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Incidence of breakthrough COVID-19 infection following non-mRNA vaccination among healthcare workers in educational hospitals in northeastern Iran

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Abstract

Background: While vaccines provide substantial protection against COVID-19, breakthrough infections remain a concern. This study aimed to determine the Incidence rate of post-vaccination COVID-19 infections among healthcare workers at teaching hospitals in Gorgan, Northeast Iran between 2020 and 2021.

Methods: In this cross-sectional study, we enrolled all 527 healthcare workers who had received at least one dose of non-mRNA COVID-19 vaccines. Vaccination data were systematically recorded and analyzed. COVID-19 infection was laboratory-confirmed by RT-PCR testing.

Results: The mean age of participants was 35.3±9.8 years. Breakthrough infections occurred in 255 participants (48.4%) after primary vaccination (First and second doses) and in 36 cases (6.83%) following booster doses. Incidence rates were significantly higher among internal medicine and infectious disease staff (p=0.006). Temporal analysis revealed peak infection incidence within 4 months post-primary vaccination, with the lowest rates observed >4 months post-booster administration.

Conclusion: While breakthrough infections occurred in a substantial proportion of participants after primary vaccination, booster doses were associated with significantly lower infection rates. Further research is needed to assess the impact of vaccination status on disease severity.

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Highlights

What is current knowledge?

- COVID-19 vaccines significantly reduce the risk of severe disease and hospitalization, but breakthrough infections can still occur, particularly with emerging variants and in high-exposure settings such as healthcare environments.
- Most available real-world data on vaccine effectiveness and breakthrough infections come from studies on mRNA vaccines, with limited evidence from non-mRNA platforms, especially in the Middle East.
- Healthcare workers are at increased risk of exposure to SARS-CoV-2, making them a priority population for vaccine evaluation and infection surveillance.

What is new here?

- This study provides the first estimate of the incidence rate of breakthrough COVID-19 infection (48.4%) among healthcare workers in northeastern Iran who received exclusively non-mRNA vaccines (Sinopharm, AstraZeneca, Sputnik V, Barekat, Bharat).
- It demonstrates that infection rates were significantly higher among staff in internal medicine and infectious disease wards, highlighting occupation-specific risk even after vaccination.
- Temporal analysis revealed that the highest incidence of breakthrough infections occurred within four months after primary vaccination, while the lowest rates were observed more than four months after booster doses, offering insight into the timing of infection risk in this population.

Introduction

The emergence of SARS-CoV-2 in Wuhan, China, in December 2019 marked the beginning of an unprecedented global public health crisis (1). Within months, COVID-19 evolved into a pandemic, with the World Health Organization (WHO) reporting over 213 million confirmed cases and 4.4 million deaths worldwide by August 2021 (2,3). The virus's rapid transmission dynamics, coupled with significant morbidity and mortality, necessitated urgent containment strategies across all affected nations (4).

Iran emerged as one of the most severely impacted countries in the Eastern Mediterranean region (5). The first confirmed case was reported in Qom on February 19, 2020, with subsequent exponential spread throughout the country (6). By September 2021, Iran ranked ninth globally in COVID-19-related mortality per capita,size, reflecting the substantial burden on its healthcare system (7). This high disease burden persisted despite implementation of various non-pharmaceutical interventions, including travel restrictions, social distancing measures, and mask mandates (8).

Vaccination has been established as the cornerstone of pandemic control, offering the most effective means to reduce severe outcomes and interrupt transmission chains (9,10). Current evidence demonstrates that COVID-19 vaccines significantly decrease hospitalization rates and mortality, with estimated effectiveness ranging from 65% to 95% against severe disease depending on the vaccine platform and circulating variants (11,12). However, growing clinical observations indicate that vaccination does not provide absolute protection against infection, particularly with the emergence of immune-evading variants of concern (13,14).

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The immunogenicity profile of vaccines varies substantially across platforms. Non-mRNA vaccines, such as CoronaVac (Sinovac) and BBIBP-CorV (Sinopharm), utilize. inactivated whole SARS-CoV-2 virions containing structural proteins (S, N, M, and E), These vaccines typically induce broader antibody responses compared to spike protein-targeted mRNA vaccines (15,16). Nevertheless, recent serological studies reveal that only 23-28% of breakthrough cases following inactivated virus vaccination demonstrate anti-N antibody responses, suggesting limited viral replication and antigen exposure despite vaccination (17,18). This pattern contrasts markedly with the robust humoral responses observed following natural infection, which typically generate antibodies against multiple viral antigens (19,20).

Healthcare workers (HCWs) represent a critical population for COVID-19 surveillance due to heightened exposure risk and pivotal role in maintaining healthcare system capacity (21,22). Numerous studies have documented increased susceptibility among HCWs, with infection rates 3-5 times higher than the general population in some settings (23,24). Vaccination programs for HCWs have therefore been prioritized globally as both a protective measure for frontline workers and a strategy to preserve healthcare capacity (25).

Iran initiated its national vaccination program in February 2021, with HCWs among the first eligible immunization (26). The primary vaccines deployed were non-mRNA platforms, including BBIBP-CorV (Sinopharm) and Gam-COVID-Vac (Sputnik V), administered as two intramuscular doses (27). While these vaccines demonstrated satisfactory safety profiles and immunogenicity in clinical trials, critical gaps remain in our understanding of their real-world performance. Existing research on breakthrough infections often lacks granularity in key areas: it seldom quantifies risk across hospital departments with varying exposure intensities, offering limited comparative analysis of primary versus booster dose effectiveness in high-risk cohorts, and rarely integrating temporal patterns of infection with local epidemic waves. Furthermore, data from the Middle East, particularly on the effectiveness of these specific vaccine platforms, remains scarce. This study addresses these gaps by examining the incidence and characteristics of breakthrough COVID-19 infections among HCWs at tertiary care teaching hospitals in Gorgan, Northeast Iran, during the peak vaccination period from February to September 2021.

Our investigation provides a quantitative assessment of breakthrough infection rates stratified by specific hospital departments, a direct comparison of infection risk following primary vaccination versus booster doses within the same high-risk cohort, and an integrated analysis of infection patterns relative to vaccination timing and local epidemic trajectories. By generating this context-specific evidence on the performance of non-mRNA vaccines in a high-exposure setting, our findings will directly inform targeted booster strategies, optimize infection control protocols, and contribute vital data from the Middle East to the global body of knowledge on vaccine effectiveness.

Methods

This cross-sectional study was conducted after obtaining approval from the University's Research Council and acquiring an ethical approval (Code: IR.GOUMS.REC.1400.289). The study population consisted of all staff working at the Shahid Sayad Shirazi and 5th Azar Educational Hospitals in Gorgan, Northeastern Iran. We used a census approach, inviting all 540 staff members; 527 consented and were enrolled (Response rate: 97.6%). We confirmed COVID-19 infections via positive RT-PCR assay, rapid antigen testing, chest CT, or characteristic clinical symptoms.

For analysis, we operationally defined breakthrough infection as an incident SARS-CoV-2 infection confirmed by positive RT-PCR occurring at least 14 days after completion of the primary vaccination series or 14 days after a booster dose, regardless of symptoms.

This definition aligns with established CDC and WHO criteria for vaccine breakthrough events.

Positive RT-PCR results served as the diagnostic gold standard for case confirmation. Although rapid antigen tests, chest CT scans, and clinical symptoms were recorded as supplementary data, these indicators alone were insufficient for primary confirmation due to specificity concerns and potential recall bias. We consequently excluded participants lacking RT-PCR confirmation, those with uncertain vaccination dates, or individuals with unreliable recall of symptom onset. This approach ensured objective diagnostic standards.

Trained interviewers collected all data using structured checklists during private hospital interviews to ensure confidentiality. Demographic information included age, sex, occupation, and hospital department, alongside underlying medical conditions such as hypertension and diabetes. We documented vaccine type and corresponding dates for all administered doses, and assessed prior infection history. Post-vaccination infection dates were recorded where applicable, alongside clinical outcomes categorized as outpatient management or hospitalization. For breakthrough cases specifically, we additionally documented dates of both symptom onset and positive RT-PCR confirmation.

This study utilized five vaccine platforms; AstraZeneca (Chimpanzee adenovirus vector), Sinopharm (Inactivated whole virus), Epotic-V (Deficient adenovirus-5 vector), Bharat (Inactivated whole virus), Barekat also used inactivated whole virus.

All collected data were analyzed in SPSS version 21 (IBM Corp., Armonk, NY, USA). Descriptive statistics are presented as mean ± standard deviation (SD) for continuous variables. Categorical variables appear as frequencies (Percentages). Normality testing utilized the Kolmogorov-Smirnov test.

We applied independent samples t-tests to normally distributed continuous variables. This included age comparisons between infected and non-infected groups. Mann-Whitney U tests assessed non-normally distributed data, specifically age comparisons between mild and severe disease groups.

Categorical associations were examined using Chi-square tests, with Fisher's exact test reserved for expected cell counts less than 5. Post-vaccination infection status was analyzed against age group, sex, underlying diseases, hospital department, and number of vaccine doses received. Disease severity outcomes (Outpatient vs. hospitalization) were similarly examined in relation to vaccine doses, underlying diseases, and hospital department.

Time to infection analyses compared proportions occurring within versus after 4 months between recipients of 1-2 doses versus 3 doses. Statistical significance was set at $p < 0.05$.

Results

The study included 527 hospital staff members who had received at least one vaccine dose, with a mean age of 35.3 ± 9.8 years. Female participants comprised 387 (73.4%) of the cohort. Regarding vaccination status, 460 individuals (87.3%) received two doses and 236 (44.8%) received three doses.

COVID-19 infection following vaccination was reported in 255 participants (48.4%), occurring after the first, second, or third dose. Among these infected individuals, 126 (49.4%) could recall the specific interval between vaccination and infection onset; notably, 78 cases (61.9%) occurred within four months' post-vaccination. Table 1 presents the detailed timing of infection relative to each vaccine dose.

Analysis of infections following the third dose specifically revealed that, 19 individuals (52.8%) were infected within two months, 10 (27.8%) between two and four months, and 7 (19.4%) after more than four months.

Table 1. Frequency distribution of the time interval between COVID-19 vaccination and infection

Time to COVID-19 infection after vaccination	Dose 1 n (%)	Dose 2 n (%)	Dose 3 n (%)	Total n (%)
Less than 2 months	13 (34.2%)	9 (17.3%)	19 (52.8%)	48 (32.5%)
2 to 4 months	7 (18.4%)	20 (38.5%)	10 (27.8%)	37 (29.4%)
More than 4 months	18 (47.4%)	23 (44.2%)	7 (19.4%)	48 (38.1%)
Total	**38 (30.2%)**	**52 (41.3%)**	**36 (28.6%)**	**126 (100%)**

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Multiple infections were documented in some participants, with 18 individuals (14.3%) experiencing two separate episodes after the first and second doses, six (4.8%) after the first and third doses, and 10 (7.9%) after the second and third doses.

Sociodemographic and clinical factors

Age distribution showed that 41.2% of participants were under 30 years old. Table 2 presents post-vaccination COVID-19 infection frequencies across age groups; the difference among groups was not statistically significant (p = 0.675). Mean age was 34.85 years among those infected and 35.66 years among those not infected (p = 0.40). Overall, participants (68.9%) were under 40 years of age.

Post-vaccination infection was reported by 73.4% of females and 26.6% of males. The frequency of infection by gender is detailed in Table 3, showing no statistically significant association (P = 0.349).

Among participants, 102 (19.4%) had underlying diseases, with hypertension (4.0%) and diabetes (3.0%) being most common. COVID-19 infection occurred in 207 (48.7%) of those without underlying diseases versus 48 (47.1%) of those with underlying diseases, with no significant difference between groups (p = 0.765).

Hospital department and vaccination status

Significant differences in infection rates were observed across hospital departments (p = 0.001). The highest proportion of infections (40.4%) occurred among staff in general wards (e.g., infectious diseases, internal medicine; Table 4).

The number of individuals infected after the first and second vaccine doses was significantly higher than those infected after three doses (p = 0.003). Time-to-infection analysis revealed that after the first and second doses, 54.5% of infections occurred within four months and 45.5% after four months following the third dose (Full vaccination series), 80.6% of infections occurred within four months and only 19.4% after four months. Accordingly, the highest proportion of infections occurred within four months following the first and second doses. Conversely, the lowest proportion occurred after four months following the third dose (p = 0.006; Table 5).

Vaccine type and disease severity

Regarding the association between the types of vaccine administered (First and second doses) and the incidence of post-vaccination infection, the infection rates were 61.1% for Barekat, 49.5% for Sinopharm and Sputnik-V, and 47.2% for AstraZeneca. This difference was not statistically significant (p = 0.19). Similarly, the type of vaccine used for the third dose showed no significant association with infection rates (p = 0.18).

Regarding disease severity, cases (242 [94.9%]) were managed as outpatients. Outpatient management rates were 94.1% following the first dose, 95.5% following the second, and 94.6% following the third. No significant association was found between the number of vaccine doses and disease severity (p = 0.182). These findings indicate that even a single dose provided substantial protection against severe disease. Hospitalization was required for 13 individuals (5.1%).

Because age data were non-normally distributed, the Mann-Whitney U test was used; no significant difference in median age was observed between mild and severe disease groups (p = 0.32).

Among those with mild disease, 199 (82.2%) had no underlying disease, whereas 43 (17.8%) did. Among 13 patients with severe disease, 8 (61.5%) had no underlying disease, and 5 (38.5%) had underlying disease. Although the prevalence of underlying diseases was higher in the severe disease group, this difference was not statistically significant (p = 0.07).

Finally, most individuals with both mild and severe disease worked in general wards. No significant association was found between disease severity and the hospital department of employment (p = 0.08).

Table 2. Frequency of COVID-19 infection after at least one vaccine dose, by age group

Post-vaccination COVID-19 infection	< 30 years n (%)	30-39 years n (%)	40-49 years n (%)	≥ 50 years n (%)	Total n (%)	P-Value Chi-squared test
Yes	108 (42.4%)	74 (29.0%)	59 (23.1%)	14 (5.5%)	255 (48.4%)	0.675
No	109 (40.1%)	72 (26.5%)	72 (26.5%)	19 (7.0%)	272 (51.6%)	
Total	**217 (41.2%)**	**146 (27.7%)**	**131 (24.9%)**	**33 (6.3%)**	**527 (100%)**	

Table 3. Frequency of COVID-19 infection after at least one vaccine dose, by gender

Post-vaccination COVID-19 infection	Male n (%)	Female n (%)	Total n (%)	P-Value Chi-squared test
Yes	63 (24.7%)	192 (75.3%)	255 (48.4%)	0.349
No	77 (28.3%)	195 (71.7%)	272 (51.6%)	
Total	**140 (26.6%)**	**387 (73.4%)**	**527 (100%)**	

Table 4. Frequency of COVID-19 infection after at least one vaccine dose, by hospital department

Post-vaccination COVID-19 infection	General wards n (%)	ICU n (%)	Surgical wards n (%)	Other* n (%)	Total n (%)	P-Value Chi-squared test
Yes	103 (40.4%)	81 (31.8%)	62 (24.3%)	9 (3.5%)	255 (48.4%)	0.001
No	87 (32.0%)	81 (29.8%)	69 (25.4%)	35 (12.9%)	272 (51.6%)	
Total	**190 (36.1%)**	**162 (30.7%)**	**131 (24.9%)**	**44 (8.3%)**	**527 (100%)**	

*Other: Administrative, Service

Table 5. Association between the time to COVID-19 infection after vaccination and the number of vaccine doses received

Time to infection after vaccination	Doses 1 and 2 n (%)	Dose 3 n (%)	Total n (%)	P-Value Chi-squared test
Less than 4 months	49 (62.8%)	29 (37.2%)	78 (100%)	0.006
More than 4 months	41 (85.4%)	7 (14.6%)	48 (100%)	
Total	**90 (71.4%)**	**36 (28.6%)**	**126 (100%)**	

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Discussion

This study examined breakthrough COVID-19 infections among 527 healthcare workers who received non-mRNA vaccines at two teaching hospitals in Gorgan, Iran. The breakthrough infection rate was 48.4%, substantially higher than rates reported in other settings. For example, research among Israeli hospital staff reported a 2.6% infection rate after two mRNA vaccine doses (4), whereas a Belgian study found a rate of 1.2% among medical personnel following mRNA vaccination (5). This substantial discrepancy likely reflects differences in vaccine platforms, as our study used exclusively non-mRNA vaccines (Sinopharm, AstraZeneca, Sputnik V, Barekat, Bharat), whereas studies reporting lower breakthrough rates primarily evaluated mRNA vaccines. This observation aligns with evidence suggesting that mRNA vaccines may confer higher initial protection against infection compared to inactivated virus platforms (15).

Consistent with several previous investigations, we found no significant association between breakthrough infection and age, gender, or underlying comorbidities (12,13). The absence of an age effect may be attributable to the relatively narrow age range of our study population (Mean 35.3±9.8 years), which limits detection of age-related differences observed in studies encompassing broader age groups (6,7). Similarly, the lack of gender difference aligns with findings from Logunov et al. (9), though the literature on this topic remains inconsistent (8).

We found a significant association between hospital department and breakthrough infection risk (p=0.001). Staff working in general wards (Internal medicine and infectious diseases) had the highest infection rates, while administrative and service personnel had the lowest. This gradient likely reflects differential exposure intensity, as general wards admitted larger numbers of COVID-19 patients during the study period. The lower rates in surgical wards may be partially attributable to pre-operative screening protocols that identified and isolated infected patients, thereby reducing staff exposure. These findings underscore the importance of department-specific risk assessment and targeted infection control measures.

Concerning the timing of breakthrough infections, we observed that 61.9% occurred within four months. After the third (Booster) dose, infections clustered in the first two months (52.8%), with only 19.4% occurring after four months. Although this pattern might suggest waning immunity, the lack of an unvaccinated comparison group or serological data precludes definitive conclusions about vaccine-induced protection. Comparable temporal patterns have been reported, with some investigators reporting that infections occurring immediately post-vaccination may reflect pre-existing exposure or incomplete immune response rather than vaccine failure (21).

We observed no significant differences in breakthrough infection rates across non-mRNA vaccine platforms (p = 0.19 for first/second doses; p = 0.18 for third dose). This finding is consistent with a large Iranian cohort study demonstrating that all vaccine platforms significantly reduced mortality compared to unvaccinated individuals, with the authors advocating for vaccination based on availability rather than platform selection (19). However, the absence of mRNA vaccines in our study limits direct comparison with platforms associated with higher efficacy in other settings (15).

Concerning disease severity, 94.9% of breakthrough were managed as outpatients, with only 13 cases (5.1%) requiring hospitalization. While this low hospitalization rate may suggest that vaccination attenuates disease severity even when breakthrough infection occurs, our cross-sectional design without an unvaccinated control group prevents any causal inference about vaccine effectiveness against severe outcomes. The small number of severe cases (n=13) also limited statistical power to identify factors associated with hospitalization, though we observed a non-significant trend toward higher underlying disease prevalence in the severe group (38.5% vs. 17.8%, p=0.07).

Significantly higher infection rates among general ward staff underscore the importance of occupation-specific risk in healthcare settings. This finding has carried practical implications for hospital infection control policies, suggesting that departments with intensive COVID-19 patient contact may benefit from enhanced protective measures, prioritized booster vaccination, and more frequent screening, regardless of individual demographic or clinical characteristics.

This study has several limitations that should be considered when interpreting the findings. First, recall bias is a major concern, as approximately half of the participants (49.4%) could not accurately recall the exact time interval between vaccination and infection, and all data on vaccination dates, infection dates, and symptom onset were collected through interviews rather than verified against medical records or official documentation. This may have introduced substantial misclassification and inaccuracies in temporal analyses. Second, despite applying a standardized case definition, the initial diagnostic criteria were heterogeneous-including PCR tests, rapid antigen tests, CT scans, and clinical symptoms-which may have led to overestimation of breakthrough infections. Although we subsequently refined the inclusion criteria to require RT-PCR confirmation, this inconsistency in case ascertainment across the study period remains a limitation. Third, the study population was limited to healthcare workers from two teaching hospitals in a single city (Gorgan), which may limit the generalizability of findings to other regions or to the general population. Fourth, the relatively young age of participants (Mean 35.3 years) and the female predominance (73.4%) may not reflect the demographics of all healthcare worker populations. Fifth, we were unable to account for potential confounders such as community exposure outside the workplace, adherence to personal protective equipment (PPE) use, or circulating SARS-CoV-2 variants during the study period, all of which could influence breakthrough infection risk. Sixth, the sample size for severe disease outcomes was small (Only 13 hospitalized cases), limiting statistical power to detect associations with disease severity. Finally, as this was a cross-sectional study, we cannot establish causal relationships between vaccination and protection, and the absence of an unvaccinated control group precludes direct estimation of vaccine effectiveness.

Conclusion

This study documented a 48.4% cumulative incidence of breakthrough infection among 527 healthcare workers who received non-mRNA vaccines at two teaching hospitals in Gorgan, Iran. Infections occurred significantly more frequently among staff in general wards (Internal medicine and infectious diseases) compared with other departments (p = 0.001). Most cases were mild: 94.9% were managed as outpatients and only 5.1% required hospitalization. Temporal analysis revealed distinct patterns: infections following primary doses clustered within four months' post-vaccination, whereas infections after booster doses decreased significantly after four months. We observed no significant differences in infection rates across vaccine platforms, age groups, sex, or underlying disease status. These findings highlight the importance of department-specific risk assessment and continued infection control measures in hospital settings, regardless of vaccination status.

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Ethical Statement

This study was approved by the Ethics Committee of Golestan University of Medical Sciences (IR.GOUMS.REC.1400.289). All participants provided written informed consent. The study was conducted in accordance with the Declaration of Helsinki.

Conflicts of Interest

The authors declare that they have no conflicts of interest related to the content of this paper.

Author Contributions

S.E and F.M. conceived and designed the study. F.M., S.E., R.G., and N.B. were responsible for data acquisition and management. All authors contributed to the study design and provided critical revisions to the analysis and manuscript. F.M. and S.E. performed the data analysis, drafted the initial manuscript, and contributed to the study conception, analytical calculations, and data interpretation. All authors reviewed and approved the final version of the manuscript.

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Data Availability Statement

The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Use of Artificial Intelligence

AI-assisted tools were used solely for language editing. They were not involved in data analysis, the drafting of scientific content, the interpretation of results, or scientific decision-making.

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