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Research Article

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Assessing awareness and practice towards Surgical Mask Regulations among the Population of Chandigarh: A Cross-Sectional Analysis

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Abstract

Introduction: During the COVID-19 pandemic, surgical masks have become a crucial protective measure to prevent the spread of the virus. While they are regulated as medical devices to ensure their effectiveness, the high demand for masks has led to an increase in counterfeit products that pose a threat to public health.

Materials and methods: In Chandigarh, India, a cross-sectional study was conducted with 350 individuals aged 15 and above who had access to social networks. An online questionnaire consisting of 20 questions on knowledge, practice, and demographics was used to collect data through convenience sampling with a chain-sampling method. Descriptive statistics and correlation and linear regression analysis were performed using SPSS version 29.0 to find a statistically significant relationship between knowledge, practice, and demographic variables.

Result: Of 350 participants in the survey 26.0% were aged 15-29, 32.6% were aged 30-39, 13.4% were aged 40-49, and 28.0% were aged 50-80. In terms of gender, 49.1% were male and 50.9% were female. The majority had a master's degree (45.7%) and were employed in the private sector (49.4%). Education had a significant impact on knowledge (t-value of 11.375, significance level < .001), but job type did not (t-value of -1.740, significance level .083). Participants' knowledge and practice had a strong positive correlation (Pearson Correlation coefficient of 1.000, significance level < .001). The constant (intercept) was significant in predicting practice, while age, gender, and job were not (significance levels > .05).

Conclusion: The study found that the community had satisfactory awareness and practice of using certified and licensed surgical masks. However, there is a need for reinforced education on the topic. The researchers recommend mass media campaigns and strict government regulation to ensure the use of certified masks and prevent the use of counterfeit ones. Continuous education is also necessary to help the public understand the importance of using certified and licensed masks for maximum protection.

Keywords: COVID-19, Surgical Mask, Government regulation, Demographics

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1. Introduction

The use of surgical masks has evolved greatly over the years, and their importance has increased greatly in recent times due to the ongoing COVID-19 pandemic. The significance of surgical masks prior to the COVID-19 pandemic was limited to medical and surgical settings, however, their use has since become widespread in the general population as well. (1, 2) Face masks are non-pharmacological public health interventions that play a vital role in controlling disease spread. In the fight against COVID-19, the importance of surgical masks cannot be overstated, as they play a crucial role in reducing the spread of the virus. (3-5)

At the beginning of the pandemic, universal mask usage by community members was a challenging issue. The WHO recommended using masks for the sick, those with clinical signs, and people who take care of them. (6) However with peak of pandemic the WHO suggested governments to enforce mask usage among community members. (7) The use of masks was considered as one of the effective strategies to decrease and control the COVID outbreak In numerous worldwide countries, such as Iran and the United States (US), people were required to use masks in public places and workplace settings. The center for disease control and prevention (CDC) confirmed that the main reason for the mandatory usage of masks is to protect the community members' health. (8-10)

The effectiveness of surgical masks in preventing the transmission of infectious diseases is dependent on their proper use and adherence to regulations. (11) The COVID-19 pandemic has highlighted the pressing need for stringent guidelines on the production, materials, quality control, labeling, distribution, and pricing of surgical masks. (12) However, the increased demand for surgical masks has led to a rise in the production of counterfeit masks. The proliferation of counterfeit surgical masks has raised concerns about the quality and effectiveness of these masks in preventing the spread of infectious diseases. (13) Local and international governing bodies should also strictly enforce legal guidelines to forbid the manufacturing of counterfeit surgical masks, with serious penalties imposed to deter those who engage in such activities. (14) The local government should also educate the general public on how to distinguish between good-quality surgical masks and counterfeit masks via social media campaigns and rallies. (15) This heightened awareness is especially important for vulnerable populations, who may be more susceptible to purchasing counterfeit masks. Research has shown that there have been significant instances of counterfeit surgical masks being sold in both online and offline markets globally. (16) The counterfeiting of surgical masks can be attributed to various factors, including a lack of stringent guidelines, weak enforcement of existing regulations, and a lack of public awareness of the distinction between genuine and fake masks. In light of this, there is a need for local and international governing bodies to enforce strict legal guidelines on the production of fake masks/protective gear, with serious penalties for those engaging in such activities. (17) The government should also educate the public on how to differentiate between high-quality masks and fake masks through the use of social media. Vulnerable subpopulations, in particular, should be made aware of the dangers posed by counterfeit masks in order to avoid falling prey to profiteers. (18,19) Furthermore, regulatory bodies have been recalling surgical masks due to their substandard quality, highlighting the need for greater regulation in this area. (20)

Therefore, the evolution of the importance of surgical masks, especially in the fight against COVID-19, has been a crucial factor in controlling the spread of infectious diseases. (21) The rise of counterfeit surgical masks has further emphasized the need for stringent guidelines and enforcement mechanisms to ensure the quality and effectiveness of surgical masks. through education and awareness campaigns, the general public can also play a role in preventing the spread of infectious diseases by using proper surgical masks and avoiding counterfeit products. This is why it is required to assess the community members' awareness, and attitude levels and develop effective strategies for improving people's awareness, and attitude toward surgical mask regulations.

2. Objectives

The objective of this study is to assess the awareness and practice of the people of Chandigarh towards the regulations on the use of surgical masks, in order to understand their perception and compliance with the rules and to identify any gaps in their knowledge and practice that could be addressed to improve public health outcomes.

3. Materials and methods

Study Design and Population:

This cross-sectional study aimed to gather information on demographics, knowledge, practice, and towards surgical mask regulations in Chandigarh, India. The study participants consisted of individuals aged 15 years and above from Chandigarh who had access to social networks.

Sample Size and Sampling Strategy:

A total of 350 individuals participated in the study, which was conducted through a convenience sampling strategy. Participants were selected using a chain-sampling method, where they were invited to share the online questionnaire with their network.

Data Collection:

Data was collected using an online questionnaire that consisted of 20 questions divided into three sections: knowledge (ten questions), practice (ten questions), and demographics (age, gender, level of education, and job). The questionnaire was administered through social networks and was completed voluntarily. Participants could only select one response from 'yes' or 'no' for each question. The study also collected demographic information including age (15-29, 30-39,40-49,50-80) Gender (Male, Female), Education (High School, Intermediate, Bachelor, Master, Ph.D.), Job(Govt, Private, Self Employed, Unemployed). The knowledge section assessed participants' understanding of surgical masks as medical devices, regulatory bodies, the importance of certification and licensing, the dangers of counterfeit masks, and how to distinguish between certified and counterfeit masks. The practice section evaluated participants' purchasing habits and opinions on surgical masks, including checking certification and licensing, paying extra for certified masks, and purchasing from specific brands. A consent form was provided on the first page of the questionnaire and participants were invited to share the link with their network.

Data analysis

The data collected in this study were analysed using descriptive statistics to calculate the frequency and percentage of the responses. To understand the relationship between the knowledge, practice, and demographic variables of the participants, Pearson Correlation and linear regression analysis were performed to control for possible confounding variables. The analysis was carried out using SPSS version 29.0. A P-value of less than 0.05 was considered statistically significant in this study.

Operational Definitions

Knowledge: A participant's awareness and understanding of surgical masks as medical devices, their regulation by different regulatory bodies, the

importance of certification and licensing the dangers of counterfeit surgical masks, and the key characteristics that distinguish certified and licensed surgical masks from counterfeit ones.

Certification and Licensing: The process of verifying and approving the quality and safety of a surgical mask through a recognized regulatory body.

Regulation: The legal process of establishing rules, policies, and standards for surgical masks to ensure their safety and quality.

Counterfeit: Surgical masks that are not certified or licensed, and do not meet the safety and quality standards established by regulatory bodies.

Surgical Mask as Medical Devices: Surgical Mask as Medical Devices refers to masks designed and manufactured to meet the standards and requirements set by regulatory bodies to be used in medical settings. These masks are intended to protect both the wearer and the patient from the spread of infectious diseases. They are made with specific materials and must meet specific criteria, such as filtration efficiency, fluid resistance, and breathability, to ensure their effectiveness in a medical setting.

4. Results

Demographic characteristics

The study included 350 participants from Chandigarh. 26.0% of the participants were aged 15-29, 32.6% were aged 30-39, 13.4% were aged 40-49, and 28.0% were aged 50-80. In terms of gender, 49.1% of the participants were male and 50.9% were female. The level of education of the participants was diverse, with 2.0% having only completed high school, 9.1% having completed intermediate level, 31.4% having obtained a bachelor's degree, 45.7% having obtained a master's degree, and 11.7% having obtained a Ph.D. The majority of the participants were employed in the private sector (49.4%), while 27.1% worked in the government sector, 13.7% were self-employed, and 9.7% were unemployed.

Table 1. Participants demographics

Demographics		Frequency (N)	Percentage %
Age	15-29	91	26.0%
	30-39	114	32.6%
	40-49	47	13.4%
	50-80	98	28.0%
Gender	Male	172	49.1%
	Female	178	50.9%
Education	High School	7	2.0%
	Intermediate	32	9.1%
	Bachelor's Degree	110	31.4%
	Master's Degree	160	45.7%
	Ph.D.	41	11.7%
Job	Private Sector	173	49.4%
	Government Sector	95	27.1%
	Self employed	48	13.7%
	Unemployed	34	9.7%

Awareness towards Surgical Mask: Regulatory Perspective

The majority of the participants (48.9%) were aware that surgical masks come under medical devices. Similarly, a larger portion of the participants (67.7%) were aware that surgical masks are regulated by different regulatory bodies in different countries. A large majority (84.9%) of the participants knew about the importance of certification and licensing of surgical masks and 84.3% of the participants believed that certifications and licensing ensure the quality and safety of surgical masks. 74.0% of the participants were aware of counterfeit surgical masks and 63.4% of the participants had encountered information about the campaign launched by the World Health Organization (WHO) to raise awareness about the dangers of counterfeit surgical masks. 86.0% of the participants believed that certification and licensing of surgical masks should be mandatory for all suppliers and manufacturers. However, only 62.6% of the participants knew the key characteristics that distinguish certified and licensed surgical masks from counterfeit ones. 66.9% of the participants had encountered information about the recall of surgical masks, and 78.6% of the participants were aware of the consequences of using counterfeit surgical masks.

Table 2. Awareness towards Surgical Mask from Regulatory Perspective among participants

Awareness Questions		Count	Column N %
Are you aware that surgical masks come under medical devices?	YES	171	48.9%
	NO	179	51.1%
Are you aware that surgical masks are regulated by different regulatory bodies in different countries?	YES	237	67.7%
	NO	113	32.3%
Do you know about the importance of certification and licensing of surgical masks?	YES	297	84.9%
	NO	53	15.1%

Do you believe that certifications and licensing of surgical masks ensures their quality and safety?	YES	295	84.3%
	NO	55	15.7%
Are you aware of counterfeit surgical masks?	YES	259	74.0%
	NO	91	26.0%
Have you encountered information about the campaign launched by the World Health Organization (WHO) to raise awareness about the dangers of counterfeit surgical masks?	YES	222	63.4%
	NO	128	36.6%
Do you believe that certification and licensing of surgical masks should be mandatory for all suppliers and manufacturers?	YES	301	86.0%
	NO	49	14.0%
Do you know the key characteristics that distinguish certified and licensed surgical masks from counterfeit ones?	YES	219	62.6%
	NO	131	37.4%
Have you encountered information about the Recall of Surgical mask?	YES	234	66.9%
	NO	116	33.1%
Are you aware of the consequences of using counterfeit surgical masks?	YES	275	78.6%
	NO	75	21.4%

Practice towards Surgical Mask: Regulatory Prospective

The half of the participants (48.9%) usually checks the certification and licensing of surgical masks before purchasing them. However, 51.1% of participants reported not checking for proper certification or licensing. 67.7% of participants have encountered a situation where they had to purchase surgical masks without proper certification, while 84.9% of participants reported that they would be willing to pay extra for a certified and licensed surgical mask.

The survey results indicated that the majority of participants (84.3%) felt confident in the authenticity of the surgical masks they purchase. 74% of participants were aware of counterfeit surgical masks and reported having encountered them, but only 26% of participants reported such incidents to the relevant authorities. The price of surgical masks was a factor in purchasing decisions for 66.9% of participants, while 86% of participants reported participating in campaigns to raise awareness about the dangers of counterfeit surgical masks.

62.6% of participants reported purchasing surgical masks from a specific certified brand, while 63.4% of participants believed that surgical masks purchased from online websites were safe to use. 78.6% of participants reported having returned a surgical mask after finding out it was counterfeit.

Table 3. Practice towards Surgical Masks from Regulatory Perspective among participant

Practice Questions		Count	Column N %
Do you usually check the certification and licensing of surgical masks before purchasing them?	YES	171	48.9%
	NO	179	51.1%
Have you ever encountered a situation where you had to purchase surgical masks without proper certification or licensing?	YES	237	67.7%
	NO	113	32.3%
Will you pay extra for a certified and licensed surgical mask?	YES	297	84.9%
	NO	53	15.1%
Are confident are you in the authenticity of the surgical masks you purchase?	YES	295	84.3%
	NO	55	15.7%
Have you ever reported a counterfeit surgical mask to the relevant authorities?	YES	259	74.0%
	NO	91	26.0%
Do you consider the price as a factor in purchasing surgical masks?	YES	234	66.9%
	NO	116	33.1%
Did you participated in any campaign to raise awareness about the dangers of counterfeit surgical masks?	YES	301	86.0%
	NO	49	14.0%
Do you usually purchase surgical masks from a specific certified brand?	YES	219	62.6%
	NO	131	37.4%
Do you believe that surgical masks purchased from online websites are safe to use?	YES	222	63.4%
	NO	128	36.6%
Have you ever returned a surgical mask after finding out it was counterfeit?	YES	275	78.6%
	NO	75	21.4%

Relationship between "Knowledge" and "Practice" Among Participants

In this study, Pearson correlation statistical techniques were used to describe the relationship between participants' level of "Knowledge" and "Practice". Based on the findings of Table 4. It can be concluded that the correlation is significant at the 0.01 level (2-tailed) with a Pearson Correlation coefficient of 1.000, indicating a strong positive relationship between the two variables. This means that "Knowledge" has a strong and positive relationship with "Practice", where an increase in "Knowledge" results in an increase in "Practice"

Table 4. Correlation between "Knowledge" and "Practice"

Parameter		Practice	Knowledge
Practice	Pearson Correlation	1	1.000**
	Sig. (2-tailed)		<.001
	N	350	350
Knowledge	Pearson Correlation	1.000**	1
	Sig. (2-tailed)	<.001	
	N	350	350
**. Correlation is significant at the 0.01 level (2-tailed).			

Relationship between Knowledge, Practice, and Demographics

Based on Table 5. It can be concluded that the correlation between Practice and Knowledge is strong and positive, with a Pearson correlation of 1.000 and a significance level of less than .001 (2-tailed). This indicates that there is a strong relationship between Practice and Knowledge.

The correlations between the other variables and Practice or Knowledge are weaker, with the highest being between Education and Practice (Pearson correlation of .560, a significance level of less than .001). The correlations between Age, Gender, and Job with Practice or Knowledge are not statistically significant, with significance levels greater than .05.

Table 5. Correlation for Practice and Knowledge and Demographics

Parameters		Practice	Knowledge	Age	Gender	Education	Job
Practice	Pearson Correlation	1	1.000**	.114*	.101	.560**	-.203**
	Sig. (2-tailed)		<.001	.032	.059	<.001	<.001
	N	350	350	350	350	350	350
Knowledge	Pearson Correlation	1.000**	1	.114*	.101	.560**	-.203**
	Sig. (2-tailed)	<.001		.032	.059	<.001	<.001
	N	350	350	350	350	350	350
Age	Pearson Correlation	.114*	.114*	1	.083	.213**	.042
	Sig. (2-tailed)	.032	.032		.122	<.001	.437
	N	350	350	350	350	350	350
Gender	Pearson Correlation	.101	.101	.083	1	.215**	-.012
	Sig. (2-tailed)	.059	.059	.122		<.001	.830
	N	350	350	350	350	350	350
Education	Pearson Correlation	.560**	.560**	.213**	.215**	1	-.227**
	Sig. (2-tailed)	<.001	<.001	<.001	<.001		<.001
	N	350	350	350	350	350	350
Job	Pearson Correlation	-.203**	-.203**	.042	-.012	-.227**	1
	Sig. (2-tailed)	<.001	<.001	.437	.830	<.001	
	N	350	350	350	350	350	350
**. Correlation is significant at the 0.01 level (2-tailed).							
*. Correlation is significant at the 0.05 level (2-tailed).							

Relationship of "Practice" with Demographics

Simple linear regression analysis was performed to predict the level of " Practice" based on various predictor variables (Age, Gender, Education, and Job). The results indicate that the constant (intercept) is significant in the model (t-value of 4.102 and a significance level of <.001). However, the "Age" and "Gender" are not significant (t-value of 0.074 and -0.380, respectively, with significance levels of .941 and .704, respectively). On the other hand, "Education" is significant in the model (t-value of 11.375 and a significance level of <.001). The "Job" is not significant (t-value of -1.740 and a significance level of .083)

Table 6. Linear regression for "Practice" on Demographics

Model		Unstandardized Coefficients		Standardized Coefficients	T	Sig.
		B	Std. Error	Beta		
1	(Constant)	.811	.198		4.102	<.001
	Age	.002	.032	.003	.074	.941
	Gender	-.028	.073	-.017	-.380	.704
	Education	.496	.044	.544	11.375	<.001
	Job	-.064	.037	-.080	-1.740	.083
a. Dependent Variable: Attitude						

Relationship of "Knowledge" with Demographics

Simple linear regression analysis was performed to predict the level of "Knowledge" based on various predictor variables (Age, Gender, Education, and Job). The results show that the constant (intercept) is significant in the model, meaning that it has a significant impact on the level of "Knowledge". However, the "Age" and "Gender" do not have a significant impact on "Knowledge" as their t-values are low and their significance levels are high (0.074 and .941 for "Age", and -0.380 and .704 for "Gender"). On the other hand, "Education" has a significant impact on "Knowledge", with a high t-value of 11.375 and a low significance level of <.001. This means that the level of education has a significant effect on the level of "Knowledge". "Job" is not significant in the model, with a low t-value of -1.740 and a high significance level of .083. This means that the type of job does not have a significant effect on the level of "Knowledge".

Table 7. Linear regression for "Knowledge" on Demographics

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	.811	.198		4.102	<.001
	Age	.002	.032	.003	.074	.941
	Gender	-.028	.073	-.017	-.380	.704
	Education	.496	.044	.544	11.375	<.001
	Job	-.064	.037	-.080	-1.740	.083
a. Dependent Variable: Knowledge						

5. Discussions

This study was aimed at evaluating the knowledge, and practice of Chandigarh people towards regulations of surgical masks. The findings showed that there was a general level of awareness among the participants regarding the regulation, certification, licensing, and counterfeit surgical masks. A majority of the participants were aware of the importance of certification and licensing and believed that these processes ensure the quality and safety of surgical masks. Additionally, a large majority of participants were aware of counterfeit surgical masks and believed that certification and licensing of surgical masks should be mandatory for all suppliers and manufacturers.

However, the results also showed that there was still room for improvement in terms of knowledge of the key characteristics that distinguish certified and licensed surgical masks from counterfeit ones. Only 62.6% of the participants knew these key characteristics. Also education and awareness-raising efforts to improve participants' knowledge of the key characteristics that distinguish certified and licensed surgical masks from counterfeit ones and encouraging participants to prioritize quality and safety when purchasing surgical masks can be beneficial for the people. The study also revealed that while half of the participants usually check the certification and licensing of surgical masks before purchasing them, 51.1% of participants reported not checking for proper certification or licensing.

In terms of practices, the results showed that 67.7% of participants have encountered a situation where they had to purchase surgical masks without proper certification. However, 84.9% of participants reported that they would be willing to pay extra for a certified and licensed surgical mask. The majority of the participants felt confident in the authenticity of the surgical masks they purchase. Education had a significant correlation between knowledge and practice.

The strength of the study is that it provides valuable information about the general level of awareness among the participants regarding surgical masks and their regulation. The study also provides information about participants' practices when purchasing surgical masks, including their willingness to pay extra for a certified and licensed mask. One of the limitations was the sample size of the study is small, with only 350 participants from Chandigarh but we believe the study will help future surveys.

6. Conclusion

We conclude that the community has a general level of awareness regarding the regulation, certification, licensing, and counterfeit surgical masks. The findings revealed that the awareness and practice of using certified and licensed masks were satisfactory among the community. We suggest continuous reinforcement by spreading awareness and educating in terms of understanding of the regulations and certifications of surgical masks among the general public, and knowledge of the key characteristics that distinguish certified and licensed surgical masks from counterfeit ones. We suggest the government should initiate mass media campaigns and enforce regulations strictly for surgical masks to ensure maximum protection against disease. We also recommend strict regulations for surgical masks it preventing counterfeiting of surgical masks.

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Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article

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