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# HMDJ

## HITEC Medical and Dental Journal

### AIMS & SCOPE

HMDJ is the journal of HITEC Institute of Medical Sciences (HITEC-IMS), Taxila. It is an open access, peer-reviewed, bi-annual journal that aims to keep the medical & dental health professionals updated with the latest information relevant to their fields.

HMDJ welcomes scholarly work from medical, dental and allied subjects (basic & clinical), community health issues and medical education. It publishes original research, review articles, case reports, editorials, letters to editor, short communication, book reviews, recent advances, new techniques, debates, adverse drug reports, current practices, and conference reports. All publications of HMDJ are peer reviewed by subject specialists from Pakistan and abroad.

### OBJECTIVES

1. To publish original, peer reviewed clinical and basic sciences articles.
2. To promote research culture in HITEC-IMS and beyond, by inculcating the habit of medical writing in doctors.
3. To assist physicians to stay informed about the developments in their own & related fields.
4. To support knowledge & experience sharing among the health professionals for the benefit of the patients.
5. To attain top-notch ethical medical journalism by delivering credible and reader-friendly publications.



# HMDJ

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# IS YOUR CLINICAL RESEARCH ETHICAL?

Hamid Shafiq<sup>1</sup>, Irfan Shah<sup>2</sup>

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What makes clinical research ethical? What are the ethics of clinical research? Is your clinical research ethical? The institutional Ethical Review Boards (IRB) and ethics committees look at these questions and based on ethical considerations of your research proposal, either approve, recommend amendments, or reject your research proposal.

The primary objective of any clinical research is to ultimately improve human health through generation of new knowledge that could be applied to human beings at large. The research participants are exposed to the potential harmful effects of the experimental diagnostic tools, pharmaceutical agents, implants, or other agents. Due attention must therefore be paid to the well-being of the participants who volunteer in order to advance our knowledge by exposing themselves to such risks and harmful effects.

There are several examples in the history of clinical research where safety of the participants was neglected. In fact, several studies, including the Tuskegee Syphilis study, the Nazi medical experimentations, the Willowbrook State School study, and many others were outrightly against the basic human rights, unlawful and unethical, to say the least. These studies mainly exposed uninformed and unaware individuals to diseases or subjected them to unproven treatments. As an aftermath of these and similar studies and to prevent violations of basic human rights and ethical principles, the need for rules & regulations governing human research became evident.

The Nuremberg Code, the Declaration of Helsinki, the International Council on Harmonization–Good Clinical Practice (ICH-GCP) guidelines and all other codes, declarations and guidelines have attempted to design and develop ethical

guidelines to protect the research participants during the planning, implementation and follow-up of clinical research studies<sup>1-3</sup>. All these guidelines emphasize upon voluntary participation, informed consent, respect, beneficence, minimized risk, and independent review during the planning and implementation of research projects.

With this background, the title question remains the same: Is your clinical research ethical? If your research is as per principles of these guidelines? Emanuel et al in their commentary on what makes research ethical have summarized the above mentioned

and other guidelines and discussed seven requirements that determine whether your research is ethical<sup>4</sup>. These requirements are: (1) social and scientific value of research, (2) validity of the method (3) fair subject selection, (4) favorable risk-benefit ratio, (5) independent review, (6) informed consent, and (7) respect for enrolled and potential participants.

To be ethical, your research should carry social and / or scientific value by contributing to the understanding of health, prevention, diagnosis, and treatment of diseases to justify exposing humans to the risks and inconveniences of clinical research. Answer to the research question should be sought using rigorous and correct research

methodology. Representative subjects should be selected after seeking informed consent, keeping in mind the risks and benefits of participating in the research. An independent review board or committee should look into all aspects of the research, identifying and addressing all ethical issues. From the moment they are recruited until their involvement is complete, all prospective and enrolled research participants should be treated with respect. This would entail monitoring their welfare and notifying them of the research's findings, as well as respecting their right to privacy, change of mind, and withdrawal from the study. If your research proposal takes care of the above, go ahead, it is ethical. If not, re-think and re-plan before taking any other steps.

## CAPSULE SUMMARY

When clinical research prioritises participants' well-being, receives informed consent, maintains a favourable risk-benefit balance, and employs rigorous scientific procedures, it is considered ethical. Independent review boards verify that ethical rules are being followed. Researchers must respect the rights and privacy of participants, and their studies must have scientific or societal value.

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# INCIDENCE OF COVID-19 DISEASE OCCURRENCE FOLLOWING VACCINATION; A CROSS-SECTIONAL ANALYTICAL STUDY

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## ABSTRACT

**Objective:** To determine the frequency of COVID-19 disease occurrence after vaccination administration in Pakistani population.

**Design:** Cross-sectional (Analytical).

**Place and Duration of Study:** Combined Military Hospital, Quetta, 3 months (June to August 2021).

**Patients and Methods:** The study was carried out after the approval by the ethical review committee of this tertiary care institute of Pakistan. Inclusion criteria adhered to 18–65 years old individuals who had been vaccinated against COVID-19. American Society of Anesthesiologists status I & II, hemodynamically stable patients were recruited in the study with optimized comorbid. After making the study protocol clear to the participants, their informed, written consent was taken. Variables for analysis included demographic profile, comorbid, vaccination history, and adverse effects experienced after vaccination. Participants were inquired about the approximate duration that elapsed after vaccination if the disease occurred, total days taken for illness resolution and PCR test results to become negative, disease severity, and symptoms of COVID-19 disease experienced after vaccination.

**Results:** Total 256 vaccinated individuals were enrolled in this study, out of which 50% were medical professionals while the remaining half were from a non-medical background. One hundred and fifty-four (60.2%) were males and 102 (39.8%) were females. After vaccination, 36 (14.1%) experienced COVID-19 infection, half (18) of these participants, developed the disease after 2-3 months of vaccination. Medical professionals were found to be more likely to encounter COVID-19 infection after getting vaccinated, as compared to non-medical professionals ( $p < 0.001$ ).

**Conclusion:** The occurrence of COVID-19 disease after vaccination was low. A bigger number from the medical profession contracted the disease, despite being vaccinated as compared to non-medical individuals. This shows that similar to other vaccinations, COVID-19 vaccination also has some failure rate but it still dispenses benefits to the maximum population. Therefore, vaccination inoculation, in addition to the precautionary measures, should be encouraged in the Pakistani population to pave the way to the middle of the road.

**Key words:** COVID-19, Incidence, Vaccination.

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## INTRODUCTION

COVID-19 has been implicated for the enormous global loss in terms of mortality, economic recession, social life disruption, and parting ways between countries globally which

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lead to endeavours and voyages in the quest for safe vaccine development and administration<sup>1,2</sup>.

World Health Organization (WHO) released the early data about COVID-19 vaccines on Nov 12, 2020. Total 212 vaccines from the following groups were under trial: the attenuated/inactivated, the traditional, genetically engineered recombinant adenovirus vectors, Ribonucleic acid (RNA) vaccines, recombinant viral vector vaccine, and Deoxyribonucleic acid (DNA) vaccines<sup>3,4</sup>.

Discerning the COVID-19 genome has accelerated researchers' struggles to the evolution across 300 vaccination programs, in various phases of clinical trials. Forty are in the clinical evaluation stage, 10 are in phase III clinical trials, and 3 have been

declared successful to trans pass stage III trial evaluations<sup>5,6</sup>.

Ida Mousten, a Danish epidemiologist experimented with Pfizer-BioNTech in health care workers outside clinical trials and elucidated it to be effective in 90% of participants<sup>7</sup>.

As per studies, reported vaccine efficacy of various brands, available in the market, are for: Moderna 94.5% after 14 or more days of 2nd dose, Pfizer 94.2% after 14 or more days of 2nd dose, AstraZeneca 81.5% after 14 or more days after 2nd dose, Johnson & Johnson one dose vaccination efficacy is 66% globally and 72% in the United States, Novavax 89.3% after seven or more days after 2nd dose, Sputnik V 91% after 21 days of 1st dose, Sinovac 50.7% without any timespan reports, and Sino pharm 78.1% with an estimated follow up of 112 days<sup>8,9,10</sup>.

As yet vaccinations of Sinopharm, Sinovac, CanSino-Bio, and Sputnik companies have been administered to the Pakistani population. The 2.47 million doses of Oxford-AstraZeneca have been acquired for immunization of approximately 1.24 a million high-risk population<sup>11</sup>.

This study was done with an objective to estimate the frequency of COVID-19 disease occurrence after vaccine administration and gauge vaccination failure in the population of Pakistan.

## MATERIAL AND METHODS

The present study was a cross-sectional, analytical study, done from June 2021 to August 2021 after its approval by the ethical review committee of The Tertiary Care Institute, Pakistan. The sample size calculated for this study was 255, calculated with a 95% confidence interval & 5% margin of error, with the open epi calculator. Hypothesized efficacy of Sinopharm (Majority of patients were vaccinated with Sinopharm in Pakistan) was considered to be 79% $\pm$ 5, as reported by WHO trials<sup>12,13</sup>. A non-probability consecutive sampling was done. Total 256 participants comprised general population and healthcare workers who volunteered for the study, without any specific randomization. Inclusion criteria adhered to were 18–65 years old individuals; medical, and non-medical professionals, vaccinated against COVID-19, PCR negative, and American Society of Anesthesiologists status I & II, individuals with hemodynamical stability and optimized comorbid. Excluded from this study were: who did not consent, pregnant women, individuals with decompensated diabetic or hypertensive profiles, asthmatics, immunocompromised people, age > 65 years, those with axillary temperature >37°C, individuals with any drug allergies, the ones who had a contraindication to vaccination, and those with a BMI > 35 Kg/m<sup>2</sup>. Moreover, exclusion criteria also adhered to individuals having a high-risk epidemiologic history within 14 days before enrolment

(e.g., travel to high-risk areas or abroad, contact history with any individual infected with SARS-CoV-2) with a negative PCR test results at the time of execution of the study.

Regarding the study protocol, all participants underwent interviews, were apprised and guided, counselled regarding the procedure, and informed, written consent from them was obtained. Vaccinated/unvaccinated status and details were confirmed by taking history, and breakthrough infection was affirmed with PCR analysis. A proforma (paper-based) was developed with the pertinent literature. Variables included demography (age, sex, profession), COVID-19 disease history before vaccination, comorbid conditions (Diabetes Mellitus, Asthma, Hypertension, Ischemic Heart Disease), vaccination history, adverse effects experienced after vaccine, injection site (redness, soreness, and swelling), in addition to other symptoms like fever or chills & rigors, fatigue/malaise, headache, gastrointestinal symptoms, and flu-like

symptoms. It was also asked whether the participants got their serum antibodies tested after the vaccine administration or not? Participants were inquired about the approximate duration that elapsed after vaccination in case the disease occurred, total days took for illness resolution and PCR test results to become negative, disease severity (mild, moderate and severe), and symptoms of COVID-19 disease experienced by them after vaccine administration (fever, chill and rigors, fatigue and malaise, headache, gastrointestinal disturbances, flu-like symptoms, shortness of breath, loss of smell and taste). The mild disease shows mild symptoms accompanied by fever, cough, and change in taste or smell. There is no dyspnea or Inflammation in the mild stage of the disease. Pneumonia can be observed in a few cases and mortality rate is low. The moderate disease includes lower respiratory tract infection (clinical and radiographic evidence) where the oxygen saturation is  $\geq$ 94%. Mild Inflammation is also observed. Severe disease shows shortness of breath, respiratory rate of  $\geq$  30 beats/minute. Oxygen saturation at the resting state is  $\leq$ 93%, and arterial partial pressure of oxygen (PaO<sub>2</sub>)/inspired oxygen concentration is (FiO<sub>2</sub>)  $\leq$ 300 mmHg. Significant inflammation is observed and mortality rate is high.

Using the IBM SPSS software (version 23.0) data were entered & analyzed. The illustrative statistics of categorical data which included age groups, gender, profession, COVID-19 history, side effects after vaccination, occurrence of infection after vaccination, and symptoms were presented as frequencies and percentages. Post-vaccination occurrence of COVID-19 infection was the outcome variable, which was compared among categorical groups encompassing profession, gender and age, along with the comorbidities by utilizing the Chi-Square test. A p-value of  $\leq$ 0.05 was taken to be statistically significant.

**CAPSULE SUMMARY**

A cross-sectional study was conducted to investigate the occurrence of COVID-19 disease after vaccination. The occurrence was minimal following vaccination. A higher number of medical personnel contracted the disease as compared to non-medical individuals. Like other vaccinations, COVID-19 immunization has some failure rate but still provides advantage to people at large.

## RESULTS

A total count of 256 vaccinated participants engaged in this study, where half of the participants were medical professionals while the remaining half were from a non-medical background. Out of 256, 154 (60.2%) were of male gender and 102 (39.8%) were of female gender. Majority of the contributors, 142 (55.5%) fell in the age group of 36-45 years, whereas 72 (28.1%) in the age group of 25-35 years, 42 (16.4%) had the age above 45 years. It was reported that 4 (1.6%) participants suffered from COVID-19 infection before getting vaccinated. Side effects followed by COVID vaccination were experienced by 36 (14.1%) vaccine recipients. The most common side effect included soreness [28/36 (77.7%)], followed by fever [18/36 (50.0%)], and fatigue/malaise [18/36 (50.0%)]. Demographic features of the participants have been précised in Table 1.

**Table 1: Summary of demographic characteristics of study participants (n=256)**

Demographics	Profession	
	Medical n=128 (%)	Non-medical n=128 (%)
<b>Age group</b>		
• 26-35 years	38 (29.7)	34 (26.6)
• 36-45 years	70 (54.7)	72 (56.3)
• >45 years	20 (15.6)	22 (17.2)
<b>Gender</b>		
• Male	80 (62.5)	74 (57.8)
• Female	48 (37.5)	54 (42.2)
<b>History of comorbid</b>		
• Hypertension	0 (0)	2 (1.6)
• Asthma	4 (3.1)	0 (0)
<b>History of COVID-19 before vaccination</b>		
• Yes	4 (3.1)	0 (0)
• No	124 (96.9)	128 (100)
<b>Experienced side effects after vaccination</b>		
• Yes	32 (25.0)	4 (3.1)
• No	96 (75.0)	124 (96.9)
<b>Type of side effect (n=36)</b>		
• Soreness	24/32 (66.6)	4/4 (100)
• Fever	18/32 (56.2)	0 (0)
• Chills / Rigors	4/32 (12.5)	0 (0)
• Fatigue / Malaise	18/32 (56.2)	0 (0)
• Headache	12/32 (33.3)	0 (0)
• Flu-like symptoms	2/32 (6.2)	0 (0)

None of the participants reported having checked the antibody titer following the COVID vaccination. After vaccination, 36 (14.1%) experienced COVID-19 infection, where the majority of the participants, 18/36 (50.0%) developed the disease after 2-3 months of vaccination. The disease lasted for 7-14 days in most of the cases, 24/36 (66.6%), who suffered from COVID-19 after vaccination and experienced mild/moderate symptoms. Moderate-Severe symptoms were experienced by 4/36 (11.1%) of the infected participants as given in Table 2. Fever [34/36 (94.4%)] was the most common symptom experienced by infected participants, followed by fatigue/malaise [32/36 (88.8%)], headache [24/36 (66.6%)] and gastrointestinal disturbance [24/36 (66.6%)] as shown in Table 2.

A remarkable association was observed between the occurrence of post-vaccination COVID-19 infection and profession. Medical professionals were observed to have been more likely to develop COVID-19 infection after getting vaccinated as compared to non-medical professionals (p<0.001). The majority of medical professionals had COVID-19 infection after 2-3 months of vaccine administration as compared to their counterparts (p=0.004). Moderate-severe symptoms were also more likely to be experienced by medical professionals as compared to non-medical professionals (p=0.001). Other comparisons are depicted in Table 2 in detail.

Table 3 shows that no significant association was found between the occurrence of post-vaccination COVID-19 and age group or gender. Whereas the history of co-occurring conditions was tracked to be correlated with the occurrence of infection. Participants with comorbidities such as hypertension and asthma were more likely to develop COVID-19 infection post-vaccination (p<0.001). Similarly, those who had a history of COVID-19 infection previously were more likely to develop COVID-19 infection again after vaccination (p=0.037). Last but not the least, those who were found to have experienced side effects after vaccination were also more prone to develop post-vaccination COVID-19 infection (p<0.01) as given in Table 3.

## DISCUSSION

The spate of COVID-19 led to global challenges resulting in a surge of emerging vaccines in order to mitigate the effects<sup>14</sup>. The vaccine is of utmost importance for the front liners and is effective in 95% of cases either limiting the disease progression or even eliminating it, as quoted by Moghadas et al<sup>15</sup>. Our study proposes a decreased disease occurrence post-vaccination thus a reduction in hospital admissions and morbidity with other safety methods under consideration is achieved.

The B.1.617.2 (delta) variant, initially dredged out in India in December 2019, was the most common variant in patients with SARS-COV-2 in April 2020, with a worldwide spread. Meagre information is yet available about the effectiveness of the COVID-19 vaccine on delta variants<sup>16</sup>. In our study, disease prevalence after vaccination was observed more in healthcare workers. Angel et al organized a study at Tel Aviv Sourasky Medical Center where a reduction of 85% of cases was detected

**Table 2: Occurrence of COVID-19 infection among vaccinated study participants**

	Overall n=256 (%)	Profession		p-value
		Medical n=128 (%)	Non-medical n=128 (%)	
<b>Occurrence of COVID-19 infection</b>	36 (14.1)	28 (21.9)	8 (6.3)	<0.001
<b>Duration after infection occurred</b>				
• <1 month	8 (22.2)	6 (21.4)	2 (25.0)	0.004
• 1-2 months	4 (11.1)	2 (7.1)	2(25.0)	
• >2-3 months	18 (50.0)	16 (57.1)	2(25.0)	
• >3 months	6 (16.6)	4 (14.2)	2 (25.0)	
<b>Duration of the infection period(days)</b>				
• 1-7	4 (11.1)	4 (14.2)	0 (0)	0.001
• >7-14	24 (66.6)	16 (57.1)	8 (100)	
• >14	8 (22.2)	8 (28.5)	0 (0)	
<b>Severity of illness</b>				
• Mild	8 (22.2)	4 (14.2)	4 (50.0)	0.001
• Moderate	24 (66.6)	20 (71.4)	4 (50.0)	
• Severe	4 (11.1)	4 (14.2)	0 (0)	
<b>Symptoms</b>				
• Fever	34 (94.4)	28 (100.0)	6 (75.0)	<0.001
• Chills / Rigors	24 (66.6)	22 (78.5)	2 (25.0)	<0.001
• Fatigue / Malaise	32 (88.8)	24 (85.7)	8 (100)	0.001
• Headache	24 (66.6)	22 (78.5)	2 (25.0)	<0.001
• GI disturbance	24 (66.6)	24 (85.7)	0 (0)	<0.001
• Flu-like symptoms	8 (22.2)	8 (28.5)	0 (0)	0.001
• Breathlessness	8 (22.2)	6 (21.4)	2 (25.0)	0.002
• Anosmia	6 (16.6)	4 (14.2)	2 (25.0)	0.001
• Ageusia	14 (38.8)	12 (42.8)	2 (25.0)	0.001

**Table 3: Association of occurrence of COVID-19 infection after vaccination with other demographic and clinical characteristics**

	Occurrence of infection		p-value
	Yes n=36 (%)	No n=220 (%)	
<b>Age group (Years)</b>			
• 26-35	10 (27.8)	62 (28.2)	0.998
• 36-45	20 (55.6)	122 (55.5)	
• >45	6 (16.7)	36 (16.4)	
<b>Gender</b>			
• Male	22 (61.1)	132 (60.0)	0.900
• Female	14 (38.9)	88 (40.0)	
<b>History of comorbid</b>			
• Hypertension	2 (5.6)	0 (0)	<0.001
• Asthma	4 (11.1)	0 (0)	
<b>History of COVID-19 before vaccination</b>			
• Yes	2 (5.6)	2 (0.9)	0.037
• No	34 (94.4)	218 (99.1)	
<b>Experienced side effects after COVID vaccination</b>			
• Yes	28 (77.8)	8 (3.6)	<0.001
• No	8 (22.2)	212 (96.4)	

post-vaccination <sup>17</sup>. In our study, antibody titers were not performed in any of the participants, this is a pondering moment that depicts the effectiveness of vaccine therapeutically<sup>18</sup>. In a study by Thompson et al performed during the initial stages of vaccination strategy in 8 different locations concluded a lowering of risk for infection communicability due to mild symptoms post-vaccination. We were also of the opinion at the end of our study that the communicability risk lowered post-vaccination in both, asymptomatic or late symptomatic people, which is important for healthcare workers' (HCWs) protection <sup>19</sup>.

Another emerging confusion post-vaccination is COVID-19 like symptoms which at times are considered post-vaccine side effects but should not be disregarded by the clinicians and the

affected should be tested for COVID-19. This was also depicted by a study conducted in Sheba Medical Center by Amit et al where co-occurrence along with re-occurrence was observed in HCWs<sup>20</sup>.

The study of Amit and Regev-Yochay et al. emphasized that in mass vaccination programs, the second dose can be slowed down when faced with a shortage of vaccines. This strategy could help in the acceleration of the national vaccination program<sup>21</sup>. In general, the slope of COVID-19 incidence generally in the population and specifically in healthcare workers went downwards post-immunization. This was also supported by a study conducted by Domi and Leitson et al. in NHS at a vaccine clinic where supporting staff and resident hospital workers presented in low numbers with the disease <sup>22</sup>.

Results of this study have elucidated that frequency of disease occurrence was greater in medical professionals despite being vaccinated, therefore exposure is still considered to be the most important factor. Getting vaccination and being immunized is no doubt the need of the hour, but unfortunately, this has transmitted a wave of incautious attitudes among the population therefore it is mandatory for the government to propagate information and knowledge among the masses. Moreover, emphasis on taking precautionary measures such as wearing masks, and avoiding overcrowding should not be denied.

### CONCLUSION

The occurrence of COVID-19 disease after vaccination was low. Medical professionals were more prone to this disease despite being vaccinated as compared to non-medical individuals. This shows that similar to other vaccinations COVID-19 vaccination also has some failure rate, still providing benefits to the maximum population. Therefore vaccine inoculation, in addition to precautionary measures, should be encouraged in the Pakistani population to pave the way to the middle of the road.

### RECOMMENDATIONS

The government should make endeavours to make availability of other brands of vaccination as well and vaccines should be available easily in the market for the acquisition of every individual. Moreover, since the virus has shown rapid mutations in different communities and parts of the world, we should make sincere efforts to develop our own vaccination, based on strains in the Pakistani population.

### AUTHORS' CONTRIBUTION

Beenish Abbas	Conception and design, Drafting the Article, Critical revision
Sana Abbas	Conception and design
Nasar Um Min Allah	Analysis and interpretation of data, Drafting the Article
Hina Ishaq	Acquisition of data, Critical revision
Khadija Tahira	Acquisition of data
Fahmeed Akhtar	Conception and design, Critical revision

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# PERCEIVED BARRIERS FOR DELAY IN AGE-APPROPRIATE VACCINATION AMONG CHILDREN ATTENDING A TERTIARY CARE HOSPITAL OF RAWALPINDI

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## ABSTRACT

**Objective:** To determine the frequency of delay in age-appropriate vaccination, association between the delay and demographic variables along with the perceived barriers associated with it.

**Design:** Descriptive, Cross-sectional study.

**Place and Duration of Study:** Department of Pediatrics, Fauji Foundation Hospital, Rawalpindi, 6 months (April to Oct 2022).

**Patients and Methods:** Four hundred children, up to 2 years of age, having their vaccination card were included in the study via convenience sampling. Questionnaire was used to evaluate the frequency of delay in age appropriate vaccination along with the perceived barriers for delay. Data were entered and analysed in SPSS 26. To evaluate the association between delay and sociodemographic factors, the Chi square test was performed.

**Results:** Overall, 21.2% of the children received at least one of the vaccines after the recommended time. Most prevalent delayed vaccine was Penta 1, OPV 1. Significant relationship between mother's age and BCG, OPV0, and Penta 1, OPV 1 with mother's age, distance from health facility, and occupation of father was observed (p-value 0.05). Statistically significant association was also found between Penta 3, OPV 3 with education of parents and occupation of father. Parents' transportation issue (29.8%) and distance from facility (25.5%) were the two most common perceived barriers.

**Conclusion:** Current study showed improvement in age appropriate vaccination as compared to previous studies. In order to increase age-appropriate coverage, vaccination initiatives should address the identified impediments.

**Key words:** : Age-appropriate vaccination, Delay, Perceived barriers, Tertiary hospital .

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## INTRODUCTION

Childhood diseases can be effectively prevented and their impact on health and lives reduced through the cost-efficient measure of vaccination <sup>1</sup>. To successfully address vaccine-preventable diseases (VPDs), extensive vaccination coverage with highly efficient vaccinations is required. The World Health Organization (WHO) aims to achieve a 90% coverage rate for childhood immunization <sup>2</sup>. The Expanded Programme on Immunization (EPI)'s success relies not only on achieving high coverage but also on ensuring the timely administration of vaccines. In particular, age-appropriate immunization during the 1st year of life is vital as the antibodies from the mother decline fast <sup>3</sup>. Failure to achieve this, can lead to reduced

immunity in children which result in the outbreaks of VPD <sup>4,5</sup>.

Despite the impressive progress made in optimizing immunization coverage, the struggle for vaccinating children continues throughout parts of the world, usually in the poorest of countries <sup>6</sup>. The COVID-19 pandemic has had a substantial impact on healthcare systems, leading to disruptions that resulted in 25 million children missing out on immunization in 2021. This number is a 5.9 million increase from 2019 and the worst decline since 2009. About 81% (105 million) newborns received 3 doses of the Diphtheria-Tetanus-Pertussis (DTP3) vaccine in 2021, shielding them from infections that can have detrimental effects like illness, disability, or death <sup>7</sup>.

A study conducted in sub-Saharan Africa revealed a significant proportion of children experiencing delays in vaccination by at least one month <sup>8</sup>. In research carried out in India, it was found that a significant percentage of children aged 10 to 23 months experienced delayed vaccination. Specifically, 23.1% of children had delayed BCG vaccination, 29.3% had delayed administration of the first dose of DPT vaccine, and 34.8% had delayed measles vaccination <sup>9</sup>.

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EPI Pakistan currently offers all children from birth to 15 months of age free protection against nine distinct avoidable antigens. In Pakistan, the EPI coverage for BCG is 80%, for DPT3 and polio3, it is 65%, and with measles, it is 67%. Despite the fact that immunisation rates for complete fundamental vaccines have been increasing in Pakistan as a result of the EPI, a sizable portion of kids (45%) in Pakistan do not receive immunisations that are age-appropriate<sup>10</sup>. According to a JW Noh study in Sindh, 20.8% of children who received complete vaccination) got all doses on time<sup>11</sup>. According to research conducted in the peri-urban area of Karachi, a concerning 55% of infants experienced delayed age-appropriate vaccination<sup>12</sup>.

Infectious disease outbreaks in children, such as meningitis, diarrheal disease, and pneumonia, may be caused by a lack of age-appropriate vaccinations. Therefore, it is crucial to take into account both the coverage rate and the timeliness of vaccination in order to maximise the benefits of the vaccination programme. Monitoring the status of age-appropriate vaccination and identifying the primary contributing factors is paramount to increasing vaccination coverage and ultimately reducing infant morbidity and mortality.

### OBJECTIVES

To determine the frequency of delay in age-appropriate vaccination and to determine association between delay and demographic variables along with perceived barriers associated with it in children visiting the Pediatrics department.

### MATERIAL AND METHODS

This descriptive cross-sectional study was conducted on children/caretakers attending reporting to vaccination centre of Fauji Foundation Hospital Rawalpindi from April to Oct 2022. Convenient sampling was used to include children up to 2 years old (who had their vaccination cards) in the study, but children

who were in a paediatric intensive care unit (PICU), required ventilator support for respiratory distress, or had a relative or absolute contraindication to live vaccines in accordance with WHO standard vaccination guidelines were excluded from the study. Study had the approval of the Institutional Ethical Review Committee.

### CAPSULE SUMMARY

The frequency of delayed age-appropriate vaccination, the relationship between the delay and demographic characteristics, and the perceived difficulties associated with it were investigated. An improvement in age-appropriate immunisation, compared to prior research was observed. Mother's age, distance from the health facility, father's work, transportation problems and facility distance were the most prevalent impediments. Vaccination campaigns should address these constraints in order to increase age-appropriate coverage.

The percentage of children who got immunisation for a given vaccine more than 4 weeks after the prescribed age was used to define the delay in age-appropriate vaccination<sup>9</sup>. Delay was observed for OPV, BCG, Penta valent and measles. Recommended as well as minimally acceptable ages for routine immunization in the EPI Pakistan is given in Table 1.

A self-administered structured pretested questionnaire translated into Urdu was used to collect data. The questionnaire consisted of four sections. Section 1 describes sociodemographic characteristics including age, gender, ethnicity, residence, type of family, distance from the health facility. Section 2 inquired about maternal factors such as maternal age, education, occupation, and vaccination during pregnancy. Section 3 consisted of paternal factors such as age, education, occupation was included. Section 4 consisted of data regarding perceived barriers for delay in vaccination.

SPSS 26 was used for data analysis, and the results were given as frequencies as well as percentages. In order to compute the association between delay and demographic variables, Chi-square test was employed.

### RESULTS

Total number of participants in the study was 400. Mean age of children was found to be 9.69 with standard deviation of 8.18.

Almost half of the sample was male i.e, 205(51.2%), 200(50%) were Punjabi and 80(20%) were Urdu speaking. Out of total sample, 289(72%) were resident of urban area, 320(80.3%)

**Table 1: Recommended & minimum acceptable ages for routine immunizations in the EPI in Pakistan**

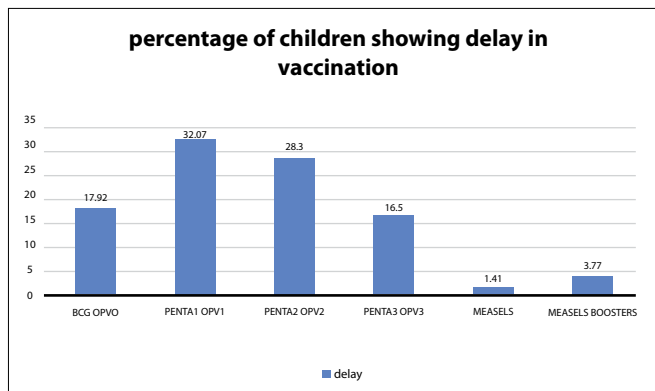
Vaccine	Minimum age	Recommended	Timely (Days)	Early (Days)	Late (Days)
OPVo, BCG	At birth	0 week/0 day	0-28	-	>23
OPV1, Penta 1	6 weeks	6 weeks/42 days	39-70	<39	>70
OPV2, Penta 2	10 weeks	10weeks/70 days	67-98	<67	>98
OPV3, Penta 3	14 weeks	14 week/98 days	95-126	<95	>126
Measles	26 weeks	39 weeks/273 days	270-301	<270	>301

children had distance of more than 2 km from medical facility, 192(48%) belonged to joint family system and 263(66%) having family income of greater than 25000 rupees. Table 3 showed maternal and paternal characteristics.

Overall 84(21.2%) of the children had delayed vaccination of at least one of the studied vaccines. Most prevalent delayed vaccine was Penta 1, OPV 1 as shown in Figure 1.

**Table 2: Sociodemographic characteristics of respondents**

Characteristics	Frequency	Percentage
<b>AGE OF MOTHER(Years)</b>		
19-24	47	11.8
25-29	213	53.3
>30	140	35
<b>EDUCATION OF MOTHER</b>		
Illiterate	47	11.8
Equal or less than 10 years of education	129	32.3
More than 10 years	224	56
<b>OCCUPATION OF MOTHER</b>		
Employed	139	34.8
Unemployed	261	65.3
<b>TETANUS VACCINATION DURING PREGNANCY</b>		
Vaccinated	371	92.8
Unvaccinated	29	7.2
<b>AGE OF FATHER(Years)</b>		
19-24	13	3.3
25-29	105	26.3
>30	282	70.5
<b>EDUCATION OF FATHER</b>		
Illiterate	25	6.3
Equal or less than 10 years of education	110	27.5
More than 10 years	265	66.3
<b>OCCUPATION OF FATHER</b>		
Employed	338	84.5
Unemployed	62	15.5



**Figure 1: Children with a delayed age-appropriate vaccination according to vaccine**

Significant relationship between mother’s age and BCG OPV0 was observed (p-value 0.05). Statistically significant relationship was found between Penta 1, OPV 1 and mother’s age, distance from health facility, and occupation of father. Statistically significant association was found between Penta 3, OPV 3 with education of parents and occupation of father. Significant association between delay in vaccine with sociodemographic, and sociodemographic factors is given in Table 3.

**Table 3: Association between delay in age-appropriate vaccination with sociodemographic variables**

Variables	On time	Delayed	p-value
<b>BCG, OPV 0</b>			
<b>AGE OF MOTHER(Years)</b>			
19-24	37	5	0.02
25-29	190	6	
< 30	130	4	
<b>PENTA 1, OPV 1</b>			
<b>AGE OF MOTHER(Years)</b>			
19-24	30	10	0.000
25-29	156	10	
<30	107	7	
<b>OCCUPATION OF FATHER</b>			
Employed	242	18	0.04
Unemployed	51	9	
<b>DISTANCE FROM HEALTH CLINIC</b>			
Less than 2 km	57	0	0.011
More than 2 km	236	26	
<b>PENTA 2, OPV 2</b>			
<b>EDUCATION OF MOTHER</b>			
Illiterate	28	6	0.04
Equal to or less than 10 years of schooling	90	4	
Greater than 10 years of schooling	109	14	

Table 3 continued...

Variables	On time	Delayed	p-value
<b>PENTA 3, OPV 3</b>			
<b>EDUCATION OF MOTHER</b>			
Illiterate	22	8	0.0000
Equal to or less than 10 years of schooling	82	0	
Greater than 10 years of schooling	94	6	
<b>EDUCATION OF FATHER</b>			
Illiterate	11	3	0.031
Equal to or less than 10 years of schooling	64	6	
Greater than 10 years of schooling	123	5	
<b>OCCUPATION OF FATHER</b>			
Employed	158	6	0.001
unemployed	40	8	
<b>MEASELS</b>			
<b>AGE OF MOTHER (Years)</b>			
19-24	12	1	0.003
25-29	84	0	
<30	68	0	
<b>EDUCATION OF MOTHER</b>			
Illiterate	21	1	0.03
Equal to or less than 10 years of schooling	65	0	
Greater than 10 years of schooling	78	0	

Education of the mother was mostly significant with all OPV and Penta vaccines, Age of mother showed association with BCG, Penta 1 OPV 1 and Measles.

According to parents' transportation issue 119(29.8%) and

distance from facility 103 (25%) are the two most common perceived barriers as shown in Figure 2.

### DISCUSSION

For the purpose of evaluating children's health, identifying trends, and planning intervention programmes, an accurate estimate of vaccination coverage is required. The current study evaluates the significant gaps from the most recent vaccination status while analysing risk factors for delaying age- appropriate vaccination. According to this hospital-based cross-sectional survey, 21.2% of patients in our study received delayed immunisation. Mustafa A's study in Karachi found that 36.3% (127) children were immunised at the recommended age <sup>10</sup>. In contrast, a study by Noronha et al. in a rural area of Goa found that 31% of vaccinations were postponed and 69% were administered on schedule <sup>13</sup>.

According to a research done by JW Noh in Sindh, 20.8% children got all immunizations according to the recommended schedule of the children who received complete basic vaccinations<sup>11</sup>.

In our study two main reasons for delay were transportation issues (29.2 %) and distance from health facility (25.5%). According to a study conducted in India, delayed vaccination is more common when it takes longer than 30 minutes to get from home to the immunization centre (74.5%) than when it takes less time (67.2%) <sup>14</sup>. According to the study, delays in immunization were most frequently caused due to parent-related factors. In our study 32.07% children reported with delays in pentavalent 1 and OPV 1 related to the age of mother (25%) and illiteracy of mother (26.6%). In our study 16.5 % children reported with delay in Penta 3/OPV3 vaccine related to illiteracy of parents and unemployment of father as the major risk factors. The findings of a study carried out in Rwanda by Nwankwo et al. revealed similar findings, which showed a significant relationship between education level and immunization status <sup>15</sup>. Two hundred and sixty one mothers in our study were unemployed and there was significant delay in vaccination status of their children as compared to the

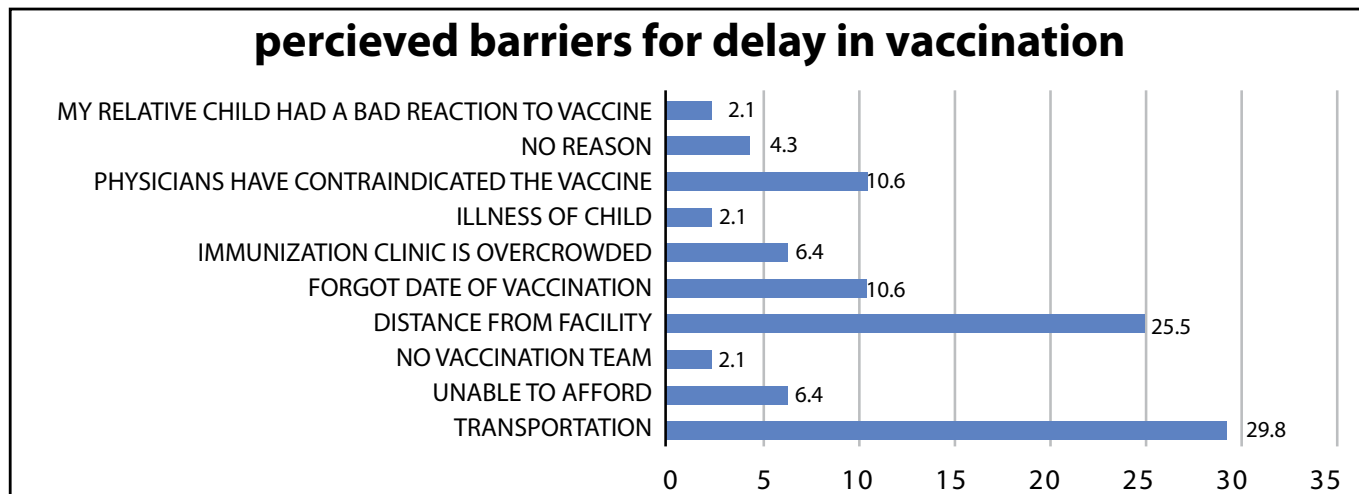


Figure 2: Perceived barriers for delay in age-appropriate vaccination

children of employed mothers<sup>15</sup>. These results were comparable to those of a research by Alrowaili et al. in Northern Saudi Arabia, which showed that 31.7% of children of stay-at-home mothers and 9.3% of children of working mothers had delayed immunization<sup>16</sup>.

Delay in BCG vaccination in our study was 18% and the main factor related with delay in BCG OPV0 was also mother’s age group. According to a study that has been published in the literature, delayed vaccination was more common among women under the age of 25 (72.1%) than moms over the age of 25 (67.1%)<sup>14</sup>.

In this study, only 1.41% children had delay in measles vaccination. In our study regarding measles, the predominant factors turned out to be age and education of the mother. It is more likely that a mother or other caregiver will vaccinate the child at the prescribed interval if she attends formal education. This conclusion, which is in line with the results from Ethiopian<sup>17</sup> and Indian<sup>9</sup> studies, suggesting that the mother/caregiver participation in proper education lowers the likelihood of late immunization. It could be that, being more educated it is easier for mothers and other caregivers to communicate with medical professionals, which affects how conscious they are of using and seeking out public health services like child vaccination<sup>17</sup>.

Additionally, having enough understanding about vaccinations improves the likelihood that the child will receive the appropriate series of vaccinations. In a similar manner, research conducted in North East Ethiopia<sup>18</sup> and central Ethiopia<sup>19</sup> revealed that inadequate vaccination knowledge aggravated the deferral in vaccination at the advised intervals. The possibility of decreasing unpleasant thoughts (adverse reaction) about childhood vaccinations as a result of information may be one factor, which would enhance practise and timeliness. In our study one factor for delay was also after listening an adverse reaction to vaccination from someone (2.1%). Additionally, the likelihood of immunizing kids on time will increase if parents are aware of the vaccination schedule and reasons for immunization<sup>19</sup>.

About 10.6% of parents, in our study, forgot about date of vaccination in our study. Literature suggested that interventions to remember or recall patients are typically deemed to be quite helpful at increasing immunization rates, and the most successful outreach techniques are those that use telephones. In order to increase vaccination rates, other methods (such as sent letters or postcards) should be used in addition to telephone outreach<sup>20</sup>.

### CONCLUSION

Overall 21.2% of the children had delayed vaccination as per recommended time of at least one of the studied vaccines. Significant relationship between mother’s age and BCG OPV0 was observed (p-value 0.05), Penta 1, OPV 1 delay was significant with mother’s age, distance from health facility,

and occupation of father. Statistically significant association was found between Penta 3, OPV 3 with education of parents and occupation of father. Parents’ transportation issue (29.8%) and distance from facility (25%) were the two most common perceived barriers.

### RECOMMENDATIONS

This study highlighted that a significant number of children received vaccinations beyond the recommended age, indicating the importance of addressing timely administration of vaccines alongside overall coverage.

Mothers/caregivers should be promptly aware on the highlighted variables through a realistic programme in order to follow the advised schedule. Policymakers should concentrate on and include the indicators of vaccine timeliness monitoring in order to improve children's immunological health.

### AUTHORS’ CONTRIBUTION

Mehwish Riaz	Conception and design, Acquisition of data, Analysis and interpretation of data, Critical revision
Fatima Farahi	Conception and design, Acquisition of data, Drafting the Article
Azalfa Malik	Conception and design, Acquisition of data, Analysis and interpretation of data, Drafting the Article
Sana Shaukat Siddiqui	Analysis and interpretation of data, Critical revision
Sana Matloob	Analysis and interpretation of data, Acquisition of data, Drafting the Article
Maham Israr Abbasi	Acquisition of data, Drafting the Article

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# FREQUENCY OF WHITE SPOT LESIONS AFTER FIXED APPLIANCE THERAPY IN A TERTIARY CARE HOSPITAL OF PESHAWAR

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## ABSTRACT

**Background:** Enamel demineralization is one of the key issues faced by clinicians during orthodontic therapy. White spot lesions (WSLs) appear on the surface of enamel when proper oral hygiene instructions are not followed during the treatment process.

**Objective:** To determine the association of white spot lesion frequency with orthodontic treatment time.

**Design:** Descriptive, Cross-sectional study

**Place and Duration of Study:** Department of Orthodontics, Peshawar Dental College, Peshawar. 12 months (February 1<sup>st</sup> 2022 to January 31<sup>st</sup> 2023).

**Materials and Methods:** Eighty orthodontic patients were picked according to inclusion criteria. They were divided in 3 groups based on treatment time, <2, 2-3 and >3 years. All subjects were examined immediately after removal of the appliances, both visually and photographically, to minimize the risk of false positive and negative results. On the basis of the extent of demineralization, patients were scored into 4 groups according to the number of WSLs.

**Results:** Patients who developed at least one WSL were 42%, 44% and 70% in the groups <2 years, 2-3 years & >3 years, respectively. The group <2 years and 2-3 years had no significant difference but group >3 year was statistically significant.

**Conclusion:** The study concluded that not following proper oral hygiene during orthodontic therapy will lead to the development of WSLs on enamel. The clinicians should ensure proper oral hygienic conditions during the early days of treatment to avoid complications. If required, extra measures must be taken into consideration in order to avoid demineralization.

**Key words:** Dental Caries, White Spot Lesions, Oral Hygiene, Orthodontic Appliances, Fixed, Orthodontic Brackets.

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## INTRODUCTION

White spot lesions (WSLs) are milky white opacities that arise from subsurface enamel porosity due to carious demineralization<sup>1</sup>. Secondary appearance of WSLs after orthodontic treatment is among the major issues faced by clinicians<sup>2</sup>. Poor oral hygienic condition during orthodontic treatment leads to demineralization of enamel and consequently accumulation of plaque on the brackets<sup>3,4</sup>. Fix appliances are believed to make it difficult for the orthodontic patients to keep up the standard oral hygiene. Additionally, they cause more plaque to remain on teeth, typically less susceptible to developing caries<sup>5</sup>.

Rapid shifts occur in the normal flora of the plaque when fixed orthodontic appliances are applied to the patient<sup>6</sup>. Plaque is occupied by bacteria that produce high level of volatile fatty acids and ferment sugar which lowers the pH in orthodontic patient as compared to non-orthodontic patient. Bacteria that occupy the plaque are usually Lactobacilli and Streptococcus mutans<sup>7</sup>. Presence of acidogenic bacteria results in the fast progression of caries in fixed orthodontic appliances. Caries development usually takes six months, but in the case of orthodontic treatment, it takes about 1 month for the appearance of WSLs<sup>8,9</sup>. WSLs are usually observed over buccal surfaces of teeth, around brackets, frequently in gingiva<sup>10</sup>.

During early days, carious lesions appear clinically as white opaque spots on the enamel surface. These spots are slightly softer in nature as compared to the surrounding enamel<sup>11</sup>. Demineralization of enamel occurs in two stages, surface softening and subsurface lesions. During surface softening, the interprismatic substances are removed, including minerals on the surface of enamel. Bacterial fermentation also plays an important role by lowering the pH that ultimately results in minerals loss<sup>12</sup>. In the second stage, subsurface lesion, minerals dissolution mainly occurs in the deeper regions of enamel. A

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porous layer covering the low mineral lesion are the WSLs that are considered to be the precursors of enamel caries<sup>13</sup>.

The development of WSLs is more prevalent in orthodontic treated individuals as compared to normal subjects. A study conducted by Julien et al reported 23.4% of the subjects having at least one WLSs after the treatment<sup>14</sup>. Another study reported the development of WSLs in 50% of the patients after orthodontic treatment<sup>15</sup>. The prevalence of WSLs varies depending on the technique used in examination. Anterior maxillary teeth are more prone to WSLs as compared to mandibular teeth. Most of the studies did not report the gender-wise prevalence study on WSLs<sup>16,17</sup>. The incidence of WSLs can vary depending on the material being used for bonding i.e. either composite or Resin Modified Glass Ionomer Cement (RMGIC)<sup>18</sup>. Use of fluoride toothpaste, gel, mouthwash, varnishes, bonding agent RMGICs, probiotic, polyols, antiseptics, sealants, casein supplements, laser, dental whitening, micro-abrasion, and resin penetration, among other methods, can be used for prophylaxis and management<sup>19</sup>. Fluoridated toothpaste and Casein Phosphopeptide-Amorphous Calcium Phosphate (CPP-ACP) paste have been seen to be effective after three follow-ups in reducing white spot lesions, while fluoridated toothpaste was observed to be more effective during the trial<sup>20</sup>.

Association of WSLs and fixed orthodontics treatment has been studied in Pakistan. A study reported that WSLs were present in 75% of the 60 patients, affecting 19% of the teeth overall. Upper lateral incisors were the most often impacted teeth (78.3%), while WSLs of the chalky white variety were more prevalent (76.2%). The most often impacted area was the middle part of the upper anterior teeth's crown<sup>21</sup>.

Studies have reported the prevalence of WSLs during orthodontic treatment, but after treatment prevalence is not reported from Pakistan. This study was carried out with the objective to determine the association of WSLs frequency with time of orthodontic treatment<sup>22,23,24</sup>.

## MATERIAL AND METHODS

The Institutional Review Board (IRB), Prime Foundation, Pakistan (Prime/IRB/2022-415), granted the ethical approval for this study. An informed written consent was taken by the participants. This descriptive, cross-sectional study was done at Peshawar Dental College where 80 orthodontic patients were selected according to inclusion criteria from February 1<sup>st</sup> 2022 to January 31<sup>st</sup> 2023. The formula  $n=2(Z_{\alpha}+Z_{1-\beta})^2\sigma^2/\Delta^2$  was used to calculate the sample size<sup>19</sup>. Post-treatment records of the patients who met the inclusion criteria were sorted out.

Both, male and female patients, previously treated in orthodontic department and having a complete previous treatment record, were included in the study.

Patients who were currently under-treatment, those with missing previous medical record and who are on daily supplemental regimen of fluoride were excluded from the study. Those who refused to take part were also excluded.

Schedule was searched for the patients meeting the inclusion criteria at the commencement of every weekend. Patients who had previously undergone orthodontic treatment in the orthodontic department, Peshawar medical college, were asked if they were willing to participate or not. A written, informed consent was taken from all subjects. Participants underwent measurements, using a standard edgewise light wire technique, by the same clinician who was involved with the patient during the entire orthodontic therapy. Patients were evaluated after removal of auxiliary and wire attachments. All the examinations were recorded on the patient examination form. According to the orthodontic treatment duration, the patients were divided in 3 groups (<2, 2-3 and >3 years).

To obtain the physical and numerical record of the teeth under examination, photography of the teeth was performed using Canon EOS 850D (Rebel T8i) camera. Dental photography enables the clinician to share the data with other experts for better diagnosis. Photography was performed using ring flashlight and camera with macro lens and lens replacement.

Before the measurements, maxillary teeth were isolated from 2<sup>nd</sup> right premolar to the 2<sup>nd</sup> left premolar, using the rolls of cotton and were air-dried for 5 seconds. Surfaces of the teeth, close to arch wires of orthodontic treatment, were examined for WSLs because these areas are more exposed to demineralization. Scoring system that was proposed by Mizrahi and Gorelick et al was used during clinical examination<sup>3,17</sup>. Scoring was done using a dental lamp with direct illumination. The proposed scoring criteria were specifically used for Premolars, anterior teeth vestibular surfaces, and the first molars in mandible and maxilla.

**Score 0** = No visible surface disruption or WSLs (no demineralization)

**Score 1** = WSLs that cover < 1/3<sup>rd</sup> of the surface or WSLs without surface disruption (mild demineralization)

**Score 2** = WSLs >1/3<sup>rd</sup> of the tooth surface or with surface disruption (moderate demineralization)

**Score 3** = WSLs with cavitation or requiring restoration (severe demineralization)<sup>20</sup>.

## CAPSULE SUMMARY

Prevalence of the white spot lesions (WSLs) after fixed appliances treatment was determined. Patients were grouped according to treatment time. The percentage of the patients who developed at least one WSL varied between 42% to 70% in different groups. Poor oral hygiene during orthodontic therapy led to the development of WSLs on enamel. Good hygienic conditions should be ensured through the initial days of therapy to avoid complications.

Data were analyzed by SPSS (Version 20.0, SPSS Inc. Chicago). Descriptive statistics were used to calculate mean, standard deviation (SD), and percentages. Frequencies and mean ± SD of WSLs among the groups were compared by using chi-square test, Fischer’s exact test & Anova test respectively. Any p- value that was ≤ 0.05, held significance.

## RESULTS

There were three subject groups analyzed for enamel demineralization in the study. The <2 years group comprised 26 subjects (15 male and 11 female), it contained the individuals who had undergone for less than two years of orthodontic treatment. The second group was the 2-3 years group that contained 34 individuals (19 male and 15 females), which included the individuals who were treated in orthodontic department for 2-3 years duration. The third group were the >3 years group of 20 subjects (10 male and 10 female), who were treated for more than three years in orthodontic department.

Table 1 shows the frequency of WSLs in the three groups of individuals. The WSLs recorded in group <2 years were 42% while 58% were the individuals with no WSLs. In group 2-3 years, WSLs was recorded in 44% and 56% had no WSLs. Age group >3 years had WSLs in 70%, which was higher as compared to the other two groups. Regarding frequency of WSLs, no significant difference was seen between group <2 years and 2-3 years (p-value > 0.05) but group >3 year had statistically significant difference (p-value 0.03).

Second group is the 2-3 years group that contains 34 individuals (19 male and 15 females), it includes the individuals treated in orthodontic department for 2-3 years duration. The third group are the >3 years group of 20 subjects (10 male and 10 female), that were treated for more than three years in orthodontic department.

Table 1 shows the frequency of WSLs in the three groups of individuals. The WSLs recorded in group <2 years were 42% in which 58% were the individuals with no WSLs. In group 2-3 years, the frequency of WSLs was recorded to be 44% and with no WSLs it was 56%. Age group >3 years had 70% WSLs which is higher as compared to the remaining two groups. The group <2 years and 2-3 years had no significant difference but group >3 year had statistical significance (p-value 0.03).

**Table 1: Shows frequency of the patients with white spot lesions <sup>a</sup>**

Groups	Total patients	No WSLs n (%)	With WSLs n (%)
<2 years	26	15 (58%)	11 (42%)
2-3 years	34	19 (56%)	15 (44%)
>3 years	20	06 (30%)	14 (70%)

<sup>a</sup> the <2 years group and group 2-3 years show low prevalence of WSLs. These groups have no significant difference. >3-year group have the highest prevalence of WSLs (p =0.03).

Table 2 delves into the distribution of WSLs on enamel. In group <2 years, the mean number of WSLs recorded was 1.15 ± 0.21. 1-3 WSLs were recorded in 10 patients which is 38% of the total group patients and 1 patient (4%) had more than 4 WSLs. In the group 2-3 years, the mean number of WSLs was recorded as 0.89±0.29 in which 19 patients (56%) were found with no WSLs on tooth enamel. Eight patients (24%) were observed having 1-3 WSLs on the tooth enamel and 7 patients (20%) with more than 4 WSLs. Group >3 years was exceptional in comparison with the other two groups where mean number of WSLs was observed as 1.38±0.18. Six subjects were found with no WSLs and 9 (45%) were found to have 1-3 WSLs. Five (25%) were observed with more than 4 WSLs on tooth enamel.

**Table 2: The distribution of WSLs in each patient group <sup>b</sup>**

Group	Mean of WSLs(±SD)	No WSLs n (%)	1-3 WSLs n (%)	>4 WSLs n (%)
<2 years	1.15 ±0.21	15 (58%)	10 (38%)	1 (4%)
2-3 years	0.89±0.29	19 (56%)	8 (24%)	7 (20%)
>3 years	1.38±0.18	06 (30%)	9 (45%)	5 (25%)

<sup>b</sup> The results of analysis show that >3years group has a high number of WSLs with mean value of 1.38±0.18 (p =0.02) which is statistically significant. The <2 years and 2-3 years groups did not show statistically significant difference from each other but <2 years and 2-3 years groups were statistically significant from >3 years group (p= 0.03).

Gender wise distribution of WSLs was checked in each study group (Table 3). In comparison to female patients, it was seen that male patients had a larger distribution of WSLs. In group <2 years, 7 (64%) male patients out of 11 were found with WSLs in contrast with females (36%). Group 2-3 years were found to be approximately similar to WSLs in both genders with a slight difference. In third group, the difference among WSLs distribution was higher as compared to other two groups, in which males were 4 (67%) and females 2 (33%). Fischer’s exact test revealed significant difference among groups (p-value 0.03).

**Table 3: Gender wise distribution of WSLs among three study groups**

Group	Male patients with WSLs n (%)	Female patients with WSLs n (%)
<2 years	7 (64%)	4 (36%)
2-3 years	8 (53%)	7 (47%)
>3 years	4 (67%)	2 (33%)

## DISCUSSION

The current study indicates that WSLs are the problem of considerable interest which is faced by the clinician during



orthodontic therapy. Fixed appliances, used in orthodontic treatment, serve as a source for the retention of plaque when the patient does not meet oral hygienic requirements during the treatment. Not maintaining good oral hygiene leads to accumulation of bacteria that are acidogenic in nature and cause demineralization of enamel. Our study results showed that 42% of individuals developed WSLs, in the group <2 years, after the fixed appliances therapy. Tufekci et al reported 38% of WSLs development in their study within six-month treatment group<sup>21</sup>. That study was conducted during the orthodontic treatment. High prevalence of WSLs in <2 years group is because of their assessment after the orthodontic therapy as compared to the said study as most of the WSLs develop at the end of orthodontic therapy.

Another study, conducted by Gorelick et al indicated the prevalence of WSLs during orthodontic treatment was 50%<sup>3</sup>. They examined the WSLs after orthodontic therapy. Including both mandibular and maxillary teeth, as well as the duration of orthodontic therapy (24 months), may explain the increased prevalence. Inclusion of more teeth groups for examining WSLs can be a turning point for reporting high prevalence as compared to less inclusion.

Examining WSLs during active orthodontic therapy is more challenging for clinicians as compared to after or without treatment. During orthodontic therapy, the crown used by clinicians must be clear of any debris and plaque. Excessive gingival tissues on the tooth or arch wire can be a cause of difficulty in detection of WSLs on enamel surface. Detection of WSLs on enamel surface requires prior air-drying. Following these steps will allow the clinician to easily identify the WSLs. On each visit, patients should be thoroughly examined, and hygienic regimen should be given to overcome the process of enamel demineralization.

## CONCLUSION

WSLs development was seen in 42, 44 and 70 percent in the groups <2, 2-3 and >3 years respectively. With the highest number in >3 years therapy, it is concluded that maintaining and guiding patient for good oral hygiene are key factors in overcoming this complication during orthodontic treatment. Oral hygiene is also necessary during the initial treatment time to prevent enamel demineralization.

## AUTHORS' CONTRIBUTION

Gulalai Jan	Drafting the Article
Zafar ul Islam	Analysis and interpretation of data
Kawish Syed	Conception and design
Hasan Ali Raza	Acquisition of data
Shahab Adil	Critical revision

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# FREQUENCY AND AWARENESS OF NEEDLE STICK INJURY IN PARAMEDICAL STAFF AND DOCTORS OF A TERTIARY CARE HOSPITAL

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## ABSTRACT

**Objective:** To determine frequency, response and awareness of needle stick injury (NSI) among healthcare workers.

**Design:** Descriptive, Cross-sectional

**Place and Duration of Study:** Fauji Foundation Hospital, Rawalpindi, 7 months (March to September 2019).

**Materials and Methods:** Study was conducted on the paramedical staff and doctors from one tertiary care hospital of Rawalpindi. After taking ethical approval and consent, a representative sample of 375 individuals was drawn by non-probability convenient sampling after applying inclusion and exclusion criteria. A validated questionnaire was used. Data was collected and analyzed on SPSS 21.

**Results:** Out of 375, two hundred and forty eight (66%) had experienced NSI, with a total of 129 female and 119 males. One hundred and forty six (59.3%) got NSI during recapping of syringes. Eighty seven (35.4%) got it while they were not wearing gloves. Five (1.3 %) got NSI during disposing off the syringe. Three (1.2%) were not well oriented due to increased work load. One hundred and forty (56.7%) claimed they were confident that their patient was not suffering from any blood-borne disease. Three hundred and forty one (90.9%) of total respondents knew about outcomes of NSI whereas sixty two (16.6%) attended a seminar/campaign regarding NSI. Three hundred and sixty nine (98.4%) of the respondents were aware of NSI and two hundred and eighty three (75%) of the total respondents knew the standard protocol. One hundred and seventy five (70%) allowed bleeding to occur after getting an NSI whereas fifty eight (23.5%) washed their hands immediately.

**Conclusion:** Needle stick injury is common in health care workers. Maximum use of disposable syringes, awareness of potential hazards of NSI, strict implementation of personal protection and NSI protocols, and rationalization of shift hours for health care workers will go a long way in preventing this potentially hazardous but preventable health care problem.

**Key words:** Needle stick injuries, Paramedical staff, Doctors, blood-borne diseases, recapping of needles.

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## INTRODUCTION

When skin is penetrated with a needle stick that was previously in contact with a body fluid, blood or soft tissue, an NSI results<sup>1</sup>. WHO reports that approximately 2 million out of 35 million healthcare workers experience exposure to infectious diseases by needle stick every year<sup>2</sup>. It is a major problem world over with an increasing frequency, stretching from 35% in Egypt to about 58% in Pakistan<sup>3,4</sup>. It has been noted that among

health care personnel, nursing staff have these injuries most frequently<sup>5</sup>. The Royal College of Nursing reported that 48% out of 4,407 nurses, had received injury by a needle or a sharp instrument that was previously used for another patient<sup>6</sup>. One study showed that out of 230 dental students, 53(23%) received an inoculation injury<sup>7</sup> while another study revealed NSI in 14.1% of medical students<sup>8</sup>.

Life threatening diseases like Hepatitis B, Hepatitis C, AIDS/HIV are spreading due to unawareness and negligence regarding NSI. NSI are the reason behind 37.6% of Hepatitis B, 39% of Hepatitis C, and 4.4% of HIV/AIDS cases seen among healthcare workers worldwide<sup>2</sup>.

Since NSI is a recognized occupational health & safety issue and is a significant risk faced by the health professionals, repeated awareness should be raised and cases should be reported as most of the times such events are considered unimportant or left unreported<sup>8</sup>. Our study will help us mark the risks factors leading to it in our own setting and also to identify the

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occupational groups most susceptible to such injuries. NSI during massive vaccination campaigns is also common and the present scenario of massive vaccination related to covid<sup>9</sup> makes this study more relevant.

## MATERIAL AND METHODS

A descriptive, cross sectional study was carried out at Fauji Foundation Hospital Rawalpindi from March to September 2019. Permission of college ethical committee was taken prior to conducting the study. Non probability (convenience sampling) was done and 375 willing paramedical staff, house officers and post graduate doctors were included in the study. The study participants filled up a ten- item, structured questionnaire. Data were analyzed by SPSS version 21.

## RESULTS

Out of 375, two hundred and forty eight (66%) had experienced NSI, with a total of 129 females and 119 males. One hundred and forty six (59.3%) got NSI during recapping of syringes. Eighty seven (35.4%) got it while they were not wearing gloves. Five (1.3 %) got NSI during disposing off the syringe. Three people (1.2%) were not well oriented due to increased work load. One hundred and forty (56.7%) claimed they were confident that their patient was not suffering from any blood-borne disease. One hundred and seventy five (70%) allowed bleeding to occur after getting NSI whereas fifty eight (23.5%) washed their hands immediately. Three hundred and forty one (90.9%) of total respondents knew about outcomes of NSI whereas sixty two (16.6%) attended a seminar/campaign regarding NSI. Three hundred and sixty nine (98.4%) of the respondents were aware of NSI and two hundred and eighty three (75%) of the total respondents knew standard protocol.

## DISCUSSION

In our study 66% of health care workers had experienced a NSI, with a slight female preponderance. Global incidence of NSI has been documented at 44% with maximum occurrence in South East Asian region (58%)<sup>10</sup>. This figure is very near to outcomes of our study and establishes the fact that NSI has a high incidence in our part of world. In other studies, 66% of health care workers had either one or more than one episode of NSI and the incidence was highest amongst nurses, paramedical staff and doctors. Nurses and paramedical staff were at a higher risk in comparison to doctors<sup>11</sup>. While another study conducted in a private hospital showed doctors being more prone to get NSI in comparison with nurses<sup>12</sup>. Other studies show it to be more prevalent among the post graduate residents and junior doctors<sup>13</sup>. Dental students were at more

risk than the medical students, for obvious reasons<sup>8,10</sup>.

In our study 98.4% of the respondents were aware of NSI, 90.9% knew about the outcomes of NSI and 75% of the total respondents knew standard protocol. Only 16.6% had attended a seminar/campaign regarding NSI. Seventy percent allowed bleeding to occur after getting NSI whereas 23.5% washed their hands immediately. High incidence of NSI, despite adequate knowledge, points that other factors may be involved. Among the nursing staff, urgency, varying shift work, and inferior skill

levels (relating to years of experience, academic degree, and younger age) contributed towards the problem<sup>14</sup>. Reasonable shift hours and supervision of junior staff may help in minimizing the risk of NSI.

A significant contributing factor to this high frequency is our inadequate understanding of blood-borne diseases and their modes of transmission. According to a study, 8.3% of healthcare workers who suffered NSI came into contact with Hepatitis B and Hepatitis C contaminated needles<sup>15</sup>. The picture is much worse in primary as well as secondary health care centers where health care providers do not have adequate information about its consequences and precautions<sup>15</sup>. In our study 56.7% claimed they were confident that their patient was not suffering from any blood-borne disease without any proof. Awareness regarding spread of these deadly diseases by NSI will alert the health care workers and will go a long way in prevention of this health care hazard.

Most frequent cases of NSI were seen during needle recapping, giving local anesthesia and carrying out scaling/polishing procedures in dental practice<sup>7</sup>. In another study, recapping of syringes was responsible for NSI in 55.1% cases<sup>13</sup>. One study done at the University of Virginia analyzed 326 cases of NSI. The injuries were caused by disposable syringes (35%), intravenous tubing & needle assemblies (26%), pre-filled syringes (12%), winged steel-needle intravenous assembly (7%), phlebotomy needles (5%), IV catheter (2%), and others (13%). Rate of injury in devices that required disassembly was 5.3 times more as compared to disposable syringes<sup>16</sup>. Phlebotomy / IV infusions were the most common cause<sup>17</sup>. In our study, 59.3% got NSI during recapping of syringes. The guidelines by Occupational Safety and Health Administration (OSHA)<sup>15</sup>, prohibit needle recapping still a large proportion of NSI happen as a result of it. As per our study, only 1.3 % suffered NSI using disposable syringes. Use of only disposable syringes may lead to a reduction in the incidence of NSI in health care workers.

Another important observation was that a limited number of healthcare workers wore gloves while using sharps and did not

## CAPSULE SUMMARY

In light of recent massive vaccination campaigns, needle stick injury (NSI) has gained importance. Frequency, response and awareness of NSI among healthcare workers was probed in a cross-sectional study. Most cases were associated with needle recapping, not wearing gloves, disposing off the syringe, consequent to disorientation due to work load and by considering their patient free from blood borne disease. Most were aware of NSI outcomes though. Following NSI protocols, and rationalization of shift hours for health care personnel can help prevent this health care issue.

use precautionary measures for the prevention of NSI. In our study 35.4% had NSI while not wearing gloves. This calls for immediate implementation of policy regarding the protection of healthcare workers.

### CONCLUSION

NSI is common in health care workers and its continuous awareness is the key to its prevention. Maximum use of disposable syringes, awareness of potential hazards, strict implementation of personal protection and NSI protocols and rationalization of shift hours for health care workers will go a long way in preventing this potentially hazardous but preventable health care problem.

### AUTHORS' CONTRIBUTION

Kiran Fatima Farooq	Conception and design, Drafting the Article
Nuwayrah Jawaid Saghir	Conception and design, Drafting the Article
Sarah Anwar	Analysis and interpretation of data
Umair Ali	Acquisition of data
Saadia Rashid	Critical revision

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# EFFECT OF STUDY HABITS ON ACADEMIC PERFORMANCE OF STUDENTS AT WAH MEDICAL COLLEGE

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## ABSTRACT

**Background:** Educational achievements depend on study habits. Medical profession requires lifelong learning, and students have to acquire a lot of knowledge and skills; they need to use good learning strategies for their academic success.

**Objective:** To identify the study habits of medical students in Wah Medical College and the effect of study habits on their academic performance.

**Design:** Descriptive, Cross-sectional.

**Place and Duration of Study:** Wah Medical College, 6 months (March to August 2021).

**Material and Methods:**

**Data Collection tools:** Hard copy of Palsane and Sharma Study Habits Inventory (PSSHI) was used for data collection. Study habits inventory contained 45 items belonging to eight areas, which were scored on a rating scale.

**Analytical methods:** Results were summed and statistically analyzed using SPSS version 23. Frequency/proportions of qualitative variables were determined. Mean and standard deviation for each item in PSSHI was calculated and added up to obtain the final score. Chi-square test (at alpha value of 0.05) was used to find out the association of variables.

**Results:** On the whole, study habits of students were 'Relatively favorable' as mean score of PSSHI was  $53.35 \pm 9.41$ . Study habits of 118 (26%), 327 (72.5%) & 6 (1.3%) students were favorable, relatively favorable and unfavorable respectively. Statistically significant positive association was noted between academic performance and study habits (p-value 0.000).

**Conclusion:** Study habits of majority of students were Relativity Favorable and with increase in PSSHI score the academic performance got better.

**Key words:** Study habits, Academic Performance, Medical Students, Palsane and Sharma Study Habits Inventory.

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## INTRODUCTION

Study skills are the tactics used by the students to acquire knowledge<sup>1,2</sup>. They include regular reading, collecting and retaining new information, managing time, selecting right objectives, opting for suitable environment and organization<sup>2</sup>. Medical profession requires dedication, hard work and lifelong learning. Medical students need to acquire a lot of knowledge and skills, as well as professionalism to make them ready for the multiplicity of their profession<sup>3,4</sup>. Study habits are exclusive for each person but it is necessary to identify the right approach<sup>5</sup>.

The students who are short of good study habits perform pathetically in assessments which further exacerbate their test fretfulness<sup>6,7</sup>. The resulting apprehension is the foremost cause of examination misconducts, rising failure rates and absenteeism from institutions. All devices like TV, cell phones and laptops disrupt the learning process, so it is necessary to avoid all these while studying<sup>2</sup>.

Globally every educational institution and all stakeholders are worried about the educational achievements of students<sup>2,6</sup>. In reality, quality of schooling is related to academic achievements which in turn assure the growth of a nation, keep the learners connected to social networks, make them ambitious and help them complete their dreams<sup>1,7</sup>. Academic performance of students depends upon several factors like enthusiasm, mindset, self-confidence and learning environment but to a large part on their study habits<sup>2,3</sup>.

The scholars' habits of studying have a pivotal effect on the educational standards and overall achievements<sup>2,6</sup>. The scores of the whole class are not alike although they are taught

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together. The students having well-planned study habit thrive and achieve more marks in exams<sup>1</sup>. The students with planned study habits do better than those having jumbled habits<sup>3</sup>. In fact learners with unorganized study habits do not have clear concepts leading to pathetic performance<sup>1</sup>. Standard of health care in a country is determined by the excellence of its medical graduates whereas worth of graduates is subjected to the morals of their training, consequently all revolve around the study habits of the learners. In a study conducted among medical students of Iran, the study habits were found to be relatively favorable and were positively associated with their academic performance ( $p < 0.0001$  and  $r = 0.229$ )<sup>1</sup>. In another study the students from Philippines had relatively favorable study habits but had no significant effect on their academic performance<sup>6</sup>.

As there is dearth of evidence regarding consequences of study habits on the educational achievements of medical graduates in Pakistan, we aim to find out the study habits of medical students in Wah Medical College and the effect of these habits on their academic performance. Quality study expertise will lead to the development of self-reliance, competency, and morale; will also lessen the apprehension concerning assessments. As a result of adopting valuable study habits, learners can reduce the time spent for academic work, and can have spare time for new activities in their lives. The results of this research will facilitate the graduates to build up favorable study habits leading to improvement in their academics.

## MATERIAL AND METHODS

A descriptive cross-sectional study was carried out at Wah Medical College from March to August 2021, involving all 500 students. The objective and procedure of data collection was clarified before distributing hard copies of questionnaires. The first section of the questionnaire included Sociodemographic information, including name, gender, study year, residence either in dormitory or day scholar, and marks (percentage) in the last passing examination.

The Palsane and Sharma Study Habits Inventory(PSSHI)<sup>3</sup> was used to determine the study habits of students. The inventory contained 45 items belonging to eight areas: budgeting time, physical condition, reading ability, note-taking, learning motivation, memory, taking examinations, and health. Scoring of the study habits inventory was done on a three-point rating scale; "0 = rarely or never", "1 = sometimes" and "2 = Always or Mostly". For the statement No's 6, 9, 13, 15, 24, 26, 34, 36, 37, 41 and 42 , scoring was reversed marking 0, 1

and 2 for 'Always', 'sometimes' and 'never' because these were negative items. Total score for study habits ranged from 0 – 90. The scores were interpreted as given below:

Score > 60-----Favorable  
 Score 31 to 60-----Relatively favorable  
 Score ≤30 -----Unfavorable

Academic performance was assessed based on marks obtained in the last professional exam.

Marks percentage	Level of academic performance
81% to 100%	-----Excellent
66% to 80%	-----Good
50% to 65%	-----Average
< 50%	-----Poor

## CAPSULE SUMMARY

Lifelong learning is required in the medical profession. Students must acquire a wide range of knowledge and skills so there is a need to employ innovative learning strategies all along.

Study habits of medical students from one medical college and their effect on student's academic performance were explored. Majority of students were found to have 'Relativity Favorable' study habits with a better academic performance with an increase in their Palsane and Sharma Study Habits Inventory (PSSHI) scores.

Students should be encouraged to organize their study activities in order to excel academically and personally, both of which are required for professional success.

Results were summed and statistically analyzed using SPSS version 23. Frequency/proportions of qualitative variables were determined. Mean and standard deviation for each item in PSSHI was calculated and added up to obtain final score. Chi-square test (at alpha value of 0.05) was used to find out the association of variables.

## RESULTS

The study planned for all 500 students of Wah Medical College, out of which 451 students responded within the given time (response rate 90.2%). Out of 451 students 295 (65.4%) were females and 156 (34.6%) were males; 177 (39.2%) were day scholars and 274 (60.8%) were hostelites; the number of students in each year of MBBS was Y1=97, Y2=103, Y3=88, Y4=108, Y5=55. The categories of academic performance and study habits are shown in Fig A.1 and A.2 respectively.

The study habits of students were 'Relatively favorable' as mean score of PSSHI was  $53.35 \pm 9.41$ . Study habits of 118 (26%), 327 (72.5%) & 6 (1.3%) students were favorable, relatively favorable and unfavorable respectively. Results regarding mean and standard deviation of individual items are shown in Tables A.1, A.2 and A.3.

Study habits of females were more favorable as compared to males (p-value 0.03) and that of day scholars than hostelites (p-value 0.015). Statistically significant association was noted between academic performance and study habits (p-value 0.000), details are presented in Table A.4.

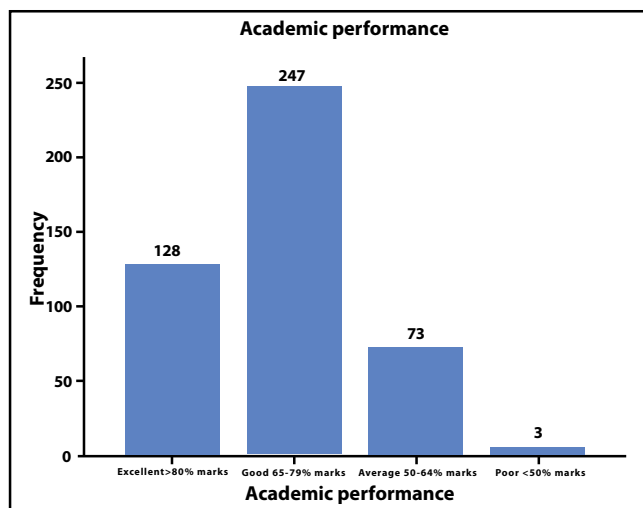


Figure A.1: Academic Performance of students

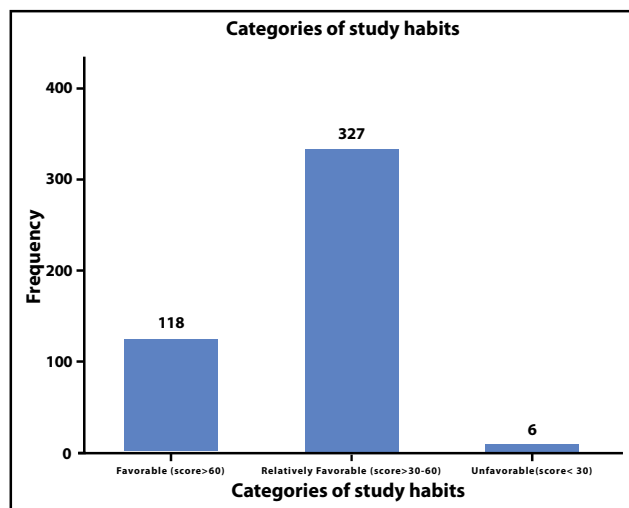


Figure A.2: Categories of study habits

Table A.1: Mean (SD) of Palsane and Sharma Study Habits Inventory

Indicators/Items	Mean ± SD
<b>Total PSSHI Score</b>	<b>53.35 ± 9.41</b>
<b>Budgeting time</b>	<b>6.39 ± 2.26</b>
1. "I study every day".	1.11± 0.71
2. "I study at a particular time of the day".	1.21± 0.73
3. "I do my homework daily".	1.15± 0.76
4. "If I have to study for a longer time, I take a rest in between".	1.60± 0.63
32. "I divide the time according to the matter to be answered in respect of the number of questions".	1.33± 0.71
<b>Physical condition</b>	<b>7.75 ± 1.7</b>
5. "I have all the required books and other relevant materials of study with me".	1.70± 0.53
6. "For the time of the study, I get disturbed by the surroundings at the time of the study".	0.77± 0.64
7. "I develop an automatic interest in the subject as soon as I start studying it".	1.39± 0.62
8. "I realize the importance of the subjects for my future career".	1.60± 0.58
9. "Other stray thoughts gradually flow in as soon as I settle down for the study".	0.71± 0.62
43. "I think that I can improve my study habits fairly".	1.59± 0.55
<b>Reading ability</b>	<b>8.96 ± 2.33</b>
10. "I read the main points before I read the chapter".	1.08± 0.78
13. "I continue my reading despite the difficulties in understanding the meaning of some words".	0.95± 0.76
14. "I read very carefully in order to understand every point".	1.70± 0.50
15. "I never read silently".	1.12± 0.76
16. "According to the importance and difficulty of the subject matter, I change and adjust the speed of my reading".	1.50± 0.62
17. "I study figures and graphs very carefully while reading".	1.38± 0.64
22. "I read books whenever I get free time, whether at home or in school/College".	0.78± 0.72
28. "I study in the library regularly".	0.46± 0.60



**Table A.2: Mean (SD) of Palsane and Sharma Study Habits Inventory**

Indicators/Items	Mean $\pm$ SD
<b>Note taking</b>	<b>2.67 <math>\pm</math> 1.8</b>
11. "I take down notes while reading".	1.11 $\pm$ 0.73
18. "During the classroom teaching, I take down notes very sincerely".	0.86 $\pm$ 0.71
19. "At home, I compare my class notes with the notes from the text books".	0.71 $\pm$ 0.75
<b>Learning motivation</b>	<b>8.44 <math>\pm</math> 1.8</b>
20. "I take the help of anybody if I do not follow anything".	1.38 $\pm$ 0.62
21. "I study the subject matter at home thoroughly before it is taught in the classroom".	0.45 $\pm$ 0.63
23. "I attend my classes regularly on time".	1.76 $\pm$ 0.50
24. "I frequently remain absent from class".	1.72 $\pm$ 0.56
25. "If a matter is to be learned by heart, I read and memorize it part by part".	1.54 $\pm$ 0.62
40. "I try to make up my deficiency in the weak subjects to my best".	1.60 $\pm$ 0.55
<b>Memory</b>	<b>4.45<math>\pm</math> 1.23</b>
12. "I try to recall the matter after reading it".	1.52 $\pm$ 0.62
26. "I cram certain things without understanding".	1.27 $\pm$ 0.63
27. "I revise the subject matter from time to time".	1.02 $\pm$ 0.62
37. "After the examination, I realize that I have made some mistakes in the answers I have written, or I have forgotten some important points".	0.64 $\pm$ 0.60

**Table A.3: Mean (SD) of Palsane and Sharma Study Habits Inventory**

Indicators/Items	Mean $\pm$ SD
<b>Taking examinations</b>	<b>11.24 <math>\pm</math> 2.4</b>
29. "During examination days also, I sleep as usual in the night".	0.94 $\pm$ 0.80
30. "Before writing the answers to the questions in the examination, I read very carefully the entire question paper".	1.61 $\pm$ 0.62
31. "In the examination, I answer the question in their serial order".	1.20 $\pm$ 0.70
33. "Before examination, I read my own notes carefully".	1.23 $\pm$ 0.72
34. "I prepare for the examinations from the guides/notes available in the market".	1.12 $\pm$ 0.75
35. "I draw an outline of answers of each question, before writing answers to the questions in the examination".	1.12 $\pm$ 0.75
36. "I feel tense at the beginning of the examination".	0.54 $\pm$ 0.63
38. "I carefully record my examination results".	1.29 $\pm$ 0.73
39. "I single out my weak subjects on the strength of my examination results".	1.37 $\pm$ 0.63
42. "I have a tendency to compare my marks with others after the results are declared".	0.83 $\pm$ 0.74
<b>Health of study</b>	<b>3.41 <math>\pm</math> 1.19</b>
41. "I get disappointed, if the examination result is not favorable".	0.72 $\pm$ 0.67
44. "I get guidance about proper study habit from my teachers".	1.09 $\pm$ 0.72
45. "I will take advantage if a guidance program in study habits is arranged".	1.60 $\pm$ 0.61

Table A.4: Association between study habits and academic performance

Academic Performance				
Study Habits	Excellent > 80% Marks	Good 65-79% Marks	Average 50-64% Marks	Poor < 50% Marks
Favorable (Score > 60)	55	50	13	0
Relatively Favorable (Score 30-60)	73	193	58	3
Unfavorable (Score < 30)	0	4	2	0
p-value	0.000			

## DISCUSSION

Study skill is the acquisition of planned and committed time for the purpose of gaining knowledge, as it is necessary to become confident and excel in life. Such skills determine the level of knowledge gained by the learners and the targets they want to achieve in future; all possible by appraising the study habits at frequent intervals<sup>8</sup>. In medical schools, un-planned study habits grossly affect the educational progress of scholars as dedicated hard work is required for lifelong learning. The study was conducted with the objective to identify the study habits of medical students in Wah Medical College and its effect on their academic performance. We endeavored to include all 500 students but a response rate of 90.2 % was achieved. PSSHI containing 45 statements, belonging to eight areas, was used.

In our research, study habits of majority of students were relatively favourable, just like the results of a study conducted in Jundishapur University of Medical Sciences<sup>9</sup> and a research by Looyeh<sup>1</sup>. In our study positive relationship among study habits and academic performance was found, with increasing study habits scores the academic performance turned out to be better. Similar association was observed in the studies among the medical students by Sreelekha<sup>10</sup> and Jafari<sup>3</sup> and among nursing students by Alimohamadi<sup>11</sup>. Unlike this no association of study habits was found with the academic performance of students in a study by Chandana<sup>12</sup> and Tus<sup>6</sup>.

In our research, study habits of females were more favourable as compared to males; these results are almost similar to research conducted in district Pulwama, J&K<sup>13</sup>. Other research also showed that the study habits of females were better than males<sup>3,14</sup>. As far as residence is concerned, study habits of day scholars were better than hostelites, just like the results obtained in a research done at Kermanshah University of Medical sciences<sup>2</sup>. But residence had no significant effect on study habits in a research conducted in Iran<sup>4</sup>.

The indicators for which we got the maximum and minimum

scores were learning motivation and note-taking respectively. Similarly, in other studies the most undesirable results were obtained for note-taking<sup>3</sup>, and the highest score for learning motivation<sup>1</sup>. Regarding budgeting time, most of the students did not have the habit of studying daily or at any specific time. The students were of the opinion of taking rest in between if they had to study for longer periods. They also distributed their time on the basis of importance of the subject in their view. The result almost matched with the study conducted by Tus<sup>6</sup>.

About physical conditions, mostly the students agreed that all the related books and other reading material were provided to them as well as they understood the importance of their field. Some were unable to concentrate because of their surroundings and roving thoughts. Similar results were obtained in other studies by Alavijeh<sup>2</sup> and Gilavand<sup>5</sup>. Regarding reading ability, the students did not have the habit of studying books in the library. But they read sensibly to comprehend each topic giving due importance to graphs and figures in the text. Similar results regarding reading ability were found in a study conducted by Looyeh<sup>1</sup> and Sharma<sup>15</sup>.

For Note-taking habits the majority of the students were not interested in taking notes regularly. Similar low results in note-taking were obtained in another study by Alavijeh<sup>2</sup>. Regarding learning motivation, most of the students had determination for seeking knowledge. They also tried making up their deficiencies in all subjects by regularly attending the lectures. Students in Iran<sup>7</sup> and Philippines<sup>6</sup> were similarly motivated to become skilled at their profession.

As far as memory is concerned the students knew the importance of memorization in MBBS and had a habit of revising the content before examination. Similar results were obtained in other studies by Gilavand<sup>5</sup> and Sharma<sup>15</sup>. For taking examinations, the students had the habit of reading questions carefully and outlined answers before attempting. Some were anxious while others had usual sleep before examination, also had the habit of critically analysing their results. The

habits of taking examinations resembled a study conducted in Philippines<sup>6</sup>. Regarding the health of study, the students had the habit of taking assistance from their teachers for study and were willing to join any mentoring platform for improving their academic performance. Iranian students also got assistance from their peers and teachers<sup>7</sup>.

### CONCLUSION

Study habits of majority of students of Wah Medical College were Relatively Favorable and those having favorable study habits perform better academically. Study habits of female students and day scholars were more favourable as compared to male students and hostelites. Students should be encouraged to organize their study activities in order to shine academically and personally as both are essential features for attaining success in their profession.

### ACKNOWLEDGEMENT

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### AUTHORS' CONTRIBUTION

Robina Mushtaq	Conception and design, Drafting the Article
Khola Waheed	Analysis and interpretation of data, Drafting the Article
Shezadi Sabah Imran,	Acquisition of data, Critical revision
Ambreen Ansar	Acquisition of data
Sadia Nadeem	Analysis and interpretation of data,
Musarat Ramzan	Conception and design, Critical revision

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# OROFACIAL CLEFTS; A CASE REPORT OF RARE TESSIER CLEFT 0

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## ABSTRACT

Orofacial clefts (OFCs) represent a common but complex congenital disorder, that significantly impacts the lives of affected individuals and their families. This study probes into the complexities of OFC management, with specific focus on a rare Tessier's Cleft 0 case in a Pakistani child. The case emphasizes upon the challenges faced in low and middle-income countries (LMICs) due to limited specialized care available.

Main aim of treatment includes profile correction, maxillary and mandibular deficiency reconstruction, nasal bridge reconstruction, and achievement of functional and aesthetic dentition. Treatment alternatives cover simultaneous palatoplasty and alveoloplasty, nasal reconstruction and early maxillary protraction therapy through iliac bone graft.

This case study focuses on the importance of a multidisciplinary approach, highlighting the Tessier classification system's utility in guiding treatment decisions. Effective communication and teamwork are important, especially in LMICs where advanced care resources are limited.

**Keywords:** Orofacial clefts, Tessier's Cleft 0, multidisciplinary care, low and middle-income countries.

**How to cite:** Haq UU, Khan W, Khan AB, Tariq S. Orofacial Clefts; a Case Report of Rare Tessier Cleft 0. HMDJ. 2023; 03(01): 30-33.

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## INTRODUCTION

Orofacial clefts (OFCs) are one of the commonest congenital abnormalities, with a significant impact on the affected persons' survival, overall general health, development, and quality of life<sup>1</sup>. These patients along with their families undergo a long, seemingly never ending suffering of a tedious phase of treatment, even in cases where early specialized care is not only available but is accessible as well<sup>2,3</sup>. In low & middle income countries (LMIC)<sup>4</sup> like Pakistan, the estimate of the burden of disease, risk factors, health care provision, availability of optimum facilities and long-term prognosis with the provided care hold a key locus in decision making.

Because of the variety of presentations and rarity of the OFCs, there are complicated aesthetic and functional dilemmas that call for specialized, frequently interdisciplinary care. Executing a therapy that has been carefully planned can lessen complications

and reduce the need for revision operations<sup>5</sup>. As we go into a preventive medicine era<sup>1,3</sup>, it is crucial to be able to gauge the effectiveness of interventions, like surgery and rehabilitation, and correlate it with the accessibility of complex tertiary care facilities with qualified staff. This often is a difficult scenario to be found in LMICs. Similar scenario was faced by our institute, as a patient with rare OFC was referred for provision of tertiary care to our department of Orthodontics. Details of this case are reported here to highlight the complexities of disease, its treatment and management in of these patients in a peripheral dental hospital.

## CAPSULE SUMMARY

A patient with the rare Tessier Cleft O is being reported. Such cases require a well-coordinated team approach besides tertiary care facilities and high clinical acumen of treating physicians. Treatment objectives are discussed.

## ETIOLOGY AND DIAGNOSIS

A young Punjabi origin Pakistani boy, aged 8 years, reported to the "Maxillofacial Surgery Clinic" at Wah Medical College, Wah Cant, who was later referred to Department of Orthodontics, Dental College HITEC-IMS, Taxila. He was initially referred by a UK based NGO/ trust that provides free surgical treatment to cleft patients throughout Pakistan.

Parents of the patient presented with the primary complaint that their son's nose was deficient and had cleft inside mouth.

There was no other family member with facial or oral cleft, or any other syndromic condition. Parents had consanguineous marriage and belong to same family lineage. He had global developmental delay, poor growth, generalized weakness

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and dragged left foot while walking. Cognitively, he did not follow commands and was slow at comprehension. Speech was impaired with recurrent nasal emission of air i.e., marked velopharyngeal insufficiency. Patient had undergone palate repair by the same NGO's free cleft camp at the age of 1 year. Still patient sometimes complained of water coming through nose.

Socioeconomic status evaluation revealed that the patient belonged to a middle class income group as per Kuppuswamy scale<sup>6</sup>.

On examination performed by pediatrician, patient's echocardiography revealed patent foramen ovale (PFO). Computed Tomography (CT) scan of the brain was performed that revealed benign enlargement of arachnoid spaces in frontal area.

His extraoral findings revealed concave profile, collapsed nose due to deficient nasal bridge but intact soft tissue structures

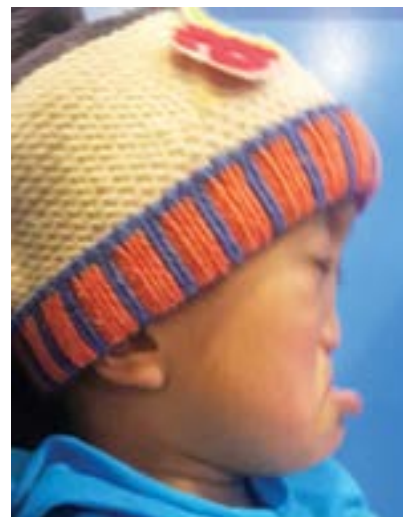
of nose, hypoplastic maxilla and deficient malar prominences (Figure 1). Intraorally, he had deciduous set of dentition with missing deciduous central incisors (#51, #61), poor oral hygiene and multiple carious teeth. Mesial step occlusal scheme was present. There was median alveolar and palatal cleft present.

CT scan was performed to further evaluate the extent and nature of the cleft defect. CT scan revealed a cleft defect in midline. Cleft started anteroposteriorly, from alveolus in place of deciduous centrals towards the posterior limit of hard palate and vertically up towards the nose, involving base of nose that was entirely absent. All the cartilaginous structures of nose were absent whereas bony part of nasal bridge was present but not fully developed. Nasal bridge was totally collapsed that provided no support to intact soft tissue structures of nose (Figure 2).

Diagnosis of Non-syndromic isolated Orofacial cleft was made and classified as Tessier's Cleft 0.



Figure 1:Extra-oral pictures.  
A-frontal view



B- Profile view

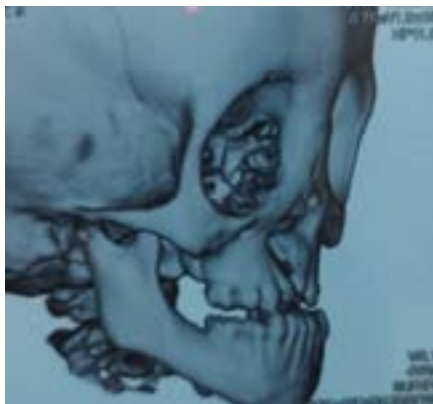


Figure 2 - CT Scan Images.  
A- Right Profile view



B- Frontal View



C- Left Profile view

## TREATMENT OBJECTIVES

Following treatment objectives were laid for this patient after discussion in Ortho-surgery conference of our institution.

1. Correction of profile deformity
2. Reconstruction of nasal bridge
3. Correction of maxillary and malar deficiency
4. Achievement of functional and aesthetic dentition
5. Replacement (prosthetic/natural) of missing teeth

## TREATMENT ALTERNATIVES

Step wise treatment timeline was decided for this patient as follows:

Initially, simultaneous palatoplasty and alveoloplasty is planned that will include bone grafting in alveolar and palatal cleft. This procedure would be followed by early maxillary protraction



Figure 3 - Tessier Classification of OFCs



Figure 4 - Tessier 0

therapy using facemask at around 6 years of age. Alternatively, early maxillary distraction osteogenesis with high Leefort I or Leefort II corticotomy, is also under consideration in place of facemask therapy.

At a later surgery, nasal reconstruction by iliac bone graft is planned to be done. Fixed appliance treatment for correction of denture problems will be planned later depending upon how the intraoral conditions unfold.

## DISCUSSION

OFCs usually present as a therapeutic challenge in terms of aesthetics as well as form and function. Treating such cases require a well-coordinated team approach besides tertiary care facilities and high clinical acumen of treating physicians.

Tessier classification<sup>7</sup> is widely used to classify OFCs (Figure 3) and a guidance towards a unified treatment. Our patient fell under Tessier 0 cleft (Figure 4), it is an exact midline facial cleft, may be accompanied by a Tessier 14 cleft (extension of the midline cleft to the cranium), with hypertelorism of a variable degree. Despite being one of the more frequent "atypical facial clefts," which have a frequency of 1 in a million live births, it is still uncommon<sup>8</sup>. Having said that, these defects are not very straight or easy to treat. A thorough and professional teamwork is required for that matter. We also planned this case after multiple discussions and re-discussions among our team and also seek advice from distant consultants. Hereafter we will be providing rationale for adopting this very treatment plan.

Simultaneous palatoplasty and alveoloplasty is considered in anticipation of development of future openbite<sup>9</sup> and vertical defect nearby cleft region. Putting alveolar bone graft might lead to elimination or reduction in intensity of vertical defect created adjacent to cleft.

Maxillary protraction is seemed to be necessary as profile concavity indicates presence of severe maxillary and malar hypoplasia. This is compounded by presence of mesial step occlusal scheme present intraorally, in contrast to normal i.e. flush terminal plane. All these extraoral and intraoral indicators point towards a future skeletal class III malocclusion that too be very severe in intensity. Ideal time to carry out maxillary protraction is round about 8 years. However in this case we are planning to undertake early maxillary protraction in anticipation that depressed nose and deficient malar prominences may slide along with the protracting maxilla as circummaxillary suture ossification may be at very initial stages. To our comprehension such effect may reduce the need of malar augmentation and also decrease the complexity of rhinoplasty for reconstructing the nasal projection. For similar reason, instead of using facemask we are considering placing extraoral distractors to protract maxilla. Another rationale for considering distraction osteogenesis is that patient is slow in following commands and is highly non-compliant towards treatment. Hence not a very good response is anticipated from a compliance dependent facemask appliance.

Ultimately, the reconstruction of nasal floor and reestablishment of nasal projection is under thought, as this was the chief complaint of the parents and also the reason for referral to us. Results of earlier done palatoplasty are anticipated to provide the foundation upon which nasal floor is to be reconstructed. Or if at all there still remains a need to reconstruct the nasal floor, or is it well supported by bone placed during palatoplasty. Following Ghareeb et al. strategy for nasal reconstruction we planned an iliac bone graft to create nasal height and projection<sup>10</sup>.

Later as the patient approaches towards permanent dentition, how it unfolds? what is the intensity of anticipated vertical openbite defect? how molars and canines settle? and amount of overjet we have at that time will be the deciding factors for planning fixed appliance orthodontics.

As we have planned the case, we expect no severe skeletal anteroposterior or vertical deformity present at adolescence that may later require orthognathic surgery (OGS). Nevertheless, if things don't go as planned, a room for reconsidering the final plan or orthodontics and OGS always exists.

## CONCLUSION

Contrary to the typical cleft lip, nose, and palate, the congenital atypical nasal clefts are extremely uncommon and exhibit a variety of anatomical aberrations; and in order to treat, they require intensive clinical knowledge, extensive professional experience, and an effective team effort. Good and effective communications among team members, deliberated discussions on treatment protocols and possible outcomes are essentials towards success of such cases. In LMICs where advanced care

is deficient, teamwork and thorough deliberation is required to bridge the gap of lack of optimum facilities required for these complex scenarios.

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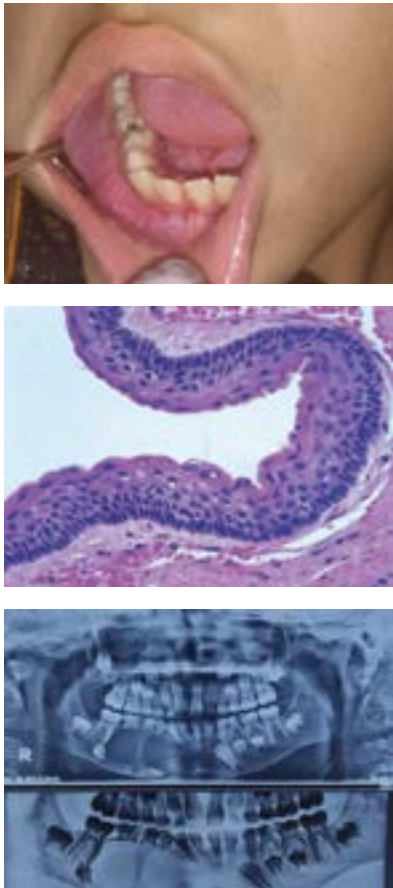
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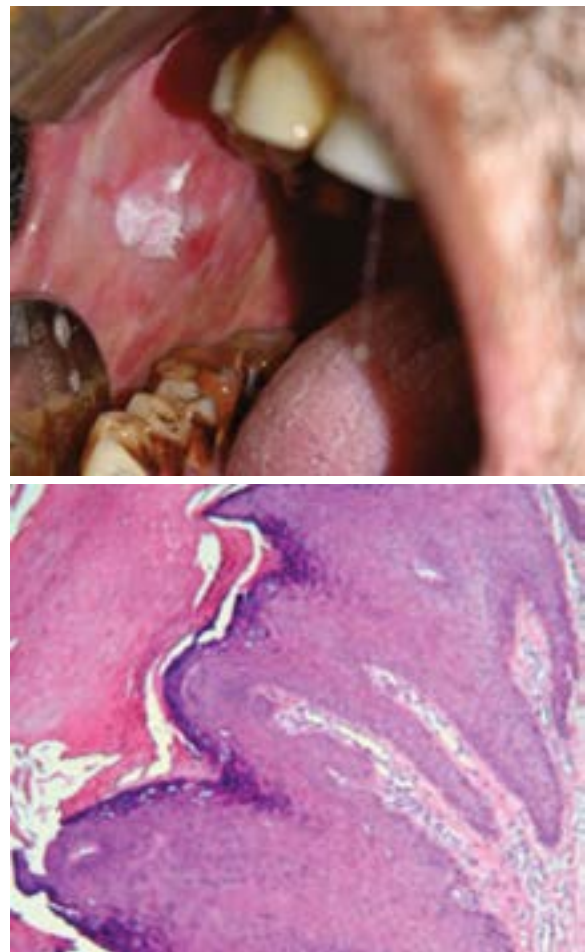
# DIAGNOSTIC CHALLENGE

Check the correct answer on page 38

## Case 1



## Case 2



An 8-year-old girl was referred to the oral and maxillofacial surgery department of HITEC dental hospital , Taxila, with a one-year history of increasing enlargement of the right jaw. The swelling was painless, with no associated complications. On examination multiple carious teeth were found. OPG revealed multilocular radiolucent lesion extending from left lower incisor to right lower 1st molar along with thinning of lower border of mandible.

**What is your diagnosis?**

A 50-year-old male presented to the oral and maxillofacial department of HITEC dental hospital, Taxila, with a complaint of limited mouth opening. On examination intraoral fibrous palpable bands were present which are diagnostic for oral submucous fibrosis and a white lesion was observed which was exophytic and painless with associated mucosal discoloration. History revealed the patient to be a hepatitis C positive truck driver, doing betel nut and gutka chewing for the last 20 years.

**What is your diagnosis?**



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  - e. **Systematic Review Article:** It should consist of a well-defined research question and should provide detailed review of a specific topic based on the existing literature. It should include the collection and analysis of data from all the relevant research in support of the research question being asked. The text should be 2500-3000 words. It should have a non-structured abstract with a minimum of three keywords.
  - f. **Meta-Analysis:** It should comprise a statistical analysis of combined results of numerous scientific studies addressing the same research questions. Meta-analysis is a quantitative and epidemiological study design that should critically analyze the results of previous scientific researches, mostly randomized controlled trials.
  - g. **Short communication:** Short communication or brief report of research works, containing new findings. The short communication consists: Title, Abstract (structured - no more than 150 words), Keywords (max. 5), Introduction, Methods, Results, Discussion, Conclusion, Ethical Consideration, Acknowledgment and References. Short communications should not exceed 2500 words from introduction through references. Short communications should contain no more than 3000 words totally. The number of tables/figures should be in maximum 3.
  - h. **Photo Essays:** The journal accepts manuscripts for consideration as photo essays. These essays include the visual presentation of material where the prima, emphasis is on the images. These images can include colored images, angiograms, optical coherence tomography, histologic sections, x-rays, ultrasounds, and other studies. The images can be an outstanding presentation of classic findings, atypical findings or new findings. These are not case reports, but rather a visual presentation of material as a teaching tool. The images need to be of the highest quality. The accompanying manuscript should be limited to a total of 300 words. A maximum of 5 separate images and 5 references can be included. Please refer to the rest of the author's instructions for other requirements for manuscripts submitted to HMDJ.
4. **SUBMISSION OF MANUSCRIPT**
    - a. All manuscript should be typed in double spacing on A-4 paper (8.25" x 11.70" = 21.0 cm x 29.70 cm) with one inch (2.5 cm) margin on both sides.
    - b. All pages must be numbered starting with the title page being page one.
    - c. Each figure and table must be submitted separately.
    - d. All manuscripts must be submitted by email to the address: editor.hmdj@hitec-ims.edu.pk or OJS (<https://hmdj.org/>)
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# DIAGNOSTIC CHALLENGE

## Answers

### Case 1

#### Diagnosis

Odontogenic Keratocyst

#### Background

- An Odontogenic Keratocyst (OKC), also known as a keratocystic odontogenic tumor (KCOT), is a benign, locally aggressive, cystic lesion that typically occurs in the jawbones.
- It originates from the remnants of dental tissues and is most commonly found in the mandible (lower jaw), particularly in the posterior region.
- One of the notable features of OKCs is their high recurrence rate. They tend to grow aggressively, with the potential to invade the surrounding bone and cause significant destruction.
- Clinical Presentation of OKC can vary. It may be asymptomatic impinge on nearby structures may lead to symptoms such as pain, swelling, and displacement of teeth. OKCs can also cause root resorption, leading to tooth mobility or loss.
- The diagnosis of an OKC is typically made through clinical examination and imaging studies, such as panoramic radiographs, CBCT and MRI. However, a definitive diagnosis often requires a histopathological examination of a biopsy specimen

#### Our Patient

A multiphase treatment was planned as patient was at risk of developing pathological fracture due to thinning of lower border of mandible. Marsupialization and biopsy was planned in the first phase of treatment. The second phase of treatment comprised enucleation of cyst after bone deposition on lower border and shrinkage of the cyst.

### Case 2

#### Diagnosis

Verrucae Vulgaris (having high association with Human Papilloma virus)

#### Background

- Verruca vulgaris, also known as oral verruca vulgaris or oral warts, is a specific type of wart that affects the mucous membranes in the oral cavity. It is caused by the human papillomavirus (HPV) and typically appears as a solitary, well-defined, and raised lesion in the mouth
- The lesions are commonly found on the tongue, lips, gums, and inside the cheeks. They can occur as a single wart or multiple warts clustered together.
- Oral warts usually have a rough, papillary surface and may resemble cauliflower-like growths. They can vary in size, ranging from a few millimeters to several centimeters in diameter.
- The color of oral verrucous vulgaris can range from white to pink or even grayish. They may have a whitish surface with tiny black dots, representing thrombosed blood vessels.
- The warts often have a firm texture and may be slightly elevated or flat.
- It may cause irritation, pain, or discomfort, particularly if they are located in areas that come into contact with food or during activities like chewing or speaking.

#### Our Patient

Excision biopsy of the lesion was taken in the department of oral surgery of HITEC dental college. Patient was found to be suffering from oral submucous fibrosis (a premalignant condition). The patient has been kept on regular monitoring and follow up so that any changes or worsening of the condition can be promptly addressed.





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