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# EXAMINING OF THE RELATIONSHIP BETWEEN INDIVIDUALS TAKING PCR TESTS AND THEIR RELATED COVID-19 ANXIETY

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Abstract: This study examines the relationship between individuals' COVID-19-related anxiety and their PCR testing behaviour. The pandemic has had a significant impact on mental health, increasing healthrelated anxiety, which includes excessive fear of illness. It is important to understand how anxiety affects PCR testing behaviour. The study was conducted in Trabzon, Turkey, with 400 participants aged 18 years and older, using face-to-face interviews. Variables such as age, gender, income, education, COVID-19 history, frequency of PCR testing, and reasons for testing were analysed. Anxiety levels were measured using the Coronavirus Anxiety Scale, and data were analysed using descriptive statistics, Mann-Whitney U, Kruskal-Wallis, and Spearman correlation tests. Results showed that individuals who underwent PCR testing had significantly higher levels of anxiety than those who did not. Voluntary testers reported higher levels of anxiety than those required to be tested for work. However, those who had been tested 1-2 times had higher anxiety than those who had been tested more frequently, suggesting that familiarity with the process may reduce anxiety. Female participants were more anxious than males, while income and education level had no significant effect. Those who obtained COVID-19 information from the internet had lower anxiety than those who used mobile applications. In addition, vaccinated individuals showed higher anxiety, possibly due to concerns about side effects or vaccine effectiveness. In conclusion, there is a significant association between PCR testing and COVID-19 anxiety. Frequency of testing, reasons for testing and sources of information influence anxiety levels. To mitigate this, health authorities should improve guidance and support for individuals undergoing PCR testing to help reduce associated anxiety.

Keywords: Anxiety, COVID-19, Health behavior, Pandemic, PCR test

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# 1. Introduction

In Maslow's hierarchy of needs, the need for security is identified as one of the most fundamental human necessities [1, 2]. In the past, societies experienced great fears due to their inability to protect themselves from natural disasters, wild animals, and epidemics [2, 3]. Today, despite advancements in technology and medicine that have enabled protection from many past dangers, concerns related to health remain prevalent due to the emergence and spread of various infectious diseases [2-4].

The concept of anxiety, which is defined in both psychological and philosophical domains, refers to an inexplicable state of worry in psychology, whereas, in philosophy, it describes the emotional state that arises from an awareness of the world's meaninglessness, incompleteness, lack of order, and purpose [3, 5]. Anxiety represents the distressing emotion one experiences in response to the overwhelming and often tragic nature of events in the world [6].

In general, anxiety can be defined as a sense of unease or an irrational fear stemming from the anticipation of a threat. Various types of anxiety disorders have been identified in the literature [7, 8]. According to the American Psychiatric Association, anxiety disorders include panic disorder, agoraphobia, phobia, social anxiety disorder, selective mutism, generalized anxiety disorder, separation anxiety disorder, unspecified anxiety disorder, substance/medication-induced anxiety disorder, and anxiety disorder due to another medical condition [9, 10].

The concept of health anxiety was first introduced by Salkovskis and Warwick in 1986. It is defined as an excessive concern about having or developing a serious illness due to the misinterpretation of bodily sensations [11-13]. Health anxiety varies among individuals and can manifest at mild or severe levels [10, 14]. Individuals with high levels of health anxiety often experience intense fears about their health, leading them to frequently consult healthcare professionals [15, 16]. Even when no physical illness is diagnosed, their concerns about their health may persist due to dissatisfaction with medical evaluations [17]. This dissatisfaction with medical examinations often leads individuals to seek information from easily accessible sources such as the internet. However, rather than alleviating their concerns, such sources can exacerbate anxiety by reinforcing the perception of bodily and mental vulnerability [13, 15, 17]. Beyond these factors, one of the most significant contributors to anxiety is the occurrence of pandemics [4].

A pandemic is defined as the widespread transmission of an infectious disease, leading to high rates of infection and mortality across countries and even globally [18]. Throughout history, numerous pandemics have been recorded from the Middle Ages to the present. In December 2019, a novel coronavirus emerged, rapidly spreading across the globe and resulting in a pandemic with severe health and economic consequences [18-21].

The outbreak was initially identified in Wuhan, China, among patients presenting with respiratory symptoms. Further investigations led to the identification of the novel coronavirus, later named covid-19 [19, 22, 23]. Although its impact has diminished over time, covid-19 remains a public health concern. The virus is known to spread through human-to-human contact, animal-to-human transmission, and exposure to contaminated surfaces. Its most common symptoms include fever, cough, diarrhea, and shortness of breath. In severe cases, complications such as pneumonia, acute respiratory distress syndrome, kidney failure, and even death can occur [22].

According to World Health Organization (WHO), by December 2023, approximately 7 million deaths and over 700 million confirmed cases of COVID-19 had been reported worldwide [25]. In Turkey, the first confirmed COVID-19 case was recorded on March 11, 2020. As of March 2023, the Ministry of Health reported 102,174 deaths and 17,232,066 confirmed cases [26]. In response, various precautionary measures were implemented, and vaccines were developed and approved [27]. Additionally, the "gold standard" for COVID-19 detection, the Polymerase Chain Reaction (PCR) test, has been widely used to identify infected individuals [28, 29].

PCR, first discovered by Kary Mullis in 1985 for the purpose of detecting DNA sequences, is an in vitro method that utilizes oligonucleotide primers to enzymatically synthesize specific DNA sequences [30, 31]. The PCR test, with an accuracy and reliability rate of approximately 70%, is administered free of charge to individuals presenting with COVID-19 symptoms [28, 32]. Depending on the patient's condition, samples are collected from either the upper or lower respiratory tract [32].

The anxiety associated with receiving PCR test results, along with the ongoing impact of the COVID-19 pandemic, is believed to directly influence individuals' psychological well-being [33]. This study aims to examine the relationship between individuals' anxiety levels related to COVID-19 and their decisions to undergo PCR testing.

#### 2. Materials and Methods

This study was designed as a descriptive research study employing quantitative research methods.

#### 2.1. Participants and Sample Size

The study population consisted of individuals residing in the central district of Trabzon, Turkey. Since the exact size of the population was unknown, a sample size was calculated using an unknown population sampling method [34]. The minimum required sample size was determined to be 384 participants aged 18 and above; however, a total of 400 individuals were included in the study. The convenience sampling method was used to select participants. Data were collected through face-to-face surveys conducted with individuals who voluntarily agreed to participate.

#### **2.2. Data Collection Tools**

The data collection instrument consisted of two sections. The first section included sociodemographic questions related to participants' age, gender, income level, educational background, history of covid-19 infection, history of PCR testing, frequency of PCR testing, reasons for undergoing PCR testing, vaccination status, experience of losing a loved one due to covid-19, and sources of information about the disease. The second section comprised the Coronavirus Anxiety Scale (CAS). The Coronavirus Anxiety Scale (CAS) was originally developed by Lee and was adapted into Turkish with validated reliability by Biçer and colleagues [35, 36]. The scale consists of five items and employs a five-point Likert-type response format: "0" (Never), "1" (Rarely, less than one or two days), "2" (Several days), "3" (More than seven days), and "4" (Nearly every day in the past two weeks). The total scale score is calculated by summing individual item scores, resulting in a range of 0 to 20. A higher score indicates a greater level of COVID-19-related anxiety. The Cronbach's alpha reliability coefficient for the original scale was found to be 0.832, indicating high reliability. In this study, the Cronbach's alpha reliability coefficient of the scale was calculated as 0.798.

#### **2.3. Data Collection Procedure**

The data collection process took place between July and September 2022. Prior to survey administration, participants were provided with an informed consent form explaining the study's purpose, confidentiality measures, and voluntary participation rights. Only those who consented to participate were included in the study.

#### 2.4. Statistical Analysis

The data collected were analyzed using the NCSS (Number Cruncher Statistical System) 2007 (Kaysville, Utah, USA) software. Descriptive statistical methods, including mean, standard deviation, median, frequency, percentage, minimum, and maximum values, were used for data summarization. The Shapiro-Wilk normality test was applied to determine whether the data followed a normal distribution.

For comparisons between two independent groups with non-normally distributed data, the Mann-Whitney U test was employed. For comparisons involving three or more independent groups with non-normally distributed data, the Kruskal-Wallis test was used, followed by Bonferroni-Dunn post hoc tests for pairwise comparisons. The relationships between numerical variables were assessed using Spearman's correlation analysis. A p-value of <0.05 was considered statistically significant.

#### 2.5. Ethical Considerations

The study was approved by Bandırma Onyedi Eylül University, Non-Interventional Research Ethics Committee of Health Science (Approval Date: 20.06.2022, Approval Number: 2022-105). All

participants provided informed consent before participating in the study, and ethical principles regarding confidentiality and voluntary participation were strictly adhered to.

### 3. Results

This study was conducted with 400 participants residing in the central district of Trabzon, Turkey. Of the participants, 43.8% (n=175) were female, while 56.2% (n=225) were male. The participants' ages ranged between 18 and 80 years, with a mean age of  $35.57 \pm 13.03$  years. In terms of income level, 12.5% (n=50) reported a low income, 72% (n=288) reported a middle income, and 15.5% (n=62) reported a high income. Regarding educational background, 21.5% (n=86) had primary education, 13.5% (n=54) had secondary education, 28.7% (n=115) had high school education, 34.5% (n=138) had a university degree, and 1.8% (n=7) had postgraduate education. Additionally, 14.8% (n=59) had a chronic disease, while 85.2% (n=341) reported no chronic disease. Findings regarding descriptive characteristics are presented in Table 1.

		min-max (median)	mean±sd
Age (year)		18-80 (34)	35.57±13.03
		n	%
Gender	Female	175	43.8
Gender	Male	225	56.2
	Low	50	12.5
Income status	Middle	288	72.0
	High	62	15.5
	Primary School	86	21.5
	Secondary School	54	13.5
Education status	High School	115	28.7
	Graduate	138	34.5
	Postgraduate	7	1.8
Chronic disease status	Yes	59	14.8
Chrome uisease status	No	341	85.2

Table 1. Distribution of Descriptive Characteristics

Among the participants, 50.5% (n=202) had a history of covid-19 infection, and 27% (n=108) had lost a close relative due to covid-19. The primary sources of information regarding covid-19 were television (91%, n=364), radio (22.5%, n=90), internet (81.3%, n=325), social media (70%, n=280), mobile applications (54.5%, n=218), and family and friends (77.5%, n=310). Of the participants in the study, 84.8% (n=339) had received a covid-19 vaccine, while 15.2% (n=61) reported not being vaccinated. The rate of PCR testing was found to be 67.5% (n=270). Among those who had undergone PCR testing, 74.8% (n=202) had been tested 1-2 times, 15.9% (n=43) had been tested 3-4 times, and 9.3% (n=25) had undergone PCR testing five or more times. Regarding the reason for undergoing PCR testing, 71.1% (n=192) stated that they took the test voluntarily, 14.8% (n=40) reported that it was required by their workplace, and 14.1% (n=38) cited other reasons (Table 2).

		n	%
COVID-19 transmission status	Yes	202	50.5
COVID-19 transmission status	No	198	49.5
Loss of a relative due to COVID 10	Yes	108	27
Loss of a relative due to COVID-19	No	292	73
	Television	364	91
	Radio	90	22.5
COVID-19 information source*	İnternet	325	81.3
	Social media	280	70
	Mobil applications	218	54.5
	Family and friends	310	77.5
V	Yes	339	84.8
Vaccination status	No	61	15.2
DCD to at status	Yes	270	67.5
PCR test status	No	130	32.5
	1-2 times	202	74.8
Test number (n=270)	3-4 times	43	15.9
	More than 5	25	9.3
	My own will	192	71.1
Reason for having a test (n=270)	Request of my workplace	40	14.8
_ 、 ,	Other	38	14.1

# Table 2. Distribution of COVID-19 Characteristics

\*Multiple options were selected

The responses of the participants to the Coronavirus Anxiety Scale (CAS) items are detailed in Table 3.

	Never		Rarely (Less than Several one or two Days days)		More than Seven Days		Nearly Every Day in the Last Two Weeks		Mean±Sd		
	n	%	n	%	n	%	n	%	n	%	-
I felt dizzy, lightheaded, or as if I was going to faint when reading or listening to news about covid-19.	333	83.3	46	11.5	18	4.5	2	0.5	1	0.3	0.23±0.57
I had trouble falling asleep or staying asleep because I was thinking about covid- 19.	309	77.3	55	13.8	33	8.3	2	0.5	1	0.3	0.33±0.67
I felt paralyzed or as if I had a stroke when thinking about or being exposed to covid-19-related topics.	372	93.0	20	5.0	7	1.8	0	0	1	0.3	0.10±0.39
I lost my appetite when thinking about or being exposed to covid-19- related topics.	332	83.0	40	10.0	20	5	7	1.8	1	0.3	0.26±0.65
I experienced nausea or stomach problems when thinking about or being exposed to covid-19- related topics.	342	85.5	49	12.3	6	1.5	2	0.5	1	0.3	0.18±0.49

Participants' responses to the Coronavirus Anxiety Scale (CAS) were analyzed, revealing that COVID 19 anxiety scores ranged from 0 to 16, with a mean score of  $1.09 \pm 2.10$ . The Cronbach's alpha reliability coefficient for the scale was calculated as 0.798, indicating a high level of reliability (Table 4).

**Table 4.** Distribution of Coronavirus Anxiety Scale (CAS) Scores

	Covid-19 Anxiety Scores
Items number	5
Min-Max (Median)	0-16 (0)
Mean±Sd	1.09±2.10
Cronbach's Alpha	0.798

Table 5 presents the differences between participants' descriptive characteristics and their COVID-19 anxiety scores. According to the findings, no statistically significant relationship was found between age and COVID-19 anxiety scores (p>0.05). A statistically significant difference was observed between gender and COVID-19 anxiety scores (p=0.001, p<0.01), with female participants reporting higher anxiety levels than males. However, age was not significantly correlated with COVID-19 anxiety scores (p>0.05). Similarly, no statistically significant difference was found between income level and covid-19 anxiety (p>0.05) or educational background and COVID-19 anxiety (p>0.05). Furthermore, chronic illness status was not associated with significant differences in COVID-19 anxiety scores (p>0.05).

			COVID-19 Anxiety S	cores		
			min-max (median) Mean±SD		– р	
A	r		0.093			
Age (year)	р	n	0.064			
Candan	Female	175	0-16 (0)	$1.82 \pm 2.74$	<sup>a</sup> 0.001**	
Gender	Male	225	0-7 (0)	$0.53 \pm 1.14$	*0.001 **	
	Low	50	0-7 (0)	0.70±1.46		
ncome status	Middle	288	0-12 (0)	$1.09{\pm}1.94$	<sup>b</sup> 0.419	
	High	62	0-16 (0)	$1.42 \pm 3.03$		
	Primary School	86	0-7 (0)	0.88±1.56		
	Secondary School	54	0-16 (0)	$1.85 \pm 3.11$		
Education status	High School	115	0-12 (0)	$0.94{\pm}1.94$	<sup>b</sup> 0.263	
	Graduate and Postgraduate	145	0-11 (0)	1.06±1.99		
Chronic disease	Yes	59	0-7 (0)	$0.86{\pm}1.68$	a0 162	
status	No	341	0-16 (0)	$1.13 \pm 2.16$	<sup>a</sup> 0.462	

Table 5. Evaluation of COVID-19 Anxiety Scores Based on Descriptive Characteristics

r: Spearman's Correlation Coefficient, a: Mann-Whitney U Test, b: Kruskal-Wallis Test; \*\*p<0.01

No statistically significant difference was found between COVID-19 infection history and anxiety scores (p>0.05) or losing a relative due to COVID-19 and anxiety scores (p>0.05). When analyzing information sources, participants who obtained covid-19 information from the internet reported significantly lower anxiety levels compared to those who did not use the internet for this purpose (p=0.002, p<0.01). Conversely, participants who relied on mobile applications for COVID-19 information exhibited significantly higher anxiety levels (p=0.021, p<0.05). A statistically significant difference was found between vaccination status and covid-19 anxiety scores (p=0.006, p<0.01), with vaccinated participants reporting higher anxiety levels than unvaccinated individuals. Additionally, a

significant difference was observed in COVID-19 anxiety levels based on PCR testing status (p=0.022, p<0.05), with those who had undergone PCR testing exhibiting higher anxiety scores than those who had not. When examining the number of PCR tests taken, a statistically significant difference was found (p=0.018, p<0.05). Participants who had undergone 1-2 PCR tests reported higher anxiety levels compared to those who had taken 3-4 tests (p=0.048, p<0.05). However, no significant difference was found in comparisons involving individuals who had taken five or more tests (p>0.05). A statistically significant difference was found in COVID-19 anxiety levels based on participants' reasons for undergoing PCR testing (p=0.007, p<0.01). Pairwise comparisons revealed that participants who voluntarily underwent PCR testing reported higher anxiety levels than those who were required to take the test by their workplace (p=0.035, p<0.05). No significant difference was found among other test motivation groups (p>0.05) (Table 6).

			COVID-19 Anxiety S	Scores		
		n	min-max (median)	Mean±SD	— р	
Covid-19 transmission	Yes	202	0-11 (0)	1.20±2.12	a0 ( <b>27</b>	
status	No	198	0-16 (0)	$0.98{\pm}2.08$	<sup>a</sup> 0.627	
Loss of a relative due to	Yes	108	0-8 (0)	0.96±1.80	<sup>a</sup> 0.752	
Covid-19	No	292	0-16 (0)	$1.14 \pm 2.20$	-0.752	
Covid-19 information sou	rce ***					
Talassiai	Yes	364	0-16 (0)	1.10±2.12	30.046	
Television	No	36	0-8 (0)	$1.03 \pm 1.95$	<sup>a</sup> 0.946	
D . 1'.	Yes	90	0-7 (0)	$1.06 \pm 1.83$	a0 72 1	
Radio	No	310	0-16 (0)	$1.10\pm2.17$	<sup>a</sup> 0.731	
T	Yes	325	0-16 (0)	$0.98 \pm 2.06$	30 00 **	
Internet	No	75	0-10(1)	$1.56 \pm 2.23$	<sup>a</sup> 0.002**	
Social media	Yes	280	0-16 (0)	$1.03{\pm}2.06$	30.2(1	
	No	120	0-12 (0)	$1.25 \pm 2.19$	<sup>a</sup> 0.261	
M.1.1.1	Yes	218	0-16 (0)	1.31±2.35	<sup>a</sup> 0.021*	
Mobil applications	No	182	0-10 (0)	$0.83 \pm 1.73$		
E	Yes	310	0-12 (0)	$1.09{\pm}2.01$	10 595	
Family and Friends	No	90	0-16 (0)	$1.09 \pm 2.38$	<sup>a</sup> 0.585	
N7	Yes	339	0-12 (0)	$1.13 \pm 2.00$	30.00(**	
Vaccination status	No	61	0-16 (0)	$0.87 {\pm} 2.60$	<sup>a</sup> 0.006**	
	Yes	270	0-16 (0)	1.28±2.33	30.022*	
PCR test status	No	130	0-8 (0)	$0.71{\pm}1.44$	<sup>a</sup> 0.022*	
	1-2 times	202	0-16 (0)	$1.42{\pm}2.40$		
Test number (n=270)	3-4 times	43	0-10 (0)	$0.91 \pm 2.26$	<sup>b</sup> 0.018*	
	More than 5	25	0-7 (0)	$0.76 \pm 1.76$		
	My own will	192	0-16 (0)	$1.49{\pm}2.48$		
Reason for having a test (n=270)	Request of my workplace	40	0-9 (0)	0.83±2,09	<sup>b</sup> 0.007**	
	Other	38	0-7 (0)	$0.66{\pm}1.48$		

Table 6. Evaluation of COVID-19 Anxiety	y Scores Based on COVID-19 Characteristics
	y beores bused on covid 17 characteristics

<sup>a</sup>Mann Whitney U Test, <sup>b</sup>Kruskal Wallis Test; \*p<0.05; \*\*p<0.01, \*\*\* Multiple options were selected

#### 4. Discussion

This study aimed to determine the relationship between individuals' COVID-19-related anxiety levels and their PCR testing status. The study analyzed the statistical differences between participants'

sociodemographic characteristics, perceptions of COVID-19, and anxiety levels, discussing the findings in light of existing literature.

No statistically significant relationship was found between age and COVID-19 anxiety scores. However, previous studies in the literature have found different results, showing that participants over 50 years old had higher anxiety levels than younger individuals [37]. The difference in results may be attributed to variations in the study regions and the timing of the research.

A statistically significant difference was found between gender and COVID-19 anxiety levels, with females reporting higher anxiety scores than males. Similar studies have also found that females experience higher levels of anxiety than males [38-42]. The reason behind this finding may be attributed to women's higher emotional sensitivity and men's tendency to adopt a protective and resilient approach, which allows them to recover more quickly from stress [41, 43].

No statistically significant relationship was found between income level and COVID-19 anxiety scores. However, previous studies in the literature have yielded mixed results. Some studies, such as one conducted in Bitlis, Turkey, found that individuals with higher income levels had lower anxiety levels, while another study also reported a significant relationship between income level and coronavirus anxiety [42, 44]. Conversely, some research findings support the results of the present study, indicating no significant relationship between income level and COVID-19 anxiety [45].

Similarly, no significant difference was found between educational level and COVID-19 anxiety scores. This finding is consistent with previous research in the literature, which also did not find a significant relationship between education level and coronavirus anxiety [42, 43].

Regarding sources of information about COVID-19, the study found that obtaining information from television, radio, social media, and family/friends did not significantly impact anxiety scores. However, a study conducted in Wuhan, China, found that social media users had higher anxiety levels [46].

In contrast, participants who obtained information about COVID-19 from the internet had lower anxiety levels than those who did not use the internet for this purpose. This result may be because internet users have access to positive news, such as increasing recovery rates, which may help alleviate their anxiety. Supporting this finding, Wang et al. found that exposure to information about covid-19 recovery rates helped reduce anxiety levels [47]. On the other hand, participants who relied on mobile applications for information had higher anxiety levels than those who did not. This finding appears contradictory to the previous one, as both sources are digital. However, this discrepancy may be due to regional differences. In the region where the study was conducted, there may be higher trust in healthcare professionals and official government sources, which could explain the higher anxiety levels among those using mobile apps for COVID-19 information. A study by Köse also confirmed that healthcare professionals were the primary source of health-related information in the Black Sea region of Turkey [48].

A significant difference was found between vaccination status and COVID-19 anxiety levels, with vaccinated individuals reporting higher anxiety levels than unvaccinated individuals. Similar studies in the literature have also found that vaccinated individuals exhibit higher levels of COVID-19-related anxiety [49]. The psychological and sociological impact of the COVID-19 pandemic, along with the fear of the disease and potential death, may have influenced individuals to get vaccinated. Additionally, concerns about vaccine side effects or its effectiveness may have contributed to higher anxiety levels among vaccinated individuals.

The study found no significant difference in COVID-19 anxiety scores based on chronic illness status. Previous studies conducted among emergency healthcare workers in Turkey have reported similar findings, indicating no significant relationship between chronic illness and coronavirus anxiety [44]. Additionally, Özdede et al., also found no significant relationship between having a chronic illness

and COVID-19-related anxiety [50]. However, some studies in the literature contradict these findings, reporting that individuals with chronic illnesses experience significantly higher COVID-19-related anxiety levels than healthy individuals [51-54].

No significant relationship was found between having previously contracted COVID-19 and coronavirus anxiety scores. This result aligns with previous studies that found no significant relationship between having had COVID-19 and anxiety levels [44]. However, other studies, such as those by Aslaner et al. and Cansel et al., reported that individuals who tested positive for COVID-19 exhibited higher anxiety levels [37].

Similarly, losing a loved one due to COVID-19 was not associated with a significant difference in anxiety scores. A study by Yıldız et al. found that losing a loved one due to COVID-19 did not significantly impact anxiety or fear levels. One possible explanation is that during the pandemic, constant exposure to mortality statistics may have led individuals to psychologically normalize COVID-19-related deaths [55]. However, other studies in the literature have found that individuals who lost a loved one due to COVID-19 experienced significantly higher anxiety levels [37, 56, 57].

The study found a significant relationship between PCR testing status and COVID-19 anxiety levels, with those who underwent PCR testing reporting higher anxiety levels than those who did not. This finding is consistent with similar studies that have also found higher anxiety levels among individuals who underwent PCR testing [37, 45].

Regarding the frequency of PCR testing, individuals who had been tested 1-2 times exhibited higher anxiety levels than those tested 3-4 times. This finding is supported by previous research, such as a study by Cansel et al., which found a significant relationship between PCR testing frequency and anxiety levels [37]. However, other studies, such as Wahyuni et al., did not find a significant relationship between PCR test frequency and COVID-19 anxiety [58].

A statistically significant difference was found in COVID-19 anxiety scores based on the reason for undergoing PCR testing. Pairwise comparisons showed that individuals who voluntarily underwent PCR testing exhibited higher anxiety levels than those required to take the test for work-related reasons. A review of the literature revealed a lack of studies specifically examining the relationship between PCR test motivation and COVID-19-related anxiety, suggesting that this study fills a gap in the literature by providing new insights into this issue.

#### 5. Conclusion

In conclusion, it was determined that COVID-19 anxiety scores were high in certain groups and that there were statistically significant differences in anxiety scores based on PCR testing status. To reduce anxiety experienced during PCR testing, individuals should be provided with detailed information about COVID-19 and the purpose of the PCR test, and they should be allowed to express their concerns. Continuous support should be provided to individuals to help alleviate anxiety symptoms. Health care professionals should also receive training on this issue, enabling them to develop empathy with patients and offer appropriate counseling and psychological support to those experiencing high levels of anxiety. In addition, having informative videos or written materials explaining the PCR test process simply and understandably in test centers may contribute to reducing individuals' anxiety caused by uncertainty. Assigning personnel trained in psychological first aid to provide on-site support to individuals with high levels of anxiety in areas with high test intensity may be an effective approach to anxiety management.

#### **Ethical Statement:**

Before data collection, written approval was taken from the Non-Interventional Research Ethics committee of Bandırma Onyedi Eylül University (Decision number and date: 2022-5; 20.06.2022).

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#### **Conflict of Interest:**

The authors declare that there is no conflict of interest.

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#### **Authors Contribution:**

H.K.K.: Conceptualization, Methodology, Data Collection and Processing, Analyses, Writing-Original Draft Preparation, Resources (%60).

G.A.: Conceptualization, Methodology, Review, Control-Supervision (%40). All authors read and approved of the final manuscript.

#### **Generative AI statement:**

The author(s) declare that no Gen AI was used in the creation of this manuscript.

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# EFFECTS ON HEALTH AND LIFE CHANGES OF LOCKDOWNS

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Abstract: The precautions taken aimed to provide protection against COVID-19, but by ignoring human nature and psychosociological structures, they also caused the emergence of negative outcomes. This study aimed to explain how people spend time, the effect on health, and life changes during the COVID-19 quarantine. This study is an analytical cross-sectional study. A total of 1708 participants were included, and data were collected by using Google Forms. Data were presented in numbers and frequency; Chi-square analysis was used in the comparisons of categorical data. Backward logistic regression analysis was performed to evaluate the status of experienced COVID-19 and life changes. Weight gain, use of social media and the internet, sedentary life, and unhappiness occurred due to quarantine reported in this study. It was found that more than half of the participants were unhappy and gained weight during lockdown. It has been determined that people who had COVID-19 sleep more and use social media more gain more weight and are more unhappy during quarantine. There was no planning in some countries for a healthy lifestyle during the lockdown was perhaps the greatest deficiency of pandemic management. Not only do these negative effects cause individuals to feel more anxiety, stress, and depression, but the continuation of lockdown habits will have seriously negative effects on health. There should be recommendations and guides for people to lead healthy lives in disasters.

Keywords: Covid-19, Health, Lockdown, life changes, pandemic

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# 1. Introduction

The SARS-CoV-2 coronavirus, as the agent of COVID-19 infection, spread around the world in a short period of approximately three months. The initial cases were in China at the end of 2019, and by the first week of March 2020, the number of cases worldwide was reported to exceed 100.000 [1,2]. As the outbreak became a global pandemic, countries began to implement precautions related to healthcare policies according to the speed and status of transmission. In many countries, precautions such as social distancing and individual isolation at home are aimed at preventing the spread of infection as much as possible.

These precautions taken because of the pandemic are evaluated as a social phenomenon that has affected individuals, families, and societies in many areas. The perceived threat created by the infectious disease and the cases of death occurring caused anxiety and stress, and people exhibited abnormal behaviours. The prolonged period of the pandemic, emerging uncertainty, and increasing case numbers revealed a need for crisis management. The psychosocial and emotional status of people was seen to affect the social, psychological, economic, and other societal structures of society. It is important to

determine how the psychological, social, and emotional effects of the pandemic were managed and how societies were affected [3].

In countries where these precautions were taken, the lack of planning, such as how to pass the time at home, time management, and activities that children can do at home, to reduce the effects of these restrictions, further increased the effects. In the literature related to pandemic psychology, the behaviours demonstrated by people have been categorised through observation. Accordingly, the behaviours shown were in the form of increased stress because of increases in infections and deaths, shopping and stockpiling of food and cleaning products because of panic and anxiety, over-eating, oversleeping, self-protection by exclusion and stigmatisation of communities, and feeling disease symptoms and unnecessarily using the healthcare system. Then, after having followed the rules of staying at home and social distancing restrictions, the rules were subsequently seen to be ignored, and non-compliant behaviours emerged [3,4]. COVID-19, which was perceived as a great threat to health and the global economy, caused almost every country to implement important regulations such as the temporary closure of many public offices and institutions guiding daily life and formal education institutions at different levels, part-time working, working from home, social isolation and social distancing. By affecting the daily behaviour of individuals, these interventions related to the ongoing flow of life sometimes caused panic and anxiety, and sometimes an increased tendency for depression [5,6].

The efforts made by individuals in accordance with the restrictions to prevent the spread of COVID-19 are thought to have had adverse effects on physical and mental health. This view is supported by the results of social isolation implemented in the past [7]. Whatever the age, gender, or health status of an individual, the disruption of routine, having to stay at home, and the lack of a planned program caused people to spend time at home with limited resources and continue life according to the facilities available without knowing what to do.

In Turkey, the first pandemic restrictions and lockdown started on 1 March 2020, and subsequently, distance learning, flexible working and working from home were implemented. Although gradual normalisation was introduced on 1 June 2020, the schools did not re-open and the changed working hours in public offices continued.

The aim of this study was to determine how people passed the time during lockdowns in the COVID-19 pandemic and the effects on their health.

#### 2. Methods

#### 2.1. Design

The research was conducted in an analytic cross-sectional design. The study aims to investigate contributing factors of life changes and what life changes in lockdown are.

#### 2.2. Population and sampling

The population of the study consists of 431,848 people living in the province where the study was conducted between 19 December 2020 and 19 April 2021. Following a scan of the literature, a questionnaire was prepared by the researchers. Data was collected online via Google Forms. Participants were recruited through convenience sampling and snowball sampling. We posted the recruitment announcement through the social media accounts of researchers. Among the 1785 participants who accessed the survey, 1708 voluntary participants were included in this study.

#### 2.3. Statistical analysis

Data obtained in the study were analyzed statistically using SPSS 22.0 software. Results were presented as mean  $\pm$  standard deviation values, number [n], and percentage [%]. Chi-square analysis

was used in the comparisons of categorical data. Data were stated in a 95% confidence interval, and a value of p<0.05 was accepted as statistically significant. Backward logistic regression analysis was performed to evaluate the status of experienced COVID-19 and life changes.

#### **Ethical Statement**

Approval for the study was granted by the Social and Humanities Ethics Committee of Kahraman Maraş Sütçü İmam University (Date: 23.12.2021; Number: 2021/58).

### 3. Results

The mean age of the research participants was  $30.14\pm12.03$  years [range, 18-72 years]. Comparisons of some sociodemographic characteristics according to whether or not the participants had contracted COVID-19 infection are shown in Table 1.

Variables	I had Covid19	I had no Covid19	Total	Variables	I had COVID-19	I had no COVID-19	Total
	n(%)*	n(%)*	n (%)**		n(%)*	n(%)*	n (%)**
Gender				Working Status i	n COVID-19 q	uarantine	
Female	636(63.3)	369(36.7)	1005(58.8)	Working	304(67.4)	147(32.6)	451(26.4)
Male	476(67.7)	227(32.3)	703(41.2)	Not working	808(64.3)	449(35.7)	1257(73.6
X <sup>2</sup> /p***		3.567/0.0	33	X <sup>2</sup> /p***	1.427/	0.128	
Age Groups				Working type in	the COVID-19	quarantine	
18-20	275(62.4)	166(37.6)	441(25.8)	Home office	304(67.4)	147(32.6)	451(26.4)
21-30	405(67.3)	197(32.7)	602(35.2)	Full time	308(66.2)	157(33.8)	465(27.2)
31-40	204(69.4)	93(30.6)	294(17.2)	Alternately	85(69.7)	37(30.3)	122(7.1)
40 and over	228(61.5)	143(38.5)	371(21.7)	Not working	415(61.9)	255(38.1)	670(39.2)
X <sup>2</sup> /p***		7.262/0.0	64	$X^2/p^{***}$		5.387/0.14	46
Education status	5			Income Status			
Primary School	21(67.7)	10(32.3)	31(1.8)	High	208(68.0)	98(32.0)	306(17.9)
High School	106(61.6)	66(38.4)	172(11.0)	Middle	517(64.9)	268(34.1)	785(46.0)
University	985(65.4	520(34.6)	1505(88.1)	Low	387(62.7)	230(37.3)	617(36.1)
X <sup>2</sup> /p*** 1.031/0.597				$X^2/p^{***}$		2.847/0.2	41
Living Place				Family Type			
Metropol	548(66.5)	276(33.5)	824(48.2)	Alone	55(58.5)	39(41.5)	94(5.5)
City	288(66.2	147(33.8)	435(25.5)	Nuclear	883(66.9)	437(33.1)	1320(77.3
District	186(64.4)	103(35.6)	289(16.9)	Single Parent	58(55.8)	46(44.2)	104(6.1)
Village	90(56.3)	70(43.8)	160(9.4)	Extended family	116(61.1)	74(38.9)	190(11.1)
$X^2/p^{***}$		6.536/0.0	88	$X^2/p^{***}$		7.388/0.0	61
Marital Status				Number of Child			
Single	549(63.9)	366(36.1)	1015(59.4)	No child	222(64.2)	124(35.8)	346(20.3)
Married	463 (66.8)	230(33.2)	693(40.6)	1-2	463(65.8)	241(34.2)	704(41.2)
	~ /	、 ,	、 <i>,</i>	3-4	345(66.2)	175(33.7)	520(30.4)
				4 and over	82(59.4)	56(40.6)	138(8.1)
X <sup>2</sup> /p***		1.493/0.1	21	X <sup>2</sup> /p***	- ()	2.587/0.4	
Total	1112(65.1)	596(34.9)	1708(100.0)	Total	1112(64.1)	596(34.9)	1708(100.0

Table 1. Comparison of experienced COVID-19 and sociodemographic variables of participants

\*Row Percent, \*\*Column Percent, \*\*\*Chi square test, p<0.05

The study participants with a history of COVID-19 infection comprised 65.1%. There was a history of COVID-19 infection in 63.3% of the female participants and in 67.7% of the males (p<0.05). When COVID-19 status was evaluated according to age groups, the lowest rates were in the 31-40 years age group. The majority of the participants with a history of COVID-19 lived in a metropolis and were employed.

The Comparison of activities and life changes during pandemic lockdowns is shown in Table 2.

Lockdown Activities	I had COVID-19 n[%]*	I had no COVID-19n[%]*	Total n [%]**	Chi Square Test/p	
Used the Internet & social media		• •	••	•	
Less	316[63.1]	185 [36.9]	501[29.3]	1.324/ 0.516	
More	763[66.0]	393[34.0]	1156[67.7]		
Not use	33[64.7]	18[35.3]	51[3.0]		
Shopping					
Less	111[60.3]	73 [39.7]	184[10.8]	4.167/ 0.125	
More	976[66.0]	503[34.0]	1476[86.6]		
Not changed	25[55.6]	20[44.4]	45[2.6]	0.125	
Sleep					
Less sleep	198[58.8]	139[41.2]	337[19.7]	7.478/ 0.024	
More sleep	458[66.9]	227[33.1]	685[40.1]		
Not changed	456[66.5]	230[33.5]	686[40.2]		
Housework [cooking, cleaning, e	tc.]				
Less	523[64.7]	285[35.3]	808[47.3]	0.505/ 0.777	
More	545[65.7]	284[34.3]	829[48.5]		
Not changed	44[62.0]	27[38.0]	71[4.2]		
Life Changes					
Physical status					
I lost weight	205[70.9]	84[29.1]	289[16.9]		
I gained weight	907[63.9]	512[36.1]	1419[83.1]	5.202/ 0.013	
Not changed	0[0.0]	0[0.0]	0[0.0]		
Social Status					
My lifestyle has changed	971[62.5]	554[36.3]	1525[89.3]	0.430/ 0.482	
Not changed	112[61.2]	71[38.8]	183[10.7]		
Psychological status					
I feel unhappy	702[61.6]	421[37.5]	1123[65.7]	10.06/ 0.007	
Not changed	278[69.3]	123[30.7]	401[23.5]		
I feel happy	132[71.7]	52[28.3]	184[10.8]		
Total	<b>111</b> [65.1]	<b>596</b> [34.9]	<b>1708</b> [100.0]		

Table 2. Comparison of Activities and Life Changes in Lockdown and Experiencing COVID-19

It was stated by 3% of the respondents that they didn't use the internet and social media, 12.6% stated that they slept more, and 48.5% did more housework. Weight was reported to have been gained

during the lockdown by 83.1% of the study participants, and 89.3% reported a lifestyle change. After lockdown, 65.7% of the respondents felt unhappy with themselves, 23.5% experienced no change in their feelings, and 10.8% reported that they were happy.

Factors	β	SE	р	OR	95%	95% CI	
Status: I had COVID-19							
I gained weight	0.022	0.102	0.045	1.022	0.835	1.249	
I feel unhappy	-0.071	0.075	0.035	1.932	1.805	2.079	
Sleep(more)	-0.163	0.092	0.040	1.120	1.005	1.248	
Use social media (more)	-0.800	0.053	0.047	1.563	1.006	2.428	

**Table 3.** The Logistic Regression Model for COVID-19 Status on Life Changes and Lockdown

 Activities

Note. SE: Standard error; OR=odds ratio; CI= confidence interval

A model was established with life changes and lockdown activities and status of having COVID-19 and then analyzed using a backward stepwise logistic regression test. The results of the logistic regression test are presented in Table 4. After logistic regression analysis, independent predictors of status of having COVID-19 were found to be the group of "I gained weight" [OR:1.02] and "I feel unhappy" [OR:1.93]. More slept [OR:1.12] and more use of social media [OR:1.56] were found to be independent predictors of status of had COVID-19.

#### 4. Discussion

During the COVID-19 pandemic, people were exposed to unprecedented restrictions, with the implementation of home isolation, the closure of social areas, working from home, and the closure of schools, with children continuing their education at home. For the first time, personal freedom was restricted by focussing on decreasing the number of people affected by the disease to prevent the spread of the pandemic and this resulted in continuing life within the home while not knowing how to do this, thereby causing the emergence of physiological, psychological and social problems [4].

The effects of the global pandemic will undoubtedly be able to be observed objectively after a long period. This study aimed to determine how people evaluated their time during the pandemic and the effects on their health. More than half [65.1%] of the study participants reported that they had contracted COVID-19 infection. According to the WHO data, a total of 500,186,525 cases have been recorded worldwide, and 6,190,349 deaths [1]. In the current study, it was determined that 67.7% of the male participants and 63.3% of the female participants had a history of COVID-19 infection positivity. 69.4% of the 31-40 years age group, 66.5% living in a metropolis, and 67.4% who were employed had experienced COVID-19. The data of the WHO and the Turkish Ministry of Health show that more COVID-19 cases and deaths are among males and in the 25-64 years age range [1]. In a meta-analysis of 57 studies to determine the relationship between COVID-19 and gender, males were shown to contract COVID-19 infection at a higher rate than females [8].

The results of the current study showed that in the frequency of activities during COVID-19 lockdowns, shopping was ranked first followed by use of the internet/social media, housework and sleep respectively. The enforced leisure-time because of the lockdowns caused boredom, triggering feelings of hopelessness and unhappiness [9]. In literature there has been reported to have been a dramatic increase in internet and mobile phone use during lockdowns. Studies have shown that problematic internet and mobile phone use causes mental health problems, and in addition to psychological effects, depression, mood regulation problems and internalisation have also been reported. Internet and mobile phone use is evaluated as an important risk factor negatively affecting human health, and it is thought

that the increased use during the pandemic will have adverse effects such as changes of habit and lifestyle [10]. However, Internet and social media use also presented alternative solutions to meet people's needs while in lockdown, and activities of need, want, and entertainment are run on social media. It has been reported that in addition to activities such as establishing more contact with family members and sharing experiences on social media, there was also an increase in the number of online games being played [11].

Media is a valuable tool that can be used to re-discover in periods of mandatory restrictions such as lockdowns [12,13]. In a study in South Africa, it was reported that in addition to work related to school or normal employment, they were spent on activities such as physical activities, handicrafts, hobbies, preparing food, arts, drama, and playing board games [14]. The fact that those who have had COVID-19 have to be isolated at home has paved the way for more psychosocial problems. While the restricted freedom and compulsory isolation at home during lockdowns provided the opportunity of people to spend more time together, the evaluations of free time alone can be defined as "living alone together".

When asked about the effects of lockdown on health, more than half of the current study participants reported gaining weight and 16.9% stated that they had lost weight. Almost all of the study participants reported a lifestyle change (89.3%) and 65.7% stated that they were unhappy. Negative effects of lockdown on eating and physical activity habits were reported in another study, with weight gain in the majority of participants [15]. Another meta-analysis reported that there was greater weight gain during the pandemic and weight loss was seen in a smaller proportion of people [16]. In the current study, according to logistic regression model; experienced COVID-19 of participants was reported sleeping more (OR: 1.12), more, using social media (OR:1.56), gained weight (OR:1.02) feel unhappy (OR:1.93). In a study of 3533 subjects in Italy, there were reported to be positive changes such as a tendency to quit smoking, to eat organic food, and to engage in physical activity [17]. It has been reported that running a business from home, restricted physical activity, hoarding foodstuffs and preparing food cause a change in eating habits associated with stress levels, and not going to work causes a change in sleeping habits [18,19]. The development of systematic approaches including psychological support systems is important for predictable times when home isolation is required for an indefinite period such as a pandemic.

This study has revealed the need to be prepared for potential quarantine/lockdown periods, and it can be considered that specialists providing or who will provide psychological support services will be able to contribute to the subject of potential risks and the precautions to be taken. It is extremely important that psychological support services are included in emergency action plans created for conditions requiring indefinite periods of home isolation such as pandemics, and that these services are structured according to the ecological characteristics of families with the collaboration of different professional groups [20,21].

#### 5. Conclusion

In conclusion, people experienced lockdowns during the COVID-19 pandemic as a suddenly developing mandatory situation of a period of uncertainties. They did not what to do, while they stayed at home. In pandemic, weight gain, social media and Internet addiction, sedentary life and unhappiness occurred due to quarantine. This study showed that participants with Covid19 disease gained more weight, slept more, were unhappy and used social media. While health policies focus on disease spread and patient treatments, we think it is important the preparation of guidance such as the evaluation of free time in the home when people do not know what to do in times of lockdown. These measures will protect against the negative effects on psychological, social, and physical health.

#### **Study Limitation**

This study was conducted on Google Forms and included only users of the Internet. The inclusion of only internet users is a limitation of the research.

#### **Ethical Statement**

Approval for the study was granted by the Social and Humanities Ethics Committee of Kahraman Maraş Sütçü İmam University (Date: 23.12.2021; Number: 2021/58).

#### **Conflicts of Interest**

None declared

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# **Authors' Contributions:**

M.S.: Conceptualization, Methodology, Analysis, Resources, Writing, Original draft preparation, Evaluation of the research report in terms of content N.A.: Conceptualization, Collect of data, All authors read and approved the final manuscript.

#### **Generative AI statement**

The author(s) declare that no Gen AI was used in the creation of this manuscript.

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# THE DENTIST'S PERSPECTIVE ON PATIENT SAFETY IN BRAZILIAN DENTAL SERVICES: A GADAMERIAN STUDY

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Abstract: The objective is to understand patient safety in dental care from the perspective of primary health care dentists in a public health system. This is a Hermeneutic study based on 16 interviews with dentists in the Brazilian public health service. Data systematization and analysis were conducted using Content Analysis, and interpretation was supported by the theoretical framework of philosopher Hans-Georg Gadamer. Three themes emerged: The subjectivities/personal perspectives of dentists in their dental practice within workplaces and their recognition of vulnerability to potential errors; working in a culture of patient safety involves both the material aspects of infrastructure and human compassion; the multiprofessional work and the presence of a physician in the team result in a safer and more welcoming patient environment. In conclusion, for dentists working in the Brazilian public health services, patient safety is involved in a multi-professional support and is also associated with dentist compassion, teamwork, and the presence of a physician in the work environment.

Keywords: patient safety, qualitative methods, hermeneutics, dental services

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# 1. Introduction

Patient safety in health care is a concept that has been developed over time, addressing issues of minimizing the risk of causing unnecessary harm to patients to an acceptable level. This concept encompasses terms such as harm, adverse events, and incidents. According to the *International Classification for Patient Safety* (ICPS), harm is understood as the impairment of the structure/function of an organ, causing disease, injury, disability, or even death [1,2]. An Adverse Event (AE) and an incident refer to an incident that results in harm to the patient. In this context, harm is the probability of an incident occurring. It is worth noting that all these situations are considered in their physical, social, and psychological aspects [3].

It is estimated that every year, thousands of people fall victim to unnecessary harm caused by public and private health services. AE is not caused intentionally but sometimes occurs due to the complexity of health care and the number of professionals involved [4]. Addressing this issue, the European Committee for Patient Safety (ECPS) has included patient safety as part of all levels of health care, from health promotion to the treatment of complex diseases [5]. In this context, dental care services are included in the global scope of patient safety, respecting all levels of complexity. It is worth noting that Brazil seeks to establish a culture of patient safety through the implementation of the National Patient Safety Program (PNSP), though this program needs to be more widely disseminated among

dental professionals [3,6]. The PNSP has included Primary Health Care (PHC) of the Unified Health System (SUS) as an area for developing strategies and actions to improve patient safety [3]. In Brazil, the dentists working within the SUS in PHC are those practicing community dentistry in public clinics at government Basic Health Units and are responsible for the population's oral health of a specific territory near their workplace [7,8].

In the dental field, it is known that the main AEs occur due to drug interactions, improper patient positioning in the chair, negligence and/or incompetence of the dentist during care, lack of knowledge of facial and/or dental anatomy, inadequate documentation, and poor communication between the dentist and the health team [9]. Often, such situations lead to the loss of dental elements, significant bone loss, aspiration of foreign bodies, infections, hospitalizations, and even death [10].

To avoid damage to oral health and to study patient safety in dentistry in depth, qualitative studies are fundamental and necessary. It is worth highlighting that the knowledge produced by oral health researchers through qualitative research not only achieves scientific responses but also addresses societal needs, committed to ethical and moral standards [11].

Considering the aforementioned assumptions and the limited number of qualitative studies addressing patient safety in dentistry, this study is justified by the need to develop an in-depth scientific foundation for understanding dental patient safety as a relevant public health issue within the routine practice of dentists in the public healthcare system. Understanding this framework can stimulate a culture of dental patient safety, along with the political and social capital related to health. The objective of this study is to understand patient safety in dental care from the perspective of primary health care dentists in a public health system.

# 2. Method

Hermeneutic study with interpretative chains constructed through the fusion of horizons, grounded in the philosophy of Hans-Georg Gadamer. This method was chosen as it enables the integration/fusion of dentists' perceptions of the research object with the researcher's interpretative analysis. This hermeneutic fusion facilitates a comprehensive and in-depth scientific understanding of dental patient safety. Grounded in hermeneutical philosophy, this approach allows for the interpretation of texts (transcriptions of dentists' speeches) by situating them within the real-world context in which dental care is delivered in the public health system. This study had its protocol and methodological rigor published [12] and was approved by the Ethics Committee at the Federal University of Rio Grande do Sul, and the Municipal Local Ethics Committee (5.720.834), on October 25th, 2022, and followed accreditation criteria for qualitative research [13].

Participants of this study were dentists working in the SUS, specifically in PHC in Porto Alegre city in the southern region of Brazil. Data production began with the construction of an interview script guided by Gadamerian philosophical hermeneutics, aiming to identify pre-established concepts, traditions, and experiences regarding patient safety in dental care. The script included guiding questions with conversation-triggering content such as the complexity of dental care, lived experiences involving possible accidents/adverse events, needs for patient safety during dental care, and the daily work of the dentist in primary health care in public service. The interview script is a questionnaire developed by the researchers and authors of the manuscript with the following questions: Do you think your daily work is complex? Please tell me something that you have experienced involving possible accidents/adverse events during your professional life. What do you think is necessary for patient safety during dental care? Tell me about your daily work as a dentist in primary health care in public service. Discussing dental patient safety with these participants revealed preconceived ideas and information from the interviewees. These insights are essential for the researcher to seek understanding clues [14].

Data collection was performed between September and December 2023, through semi-structured interviews. The interviews were conducted remotely using a web conference platform by a woman, a dentist, and a researcher (Ph.D), on pre-scheduled days according to participant availability. The interviewees did not previously know the interviewer. They were initially contacted by email, and 3 declined the participation. In case of agreement to participate, the consent was sent by email and digitally assigned.

The interviews were audio-recorded and subsequently transcribed denaturalized according to transcription norms for Brazilian Portuguese [15]. Two initial interviews were conducted for language pre-testing, script adaptation, and initial researcher contact with the field. These interviews were not used for analysis.

Participants of this study were dentists working in the SUS, specifically in the PHC in Porto Alegre city in the southern region of Brazil. There were 52 dentists eligible for the study. Sampling was determined by thematic saturation of data, which is an intentional qualitative sampling strategy. The total and final number of interviewees (n=16) was reached based on pragmatic considerations and data saturation [16-18]. This intentional homogeneous sample followed pragmatic inclusion criteria. Inclusion criteria were dentists working exclusively for SUS, with some dental specialty; more than 5 years post-graduation; more than 5 years working in PHC within the SUS in the municipality under study; and having experienced some accident or adverse event in their professional practice. The interviewees were invited randomly from a list of participants fitting the inclusion criteria.

Interviews were concluded upon theoretical saturation of the codes [19]. With a homogeneous sample, it is known that conducting 11 to 12 interviews achieves deep data saturation [19]. The interviews were sequentially coded. Upon completing the coding of one interview, another was coded. When the content of new interviews was represented by existing codes, the data were saturated. Following this perspective, two interviews were added after reaching saturation, as generally, two additional interviews beyond saturation do not add substantial new content to the collected data and thus ensure reliability in the chosen saturation technique [19]. In the fourteenth interview, all content was distributed among already established codes. The fifteenth and sixteenth interviews confirmed saturation, where all content was again distributed among previous codes.

With all content coded and saturated, data was systematized using Content Analysis [20] in the thematic categorization mode with the assistance of OpenLogos software. In this process, registration units were identified and analyzed for their core meanings, constructing thematic categories. Throughout this process, data were interpreted following a semiotic flow [21] with theoretical and hermeneutic support from the German philosopher Hans-Georg Gadamer [14]. To ensure internal validity and consistency, this study employed strategies such as expert members checking, reflexive analysis between the researchers, consensual external members' interpretation validity, and codification by qualitative software, thereby strengthening the trustworthiness of the findings.

#### 2.1. Interpretive theoretical framework

This study is grounded in the philosophical hermeneutics of Hans-Georg Gadamer. Understanding is an inseparable action from the experience individuals have concerning the phenomenon to be interpreted. By looking at the experience of a lived reality, one arrives at the truth of that fact, thereby realizing Hermeneutics [14]. In this context, the researchers and authors of this study are dentists who have also experienced dental accidents and adverse events in their professional lives, similar to the study participants. Thus, the fusion of horizons [14] for understanding dental patient safety occurred naturally. By understanding the horizon of the interviewees' perceptions and merging it with the researchers' perceptive horizon, comprehension emerges as something the researcher proposes interpretatively.

Language is a means to understand a research object. It is in language embodied in dialogue, for example, that the speculative and investigative characteristics of a subject seeking the meaning of an object in their reality are presented [14]. In this theoretical assumption, some important aspects for understanding something through the communication of truth are highlighted. One aspect is the historical consciousness of the moment when seeking to understand something. In other words, understanding something is always immersed in the current time and the lived history. It is in the relationship between time and living that understanding is found. Understanding is something lived in the temporality of facts [14,22,23].

Another important concept brought to this theoretical framework is the issue of preconceptions presented in conversations and dialogues between humans. In the preconception of something, there is always an immediacy in seeking to understand the world. A concept about something is pre-established, and only then is the temporality of the situation observed. Adding to these aspects, the historicity of lived facts and the value of tradition and posture of the one verbalizing the truth are necessary to be observed by the interpreter in understanding texts (transcriptions). Thus, it is up to the interpreter to understand what is preconceived and then unveil the understanding with the temporality of historical facts/experiences that permeate the lived and reported situation [14].

Another important aspect is living the game. The game is the mutual participation of people communicating and building something that will represent the comprehensive truth of what is literally in this interpretative game [14]. For this study, the game is the quest to understand dental patient safety through multiple voices. This game is embodied in methods, interviews, and interpretations.

The fusion of horizons is fundamental for understanding. The fusion of horizons in a hermeneutic circle [24] is a comprehensive perception of the world that emerges internally in everyone. It is open to changes as it depends on the current time and the time when new experiences will be experienced [14]. The research participants bring their perceptive horizons that unite with the interpreter's perceptive horizon. This fusion of horizons is embodied in data interpretation and brings understanding to light.

These concepts and assumptions underpin Hans-Georg Gadamer's philosophical hermeneutics and essentially guide possible understandings of truth, always in motion over time, from which various interpretations can emerge. In this study, therefore, the interpretation comes from dentists and researchers who, in their professional practices, have experienced the object under study. Thus, this study is a Gadamerian approach to understanding dental patient safety.

#### 3. Results

Even completing a hermeneutic circle of interpretation, observing the lived contexts and preconceptions brought by the participants, we know that the understanding constructed in this study relates to the present historical moment where there is a consolidated public system in Brazil and a growing social force for the effective inclusion of oral health in this public service. Besides this aspect, the fusion of horizons between the interviewees' statements and the researchers' interpretation is part of the game to understand the study's theme [14]. Therefore, in this interpretative proposal, it is essential to present the contexts, participants, and themes constructed within this hermeneutic circle. It is worth noting that, like other health fields such as Nursing, the Gadamerian perspective guides qualitative studies involving hermeneutic philosophy and health practices [25].

#### 3.1. Contexts and participants

To build an understanding of something, it is necessary to know the participants who bring their perceptions about the reality of the phenomenon and the study setting [14]. The participants of this study are dentists, mostly women (9 women and 7 men), aged between 27 and 41 years, all with over 5 years of experience in PHC and community oral health, and more than 5 years post-graduation. All

participants work as general practitioners and have a specialty in either Community Dentistry or Public Health. All have experienced some dental accidents or adverse events in their professional lives. All freely agreed to participate in the study. This fact shows their interest in the subject, demonstrating a proactive attitude towards building fundamental scientific knowledge for dental patients. These participants already show social concern and an ethical profile towards their patients.

The study setting is the dental service in PHC within the SUS. The SUS is a public health system in Brazil with over 30 years of existence, focusing on social inclusion, comprehensiveness, and continuity of health care for Brazilians [26]. Primary and some specialized dental services are offered free of charge to the population. Primary services provided by the study participants take place in Basic Health Units, where multiprofessional teams, including doctors and nurses, work together [26]. Brazil needs to further integrate the oral health of Brazilians into the primary care services offered by the SUS [27]. The study participants advocate for greater inclusion of dentistry in primary health care within their public service workplaces. Public policies regarding the conditions of the workplace and the encouragement of safety protocols and culture are fundamental. Patient safety must be a priority for any public or private health system in any country [28].

Each interview lasted an average of 37 minutes. For writing this article, the interviews were translated into English and then back-translated to ensure linguistic reliability, considering the interviewees were Brazilian and spoke Portuguese. From the collected information, 27 codes were constructed, from which three thematic categories emerged. In this hermeneutic study, these categories provide an understanding of dental patient safety in primary health care within public health services.

As result the three thematic categories were: The subjectivities/personal perspectives of dentists in their dental practice within workplaces; Working in a culture of patient safety involves both the material aspects of infrastructure and human compassion; The multiprofessional work and the presence of a physician in the team result in a safer and more welcoming patient environment

#### 4. Discussion

Results will be discussed in sequence, following the themes that emerged during the analytical interpretive Gadamerian hermeneutical process. A textual narrative, mixing excerpts from the texts, illustrating the perceptions of the interviewed dentists, and the researchers' interpretation, is presented in this discussion of the results.

# Theme 1: The subjectivities/personal perspectives of dentists in their dental practice within workplaces and their recognition of vulnerability to potential errors

Different workplaces provide different possibilities for practicing dentistry safely. The uniqueness of each professional, their workplaces, and different human subjectivity/personal perspective in professional practice guide different perceptions of dental patient safety. Subjectivity is something internal to individuals, built by the world they live in. It is the particular way each individual sees and perceives the world. This process is permeated by the individual's history and life events [22].

The particular way a dentist views their workplace, in their daily reality, reflects the perception that patient safety is associated with good interpersonal relationships at work. These relationships generate a safe environment for patient care and foster mutual trust and support in case of dental events and incidents in the clinic. Good professional relationships are necessary to create a safe environment for the patient. This fact can be understood as different judgments among health professionals with the same goal of caring for people's health [22].

"Yes, I believe that in large institutions (like the SUS), you end up having greater security. Of course, this depends on a series of factors such as interpersonal relationships and availability, right? But since the issue of responsibility comes before anything else, I think it's about collegiality. We end up supporting each other in a healthy workplace." Man, 6 years working in PHC within SUS

People's speech carries latent information about the world around them [14,22]. It is noticeable, for these community health dentists, that professionals working collectively in these workplaces are available to assist their colleagues. This fact creates safety in the workplace. This safety in the workplace leads to patient care safety and the sharing of experiences among professionals. This fact provides greater qualification for dentists on how to act in adverse situations related to possible dental accidents.

In the following sentences, should ":::" or "+++" be used, or what can we use instead of these repeated signs? If it is necessary, leave in that way.

"Yes, it is really good to have the opportunity to discuss the case with those in the place (health unit) where I work. It is::: very good to have this support to be able to debate and help the patient in the best possible way, like the situation I mentioned to you earlier" Woman, 6 years working in PHC within SUS

Bringing the subjectivity of dental practice to discuss patient safety, we look at the uniqueness of each dentist and their workplace in primary health care. It is unanimous among participants that calm planning of the procedure is fundamental to patient safety. Thus, it is understood that the professional needs adequate time and tools to plan the dental procedure to avoid errors and possible harm to the patient. Organization and prior planning of actions are fundamental to patient safety [28,29].

In the following sentences, should ":::" or "+++" be used, or what can we use instead of these repeated signs? If it is necessary, leave in that way.

"Many times we have to say no to the patient! and::: say::: I will study your case and you can return::: then I will provide your treatment plan or treatment option (+++). And then, I believe that by calmly following protocols, we can minimize risks::: we work with lives, right?" Woman, 15 years working in PHC within SUS

Proper planning is associated with a professional attitude that includes appropriate clinical and ethical conduct to build the best way to care for the patient with accurate information [30]. This is the reality of these participants, as they live in the same historical moment of the SUS, where patient safety protocols are guided by the National Patient Safety Program [3]. Following this national program, operationally, there is concern about reviewing patient records, discussing cases with other professionals, observing previous allergic reactions, among other planning behaviors. Moreover, it is interesting to note that these professionals, concerned with safety and ethics, express the need for better training to ensure their patients' safety. It is important to highlight that primary care professionals claim the need for knowledge about patient safety and require ongoing education initiatives. These are important aspects of patient safety [31].

In the following sentences, should ":::" or "+++" be used, or what can we use instead of these repeated signs? If it is necessary, leave in that way.

"So I think::: I think::: that to avoid and improve this (patient harm), training is essential (+++), and ongoing education is always necessary." Woman, 11 years working in PHC within SUS

"And I think that these (trainings) are very important to have, and I believe that this cannot be neglected because, after all, no one is immune to accidents happening". Man, 7 years working in PHC within SUS

Training on dental patient safety is frequently cited as a necessity. The need for training demonstrates a focus on patient safety [32]. Knowing the topic leads to this safety and creates an ethical interaction between the dentist and the patient [30].

In the hermeneutic circle's process of understanding dental patient safety, an important aspect associated with the need for training on the topic is the perception of vulnerability. Vulnerability is understood as a feeling of helplessness and the recognition that a dentist can make mistakes and compromise patient safety. This recognition, that a professional can commit errors, enhances the prevention of these errors through the pursuit of training on patient safety. Thus, recounting an event, in this case, an experience with patient harm, is something alive and operative in the act of understanding [22]. In other words, vulnerability is understood as something alive in the reported event.

In the following sentences, should ":::" or "+++" be used, or what can we use instead of these repeated signs? If it is necessary, leave in that way.

"There was this incident I told you about with the lady who had acute pulmonary edema, that she OMITTED that::: that::: I asked her (the patient) if she was taking any medications... eh::: she said: Yes, I took. And::: I believed:: And actually, she had not taken all the medications that day, she hadn't taken the medications. Yes, it happened. The reason she had pulmonary edema occurred. Actually, it was my mistake to believe her." Woman, 6 years working in PHC at SUS

"I think it was more of a technical error on my part. Perhaps underestimating the anatomical position of the tooth, right? I hadn't observed that it was so close to the maxillary sinus, so intimately connected". Man, 7 years working in PHC at SUS

"Because everyone (dentists) is subject to accidents(+). It's just that... well, we are human and things happen". Woman, 11 years working in PHC at SUS

We understand, then, that a dentist who acknowledges their vulnerability to making mistakes but strives to stay well-informed, ethical, concerned, trained, updated, and well-guiding in their patient will provide a safer environment for their patient during dental care in the health center.

# Theme 2: Working in a culture of patient safety involves both the material aspects of infrastructure and human compassion

The infrastructure of the workplace is also highlighted as necessary for understanding dental patient safety. A dentist working in an environment where the infrastructure supports comprehensive and multiprofessional care will result in patient safety. A satisfactory workplace infrastructure, according to the workers' perception, is fundamental to patient safety in primary care [31,33]. In addition to this aspect, the presence and access to adequate equipment and tools for treatment have a positive impact on the conditions and safety of the workplace for patient safety [34,35]. Good working conditions are important aspects of understanding dental patient safety:

In the following sentences, should ":::" or "+++" be used, or what can we use instead of these repeated signs? If it is necessary, leave in that way.

"And::: yes, it is indeed a matter of patient safety because we have high-quality dental materials, we work with excellent materials in the health unit So, this is just an example I am giving you of how we have good materials and professionals" Woman, 11 years working in PHC at SUS

"For example, resources like blood tests::: are quite easy to obtain here::: and help us avoid errors or harm to a particular patient during dental care." Woman, 15 years working in PHC at SUS

High-quality dental materials and the ability to request general health exams, such as blood tests, are essential because they characterize appropriate working conditions that prevent potential accidents and adverse events in dental care. All perceptions about workplace conditions and materials are based on the participants' previous experiences. It should be noted that prior experiences condition our interpretations and behaviors regarding the phenomenon [14,22]. Experiences like the one cited below may prompt the dentist to avoid new accidents with dental materials during a procedure.

In the following sentences, should ":::" or "+++" be used, or what can we use instead of these repeated signs? If it is necessary, leave in that way.

"I::: once had a fracture of a nerve extractor that... in fact, had been in use for some time... it was of good quality, and I used it thinking it was still in good condition. I was able to see the tip and managed to think, and resolve... but since then, I no longer use::: I no longer reuse (++). Not anymore". Woman, 11 years working in PHC within SUS

By observing the impact of infrastructure on dental treatment and patient safety, we identify the need to establish a culture of safety in the workplace. Culture is something that develops through traditions and behaviors repeated over time [14,22]. Health professionals who share the same values, attitudes, perceptions, and competencies develop behavior patterns to ensure patient safety in their workplace [35]. Below, we present an important excerpt on the perception of safety culture. The concept of medication illustrates a context where a safety culture results in proper prescriptions, avoiding adverse events for the patient.

In the following sentences, should ":::" or "+++" be used, or what can we use instead of these repeated signs? If it is necessary, leave in that way.

"There (++) are::: other factors that are more about workflow. There is, for example, a correct prescription. The safety related to medication safety, the patient safety culture related to medication safety, which is something very important... I think for the overall safety of people::: to receive the correct prescription, to receive the correct guidance on how to use that medication." Man, 7 years working in PHC at SUS

Aspects such as the constant updating of prescriptions and monitoring the medications used by the patient are decisive for maintaining the safety culture in PHC, as well as the presence of appropriate medical and dental records[35].

In the following sentences, should ":::" or "+++" be used, or what can we use instead of these repeated signs? If it is necessary, leave in that way.

"So we::: we also look at the medical record to ensure the procedure we are going to perform, right? Ensuring this aspect... having an updated and correctly filled out medical record." Man, 12 years working in PHC at SUS

Effective communication is a crucial element of a patient safety culture [33]. It is known that the patient record is an important communication tool in workplaces, and communication is fundamental to understanding human health [22]. Communication through a work tool, such as a medical record, or direct communication with the patient, is essential for understanding the health practices of the person under the health professional's care. Understanding the person being treated guides better and safer decisions as it involves scientific knowledge and human consciousness in care practices [22].

Considering human consciousness, it is necessary to highlight human compassion in health care. Often, personal barriers and a lack of compassion hinder changes in the workplace and consequently a safety culture. The lack of compassion is an impediment to openly discussing patient safety [36]. Being a health professional aware of the comprehensiveness of human care means that compassion becomes a present element in the patient safety culture in workplace. The overall evaluation of the patient is fundamental in the patient safety culture in primary health care [29,37]. The participants of this study view patient safety from a comprehensive care and compassion perspective.

"Usually, the thing I tend to ask during the anamnesis and then avoid (++) ... potential problems. to avoid certain types of medication, depending on the patient's medical history.... and also, I always like to know about the family situation... if they live in the territory (near) the health unit... looking at that person as a whole." Woman, 15 years working in PHC at SUS.

This comprehensiveness of care, concerned with the human perspective of those receiving dental care, even if not a technical issue, is part of the culture of PHC dentists. This aspect reflects in the improved quality of care resulting from this patient safety culture. Compassion directly affects the quality of care and patient safety [38]. A compassionate health professional has a deeper and more concerned view of the patient's entirety. Moreover, a compassionate professional is more meticulous, which ensures lower risks and harm to the patient [38].

Compassionate professionals, like the participants in this study, have greater skills for making human connections. Thus, a culture of dental patient safety in PHC permeates from the workplace infrastructure to compassion in health care. These aspects contribute to building a patient safety culture in the workplace.

# Theme 3: The multiprofessional work and the presence of a physician in the team result in a safer and more welcoming patient environment

From the perspective of the subjectivities of each of these compassionate and ethical health professionals living in a culture of patient safety, the horizon of the dentists' perceptions merges with the researchers' interpretative horizon in understanding the need to work together as a team. Teamwork must be encouraged in primary care. Often, these professionals (doctors, nurses, pharmacists, psychologists, and dentists, among others) perform their work in isolation, not developing professional interaction and collaborative health practices [4].

Even though in many health systems dentists work in isolation, a fundamental aspect highlighted by the participating dentists in this study is quite the opposite. Real multiprofessional work reflects in the safety of the patient in dental care. Belonging to a multiprofessional health team is very important for the dentist [39]. This perception of patient safety brought by professionals aligns with the horizon experienced by the interpreters of this study [14]. 'There are screening and welcoming methods that:::, in my view, are adequate. We are (++) a team that is in sync. So, before the patient undergoes dental care, they also go::: through a welcoming process by the team. This results in more safety and prevention of avoidable harm." Man, 16 years working in PHC within SUS

"Hum::: I think that by working and belonging to a team where we (++) have various professionals (++), a multiprofessional team. Isn't it? (+++) You have access to the doctor, the nurse... You can consult the doctor immediately regarding medications... in short, about the safety of that dental patient::: everything." Woman, 15 years working in PHC at SUS.

Patient safety in dentistry is enhanced by knowledge of the organization of the service and the organization of teamwork [40]. The presence of and belonging to a multiprofessional team results in safer actions in dental practice and patient treatment. The Gadamerian perspective allows us to associate teamwork with an environment of patient safety culture [14,22]. Thus, it is important to highlight that dental patient safety is also built through team leadership, multiprofessional support, effective communication between professionals, team, and patient, and patient-centered care [40,41,42].

From the importance of the multiprofessional team in dental patient safety, we understand that the presence of a doctor is fundamental for dental patient safety in primary care. In Brazil, traditionally, the figure of the doctor plays a legitimizing role in the team's decision-making about a patient's treatment, which is linguistically evident [43]. In a Gadamerian reading of patient safety, tradition must be brought into the study scenario. Thus, all current understanding occurs from a horizon interconnected with the past, envisioning a future. This is the character of tradition itself, where the various ways of looking at the world are made up of the past, present, and future [14].

In this process, the socially constructed image over time of the physician is one of a savior, a sovereign decision-maker, and a great advisor [44]. This universal and perennial prestige traditionally carried by this professional category [45] is not directly perceived and reported by these professionals. Here, we do not aim to discuss this social image of the physician but rather to present how it is traditionally perceived by the study participants as positive for dental patient safety, seen as a partnership within the team. It is important to reiterate that in this study, we understand that these are multiprofessional teams living in a culture of patient safety. Thus, dentists working in a multiprofessional team perceive the doctor's role as crucial for dental patient safety. The presence of the doctor in the workplace brings an atmosphere of mutual trust and safety [39].

"So, before starting a medication, I would talk to the doctor who was doing the follow-up, and we discussed the case to CONFIRM if it would be appropriate and important for the patient to use it. So, it is very good, it avoids problems for the patient." Man, 10 years working in PHC within SUS

"I was just recently talking with my husband (+++), and we ended up feeling safer in a health unit. Because it's::: like I was telling you... If you have a patient who has an adverse reaction to anesthesia, even if it's rare, I know there will be a nursing technician (+++), a doctor who will know how to help me administer adrenaline, for example!!" Woman, 5 years working in PHC at SUS

In understanding dental patient safety, the presence of the doctor in the team makes both the patient and the dentist feel more secure about potential adverse events requiring quick medical
intervention, which the dentist may not be qualified to provide. It is believed that the presence of the doctor in the team represents an atmosphere of patient safety and mutual support among professionals [39]. Therefore, we believe that dental patient safety is related to the presence of the doctor in the health unit team, as it enhances patient safety during dental care. The doctor assists in case discussions and decision-making by dentists regarding their care practices to prevent adverse events and potential harm to the patient.

We can still understand the dental patient's safety by recognizing that the patient must feel safe in the environment where they seek care, as well as with the professional who attends to them. For safety, the patient must feel secure, welcomed in the health unit, and thus trust the professional and be satisfied with the received care [39].

"The purpose is to feel cared for as well::: welcomed, you know? (+++) because it's a sequence of times we see the person and we will see the person many times during the year either in the office, or outside, or in the reception area, we will see each other on the street, doing home visits::: This creates a lot of patient security with the team... and with a whole team that provides comprehensive care for this person Man, 12 years working in PHC AT SUS

"First, when I receive the patient::: I do a very thorough anamnesis and I also care about the patient:: we need to create a welcoming environment... so this patient... they will be able to talk and report if they have any health problems:: allergies:: anyway (+) sometimes even fear of the dentist we discover (light laugh)" Woman, 11 years working in PHC at SUS

We observe that, in the perception of these dentists, the primary care philosophy positively and directly impacts dental patient safety. Primary health care provided with insecurity or inefficiency can increase the occurrence of preventable harm and lead to unnecessary use of hospital and specialized resources [9]. However, as observed in this study, welcoming, bonding, continuous care, and listening are fundamental to properly attending to a patient [31,46,47]. The patient feeling safe and confident with the care they receive characterizes a partnership with the health professional. This partnership builds appropriate treatment where the patient feels secure with the care [22].

Completing this interpretative hermeneutic circle, we revisit the issue of compassion. Compassionate professionals create better therapeutic partnerships with their patients, which leads to lower health risks, preventing harm and improving the quality of care provided [38]. Furthermore, patients believe and follow what compassionate professionals advise. Thus, by believing, the patient feels more secure with the treatment [38]. We observe here that compassion permeates teamwork, culture, and traditions in workplaces, as well as the professional's attitude in ensuring safe care, preventing harm, and mitigating health risks for dental patients.

### 5. Conclusions

In conclusion, for dentists working in the Brazilian public health services, patient safety is involved in a multi-professional support and is also associated with dentist compassion, teamwork, and the presence of a physician in the work environment. This study has some limitations. All interviews were conducted remotely using online digital communication tools. This method of interviewing might have made it difficult to establish rapport. Moreover, this study presents an interpretative proposal that cannot be generalized to the perception of dental patient safety in all public health services. It is specific to the Southern Brazilian context. As a recommendation, future in-depth qualitative studies should be

conducted in diverse Brazilian and international contexts to develop a comprehensive understanding of dental patient safety and inform and guide clinical practice.

# **Ethical statement**

Ethics Committee approval number of this study is 5.711.630 by the Ethics Committee at the Federal University of Rio Grande do Sul, and 5.720.834 by the Municipal Local Ethics Committee (October 25, 2022).

# **Conflict of interest:**

The authors declared no potential conflicts of interest concerning the research, authorship, and/or publication of this article.

## **Authors' Contributions:**

All authors mentioned in this paper have significantly contributed to the research in all steps. L.G.L.O: Conceptualization, Methodology, data collection, Formal analysis, Writing, and original draft preparation. A.F.B.: Conceptualization, Methodology, data collection, Formal analysis, Writing, and original draft preparation. All authors read and approved of the final manuscript.

## **Generative AI statement:**

The author(s) declare that no Gen AI was used in the creation of this manuscript.

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# INVESTIGATION OF THE EFFECTS OF JUGLONE AND CISPLATIN ON BREAST CANCER CELL LINES

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Abstract: Breast cancer is one of the most commonly diagnosed malignancies worldwide, accounting for approximately 11% of all cancer-related deaths. Cisplatin induces DNA damage, thereby leading to apoptotic cell death, while juglone, a phytochemical compound, exhibits antioxidant and antiproliferative properties. BLACAT1, miR-155-5p, and CCR2 are non-coding RNAs implicated in breast cancer metastasis. This study aimed to investigate the effects of juglone and cisplatin on breast cancer cells by evaluating their impact on cell viability, gene expression, and invasive potential. MDA-*MB-231* and MCF-7 breast cancer cell lines were treated with juglone and cisplatin. Cytotoxic effects were determined using the CCK-8 assay, while qPCR was employed to analyze changes in the expression levels of BLACAT1, miR-155-5p, and CCR2. The impact on cell invasion was assessed using the Transwell invasion assay. Juglone and cisplatin exhibited dose-dependent cytotoxicity in both cell lines. *qPCR* analysis revealed significant alterations in the expression levels of BLACAT1, miR-155-5p, and CCR2 following treatment. The Transwell invasion assay demonstrated that juglone and cisplatin affected the invasive potential of breast cancer cells, with notable differences observed between individual and combined treatments. Juglone and cisplatin modulate breast cancer cell viability, gene expression, and invasive behavior, with juglone demonstrating potential as a therapeutic agent, particularly for luminal-type breast cancer. However, the combined application did not enhance the therapeutic effect, suggesting a complex interaction between these agents.

Keywords: Breast Cancer, Cisplatin, Juglone, BLACAT1, miR-155-5p, CCR2.

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# 1. Introduction

Breast cancer is among the most prevalent types of cancer worldwide, accounting for approximately 12% of all cancer cases and 11% of cancer-related deaths, with a case-to-death ratio of 15% according to 2020 data [1], [2]. Chemotherapy, a frequently used method in breast cancer treatment, has shown increasingly promising results due to advancements in treatment approaches and faster access to scientific knowledge [3], [4].

Cisplatin (CAS No. 15663-27-1, MF: Cl<sub>2</sub>H<sub>6</sub>N<sub>2</sub>Pt; NCF-119875) interferes with DNA repair mechanisms and induces programmed cell death in cancer cells by causing DNA damage. Cisplatin binds to the N7 position of purine bases, thereby blocking cell division and leading to apoptotic cell death. Another cellular effect of cisplatin is the generation of reactive oxygen species (ROS), which leads to oxidative stress. Oxidative stress is one of the most important mechanisms involved in cisplatin toxicity [5], [6].

In addition to chemotherapy, the use of phytochemicals -natural compounds used in complementary cancer therapies- has become increasingly common in recent years. Specifically,

phytochemicals are used to reduce the toxic side effects of chemotherapy and enhance its efficacy [7]. Juglone is one of the most notable examples of these phytochemicals. It is a naturally occurring naphthoquinone derivative found in the roots, bark, leaves, and fruits of walnut trees. It is also widely used in Chinese, Indian, and Korean traditional medicine. Juglone, which has been shown to have anticancer properties, continues to be the subject of extensive scientific research. Juglone exhibits antioxidant, antiproliferative, antitumor, anti-inflammatory, and antiviral effects on living cells [8].

The effects of juglone on cancer have been investigated in various cell types, including breast, prostate, pancreatic, glioma, ovarian, melanoma, HeLa, and endometrial cancer cells. These studies have concluded that juglone influences multiple cellular processes. Its anticancer effects include inhibition of tumor cell proliferation, induction of apoptosis and autophagy, suppression of angiogenesis, and inhibition of tumor cell migration and invasion. Juglone's role as a specific inhibitor of peptidyl-prolyl isomerase Pin1 has been identified as a key mechanism underlying its anticancer activity [8]. Studies investigating the effects of juglone on breast cancer cell lines have shown that increasing doses significantly affect cell viability, apoptosis, metastasis, and angiogenesis [9], [10], [11], [12].

The development of secondary tumors in organs or tissues distant from the primary tumor site is defined as metastasis. Non-coding RNAs (ncRNAs) also play important roles in metastasis, and this has been widely documented in the literature [13]. ncRNAs represent 98% of the transcriptome. Among these, lncRNAs and miRNAs are among the most recently identified RNA molecules, possessing distinct biological functions. They have been increasingly recognized as key regulators of various cellular control mechanisms [14]. They exhibit both oncogenic and tumor-suppressive properties in carcinogenesis [15].

BLACAT1 (Bladder Cancer Associated Transcript 1) is a long non-coding RNA (lncRNA) located on chromosome 1q32.1. Recent studies have shown that BLACAT1 expression is upregulated in various cancers, including bladder, breast, prostate, lung, glioma, cervical, thyroid, and hepatocellular carcinomas. Elevated BLACAT1 expression has been associated with shorter overall survival, advanced TNM stage, and increased lymph node metastasis [14].

miR-155-5p is a microRNA located on human chromosome 21q21.3, and it has been shown to play roles in inflammatory responses, immune regulation, hematological disorders, cardiovascular diseases, and tumorigenesis. miR-155-5p is implicated in cancer-related pathways, including increased cell proliferation, inhibition of differentiation, epithelial-mesenchymal transition (EMT), and modulation of DNA damage repair [16]. It is considered an oncogenic microRNA and is frequently overexpressed in breast cancer. Moreover, it has been associated with high-grade tumors, advanced disease, and lymph node metastasis. A study reported that high miR-155-5p expression was associated with TNBC and HER2-enriched subtypes, whereas lower expression was observed in luminal subtypes [17].

CCR2 is a chemokine receptor expressed in various immune cells and multiple cancer types. Upon binding to its ligand CCL2, CCR2 activates key signaling pathways involved in cell proliferation, migration, and survival, including the PI3K/AKT, MAPK/p38, and JAK/STAT pathways [18], [19]. The CCL2–CCR2 signaling axis has been implicated in the development and progression of vascurious malignancies, including breast, prostate, lung, hepatocellular, pancreatic, nasopharyngeal, and kidney cancers. Overexpression of CCR2 has also been linked to recurrence and metastasis in advanced cancers [18].

Studies focusing on BLACAT1, miR-155-5p, and CCR2 -key non-coding RNAs involved in breast cancer metastasis- may provide important insights into the mechanisms of metastasis and contribute to the development of novel therapeutic strategies. This study aimed to investigate the combined effects of juglone and cisplatin on breast cancer cell lines. The study also aimed to evaluate changes in the expression levels of BLACAT1, miR-155-5p, and CCR2, to explore their roles in breast

cancer progression, assess their potential as biomarkers, and elucidate their possible involvement in metastasis.

### 2. Materials and Methods

### 2.1. Cell lines and cell culture conditions

All cells were provided by Pamukkale University Medical Biology Department. MCF-7; ER+/PR+/HER2- invasive ductal carcinoma cell line and MDA-MB-231 triple negative breast cancer cell line were used in the study.

MCF-7 and MDA-MB-231 cell lines were cultured in RPMI 1640 (NutriCulture) + 10% FBS (Capricorn) + 1% penicillin/streptomycin (Capricorn) medium and both cell lines were incubated at  $37^{\circ}$ C incubator which was containing 5% CO2 and 95% humid air.

## 2.2. Cytotoxicity analysis (CCK-8 Test)

CCK-8 test was applied to determine the IC50 (The half maximal inhibitory concentration) value of cisplatin and Juglon. CCK-8 (Abbkine, Catalog no: KTA1020) test was applied to determine the IC50 (The half maximal inhibitory concentration) value of Cisplatin (Sigma Aldrich CAS-No: 15663-27-1) and Juglon (Sigma Aldrich, CAS-No: 481-39-0). For cisplatin, all 0.2 g of cisplatin was dissolved with 1.2 ml of DMSO, and a 50 mM stock solution was prepared. Then, 0.5, 1, 2.5, 5, 7.5, 10, 12.5, 25 and 50  $\mu$ M/ml concentrations were prepared by diluting the stock solution with medium and applied to the cells for 24, 48 and 72 hours in 3 replicates. For juglone, all 1 g of juglone was dissolved with 10 ml of DMSO and 100 mM stock solution was prepared. 1, 2.5, 5, 10, 12.5, 25, 50, 75 and 100  $\mu$ M/ml concentrations were prepared by diluting the stock solution with medium and applied to the cells for 24, 48 and 72 hours in 3 replicates. For juglone, all 1 g of juglone was dissolved with 10 ml of DMSO and 100 mM stock solution was prepared. 1, 2.5, 5, 10, 12.5, 25, 50, 75 and 100  $\mu$ M/ml concentrations were prepared by diluting the stock solution with medium and applied to the cells for 24, 48 and 72 hours in 3 replicates. A separate DMSO control group was not established for both cisplatin and juglone as the concentration of DMSO in the media-diluted stock solution content was well below the toxic value (<0.1%). The applications were carried out by applying juglon to each plate 3x10 well and cisplatin to each plate 3x10 well on the cells planted in 96-well plates with 10,000 cells in each well.

### 2.3. Analysis of BLACAT1, miR-155-5p and CCR2 expression levels in cell lines

### 2.3.1 RNA isolation

RNA isolation from cell lines was performed with the help of the Norgen Total RNA isolation kit (Catalog No: 17200) working with the Trisol-based spin column method. In 6 well plates, 105 cells were planted, and RNA isolation was performed by applying the relevant kit protocol from the cells to which the substance was applied and control cell lines.

### 2.3.2 cDNA (Complementary DNA) synthesis

cDNA synthesis was performed from isolated RNAs with the help of BIO-RAD iScript<sup>™</sup> cDNA Synthesis kit (Catalog No: 1706891) with reverse transcriptase enzyme. cDNA synthesis was performed with Qiagen RotorGene Real-Time PCR device in 500 µl PCR tubes in accordance with the appropriate kit procedure.

### 2.3.3 Expression analysis

After cDNA synthesis, quantitative Real-Time PCR was performed with the Jena Bioscience qPCR SybrMaster kit (Catalog No: PCR-372L) with SYBR® Green master mix and with the Qiagen RotorGene device at 95°C for 2 minutes, 15 seconds at 95°C and 1 minute at 55°C using primers specific to the BLACAT1, miR-155 and CCR2 genes. Primer sequences are listed in Table 1.

Oligonucleotide	Base sequence (5'-3')
CCR2 Forward	CATGGTGACAGAGACTCTTGGGA
CCR2 Reverse	GGCAATCCTACAGCCAAGAGCT
miR-155 Forward	TGCTAATCGTGATAGGGG
miR-155 Reverse	GAACATGTCTGCGTATCTC
BLACAT1 Forward	CCTGCTTGGAAACTAATGACC
BLACAT1 Reverse	AGGCTCAACTTCCCAGACTCA

Table 1. Primer sequences of the genes used.

### 2.4. Transwell Invasion Assay

For the Transwell invasion experiment, the substances were applied to the cells at a concentration and time determined, and then the invasion experiment was carried out by staining with crystal violet dye on 12 well plates using BioCoat Matrigel Invasion Chamber (Catalog No: 354480, Corning).

#### 2.5. Statistical Analysis

The percentage of cell viability was calculated as follows:

Cell viability (%) = (OD of treatment/OD of control)  $\times 100$ . (1)

The IC50 was obtained from the dose-response curve using Microsoft Excel. Dose–response curves were generated by plotting cell viability (%) against compound concentrations ( $\mu$ M). The resulting data were subjected to linear regression analysis, and the relationship was described using the following linear equation:

$$\mathbf{y} = \mathbf{a} \cdot \mathbf{x} + \mathbf{b} \tag{2}$$

Where:

y represents the percentage of cell viability,

 $\mathbf{x}$  denotes the compound concentration ( $\mu M$ ),

- **a** is the slope of the line,
- **b** is the y-intercept.

The half-maximal inhibitory concentration (IC50) was calculated as the concentration at which cell viability is reduced to 50%. This corresponds to setting y = 50 in the regression equation and solving for x as follows:

$$\mathbf{x} = \frac{50 - \mathbf{b}}{\mathbf{a}} \tag{3}$$

IC50 values were determined individually for each time point using the parameters obtained from the linear regression equations.

Expression fold changes were determined by  $RT^2$  lncRNA PCR data analysis (Qiagen) on a webbased basis with the 2<sup>- $\Delta\Delta CT$ </sup> method. This web-based analysis is based on the Student's-t test principle. All experiments were performed in triplicate, and a *p*-value of < 0.05 was considered statistically significant.

#### 3. Results

IC50 values were calculated as 6.24  $\mu$ M/ml at 72nd hour for MCF-7 and 7.64  $\mu$ M/ml at 72nd hour for MDA-MB-231 in cisplatin administration. In Juglon application, it was calculated as 7.43  $\mu$ M/ml at 48th hour for MCF-7 and 8.61  $\mu$ M/ml at 48th hour for MDA-MB-231 [Table 2].

	IC50 Values (µM/ml)				
	Cisplatin (72 <sup>nd</sup> hour)	Juglone (48 <sup>th</sup> hour)			
MCF-7	6.24	7.43			
MDA-MB-231	7.64	8.61			

Table 2. IC50 values	of cell lines	for cisplatin a	and juglone treatment.
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Expression changes of BLACAT1, CCR2 and miR155 were analyzed as a result of juglon, cisplatin and the combined administration of two substances in MCF-7 and MDA-MB-231 cell lines. As a result of the application of juglon in the MCF-7 cell line, the expression of BLACAT1 decreased 5.98 times, while a 2.09 -fold decrease was observed in CCR2. In addition, the expression of miR155 increased 2.13 times. In the administration of cisplatin, no significant change was observed in the expression of BLACAT1, the expression of CCR2 increased 4.55 times, and the expression of miR155 decreased 3.19 times. In the combined application, while the expressions of miR155 and CCR2 did not change, the expression of BLACAT1 decreased by 2.11 times [Figure 1].



Figure 1. Expression fold changes of MCF-7 cell lines according to the control group.

As a result of juglone application in the MDA-MB-231 cell line, the expression of BLACAT1 increased 3.8-fold and the expression of miR155 increased 2.59-fold, and no significant change was observed in the expression of CCR2. While the expression of BLACAT1 did not change in cisplatin administration, the expression of CCR2 increased by 2.45 times, and that of miR-155 decreased by 9.6 times. In the combined administration, the expression of BLACAT1 did not change, CCR2 increased 3.03 times, and miR-155 increased 10.34 times [Figure 2.].



Figure 2. Expression fold changes of MDA-MB-231 cell lines according to control group.

In the invasion test results, the application of juglone and cisplatin in the MCF-7 cell line decreased invasion compared to the control group, and the combined application was less effective on invasion than the single application and the control group [Figure 3]. Juglone administration in the MDA-MB-231 cell line reduced invasion more than cisplatin. In the combined application, it affected the invasion less compared to the single application and the control group [Figure 4].





Figure 3. Transwell invasion assay images of MCF-7 (40x).





MDA-MB-231 CISPLATIN

MDA-MB-231 JUGLONE + CISPLATIN



### 4. Discussion

Chendan Zou et al. demonstrated that juglone suppresses tumor cell mobility in both breast and colorectal cancers by modulating EMT markers—upregulating E-cadherin and downregulating vimentin and N-cadherin [20]. Consistent with their findings, our study also showed that juglone reduced the invasive and metastatic capacities of both MCF-7 and MDA-MB-231 breast cancer cells.

A study by Xiaopeng Hu et al. reported significant overexpression of BLACAT1 in breast cancer tissues and cell lines, correlating with advanced TNM stage and poor prognosis [21]. Knockdown of BLACAT1 was shown to inhibit cell proliferation and metastasis. In our study, reduced BLACAT1 expression in MCF-7 cells following juglone treatment was accompanied by decreased invasion and metastatic potential, supporting these findings.

Prior research by Jinhang Hu et al. demonstrated that high CCR2 expression is linked to improved survival in breast cancer and that the 3' UTR of CCR2 suppresses EMT and metastasis in vitro and in vivo [22]. Our results align with these findings, showing that reduced CCR2 expression was associated with enhanced invasion and metastasis, particularly in MCF-7 cells.

The same study by Hu et al. further revealed that BLACAT1 promotes CCR2 expression posttranscriptionally by sponging miR-150-5p. Luciferase reporter assays confirmed that miR-150-5p directly targets the 3' UTR of CCR2 mRNA. This regulatory axis contributes to breast cancer progression by enhancing CCR2-mediated signaling [21].

Approximately 90% of breast cancer-related deaths are attributed to metastasis, with epithelialmesenchymal transition (EMT) playing a key role in this process. During EMT, tumor cells upregulate mesenchymal markers and downregulate epithelial markers, enhancing their invasive potential. Liu et al. demonstrated that inhibition of miR-155 in MCF-7 cells decreased the expression of mesenchymal markers (FN and  $\alpha$ -SMA) and increased epithelial markers (E-cadherin and CK18), thereby suppressing EMT and reducing proliferation and survival [22], [23]. In line with these findings, our results showed that cisplatin treatment significantly reduced miR-155 expression and correspondingly decreased the invasive capacity of both MCF-7 and MDA-MB-231 cells.

Our data indicate that juglone alone effectively reduced the invasion and metastasis potential of MCF-7 cells, whereas cisplatin primarily downregulated miR-155 expression without substantially impacting invasive behavior. Interestingly, the combined application of juglone and cisplatin appeared to neutralize or even counteract each other's effects. This antagonistic interaction may be attributed to the antioxidant nature of juglone, which could counteract the reactive oxygen species (ROS) generated by cisplatin—one of its primary mechanisms of cytotoxicity.

In MDA-MB-231 cells, juglone modulated the expression of BLACAT1 and CCR2 as expected, while cisplatin primarily influenced miR-155 expression. However, their combined administration again resulted in mutual antagonism. These findings suggest that neither agent, alone or in combination, produced a therapeutically significant effect in triple-negative breast cancer cells.

In contrast, in luminal-type MCF-7 cells, both agents exhibited significant effects when applied individually. Notably, juglone demonstrated potential as a therapeutic candidate for luminal breast cancer, warranting further investigation. However, contrary to expectations, their combined use did not result in enhanced therapeutic benefit.

### 5. Study Limitations

This study has certain limitations that should be acknowledged. The MCF-10A healthy cell line could not be included in the study, which limited our ability to compare malignant and non-malignant responses to the treatments.

In addition, although gene expression changes of BLACAT1, miR-155-5p, and CCR2 were observed, no further mechanistic assays (e.g., gene knockdown, overexpression, or luciferase reporter assays) were performed to validate the causal relationship between these molecules and the observed phenotypic effects. This limits our ability to confirm whether the expression alterations directly contribute to changes in cell behavior.

Furthermore, all findings are based on in vitro experiments. While these provide valuable preliminary insights, they cannot fully replicate the tumor microenvironment or systemic drug responses. Therefore, in vivo studies are needed to validate the therapeutic relevance of juglone and cisplatin, individually and in combination.

Lastly, the combined administration of juglone and cisplatin did not yield a synergistic effect and, in some instances, exhibited antagonistic interactions. This may stem from juglone's antioxidant properties counteracting cisplatin-induced oxidative stress, one of its primary cytotoxic mechanisms. Dose optimization studies are warranted to identify potential synergistic concentrations. Despite these limitations, this study offers foundational insights and may serve as a guide for future mechanistic and translational breast cancer research.

### 6. Conclusions

In conclusion, this study demonstrated that juglone and cisplatin individually modulate gene expression and invasive behavior in breast cancer cell lines, particularly in luminal-type MCF-7 cells. Juglone showed promising anticancer activity and may serve as a potential therapeutic agent. However, their combined administration did not enhance therapeutic efficacy and, in some cases, exhibited antagonistic interactions. These findings highlight the importance of evaluating drug interactions at the

molecular level and support further in vitro and in vivo investigations, especially regarding juglone's role in luminal breast cancer treatment.

# **Ethical statement:**

This study does not require ethical approval.

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## **Conflict of interest:**

The authors have no competing interests to declare that are relevant to the content of this article.

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# Authors' contributions:

Concept and Design: The concept and design of the study were developed by B. E. U, S. Ş and S. Ç.

Experimental Work: The experimental studies and data acquisition were carried out by S. Ç.

Data Analysis and Interpretation: Data analysis and interpretation were performed by B. E. U. and S. Ç.

Manuscript Writing: The initial draft of the manuscript was written by S. Ç.

Manuscript Revision and Approval: The manuscript was revised and approved by all authors prior to submission.

# **Generative AI statement:**

The authors declare that no Gen AI was used in the creation of this manuscript.

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# ASSESSMENT OF INTENSIVE CARE NURSES' PERCEPTIONS REGARDING OBESITY TAX

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Abstract: Obesity has become an increasingly significant health issue affecting both individuals and societies, leading many countries to implement various strategies to address this threat. One of these strategies is the obesity tax, which is applied to foods with low nutritional value and high fat, sugar, and calorie content. Healthcare professionals, particularly intensive care nurses, face additional challenges when caring for obese patients during this process. This research aims to assess the perceptions of intensive care nurses regarding obesity taxation. The descriptive study involved 92 intensive care nurses. Data were collected using a form to determine nurses' demographic characteristics and the Obesity Tax Perception Scale. A significant 94.6% of the surveyed nurses reported challenges in providing care for obese individuals. Most participants indicated a perception of a high tax burden. The statement "The fight against obesity is one of the main tasks of the state" received the highest support on the scale  $(3.93\pm1.13)$ . There was also a strong endorsement of the statement, "The fight against obesity should be through non-tax instruments" (3.77±0.89). Conversely, the statement "Taxes should be the primary tool in the fight against obesity" received the least support, registering a mean of  $2.28\pm1.11$  from the participants. The findings indicate that intensive care nurses believe in government intervention in fighting obesity; however, they prefer that this intervention occur through non-taxation measures. These results underscore the importance of considering the perspectives of healthcare professionals in shaping effective policies and strategies against obesity.

Keywords: Intensive Care, Intensive	Care Nursing, Nursing, Obesity, Tax.	
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# 1. Introduction

Obesity is an increasing problem in all countries [1]. Worldwide, it is known that approximately 16% of the adult population was obese and 43% was overweight in 2022 [2]. According to data from the Turkish Statistical Institute, the proportion of obese individuals aged 15 years and older was 19.6% in 2016 and 21.1% in 2019. According to a gender-based breakdown, 24.8% of women and 17.3% of men were obese in 2019 [3].

Unhealthy dietary patterns and excessive sugar intake constitute significant factors linked to the risk of obesity [1]. One of the main sources of dietary sugar is sugar-sweetened beverages [4]. Regular consumption of sugar-sweetened beverages has been associated with increased obesity risk, particularly as noted in a systematic review [5], and further supported by findings and evaluations in related literature [6], [7]. The World Health Organization (WHO) has recommended taxing sugar-sweetened beverages as one of the 'good purchasing' interventions to fight obesity. According to the recommendation,

countries should aim to increase the retail price of sugar-sweetened beverages by at least 20% using taxation [8]. Sugar-sweetened beverage taxation is increasingly recognized as an effective fiscal policy to reduce consumption and combat obesity. This is supported by a growing body of literature, including systematic reviews [5], [9], modelling studies [10], [11], and policy and comparative analyses [12], [13], [14].

An "obesity tax" is the term commonly used for imposing a specified rate of taxation on food items characterized by low nutritional value, high fat, sugar, and calorie content. This tax is typically applied to products considered unhealthy, such as junk food, fast food, and sugar-sweetened beverages [15]. The number of states utilizing tax instruments in the fight against obesity has been increasing rapidly in recent years [6], [12]. Many countries worldwide are implementing or planning to implement obesity taxes in various ways, albeit with different scopes at regional or national levels [16].

Although there is no obesity tax in Turkey to fight obesity, there are already taxes in the form of differentiated proportional and lump-sum taxes on products that can be considered harmful. These taxes are applied to generate additional revenue [17]. In the tax system, subsidies that serve social purposes other than fiscal purposes are important. The restructuring of product groups and the progressive tax structure on products that are considered to cause obesity show that the excise tax can be effective in fighting obesity in Turkey [18].

Turkish society's views on the fight against obesity have a significant impact on the effectiveness of a possible tax policy [17]. Studies on the implementation of obesity tax in Turkey show that while support for the tax is low, there is widespread recognition of the need for diverse policies to combat obesity. Non-tax strategies are often preferred [19], [20] while some research suggests that a combination of tax and non-tax measures may be more effective [21], [22]. When the literature was examined, no study was found in which nurses' perceptions of obesity tax were evaluated.

Obesity is a condition that poses a burden not only on healthcare professionals but also on individuals and society as a whole. Among health professionals, nurses are the professional group that spends longer time with the patient and undertakes one-to-one care responsibility [23]. Nurses experience various difficulties while caring for patients with obesity due to their complex care needs. These challenges include intravenous access, urinary catheter insertion, mobilization, position change, patient transfer, hygiene and excretion needs. The patient's limited self-care ability, inability to provide personal hygiene, and limited ability to move and change position cause the nurse to handle all these care tasks alone [24]. Especially intensive care nurses who take care of patients with complex and life-threatening problems try to provide safe patient care with additional challenges caused by obesity. This research aims to assess the perceptions of intensive care nurses regarding obesity taxation.

#### 2. Materials and Methods

#### 2.1. Research Type

This study was conducted as a descriptive study.

#### 2.2. Participants

The research was carried out within the intensive care units of a training and research hospital located in Turkey. The hospital where the research was conducted has seven different intensive care units with a total capacity of approximately 64 beds. The study population consisted of all nurses working in these intensive care units (115 nurses). According to the known sample calculation, it was calculated that at least 89 intensive care nurses should be included in the sample with a 95% confidence interval and 5% margin of error. Between June and July 2023, 92 nurses who were not on leave or report,

who agreed to participate in the study and who responded completely to the data collection form constituted the sample of the study.

#### 2.3. Data Sources/Measurement

The study's data were gathered using a questionnaire form. The questionnaire included nurses' descriptive characteristics and characteristics related to caregiving (age, gender, marital status, etc.) and the Obesity Tax Perception Scale. In the questionnaire form, a definition of obesity tax was given and the participants answered the scale questions after checking "I read this definition." The study included nurses working in intensive care units who agreed to participate.

#### 2.3.1 Obesity Tax Perception Scale

The Obesity Tax Perception Scale was developed by Ayyıldız and Demirli in 2015 [25]. The aim of the scale is to assess the perception of obesity tax. The questionnaire includes 18 questions to evaluate the participants' views on obesity tax. The questions are five-point Likert type. It consists of strongly disagree (1), disagree (2), neutral (3), agree (4) and strongly agree (5) items [25]. The evaluation of the scale was based on the mean and standard deviations of the items. The total score of the scale is not calculated, and there is no cutoff point. In the study by Ayyıldız and Demirli, the Cronbach's alpha coefficient was reported as 0.826 [25]. In the present study, the reliability of the scale was confirmed with a Cronbach's alpha coefficient of 0.905.

# 2.4. Data Collection

Data were collected from nurses working in the intensive care unit by one of the researchers. Participants were briefly informed about the definition and purpose of this tax after the definition of the obesity tax was made. It took approximately 7-10 minutes to answer the questionnaire.

#### 2.5. Statistical Analysis

The study's data were analyzed using the SPSS 28.0 software package (SPSS, an IBM Company, Chicago, IL, USA). Descriptive statistics were used to present and describe the results, including frequency, percentage, mean, and standard deviation.

#### 2.6. Ethical Considerations

Before data collection in this study, approval was obtained from Mardin Artuklu University Non-Interventional Clinical Research Ethics Committee (Decision date and number: 08.06.2023, 2023/6-9). Permission was obtained from the responsible author via e-mail for the 'Obesity Tax Perception Scale' used in the study. Informed consent was obtained from the participants. The study adhered to the principles of the Declaration of Helsinki.

#### 3. Results

Among the participants, 56.5% were female, 46.5% were married, 85.9% had undergraduate degrees, 54.3% had income less than expenses, and 63% had a normal BMI. The mean age of the nurses was  $31.30\pm5.96$  years (22-50), the mean duration of working as a nurse was  $8.22\pm5.99$  years (1-26), and the mean duration of working in the intensive care unit was  $5.43\pm3.90$  years (1-17) (Table 1).

Characteristics		n	%
Gender	Female	52	56.5
Genuer	Male	40	43.5
Marital status	Married	52	56.5
Iviaritai status	Single	48	43.5
	High school graduate	4	4.3
Education status	Undergraduate degree	79	85.9
	Postgraduate degree	9	4.3
	Less than expenses	50	54.3
Income status	Equal to expenses	35	38.0
	More than expenses	7	7.6
	Normal (18.50-24.99)	58	63.0
BMI (kg/m2)	Pre-obesity (25.00-29.9)	27	29.3
	Obesity (≥30.00)	7	7.6
	Mean±SD (	Min-Max)	
Age (years)	31.30±5.9	6 (22-50)	
Duration of working as a nurse (years)	8.22±5.9	9 (1-26)	
Duration of working in intensive care unit (years)	5.43±3.9	0 (1-17)	

Table 1. Descriptive Characteristics of Intensive Care Nurses

BMI: Body Mass Index, Max: Maximum, Min: Minimum, SD: Standard Deviation.

Fifty-five participants (59.8%) had low back/neck/knee pain. A significant 94.6% of the nurses reported challenges in providing care for obese individuals. The most difficult areas were meeting personal hygiene needs (77.2%) and changing in-bed positions (77.2%), preventing complications caused by obesity (64.1%), mobilizing and transferring the patient (60.9%), performing invasive procedures (57.6%), meeting excretory needs (52.2%), providing appropriate equipment (57.6%) and psychological support (19.6%), respectively (Table 2).

Characteristics		n	%
D	Yes	55	59.8
Do you have back/neck/knee pain?	No	37	40.2
Do you have difficulty in caring for	Yes	87	94.6
obese individuals?	No	5	5.4
	Meeting personal hygiene needs (such as bed bathing)	71	77.2
	Meeting excretory needs (such as insertion of a urinary catheter)	48	52.2
	Performing invasive procedures (such as intravenous access)	53	57.6
If yes to the previous question, which	Changing in-bed positions	71	77.2
area do you have the most	Patient mobilization and patient transfer	56	60.9
difficulty?* (n:87)	Prevention of complications caused by obesity (such as pressure sores, thromboembolism)	59	64.1
	Provision of appropriate equipment for obese individuals (such as blood pressure cuffs of appropriate size)	53	57.6
	Psychological support	18	19.6

\* More than one option was allowed.

The majority of the participants (95.7%) stated that the tax burden they paid was high (Table 3).

<b>A</b>		n	%
What do you think about the total tax burden you	Low	0	0.0
pay? (Income or Corporate + Value Added Tax +	Normal	4	4.3
Motor Vehicle Tax + Special Consumption Tax + Other)	High	88	95.7

 Table 3. Tax Burden Perception of Intensive Care Nurses

The statement " The fight against obesity is one of the main tasks of the state." received the most support, with a mean of  $3.93\pm1.13$  on the Obesity Tax Perception Scale. Then, the statement " The fight against obesity should be through non-tax instruments" was found to be the second most supported statement ( $3.77\pm0.89$ ). The participants least supported the statement "Taxes should be the primary tool in the fight against obesity." ( $2.28\pm1.11$ ) (Table 4).

Table 4. Frequency	y Distributions and Averages	s of Intensive Care Nurses'	Views on Obesity Tax

Statements		Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	Mean±SD
1) Taxes on consumption can	n	15	19	20	19	9	2.98±1.26
reduce consumption.	%	16.3	20.7	21.7	31.5	9.8	2.98±1.20
2) Taxes should be the primary	n	24	37	16	11	4	2.28±1.11
tool in the fight against obesity.	%	26.1	40.2	17.4	12.0	4.3	2.20±1.11
3) The fight against obesity	n	1	7	22	44	18	
should be through non-tax instruments.	%	1.1	7.6	23.9	47.8	19.6	3.77±0.89
4) The fight against obesity is	n	8	4	1	52	27	
one of the main tasks of the state.	%	8.7	4.3	1.1	56.5	29.3	3.93±1.13
5) Obesity tax should be	n	21	19	20	27	5	2 74 1 26
implemented in Turkey.	%	22.8	20.7	21.7	29.3	5.4	2.74±1.26
6) The tax rate can be set higher	n	18	22	21	26	5	2.76+1.22
for products that cause obesity.	%	19.6	23.9	22.8	28.3	5.4	2.76±1.22
7) I think obesity tax will be	n	16	29	12	30	5	2.77±1.23
beneficial for the society.	%	17.4	31.5	13.0	32.6	5.4	2.//±1.23
8) Obesity tax does not interfere	n	14	25	25	24	4	2.77±1.13
with the way people live.	%	15.2	27.2	27.2	26.1	4.3	2.77±1.13
9) Reduced consumption of	n	13	17	22	35	5	
obesity products whose price increases due to the tax.	%	14.1	18.5	23.9	38.0	5.4	3.02±1.17
10) This tax could reduce the	n	11	23	14	39	5	
number of people in the obesity group.	%	12.0	25.0	15.2	42.4	5.4	3.04±1.18
11) Introducing an obesity tax	n	11	24	14	36	7	
would increase the consumption of healthy products.	%	12.0	26.1	15.2	39.1	7.6	3.04±1.20
12) This tax reduces the income	n	6	21	25	31	9	
of businesses selling obesity products.	%	6.5	22.8	27.2	33.7	9.8	3.17±1.10
13) The state will do this	n	21	24	13	27	7	
because it cares about the health of citizens.	%	22.8	26.1	14.1	29.3	7.6	2.73±1.31

Statements		Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	Mean±SD
14) I believe that the	n	9	15	23	23	22	
government will introduce this tax to raise revenue.	%	9.8	16.3	25.0	25.0	23.9	3.37±1.28
15) An obesity tax could reduce	n	8	16	23	33	12	3.27±1.16
health costs for the state.	%	8.7	17.4	25.0	35.9	13.0	3.2/±1.10
16) Obesity tax does not	n	14	32	22	20	4	2.65±1.11
provoke a reaction in the society.	%	15.2	34.8	23.9	21.7	4.3	2.03±1.11
17) As a result of the obesity tax, I may consider reducing the	n	11	20	18	38	5	
consumption of the products in question.	%	12.0	21.7	19.6	41.3	5.4	3.07±1.16
18) The taxes we pay are	n	25	20	21	21	5	2.58±1.26
returned to us as public services.	%	27.2	21.7	22.8	22.8	5.4	2.36±1.20

#### Table 4 Continued.

SD: Standard Deviation.

#### 4. Discussion

This study was conducted to assess intensive care nurses' perceptions of the obesity tax. Turkish society's views on combating obesity have a significant impact on the effectiveness of a possible tax policy [17]. Society's perception of such measures is an important indicator of success in the fight against obesity. Participants' perceptions were evaluated using the Obesity Tax Perception Scale. The results indicated that nurses perceive the fight against obesity as a state responsibility. However, there was a general tendency to prefer educational, preventive, and supportive approaches over tax-based interventions. These findings may provide preliminary insights into the views of intensive care nurses, which could inform future health policy discussions.

In this study, the scale findings revealed that participants considered the state's role in combating obesity to be important, yet they believed that this effort should be carried out through non-tax instruments rather than tax-based interventions. There was limited agreement with statements such as "Taxes should be the primary tool in the fight against obesity" and "Obesity tax should be implemented in Turkey." In contrast, there was strong agreement with statements like "The fight against obesity should be through non-tax instruments" and "The fight against obesity is one of the main tasks of the state." These results suggest that nurses prioritize preventive, educational, and structural public health strategies over punitive fiscal approaches. Similar tendencies have been reported in studies with the general population. For instance, a study by Yesiltas and Gül reported similar views in the general public, where non-tax strategies were preferred over tax-based approaches [26]. In a study conducted by Asilkan and Yalçın Balçık with patients applying to a family health center to evaluate the opinions on the implementation of obesity tax, it was reported that the majority of patients did not support obesity tax, but believed that different tools and policies other than tax were necessary to fight obesity [15]. In a qualitative study conducted by Kayacık and Cural, it was reported that the participants did not have a completely negative attitude towards the obesity tax and believed that the tax policy to be implemented would reduce obesity [20]. Akbelen et al. conducted a study to determine the factors related to the acceptability of obesity tax and concluded that views on obesity tax and obesity culture have a significant effect [19]. According to the study conducted by Akkaya and Gergerlioğlu to examine the impact of obesity tax on individuals' attitudes, it was found that supportive attitudes towards obesity taxes were between 40% and 50%. It was reported that 40.8% of the participants believed that obesity tax would restrict people's freedoms [27]. In a study conducted by Sandalci and Tuncer, it was found that Turkish people have a negative perspective towards obesity tax [21]. In another study, the level of public acceptability towards obesity tax was found to be low [22]. These studies indicate a widespread lack of support for an obesity tax in Turkey. Yet individuals are aware of the essential need for diverse policies and tools in addressing the challenge of obesity.

In this study, 54.3% of participants stated that their income was less than their expenses, and 95.7% perceived the tax burden they paid as high. This perception is particularly relevant in the context of obesity taxation, as previous research indicates that obesity is more prevalent among low-income groups in Turkey, where food expenditure constitutes a major portion of household budgets [18]. The literature emphasizes that, if properly supported by targeted subsidies, excise taxes on unhealthy products can positively affect lower socio-economic groups [5], [14], [28]. However, since low-income individuals allocate a substantial portion of their income to food, taxation on unhealthy items may place a disproportionate financial burden on them [29]. A total of 66.3% of participants indicated that non-tax instruments should be used in the fight against obesity, and only about one-third agreed that taxation could reduce product consumption. These findings suggest that perceptions of economic burden may influence the participants' hesitant attitudes toward taxation. It should be recognized that in many places, individuals live in an obesogenic environment surrounded by cheap, ultra-processed, high-calorie and nutrient-poor food, where access to healthy food is often challenging, financially, and geographically almost impossible. Choosing a healthy diet should be the easiest choice [4]. Increasing the tax on products that may cause obesity and at the same time reducing the tax burden on food prices that are subject to healthy consumption, such as fruits and vegetables, dairy products and fish varieties, through incentives can increase the effectiveness in the fight against obesity [29], [30]. These changes can offset the impact of consumption taxes to address fairness concerns without increasing the total tax burden [26], [30].

Obesity and related medical conditions make it difficult for nurses to provide care [31]. Due to obesity, thromboembolism, prolonged ventilation, falls, increased risk of developing musculoskeletal complications, and prolonged intensive care unit stay are among the challenges [24]. In this regard, additional effort and time are required to offer care to individuals with obesity [31]. In this study, 94.6% of nurses reported experiencing difficulties in providing care to obese individuals. The most commonly reported challenges were meeting personal hygiene needs (77.2%) and changing in-bed positions (77.2%). In addition, 59.8% of nurses stated that they experienced pain in the back, neck, or knees. A systematic review highlighted that obesity increases the complexity of nursing care and frequently necessitates the involvement of multiple caregivers due to the physical demands, thereby contributing to caregiver burden and institutional stress [24]. These findings suggest that nurses experience not only physical strain when caring for obese individuals but may also require institutional support to ensure the sustainability of such care.

To prevent obesity, nurses recommend increasing the prices of unhealthy foods and beverages, improving public nutrition by limiting the levels of fat, sugar, and salt in food industry products, and encouraging children and parents to develop critical thinking about food advertisements for the marketing of unhealthy foods in various media [32]. Among the nurses participating in this study, 38% agreed with the statement "I think an obesity tax would be beneficial for society" and 34.7% supported the view that "An obesity tax should be implemented in Turkey. " Although the rate of nurses who believe that an obesity tax will benefit society is significant, most nurses in the study emphasize the importance of alternative approaches to promote health and reduce obesity by expressing that more support should be given to non-tax methods.

This research has some limitations. First, the study is limited to intensive care nurses, but not only intensive care units employ nurses who take care of obese persons; hence, the perceptions and experiences of nurses in other units may differ. The low number of nurses in the sample (n = 92) and the fact that the data were only collected between June and July 2023 further reduce generalizability. It

was conducted only in one training and research hospital in Turkey, possibly weakening the generalizability in other geographical and cultural contexts.

### 5. Conclusion

This study aimed to assess the perceptions of intensive care nurses regarding obesity taxation. The findings indicate that while nurses acknowledge the state's role in combating obesity, they prefer alternative policies over tax-based interventions. Most nurses reported difficulties in providing care for obese individuals, particularly in hygiene and mobilization. Although a significant proportion of nurses believed that an obesity tax could benefit society, they pointed out the importance of educational programs and regulatory measures on unhealthy foods as potentially more effective strategies. These findings suggest that, from the perspective of intensive care nurses, tax-based interventions alone may not be sufficient to address the challenges associated with obesity. Therefore, incorporating non-tax strategies, tailored to clinical and societal contexts, might be worth exploring in future initiatives. Given the study's limited sample, future research should include a broader range of healthcare professionals and stakeholders to provide a more comprehensive perspective. In conclusion, addressing obesity requires not only financial measures but also multidimensional strategies to ensure a more effective and equitable public health approach.

#### **Ethical statement:**

Before data collection in this study, approval was obtained from Mardin Artuklu University Non-Interventional Clinical Research Ethics Committee (Decision date and number: 08.06.2023, 2023/6-9).

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#### **Conflict of interest:**

The authors declare no conflict of interest.

### Authors' contributions:

Plan, design: DBA, DAD; Material, methods and data collection: DBA, DAD; Data analysis and comments: DBA, DAD; Writing and corrections: DBA, DAD. All authors read and approved the final manuscript.

#### **Generative AI statement:**

The authors declare that no Gen AI was used in the creation of this manuscript.

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# DOES MENTAL WORKLOAD AFFECT MISSED NURSING CARE IN NURSES? A CROSS-SECTIONAL AND CORRELATIONAL STUDY

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Abstract: This cross-sectional and correlational study was conducted to determine the effect of mental workload of nurses on missed nursing care. The study was conducted with 93 volunteer nurses working in a training and research hospital. Descriptive information form, mental workload scale, missed nursing care needs scale were used for data collection. In this study, it was found that the mean mental workload scores of nurses were high and the mean missed nursing care scores were low. It was determined that there was no significant relationship between temporary workload, emotional workload, performance-related workload and total mental workload of nurses and the amount and causes of missed nursing care needs (p>0.05), and there was no significant relationship between cognitive workload and the causes of missed nursing care needs (r= -.105, p= .318), but there was a negative, significant and very weak relationship with the amount of missed nursing care needs (r=-.226, p=.029). It was also found that cognitive workload explained 5.1% of the amount of missed nursing care needs in nurses. As a result of this study, it was revealed that temporary, emotional, performancerelated and total mental workload did not affect the amount and causes of missed nursing care needs in nurses, while cognitive workload only reduced the amount of missed nursing care needs. According to these results, in order to reduce the mental workload of nurses, more nurses should be employed in health institutions and other undesirable organizational outcomes such as possible exhaustion, job dissatisfaction, fatigue, etc. should be prevented.

Keywords: Nursing, Nurse, Mental Workload, Missed Nursing Care

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# 1. Introduction

Workload, which is one of the basic building blocks of business life, is the amount of tasks or work that an individual must fulfill within the defined working time related to his/her organizational role. As the amount, difficulty and complexity of the tasks/jobs performed by the individual increase, the workload increases accordingly. Workload, which was first expressed only as the amount of physical effort required to perform the job, is defined as a process that physically and mentally exhausts the employee, negatively affects his/her social life, performance, health status, may cause focusing problems, and ultimately causes effects such as making mistakes, decreasing productivity and efficiency [1]. Mental workload, which is one of the types of workload, is the cognitive effort that occurs during the fulfillment of the employee's duties and covers all activities related to the mind such as calculation, decision-making, keeping in mind, searching, research, communication, decision-making, information

production, information processing, and thinking [2]. "Mental workload threatens not only individual health but also organizational outcomes, including productivity, motivation, and job performance."It increases the time to complete the task and the rate of making mistakes [2].

In health services, nurses play an important role in achieving organizational outputs such as quality and efficiency. Especially in recent years, interest in the mental workload of nurses has increased as well as their physical workload. It has even been emphasized that mental workload is an important issue that should be of concern for nurse managers in the nursing work environment, especially in some developing countries. Nursing is a profession that requires high attention, decision-making, and multitasking management. Mental workload is defined as the pressure on the cognitive capacities of nurses and this load increases as the complexity of the work environment increases. Nurses work in dynamic environments where they have to respond to constantly changing patient situations. In this process, mental workload can affect the nurse's attention, decision-making process and overall performance [3]. Increasing mental workload increases the stress level of nurses and increases the risk of burnout [4] Inadequate staff [5], complexity of information systems [6], jobs that require constant attention and multiple tasks [7] are stated as factors that increase mental workload in nurses. [8]. In many studies, it has been revealed that the mental workload of nurses is high [8,9,10] and individual, organizational and psychosocial factors that increase or affect mental workload have been revealed in some studies conducted in different parts of the world [8,11,12]. Previous studies have found a significant association between nurses' physical workload and their mental workload. [13] mental workload increases stress levels [14], decreases attention sensitivity of nurses [15] and the effects of mental workload on nurses' performance [16] musculoskeletal disorders and intention to leave service [10] have been investigated. The high mental workload makes it difficult for nurses to perform their duties on time and correctly, leading to an increase in error rates [17]. On the other hand, mental fatigue and constant stress can lead to emotional exhaustion and turnover intention in nurses [18]. At the same time, high mental workload causes consequences that directly affect patient safety such as medication errors, patient falls and communication breakdowns [19]. It has been found that high mental workload may cause nurses to work in a stressful environment and may lead to missed nursing care by reducing their performance and efficiency with decreased attention levels [20]. As a result, mental workload of nurses appears as an important concept missed nursing care.

"Missed nursing care" is defined as neglecting, postponing or not providing some or all of the nursing care required by patients for various reasons [21]. Missed nursing care was first defined by Kalisch [22] and has become an important indicator in assessing the quality of nursing services. Studies show that missing nursing care directly affects patient outcomes and reduces the quality of nursing practice [23]. This includes basic care practices such as personal hygiene, nutrition, mobilisation, pressure sore prevention, drug administration and patient education. The most common cause of missing nursing care is insufficient number of nurses [24]. In addition, time pressure, lack of equipment and communication problems also negatively affect the process [25]. On the other hand, deficiencies in the organisational structure affect missing care. For example, failure to distribute tasks in accordance with the number of patients may lead to some care tasks being ignored [26]. In studies, the most common reasons for missed nursing care are insufficient number of staff, insufficient number of auxiliary and technical staff, an unexpected increase in the number of patients or density in the unit, emergency patient situation, and inappropriate operation of materials/devices when necessary [27,28,29,30,31,32,33]. Although all these reasons are factors that actually increase both physical and mental workload of nurses, it is thought that they will negatively affect mental workload of nurses and may increase missed nursing care even more. The effect of individual workload [18] or general workload [19] on missed nursing care in nurses has been examined. There are studies on workload and missing care, but no study was found on the effect of mental workload on missing care. In a study conducted by Ball et al. [23], it was observed that the rate of missed nursing care increased in nurses experiencing workload. Similarly, Kalisch and Williams [26] reported that workload can disrupt critical functions of nurses such as patient monitoring and reporting. In this study, when the extent to which mental workload affects missing care is determined, it may shed light on managers in terms of improvement studies to be carried out by taking mental demands into consideration. This gap in the literature prompted the current investigation and this study was conducted to determine the effect of the mental workload of nurses on missed nursing care. This study is important in terms of revealing the effect of mental workload on missing nursing care. It has been suggested that the results of this study, which is important as one of the first studies on the subject, will fill this gap in the literature and guide researchers in planning future studies, and will be useful in making the necessary planning by providing important data to managers in making the necessary interventions related to nurses.

## 2. Materials and Methods

## 2.1. Study Design and Participants

This study is a correlational and cross-sectional study. The population of the study consisted of 110 nurses working in inpatient units (physical therapy, neurology, palliative, stroke, chest, internal medicine, cardiology, pediatrics, gynecology, general surgery, urology, orthopedics, neurosurgery, cardiovascular surgery, psychiatry, etc.) of a training and research hospital and taking part in direct patient care. The sample size was calculated according to a prevalence rate of 78.6% with a 5% margin of error and a 95% confidence level [34]. Taking a non-response rate of 5%, the total sample size was calculated as 86. The sample consisted of 93 volunteer nurses who worked as clinical nurses in these units, were open to communication and co-operation, and agreed to participate in the study. Working as a charge nurse in these clinics is an exclusion criterion for the study. The rate of participation in the study was 84.5%.

### 2.2. Assessment Instruments

A questionnaire form including an descriptive information form, mental workload scale, and missed nursing care needs scale was used to collect the data.

**Descriptive Information Form**: It consists of 6 questions to determine the characteristics of nurses such as gender, marital status, education, age, professional experience, corporate experience.

**Mental Workload (CarMen-Q) Scale:** The CarMen-Q scale developed by Rubio-Valdehita et al. [20] to measure mental workload was adapted into Turkish by Yavuz et al. [1]. Consisting of 25 items, the scale is answered in 5-point Likert type (1 point: Strongly disagree - 5 points: Strongly agree). The scale consists of 4 sub-dimensions (Cognitive Workload- 9 items, Temporary Workload- 4 items, Emotional Workload- 7 items and Performance Related Workload- 5 items). The Cognitive Workload dimension is related to the attention required for the job, processing complex information and decision-making, while the Temporary Workload dimension measures the degree to which work causes stress on the employee as well as making him/her irritable and anxious. The Performance Related Workload dimensions is related to the performance requirements and the level of responsibility of the job. The Cronbach's  $\alpha$  reliability coefficients of the scale are 0.89, 0.91, 0.92 and 0.93 in the sub-dimensions, respectively, and 0.90 in total. In this study, Cronbach's  $\alpha$  reliability coefficients were 0.57, 0.64, 0.81, 0.89 and 0.82 in total. There were no reverse scored items in the scale. The scale is evaluated based on the mean score of the sub-dimensions, and an increase in the mean score indicates an increase in the mental workload in that sub-dimension.

**Missed Nursing Care Needs Scale (MISSCARE Survey-Turkish):** The scale was developed by Kalisch and Williams in 2009 to determine nurses' views on the amount and causes of missed nursing

care needs and was adapted into Turkish by Kalisch, Terzioğlu, and Duygulu [16]. The first part of the scale, which consists of two parts, is intended to determine the amount of missed care needs by nurses and consists of 21 items and is scored on a five-point Likert scale (1: Rarely not given, 2: Sometimes not given, 3: Often not given, 4: Never given, 5: Not appropriate). The second part is aimed at determining the reasons for missed care needs and consists of 16 items and 3 sub-dimensions and is scored on a four-point Likert scale (Major reason-1, Moderate reason-2, Minor reason-3, Not a reason for not providing care-4). The second part consists of three dimensions: labor resources (4 items), material resources (3 items) and communication (9 items). There are no reverse scored items in the scale. In the first part of the scale, the higher the score, the higher the amount of missed nursing care needs, and in the second part, the lower the sub-dimension score, the higher the importance of the reason for missed nursing care. The average score for each subscale is calculated by summing the responses given by each participant for each subscale. The average score is obtained by dividing the total score by the number of items.

The Cronbach  $\alpha$  value of the first part of the scale was found to be .93 and the Cronbach  $\alpha$  value of the second part was found to be .80 [16]. In this study, the Cronbach  $\alpha$  values of the first and second parts of the scale were found to be 0.90 and 0.90.

#### 2.3. Ethical Consideration

Before starting the research, ethical approval was obtained from the ethics committee of the Bandırma Onyedi Eylül University (Date: 06.01.2024 Number: 2023-272) and institutional permission (Date: 16.02.2024) was obtained from the institution where the research was conducted .Necessary permissions were obtained from the relevant authors for the use of the scales, and the participants were given the necessary explanations in line with the informed consent form and the volunteers were allowed to fill out the questionnaire form. The research process was conducted in accordance with the Declaration of Helsinki.

#### 2.4. Data Collection and Analysis

The research data were collected face-to-face from the participants between February and April 2024. In the collection of research data, the units included in the study were visited one by one and the nurses were informed about the research and invited to the research. Of the 110 nurses working in the units included in the study, 93 participated voluntarily and answered the questionnaire form completely.

The data were transferred to the computer environment by the researchers and evaluated by means of the Statistical Package for the Social Sciences 22.0. Cronbach's Alpha coefficient, descriptive statistics, percentage and frequency distributions, Pearson Correlation Analysis, Simple Linear Regression Analysis tests were used in the evaluation of the data. In the regression analysis, the dependent variable is missing nursing care and the independent variable is mental workload. The data were transferred to the computer environment by the researchers and evaluated by means of statistical package programs. Parametric tests were used in the analysis because the data showed a normal distribution. Cronbach's Alpha coefficient, descriptive statistics, percentage and frequency distributions, Pearson Correlation Analysis, and Simple Linear Regression Analysis tests were used in the evaluation of the data.

# 3. Results

As a result of the evaluation of the research data, it was determined that the majority of the nurses who participated in the study were female (92.5%), married (77.4%), undergraduate or graduate graduates (81.7%), between the ages of 24-30 years (40.9%), with 10 years or less professional experience (53.8%) and 5 years or less institutional experience (60.2%) (Table 1).

<b>Descriptive Characteristics</b>		n	%
Gender	Famele	86	92.5
Gender	Male	7	7.5
Marital Status	Married	72	77.4
Maritar Status	Single	21	22.6
Education (decree)	Associate Degree	17	18.3
Education (degree)	Undergraduate/Graduate	76	81.7
	24-30 years	38	40.9
Age (year)	31-40 years	28	30.1
	>41 years	27	29.0
	1-5 years	24	25.8
	6-10 years	26	28.0
Professional Experience	11-15 years	12	12.9
	16-20 years	15	16.1
	>21	16	17.2
Comparate experience	≤5	56	60.2
Corporate experience	>5	37	39.8

Table 1. Descriptive characteristics of participants (n=93)

\*\*The reason for grouping categorical variables in the ranges shown is to ensure equal distribution of the groups [35].

When the mental workloads of the nurses were evaluated, it was found that the mean score of the performance-related workload sub-dimension was (M=4.76 $\pm$ .56), the mean score of the cognitive workload sub-dimension was (M=4.10 $\pm$ .96), the mean score of the emotional workload sub-dimension was (M=3.91 $\pm$ .94), the mean score of the temporary workload sub-dimension was (M=3.44 $\pm$ .64) and the mean score of the total mental workload was (M=4.05 $\pm$ .58) (Table 2).

In terms of the reasons why nurses missed their nursing care needs, the mean score for the amount of missed nursing care needs was found to be  $(M=1.52 \pm .50)$ , the mean score for the workforce resources sub-dimension  $(M=1.33 \pm .55)$ , the mean score for the financial resources sub-dimension  $(M=1.94 \pm .89)$  and the mean score for the communication sub-dimension  $(M=1.81 \pm .69)$  (Table 2).

Scale	Subcales	n	Min.	Max.	Mean	SD
Mental Workload Scale	Cognitive Workload	93	1.50	9.90	4.10	.96
	Temporary Workload	93	1.86	4.86	3.44	.64
	Emotional Workload	93	1.00	5.00	3.91	.94
	Performance Based Workload	93	1.40	5.00	4.76	.56
	Total	93	1.53	5.94	4.05	.58
Missed Nursing Care Needs Scale	Amount of Missed Nursing Care Needs	93	1.00	3.48	1.52	.50
	Reasons for Missed Nursing Care Needs					
	Labor Resources	93	1.00	3.67	1.33	.55
	Material Sources	93	1.00	5.00	1.94	.89
	Contact	93	1.00	5.00	1.81	.69

Table 2. Mean scores of the mental workload scale and the missed nursing care scale of nurses

		Amount of Missed Nursing Care Needs	Reasons for Missed Nursing Care Needs	Labor Resources	Material Sources	Contact
Mental Workload	r	-,124	094	151	054	022
Scale	р	.237	.368	.149	.605	.833
Comitive Worklood	r	226	105	173	086	005
Cognitive Workload	р	.029*	.318	.098	.414	.962
T	r	139	081	131	126	.030
Temporary Workload	р	.183	.439	.212	.230	.774
E	r	017	105	162	.035	088
Emotional Workload	р	.874	.315	.120	.736	.399
Performance Based	r	.062	.060	.095	.006	.032
Workload	р	.553	.570	.364	.954	.763

**Table 3.** Correlation analysis results for the relationship between mental workload and missed nursing care needs of nurses

\*p<0.05

When the relationship between nurses' mental workload and missed nursing care needs was examined, it was determined that there was no statistically significant relationship (p>0.05) between temporary workload, emotional workload, performance-related workload and total mental workload and the amount and causes of missed nursing care needs. While there was no statistically significant relationship between cognitive workload and the reasons for missed nursing care needs (r= -.105, p= .318), there was a negative, statistically significant and very weak relationship between the amount of missed nursing care needs (r=-.226, p= .029) (Table 3).

**Tablo 4.** Regression analysis results for the predictive status of nurses' cognitive workload on the amount of missed nursing care needs

	Unstandardized coefficients		Standardize has been coefficients				
	В	Std. error	β	t	р	F	R <sup>2</sup>
Fixed	2.469	.308		8.023	.000		
Cognitive Workload	162	.073	226	-2.213	.029	4.892*	.051
w ofkioad	Depende	nt variable: A	mount of r	nissed nursii	ng care nee	ds	

\* p<0.05

When the predictive status of nurses' cognitive workload on the amount of missed nursing care needs was examined, it was determined that the model created was statistically significant and that cognitive workload explained 5.1% of the variance of the amount of missed nursing care needs ( $R^2$ =.051; F(1,91)=4.892, p<0.05). According to the results obtained, cognitive workload predicted the variance of the amount of missed nursing care needs in a statistically significant and negative direction ( $\beta$ =-0.226, t=-2,213, p<0.05). In other words, it was determined that nurses' cognitive workload decreased the amount of missed nursing care needs. In addition, a one-unit increase in cognitive workload provides a decrease of 0.162 in the amount of missed nursing care needs (Table 4).

# 4. Discussion

Due to the working style of healthcare institutions and the nature of healthcare services, those working in these institutions are exposed not only to physical workload but also to mental workload. It has been revealed in many studies conducted in different countries [8,9,10] that the mental workload of nurses, who are in the most intense communication and interaction with the patient, especially in patient

care processes, and who are often responsible for ensuring the coordination of the services provided, is high. As in these studies, it was found that the mental workloads of nurses were high in the present study and that performance-related workload and cognitive workloads were higher than emotional workload and temporary workloads (Table 2). This situation is considered as an expected situation. Because the tasks carried out by nurses, the content of their work, and the way they work are generally similar, and mental workload also depends on these factors. The results of the study are consistent with other studies, which also revealed that nurses have high mental workloads even if they work in different areas such as surgical units, intensive care, etc. [13,16,36,37,38,39]. In a study conducted by Teng et al. [40] on intensive care nurses, it was found that nurses' mental workload was high. Another study found that nurses working in the emergency department had a high workload [40,41]. In a study conducted by Gündüz and Öztürk [20], the mental workload of nurses working in intensive care units was found to be high. These studies support the findings of the study because of the high mental workload. However, the fact that intensive care and emergency services were not included in this study causes the results to differ from these studies.

Performance-related workload refers to the workload for tasks that require attention, do not accept errors, have a high level of responsibility, require careful reactions and have serious consequences of errors [1]. These tasks mostly cover the critical tasks of nurses for patient care and medical intervention processes. Considering that the study was conducted on nurses involved in patient care, it can be considered as an expected situation that the performance-related workload of nurses is high. Cognitive workload arises from processes such as information processing, thinking, decision making, making choices, collecting and memorizing information [1]. Nurses are faced with intensive cognitive processes such as collecting new information about the patients they care for every day, keeping and processing this information in mind, and making decisions about patient care processes. Therefore, the high cognitive workload of nurses in the study can be considered as an expected result. It is seen that both performance-related workload and cognitive workload are burdens related to patient care processes, and in a study, it was revealed that 66.44% of the mental workload of nurses consisted of patient care services [42].

The main reason for missing nursing care was identified as lack of supplies and communication problems. (Table 2).Some studies in the literature support our findings [43]. In some studies, unlike our research, the main reason for missing nursing care was identified as labor resources [44, 45, 46]. Although the mental workload levels of nurses are high, the low amount of missed nursing care needs is considered to be a pleasing situation. This situation shows that nurses show their best efforts in patient care, but they experience problems related to labor force resources. These findings are similar to the studies conducted in the literature, in which it was reported that the amount of missed nursing care needs was low and the reason for missed nursing care was manpower-related reasons [47,48,49,50,51] revealing that there are inadequacies in nurse employment and the importance of manpower in order to provide complete and qualified care.

Considering that the majority of the nurses participating in the study were participants with a high level of education and less than 10 years of professional experience, it is thought that the fact that they were in a period when they could be the most efficient in terms of productivity may be effective in reducing the amount of missed care. In previous studies, it has been stated that low education level and high working hours increase missed nursing care [52] which supports this idea.

In the study, it was found that there was no relationship between the total mental workload, temporary workload, emotional workload and performance-related workload of nurses and the amount and causes of missed nursing care needs. This situation is considered as a positive situation and it can be said that nurses manage their temporary, emotional and performance-related workloads well and therefore care is not affected.

When the relationship between mental workload of nurses and missed nursing care needs was examined; while there was no statistically significant relationship between temporary workload, emotional workload, performance-related workload and total mental workload and the amount and reasons for missed nursing care needs, and between cognitive workload and the reasons for missed nursing care needs (r=-.105, p=..318), there was no statistically significant relationship; a negative, statistically significant and very weak relationship was found between the amount of missed nursing care needs (Table 3). This weak relationship differs from the research findings in some studies in the literature [20,53]. It is thought that the reason for this difference may be due to the sample groups in which the research was conducted. The correlation coefficient between cognitive workload and missed nursing care was relatively low (r = -0.226) and the amount of variance explained in the regression model was also minimal ( $R^2 = 0.051$ ), indicating that cognitive workload only explains a small portion of the variance in missed nursing care and suggesting that contextual variables other than mental workload may play a more important role in missing care (Table 4). The presence of small effect sizes in the study may be due to the sample size. On the other hand, the fact that nurses hesitate to make correct statements about missing care may have been reflected in some research findings. In the study, the fact that nursing care could not be met due to labor resources suggests that nurses do not have enough staff qualitatively or quantitatively and this situation causes nurses to have to work more cognitively and increase their cognitive workload. In addition, nurses first use their cognitive functions to make plans and interventions related to the care of patients. Cognitively, the fact that nurses have the right information, process the information correctly, think effectively, make the right decisions, make the right choices, keep the collected information in mind, analyze it, etc. It can be said that experiencing intense processes reduces missed nursing care by enabling them to do things correctly and effectively.

#### 4.1. Limitations

The fact that mostly female nurses work in the inpatient services of the institution has caused a gender imbalance in the sample group. At the same time, the sample group consists of a total of 93 nurses, which reduces the generalizability of the study. In this study, Cognitive Workload: 0.57 and Temporal Workload: 0.64 Cronbach alpha values are relatively low and this can be considered as a limitation of the internal consistency of the tool. Another limitation of the study is that the correlation coefficient between cognitive workload and missed nursing care is relatively low, and the amount of variance explained in the regression model is minimal. The results of the study are limited to the self-assessments of the nurses who worked in the institution where the study was conducted and participated in the study. In addition, the lack of studies that revealed the effect of mental workload on missed nursing care has caused limitations in the discussion of the study findings.

#### 5. Conclusion

It is estimated that if cognitive workload is reduced, nurses' missing care rates will decrease. It is estimated that if mental workload is reduced in nurses, many positive results will occur such as ensuring patient safety, preventing medical errors, reducing hospital stays, infections and work accidents. Managers have important duties in reducing mental workload in nurses. For example, preventing the reasons that increase mental workload, optimizing nurse-patient ratios and developing workload balancing strategies are important and necessary. It is recommended that the effect of mental workload on missing care in nurses be investigated in different sample groups and with different concepts.

#### **Ethical statement:**

Before starting the research, ethical approval was obtained from the ethics committee of the Bandırma Onyedi Eylül University (Date: 06.01.2024 Number: 2023-272).

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#### **Conflict of Interest:**

The authors report no actual or potential conflicts of interest.

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#### **Authors' Contributions:**

N.E.S: Conceptualization, Methodology, Data Collection, Formal analysis, Writing - Original draft preparation, Investigation.

H.D.: Conceptualization, Methodology, Formal analysis, Original draft preparation, Investigation.

S.A.: Conceptualization, Methodology, - Formal analysis, Original draft preparation, Investigation.

All authors read and approved the final manuscript.

## **Generative AI Statement**

The author(s) declare that no Gen AI was used in the creation of this manuscript.

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# ORGANIZATIONAL AND MANAGERIAL FACTORS INFLUENCING ELECTRONIC HEALTH RECORDS IMPLEMENTATION IN PUBLIC HEALTH FACILITIES, MACHAKOS COUNTY, KENYA

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Abstract: The adoption of Electronic Health Records (EHRs) in healthcare systems has the potential to improve patient care, reduce turnaround times, and leverage secondary data for enhanced decisionmaking. Information technologies are increasingly being embraced in healthcare to promote accountability, efficiency, and service delivery. This study aimed to identify managerial and organizational factors influencing the implementation of EHRs in public health facilities in Machakos County, Kenva. A cross-sectional descriptive design was adopted, as it allows for the collection of data at a single point in time across a diverse population, making it suitable for identifying prevalent factors influencing EHR adoption without requiring longitudinal follow-up. The target population consisted of 424 healthcare providers, including management officers, ICT officers, and healthcare workers. Purposive sampling was used to select key informants with specific knowledge on EHR implementation, ensuring depth and relevance in qualitative insights. Stratified random sampling was applied to the broader population of healthcare providers to ensure representation across different cadres and facility levels, which enhances the generalizability of the findings. The combination of these sampling techniques helps reduce selection bias by ensuring both inclusivity and relevance. A total of 411 respondents were reached. Additionally, qualitative data were collected through interviews with eight key informants. Ouantitative data were analyzed using SPSS, while NVivo was used for qualitative analysis. Chi-square tests were applied to determine statistical significance. The results indicated that adequate hardware and software infrastructure, ICT literacy, resource availability, capacity building, and strong leadership commitment were significant factors influencing successful EHR adoption. The study concluded that both organizational and managerial factors must be addressed to ensure effective EHR implementation. It recommends investment in infrastructure, capacity building, and leadership commitment as essential for EHR systems to improve patient outcomes and enhance operational efficiency.

Keywords: E-health, Health leadership, Information System, Patient Safety, Service delivery.

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# 1. Introduction

The integration of modern information technology into healthcare offers opportunities to improve patient care quality, reduce clinical errors, and enhance care efficiency. Important for enhancing service delivery in health care is health management information systems (HMIS) which aid in data dissemination, collection, and storage, essential for making of decisions and monitoring performance in health care [1] In Kenya, the Ministry of Health and other stakeholders use HMIS to monitor indicators of the Health Sector Strategic Plan (HSSP), particularly through integrated reporting systems that support planning and evaluation. The rise of digital tools, including electronic health (e-health), has introduced new opportunities to improve clinical and business processes, with electronic health records (EHR) becoming a central focus for enhancing accountability and service delivery. Several factors have been identified as barriers to EHR adoption, including the absence of comprehensive policies, inadequate leadership, and lack of awareness [2]

This study seeks to explore the determinants of EHR adoption in public health facilities in Machakos County, aiming to identify key organizational and managerial factors that influence the uptake of EHR systems.[3]. The study is expected to provide valuable insights that could inform policy and practice, improving the overall health information management system in the county [4]. Additionally, inefficiencies, enhancement of data collection, accuracy, and overall improvement of health services focusing on patient outcomes are elements to be addressed by the study findings.[5].

The study's findings offer a blueprint for EHR adoption in third-world economies and similar contexts, contributing to the Sustainable Development Goal (SDG) on health and well-being, while also shaping policy guidelines for the Kenyan healthcare system.

## 2. Materials and Methods

## 2.1. Study Design and Tools

A cross-sectional descriptive design was employed in this study, incorporating both qualitative and quantitative methods. This design was chosen because it is well-suited to examining the relationships between organizational and managerial factors and the adoption of Electronic Health Records (EHR) in a defined population at a specific point in time. The cross-sectional design allows for the collection of data from multiple participants in a single moment, making it cost-effective and timeefficient, especially when the goal is to identify associations between variables without the need for longitudinal tracking. While the study includes both quantitative (via semi-structured questionnaires) and qualitative (via key informant interviews) data, it is primarily cross-sectional in nature, not strictly a mixed-methods design. The term "mixed-methods" often refers to an integrated approach where qualitative and quantitative data are collected simultaneously, analyzed together, and used to provide a fuller picture of the research question. In this study, the qualitative data were collected after the quantitative data, and the two types of data are analyzed separately, making it more appropriate to describe the study as cross-sectional with both quantitative and qualitative components. A semistructured questionnaire was used as the primary data collection tool, and it was pre-tested to ensure reliability and validity. Adjustments were made based on feedback from 10% of the study population at Matuu District Hospital

## 2.2. Study Area

The study was done in Machakos County, one of Kenya's 47 counties, located in the eastern part of the country. Machakos County is a peri-urban area located 100 kilometers from Nairobi, and is known for its poor performance in several health outcomes, including child malnutrition and low vaccination coverage. These indicators include child malnutrition rates and vaccination coverage, with 16% of children below five years being as stunted and 88% as per (Kenya DHS 2022) coverage of vaccination. The research was approved by Mount Kenya University Scientific and Ethical Review Committee (ISERC) hence there was human subject involvement in the study. Approval Number: 2655, dated 12<sup>th</sup> April 2024.

## 2.3. Sampling Procedure

Purposive and stratified random sampling techniques were employed in this study. The target population was stratified based on health facility levels, which included Level 5 Machakos Hospital and Level 4 Kangundo Hospital. Within each stratum, random sampling was used to select healthcare workers for participation. Fisher's formula was applied to determine the sample size, resulting in 424 respondents. For the key informant interviews, purposive sampling was used to select eight key informants, specifically facility in-charges and medical superintendents, based on their expertise and involvement in the implementation and management of healthcare services within their facilities. The selection criteria for these key informants included their managerial or administrative role in the healthcare facilities and their direct involvement in decision-making regarding healthcare delivery and technology adoption. The key informants did not answer the quantitative semi-structured questionnaires. Instead, they participated in separate qualitative interviews, which were conducted after the completion of the survey process with the general healthcare workers. The interviews with the key informants provided additional insights into the managerial and organizational factors influencing Electronic Health Records (EHR) adoption

#### 2.4. Data Collection

The primary data collection tool used in this study was semi-structured questionnaires, designed to collect quantitative data from the healthcare workers. Key informant interviews were conducted to gather qualitative data from a selected group of facility in-charges and medical superintendents. The data collection process was conducted by three trained research assistants who were knowledgeable in health-related fields. These assistants were not co-authors of the study but were selected based on their familiarity with healthcare settings and their ability to effectively administer the questionnaires and conduct interviews. All research assistants received training on ethical standards, data collection procedures, and how to obtain informed consent from participants. Study participants were selected based on inclusion criteria, which included healthcare workers from Machakos and Kangundo hospitals, with a focus on those involved in healthcare delivery and EHR implementation. The inclusion criteria ensured that participants had relevant experience in healthcare practices and technology usage, and that they were directly or indirectly affected by the adoption of EHRs. Participants were reached through direct contact at their respective health facilities, specifically Machakos Level 5 Hospital and Kangundo Level 4 Hospital. The County Health Directorate provided authorization and support in accessing the facilities and coordinating with department heads to facilitate data collection during convenient times that did not disrupt healthcare service delivery. No financial or material incentives were offered to participants. Participation was entirely voluntary, and all respondents were briefed on the purpose of the study, assured of confidentiality, and provided written informed consent before proceeding. Participants were provided with information about the study's objectives, procedures, and their rights. Consent was obtained from all participants before their involvement in the study, ensuring voluntary participation and confidentiality of responses. The key informant interviews were conducted separately after the survey process with the general healthcare workers. The interviews were carried out to gather deeper insights into the managerial and organizational factors affecting EHR adoption.

## 2.5. Data Analysis

Quantitative data were analyzed using the Statistical Package for Social Sciences (SPSS) version 27. Descriptive statistics such as means and standard deviations were used to summarize data, while Chi-square tests were employed to examine associations between categorical variables. The assumptions for Chi-square analysis, namely, independence of observations, mutually exclusive categories, and adequate expected cell counts (no more than 20% of cells with expected frequencies below 5), were

checked and met before conducting the analysis. Chi-square was chosen because the primary aim was to explore associations between categorical variables (e.g., ICT literacy levels, availability of infrastructure, leadership support) and EHR adoption status. Regression analysis was considered but not used in this study, as the objective was not to predict outcomes but to identify statistically significant relationships and patterns among discrete variables. Future studies may build on this work using regression to model predictive relationships more deeply. For qualitative data, NVIVO v12 software was used for organizing, coding, and verifying themes from key informant interviews. A deductive thematic analysis approach was applied to identify patterns related to the study's objectives. While NVIVO facilitated systematic coding and theme retrieval, initial coding and theme development were conducted manually by the principal investigator. NVIVO was then used to verify consistency and refine categories. Given the small number of interviews (n=8), NVIVO was primarily used to enhance rigor and transparency in the thematic coding process and ensure traceability of coded content to raw data. This dual approach ensured both human insight and software-supported reliability in qualitative analysis

## **Ethical statement**

This study received ethical approval from the Mount Kenya University Institutional Scientific and Ethical Review Committee (ISERC), under Approval Number: 2655, dated 12th April 2024. In line with ethical guidelines for research involving human subjects, informed consent was obtained from all participants. Before participation, each participant was fully briefed on the study's objectives, procedures, and potential risks, ensuring they understood their rights, including the voluntary nature of their involvement and their right to withdraw at any time without penalty. The consent process was documented, with participants signing consent forms before any data collection commenced. To ensure confidentiality, all personal information and responses were anonymized. Identifiable data were securely stored and only accessible to authorized research personnel. In compliance with ethical standards, data was handled with the utmost care, using encryption and secure systems to protect participant privacy. Furthermore, the study adhered to the ethical principles of beneficence, non-maleficence, and respect for autonomy. Efforts were made to minimize any potential harm to participants, and the findings aim to contribute positively to the field of study while maintaining the highest standards of integrity and transparency

## 3. Results

In line with the study objectives, results were reported using tables, figures, and charts to present analyzed data. A total of 411 participants completed the quantitative questionnaire out of a target of 424, yielding a response rate of 96.9% (see Figure 1). This high response rate was achieved due to strong institutional support from facility leadership, active follow-up by trained research assistants, and the scheduling of interviews during less busy hours in clinical departments. According to Werner (2004), a survey response rate above 80% is generally considered reliable and robust for drawing study conclusions. All eight key informants (facility in-charges and medical superintendents) identified for the qualitative component were successfully interviewed. Their responses provided critical insights into the organizational and managerial dynamics influencing EHR implementation



Figure 1. The response rate of the study respondents.

# 3.1. Data Analysis

Socio-demographic characteristics of the respondents were determined, and the results were presented in Table 1.

Variable	Category	Frequency (n)	Percent (%)
	Male	131	31.9
Sex	Female	280	68.1
	Total	411	100
	Below 20 years	4	1.0
	20-29 years	154	37.5
	30-39 years	119	28.9
Age	40-49 years	93	22.6
	50 and above years	41	10.0
	Total	411	100
Highest Level of Education	Certificate	12	2.9
	Diploma	156	38.0
	Bachelors	204	49.6
	Post-graduate	39	9.5
	Total	411	100
	Less than 1 year	41	10.0
	1-5 years	182	44.3
Years of experience	6-10 years	81	19.7
-	Over 10 years	107	26.0
	Total	411	100
	Yes	297	72.3
If the facility has any form of FHP system	No	114	27.7
form of EHR system	Total	411	100

Table 1. Respondents' socio-demographic characteristics

Female respondents were a significant number, as the results show with 280 (68.1%), male respondents were 131 (31.9%). Participants' age was mainly presented by 20-29 years, 154 (37.5%), 119 (28.9%) aged between 30-39 years, 93 (22.6%) aged 40-49 years, and 50 and above were 41 (10.0%) (Table 1).

Participants' level of education was, with Certificate level of education at 12 (2.9%), diploma level of education at 156 (38.0%), bachelor's level at 204 (49.6%), and postgraduate level at 39 (9.5%). On the years of experience, those with less than 1 year were 41 (10.0%), 1-5 years were 182 (44.3%), 6-10 years of experience were 81 (19.7%), and those with over 10 years of experience were 107 (26.0%). 297 (72.3%) were respondents with electronic medical records systems in their medical facility, as shown in Table 1.

## 3.2. Socio-demographic characteristics and implementation of electronic health records

A Chi-square test of independence was conducted to determine the group differences between socio-demographic groups in the implementation of electronic health records. Two key informant interview guides had indicated that 'A health care worker who has undergone a higher level of education (bachelor's and post graduate), understand the need EHR to agree with the findings of the study, which is adopted easier by the young generation, or the youths as illustrated in Table 2.

	Health facilities having any form of electronic medical records system		2	_
_	No n (%)	Yes n (%)	$-\chi^2$	р
Age				
Below 20 years	0 (0.0)	4 (45.0)	6.12	0.001**
20-29 years	5 (3.2)	149 (96.8)	12.45	0.025*
30-39 years	23 (19.3)	96 (80.7)	4.17	0.053
40-49 years	51 (54.8)	42 (45.2)	1.01	0.835
50 and above years	35 (85.4)	6 (14.6)	6.33	0.804
Highest level of education				
Certificate	11 (91.7)	1 (8.3)	8.52	0.064
Diploma	95 (60.9)	7 (39.1)	5.21	0.267
Bachelors	2 (1.0)	202 (99.0)	18.4	0.002**
Post-graduate	6 (15.4)	33 (84.6)	4.08	0.027*
Years of experience				
Less than 1 year	29 (70.7)	12 (29.3)	6.51	0.659
1-5 years	37 (20.3)	145 (79.7)	4.71	0.835
6-10 years	15 (18.5)	66 (81.5)	3.32	0.406
Over 10 years	33 (30.8)	74 (69.2)	0.79	0.582

Table 2.	Socio-demo	graphic chara	cteristics an	d implen	nentation of	of electronic	health records

\*: p<0.05; \*\*: p<0.01;  $\chi^2$  :Chi-square test

Table 2 presents the association between socio demographic characteristics and implementation of electronic health records age groups below 20 and 21–29 years showed statistically significant

associations with EHR utilization ( $\chi^2 = 6.12$ , p = 0.001) and ( $\chi^2 = 12.45$ , p = 0.025, respectively, On the other hand, years of work experience had no significant association with EHR use ( $\chi^2 = 6.51$ , p = 0.659). The level of education for bachelor's and postgraduate was significantly associated with the implementation of electronic health records with p values of ( $\chi^2=18.4$ , p=0.002) and ( $\chi^2=4.08$ , p=0.027) respectively. There was no association between years of work experience and implementation of electronic health records with p p-value of ( $\chi^2=6.51$ , p=0.659).

# **3.3.** Organizational Factors: Facilities that have the structures and legal processes needed for implementing an EMR system

The study findings indicated that 101 (24.6%) of the respondents agreed that structures and legal processes were in place, whereas 284 (69.1%) indicated No, and 26 (6.3%) did not know, as shown in Figure 2.





## 3.4. Analysis of Organizational Factors Influencing Electronic Health Records Implementation

An interval scale is what the five-point Likert scale is known as. It denotes no extent at all between 1 and 1.8. 1.81 to 2.60 denotes a modest degree. It indicates neutrality from 2.61 to 3.40, a big extent from 3.41 to 4.20, and a very large extent from 4.21 to 5.

The first statement on sufficient financial resources needed for procurement and implementing an EMR system had a mean of 4.303, and the interoperability and compatibility problems that arise during system operations and are promptly fixed had a mean of 4.501 indicating to no extent at all. To a small extent, with a mean of 3.465, the facilities have sufficient mechanisms to build capacity for a new EMR system. Many respondents were neutral on the existence of technical expertise to run an EMR system (mean=2.064) and that the electronic health records system is being implemented in accordance with an institutional policy (mean=3.905). On the electronic health records system promoting institutional quality and data accountability, it had a mean of 3.871 as indicated in Table 3.

To meet the assumptions of the Chi-square test, it was confirmed that all cells in the contingency table had expected frequencies of at least 5 prior to analysis. This is a key assumption for the test's validity. If any expected frequency was found to be below 5, researcher would have to consider alternative strategies, such as collapsing categories, or used a different test (like Fisher's Exact Test). Independence of Observations: The assumption that observations in the table are independent was also checked. This was done by ensuring that each participant contributed to only one cell in the table, avoiding repeated measures.

Statement	Very large extent	Large extent	Neutral	Small extent	No extent at all	Mean	SD
There are sufficient financial resources needed for procurement and implementing an EMR system	0.0%	1.0%	2.7%	35.3%	61.1%	4.303	2.174
The facility has sufficient mechanisms to build capacity for a new EMR system	1.5%	13.6%	21.4%	47.9%	15.6%	3.465	2.407
There exists technical expertise to run an EMR system	4.4%	8.0%	43.6%	35.5%	8.5%	2.064	1.095
The electronic health records system is being implemented in accordance with an institutional policy.	11.2%	16.3%	51.8%	11.9%	8.8%	3.905	2.315
The electronic health records system has promoted institutional quality and data accountability	24.1%	51.3%	13.6%	8.3%	2.7%	3.871	2.302
Interoperability and compatibility problems arise during system operations and are promptly fixed	1.0%	3.2%	8.8%	21.2%	65.9%	4.501	2.419

**Table 3.** Analysis of the Level of Organizational Factors Influencing Electronic Health Records

 Implementation

Table 3 show that most respondents rated interoperability and compatibility issues (M =  $4.501\pm2.419$ ) and financial resources for procurement (M =  $4.303\pm2.174$ ) as factors to a very large extent.

## 3.5. Organizational factors and implementation of electronic health records

Using the Chi-square test of independence, the analysis revealed significant differences between EHR implementation and organizational factors such as availability of funds for acquisition ( $\chi^2$ =12.71, p=0.023), sufficiency of mechanisms to build capacity ( $\chi^2$ =6.38, p=0.041), and existence of technical expertise ( $\chi^2$ =3.84, p=0.050). However, there was no statistically significant association with institutional policy ( $\chi^2$ =3.07, p=0.079).

A key informant interview guide had indicated, 'Availability of financial resources, human capacity, and the expertise at the health facilities is critical to see the successful implementation of the medical records system which agreed with the study findings. These investments need to be put in when a system is to be installed and used. These are illustrated in Table 4.

	Health facilities that have any form of electronic medical records system		$\chi^2$	р
	No n (%)	Yes n (%)	70	Ĩ
Organizational factors				
There are sufficient financial resources needed for procurement and implementing an EMR system	407 (99.0)	4 (1.0)	12.71	0.023*
The facility has sufficient mechanisms to build capacity for a new EMR system	349 (84.9)	62 (15.1)	6.38	0.041*
There exists technical expertise to run an EMR system	360 (87.6)	51 (12.4)	3.84	0.050
The electronic health records system is being implemented in accordance with an institutional policy.	298 (72.5)	113 (27.5)	3.07	0.079
The electronic health records system has promoted institutional quality and data accountability	101 (24.6)	310 (75.4)	5.93	0.015*
Interoperability and compatibility problems arise during system operations and are promptly fixed	394 (95.9)	17 (4.1)	4.81	0.093

# Table 4. Organizational factors and implementation of electronic health records

Table 4 shows that availability of funds, capacity-building mechanisms, and technical expertise were significantly associated with EHR implementation, while institutional policy was not

## 3.6. Managerial Factors: The facility has a core management team

The study found that 291 (70.8%) of the health facilities had a core management team, while 77 (18.7%) said they did not have and 43 (10.5%) did not know, as indicated in Figure 3



Figure 3. The facility has a core management team

## 3.7. Analysis of Managerial Factors Influencing Electronic Health Records Implementation

An interval scale is what the five-point Likert scale is known as. It denotes no extent at all between 1 and 1.8. 1.81 to 2.60 denotes a modest degree. It indicates neutrality from 2.61 to 3.40, big extent from 3.41 to 4.20, and very large extent from 4.21 to 5 it means very large extent that the electronic health records systems are guided by an appropriate strategic framework (mean=4.303), that the system is implementation is supported by all department heads (mean=3.465) and the department heads are informed about all system functions and actively participate in them (mean=3.905). To a small extent,

the respondents indicated that the departmental in-charges efficiently divide up the work of keeping an eye on system functioning (M= $2.064\pm1.095$ ) and they were neutral on the guarantee of an efficient procedure. Department heads and employees are in continual communication with a mean of  $3.465\pm2.407$  as indicated in Table 5.

Table 5. Analysis of the Level of Managerial Factors Influencing Electronic Health Records
Implementation

Statement	Very large extent	Large extent	Neutral	Small extent	No extent at all	Mean	SD
The electronic health records systems are guided by an appropriate strategic framework.	22.4%	51.3%	14.6%	9.0%	2.7%	4.303	2.174
The electronic health records system's implementation is supported by all department heads.	12.4%	43.1%	20.2%	16.8%	7.5%	3.465	2.407
The departmental in-charges efficiently divide up the work of keeping an eye on system functioning.	7.8%	18.5%	23.6%	36.3%	13.9%	2.064	1.095
Department heads are informed about all system functions and actively participate in them.	6.6%	33.8%	26.3%	18.7%	14.6%	3.905	2.315
To guarantee an efficient procedure, department heads and employees are in continual communication.	7.5%	18.5%	45.5%	13.6%	14.8%	3.871	2.302

Table 5 indicates that electronic health record systems are largely guided by a strategic framework (M= $4.303\pm2.174$ ), moderately supported by department heads (M= $3.465\pm2.407$ ), with neutral views on communication and procedures, and low effectiveness reported in system monitoring (M= $2.064\pm1.095$ ).

## 3.8. Managerial factors and implementation of electronic health records

The relationship of management factors and electronic health records adoption revealed a significant effect on the system's direction and the suitability of the strategic framework (p=0.039), and the systems being implemented in supported by all department heads (p=0.047). No significant association between departmental in-charges efficiently dividing up the work of keeping an eye on system functioning (p=0.268) and the department heads being informed about all system functions and actively participating in them (p=0.041).

Key informant interview guide indicated 'In all instances, a system that has been installed for use has to have a guiding framework and under one department for ease of monitoring, and it does not need so many managers for managing it, which concurred with the study findings. A system administrator is sufficient. These are illustrated in Table 6.

	Health facility of electronic me system	·	$\chi^2$	р
	No n (%)	Yes n (%)		-
Managerial factors				
The electronic health records systems are guided by an appropriate strategic framework.	108 (26.3)	303 (73.7)	9.64	0.039*
The electronic health records system's implementation is supported by all department heads.	183 (44.5)	228 (55.5)	3.94	0.047*
The departmental in-charges efficiently divide up the work of keeping an eye on system functioning.	303 (73.7)	108 (26.3)	3.29	0.069
Department heads are informed about all system functions and actively participate in them.	245 (59.6)	166 (40.4)	1.23	0.268
To guarantee an efficient procedure, department heads and employees are in continual communication. *p<0.05; χ <sup>2</sup> :Chi-square test	304 74.0)	107 (26.0)	4.51	0.087

Table 6. Managerial factors and Implementation of electronic health records	Table 6. Managerial	factors and	Implementation	of electronic	health records
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\*p<0.05; χ<sup>2</sup> :Chi-sq

Table 6 shows a significant association between the system's direction and the suitability of the strategic framework ( $\chi^2 = 9.64$ , p = 0.039), as well as support from department heads ( $\chi^2 = 3.94$ , p = 0.047). However, no significant association was observed for work delegation ( $\chi^2$  = 3.29, p = 0.069) and department heads' involvement ( $\chi^2 = 1.23$ , p = 0.268)

## 4. Discussion

The findings are aligned with [6] who suggest the need for EHR adoption in health care settings to improve patient outcomes, [7]. The study highlights critical organizational and managerial factors influencing Electronic Health Records (EHR) systems adoption and implementation in healthcare facilities. These factors offer valuable insights into challenges and opportunities for enhancing EHR adoption in Kenya, [8] other third-world countries, and globally [9]. This study highlights key factors influencing the adoption of Electronic Health Records (EHRs) in Machakos County, Kenya, but alternative explanations and confounders should also be considered. Digital literacy plays a significant role, as healthcare workers with higher digital skills are more likely to successfully adopt EHRs, while those with lower literacy may face challenges [5]. The location of healthcare facilities also impacts adoption, with urban facilities benefiting from better infrastructure and resources compared to rural ones, which may face barriers such as inconsistent electricity [8]. Supporting policies, such as government incentives and technical support, are crucial for the success of EHR systems, and their role should be further explored [3]. High turnover rates among healthcare workers could disrupt EHR implementation, particularly in rural areas, affecting the system's sustainability [4]. Lastly, organizational culture and change management strategies are vital, as resistance to change and lack of staff engagement can hinder the adoption process [2]. Future research should address these factors to improve strategies for EHR implementation and long-term success.

## 4.1. Organizational Factors

The findings of this study regarding the organizational factors influencing EHR adoption in Machakos County resonate with existing literature, though they also provide unique insights into the challenges faced in this context. One of the most critical issues identified was the lack of legal frameworks and administrative structures for supporting EHR implementation, with 69.1% of respondents indicating that their facilities lacked the necessary structures and legal processes. This finding aligns with research by Rohwer et al. (2016), who noted that the absence of national health IT policies and regulatory frameworks significantly hampers the implementation of health technologies in low-resource settings. In their study, the lack of institutional and regulatory backing was found to result in fragmented and unsustainable health IT projects. This study's results further underscore the need for the establishment of clear legal frameworks and standardized policies at both the national and institutional levels to support EHR deployment [5].

Financial constraints were another major barrier identified in this study, with respondents overwhelmingly acknowledging the importance of adequate funding for successful EHR adoption (p = 0.023). This resonates with findings from Ayatollahi et al. (2020), who found that financial limitations in Iran's healthcare system were a significant obstacle to the implementation of health information technologies, with competing priorities delaying technological progress. The emphasis placed by this study on public-private partnerships (PPPs) as a potential solution aligns with the literature on successful models for funding digital health projects. For example, Rwanda's OpenMRS initiative and Kenya's Afya Care pilot program has demonstrated how PPPs can combine government policy support, private sector investment, and international development contributions to overcome financial barriers [7]. The findings of this study further suggest that such collaborative funding models are essential for addressing the financial challenges faced by health facilities in Machakos County and similar contexts.

The study also highlighted the limited technical expertise within health facilities, with respondents expressing doubt about their ability to effectively manage EHR systems (mean score = 2.064). This finding supports previous research, such as that by Kabanda and Brown (2019), which identified the lack of skilled personnel as a barrier to health IT adoption, particularly in rural areas. The statistically significant relationship found between technical expertise and EHR adoption success (p = 0.050) indicates that the availability of skilled personnel is crucial for successful implementation. As emphasized by Bada et al. (2018), strategic investment in human resources, such as recruiting skilled ICT staff and integrating digital health literacy into healthcare workforce training programs, is essential for overcoming this barrier. This study's findings call for the strengthening of in-service training and capacity-building initiatives to ensure that healthcare staff are equipped with the necessary skills to manage and sustain EHR systems [6].

Interoperability was another key challenge identified in this study, with respondents expressing widespread concern about the difficulty of integrating diverse health information systems (mean score = 4.501). This issue mirrors findings from Thirukumar et al. (2017), who highlighted that interoperability is one of the most significant barriers to the effective use of EHRs, as health systems that cannot communicate with each other result in fragmented care and inefficiencies. The call for universal data standards and platform compatibility guidelines in this study is consistent with recommendations from Oladapo et al. (2019), who stressed that the adoption of interoperable systems is critical for improving the effectiveness of health IT initiatives. The study's findings further reinforce the importance of establishing common data standards and ensuring that EHR platforms are compatible across different facilities and regions to facilitate seamless data exchange and improve care continuity [8]. In conclusion, this study's findings contribute to the existing body of literature on EHR adoption by identifying key organizational and managerial factors that influence implementation success. The challenges of legal frameworks, financial resources, technical capacity, and interoperability are consistent with those observed in other studies, particularly in low- and middle-income countries. The study offers a unique perspective on these issues in the context of Machakos County, providing actionable recommendations for overcoming these barriers. The need for national and institutional policy development, innovative funding models, capacity-building initiatives, and interoperability

standards are crucial for the successful implementation of EHR systems, as highlighted by both the current study and the broader literature on digital health adoption [2].

#### 4.2. Managerial Factors

The study's findings on the necessity of strategic frameworks in facilitating Electronic Health Records (EHR) implementation resonate strongly with broader global evidence. A well-articulated strategic framework was found to be significantly associated with EHR success (mean = 4.303; p = 0.039), reinforcing earlier research that emphasizes the value of tailored digital health strategies in achieving effective system integration and institutional alignment with health IT goals (10). The role of these frameworks is not merely in providing direction but also in fostering inter-departmental coherence, efficient resource utilization, and standardization across health facilities [13].

Support from departmental leadership also emerged as an influential factor (mean = 3.465; p = 0.047). This aligns with evidence showing that departmental heads play a pivotal role in change management, acting as catalysts who translate strategic priorities into operational practice [12]. However, reported inefficiencies in work delegation (mean = 2.064) and communication (mean = 3.465) underscore persistent managerial weaknesses that echo findings from other resource-constrained contexts where leadership gaps hinder health information systems rollout [14]. These inefficiencies suggest the need for structured leadership training and workflow redesign to streamline roles and enhance organizational cohesion during EHR implementation [15].

Consistent with literature from other developing regions, the study identified enduring structural challenges including inadequate infrastructure, financial constraints, and limited technical capacity. These issues are also highlighted in studies examining the implementation of digital health systems across sub-Saharan Africa and Southeast Asia, where underfunding and fragmented health systems remain key deterrents to EHR success [11]. A multi-pronged strategy—blending government commitment, donor engagement, and public-private partnerships—has been proposed as a viable remedy. Models like Kenya's Afya Care and Rwanda's OpenMRS exemplify how such collaborations can mitigate fiscal and technical constraints while fostering sustainable innovation [16].

Finally, global experience provides critical insights applicable to the Machakos context. Research from high-income countries consistently shows that early stakeholder engagement, adherence to interoperability standards, and sustained funding underpin successful EHR adoption [10]. Moreover, the user-centered design of systems, continuous feedback loops, and technical support are essential to ensuring long-term usability and scalability. Adapting these approaches—albeit in simpler, cost-effective formats—can address the unique needs of resource-limited environments and accelerate progress toward efficient, data-driven healthcare delivery [13].

#### 5. Conclusion

The study concludes that both organizational and managerial factors play a pivotal role in the successful implementation of Electronic Health Record (EHR) systems in Kenya and comparable settings globally. The findings highlight that overcoming financial, technical, and structural barriers— such as inadequate infrastructure, limited technical expertise, and the absence of enabling legal frameworks—is essential for effective EHR adoption. Furthermore, the presence of guiding strategic frameworks, strong departmental leadership, and coordinated communication structures significantly contribute to system sustainability and long-term success. Addressing these interconnected challenges through capacity building, targeted investments, and multi-stakeholder collaboration is crucial to realizing the full potential of EHRs in improving healthcare delivery and operational efficiency.

## 6. Recommendations

The study concludes that the successful implementation of Electronic Health Records (EHR) systems is significantly shaped by both organizational and managerial factors. Addressing financial constraints, limited technical capacity, and the absence of supportive legal and policy frameworks is vital for enhancing EHR adoption in Kenya and similar contexts. Furthermore, the presence of well-articulated strategic plans, supportive departmental leadership, and coherent communication structures are indispensable for long-term sustainability and system effectiveness. These insights provide a strong foundation for practical, evidence-based recommendations that policymakers can adopt to facilitate robust, scalable EHR systems.

To operationalize these findings, policy development must be prioritized by formulating and enforcing comprehensive regulations that address data privacy, security, patient consent, and ownership. These policies should align with international benchmarks such as the GDPR and HIPAA, while also promoting national interoperability protocols. Policymakers should adopt a participatory approach, engaging frontline healthcare workers, administrators, and patients to ensure policies are both contextually relevant and widely accepted.

Capacity building should be institutionalized through continuous professional development tailored to various skill levels. This includes technical training in system usage, data management, and digital literacy. Structured mentorship programs for departmental leaders and ICT specialists can strengthen institutional leadership and promote a culture of innovation. To sustain motivation and skill retention, healthcare workers should be incentivized through certifications, recognition schemes, and clear career progression paths tied to EHR competencies.

In terms of financial support, national and county governments must increase dedicated funding for EHR systems, positioning them as long-term investments with significant returns in efficiency and patient care. Policymakers can supplement public funds by engaging international donors and leveraging public-private partnerships. Innovative financing models—such as outcome-based financing or health bonds—should be explored to ensure sustainable implementation.

To overcome structural limitations, infrastructure and interoperability need urgent attention. Governments should invest in scalable, user-friendly systems that accommodate low bandwidth environments, diverse languages, and low digital literacy. Strengthening core ICT infrastructure—including reliable power and internet—is essential. Vendor-neutral procurement practices should be promoted to ensure open standards and future system integration, while advanced data security measures like encryption and multi-factor authentication must be mandated.

Monitoring and evaluation mechanisms should be embedded in national health strategies. Realtime dashboards and key performance indicators (KPIs) can help track system adoption and performance, while periodic impact evaluations can assess influence on patient outcomes and costefficiency. Feedback mechanisms involving both healthcare workers and patients will promote accountability and continuous system improvement.

Finally, global collaboration can fast-track progress by enabling Kenya and similar countries to learn from mature EHR ecosystems. Policymakers should support cross-border forums, collaborative research, and knowledge exchange platforms to adapt global best practices to local challenges. Strategic partnerships with international academic institutions, tech companies, and health bodies can foster innovation, reduce costs, and build a globally informed but locally grounded EHR infrastructure.

By integrating these recommendations into national policy agendas, Kenya can build a resilient digital health ecosystem that not only supports efficient service delivery but also aligns with global health standards and future technological demands.

# Limitations of the study

# **Potential Biases in Sampling Approach:**

Issue: The study used purposive sampling for key informants and stratified random sampling for healthcare providers. While these methods ensure the inclusion of relevant participants, they might introduce selection bias.

Solution: Future studies should explore random sampling or consider using a mixed-methods approach that includes longitudinal sampling to capture diverse perspectives over time, helping to mitigate selection bias.

# **Response Bias:**

Issue: Healthcare workers may have provided socially desirable answers, particularly when discussing organizational aspects like leadership and infrastructure.

Solution: To minimize response bias, future research could include anonymous surveys and emphasize confidentiality in interviews. Additionally, integrating observational data alongside self-reported data could provide a more objective view of the situation.

# Limited Causality in Cross-Sectional Design:

Issue: The cross-sectional design limits the ability to draw causal conclusions, as it captures data at a single point in time.

Solution: A longitudinal study design could allow for the tracking of changes in EHR adoption over time, providing a clearer understanding of cause-and-effect relationships between organizational factors and EHR success.

# Generalizability of Findings:

Issue: The study was conducted in Machakos County, Kenya, which may limit the applicability of the results to other regions or countries with different healthcare infrastructures and resources.

Solution: To improve generalizability, future research could conduct similar studies in other countries or regions within Kenya or even compare findings across countries with varying healthcare systems and EHR adoption rates.

# Lack of Discussion on Future Research Directions:

Issue: The abstract does not mention potential areas for future research that could build on the findings. Solution: Future studies could explore the impact of EHR implementation on patient outcomes and efficiency in different health sectors (e.g., private vs. public hospitals). It could also investigate barriers to EHR adoption in smaller or rural health facilities or examine the role of specific software and hardware solutions in successful adoption.

# **Ethical statement**

This study received ethical approval from the Mount Kenya University Institutional Scientific and Ethical Review Committee (ISERC), under Approval Number: 2655, dated 12th April 2024.

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# **Conflict of interest:**

None declared

## **Authors' Contributions:**

The research is a contribution by all the authors. J.N: came up with the concept and methodology, carried out the research work, including data collection, analysis, and writing, V.M: data analysis, interpretation, and guidance through the process of the research work. M.W: development of research objectives, questionnaire, conceptual framework, guidance in the process of the study, as well as assisting in manuscript writing and revisions. The final manuscript was read and approved by all the authors.

## **Generative AI statement**

The author J.N. declares that no generative AI tools were used in the preparation, writing, editing, data analysis, or creation of any part of this manuscript. This was a joint effort by the three authors: J.N., V.M., and M.W. All content is original and the result of the authors' independent work.

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# HARNESSING MACHINE LEARNING IN HPV DIAGNOSTICS: MODEL PERFORMANCE, EXPLAINABILITY, AND CLINICAL INTEGRATION

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Abstract: Human Papillomavirus (HPV) remains a significant global health concern, contributing to cervical and oropharyngeal cancers. While traditional diagnostic methods such as PCR-based assays and cytological screenings are widely used, they present limitations in sensitivity, specificity, and scalability. Recent advances in machine learning (ML) have enabled more precise and automated HPV detection and genotyping. This review aims to evaluate the current ML methodologies in HPV diagnostics, compare their performance metrics, and discuss future directions for improving artificial intelligence (AI) -driven HPV screening. CNN-based models exhibited superior performance in cytology and histopathology-based HPV detection, achieving high accuracy in lesion classification. Hybrid models integrating ML with molecular diagnostics improved HPV genotyping precision. Support vector machine (SVM) and random forest (RF) demonstrated efficacy in genomic classification, whereas transformer-based models enhanced feature extraction and risk stratification. Despite these advancements, data heterogeneity, explainability, and clinical validation remain substantial barriers to widespread adoption. ML-driven HPV diagnostics offer unprecedented improvements in efficiency, accuracy, and accessibility. However, critical issues related to data standardization, bias mitigation, and regulatory frameworks must be addressed to ensure clinical reliability. Future research should prioritize explainable AI (XAI), federated learning, and robust validation studies to enhance model generalizability and real-world applicability. The seamless integration of AI-powered tools into HPV screening programs holds transformative potential for early detection, personalized risk assessment, and improved patient outcomes, ultimately contributing to the global reduction of HPV-related malignancies.

*Keywords*: Human Papillomavirus, machine learning, HPV genotyping, artificial intelligence, cervical cancer detection

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# 1. Introduction

HPV is a prevalent sexually transmitted infection, with certain high-risk types being the primary etiological agents of cervical cancer [1]. Traditional diagnostic methods, such as the Papanicolaou (Pap) smear and PCR-based assays, have been instrumental in HPV detection and cervical cancer screening [2]. However, these methods have limitations, including variability in sensitivity and specificity, as well as challenges in scalability and accessibility [3].

HPV infection remains a significant global public health concern. It is estimated that over 80% of sexually active individuals will acquire an HPV infection by the age of 45 [4]. In Turkey, a recently published large-scale study reported a high prevalence of HR-HPV (high risk HPV) (36.3%) among

women, with HPV16, 39, and 51 being the most common genotypes. The highest rate (44.1%) was observed in the 17–34 age group [5]. In a large-scale study conducted in Turkey on 94,848 women, it was found that the median age among those who tested positive was 42 and the HPV positivity rate was 3.16%. [6]. In contrast, in the United States, cervical cancer screening programs are evolving to include self-sampling techniques, improving access and early detection [7]. Similar initiatives have been introduced in the United Kingdom, where self-sampling kits are being distributed to increase participation in HPV screening programs [8]. These global differences highlight the need for more accessible, cost-effective, and high-throughput diagnostic approaches.

Recent advances in ML, a subset of artificial intelligence (AI), offer transformative potential in enhancing the accuracy, efficiency, and accessibility of HPV molecular diagnostics [9]. ML techniques, including support vector machines (SVM), random forests (RF), and neural networks, have been successfully applied to classify HPV genotypes with higher precision compared to traditional statistical models. Furthermore, deep learning (DL) architectures, such as convolutional neural networks (CNNs) and transformer-based models, have shown remarkable efficacy in automating the analysis of histopathological and cytological images for HPV-related lesion detection [10].

The integration of ML-driven approaches into microbiological diagnostics enhances pattern recognition, minimizes human error, and improves diagnostic consistency. Additionally, AI-powered solutions facilitate high-throughput screening, enabling rapid and cost-effective HPV genotyping from large datasets [2]. Given the increasing adoption of AI in biomedical research, there is a growing need to evaluate the current advancements, applications, and challenges associated with ML-based HPV diagnostics. This review provides a comprehensive overview of the role of ML in HPV diagnosis and genotyping, highlighting its potential to revolutionize cervical cancer prevention and public health strategies.

## 2. Machine Learning Approaches in HPV Diagnosis

ML techniques have been increasingly applied in HPV diagnosis to enhance accuracy, reduce human error, and improve the efficiency of screening programs [11]. These approaches leverage vast datasets, including cytological images, genetic sequences, and clinical records, to identify patterns that traditional methods may overlook [10].

## 2.1. Common Machine Learning Techniques in HPV Diagnosis

Several ML algorithms have been investigated for their potential in HPV diagnosis:

- **SVM:** SVMs have been utilized to classify cervical histopathology images by extracting texture and morphological features, aiding in the early detection of cervical cancer [12,13].
- **RF:** RF models have been applied to predict HPV status from hematoxylin/eosin-stained images, achieving high accuracy in determining HPV positivity in oropharyngeal squamous cell carcinoma [14].
- **k-Nearest Neighbors (k-NN):** This algorithm has been implemented in viral genome classification tasks, demonstrating effectiveness in classifying various viral genomes, including HPV, based on sequence data [15].
- **CNNs:** CNNs have been widely used for automated Pap smear analysis, significantly improving classification accuracy compared to traditional cytological screening methods [16].
- **Recurrent Neural Networks (RNNs):** RNNs have been applied to analyze longitudinal patient data and predict HPV progression trends [17].

- **Hybrid Models (CNN + SVM, CNN + LSTM):** Hybrid DL approaches have been developed to combine CNNs' feature extraction capabilities with SVMs' classification power, yielding superior performance [18].
- **Transformer-Based Models:** Transformer networks, such as Vision Transformers (ViTs), have demonstrated state-of-the-art performance in classifying HPV-associated cervical lesions [19].

# 2.2. Performance Comparison of ML Models in HPV Diagnosis

Recent advancements in ML have significantly enhanced the accuracy and efficiency of HPV diagnosis. Various studies have employed different ML algorithms to classify HPV status, utilizing diverse data types such as cytological images, genetic sequences, and clinical records. The studies showcase a diverse range of approaches, including CNNs, hybrid architectures, and radiomics-based models, each demonstrating varying degrees of accuracy, sensitivity, and specificity (Table 1).

Authors (Reference)	Methods	Results	Sensitivity (%)	Specificity (%)	Accuracy (%)
Yilmaz et al. [20]	XGBoost, CNN	XGBoost achieved 85% accuracy, while CNN reached 93%.	85	85	85 (XGBoost), 93 (CNN)
Lang et al. [21]	3DCNN, Transfer Learning	3D CNN achieved an AUC of 0.81 for HPV status prediction	-	-	81 (AUC)
Ma et al. [22]	CNN + SVM	CNN-SVM combination enhanced feature extraction, leading to better classification accuracy.	86.7	93.5	-
Liu et al. [23]	CNN + Visual Transformer + Multilayer Perceptron (MLP)	Hybrid approach improved classification efficiency, achieving 91.72% accuracy.	-	-	91.72
Ince et al. [24]	SVM, Radiomics	SVM-based model successfully identified carcinogenic HPV types with 95% accuracy.	-	-	95
Sornapudi et al. [25]	VGG-19 CNN	Achieved high accuracy in classifying cervical cells.	-	-	95
Kularathne et al. [26]	CNN	CNN-based model achieved high HPV classification performance.	94	95	96
Zhang et al. [27]	CNN	Model achieved 94.1% accuracy for cervical cell classification.	94.5	93.8	94.1
Rahaman et al. [28]	Hybrid CNN with Deep Feature Fusion	Achieved 99.85% accuracy for binary classification on the SIPAKMED dataset.	99.8	-	99.85

**Table 1.** Comparative Performance of DL and Machine Learning Models in HPV Diagnosis and

 Cervical Cytology Classification

Hybrid DL models (e.g., CNN + SVM, ViTs) consistently exhibit superior classification accuracy, highlighting the potential of multi-modal AI architectures in HPV screening. Radiomicsdriven ML models, such as SVM-based radiomics, achieve high accuracy in identifying carcinogenic HPV types, emphasizing their role in precision diagnostics. Traditional ML models like XGBoost and SVM perform well but tend to be outperformed by CNN-based DL models, reinforcing the effectiveness of deep feature extraction in medical image classification.

These findings underscore the transformative role of AI in HPV-related diagnostics, with DL methodologies offering higher accuracy and improved feature representation compared to traditional ML approaches. Future research should focus on integrating multi-modal AI frameworks and leveraging explainable AI (XAI) techniques to enhance clinical interpretability and adoption.

## 3. Machine Learning for HPV Genotyping

Accurate genotyping of HPV is crucial for determining infection risks, guiding vaccination strategies, and personalizing treatment approaches [29]. Traditional genotyping methods, such as PCR-based assays and hybrid capture, are widely used but have limitations in specificity, sensitivity, and throughput. With the increasing availability of genomic, proteomic, and imaging data, DL models have emerged as powerful tools in HPV genotyping, offering improved accuracy and automation [28].

## 3.1. Common Machine Learning Techniques in HPV Genotyping

Several ML and DL approaches have been investigated for HPV genotyping:

- **SVM:** SVM models have demonstrated high accuracy in distinguishing high-risk HPV types using genetic sequencing data [30].
- **RF:** RF classifiers have been applied in predicting HPV genotypes based on viral sequence features, improving specificity compared to conventional assays [31].
- **k-NN:** This algorithm has been successfully implemented in HPV subtype classification using molecular signature data [32].
- **XGBoost:** Extreme Gradient Boosting (XGBoost) models have been trained on HPV genomic datasets, outperforming traditional PCR-based methods in classification accuracy [33].
- **CNNs:** CNN-based models have been effective in feature extraction from histopathological slides, improving image-based HPV detection through DL on Pap smear, biopsy samples, and H&E-stained tissue images [34].
- **RNNs:** RNNs have been applied to analyze longitudinal patient data and predict HPV progression trends [35].
- **Transformer-Based Models:** ViTs have demonstrated state-of-the-art performance in classifying HPV-associated cervical lesions [36].
- **Hybrid Models (CNN + SVM, CNN + LSTM):** Hybrid models combining CNNs with SVMs or Long Short-Term Memory networks (LSTMs) have been developed to enhance HPV genotyping accuracy by integrating spatial and temporal features [37].

Conventional machine learning models, such as SVM and RF, have demonstrated high discriminatory performance in detecting HR- HPV genotypes—particularly HPV-16—when trained on well-curated genomic datasets. However, model-specific evidence regarding the accurate identification of HPV-18 remains limited, indicating the necessity for further studies focusing on genotype-level classification performance [31,41].

# 3.2. Performance Comparison of ML Models in HPV Genotyping

ML models have been extensively applied in HPV genotyping, offering improved accuracy and efficiency compared to conventional molecular techniques. Various approaches, including k-NN, SVM,

RF and hybrid DL models, have demonstrated their potential in classifying high-risk HPV types. The table below summarizes the performance metrics of different ML models used for HPV genotyping, highlighting their sensitivity, specificity, and overall accuracy (Table 2).

Authors (Reference)	Methods	Results	Sensitivity (%)	Specificity (%)	Accuracy (%)
Shakil et al. [38]	k-NN	Achieved 91.62% accuracy using feature selection and explainable AI	99.31	40.91	91.62
Zhai et al. [39]	XGBoost	XGBoost model achieved 81.3% accuracy in predicting high-grade CIN recurrence	81.3	79.2	81.3
Wong et al. [40]	SVM - Linear	SVM-based model classified HPV genotypes with high specificity	56.25	90.91	-
Wong et al. [40]	RF	RF model achieved high specificity for HPV genotyping	53.13	90.91	-
Remita et al. [41]	SVM	SVM-based model successfully identified carcinogenic HPV types with 99.5% accuracy	99.2	99.8	99.5
Remita et al. [41]	RF	RF model reached 99.97% accuracy in HPV classification	99.6	99.99	99.97
Asensio-Puig et al. [31]	RF	RF model achieved high genotyping accuracy	99.5	99.3	99.5
Asensio-Puig et al. [31]	SVM	SVM model provided 98.0% accuracy in HPV lineage classification	98.0	97.8	98.0
Asensio-Puig et al. [31]	k-NN	k-NN model achieved high sensitivity in HPV16 lineage classification	98.0	97.9	98.0
Rahaman et al. [28]	Hybrid CNN with Deep Feature Fusion	Achieved 99.85% accuracy for binary classification on the SIPAKMED dataset	99.8	-	99.85
Klein et al. [34]	CNN on H&E- stained images	Achieved 92.0% accuracy in detecting HPV-positive cases	-	-	92.0

Table 2. Performance Comparison of Machine Learning Models in HPV Genotyping

Hybrid CNN models (e.g., DeepCervix) exhibit the highest accuracy (99.85%), reinforcing the role of DL in enhancing HPV genotyping precision. R and SVM consistently achieve high accuracy, demonstrating their effectiveness in genomic classification. Traditional ML models like XGBoost and k-NN perform well but show variability in sensitivity and specificity, indicating the need for further optimization and dataset refinement.

These results emphasize the growing importance of AI in HPV diagnostics, paving the way for more robust, scalable, and clinically applicable genotyping models. Future research should explore multi-modal AI integration and federated learning to further improve the reliability of HPV classification algorithms.

## 4. Future Perspectives and Challenges

Despite significant advancements in AI for HPV diagnosis, several challenges hinder widespread clinical adoption. A primary concern is the need for large, high-quality, and diverse datasets to train robust ML and DL models. Many current studies rely on small or regionally biased datasets, limiting model generalizability. Collaborative efforts to establish global HPV data repositories and implement

federated learning frameworks could mitigate this issue. Federated learning allows multiple institutions to collaboratively develop ML algorithms without sharing raw data, thereby preserving patient privacy while enhancing model robustness [42,43]

Another challenge is model interpretability and explainability, which are critical for clinical adoption. Most DL models function as "black boxes," making it difficult for clinicians to understand decision-making processes [44]. XAI models that provide transparent and interpretable outputs could enhance clinician trust and regulatory approval [45].

Algorithmic bias and fairness in AI-driven HPV diagnosis is another pressing issue. Studies have shown that machine learning models can exhibit biases due to imbalanced training data, leading to disparities in diagnostic accuracy across different demographic groups [46]. Ensuring diverse and representative datasets, along with bias-mitigation techniques, is essential to promote equitable healthcare outcomes [47,48].

In addition, data privacy and security remain significant concerns. AI models trained on patientsensitive information must comply with data protection regulations such as the General Data Protection Regulation (GDPR) and Health Insurance Portability and Accountability Act (HIPAA) to ensure confidentiality [49]. Federated learning, which enables AI training across decentralized institutions without data sharing, has been proposed as a promising solution [50,51].

Lastly, clinical validation and regulatory approval of AI-based HPV diagnostics pose substantial challenges. Despite promising research results, only a limited number of AI models have been validated in real-world clinical settings or received regulatory approval from organizations such as The U.S. Food and Drug Administration (FDA) [48,52].

Implementing DL solutions requires substantial computational resources and technical expertise. Addressing these barriers through investments in infrastructure and training for healthcare professionals is vital for the successful deployment of DL-based HPV genotyping tools [53].

As new data becomes available, DL models must be continuously validated and updated to maintain their accuracy and relevance. Establishing protocols for regular model evaluation and incorporating new findings will help keep the models current and effective [54].

Achieving regulatory approval for DL-based diagnostic tools involves rigorous validation and standardization processes. Collaborating with regulatory bodies to develop clear guidelines and standards will facilitate the integration of these tools into clinical practice [55].

Future research should focus on conducting large-scale, multi-center validation studies to ensure AI models perform reliably across diverse populations and clinical environments.

In summary, while ML and DL present transformative opportunities for HPV diagnosis, overcoming challenges related to data availability, model transparency, fairness, security, and regulatory compliance is critical. Future research should focus on developing scalable, ethical, and clinically validated AI models that can be seamlessly integrated into existing diagnostic workflows to enhance patient care globally.

#### 5. Integration of Machine Learning with Other Technologies for HPV Diagnosis

The integration of ML with advanced diagnostic technologies has significantly enhanced the accuracy and efficiency of HPV detection. By combining ML algorithms with various diagnostic modalities, healthcare professionals can achieve more precise and timely identification of HPV-related conditions, ultimately improving patient outcomes.

One of the most impactful applications of ML in HPV diagnostics is its integration with imaging technologies to improve the detection and classification of cervical lesions. AI-assisted systems employ

DL models to analyze cytological images, differentiating between normal and abnormal cells, thereby enhancing early cervical cancer screening efforts [56].

Incorporating ML with molecular diagnostic methods has also significantly advanced the identification of HPV genotypes and associated biomarkers. For instance, a diagnostic study demonstrated that integrating HPV genotyping into an AI-driven model substantially improved its predictive accuracy for cervical cancer in women with high-risk HPV infections [57]. Additionally, the development of an HPV genotype detection platform utilizing aggregation-induced emission (AIE) and flow-through hybridization technologies has further enhanced the sensitivity and efficiency of molecular diagnostics [58]. These AI-powered approaches facilitate precise HPV genotyping and biomarker identification, improving the overall management of HPV-related conditions.

Furthermore, self-supervised learning approaches have emerged as promising tools to enhance cervical cytology diagnostics, particularly in resource-limited settings. By leveraging unlabeled images from Pap smear tests, these methods improve performance across various diagnostic tasks, making them highly applicable in low-data environments [59].

Another significant advancement is using multiple instances learning frameworks to detect HPV infection in head and neck cancers through routine histological images. These models enable the analysis of tissue samples to predict HPV status, assisting in patient stratification and informed clinical decision-making [60].

Additionally, the fusion of ML with optical coherence microscopy has facilitated the development of computer-aided diagnostic (CAD) systems for cervical tissue analysis. DL models process high-resolution 3D images to accurately classify cervical tissue types, significantly enhancing diagnostic precision [61].

The integration of machine learning with diverse technological platforms has revolutionized HPV diagnostics, offering higher accuracy, efficiency, and accessibility. These AI-driven methodologies not only enhance early detection and classification but also provide scalable and cost-effective solutions for improving global HPV screening programs. As these technologies continue to evolve, their implementation in clinical settings will play a pivotal role in optimizing patient care and advancing cervical cancer prevention strategies.

## 6. Ethical and Regulatory Challenges in AI-Based HPV Diagnostics

The integration of AI into healthcare, particularly in the diagnosis of HPV, offers significant advancements. However, it also introduces several ethical and regulatory challenges that must be addressed to ensure safe and equitable implementation.

#### 6.1. Data Privacy and Security

AI models require extensive datasets containing sensitive patient information, raising concerns about data privacy and security. Ensuring compliance with regulations such as the GDPR is essential to protect patient confidentiality. Implementing robust data anonymization techniques and security measures is crucial to prevent unauthorized access and data breaches [62].

The GDPR establishes three key principles for AI-driven decision-making: transparency, ensuring individuals are informed about AI decisions and understand their logic; human oversight, requiring human intervention to validate or override automated decisions; and fairness & non-discrimination, mandating that AI systems minimize bias, ensure accuracy, and prevent discriminatory outcomes. These principles enhance accountability, reliability, and ethical AI use, particularly in healthcare applications [63].

The increasing popularity of machine learning approaches and the rising awareness of data protection and data privacy present an opportunity to build truly secure and trustworthy healthcare

systems. Regulations such as GDPR and HIPAA present broad guidelines and frameworks, but the implementation can present technical challenges [64].

Addressing these ethical and regulatory challenges is crucial for the successful implementation of AI-based HPV diagnostics, ensuring that technological advancements translate into improved patient outcomes while upholding ethical standards and regulatory compliance.

## 6.2. Algorithmic Bias and Fairness

The effectiveness of AI systems in healthcare is profoundly influenced by the quality and diversity of their training data. When datasets lack representation or contain biases, AI models can inadvertently perpetuate existing health disparities, disproportionately impacting certain demographic groups. For instance, AI models trained on homogeneous datasets may not generalize well to diverse populations, leading to less accurate predictions for underrepresented groups [65]. This issue is exacerbated when AI systems are developed using data that do not reflect the demographic diversity of the patient population, resulting in unequal outcomes and potentially widening existing health disparities [66]. Addressing these biases is crucial for developing fair and equitable AI-based diagnostic tools that serve all segments of the population effectively. Ensuring diversity in training data and implementing bias detection and mitigation strategies are essential steps toward achieving this goal [67].

## 6.3. Transparency and Explainability

AI algorithms often function as "black boxes," rendering their decision-making processes opaque to clinicians and patients. This opacity can hinder trust and impede the adoption of AI-driven tools in clinical settings. Enhancing transparency and explainability is essential to bridge this gap [68]. XAI aims to demystify these complex models, providing clear insights into how decisions are made, thereby fostering confidence among healthcare professionals and patients alike. For instance, integrating XAI into clinical decision support systems can elucidate the rationale behind AI-generated recommendations, enabling clinicians to make informed choices and facilitating patient understanding [69]. Moreover, regulatory frameworks increasingly emphasize the need for transparency in AI applications to ensure ethical and accountable use in healthcare. By prioritizing explainability, AI systems can become more trustworthy, ultimately enhancing their integration into medical practice and improving patient outcomes [70].

#### 6.4. Regulatory Approval and Standards

The integration of AI-based medical diagnostics into clinical practice necessitates stringent evaluation and approval by regulatory authorities to ensure both safety and efficacy. FDA has been proactive in this domain, authorizing numerous AI/ML-enabled medical devices, with a significant concentration in radiology applications. Notably, two-thirds of these radiology devices received marketing authorization between August 2020 and July 2023 [71]. Establishing comprehensive guidelines and standards is imperative to navigate the intricate regulatory landscape surrounding AI in healthcare. Standardization promotes interoperability and compatibility among diverse AI systems, facilitating seamless integration into existing healthcare infrastructures. Moreover, standardized frameworks enhance trust among healthcare professionals and patients, ensuring that AI applications adhere to consistent safety and performance benchmarks [72]. The FDA has recognized the dynamic nature of AI technologies and is adapting its regulatory approaches accordingly. By focusing on the total product lifecycle of AI tools, the FDA aims to balance patient safety with the promotion of innovation in healthcare. This adaptive regulatory stance is crucial for accommodating the rapid evolution inherent in AI applications [73].

In summary, the successful deployment of AI-based medical diagnostics hinges on rigorous regulatory oversight and the establishment of clear, standardized guidelines. Such measures are essential for ensuring that these advanced technologies are both safe and effective, thereby fostering their integration into routine clinical practice.

#### 6.5. Clinical Responsibility and Legal Implications

AI in medical diagnostics introduces complex questions regarding clinical responsibility and legal liability, particularly in instances of misdiagnosis or errors. Establishing clear delineations of accountability between healthcare providers and AI developers is paramount to navigate potential legal challenges and uphold patient safety.

In scenarios where AI systems function autonomously, it is advocated that developers assume liability for any resultant harm, provided the technology is utilized correctly and within its intended scope. This perspective emphasizes the necessity for AI creators to secure medical malpractice insurance to cover potential damages arising from their innovations. Conversely, when AI serves as an assistive tool, the onus remains on physicians to critically assess AI-generated recommendations, as they retain full responsibility for clinical decisions made [74].

The potential for clinicians to become "liability sinks" in the event of AI-related errors is a pressing concern. Healthcare professionals often feel personally accountable for patient safety incidents, even when such events may be attributed to systemic issues or AI malfunctions. This underscores the importance of defining the extent of clinician responsibility in the context of AI-assisted care [75].

Moreover, the rapid advancement of AI technologies in healthcare necessitates the development of robust regulatory and ethical frameworks. These frameworks are essential to manage safety concerns, privacy issues, and potential biases inherent in AI systems, ensuring that their integration into clinical practice does not compromise patient care standards [76].

In summary, as AI continues to revolutionize medical diagnostics, it is imperative to clearly define the legal and ethical responsibilities of both AI developers and healthcare providers. Such clarity will be instrumental in mitigating legal risks and safeguarding patient well-being in the evolving landscape of AI-enhanced healthcare.

#### 7. Conclusion

The integration of ML into the molecular diagnosis and genotyping of HPV represents a transformative shift in clinical microbiology and public health. While traditional diagnostic methods— such as PCR-based assays and cytological screening—have long been the foundation of HPV detection, they are often constrained by variability in sensitivity, labor-intensive protocols, and reliance on expert interpretation. In contrast, ML-driven approaches offer a highly accurate, automated, and scalable alternative, significantly enhancing diagnostic precision and accessibility.

Over the past decade, ML models—ranging from SVMs and RFs to neural networks—have demonstrated superior diagnostic capabilities in HPV classification, risk stratification, and disease progression modeling. The application of CNN-based architectures for cytological and histopathological image analysis has yielded remarkable improvements in lesion detection accuracy, while hybrid models integrating AI with molecular diagnostics have enabled more precise HPV genotyping. These advances hold particular promise for low-resource settings, where expert pathologists and advanced molecular assays may not be readily available.

Despite these promising developments, several challenges must be addressed before AI-driven HPV diagnostics can be seamlessly integrated into routine clinical workflows. Model generalizability, influenced by dataset diversity and bias, remains a key limitation, necessitating the development of globally representative training datasets. Additionally, the "black-box" nature of many DL models raises

concerns about interpretability and clinical trust, underscoring the need for XAI frameworks. Regulatory hurdles further complicate adoption, as AI-based diagnostic tools must undergo rigorous clinical validation and approval processes to ensure safety and reliability.

Looking ahead, future research should focus on developing multi-modal AI systems that integrate genomic, proteomic, and imaging data to enhance diagnostic accuracy. The incorporation of federated learning approaches may mitigate data privacy concerns by enabling collaborative model training without direct data sharing. Furthermore, strengthening ethical frameworks and algorithmic fairness measures will be essential to minimize bias and ensure equitable healthcare outcomes.

In conclusion, ML-based methodologies are poised to revolutionize HPV diagnostics and genotyping, offering a powerful, scalable, and cost-effective solution for early detection and risk stratification. As these technologies continue to evolve, interdisciplinary collaborations between data scientists, microbiologists, and clinicians will be critical in bridging the gap between AI innovation and real-world clinical application. By harnessing the full potential of AI-driven HPV screening and molecular diagnostics, healthcare systems worldwide can take a decisive step toward reducing the burden of HPV-related malignancies and improving global cervical cancer prevention strategies.

#### **Ethical statement:**

This review article does not require ethics committee approval or any special permission, as it does not involve human or animal subjects, experiments, or hazardous procedures.

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## **Conflict of interest:**

The author declares that there is no conflict of interest.

#### **Generative AI statement**

The author declares that no Gen AI was used in the creation of this manuscript.

## Authors' contributions:

The author was solely responsible for the conceptualization, methodology, investigation, formal analysis, and writing of the manuscript. The author read and approved the final version of the manuscript.

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