
**Keywords:** clinical characteristics, covid-19, sars-cov-2, flirt variant, kp.2

## Introduction

The emergence and evolution of SARS-CoV-2 variants continue to challenge global public health efforts. In 2023, the BA.2.86 variant attracted considerable attention [1]. It was categorized as a variant under monitoring (VUM) by the World Health Organization (WHO) on August 17, 2023 [2]. By late 2023, attention had shifted to its descendant, JN.1 (BA.2.86.1), leading to increased worldwide cases [1]. Consequently, BA.2.86 and its descendant JN.1 were reclassified by the WHO as variants of interest (VOI) on November 21, 2023 [2], and December 20, 2023 [3], respectively.

Before the emergence of JN.1* (*indicates JN.1 and all its sub-lineages), the most prevalent variants were XBB and its sub-lineages. As the XBB evolved, several variants with mutations at key sites in the spike (S) protein - L455 and F456 - have been identified. During the same period, the so-called FLip variants

appeared, characterized by spike (S) protein mutations - L455F and F456L - in the backbone of XBB.1.5, hence named “FLip”. Since the emergence of JN.1, these mutation sites in the S protein have remained hotspots, leading to the appearance of the so-called SLip variants. The “SLip” variants combine the JN.1 spike protein (possessing L455S) with the F456L mutation. Therefore, it was named “SLip”. More recently, the so-called FLiRT variant emerged, featuring an additional R346T mutation on the “SLip” backbone, thus named “FLiRT”. The KP.2 (JN.1.11.1.2) SARS-CoV-2 variant, a descendant of the JN.1 variant, is an example of the “FLiRT” variant [4]. It was officially designated as KP.2 on May 3, 2024. The KP.2 variant is characterized by three defining FLiRT mutations in the S protein - F456L, R346T, and V1104L [5]. Due to its increasing global prevalence, the WHO has classified KP.2 and KP.3 as VUM [6]. The earliest documented sample of the KP.2 variant was collected on January 2, 2024 [5]. Globally, KP.2 accounted for 22.7% of sequences in Week 21, 2024 [6].

Considering the increasing prevalence of the KP.2 variant globally, there is a pressing need to understand its impact at a regional level. Maharashtra, a state in India with a significant population density and diverse demographics, offers a valuable case study for observing the behavior of this variant. Therefore, this study aimed to understand the appearance, prevalence, and clinical outcomes of the KP.2 variant within Maharashtra.

## Materials And Methods

This study is a part of the sequencing efforts in Maharashtra under the Indian SARS-CoV-2 Genomics (INSACOG) consortium to investigate the evolutionary patterns of SARS-CoV-2.

### Lineage analysis of SARS-CoV-2 whole genome sequences in Maharashtra

To trace the first appearance and the spread of the KP.2 SARS-CoV-2 variant in Maharashtra, whole genome sequences of the virus, collected between November 1, 2023, and June 24, 2024, were analyzed. These sequences, submitted by various sequencing laboratories across states and union territories, were downloaded with permission from the Indian Biological Data Centre (IBDC) database [7]. Only entries with complete metadata, including geographic locations and sample collection dates, were included in the study. The sequences used can be found in Tables *4*-*5* (Appendices). Lineage and clade analysis were performed using Nextclade software (version 3.8.0).

### Collection of demographic and clinical data of SARS-CoV-2 positive cases in Maharashtra

Demographic details, including age, sex, area of residence, contact number, and dates of sample collection and testing, were obtained from the metadata provided to sequencing laboratories by real-time PCR (RT-PCR) testing centers. Telephonic interviews were conducted with each patient to verify demographic details and gather clinical information. Information collected included symptoms, type of isolation, hospitalization, oxygen requirements, treatments, and vaccination status. The questionnaire template used in the study is available in Tables *4*-*5* (Appendices). Patients who did not consent to disclose their clinical history during the interview were noted and excluded from the study.

Daily records were collected from the State’s District Health Services Department, including daily SARS-CoV-2 testing and test positivity rates from November 1, 2023 and June 24, 2024. This data was used to assess any surge in COVID-19 cases associated with the appearance of the KP.2* SARS-CoV-2 variant in Maharashtra. Additionally, SARS-CoV-2 test positivity rates from clinical samples were compared with viral loads in wastewater from the Pune Municipal Corporation. To establish the correlation, the publicly accessible dashboard describing SARS-CoV-2 variants in Pune’s wastewater sampling was studied [8].

### Statistical analysis

All demographic and clinical data were recorded and analyzed using Microsoft® Excel, and analysis was performed using Microsoft® Excel. The continuous variables were presented as the median and interquartile range (IQR). The categorical variables were presented as numbers and percentages.

## Results

### Distribution of SARS-CoV-2 lineages in Maharashtra and India

A total of 5,173 downloaded sequences were included in the study. Following Nextclade Pangolin nomenclature, 129 different lineages were identified between November 1, 2023, and June 24, 2024. JN.1* was the most common lineage (65.96%), followed by KP.2* (7.83%) and KP.1* (3.27%) (Table *1*).

| Pangolin Lineage | Nextclade Clade | Count |
|---|---|---|

| | | | | |
|---|---|---|---|---|
| BA.1 | BA.1.1 | 21K | 1 | 1 (0.02%) |
| BA.2* | BA.2 | 24A | 155 | 156 (3.02%) |
| | BA.2.10.1 | 23F | 1 | |
| BA.2.38 | BA.2.38 | 21L | 1 | 1 (0.02%) |
| BA.2.86* | BA.2.86 | 23I | 2 | 130 (2.51%) |
| | BA.2.86.1 | | 28 | |
| | KU.1 | 24A | 7 | |
| | KU.2 | | 19 | |
| | KZ.1 | | 3 | |
| | KZ.1.1 | | 11 | |
| | LB.1 | | 37 | |
| | LC.1 | | 23 | |
| JN.1* | JN.1 | | 1045 | 3412 (65.96%) |
| | JN.1.1 | | 1194 | |
| | JN.1.1.1 | | 2 | |
| | JN.1.1.3 | | 2 | |
| | JN.1.1.5 | | 11 | |
| | JN.1.1.6 | | 22 | |
| | JN.1.1.7 | | 6 | |
| | JN.1.10 | | 4 | |
| | JN.1.11 | 24B | 421 | |
| | JN.1.11.1 | | 143 | |
| | JN.1.13 | | 1 | |
| | JN.1.15 | | 1 | |
| | JN.1.16 | | 6 | |
| | JN.1.16.1 | | 5 | |
| | JN.1.18 | | 72 | |
| | JN.1.18.1 | | 3 | |
| | JN.1.19 | | 2 | |
| | JN.1.2 | | 3 | |
| | JN.1.20 | | 3 | |
| | JN.1.22 | | 10 | |
| | JN.1.25 | | 18 | |
| | JN.1.25.1 | | 32 | |
| | JN.1.28 | | 3 | |
| | JN.1.28.1 | | 1 | |
| | JN.1.29 | | 1 | |
| | JN.1.3 | | 4 | |
| | JN.1.30 | | 109 | |
| | JN.1.30.1 | | 35 | |

| | | | | | |
|---|---|---|---|---|---|
| | JN.1.32 | 24A | | 9 | |
| | JN.1.33 | | | 1 | |
| | JN.1.37 | | | 1 | |
| | JN.1.38 | | | 2 | |
| | JN.1.39 | | | 15 | |
| | JN.1.4 | | | 34 | |
| | JN.1.4.2 | | | 1 | |
| | JN.1.4.4 | | | 1 | |
| | JN.1.4.5 | | | 21 | |
| | JN.1.4.7 | | | 1 | |
| | JN.1.40 | | | 1 | |
| | JN.1.43.1 | | | 1 | |
| | JN.1.44 | | | 1 | |
| | JN.1.47 | | | 1 | |
| | JN.1.48 | | | 100 | |
| | JN.1.48.1 | | | 11 | |
| | JN.1.5 | | | 22 | |
| | JN.1.6 | | | 3 | |
| | JN.1.6.1 | | | 1 | |
| | JN.1.7.2 | | | 1 | |
| | JN.1.8 | | | 7 | |
| | JN.1.8.3 | | | 8 | |
| | JN.1.9 | | | 2 | |
| | JN.1.9.2 | | | 8 | |
| JN.12 | JN.12 | 23I | | 1 | 1 (0.02%) |
| JN.2 | JN.2 | | | 3 | 3 (0.06%) |
| JN.6 | JN.6 | | | 1 | 1 (0.02%) |
| KP.1* | KP.1 | 24B | | 35 | 169 (3.27%) |
| | KP.1.1 | | | 98 | |
| | KP.1.1.1 | | | 30 | |
| | KP.1.2 | | | 6 | |
| KP.2* | KP.2 | | | 299 | 405 (7.83%) |
| | KP.2.1 | | | 2 | |
| | KP.2.2 | | | 9 | |
| | KP.2.3 | | | 95 | |
| KP.3 | KP.3 | | | 69 | 69 (1.33%) |
| KP.4* | KP.4 | | | 15 | 105 (2.03%) |
| | KP.4.1 | | | 39 | |
| | KP.4.2 | | | 51 | |

| | | | | |
|---|---|---|---|---|
| XBB* | XBB.1 | 23B | 5 | 7 (0.14%) |
| | XBB.1.28.1 | 23F | 1 | |
| | XBB.1.41.1 | | 1 | |
| XBB.1.5* | GK.1.1 | 23G | 1 | 5 (0.1%) |
| | JD.1.1 | 23A | 2 | |
| | JD.1.1.1 | | 1 | |
| | XBB.1.5.45 | | 1 | |
| XBB.1.9* | EG.5.1 | 23F | 1 | 29 (0.56%) |
| | EG.5.1.1 | 23H | 2 | |
| | EG.5.1.8 | 23F | 1 | |
| | FL.1.5.1 | 23D | 1 | |
| | FL.13.2 | | 1 | |
| | FL.13.4 | | 1 | |
| | FL.4.8 | 23H | 1 | |
| | HK.3 | | 2 | |
| | HK.3.1 | | 2 | |
| | HV.1 | 23F | 11 | |
| | HV.1.11 | | 3 | |
| | JG.3 | | 2 | |
| | JG.3.2 | | 1 | |
| XBB.2.3* | GE.1 | 23E | 18 | 52 (1.01%) |
| | GE.1.1 | | 1 | |
| | GJ.1 | | 3 | |
| | GJ.1.1 | | 1 | |
| | GJ.3 | | 1 | |
| | GJ.6 | | 1 | |
| | GS.1 | | 1 | |
| | GZ.1 | | 1 | |
| | JE.1.1.1 | | 1 | |
| | JY.1 | | 11 | |
| | JY.1.1 | | 6 | |
| | XBB.2.3 | | 3 | |
| | XBB.2.3.19 | | 1 | |
| | XBB.2.3.3 | | 3 | |
| | FU.3 | | 1 | |
| | JF.1.1 | | 1 | |
| | XBB.1.16 | | 37 | |
| | XBB.1.16.1 | | 5 | |
| | XBB.1.16.11 | | 16 | |
| XBB.1.16* | XBB.1.16.17 | 23B | 9 | 78 (1.51%) |

| | | | | |
|---|---|---|---|---|
| | XBB.1.16.18 | | 1 | |
| | XBB.1.16.19 | | 1 | |
| | XBB.1.16.2 | | 2 | |
| | XBB.1.16.20 | | 1 | |
| | XBB.1.16.24 | | 4 | |
| XBB.1.19* | GW.5.1.1 | 22F | 1 | 3 (0.06%) |
| | GW.5.3.1 | | 2 | |
| Recombinant | XDA | Recombinant | 7 | 28 (0.54%) |
| | XDD | | 2 | |
| | XDK.1 | | 19 | |
| Unassigned | | | 518 | 518 (10.01%) |
| Grand Total | | | 5173 | 5173 (100%) |

**TABLE 1: SARS-CoV-2 variant distribution in India**

Based on sequences submitted to the Indian Biological Data Centre (IBDC)

In India, the distribution of SARS-CoV-2 variants over time indicates that the JN.1 variant and its associated lineages remained prevalent until early 2024 (Figure *1*) The KP.2* variant was first identified in Indian sequences on December 2, 2023 (Week 48, 2023), in Odisha. By mid-2024, KP.2* had become the most widespread variant nationwide. Its prevalence rose from 0.56% in Week 52, 2023, to 18.18% in Week 7, 2024. Among all sequences submitted by different states, 8.70% were of the KP.2* variant. Maharashtra accounted for the highest proportion of KP.2* sequences (248/405, 61.23%), followed by West Bengal (38/405, 9.38%), Gujarat (27/405, 6.67%), and Rajasthan (24/405, 5.93%) (Figure *2*).

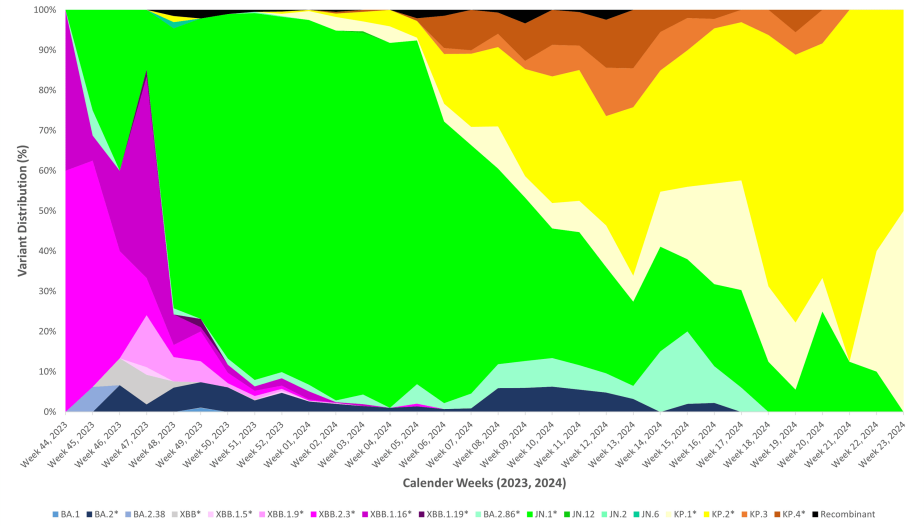


**FIGURE 1: Temporal distribution of SARS-CoV-2 variants in India**

Based on sequences submitted to the Indian Biological Data Centre (IBDC)

Image credits: Rashmita Das

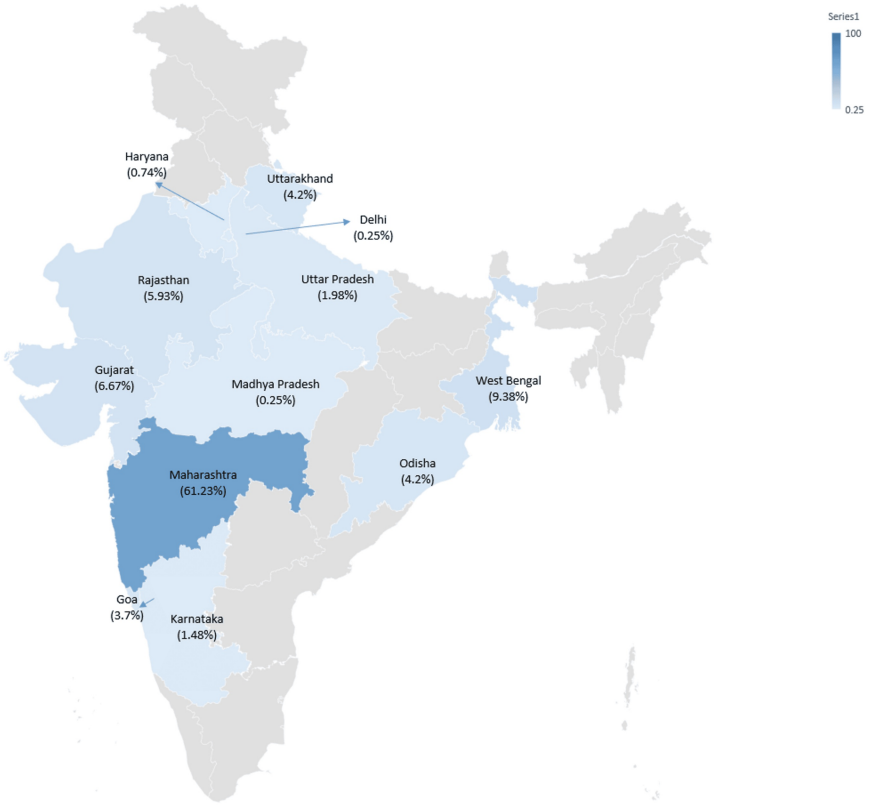


**FIGURE 2: Geographic distribution of the KP.2* SARS-CoV-2 variant in India**

Based on sequences submitted to the Indian Biological Data Centre (IBDC)

Image credits: Rashmita Das

Figure *3* illustrates the weekly distribution of SARS-CoV-2 variants in Maharashtra over six months, reflecting the national trend. The KP.2* variant was first identified on January 24, 2024 (Week 4, 2024), and its prevalence increased from 1.79% in Week 4, 2024, to 50% by Week 11, 2024.

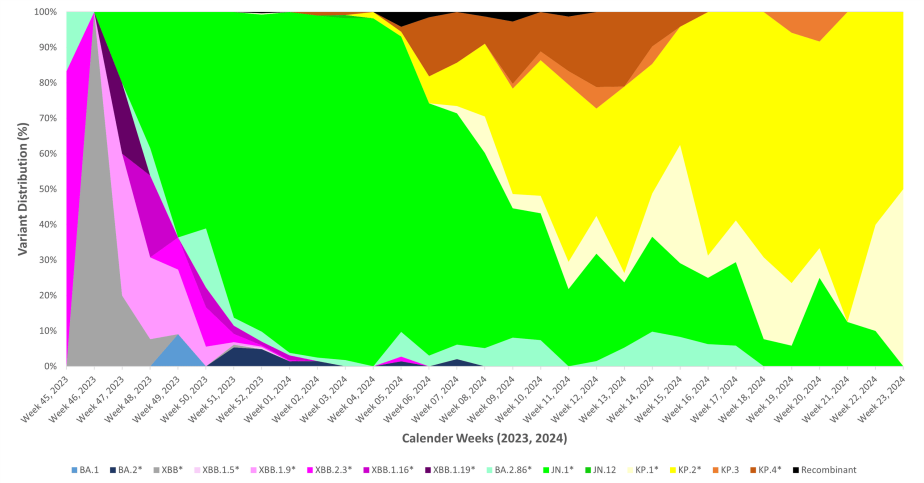


**FIGURE 3: Temporal distribution of SARS-CoV-2 variants in Maharashtra**

Based on sequences submitted to the Indian Biological Data Centre (IBDC)

Image credits: Rashmita Das

## SARS-CoV-2 testing and positivity trends in Maharashtra

Figure 4 provides an overview of SARS-CoV-2 testing in Maharashtra, depicting the total number of tests conducted (including RT-PCR and antigen testing) and the positivity rate over six months. January 2024 saw the highest testing and positive cases, though the positivity rate was relatively low at 0.79%. From February 2024 onward, both testing and positive cases gradually declined. The positivity rates varied, with significant increases in March (2.66%) and June 2024 (2.20%). The positivity rate of 2.71% occurred in June 2024, despite the lowest testing, suggesting a higher proportion of positive cases among those tested.

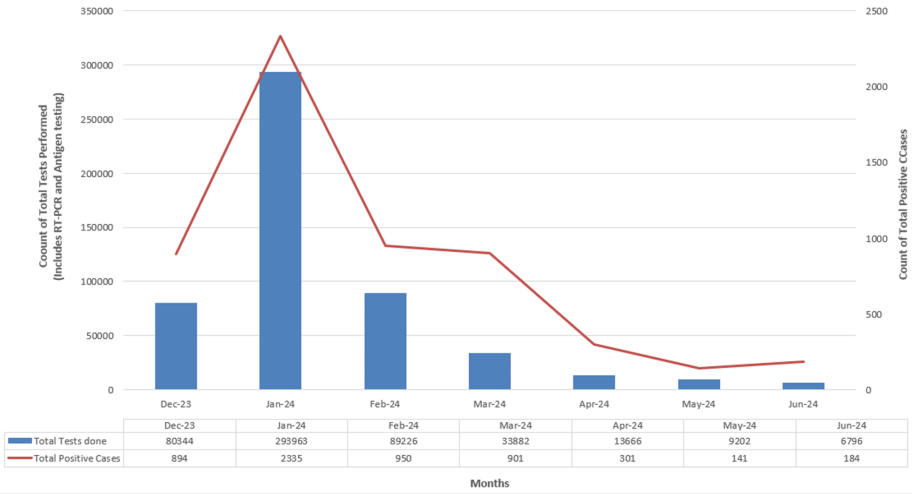


**FIGURE 4: Weekly tests performed versus weekly count of positive cases in Maharashtra over six months**

Image credits: Rashmita Das

## Trends in SARS-CoV-2 positivity in Pune Municipal Corporation's wastewater

Figure 5 displays the trends in COVID-19 clinical cases in Pune over six months from November 1, 2023 to April 17, 2024. A notable peak is observed in early January 2024, reflecting similar trends observed across Maharashtra. Following the peak, the number of cases gradually declined, settling into a relatively steady level from late January to April 2024.


**FIGURE 5: Trends in COVID-19 clinical cases in Pune city**

Figure reproduced from the image available at the wastewater surveillance dashboard for infectious diseases (COVID-19, H1N1, H3N2, Influenza-A) – the Pune Knowledge Cluster (PKC) [8].

Figure 6 indicates the cumulative viral load (in copies per liter) across different sewage treatment plants (STPs) in Pune city over the six-month period. Notable peaks in viral load were observed in several STPs in December 2023 and March 2024, suggesting a widespread increase in viral load in the city. This aligns with the observed trends in COVID-19 case positivity within the city during the same timeframe.

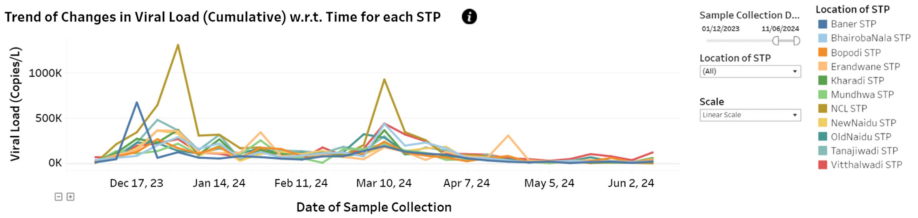


**FIGURE 6: Trends in viral load variations in wastewaters across Pune city**

Figure reproduced from the image available at the wastewater surveillance dashboard for infectious diseases (COVID-19, H1N1, H3N2, Influenza-A) – the Pune Knowledge Cluster (PKC) [8].

STP: sewage treatment plant

Figure 7 illustrates the prevalence of different SARS-CoV-2 variants in wastewater samples from Pune city over the six-month period. Initially, in November and December 2023, the JN.X and BA.2.86.X variants were the most dominant variants. Subsequently, a visible shift occurred in the variant distribution, with the KP.2.X variant becoming the dominant lineage during the latter half of the period. The KP.2.X variant first appeared in the wastewater data around late November 2023.

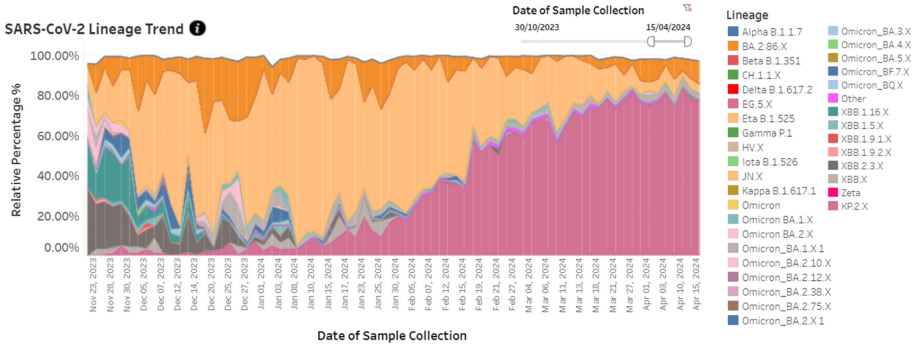


**FIGURE 7: Trends in SARS-CoV-2 lineages detected in wastewaters across Pune city**

Figure reproduced from the image available at the wastewater surveillance dashboard for infectious diseases (COVID-19, H1N1, H3N2, Influenza-A) – the Pune Knowledge Cluster (PKC) [8]

## Demographic and clinical characteristics of KP.2* SARS-CoV-2 variant in Maharashtra

Complete metadata was available for 274 cases included in the demographic study (Table 2). Among these 274 participants, 52.19% were male and 47.81% were female. The median age of the study population was 42 (IQR: 25-63) years. The largest age group comprised individuals aged 60 years and above, making up 30.66% of the study population. Most participants were from Pune (54.01%), followed by Thane (32.12%).

| Demographic Characteristics | Count (%) |
|---|---|
| Gender-wise distribution | |
| Male | 143 (52.19%) |
| Female | 131 (47.81%) |
| Age-wise distribution (years) | |
| 0-9 | 15 (5.48%) |
| 10-19 | 24 (8.76%) |
| 20-29 | 43 (15.69%) |
| 30-39 | 41 (14.96%) |
| 40-49 | 37 (13.50%) |
| 50-59 | 30 (10.95%) |
| 60 and above | 84 (30.66%) |
| Area-wise distribution in Maharashtra | |
| Ahmednagar | 1 (0.36%) |
| Akola | 1 (0.36%) |
| Amravati | 11 (4.01%) |
| Chhatrapati Sambhajinagar | 3 (1.09%) |
| Kolhapur | 5 (1.82%) |
| Mumbai | 2 (0.73%) |
| Nagpur | 1 (0.36%) |
| Nashik | 2 (0.73%) |
| Pune | 148 (54.01%) |
| Sangli | 1 (0.36%) |
| Satara | 1 (0.36%) |
| Solapur | 10 (3.65%) |
| Thane | 88 (32.12%) |

**TABLE 2: Demographic characteristics of KP.2* SARS-CoV-2 variant in Maharashtra**

From this subset of 274 cases, attempts to contact 59 (21.53%) participants were unsuccessful due to non-response to calls, 33 (12.04%) had invalid numbers, and 22 (8.03%) participants declined participation in the study. Therefore, 160 (58.39%) participants were successfully contacted and included in the clinical research. Table *3* summarizes the clinical characteristics, vaccination status, and outcome of KP.2* cases in Maharashtra. Most KP.2* cases had symptomatic disease (95.63%) with mild symptoms. The most common symptoms were fever (67.50%), cold (54.38%), cough (50%), sore throat (27.5%), body ache (26.88%) and fatigue (26.25%). Underlying comorbid conditions, either alone or in combination, were reported in 25.62% of cases, with hypertension (65%), diabetes mellitus (42.50%), and chronic obstructive pulmonary disease (17.50%) being the most common conditions. Regarding the vaccination status, 89.38% (143 out of 160) of cases received at least one dose of the COVID-19 vaccine, while 10% (16 out of 160) were not vaccinated. Most unvaccinated individuals were children aged 0 to 9 years (7 out of 16, 43.75%) and children aged 10-19 years (4 out of 16, 25%).

Of all the cases, 33.13% (53 out of 160) required hospitalization. Nearly all the home-isolated patients (91.59%, 98 out of 107) received conservative treatment. In contrast, hospitalized patients often received conservative care (27 out of 53, 50.94%) or required supplemental oxygen/steroids/antiviral therapy (26 out of 53, 49.06%). The recovery rate was high; out of 160 cases, 99.38% of cases (159 out of 160) recovered from

the disease, while 0.62% (1 out of 160) succumbed.

| Clinical Characteristics | Count (%) |
|---|---|
| History of previous infection | |
| Yes | 22 (13.75%) |
| No | 138 (86.25%) |
| Presence of comorbidities | |
| Present | 41 (25.62%) |
| Hypertension (HTN) | 14 (34.15%) |
| Diabetes mellitus (DM) | 6 (14.63%) |
| Underlying heart disease | 2 (4.88%) |
| Chronic obstructive pulmonary disease (COPD) | 3 (7.32%) |
| Thyroid dysfunction | 1 (2.44%) |
| HTN + DM | 9 (21.95%) |
| DM + COPD | 1 (2.44%) |
| HTN + COPD | 1 (2.44%) |
| HTN + COPD + thyroid dysfunction | 1 (2.44%) |
| HTN + DM + cerebrovascular attack | 1 (2.44%) |
| COPD + malignancy | 1 (2.44%) |
| Parkinson’s disease | 1 (2.44%) |
| Absent | 119 (74.38%) |
| Vaccination status | |
| Vaccinated | 143 (89.38%) |
| One dose | 9 (6.29%) |
| Two doses | 86 (60.14%) |
| Booster dose (precautionary dose) | 48 (33.57%) |
| Not vaccinated | 16 (10%) |
| Data not available | 1 (0.62%) |
| Symptom status | |
| Symptomatic | 153 (95.63%) |
| Asymptomatic | 7 (4.37%) |
| Presenting symptoms | |
| Fever | 108 (65.50%) |
| Cold | 87 (54.38%) |
| Cough | 80 (50%) |
| Sore throat | 44 (27.50%) |
| Body ache | 43 (26.88%) |
| Fatigue | 42 (26.25%) |
| Breathlessness | 19 (11.88%) |
| Headache | 14 (8.75%) |

| | |
|---|---|
| Vomiting | 12 (7.50%) |
| Loss of taste | 5 (3.13%) |
| Loss of smell | 3 (1.88%) |
| Diarrhea | 3 (1.88%) |
| Type of isolation | |
| Home isolation | 107 (66.87%) |
| Hospital isolation/hospitalization | 53 (33.13%) |
| Type of treatment received | |
| No treatment | 8 (5.0%) |
| Symptomatic treatment (antipyretics, antihistaminic, multivitamins) | 125 (78.13%) |
| Oxygen therapy | 12 (7.50%) |
| Invasive | 1 (8.33%) |
| Non-invasive | 11 (91.67%) |
| Antiviral treatment | 8 (5.0%) |
| Steroid | 1 (0.63%) |
| Antiviral treatment + oxygen therapy | 4 (2.50%) |
| Antiviral treatment + oxygen therapy + steroid | 2 (1.25%) |
| Outcome of disease | |
| Alive | 159 (99.38%) |
| Dead | 1 (0.62%) |

**TABLE 3: Clinical characteristics of KP.2* SARS-CoV-2 variant in Maharashtra**

## Discussion

JN.1 remains the most frequently reported VOI globally, though its prevalence has declined from 56% in Week 18 to 47.1% in Week 21. Conversely, its descendant lineages, KP.2 and KP.3, have shown increasing prevalence, rising to 22.7% and 22.4% in Week 21 from 14.6% and 13% in Week 18, respectively [6]. Early analysis of KP. 2's relative effective reproductive number (Re) using sequences from the USA, UK, and Canada indicated that the KP.2 Re exceeded that of JN.1 by 1.22 times in the USA, 1.32 times in the UK, and 1.26 times in Canada. Also, the Re of KP.2.3 (a sub-lineage of KP.2) was higher than that of KP.2. KP. 2's three substitutions in the S protein compared to JN.1 potentially contributed to its increased viral fitness. This analysis predicted KP.2's rise to global dominance, a position it reached in the UK by early April 2024 (prevalence of 20%) [9]. The KP.2* variant currently shows a global relative growth advantage of 30% (confidence interval 29-30%) [10]. Similarly, KP.2*'s relative growth advantage in India is 22% (confidence interval 19-25%) [11].

Further, a study by Kaku et al. supports the findings on the enhanced immune evasion and increased reproductive number (Re) of KP.2. They showed that KP.2 exhibited greater resistance to neutralization than the parental JN.1 [9]. Neutralization titers against KP.2.3 were 2.0-fold to 2.9-fold lower than those for JN.1 [12]. Another study investigated the JN.1-derived subvariants for their susceptibility to neutralization by sera from infected/vaccinated individuals, as well as monoclonal antibodies (Mabs). The study found that the three FLiRT mutations - L455S, F456L, and R346T - altered the epitopes targeted by therapeutic Mabs, reducing the sensitivity to neutralization by sera and Mabs [4]. Notably, KP.2.3 displayed higher pseudovirus infectivity and stronger immune resistance than KP.2. This highlights the crucial role of Ser31del mutation in enhancing infectivity and immune evasion capabilities among variants having the said mutation [12].

Kaku et al. also found that the infectivity of the KP.2 pseudovirus in human HOS-ACE2/TMPRSS2 cells was significantly lower than JN.1 [12]. Homology modeling indicated that the L455S and F456L mutations reduce the binding of spike protein to ACE2 receptors. However, the additional R346T mutation in the FLiRT and KP.2 variants strengthened the conformational stability of the receptor-binding motif, counteracting the effects of L455S and F456L mutations [4]. The R346T mutation increased receptor-binding affinity by

approximately 50% and pseudovirus infectivity by around 40% [13].

The study highlights significant fluctuations in SARS-CoV-2 clinical testing and the positivity rates. January 2024 experienced the highest volume of tests and confirmed cases, yet the positivity rate remained comparatively low. Conversely, June 2024 saw the lowest testing volume but the highest positivity rate, suggesting that these figures may not accurately represent the actual disease burden within the community. The WHO has also indicated that trends in reported cases and deaths should be interpreted cautiously, as factors like reduced testing, sequencing, and reporting delays can distort actual figures across various regions [6]. Additionally, the data from Pune city, which had the most KP.2 cases in this study, shows a lower clinical detection of positive cases from February to April 2024 (Figure *5*). However, analysis of wastewater samples from the Pune metropolitan region revealed that by April 2024, the KP.2.X variant had appeared as the predominant variant in wastewater (Figure *7*) [8]. Also, the global wastewater surveillance data suggests that clinical testing might underreport the actual disease burden by approximately 2-19 times [6]. Therefore, relying solely on case-based surveillance may not suffice for the timely identification of novel variants. Broader, population-level surveillance strategies, particularly wastewater-based surveillance, are essential.

The study tracks the appearance and spread of the KP.2 variant in Maharashtra and India and provides a comprehensive description of the clinical characteristics associated with the variant. However, it suffers from a few limitations. Primarily, the study's findings rely on data from individuals who underwent COVID-19 testing, had their samples sequenced and consented to participate in the study. This means the results may not fully capture the true extent of the disease. As the study focuses solely on data from Maharashtra, its applicability to other regions and populations with different demographic profiles may be limited. Also, the clinical data were collected through telephonic interviews, which could introduce recall bias in the study. Therefore, further studies must be conducted to improve accuracy and representativeness to include broader geographic areas and populations.

## Conclusions

The KP.2* variant has emerged as the dominant SARS-CoV-2 variant in India, causing symptoms such as fever, cold, cough, sore throat, body ache, and fatigue. Although these symptoms were generally not severe, the variant's increased transmissibility and ability to evade immune responses underscore the virus's ongoing adaptability. Our study highlights the critical need for genomic surveillance based on clinical cases. With declining active surveillance SARS-CoV-2 testing rates, innovative surveillance methods like wastewater monitoring help to accurately assess the true burden of COVID-19. The study underscores that both of these epidemiological methods enable the public health authorities to forecast, mitigate, and prepare for potential outbreaks more effectively.

## Appendices

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**TABLE 4: IDs of the sequences used in the study**

Downloaded from the Indian Biological Data Centre (IBDC), Regional Centre for Biotechnology, Department of Biotechnology, Ministry of Science and Technology, Government of India, with their permission.

| **Demographic Data** | |
|---|---|
| 1. Sample ID | |
| 2. Patient Name | |
| 3. Gender | |
| 4. Age (in years) | |
| 5. Phone No | |
| 6. District of Residence | |
| 7. Sample collection date | |
| 8. SARS-CoV-2 Variant | |
| **Clinical Data** | |
| 1. Presence of Symptoms | 1. Present 2. Absent |
| a. Fever | 1. Yes 2. No |
| b. Cold | 1. Yes 2. No |
| c. Cough | 1. Yes 2. No |
| d. Sore throat | 1. Yes 2. No |
| e. Breathlessness | 1. Yes 2. No |
| f. Headache | 1. Yes 2. No |
| g. Runny Nose | 1. Yes 2. No |
| h. Weakness | 1. Yes 2. No |
| i. Myalgia | 1. Yes 2. No |
| j. Body ache | 1. Yes 2. No |
| k. Vomiting | 1. Yes 2. No |
| l. Diarrhea | 1. Yes 2. No |
| m. Loss of Taste | 1. Yes 2. No |

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| n. Loss of Smell | 1. Yes 2. No |
| o. Other Symptoms (If Any) | |
| 2. Presence of Co-morbidities | 1. Present 2. Absent |
| What Co-morbidities present | |
| 3. Home isolation | 1. Yes 2. No |
| 4. Hospitalization/ Institutional Quarantine | 1. Yes 2. No |
| 5. Oxygen requirement | 1. Yes 2. No |
| a. Non-Invasive | 1. Yes 2. No |
| b. Invasive (Intubation) | 1. Yes 2. No |
| 6. History of Previous Infection | 1. Yes 2. No |
| 7. Travel history | 1. Yes 2. No |
| 8. Vaccine Taken | 1. Yes 2. No 3. Not Applicable |
| 9. Vaccine name | 1. Covishield 2. Covaxin 3. Pfizer 4. Others |
| a. Dose 1 Taken | 1. Yes 2. No |
| b. Dose 2 Taken | 1. Yes 2. No |
| c. Booster (Precautionary) Dose Taken | 1. Yes 2. No |
| 10. Type of Treatment received? | 1. Symptomatic (Antipyretics, multivitamins, antihistaminic) 2. Oxygen therapy 3. Steroids 4. Antivirals 5. Monoclonal Antibodies 6. Others (Specify) |
| 11. Outcome | 1. Alive 2. Dead |

**TABLE 5: Questionnaire template used for the telephonic interview**

# Additional Information

## Author Contributions

All authors have reviewed the final version to be published and agreed to be accountable for all aspects of the work.

**Concept and design:** Rajesh P. Karyakarte, Rashmita Das, Varsha Potdar

**Acquisition, analysis, or interpretation of data:** Rajesh P. Karyakarte, Rashmita Das, Bhakti Kulkarni, Marie Joy, Mansi Mishra, Kalyani Jagarwal, Preeti Pawar, Damini More, Gilbert Chamy, Viswanathan DV, Sushma Yanamandra, Nyabom Taji, Jyoti Gurav, Varsha Potdar, Suvarna Joshi, Jyoti Bhagat

**Drafting of the manuscript:** Rajesh P. Karyakarte, Rashmita Das, Varsha Potdar

**Critical review of the manuscript for important intellectual content:** Rajesh P. Karyakarte, Rashmita Das, Bhakti Kulkarni, Marie Joy, Mansi Mishra, Kalyani Jagarwal, Preeti Pawar, Damini More, Gilbert Chamy, Viswanathan DV, Sushma Yanamandra, Nyabom Taji, Jyoti Gurav, Varsha Potdar, Suvarna Joshi, Jyoti Bhagat

**Supervision:** Rajesh P. Karyakarte, Rashmita Das, Sushma Yanamandra, Nyabom Taji, Varsha Potdar

## Disclosures

**Human subjects:** Consent was obtained or waived by all participants in this study. Institutional Ethics Committee, Byramjee Jeejeebhoy Government Medical College, Pune issued approval BJGMC/IEC/Pharmac/ND-Dept 0721233-233. Institutional Ethics Committee has unanimously approved your project topic. **Animal subjects:** All authors have confirmed that this study did not involve animal

subjects or tissue. **Conflicts of interest:** In compliance with the ICMJE uniform disclosure form, all authors declare the following: **Payment/services info:** All authors have declared that no financial support was received from any organization for the submitted work. **Financial relationships:** All authors have declared that they have no financial relationships at present or within the previous three years with any organizations that might have an interest in the submitted work. **Other relationships:** All authors have declared that there are no other relationships or activities that could appear to have influenced the submitted work.

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