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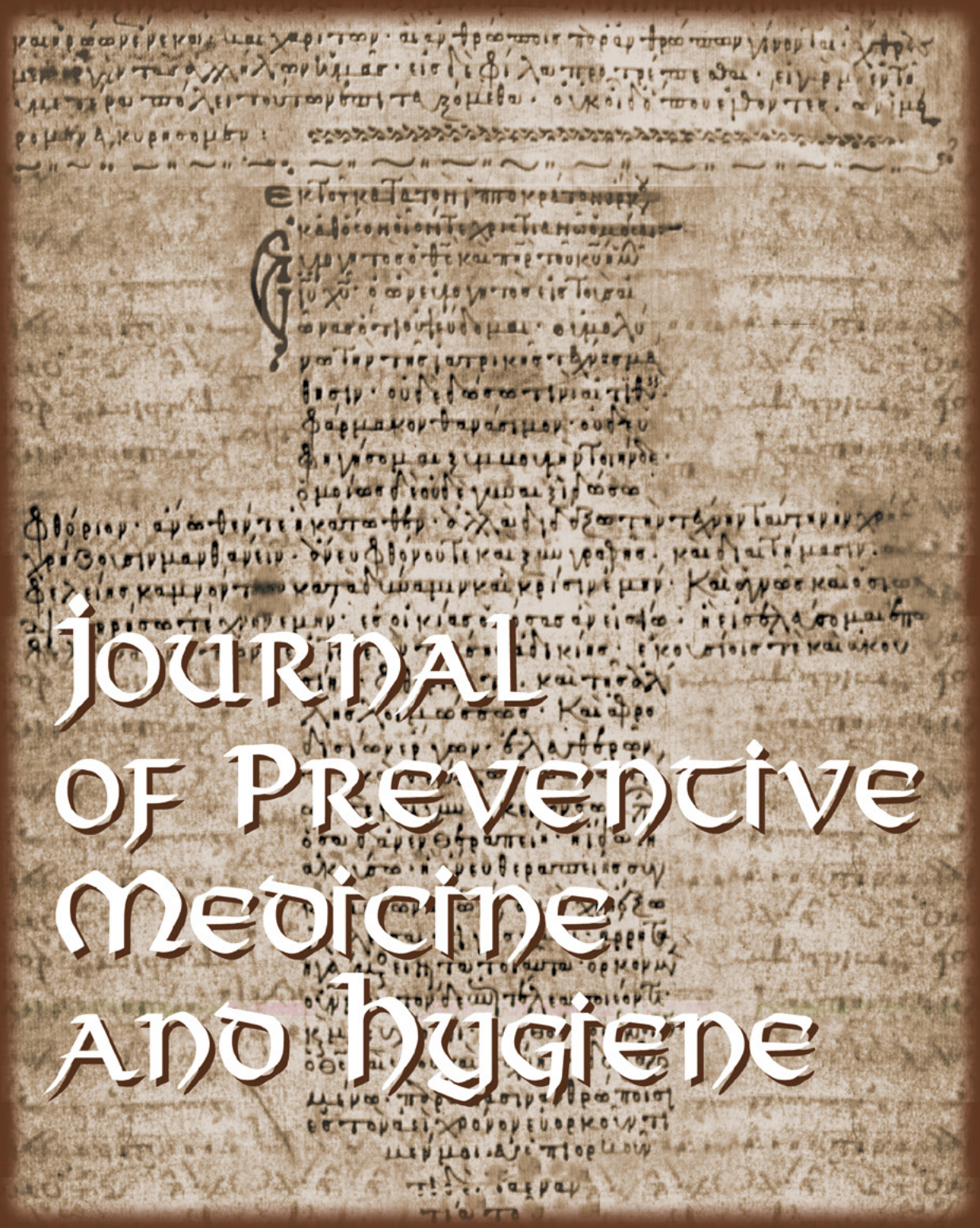

The original document of Hippocrates' oath

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CONTENTS

COVID-19

ORIGINAL ARTICLE

Drive-through vaccinations prove successful in immunizing mountain communities against tick-borne encephalitis during the COVID-19 pandemic

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Keywords

TBE vaccine • Drive-through • COVID-19

Summary

In March 2020, the COVID-19 pandemic disrupted most of the routine outpatient activities in Italian hospitals and Prevention Departments, including those vaccinations which were not urgent and/or scheduled for children aged 0-6 years. Since June 2020, when the pandemic entered a milder phase, in the alpine Province of Belluno (Veneto, North-Eastern Italy), 12,152 doses of vaccine against tick-borne encephalitis have been administered by means of the innovative "drive-through" modality. No significant adverse events have occurred and popular demand has steadily grown, proving the "drive-through" approach to be safe, efficient and successful.

Introduction

In March 2020, in all Italian Regions, the COVID-19 emergency prompted suspension of all outpatient services in the Prevention Departments of the Local Health Units, with the sole exception of urgent or non-deferrable activities. Most vaccinations were therefore suspended (unless urgent or scheduled for children aged 0-6 years) [1].
In this context, new strategies were required, in order to deal with the backlog of postponed appointments as soon as the COVID-19 epidemiological scenario would allow at least partial resumption of routine healthcare services. For this purpose, the World Health Organization (WHO) provided some guiding principles for routine immunization activities during the pandemic [2, 3]. On the basis of these, the Veneto Region (in North-Eastern Italy) also provided its Local Health Units with guidelines for the management of the activities of Prevention Departments during the so-called "phase 2" of the pandemic [4]. These guidelines included recommendations to: ensure hygiene, ventilation, and social distancing among healthcare workers and children in waiting rooms and in the rooms devoted to vaccination; minimize the number of rooms visited by combining medical examinations and vaccination during the same visit; specifically train the dedicated healthcare personnel; allocate separate areas for immunization services in hospitals, if possible; and temporarily avoid mass vaccination campaigns.
In this scenario, drive-through vaccination has emerged as a rapid and safe means of immunizing large numbers of young people and adults whose vaccinations were due in the full pandemic period (March-May 2020) and whose appointments had to be rescheduled. This innovative modality had previously been experimented internationally for vaccinations [5, 6], and has recently been widely adopted for the administration of swab tests for COVID-19 [7-9].
Here, we describe the experience of the Province of Belluno (Veneto Region), a vast alpine territory where over 12,000 people have been vaccinated against tick-borne encephalitis (TBE) since the beginning of summer by means of the drive-through modality.

Methods

Context

The Province of Belluno, in the Veneto Region, is a mountainous territory in the Alps, in North-eastern Italy, with a population of 201,972. In the period 2006-2018, 153 cases of TBE were notified in this territory, with a mean incidence rate (IR) of 5.89 cases/100,000 inhabitants during the decade 2007-2017; the area is therefore defined as "high endemic" (IR > 5/100,000). Most cases are notified between April and October, and males between 50 and 70 years old are most frequently involved. However, it must be pointed out that milder cases, which constitute the vast majority, are largely under-diagnosed [10] and that the cases of TBE reported in the Province of Belluno account for approximately 40% of all Italian cases.
Therefore, since 2019, the Local Health Unit (AULSS 1 "Dolomiti") has offered anti-TBE vaccination free of charge to all residents who request it [11].
Furthermore, from the end of February to the first week

of September 2020, 1,281 cases of COVID-19 were detected in the Province of Belluno [12], with an IR of 634 positive cases/100,000 inhabitants.

Logistics and organization

Subjects were invited to attend for anti-TBE vaccination according to priorities defined on the basis of the preexisting waiting list. Priority was given to:

- subjects who should have received the 1st dose of vaccine during the lock-down;
- categories exposed to occupational risks who were waiting for the 2nd or 3rd dose of vaccine;
- individuals who were already on the waiting list, but not yet scheduled to receive the 1st dose of vaccine;
- new requests for appointments for the 1st dose of vaccine;
- people waiting for their 2nd dose appointment to be scheduled;
- those waiting for their 3rd dose appointment to be scheduled.

During each session, appointments were initially scheduled at a rate of one every five minutes. Subsequently, the high volume of requests made it necessary to schedule one appointment every two minutes, in order to vaccinate approximately 30 people per hour, and finally one every minute. The appointments were communicated by telephone or letter, together with the following information:

- date and time of the scheduled convocation;
- specification that it was compulsory to come by car and to wear a face mask;
- recommendation to wear clothing, preferably a t-shirt, that would facilitate injection of the vaccine;
- description of the exact route to the vaccination site and of the subsequent way out;
- obligation to wait for 15 minutes in a dedicated car park after administration of the vaccine, without wearing a face mask, in order to enable the supervising operator to recognize pallor or other signs of adverse events.

The drive-through vaccination site was a tent, generally provided by local volunteers, equipped with all the standard equipment of an in-hospital ambulatory setting:

- refrigerator (2-8°C) for the correct storage of the vaccine for the entire duration of the daily activity, equipped with separate compartments for pediatric doses and adult doses;
- desk and chairs;
- photocopies of a sufficient number of pre-vaccination anamnestic questionnaires;
- two computers endowed with the Region's official software (*SiaVr*) for vaccinations, correctly installed and functioning;
- two trolleys carrying the vaccine administration material;
- emergency trolley;
- wheelchair and stretcher in case a patient needed to be transferred from his/her car into the drive-through tent;
- containers for special waste and for other waste, according to the various disposal needs;
- rigid needle containers;
- at least one kidney-shaped basin for each trolley;
- sanitizing gel;
- gauze and disinfectant.

Before each vaccination session, the personnel were responsible for checking that the above-listed material was present in an adequate quantity. During each session, a medical doctor had to be available - either physically present at the drive-through site (if this was far from the local hospital) or able to reach the site rapidly in the event necessity (if the site was within the perimeter of the local hospital). The remaining personnel consisted of two healthcare assistants or nurses, one of whom administered the pre-vaccination questionnaire and registered each vaccination on the regional software, while the other administered the vaccine. An auxiliary operator patrolled the post-vaccination parking area to check for the possible occurrence of adverse reactions.

In the event of any adverse reaction, the three operators were trained to transfer the patient immediately from his/her car to the wheelchair or stretcher, and then to convey him/her promptly to the tent or to the emergency room, according to the severity of the clinical symptoms.

The personnel responsible for the procurement of vaccines had to request the vaccine doses from the hospital pharmacy, possibly well in advance, in accordance with the schedule of vaccination sessions, in order to avoid any shortage.

Three sites were designated for the drive-through vaccinations:

1. one in the car park (Fig. 1) outside San Martino local hospital in Belluno (the Province's largest town);
2. one in the market square of the small town of Pieve di Cadore (less than 5 minutes from the local hospital), by agreement with the local municipal administration;
3. one in the car park outside the offices of the Prevention Department in the town of Feltre (the second-largest town in the Province).

A fourth site, in the small town of Caprile, was being opened at the time when this article was written. Each of the four locations had previously been inspected by technicians and IT specialists from the Local Health Unit and by the Hygiene and Public Health Service, in order to evaluate the spaces available, check the electricity supply and Internet connection, and determine the pathways through and the positioning of the vaccination sites.

Fig. 1. Drive-through site outside San Martino Hospital in Belluno; right: a line of cars queuing before vaccination; left: the tent; center: cars parked after vaccination.

Results

By the end of August 2020, a total of 12,152 doses of vaccine against TBE (first, second, third and booster doses) had been administered to 12,083 people at the various sites in the Province of Belluno (Tab. I):

- a total of 8,284 doses administered to 8,193 people (91 people received the first and the second doses within the period) in Belluno since the 24th June 2020, in 43 sessions (average of 193 vaccinations per day);
- a total of 2,193 doses administered in Pieve di Cadore since the 20th July in 12 sessions (average of 183 vaccinations per day);
- a total of 1,697 doses administered in Feltre on three Sundays during all-day (8 am – 7 pm) sessions.

Overall, in 2020, 18,846 doses of vaccine against TBE have been administered, including 6,694 doses administered in outpatient departments at the beginning of the year, before the lock-down, and 12,152 doses administered up to the end of August in the drive-through modality.

These figures compare favorably with those recorded in the previous year: indeed, after May 2019, when the free-of-charge TBE vaccination was introduced, 8960 inhabitants of the province received at least one dose of vaccine and 13,494 doses were administered overall in 2019, according to the regional database.

Adverse events

No major adverse events occurred. As for minor events, two cases of pre-syncope and two of syncope were registered; these were probably due to the high summer temperatures combined with emotional factors (especially in the case of an adolescent). Following the first minor events, all vaccinees were strongly recommended to leave their car windows open.

In 2019, too, no major adverse events were reported, whereas 20 minor events occurred: headache, paresthesia, pre-syncope and syncope.

Conclusions

To our knowledge, this is the first case-report on anti-TBE vaccination carried out by means of the drive-through modality during a worldwide pandemic.

The experience of the Local Health Unit "AULSS 1 Dolomiti" in the Province of Belluno indicates that this innovative modality is a safe and efficient means of vaccinating large numbers of people while still maintaining social distancing.

According to the literature, drive-through vaccination has been implemented in some other countries, though almost exclusively for mass immunization against seasonal influenza. Specifically, in the USA, drive-through vaccinations were first carried out more than 20 years ago in Kentucky [6, 13-14], and have been repeated yearly ever since. In North Carolina [15] and New Mexico [16, 17] flu vaccines have also been occasionally administered in the drive-through modality in the last two decades. In these and other [18] American contexts, drive-through vaccination proved successful in immunizing local communities against seasonal influenza.

During the current COVID-19 pandemic, drive-through vaccination has become more common and is now being adopted in several contexts. In New South Wales, Australia, for instance, local health authorities have drawn up guidelines for general practitioners who choose the drive-through option for seasonal influenza vaccination [19]. In terms of logistics, pre-vaccination arrangements (appointments, anamnestic assessment), safety precautions and emergency equipment, these guidelines are comparable to those issued by the Local Health Unit "AULSS 1 Dolomiti" in Belluno.

In Europe, the British National Health Service provided drive-through vaccination against measles-mumps-rubella and papillomavirus for adolescents during the summer [20].

Moreover, analysis of the trend in anti-TBE vaccinations in the Province of Belluno reveals that the number of people requesting vaccination has steadily increased since this free-of-charge service was introduced in May 2019 [11]. This indicates that the drive-through modality has not only proved to be a safe means of ensuring continuity of the service during a milder phase of the COVID pandemic, but also meets with users' approval, despite the relatively few drive-through sites available (in comparison with the more numerous ambulatory facilities) and the traveling distances involved.

Finally, in the Province of Belluno, the drive-through modality enabled more than 100 people per session (3/3.5-hours) to be vaccinated through the use of only three healthcare workers and one medical doctor. By contrast, in a traditional indoor clinic, the current regulations on social distancing and sanitization of the clinic after each vaccination would have allowed only one person to be vaccinated approximately every 15 minutes. The drive-through modality therefore proved able to maintain the efficiency of the service and also to save doctors, nurses and healthcare assistants precious hours of work in these challenging times of the pandemic.

Tab. I. Number of doses of anti-TBE vaccine administered at each of the three sites from 24th June to 31st August 2020, and number of people who were vaccinated; 91 people in Belluno received both the first and the second doses.

	Doses	Subjects vaccinated
Belluno	8,193	8,284
Pieve di Cadore	2,193	2,193
Feltre	1,697	1,697
Total	12,152	12,083

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Conflict of interest statement

The authors declare no conflict of interest.

Authors' contributions

All authors contributed equally to this work.

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ORIGINAL ARTICLE

Did Iranians respect health measures during Nowruz holidays? A study on Iranians' knowledge, attitude and practice toward COVID-19

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Keywords

Knowledge • Attitude • Practice • COVID-19

Summary

Introduction. *Since December 2019, the COVID-19 outbreak has affected almost every country in the world, including Iran. General awareness and commitment to recommendations made by health officials have important role in control of the outbreak. The aim of the current study was to assess the knowledge, attitude, and practice (KAP) of Iranians concerning COVID-19 after Nowruz (Persian New Year Holiday) in Iran and identifying its determining demographic and socioeconomic factors.*

Method. *A cross-sectional study was designed. We translated and culturally adopted Zhong's questionnaire to Persian, which is designed to assess people's knowledge, attitude, and practice toward COVID-19. We used online Google forms to send the questionnaire via social platforms throughout the country. A total of 1015 Iranians participated in the study.*

Results. *The mean knowledge score among our participants was 10.60, with an overall correct response rate of 88.35%. Higher knowledge score was associated with higher education, being a professor, and residing in cities. Lower knowledge score was associated with being unemployed, marital status other than single or married, and living in rural areas. Almost all of our participants had favorable attitudes and practices toward COVID-19.*

Conclusion. *Overall, Iranians showed a satisfactory KAP towards COVID-19. We suggest more attention to informing people living in rural areas and unemployed, as they were related to more risky behaviors and had lower knowledge scores regarding COVID-19.*

Introduction

In December 2019, China reported the outbreak of the novel Coronavirus, later named COVID-19, in the city of Wuhan in Hubei Province [1]. The virus spread rapidly throughout the world. World Health Organization (WHO) announced the situation as a global pandemic on March 12, 2020, and noted that this is the first pandemic by a coronavirus and the first pandemic that can be controlled at the same time [2].

The first officially confirmed cases of COVID-19 in Iran were announced on February 19, 2020, in Qom province [3]. Numbers have been rising day by day, and as of April 18, 2020, about one week after the Nowruz holidays in Iran, 79,494 cases and 4958 deaths are confirmed in Iran, more than any other country in the Eastern Mediterranean Region [4].

National health administrations in Iran, as well as international health organizations such as the Centers for Disease Control and Prevention (CDC) and WHO, started making recommendations based on the current knowledge about the situation. They aimed to restrict the direct social contacts, increase public awareness about the symptoms of COVID-19 and protection against it, and promote thoughtful use of medical equipment such as masks [5-7].

Some governors adopted isolating their cities as a strategy to fight against the spread of COVID-19. Iranian officials decided not to impose compulsory quarantines and sufficed to recommend people to stay at their homes and applied limited restrictions in commuting between and within the cities.

The first weeks of the COVID-19 outbreak in Iran coincided with Nowruz (Persian New Year Holiday), which Iranians celebrate with family gatherings and travel. The president of Iran and health authorities requested people to stay home for New Year celebrations, but unfortunately, some citizens ignored it, and more than 1.2 million people took the roads to travel during the holidays [8].

To combat the current pandemic requires the public to understand the situation and trust officials who are trying to limit the spread of COVID-19. To gain people's cooperation and trust for self-isolation, basic knowledge about the means of virus transmission and prevention methods is necessary, and affects their attitude and practice towards COVID-19, according to the Knowledge, Attitude, and Practice (KAP) theory [9].

As it has not been studied before, understanding the level of public awareness about COVID-19 has vital importance in facilitating the management of its outbreak in Iran. In this study, we aimed to assess the Iranians'

public knowledge, attitude, and practice (KAP) toward COVID-19, right after the Nowruz holidays.

Methods

Questionnaire

Zhong et al. designed a reliable questionnaire to assess KAP toward COVID-19 amongst Chinese residents nearly one week after the Hubei Province's lockdown initiation [10]. In the first stage, we provided the Persian version of the questionnaire. Two independent translators translated the questionnaire from English to Persian (T1 and T2). An expert panel, including the translators, two cardiologists, and an infectious medicine specialist, reviewed the Persian translations and synthesized a unit translation of the questionnaire according to both translations. As guidelines and recommendations on COVID-19 are constantly changing, we revised the questions and answers according to the latest recommendations of WHO [5]. For cultural adaptation, three questions were added to the practice section of the questionnaire. The panel approved the face validity of the questionnaire. The knowledge section of the questionnaire also has acceptable internal consistency, according to Zhong et al. study [10].

We sent the questionnaire to fifty Iranians and asked them to evaluate its fluency. According to their comments, we made some changes to the questionnaire and the final version was approved by the expert panel.

The questionnaire is made of three sections. The first section includes 12 statements and gauges knowledge about COVID-19. K1 to K4 statements are about clinical presentations of COVID-19, K5 to K7 are about its transmission routes, and the last five statements are about prevention. The participants may select *True*, *False*, or *I do not know* for each statement. Each correct answer values, one point, and total knowledge score can be as high as 12. A higher score indicates better knowledge of COVID-19. The second section evaluates attitude toward COVID-19 and consists of two *Yes*, *No* questions. The third section assesses the participants' practice concerning the COVID-19 outbreak and consists of five *Yes*, *No* questions.

In the questionnaire, we included questions on demographic characteristics of the participants, such as age, gender, marital status, provinces they live in, educational level, and occupational status. The questionnaire began with a complete explanation of the study goals and an indication of volunteer participation in the study. Participants could agree and move on to the question segments as they wish. Our study is approved by the Ethics Committee of Tehran University of Medical Sciences and Iran National Committee for Ethics in Biomedical Research with Ethics Code IR.TUMS.MEDICINE.REC.1399.239.

Participants

We included volunteer participants who were born and lived in Iran, were able to read Persian, and at least were 15 years old. According to the 2016 census in Iran, the population of Iranians who are 15 years old or older is about 61,000,000 [11]. Considering the margin of error of 1% to 5% and Confidence level of 95%, according to the formula of the *Sample size* we targeted a sample size of 385 to 9,603 people.

$$Sample\ size = \frac{\frac{P(1-P)Z^2}{e^2}}{1 + (\frac{P(1-P)Z^2}{Ne^2})}$$

Procedure

We uploaded our questionnaire in Google forms [12] and used popular social media platforms in Iran, such as Telegram and WhatsApp, to distribute the questionnaire throughout the country. We sent people explanatory messages alongside the link to the questionnaire. Questionnaires were completed anonymously, and we asked people to ignore the message if they are not willing to participate in the study. Data collection lasted from April 4 to April 10, 2020. This period is about six weeks after the start of the COVID-19 outbreak in Iran and just after the Nowruz holiday. We got 1,015 responses during this period. We had participants from 27 out of 31 provinces of Iran.

Data analysis

We calculated the percentage of participants in each demographic group, and the rate of the correct answers to each knowledge question and yes or no responses to each attitude or practice statement. Mean knowledge score and its standard deviation (SD) were calculated for the whole population and demographic groups. The result of the Kolmogorov-Smirnov test showed that knowledge scores were not distributed normally ($p < 0.001$), therefore we used the Kruskal-Wallis analysis to see whether there was a significant difference within demographic groups or not. If we observed a significant difference between groups with the Kruskal-Wallis analysis, a complementary Mann-Whitney test was used for paired groups to find where the exact difference was.

The percentage of yes and no answers to each attitude and practice statement was calculated for demographic groups, and the Chi-squared test was used to see whether there is a significant difference between groups or not. For each attitude and practice question, we calculated the mean and SD of knowledge score across those who answered the question with yes and no. We used the Kruskal-Wallis analysis to see whether there is a significant difference between them or not. We considered the level of significance at 0.05.

Results

A total of 1015 participants completed the questionnaire with a mean age of 35.32 years (SD: 11.95; range: 15-80). The number of participants from each province is shown in Table I.

Table II designates the statements of the knowledge section of the survey and the number of correct answers to

Tab. I. Participants distribution among Iran provinces.

Provinces	Number of participants	Percentage of participants
Alborz	23	2.3 %
Bushehr	16	1.6 %
East Azarbayjan	11	1.1 %
Fars	10	1.0 %
Gilan	45	4.4 %
Hamedan	21	2.1 %
Hormozgan	170	16.7 %
Isfahan	30	3.0 %
Kerman	11	1.1 %
Kermanshah	10	1.0 %
Khuzestan	13	1.3 %
Markazi	28	2.8 %
Mazandaran	122	12.0 %
Razavi Khorasan	29	2.9 %
Tehran	419	41.3 %
Other	55	5.5%

each statement. The mean COVID-19 knowledge score is 10.60 (SD: 1.48, range: 0-12), and the overall correct response rate to the knowledge statements is 88.35%. The K5 statement appears to be the most challenging for our respondents, as only 49.7% of them chose the correct answer to that statement.

The demographic characteristics of the participants and their mean knowledge scores are shown in Table III. Marital statuses other than single or married (divorced, widowed, etc.) were associated with a lower knowledge score ($p < 0.05$). No significant difference was seen between those who were single or married. Higher educational level was related to higher knowledge about COVID-19. Knowledge scores were significantly different comparing three different groups of educational level ($p < 0.05$) with participants, who had a bachelor's degree or more, got a higher knowledge score. Among different occupations, teachers and professors had the most top knowledge scores, and on the other hand, unemployed participants on average got lower points.

Table IV shows attitudes regarding COVID-19 by demographic characteristics. In total, 85.3% of the participants thought that COVID-19 would eventually be controlled. Attitude regarding the success in the control of COVID-19 differed across age groups and marital status categories, significantly ($p < 0.05$). Participants, who were 45-59 years old, were more optimistic regarding success in controlling the disease. Almost all of the respondents (97.8%) believed that their practice of hygienic and health measures would help in controlling the spread of COVID-19. This attitude (A2) differed significantly among occupational groups ($p < 0.05$), and 100% of teachers and professors agreed to this statement.

Tab. II. Percent of correct answers to questions of knowledge section and participants' attitude and practice toward COVID-19.

Statements	
Knowledge	Correct answers (%)
K1. The main clinical symptoms of COVID-19 are fever, fatigue, dry cough, and shortness of breath	978 (96.4)
K2. Unlike the common cold, stuffy nose, runny nose, and sneezing are less common in persons infected with the COVID-19 virus	755 (74.4)
K3. There currently is no effective cure for COVID-2019, but early symptomatic and supportive treatment can help most patients recover from the infection	936 (92.2)
K4. Not all persons with COVID-2019 will develop into severe cases. Only those who are elderly, have chronic illnesses, and are obese are more likely to be severe cases	925 (91.1)
K5. Eating or contacting animals would result in the infection by the COVID-19 virus	504 (49.7)
K6. Persons with COVID-2019 cannot infect the virus to others when a fever is not present	881 (86.8)
K7. The COVID-19 virus spreads via respiratory droplets of infected individuals	947 (94.7)
K8. Ordinary residents can prevent the infection by the COVID-19 virus by washing their hands frequently	900 (88.7)
K9. It is not necessary for children and young adults to take measures to prevent the infection by the COVID-19 virus	969 (95.5)
K10. To prevent the infection by COVID-19, individuals should avoid going to crowded places such as train stations and avoid taking public transportations	994 (97.9)
K11. Isolation and treatment of people who are infected with the COVID-19 virus are effective ways to reduce the spread of the virus	978 (96.4)
K12. People who have contact with someone infected with the COVID-19 virus should be immediately isolated in a proper place. In general, the observation period is 14 days	980 (96.6)
Attitudes and practices	Yes (%) / No (%)
A1. Do you agree that COVID-19 will eventually be successfully controlled with the application of the right strategies?	866 (85.3) / 149 (14.7)
A2. Do you agree that taking health measures by you will help in controlling the spread of the COVID-19?	993 (97.8) / 22 (2.2)
P1. Have you gone to any crowded place in the past week?	82 (8.1) / 933 (91.9)
P2. Have you traveled in the past month?	44 (4.3) / 971 (95.7)
P3. When greeting people during the past month, have you shake their hands or kissed them?	50 (4.9) / 965 (95.1)
P4. Have you visited your relatives or friends during the Nowruz holiday?	100 (9.9) / 915 (90.1)
P5. In the past month, have you washed your hand frequently with soap and water or alcohol-based solutions?	978 (96.4) / 37 (3.6)

Tab. III. Demographic characteristics of participants and knowledge score of COVID-19 by demographic variables.

Characteristics		Number of participants (%)	Knowledge score (mean ± SD)	P value
Gender	Male	432 (42.6)	10.64 ± 1.54	0.16
	Female	583 (57.4)	10.57 ± 1.44	
Age group	15-29	397 (39.1)	10.47 ± 1.67	0.063
	30-44	403 (39.7)	10.67 ± 1.31	
	45-59	165 (16.3)	10.77 ± 1.49	
	60+	50 (4.9)	10.50 ± 1.18	
Marital status	Single	432 (42.6)	10.63 ± 1.47	**0.014**
	Married	561 (55.3)	10.61 ± 1.50	
	Other	22 (2.2)	9.91 ± 1.31	
Educational level	High school or less	25 (2.5)	9.28 ± 2.46	**< 0.001**
	High school diploma or college	203 (20.0)	10.01 ± 1.98	
	Bachelor's degree and higher	787 (77.5)	10.77 ± 1.23	
Occupation	Student	168 (16.6)	10.37 ± 1.62	**0.004**
	Teacher/Professor	84 (8.3)	10.89 ± 1.05	
	Health care worker	64 (6.3)	10.66 ± 1.03	
	Office worker	236 (23.3)	10.68 ± 1.17	
	Retired	81 (8.0)	10.49 ± 1.87	
	Unemployed	167 (16.5)	10.30 ± 1.90	
	Other	215 (21.2)	10.84 ± 1.36	
Place of living	City	966 (95.2)	10.66 ± 1.35	**< 0.001**
	Village	49 (4.8)	9.43 ± 2.90	

Mean ± standard deviation knowledge score in whole population: 10.60 ± 1.48

Tab. IV. Attitudes regarding COVID-19 by demographic characteristics.

Characteristics		Number (percent) of each answer					
		A1: final success in control of outbreak			A2: people's role in control of outbreak		
		Yes	No	P-value	Yes	No	P-value
Gender	Male	364 (84.3)	68 (15.7)	0.411	425 (98.4)	7 (1.6)	0.303
	Female	502 (86.1)	81 (13.9)		568 (97.4)	15 (2.6)	
Age group	15-29	315 (79.3)	82 (20.7)	**< 0.001**	386 (97.2)	11 (2.8)	0.459
	30-44	349 (86.6)	54 (13.4)		394 (97.8)	9 (2.2)	
	45-59	157 (95.2)	8 (4.8)		164 (99.4)	1 (0.6)	
	60+	45 (90.0)	5 (10.0)		49 (98.0)	1 (20)	
Marital status	Single	351 (81.3)	81 (18.8)	**0.004**	422 (97.7)	10 (2.3)	0.766
	Married	494 (88.1)	67 (11.9)		549 (97.9)	12 (2.1)	
	Other	21 (95.5)	1 (4.5)		22 (100.0)	0 (0.0)	
Educational level	High school or less	22 (88.0)	3 (12.0)	0.388	25 (100.0)	0 (0.0)	0.727
	High school diploma/college	179 (88.2)	24 (11.8)		198 (97.5)	5 (2.5)	
	Bachelor's degree and higher	665 (84.5)	122 (15.5)		770 (97.8)	17 (2.2)	
Occupation	Student	135 (80.4)	33 (19.6)	0.326	167 (99.4)	1 (0.6)	**0.002**
	Teacher/professor	74 (88.1)	10 (11.9)		84 (100.0)	0 (0.0)	
	Health care worker	54 (84.4)	10 (15.6)		63 (98.4)	1 (1.6)	
	Office worker	201 (85.2)	35 (14.8)		231 (97.9)	5 (2.1)	
	Retired	72 (88.9)	9 (11.1)		80 (98.8)	1 (1.2)	
	Unemployed	149 (89.2)	18 (10.8)		156 (93.4)	11 (6.6)	
	Other	181 (84.2)	34 (15.8)		212 (98.6)	3 (1.4)	
Place of living	City	827 (85.6)	139 (14.4)	0.245	946 (97.9)	20 (2.1)	0.346
	Village	39 (79.6)	10 (20.4)		47 (95.9)	2 (4.1)	
Mean knowledge section score (SD)		10.66 (1.36)	10.23 (2.03)	**0.030**	10.64 (1.37)	8.95 (3.79)	**0.015**

Tab. V. Practices regarding COVID-19 by demographic characteristics.

Characteristics		Number (percent) of each answer														
		P1: going to crowded places			P2: travel in the past month			P3: shaking hands or kissing			P4: visiting others			P5: washing hands frequently		
		Yes	No	P	Yes	No	P	Yes	No	P	Yes	No	P	Yes	No	P
Gender	Male	59 (13.7)	373 (86.3)	< 0.001	31 (7.2)	401 (92.8)	< 0.001	24 (5.6)	408 (94.4)	0.425	51 (11.8)	381 (88.2)	0.072	417 (96.5)	15 (3.5)	0.800
	Female	23 (3.9)	560 (96.1)		13 (2.2)	570 (97.8)		26 (4.5)	557 (95.5)		49 (8.4)	534 (91.6)		561 (96.2)	22 (3.8)	
Age group	15-29	31 (7.8)	366 (92.2)	0.519	23 (5.8)	374 (94.2)	0.040	30 (7.6)	367 (92.4)	0.007	49 (12.3)	348 (87.7)	0.006	384 (96.7)	13 (3.3)	0.420
	30-44	32 (7.9)	371 (92.1)		19 (4.7)	384 (95.3)		15 (3.7)	388 (96.3)		43 (10.7)	360 (89.3)		385 (95.5)	18 (4.5)	
	45-59	17 (10.3)	148 (89.7)		2 (1.2)	163 (98.8)		2 (1.2)	163 (98.8)		7 (4.2)	158 (95.8)		159 (96.4)	6 (3.6)	
	60+	2 (4.0)	48 (96.0)		0 (0.0)	50 (100.0)		3 (6.0)	47 (94.0)		19 (2.0)	49 (98.0)		50 (100.0)	0 (0.0)	
Marital status	Single	34 (7.9)	398 (92.1)	0.967	21 (4.9)	411 (95.1)	0.770	24 (5.6)	408 (94.4)	0.727	48 (11.1)	384 (88.9)	0.384	415 (96.1)	17 (3.9)	0.878
	Married	46 (8.2)	515 (91.8)		22 (3.9)	539 (96.1)		25 (4.5)	536 (95.5)		49 (8.7)	512 (91.3)		542 (96.6)	19 (3.4)	
	Other	2 (9.1)	20 (90.9)		1 (4.5)	21 (95.5)		1 (4.5)	21 (95.5)		3 (13.6)	19 (86.4)		21 (95.5)	1 (4.5)	
Educational level	High school or less	3 (12.0)	22 (88.0)	0.368	2 (8.0)	23 (92.0)	0.397	3 (12.0)	22 (88.0)	0.120	4 (16.0)	21 (84.0)	0.481	21 (84.0)	4 (16.0)	< 0.001
	High school diploma/college	12 (5.9)	191 (94.1)		6 (3.0)	197 (97.0)		13 (6.4)	190 (93.6)		22 (10.8)	181 (89.2)		191 (94.1)	12 (5.9)	
	Bachelor's degree and higher	67 (8.5)	720 (91.5)		36 (4.6)	751 (95.4)		34 (4.3)	753 (95.7)		74 (9.4)	713 (90.6)		766 (97.3)	21 (2.7)	
Occupation	Student	6 (3.6)	162 (96.4)	0.001	12 (7.1)	156 (92.9)	0.083	11 (6.5)	157 (93.5)	0.142	19 (11.3)	149 (88.7)	0.054	160 (95.2)	8 (4.8)	0.024
	Teacher/professor	6 7.1)	78 (92.9)		5 (6.0)	79 (94.0)		4 (4.8)	80 (95.2)		12 (14.3)	72 (85.7)		77 (91.7)	7 (8.3)	
	Health care worker	11 (17.2)	53 (82.8)		2 (3.1)	62 (96.9)		4 (6.3)	60 (93.8)		7 (10.9)	57 (89.1)		62 (96.9)	2 (3.1)	
	Office worker	23 (9.7)	213 (90.3)		14 (5.9)	222 (94.1)		11 (4.7)	225 (95.3)		30 (12.7)	206 (87.3)		234 (99.2)	2 (0.8)	
	Retired	50 (6.2)	76 (93.8)		0 (0.0)	81 (100.0)		0 (0.0)	81 (100.0)		2 (2.5)	79 (97.5)		79 (97.5)	2 (2.5)	
	Unemployed	5 (3.0)	162 (97.0)		4 (2.4)	163 (97.6)		13 (7.8)	154 (92.2)		10 (6.0)	157 (94.0)		157 (94.0)	10 (6.0)	
	Other	26 (12.1)	189 (87.9)		7 (3.3)	208 (96.7)		7 (3.3)	208 (96.7)		20 (9.3)	195 (90.7)		209 (97.2)	6 (2.8)	
	Student	6 (3.6)	162 (96.4)		12 (7.1)	156 (92.9)		11 (6.5)	157 (93.5)		19 (11.3)	149 (88.7)		160 (95.2)	8 (4.8)	
Place of living	City	79 (8.2)	887 (91.8)	0.606	42 (4.3)	924 (95.7)	0.929	46 (4.8)	920 (95.2)	0.283	97 (10.0)	869 (90.0)	0.369	933 (96.6)	33 (3.4)	0.084
	Village	3 (6.1)	46 (93.9)		2 (4.1)	42 (4.3)		4 (8.2)	45 (91.8)		3 (6.1)	46 (93.9)		45 (91.8)	4 (8.2)	
Mean knowledge section score (SD)		10.50 (1.39)	10.61 (1.49)	0.433	10.45 (1.15)	10.61 (1.50)	0.135	10.08 (1.82)	10.63 (1.46)	0.015	10.49 (1.42)	10.61 (1.49)	0.183	10.64 (1.37)	9.49 (3.12)	0.013

Different practices concerning COVID-19 by demographic characteristics are shown in Table V. The majority of the respondents did not go to crowded places in the past week (91.9%). Only 4.3% of our participants reported traveling, and 4.9% of the participants had shaken hands or kissed others in the last month. 9.9% of them visited their family and friends during the Nowruz holiday. Almost all of our participants washed their hands frequently during the last month (96.4%). Health care workers were in crowded places more than others ($p < 0.05$). Youths (age group: 15-29 years old) traveled, shook hands or kissed others, and visited others during Nowruz, significantly more than other age groups. Washing hands frequently is significantly associated with higher educational levels ($p < 0.001$). Office workers sanitized their hands more commonly than other occupational groups ($p < 0.05$). The mean knowledge score was significantly higher in respondents who sanitized their hands frequently than those who did not ($p < 0.05$).

Discussion

We evaluated Iranians' knowledge, attitude, and practice (KAP) toward COVID-19. Previously similar studies were conducted in the USA and China to evaluate KAP toward COVID-19 in their populations. The mean knowledge score of our participants was 10.6 in our study, resembling the mean knowledge score reported by Zhong et al. in their study (10.8) [10]. This mean score suggests a satisfactory level of knowledge about COVID-19 in these two populations. The mean knowledge score in the USA's population is considerably lower (9.72) [13], which might be due to the USA's less experience with such epidemics in the past and the fact that the study was conducted in the first weeks of the COVID-19 outbreak in the USA.

In our study, the mean knowledge score is higher among participants with higher educational levels, which is in line with previous studies. Only 2.5% of our respondents had a high school level of education or less, which can be a confounding factor in our study, as we have a 12.4% illiteracy rate among Iranians [14]. Regarding the rate of illiteracy in Iran, the real knowledge level toward COVID-19 can be less in the general Iranian population. Mean knowledge score was lower among unemployed participants in our study, which matches what Clements reported, as the knowledge level was lower in participants with lower incomes. The lower level of knowledge among those with less income and lower educational levels may indicate the correlation of socioeconomic factors to knowledge toward COVID-19. We recommend placing more focus on informing and empowering lower socioeconomic societies against COVID-19, as they are the most vulnerable population in this outbreak. For example, those who had washed their hands more frequently had higher levels of knowledge in our study.

Besides, those with higher levels of education had washed their hands more regularly. As hand washing is one of the main ways to prevent the spread of the infectious agent, lack of enough hand washing can lead to the spreading of COVID-19 among those with a lower level of knowledge.
The COVID-19 knowledge level is lower in the rural population in comparison with the urban population. The rate of illiteracy is 21.5% in rural areas of Iran, comparing to 9.2% in urban society [14]. Lower-income and lower educational levels may be determining factors in the rural population's lower awareness of COVID-19.
The mean knowledge score was higher among those who were confident of ultimate control of COVID-19 with the right strategies, which is in line with what Zhong et al. reported before. Participants who were single and those who were younger were less optimistic about the success in controlling the epidemic. As the knowledge score does not significantly differ between age groups and marital statuses, other factors may be contributed to the pessimism of this group of our participants. A study suggests that hopelessness is most prevalent among 24-30 years old age group in Iran [15].
Zhong et al. and Clements reported a correlation between knowledge score and age among Chinese and American populations; in contrast, we did not find any difference between the knowledge score of various age groups. Our study's 15 to 29 years old people had significantly higher knowledge scores (mean = 10.47) than the same age group in Clements study (mean = 9.19). It appears age is not a determining factor regarding knowledge about COVID-19 in Iran, and other factors are more important.
The KAP theory suggests that an increase in knowledge can lead to a more approving attitude and practice. In this case, we hypothesized that a higher understanding of the public about COVID-19 should lead to more trust in health authorities and follow health recommendations. The majority (85%.3) of our participants were optimistic about the successful control of the COVID-19 outbreak, which is less than what Zhong et al. reported among the Chinese population (90.8%). This difference might be due to acquiring different strategies by Iran and China, as china set more restrictions and handled the situation more vigorously. On the other hand, news of the death of two patients due to COVID-19 was among the first news published about the outbreak in Iran [16], which led to public panic and despair about COVID-19 in Iran.
Almost all (97.8%) of our participants believed that taking health measures by them is helpful in the control of the COVID-19 outbreak. These participants had higher knowledge scores compared to those who did not believe in the efficacy of taking health measures, which indicates the importance of people's awareness and how it affects their behaviors.
Among our survey's participants, 8.1% reported visiting crowded places in a week ago. Based on Zhong's findings, only 3.6% of Chinese people did the same, which may be due to strict isolating orders of the government of China. We conducted our survey one week after the Nowruz holiday in Iran when almost nobody goes to work. We assume that the percentage of people who leave their houses will go up, as most of the occupations are reopening. Clements findings showed that 30% of Americans had attended large gatherings recently, as there were no restriction orders in the USA at the time of conducting this study.
There is no significant difference between level of knowledge among those who had visited crowded places and those who had not. Based on our findings, there is an association between visiting crowded places with occupation and gender. Unemployed participants went to crowded places less (3%) among all professions, and male (13.7%) participants tended to go to crowded places more than females (3.9%). A quarter of our female participants were unemployed, comparing to 4.9% of men. These findings may suggest that the main determining factor of visiting crowded places is occupation, and emphasizes on the necessity of applying restrictions for reopening the jobs.
Knowledge scores did not significantly differ between participants who travel during the last month and those who didn't. In our study, traveling was directly associated with the male gender and younger age. A study shows that risk-taking behaviors are more common among males and younger adults, which may explain our findings regarding traveling during the COVID-19 outbreak [17].
Participants who were 15 to 29 years old had significantly kissed or shook hands and visited others during Nowruz, more comparing to other age groups. These results show that among our participants, teenagers and younger adults have neglected the recommendations of health officials during Nowruz. Similar findings reported by Zhong et al. in which younger participants had less compliance toward wearing face masks. As knowledge scores were not significantly different among different age groups, such behaviors may be related to more risk-taking behavior in younger adults [18]. Further actions are needed to increase younger populations' compliance in taking health measures.

Limitations

Although we tried our best to include all groups of people in our study, the distribution of people by socioeconomic status is not like current Iran's status. The reason for such differences may be explained by the fact that people with better socioeconomic status have more access to social media platforms, and more fractions of them may decide to participate in voluntary studies such as our study. Future studies concentrating on those with low socioeconomic status may be indicated to assess their knowledge, attitude, and practice toward COVID-19.

Conclusions

The level of knowledge about COVID-19 is satisfactory in Iranians who participated in our study. Those with lower education levels and those who were unemployed had significantly less knowledge about COVID-19, which indicates the lower levels of knowledge in those with low socioeconomic status. People's jobs were related to their presence in crowded areas, which indicates the need for precise assessment of the situation for re-

opening the jobs in Iran as it can lead to the spread of COVID-19. Risky behaviors such as kissing other or visiting families are more prevalent among younger adults who should be considered for further actions.

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Conflict of interest statement

The authors declare no conflict of interest.

Authors' contributions

ANA conceived the study. ANA and FA did the statistical analysis, made the survey form, gathered data, and drafted the manuscript. PP, RA, MSK, and RAB contributed in data gathering. All authors revised the manuscript and performed a review of the literature. All authors have read and approved the latest version of the manuscript for publication.

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ORIGINAL ARTICLE

Assessing Iran's health system according to the COVID-19 strategic preparedness and response plan of the World Health Organization: health policy and historical implications

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Keywords

COVID-19 • Prepardness and response to pandemic • Iran • Qualitative study

Summary

Background. *The role of health systems in the management of disasters, including natural hazards like outbreaks and pandemics, is crucial and vital. Healthcare systems which are unprepared to properly deal with crises are much more likely to expose their public health workers and health personnel to harm and will not be able to deliver healthcare provisions in critical situations. This can lead to a drammatic toll of deaths, even in developed countries. The possible occurrence of global crises has prompted the World Health Organization (WHO) to devise instruments, guidelines and tools to assess the capacity of countries to deal with disasters. Iran's health system has been hit hardly by the COVID-19 pandemic. In this study, we aimed to assess its preparedness and response to the outbreak.*

Methods. *The present investigation was designed as a qualitative study. We utilized the "COVID-19 Strategic Preparedness and Response Plan" devised by WHO as a conceptual framework.*

Results. *The dimension/pillar which scored the highest was national laboratories, followed by surveillance, rapid response teams and case investigations. Risk communication and community engagement was another pillar receiving a high score, followed by infection prevention and control and by country-level coordination, planning and monitoring. The pillars/dimensions receiving the lowest scores were operational support and logistics; case management; and points of entry.*

Discussion. *The COVID-19 pandemic has represented an unprecedent event that has challenged healthcare systems and facilities worldwide, highlighting their weaknesses and the need for intersectoral cooperation and collaboration during the crisis. Analyzing these experiences and capitalizing on them, by strengthening them,will help countries to be more prepared to face possible future crises.*

Background

On December 30th 2019, the People's Republic of China reported a cluster of atypical pneumonia cases occurred in the city of Wuhan, Hubei Province. A novel coronavirus, initially termed as 2019-nCov and later named as "Severe Acute Respiratory Syndrome Coronavirus type 2" (SARS-CoV-2), was identified as the infectious agent responsible for the "coronavirus disease 2019" (COVID-19), a generally mild but occasionally severe and life-threatening infection [1, 2]. On January 13th 2020, public health officials confirmed a COVID-19 case in Thailand, the first case recorded outside mainland China [3], pointing at the global, quick spread of the virus, despite initial allegations that the human-to-human transmission potential of the coronavirus was limited.

As of January 30th 2020, the "World Health Organization" (WHO) characterized the ongoing COVID-19 outbreak as a "Public Health Emergency of International Concern" (PHEIC) and later, on March 11th 2020, as a global pandemic [4, 5]. As of April 13th, over 1,800,000 confirmed and 410,000 recovered cases have been reported, as well as over 100,000 deaths, in more than 210 countries and territories, including developed and developing settings. Data from mainland China shows that up to 15-20% of COVID-19 cases need hospitalization, with approximately 15% of them being severe and 5% requiring intensive care [6]. The spread of the virus has strained and overwhelmed the public health capacity of healthcare systems worldwide [7, 8], challenging their resilience [9, 10].

The role of health systems in the management of Emerging and reemerging infections like outbreaks and pan-

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demics, such as the "Middle East Respiratory Syndrome" (MERS) and the "Severe Acute Respiratory Syndrome" (SARS), is crucial and vital, and their resilience can be defined as "*the capacity of health actors, institutions, and populations to prepare for and effectively respond to crises; maintain core functions when a crisis hits; and, informed by lessons learned during the crisis, reorganize if conditions require it*" [11]. Healthcare systems which are unprepared to properly deal with crises are much more likely to expose their health care workers to harm [12, 13]. Furthermore, unprepared health systems will not be able to deliver healthcare provisions in critical situations, and this can lead to a drammatic toll of deaths, even in developed countries [14-16].

The possible occurrence of global crises has prompted the WHO to devise instruments, guidelines and tools to assess the capacity of countries to deal with disasters. These include the "International Health Regulations" (IHR) "Monitoring and Evaluation Framework and the Global Health Security Agenda country assessment" and its consolidated version "Joint External Evaluation" (JEE) [17, 18]. In more detail, these tools enable to measure country public health capacity to prevent, detect, and rapidly respond to risks, whether occurring naturally or due to deliberate or accidental events.

On February 19th 2020, Iran has reported its first confirmed COVID-19 case [19]. As of April 13th 2020, more than 73,000 people have been infected, 45,000 have recovered, and more than 4,500 have died [20]. Currently, 981 hospitals with more than 130,000 beds are providing health services to over 80 million people. The ongoing outbreak is responsible for 79.2% of all deaths and 74% (71.5-76.4%) of the burden of disease attributable to non communicable disorders. Iran's health system has been hit hardly by the COVID-19 pandemic. In this study, we aimed to assess its preparedness and response to the outbreak.

Methods

The present investigation was designed as a qualitative study. We utilized the "COVID-19 Strategic Preparedness and Response Plan" devised by WHO as a conceptual framework.

Conceptual framework

The "COVID-19 Strategic Preparedness and Response Plan" consists of eight dimensions/pillars to measure the capacity of countries' health systems to respond to the COVID-19 pandemic [21]. These are: 1) country-level coordination, planning, and monitoring (12 actions); 2) risk communication and community engagement (11 actions); 3) surveillance, rapid response teams, and case investigation (10 actions); 4) points of entry (5 actions); 5) national laboratories (10 actions); 6) infection prevention and control (IPC) (13 actions); 7) case management (11 actions); and, finally, 8) operational support and logistics (6 actions). Each dimension/pillar has three steps indicating the set of actions that need to be taken and implemented by the national health system.

Data collection

Data was collected through a purposeful content analysis, based on the WHO's tool and its related eight dimensions/pillars. Relevant documents, including programs, reports, guidances, action plans, official statements of country's officials, were retrieved by mining the official websites of the Ministry of Health and Medical Education (MoHME) (https://behdasht.gov.ir/step2corona), the Parliament)https://rc.majlis.ir/fa/report?keyword=&lu_type=&contact=&from_publish_date=&to_publish_date=&tag=&tag_lang=&o=&ot=d&departments= (and the Government (http://www.qavanin.ir/), Universities and hospitals.

Data analysis

After collecting the relevant documents, these were analyzed and scored independently by two researchers, based on the above-mentioned Conceptual Framework. Three possible replies for each dimension/pillar were considered: "yes", "no", and "unclear". The results of the two researchers were compared, and any disagreement was discussed, until a consensus was reached. Furthermore, a committee of 20 experts, including provincial, national, and university policy- and decision-makers was established to review and evaluate the scores assigned to each pillar/dimension. Cohen's kappa coefficient was used to assess the level of agreement. Once again, potential disagreement was resolved by discussion until a consensus was achieved.

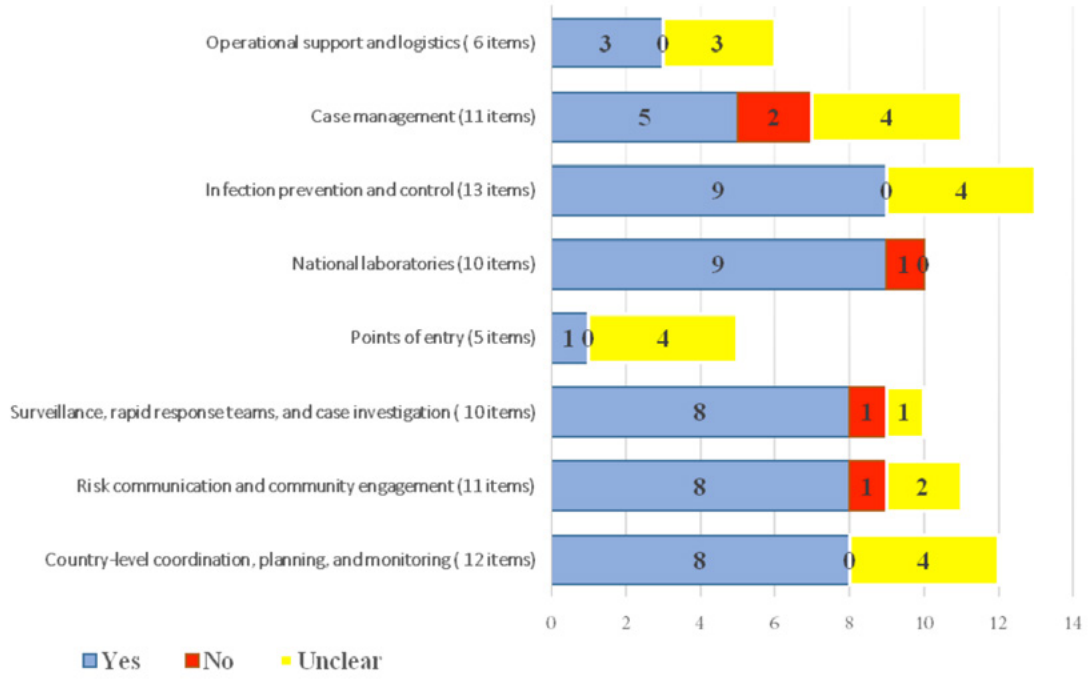
Results

The resilience, readiness and preparedness of Iran's health system to cope with the COVID-19 pandemic has been evaluated based on the WHO's "Strategic Preparedness and Response Plan" items. Scores are pictorially reported in Figure 1 and Table I. The dimension/pillar which scored the highest was national laboratories, followed by surveillance, rapid response teams and case investigations. Risk communication and community engagement was another pillar receiving a high score, followed by infection prevention and control and by country-level coordination, planning and monitoring. The pillars/dimensions receiving the lowest scores were operational support and logistics; case management; and points of entry. The evaluation of the Iran's health system according to the COVID-19 strategic preparedness and response plan of the WHO is reported in Appendix.

Discussion

The WHO has issued a checklist of operational planning documents to guide and inform in an evdence-based fashion the response and preparation of countries to the currently ongoing outbreak [22]. The purpose of this program was to provide immediate support to governments to implement measures and interventions aimed at containing and managing the pandemic [23]. Furthermore,

Fig. 1. Iranian health system preparedness score in response to COVID-19 pandemic.



the WHO has also set a series of field-visits around countries. For instance, Dr. Hamelmann, WHO's Representative for Iran, has planned visits to this country from March 2nd to March 12th 2020, to assess the extent of difficulties and challenges faced by the Iranian healthcare system and provide critical feedback on Iran's response capacity.

Based on the experiences of the previous outbreaks [24, 25], including SARS and MERS, the Iran Ministry of Health has sought to provide the best response according to the country's cultural, social and economic conditions [26]. In Iran, on March 28th 2020, the "COVID-19 Epidemiology Committee" was established [27] to investigate the epidemiological situation, reviewing documents and facts, and predict the disease trend, by simulating hypothetical scenarios under the implementation of different behavioral, non-pharmacological interventions (NPIs), including physical/social distancing, self-isolation, quarantine and even lock-down [28].

Pillar 1: National laboratories

This dimension/pillar obtained the highest score based on the evaluation of the panel of researchers and experts. Before the first official COVID-19 case in Iran (February 19th 2020), when the disease was confined within mainland China, an early diagnosis of the disease was delayed due to the unknown characteristics of the infectious agent and the lack of specific diagnostic kits. In late January, the disease caused by the virus was apparently mild, circulating in several cities, and, since the first cases were asymptomatic or had no specific symptoms, the Iranian health system could not promptly identify the virus at that time. The first identified cases were reported on February 19th 2020, when assays based on Real-Time Polymerase Chain Reaction (PCR) were available, enabling to confirm the first two deaths occurred in the Qom province as attributable to the viral outbreak [29]. Earlier, the Pasteur Institute of Iran (as the National Reference Labora-

Tab. I. Evaluation of the preparedness of Iranian health system to the COVID-19 pandemic.

Items	Yes (%)	No (%)	Unclear (%)	Kappa
Country-level coordination, planning, and monitoring	66.66	0	33.34	0.73
Risk communication and community engagement	72.72	9.1	18.18	0.68
Surveillance, rapid response teams, and case investigation	80	10	10	0.81
Points of entry	20	0	80	0.71
National laboratories	90	0	10	0.86
Infection prevention and control	69.23	0	30.77	0.68
Case management	45.45	18.19	36.36	0.79
Operational support and logistics	50	0	50	0.87
Total	65.38	6.42	28.20	0.76

tory – NRL – for COVID-19) had begun designing techniques for the molecular detection of the virus, utilizing pan-coronavirus kits instead of COVID-19 specific diagnostic assays. Furthermore, initially there were few laboratories, with the only *ad hoc* COVID-19-related facilites being based in the capital (Tehran), in Qom and Arak, areas characterized by a high prevalence rate of COVID-19. Later, the network of COVID-19 dedicated laboratories across the country was strenghtened with the establishment of 126 laboratories (40 of which belonging to the private sector), to respond more quickly and effectively to the outbreak.

The country's testing capacity has reached the figure of about 10,000 daily tests, with the ambitious goal of delivering more than 20,000 tests per day [30]. Iran's testing capacity is low compared to developed countries. Creating a global rapid response network of diagnostic kits and medical supplies manufacturers will enable the Iranian healthcare system to be equipped more quickly and adequately during future health crises.

To strengthten the technological know-how of the Iranian manufacturers, the Pasteur Institute of Iran has invited more than 50 companies to produce kits, of which five have been approved, since production kits have to be comparable to the WHO's reference kits and have to be approved by the MoHME. All services provided by the laboratory network are delivered almost free of charge (being paid by the government and insurance companies) for COVID-19 inpatients and outpatients, and sampling is done through hospital referrals from urban and rural primary healthcare (PHC) centers. Iran, along with the WHO and the Pasteur Institute's global network, is seeking to sequence the genome of the coronavirus and its local mutations, collaborating as well for good laboratory practices (GLPs). Although the embargo and economic sanctions have affected Iran's capacity to respond to health crises [31, 32], including purchasing, transferring goods/materials, and cooperating with other facilities abroad to expand laboratory capacity, the global laboratory network has rapidly improved its response and reaction to the pandemic.

Pillar 2: Surveillance, rapid response teams, and case investigation

According to the indicators of the "Sustainable Development Goals" (SDGs), Iran is the third country in the Eastern Mediterranean region (EMRO) after Bahrain and Egypt in terms of the implementation of an electronic health system, capturing, for instance, birth and death rates [33]. This electronic health system was finally fully established after the 2015 "Health Transformation Plan" (HTP), with electronic accounts being available for more than ten millions of rural and urban citizens. In Iran, more than 100,000 health service providers are using the electronic health information system in more than 30,000 centers [34]. The deployment of an electronic health system was beneficial in dealing with the new virus and the related pandemic.

In the management of infectious diseases, especially those emerging/re-emerging, it is crucial to provide up-to-date guidelines for physicians and service providers [35, 36] in order to implement adequate, evidence-based diagnostic, protective, and therapeutic protocols.

Initially, in Iran, assessing gaps in active case finding was not comprehensive, documented, and study-oriented, but mainly based on feedback and single cases. Subsequently, the guidelines issued by the WHO and the "Centers for Disease Control and Prevention" (CDC) were translated immediately after the request of the "Coronavirus National Committee" and modified and adapted according to the country's health system.

The Ministry of Health monitored adherence to the protocols of all public and private health centers. Records of patients were extracted from the health information system and reviewed, and related interventions were designed *ad hoc* as needed. Data related to clinical and demographic indicators were updated regularly, and rapid response teams were established to identify and actively trace cases. Asymptomatic cases were initially not followed-up and, in a second period, followed-up by phone. Outpatient cases without severe symptoms were tested rarely. Low testing capacity is, indeed, the major variable negatively impacting disease surveillance.

Pillar 3: Risk communication and community engagement

The "National risk-communication and community engagement plan for COVID-19" in Iran was designed based on the national flu response program, with precise strategies and tasks for each ministriy as well as with the measures to control borders and various scenarios simulations.

Regarding the general population, in addition to the basic principles of prevention such as hands washing and observing safe distances, infected areas or areas with a high probability of infection were promptly identified. Social media and networks have constantly informed and updated the at-risk population.

Specific groups, such as the elderly, people with underlying co-morbidities, especially chronic diseases, and high-risk workers, including medical staff, received special messages from the Ministry of Health and were monitored by phone.

Famous individuals (actors, religious leaders, and celebrities), Non-Governmental Organizations (NGOs), and social activists [37] provided COVID-19 related messages to the community, as well as television and radio programs broadcasted non-scientific, popular interventions to increase awareness about the infection.

Pillar 4: Infection prevention and control

Ensuring staff safety during an emergency is crucial for maintaining the capacity of a country's health system [38, 39]. With the spread of the disease to all provinces of Iran, the country's health system faced the challenge of a lack of front-line health workers. Infection prevention and control (IPC)-related capacity at all levels of the healthcare system, including public and private sectors, and pharmacies at the national and provincial levels, is constantly updated by monitoring indicators such as the number of intensive care units (ICU) beds,

human resources available, medications, and related protection items. The country was able to assess IPC-related capacity to respond to COVID-19 and make relevant decisions.

Private hospitals were prepared to accept referrals if capacity of public facilities was saturated. Safe recovery beds were provided for the patients after discharge so that the ICU/critical care units (CCU) beds would be discharged faster, and patients would not spend their recovery period in isolated places contaminating the society.

The plan for monitoring healthcare personnel exposed to confirmed COVID-19 cases was initially challenged by the shortages of protective equipment in some centers, which was resolved by increasing the production capacity of personal protective equipment (PPE). IPC guidance was provided to patients, health workers, and the general public. However, sanitizers for hand washing and personal hygiene could not be provided in high-risk and crowded places. Also, regular testing of health care providers and hospital staff could not be alaways performed in a timely manner to ensure their safety. On the other hand, mental health support was provided to the healthcare staff.

Pillar 5: Country-level coordination, planning, and monitoring

One of the challenges in the management of COVID-19 is bureaucracy and the executive barriers to cross-sectoral cooperation. The lack of multidisciplinary teams for implementing the necessary coordination to produce evidence in the field of IPC, especially in developing countries, affects the rapid and successful response to the spread of infections and emerging diseases [40, 41].

Prior to the outbreak, the Supreme Council for Health and Food Security was the center for inter-sectoral cooperation and joint activities with health-oriented activities in Iran. After the first confirmed COVID-19 case in Iran, in addition to the council chaired by the President, a special council was set up as the "National COVID-19 Command Center", which includes the country's ministers. This council has social, economic, educational, health, security, and labour support committees. Decisions in this committee, with the leading role of the Ministry of Health, are made collectively, and all public and private sectors are required to comply with them.

Various departments of the Ministry of Health, including those dealing with non-communicable and communicable disorders, maternal, neonatal and community health, were instructed by the National Headquarters and the Minister of Health to prepare and implement programs for high-risk populations, including phone tracking of more than 9 million people with chronic diseases, preparation of standards and nutritional recommendations for healthy indviduals as well as patients. Decision to escalate or lift restrictions depended on the geographical areas, their epidemiological features (hotspots, low *versus* high prevalence rates) and type (commercial, residential, or industrial).

Pillar 6: Points of entry

The world is facing new, unprecedentd challenges in controlling infectious diseases in the 21st century, since globalization, urbanization and new lifestyles make it easier for infections to quickly spread between countries [42]. In the first month of the epidemic in Iran, by examining the records of patients' travels, travel restrictons were implemented, including limiting or banning intercity trips. Active cases surveillance was established at borders. More than 70 million people have been screened electronically and by telephone, and cases have been reported to the WHO. Funeral protocols for deaths from COVID-19 or other causes were planned in advance to avoid gatherings.

At the beginning of the spread of the disease, 212,000 people from Iranian airports (Tehran, Rasht, and Arak) traveled to international destinations; also, several thousand people from other countries entered Iran [43]. This contributed to the diffusion of the virus. Adopting and implementing stricter rules regarding the control of points of entry, especially hotspots or epicenters, was therefore crucial.

Pillar 7: Case management

In the field of case management of infectious diseases, ensuring high standard of care and therapeutic interventions to reduce the prevalence and mortality rates is of paramount importance [44]. Currently, the only way to deal with COVID-19 is through support, and prevention to reduce transmission in society [45]. Recommendations for mild cases have been communicated by social media and educational materials have been prepared in collaboration with the WHO and divulged through medical universities. Motorcycle ambulances were very helpful in investigating the initial cases in large cities. They were sent to transport the persons in need, and at the same time, the person's family received basic training and information about the disease. According to the principles of the WHO, nutritional and activity principles for patients were prepared by the Nutrition Improvement Office of the Ministry of Health and were implemented in all medical centers.

Pillar 8: Operational support and logistics

While developed countries have adequate funds to support and respond to COVID-19 rather than developing ones, Iran has also suffered due to sanctions and reductions in oil price. However, the Supreme Council for Health and Food security implemented some necessary policies to support vulnerable groups including delayed bills such as electricity and bank loan repayments, despite financial constraints [46].

As the number of patients increased, the Minister of Health asked to speed up mask production, and in a letter asked the President for a credit of 250 million Euros [47]. All religious and non-religious ceremonies, celebrations and gatherings, entertainment and sports centers were closed. Schools and universities were also closed. Efforts were made to provide online courses. Hotels and accommodation centers almost did not accept anymore guests [42]. The military force contributed to support the fight against COVID-19, by cleaning up public areas from possible sources of the virus and creating urgent hospital beds.

Sixty-seven Iranian Universites of Medical Sciences, thousands of general practitioners, clinical specialists, nurses, and basic medical scientists contributed to the support. Using the capacity of donors was very helpful, especially at the beginning of the epidemic. Also, NGOs mobilized people's capacity.

Recommendations

Countries should find a balance between disease-related and economic policies, in order to mnimize financial losses and protect vulnerable groups by providing subsidized protective items (such as masks and disinfectants). Control of internal borders and restriction of travels across inter-provincial borders as well as of international travels have played a crucial role in controlling the spread of the disease.
The involvement of all relevant stakeholders and the technical support of international organizations, including the WHO, have given Iran the opportunity to take appropriate actions.

Limitations

The present study is a pilot study, devised as a qualitative investigation. More quantitative information should be collected.

Conclusion

The COVID-19 pandemic has represented an unprecedent event that has challenged healthcare systems and facilities worldwide, highlighting their weaknesses and the need for inter-sectoral cooperation and collaboration during the crisis. Analyzing these experiences and capitalizing on them, by strengthening them, will help countries to be more prepared to face possible future crises. Studies such as those based on the WHO framework can identify weaknesses and help researchers and policy-makers investigate and address them. By determining the current crisis situation, health systems can increase their capacity for similar crises in the future.

Ethical approval

Ethical approval was not required for this work as no new empirical data were collected.

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Conflict of interest statement

The authors declare no conflict of interest.

Authors' contributions

MKG, MaB, AB, MeB and NLB were the principal investigators who contributed to the conception and design of the study, collected, entered, analyzed, interpreted the data, prepared the manuscript. AB acted as a corresponding author. SA, HAG, SS and MM contributed to data analysis, interpretation and drafted the manuscript. All authors read and approved the final manuscript.

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Appendix

The Iran's health system according to the COVID-19 strategic preparedness and response plan of the WHO.

Tab. A. Country-level coordination, planning, and monitoring.

	Yes	No	Unclear
Activate multi-sectoral, multi-partner coordination mechanisms to support preparedness and response	X		
Engage with national authorities and key partners to develop a country-specific operational plan with estimated resource requirements for COVID-19 preparedness and response, or preferably adapt, where available, an existing Influenza pandemic preparedness plan			X
Conduct initial capacity assessment and risk analysis, including mapping of vulnerable populations	X		
Begin establishing metrics and monitoring and evaluation systems to assess the effectiveness and impact of planned measures			X
Establish an incident management team, including rapid deployment of designated staff from national and partner organizations, within a public health emergency operation centre (PHEOC) or equivalent if available	X		
Identify, train, and designate spokespeople	X		
Engage with local donors and existing programmes to mobilize/allocate resources and capacities to implement operational plan	X		
Review regulatory requirements and legal basis of all potential public health measures	X		
Monitor implementation of CPRP based on key performance indicators in SPRP and produce regular situation report			X
Conduct regular operational reviews to assess implementation success and epidemiological situation, and adjust operational plans as necessary	X		
Conduct after action reviews in accordance with IHR (2005) as required	X		
Use COVID-19 outbreak to test/learn from existing plans, systems and lesson-learning exercises to inform future preparedness and response activities			X

Tab. B. Risk communication and community engagement.

	Yes	No	Unclear
Implement national risk-communication and community engagement plan for COVID-19, including details of anticipated public health measures (use the existing procedures for pandemic influenza if available)	X		
Conduct rapid behaviour assessment to understand key target audience, perceptions, concerns, influencers and preferred communication channels	X		
Prepare local messages and pre-test through a participatory process, specifically targeting key stakeholders and at-risk groups	X		
Identify trusted community groups (local influencers such as community leaders, religious leaders, health workers, community volunteers) and local networks (women's groups, youth groups, business groups, traditional healers, etc.)	X		
Establish and utilize clearance processes for timely dissemination of messages and materials in local languages and adopt relevant communication channels			X
Engage with existing public health and community-based networks, media, local NGOs, schools, local governments and other sectors such as healthcare service providers, education sector, business, travel and food/agriculture sectors using a consistent mechanism of communication	X		
Utilize two-way "channels" for community and public information sharing such as hotlines (text and talk), responsive social media such as U-Report where available, and radio shows, with systems to detect and rapidly respond to and counter misinformation	X		
Establish large scale community engagement for social and behaviour change approaches to ensure preventive community and individual health and hygiene practices in line with the national public health containment recommendations	X		
Systematically establish community information and feedback mechanisms including through: social media monitoring; community perceptions, knowledge, attitude and practice surveys; and direct dialogues and consultations		X	
Ensure changes to community engagement approaches are based on evidence and needs, and ensure all engagement is culturally appropriate and empathetic	X		
Document lessons learned to inform future preparedness and response activities			X

Tab. C. Surveillance, rapid response teams, and case investigation.

	Yes	No	Unclear
Disseminate case definition in line with WHO guidance and investigation protocols to healthcare workers (public and private sectors)	X		
Activate active case finding and event-based surveillance for influenza-like illness (ILI), and severe acute respiratory infection (SARI)	X		
Assess gaps in active case finding and event-based surveillance systems		X	
Enhance existing surveillance systems to enable monitoring of COVID-19 transmission and adapt tools and protocols for contact tracing and monitoring to COVID-19	X		
Undertake case-based reporting to WHO within 24 hours under IHR (2005)	X		
Actively monitor and report disease trends, impacts, population perspective to global laboratory/ epidemiology systems including anonymized clinical data, case fatality ratio, high-risk groups (pregnant women, immunocompromised) and children	X		
Train and equip rapid-response teams to investigate cases and clusters early in the outbreak, and conduct contact tracing within 24 hours	X		
Provide robust and timely epidemiological and social science data analysis to continuously inform risk assessment and support operational decision making for the response	X		
Test the existing system and plan through actual experience and/or table-top or simulation exercises, and document findings to inform future preparedness and response activities			X
Produce weekly epidemiological and social science reports and disseminate to all levels and international partners	X		

Tab. D. Points of entry.

	Yes	No	Unclear
Develop and implement a points of entry public health emergency plan			X
Disseminate latest disease information, standard operating procedures, equip and train staff in appropriate actions to manage ill passenger(s)			X
Prepare rapid health assessment/isolation facilities to manage ill passenger(s) and to safely transport them to designated health facilities			X
Communicate information about COVID-19 to travellers	X		
Regularly monitor and evaluate the effectiveness of readiness and response measures at points of entry, and adjust readiness and response plans as appropriate			X

Tab. E. National laboratories.

	Yes	No	Unclear
Establish access to a designated international COVID-19 reference laboratory	X		
Adopt and disseminate standard operating procedures (as part of disease outbreak investigation protocols) for specimen collection, management, and transportation for COVID-19 diagnostic testing	X		
Identify hazards and perform a biosafety risk assessment at participating laboratories; use appropriate biosafety measures to mitigate risks	X		
Adopt standardized systems for molecular testing, supported by assured access to reagents and kits	X		
Ensure specimen collection, management, and referral network and procedures are functional	X		
Share genetic sequence data and virus materials according to established protocols for COVID-19		X	
Develop and implement plans to link laboratory data with key epidemiological data for timely data analysis	X		
Develop and implement surge plans to manage increased demand for testing; consider conservation of lab resources in anticipation of potential widespread COVID-19 transmission	X		
Monitor and evaluate diagnostics, data quality and staff performance, and incorporate findings into strategic review of national laboratory plan and share lessons learned	X		
Develop a quality assurance mechanism for point-of-care testing, including quality indicators	X		

Tab. F. Infection prevention and control.

	Yes	No	Unclear
Assess IPC capacity at all levels of healthcare system, including public, private, traditional practices and pharmacies. Minimum requirements include functional triage system and isolation rooms, trained staff (for early detection and standard principles for IPC); and sufficient IPC materials, including personal protective equipment (PPE) and WASH services/hand hygiene stations	X		
Assess IPC capacity in public places and community spaces where risk of communtiy transmission is considered high			X
Review and update existing national IPC guidance: health guidance should include defined patient-referral pathway including an IPC focal point, in collaboration with case management. Community guidance should include specific recommendations on IPC measures and referral systems for public places such as schools, markets and public transport as well as community, household, and family practices	X		
Develop and implement a plan for monitoring of healthcare personnel exposed to confirmed cases of COVID-19 for respiratory illness	X		
Develop a national plan to manage PPE supply (stockpile, distribution) and to identify IPC surge capacity (numbers and competence)	X		
Engage trained staff with authority and technical expertise to implement IPC activities, prioritizing based on risk assessment and local care-seeking patterns	X		
Record, report, and investigate all cases of healthcare-associated infections	X		
Disseminate IPC guidance for home and community care providers	X		
Implement triage, early detection, and infectious-source controls, administrative controls and engineering controls; implement visual alerts (educational material in appropriate language) for family members and patients to inform triage personnel of respiratory symptoms and to practice respiratory etiquette	X		
Support access to water and sanitation for health (WASH) services in public places and community spaces most at risk			X
Monitor IPC and WASH implementation in selected healthcare facilities and public spaces using the Infection Prevention and Control Assessment Framework, the Hand Hygiene Self-Assessment Framework, hand hygiene compliance observation tools, and the WASH Facilities Improvement Tool			X
Provide prioritized tailored support to health facilities based on IPC risk assessment and local care-seeking patterns, including for supplies, human resources, training	X		
Carry out training to address any skills and performance deficits			X

Tab. G. Case management.

	Yes	No	Unclear
Map vulnerable populations and public and private health facilities (including traditional healers, pharmacies and other providers) and identify alternative facilities that may be used to provide treatment		X	
Identify Intensive Care Unit capacity	X		
Continuously assess burden on local health system, and capacity to safely deliver primary healthcare services		X	
Ensure that guidance is made available for the self-care of patients with mild COVID-19 symptoms, including guidance on when referral to healthcare facilities is recommended			X
Disseminate regularly updated information, train, and refresh medical/ambulatory teams in the management of severe acute respiratory infections and COVID-19-specific protocols based on international standards and WHO clinical guidance; set up triage and screening areas at all healthcare facilities	X		
Establish dedicated and equipped teams and ambulances to transport suspected and confirmed cases, and referral mechanisms for severe cases with co morbidity	X		
Ensure comprehensive medical, nutritional, and psycho-social care for those with COVID-19	X		
Participate in clinical expert network to aid in the clinical characterization of COVID-19 infection, address challenges in clinical care, and foster global collaboration (optional based on country capacity)	X		
Prepare to assess diagnostics, therapeutics, and vaccines for compassionate use, clinical trials, regulatory approval, market authorization, and/or post-market surveillance, as appropriate			X
Adopt international R&D blueprint guidance and WHO protocols for special studies (companionate use, Monitored Emergency Use of Unregistered and Investigational Interventions) to investigate additional epidemiological, virologic, and clinical characteristics; designate a clinical trial or study sponsor			X
Evaluate implementation and effectiveness of case management procedures and protocols (including for pregnant women, children, immunocompromised), and adjust guidance and/or address implementation gaps as necessary			X

Tab. H. Operational support and logistics.

	Yes	No	Unclear
Map available resources and supply systems in health and other sectors; conduct in-country inventory review of supplies based on WHO's a) Disease Commodity Package (DCP) and b) COVID-19 patient kit, and develop a central stock reserve for COVID-19 case management			X
Review supply chain control and management system (stockpiling, storage, security, transportation and distribution arrangements) for medical and other essential supplies, including COVID-19 DCP and patient kit reserve in-country	X		
Review procurement processes (including importation and customs) for medical and other essential supplies, and encourage local sourcing to ensure sustainbility	X		
Assess the capacity of local market to meet increased demand for medical and other essential supplies, and coordinate international request of supplies through regional and global procurement mechanisms	X		
Prepare staff surge capacity and deployment mechanisms; health advisories (guidelines and SOPs); pre- and post-deployment package (briefings, recommended/mandatory vaccinations, enhanced medical travel kits, psychosocial and psychological support, including peer support groups) to ensure staff well-being			X

Overview

Universal Health Coverage to counteract the economic impact of the COVID-19 infection: current practices and ethical challenges

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Keywords

COVID-19 • Economic crisis • Health crisis • Health policy • Health financing • Universal health coverage • Ethical issues

Summary

In late December 2019, the first case of an emerging coronavirus was identified in the city of Wuhan, Hubei province, in mainland China. The novel virus appears to be highly contagious and is rapidly spreading worldwide, becoming a pandemic. The disease is causing a high toll of deaths. Effective public health responses to a new infectious disease are expected to mitigate and counteract its negative impact on the population. However, time and economic-financial constraints, as well as uncertainty, can jeopardize the answer. The aim of the present paper was to discuss the role of Universal Health Coverage to counteract the economic impact of the COVID-19 infection. Appropriate financing of the health system and ensuring equitable access to health services for all can, indeed, protect individuals against high medical costs, which is one of the most important goals of any health system. Financing profoundly affects the performance of the health system, and any policy that the health system decides to implement or not directly depends on the amount of available funding. Developed countries are injecting new funding to cope with the disease and prevent its further transmission. In addition to psychological support and increased societal engagement for the prevention, control, and treatment of COVID-19, extensive financial support to governments by the community should be considered. Developed and rich countries should support countries that do not have enough financial resources. This disease cannot be controlled and contained without international cooperation. The experience of the COVID-19 should be a lesson for further establishing and achieving universal health coverage in all countries. In addition to promoting equity in health, appropriate infrastructure should be strengthened to address these crises. Governments should make a stronger political commitment to fully implement this crucial set of policies and plans.

Healthcare systems and Universal Health Coverage

Healthcare systems around the world are striving to respond to the expectations and needs of their citizens by implementing different policies and programs and ensuring that they are continually enhancing and improving community health [1].

However, unexpected challenges could arise due to environmental issues, increased urbanization, globalization and aging. All these factors can, indeed, accelerate the transmission of communicable diseases worldwide, leading to viral outbreaks [2]. Due to the pace of change in the world, health systems need to implement adequate reforms and preparedness plans. In addition to crises such as emerging diseases, due to political and economic crises, health systems have faced many problems in financing and providing appropriate healthcare services to society [3]. In many cases, the response of health systems to these crises is inadequate even with anticipatory plans, potentially because of the overwhelmed and strained public health capacity, and the high costs incurred [4]. Little funding and scarcity of resources, lack of human resources and equipment, inadequate government support, poor information systems infrastructure, and insurance problems are among the factors that can impact the adequacy of health systems' response [1, 5].

Health systems should be resilient and continue providing basic care, even during the most challenging circumstances, including public health emergencies. Empowering healthcare settings' capacity following the International Health Regulations (IHR 2005) is an essential element of the universal health coverage (UHC) program. Health emergency preparedness, as a critical element of UHC, can help prevent and adequately respond to disasters, minimizing their health and economic impact [6].

UHC is one of the Sustainable Development Goals (SDGs) [7, 8] in that it ensures that all community members have access to preventive, therapeutic, rehabilitation, and supportive healthcare in an effective and appropriate fashion. These high-quality health provisions are tailored to their needs [9].

Efforts to expand UHC represent fundamental health policy reforms as they enable to achieve valuable suc-

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cess by the implementation of various programs [10]. Many countries have taken steps to achieve UHC, including Thailand [11], and Turkey [12] in order to protect their population against health costs by providing appropriate services [13].

Dr Tedros Adhanom Ghebreyesus, Director-General of the World Health Organization (WHO), has recently stated that "*universal health coverage is ultimately a political choice. It is the responsibility of every country and national government to pursue it*." Strengthening health systems is the best way to protect against health crises, and achieving UHC is the best strategy to make health systems resilient [14].

The aim of the present paper was to discuss the role of UHC to counteract the economic impact of the currently ongoing pandemic.

The COVID-19 outbreak

In late December 2019, the first case of an emerging coronavirus ("Severe Acute Respiratory Syndrome Coronavirus type 2" or SARS-CoV-2) was identified. The novel virus appears to be highly contagious and is rapidly spreading worldwide, becoming a pandemic. The disease is causing a high toll of deaths [15, 16].

In 2009, when an outbreak caused by a novel strain of influenza A virus, H1N1, occurred, the WHO reported that H1N1 spread to 214 countries, affecting about 1.5 million people and killing 25,000 people [17]. The pandemic caused by the COVID-19 has a higher speed, incidence and mortality rates compared to H1N1, and the trend seems to be increasing [18].

Given that behavioral, non-pharmacological interventions (NPIs), such as social distancing, self-isolation, quarantine and lock-down of entire communities and territories, are an effective way to prevent and control this disease interrupting the transmission chain and considering that, in the absence of specific therapeutics or vaccines, people will be unable to be engaged in social activities for a long time, it seems that COVID-19 can cause many health and economic problems [19]. Health systems in every country should respond effectively to this infectious disease reducing its impact on the general population, since inappropriate responses to this crisis can have a profound effect on the countries [20, 21].

UHC-related service coverage index (SCI) improved from 2000 to 2017, but the pace of progress has slowed since 2010, and the coverage needs to double at least to reach the SDG target of UHC by 2030. Policy priorities for country groups can vary depending on the situation of each country, ranging from building the foundations of health systems (for countries with low service coverage and relevant financial hardship) to continue providing efficient, high-quality healthcare services (for high and upper-middle-income countries) [22]. Therefore, health system's appropriate responses to a crisis depend on the readiness and preparedness of that country based on UHC-related achievement indicators.

Effective public health responses to a new infectious disease are expected to mitigate and counteract its negative impact on the population. However, time and economic-financial constraints, as well as uncertainty, can jeopardize the answer [23].

Previous experience with emerging pathogens, such as the virus of the "Severe acute respiratory syndrome" (SARS) and H1N1 have shown that countries' health systems must respond to different aspects of the disease [17]. In all countries, health policy- and decision-makers are working to identify the virus in infected people and to prevent further infections and transmission of the disease to other individuals. In addition to health promotion activities such as public health education, monitoring people's movement, reducing people's social interactions and contacts, identification of people with the COVID-19 infection is important [24]. The high cost of diagnosis is one of the main concerns of implementing this policy. Many people refuse to go to health centers and receive services because of the high costs they can incur, and are concerned that they will not be able to pay for them if their testing is positive and the hospitalization and treatment process begins [25].

Appropriate financing of the health system and ensuring equitable access to health services for all can protect individuals against high medical costs, which is one of the most important goals of any health system. Financing profoundly affects the performance of the health system, and any policy that the health system decides to implement or not directly depends on the amount of available funding [26, 27].

The high cost of diagnosis and treatment of the COVID-19 infection makes it impossible for most the vulnerable individuals to access healthcare services [16]. It seems that due to the problems that COVID-19 has caused to the economies of countries, including the shutdown of many economic activities and making many people staying home instead of going to work, attention to the economic issues of families should be taken seriously by governments [28]. During crises, governments are under heavy economic pressure to maintain essential services, especially those provided in the health sector, and people expect governments to pay more attention to health issues [29].

Access to health services for all means achieving equity in health. The COVID-19 infection requires a range of services and equipment that must be provided by governments to ensure that no financial problems arise [30]. People's healthcare processes associated with the COVID-19 infection can include: visits by physicians and health centers, diagnostic tests (kits, Computed Tomography scans), with, in case of positive test and symptoms, hospitalization and related treatment costs (medications) [31].

Each of these services costs a lot to individuals, especially in developing countries. If people are recovering and are discharged from hospitals to their homes, people should spend their time at home recovering, and home care will also be expensive [3]. Also, due to illness, people are forced to stop doing work-related activities.

Failure to do business, fear of unemployment and job loss are also other major concerns. People need to have hygienic detergents (antiseptics) and masks to prevent the disease [32].

Lack of access for all to COVID-19 services can cause health inequality. All governments should do their best to avoid this, despite the economic problems and lack of funding [33]. Especially in relation to COVID-19, hospital services are very important. The need to deal with this crisis requires the implementation of a wide range of policies and programs that respond to the needs of all who may be infected [34].

Regarding the costs of diagnosis and treatment, governments can make them free of charge by allocating and releasing new funds. Of course, this is a tough program and it will face resistance, but it is valuable in the face of the benefits it will have. Introducing essential subsidies for people's living expenses, giving public subsidies to health-related industries, providing social security policies for sick, disabled and unemployed people can alleviate their worries about dealing with their illness. In particular, in the present crisis, poor subjects should be given much attention [16, 23].

The role of UHC can be more relevant when crises such as the COVID-19 infection occur. Proper implementation of this policy, while ensuring equity in health, can ensure the use of services among all people. Even though governments may not cover all the costs of health provisions, UHC would help reduce the costs [13, 35, 36].

In the post-coronavirus period, we will need to update UHC standards with criteria such as global health security, information transparency, and new related ethical principles [35], which represent future ethical challenges that need to be addressed. Information transparency and cooperation between countries will accelerate the control and management of outbreaks, especially if caused by emerging and unknown pathogens, by sharing data in real-time. Big data analytics is expected to play a major role in this regard [37].

Governments can also greatly help reduce costs by alleviating the worries of many individuals with different insurance conditions. One of the important plans in this crisis is to waive COVID-19 related costs. Insurance can implement emergency programs that give their users discounts or incentive programs to encourage people in good economic conditions to help poor subjects [13, 36]. Due to the uncertainty of the diagnostic or therapeutic processes related to COVID-19, insurers can change the service packages they covered before the disease and implement some degrees of flexibility with respect to the disease [38].

In some countries, health infrastructure is not sufficiently developed. These countries are facing great issues with COVID-19, with a large number of people refusing to go to health centers because of financial inability. Failure to follow patients will lead to further transmission of the disease to other people in the community. Without evaluating and treating these people, it is very difficult to deal with the COVID-19 infection [39].

Strengthening the health financing response to COVID-19 can be done by:

- reducing out-of-pocket payments, which represent a major barrier to access to treatment and preventive services, expanding health services with public funding [40];
- using a variety of financial resources, including donations, national reserve funds, and prioritizing budget [41];
- accelerating the transfer of financial resources to providers so that there is no interruption in the delivery of services and speeding up the supply of goods and equipment needed [40];
- improving payment methods in coordination with insurance organizations [42];
- finding new ways to cover healthcare provisions during crisis, including post-treatment care [42];
- ensuring government commitment to pay public and private providers for COVID-19 related services to disadvantaged people [41, 42];
- enforcing juridical provisions as adequate response to crisis [41]; and,
- guaranteeing tax discounts and waivers to providers [41].

Since increasing individual funding is not enough to achieve UHC, countries should use various financial resources to attain UHC. Indicators of the achievement of these goals could be:

- the population proportion that has access to essential high-quality health services; and,
- the population proportion that spends a large amount of its household income on health.

Ensuring the establishment of critical elements of UHC is a way to strengthen healthcare systems in terms of resources availability, constraints, accessibility, and capacity. There are several lessons that can be learnt from the COVID-19. Several ethical principles related to healthcare need to be properly addressed in order to ensure people's access to health services, since health is a human right. Both at the individual and collective level, UHC is the best way to protect people from unexpected crises and to guarantee this human right by optimizing resource allocation, especially in settings characterized by economic-financial constraints [43].

Due to the lack of resources, various health-related ethical principles during the pandemic have been faced, challenging the healthcare providers, especially when they had to choose between treating an old, frail subject or managing a young patient. Other ethical issues concerned financing schemes for the implementation of prevention and treatment interventions by governments, as well as the testing procedures of candidate vaccines among volunteers [44].

Achieving UHC means to have a more responsive healthcare system, able to meet the needs of the population. Therefore, countries with better UHC indicators and standards will face fewer moral and ethical challenges in delivering healthcare services and provisions [9].

Conclusion

Funding mechanisms and processes vary across countries. Health policy- and decision-makers should work together with governments to develop appropriate policies to ensure good decision making. The economy of countries will be affected by the COVID-19. Undoubtedly, in developing countries no additional economic resources can be used during this crisis. Developed countries are trying to face the pandemic by injecting new funding to cope with the disease and prevent its further transmission. In addition to psychological support and increased societal engagement for the prevention, control and treatment of COVID-19, extensive financial support to governments by the community should be considered, especially in developing settings. Developed and rich countries should support those countries that do not have enough financial resources. This disease cannot be, indeed, controlled and contained without international cooperation and collaborations among stakeholders. The experience of the COVID-19 should be a lesson for further developing and establishing UHC in all countries. In addition to promoting equity in health, appropriate infrastructure should be strengthened in order to address future crises. Governments should make a stronger political commitment to fully implement this crucial set of policies and reforms.

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Conflict of interest statement

The authors declare no conflict of interest.

Authors' contributions

MB, NLB designed the study. MB, MHI-N conceived the study; MB, NLB and MM drafted the manuscript; MB, MKG, MM, AB revised the manuscript. MB, NLB, MM, AB, MHI-N and MKG performed a search of the literature. All authors critically revised the manuscript. All authors have read and approved the latest version of the paper for publication.

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Review

Prevalence of insomnia among university students in South Asian Region: a systematic review of studies

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Keywords

Insomnia • Prevalence • University students • Systematic review • South Asia

Summary

Introduction. *Insomnia is a global health problem among university students which is associated with various psychiatric problems like depression and anxiety. While different developed and developing countries assessed the prevalence of insomnia in youth, currently there is hardly systematic review of studies found based on the prevalence of insomnia in South Asia.*
Aims. *The aim of this study is to systematically review the evidence relating to the prevalence rate of insomnia in university students in South Asian countries.*
Methods. *Electronic searches of three databases, PubMed, Cochrane library, and Worldwide science were performed from 2010 to 2020 before April. In total, seven studies were included for evaluating insomnia in South Asian region among university students.*
Results. *The prevalence rates of insomnia of the seven studies ranged between 35.4% (95% CI: 32.4-38.5%) and 70% (95% CI: 65.7-74.1%). The pooled prevalence of insomnia among university students was 52.1% (95% CI: 41.1-63.1%).*
Conclusions. *This review emphasized that insomnia in university students might be a common health issue to give full concentration in their studies and academic performance. Thus, more attention should be given to the determinants of insomnia among university students, so that it could be helpful to identify the main causes of insomnia and effective measures could be taken.*

Introduction

Insomnia is a disease condition when an individual finds difficulty in sleeping or remaining asleep [1] and it is associated with various psychiatric conditions like depression, anxiety, etc. [2-4]. Many recent studies have found that insomnia is a common psychiatric problem among young adults and university students [5, 6]. Other studies found that the prevalence rate of the poor sleeping condition is high among undergraduate students in the world [7]. Sleep quality and quantity among young adults especially university students has been changed due to the rapid development of technology such as using social media, the internet, etc. [8, 9] and there is a positive relationship between insomnia and the use of social media through the internet [10]. It is believed that poor sleep quality has an effect on physical and mental health and also causes mental problems such as anxiety and depression [11, 12]. Another study found that the effects of sleep disturbance have secondary behavioral consequences such as impaired social relationships, increased risk-taking behavior, and road accidents, etc. [13]. Sleep restriction among healthy young adults has been suffered from deleterious effects on endocrine functions, metabolic and inflammatory responses [14]. Many studies have shown that sleep is associated and affected by increasing years in university education [15, 16]. As university students represent the future of the society, the cost of sleep disturbance is high [17, 18].
Although the prevalence rate of insomnia increases day by day among adolescents, adults and university students, university students have received a little attention than others [5, 19, 20]. In a study which has found that 30% of the adult population from different countries have had symptoms of insomnia [21]. Other studies reported that the incidence of sleeping problem among university students was 14.9 to 70.3% [22, 23]. The variations of the prevalence of sleep problems appear to be affected by many factors such as geographical location, methods of assessment etc. [6, 24]. The evaluation method of insomnia varied from studies to studies. Some studies showed a low prevalence of insomnia using Diagnostic and Statistical Manual of Mental Disorders (DSM-IV) or international classification of sleep disorder [6], some studies showed a high prevalence of insomnia without using any restrictive and standardize criteria [24, 25] and some studies evaluate the rate of insomnia using quantitative scales only [5, 26]. The present systematic review was aimed at to evaluate and explore high-quality studies and identify the prevalence of insomnia among university students in the South Asian Region from 2010 to 2020.

Methods

The reporting of this review follows the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement.

Search strategy

The following electronic databases were searched: PubMed, Cochrane library and Worldwide science to identify peer reviewed articles, published between January 2010 and April 2020, reporting sleeping quality among university students. We used combinations of medical subject headings (MeSH) and free text words. Searches used the keywords ("insomnia" or "sleep quality" or "sleep disturbance" or "sleep disorder") AND ("prevalence" or "cross-sectional study") AND ("university student" or "undergraduate" or "young adult" or "medical student") AND ("Afghanistan" or "Bangladesh" or "Bhutan" or "Nepal" or "India" or "Maldives" or "Sri Lanka" or "Pakistan"). Searches were limited to articles published in English.

Selection process

Two researchers have screened the titles and abstracts and then full texts were retrieved for selected records. Finally, a quality assessment was performed during data extraction by another researcher.

Data extraction

Articles were considered for inclusion if the study was cross-sectional study; studies included students in medical college or university; studies included an aim to provide the prevalence of sleeping quality, studies measured the sleeping quality with some quantitative and validated scales, studies carried out in South Asian region (Bangladesh, India, Afghanistan, Bhutan, Nepal, Pakistan, Sri Lanka and Maldives). The exclusion criteria were: a) failure to provide the separate prevalence of sleeping quality; b) studies didn't include response rate; c) other epidemiological studies such as clinical trials. Demographic data, response rate, sample size, diagnostic scales used and prevalence data on student's sleeping quality were abstracted.

Quality assessment

The quality assessment instruction used in our study which was adopted from the article Ibrahim et al. [27]. The instruction included: 1) defined the population of study clearly; 2) selected the population randomly; 3) represented university students; 4) response rate ≥ 70%; 5) used validated scales for measuring sleeping quality; 6) sample size ≥ 300; 7) reported standard deviation (SD) or confidence interval (CI).

Statistical analysis

Heterogeneity by reporting the I^2 (% residual variation due to heterogeneity) and τ^2 (method of moments estimates of between-study variance) of the pooled estimate were assessed. A random effects model was used to pool the prevalence of insomnia as higher heterogeneity was expected. The 95% CI had been reported in a pooled analysis. All analysis was done by using MetaXL software version 5.3 in the Excel sheet.

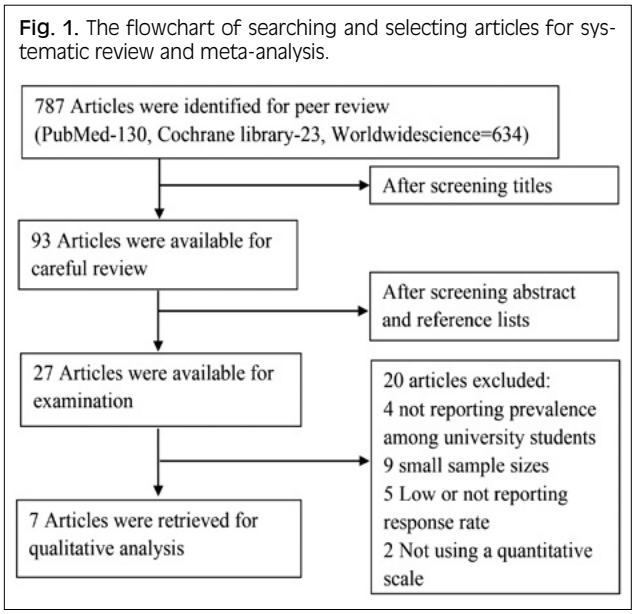


Fig. 1. The flowchart of searching and selecting articles for systematic review and meta-analysis.

Results

In this review, 787 peer reviewed articles were identified and after examining the titles, abstracts, and reference lists, 27 articles were retrieved. After careful reading and quality assessment, seven articles [28-34] were included in this study. Twenty articles were excluded as they didn't maintain the criteria we followed (Fig. 1).

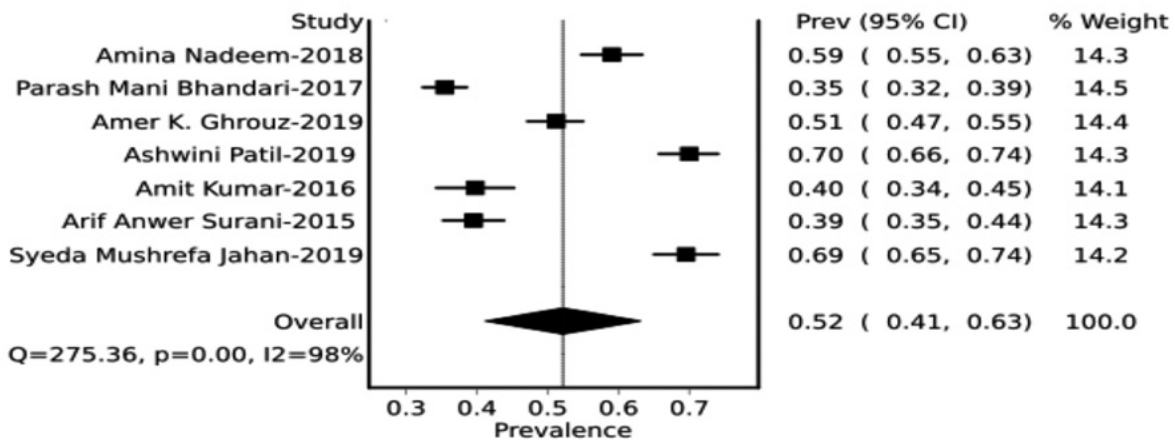
Table I represents the demographic and methodological information of the selected studies from 2010 to 2020 before April. The overall sample size in the current review was 3,739 with a minimum of 308 and a maximum of 937. The mean age was ranged from 19 to 24 years. The percentage of males in the studies ranged from 37.1 to 57.14%. Three out of the seven studies were carried out in India, two in Pakistan and one in Nepal and Bangladesh. Among the seven studies, five studies used a simple random sampling method and two used a convenience sampling method. Moreover, all studies were cross-sectional studies.

Figure 2 shows the forest plots of insomnia among university students. The prevalence rates of insomnia of the seven studies ranged between 35.4% (95% CI: 32.4-38.5%) and 70% (95% CI: 65.7-74.1%). The pooled prevalence of insomnia among university students was 52.1% (95% CI: 41.1-63.1%).

Discussion

In the 27 studies examined, some studies failed to report the prevalence of insomnia, some didn't use proper measurement scales, and some did not show a response rate. A higher prevalence of insomnia (52.1%, 95% CI: 41.1-63.1%) was observed in this review than normal people of similar age (7.4%, 95% CI: 5.8-9.0%) [6]. Some studies outside of South Asia, reported that the prevalence of insomnia was 51.8% in Chile [35] and 58.7% in Lebanon [36] which was similar and higher than our find-

Fig. 2. Forest plots about Insomnia studies among university students.



ings respectively. Another study in Pakistan found that the poor sleeping quality among medical students was 77% and among them, 7.6% reported self-medication as a cause of insomnia [37]. Some developed countries showed a low prevalence of insomnia among university students than our findings in this review. In the USA, the prevalence of insomnia was 12% and among them 8% were males and 14% were females [38]. In China, the rate of insomnia prevalence was 18.80% [39] and in Japan, it was 25.6% [40].

Some factors were related to the high prevalence of insomnia among university students reported in many studies and these contributing factors were stress for concerning their future and employment, late night work on the computer, social interactions with friends, environmental noise, etc. [41-45]. A study in Nepal found that 31.5% of medical students suffered from sleep deprivation due to late night internet use [46]. Among the seven selected studies, one study reported that females had a higher prevalence of insomnia compared with males which was similar to many previous studies [47-50]. Good sleep quality reported by participants is a good sign, as according to WHO good health and well-being could be maintained by good sleep hygiene [51].

Pittsburgh Sleep Quality Index (PSQI) is a widely used instrument for assessing sleep quality and it measures sleep quality along with seven components [52]. In our review, all the studies have used PSQI for measuring the prevalence of insomnia among university students. However, different types of scales can be used to measure the prevalence of insomnia and many differences are observed in the prevalence of insomnia when using different scales. So, more well-designed studies are required for the evaluation of insomnia prevalence among university students.

This review has several strengths and limitations. As

Tab. I. The information on the demographic and methodologies of selected studies from 2010 to 2020.

Research	Amina et al.	Parash et al.	Amer et al.	Ashwini et al.	Amit et al.	Arif et al.	Syeda et al.
Year	2018	2017	2019	2019	2016	2015	2019
Country	Pakistan	Nepal	India	India	India	Pakistan	Bangladesh
Sample	1AB	1A	1A	1B	1B	2B	2A
Insomnia scale	PSQI	PSQI	PSQI	PSQI	PSQI	PQSI, ESS	PQSI
Cut-off	> 5	> 5	> 5	> 5	> 5	> 5, > 10	> 5
Sample size	520	937	617	463	308	504	390
Response rate	85.8%	92%	95.07%	92.6%	96.25%	77.5%	75%
Sex male (%)	37.1	45.4	51	38.2	57.14	40.5	40.3
Mean age(± ± ± SD)	20.25 (1.5)	21.01 (2.18)	23.4 (3.6)	19.55 (1.04)	21.4 (1.85)	20 (1.4)	NR
Total Prevalence(%)	59.04	35.4	51	70	39.6	39.5	69.5
Covariates measured	Sleep quality was higher among non-medical students than in medical students	Depression, internet addiction	Physical activity, depression, anxiety	Computer vision syndrome, headache, light sensitivity, double vision	Analgesic self-medication, headache	Poor sleep quality was higher among females	Association of social status and internet use with sleep quality was measured

PSQI = Pittsburgh Sleep Quality Index; ESS = Epworth Sleepiness Scale; SD = Standard Deviation; 1 = random sampling; 2 = convenience sampling; A = university sample; B = medical sample; NR = Not Reported.

high-quality studies were used, there is no possibility of publication bias. The limitation of this review is, missed the studies which were not published in English and did not include all studies reporting the prevalence of insomnia as they did not use a formal and standard scale and did not define the sample accurately.

Conclusions

Despite all limitations, this systematic review provided the evidence of the prevalence rates of insomnia among the university student in South Asian countries. As the pooled prevalence of insomnia is considerably higher than the general population, this review emphasized that insomnia in university students is a common health issue and more attention should be given to reduce insomnia among university students.

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Conflict of interest statement

The authors declare no conflict of interest.

Authors' contributions

AIC has designed the study and contributed on the data extraction, data analysis, interpretation and the manuscript writing. SG has contributed on the data extraction and analysis. She has also helped in the manuscript writing and critically review the manuscript as well. MFH and KKAS contributed on data extraction. FA contributed on data extraction and data analysis.

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Review

Immunogenicity and antibody persistence of diphteria-tetanus-acellular pertussis vaccination in adolescents and adults: a systematic review of the literature showed different responses to the available vaccines

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Keywords

Immunogenicity • Antibody persistence • Diphtheria-tetanus-acellular *Bordetella pertussis* vaccination • Adolescents • Adults

Summary

Introduction. *In industrialized countries, the routine use of Bordetella pertussis vaccines has shifted the burden of Bordetella pertussis disease from children to infants, adolescents and adults, leading to the necessity for booster doses.*
Materials and methods. *We prepared a review according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) with the aims of: a) describing the immunogenicity of the main available vaccines for adolescents and adults; b) describing antibody persistence after immunization with the main vaccines available in childhood and adults and, also, possible co-administration; and c) identifying the gold standard for adolescent and adult immunizations.*
Results. *We identified 6906 records. After removing duplicate records, we included 12 RCT (Randomized Controlled Trial) (people aged 11-73): 7 of these studies had only 1 control group, 4 had 2 control groups and 1 had 5 control groups; moreover, of the 12 studies included, only 2 regarded co-administration, while all concerned immunogenicity. Nine of the 12 studies had a Jadad score above 3 points, and 10 out of 12 met the criteria of Cochrane Back Review Group Criteria List for Methodological Quality Assessment.*
Discussion and conclusion. *We found a limited number of good-quality RCTs investigating our object. The 5-component vaccines, although containing a lower dose of antigen, proved more effective than the 1-component vaccine. Evidence supports the use of 5-component vaccines for booster sessions in adolescence and adulthood.*

Introduction

In industrialized countries, the routine use of *Bordetella pertussis* vaccines has shifted the burden of *Bordetella pertussis* disease from children to infants, adolescents and adults [1]. Although this disease is not generally as severe in adolescents and adults as in infants, it nevertheless has a heavy impact on morbidity and mortality; furthermore, these older age-groups are often the reservoir of infection for infants [2]. As the incidence of *Bordetella pertussis* in adults and older individuals has been seen to be increasing, reduced-dose acellular *Bordetella pertussis* vaccines combined with diphtheria and tetanus toxoids (Tdap) are required. The goals of Tdap booster doses are to protect older vaccinees, reduce the circulation of the bacterium, and thereby protect young infants [3].
Responses to immunization vary according to the different vaccines used and the immunization and infection history of vaccinees; in the scientific literature, immunity is evaluated through the assay of IgG anti-pertussis toxin (IgG anti-PT) antibodies by means of the ELISA method [4].
The following vaccines are currently available: Tdap5 vaccine, produced by Sanofi Pasteur [5], which is an adsorbed combination vaccine containing purified diphtheria and tetanus toxoids and five purified components of *Bordetella pertussis*; Tdap3, which contains purified diphtheria and tetanus toxoids and 3 purified components of *Bordetella pertussis* and is produced by Glaxo-Smith Kline [6]; *and* Tdap1, which is a combined adsorbed tetanus, low-dose diphtheria and monocomponent ap vaccine produced by Statens Serum Institut [7].
The aims of the present study were: a) to describe the immunogenicity of the main available vaccines for adolescents and adults; b) to describe antibody persistence in adults after immunization with the main vaccines available and, also the possible co-administration of these vaccines.

Materials and methods

In accordance with PRISMA guidelines [8], we searched the main scientific libraries (PubMed including MEDLINE, Web of Science and Embase) for randomised controlled trials, cohort studies, or longitudinal studies reporting the immunogenicity and persistence of antibodies against diphtheria tetanus pertussis, for articles indexed up to the date of the search, with no language restrictions. Table I shows the keywords search strategy for one data-

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base, Web of Science. Studies were included if they investigated vaccine-induced immunity in healthy individuals who received a DTPa and Tdpa vaccine, including different dosages and time-points of vaccine administration. Studies featuring child or maternal immunity, those with only one arm, and those that were not randomized were excluded. We excluded all case studies/reports, letter to editors, review papers, personal opinions and any other type of study with inconsistent data or which did not report original data. We also conducted hand searches of the reference lists of included studies and related reviews. We exported all studies retrieved from the electronic searches for deduplication and screening. Two review authors (CG and RS) independently screened the titles and abstracts to identify potentially eligible studies, and any disagreements between the two authors were resolved by discussion and consensus. We obtained the full texts of all potentially eligible studies. Two authors (RS and CG) independently screened the full texts and identified included studies, resolving discrepancies through discussion and consensus.

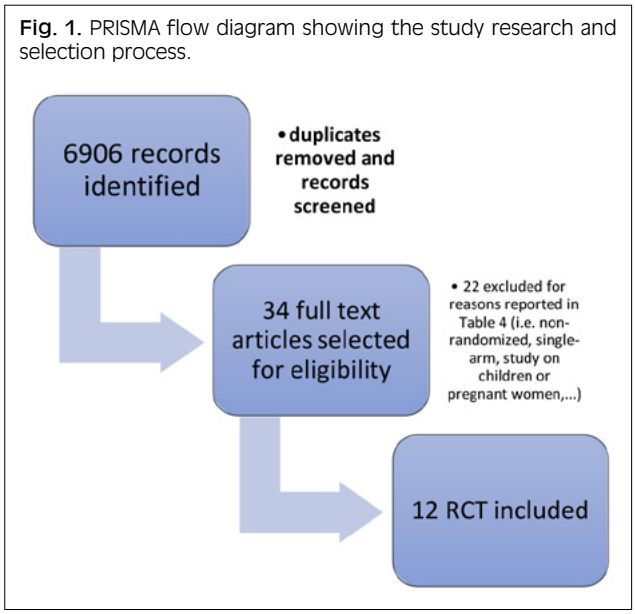

Fig. 1. PRISMA flow diagram showing the study research and selection process.

Data extraction

Two independent reviewers (CG and RS) identified potentially relevant articles and collected the following data: first author's last name; year of publication; study design; total number of participants; age range; gender; exclusion criteria and study arms with number of vaccinated participants in each arm.

Evaluation of study quality

Two reviewers (CG, RS) independently assessed the quality of individual studies included in the systematic review. The Jadad scale for reporting randomised controlled trials (RCTs) was employed [9]. This assigns an overall score of the methodological quality of a study from zero to five. We also evaluated the studies according to the Cochrane risk of bias tool for randomized controlled trials [10]. The domains assessed are: randomization method, allocation concealed, similar baseline, patient-blinded, provider-blinded, assessor-blinded, co-intervention avoided, acceptable compliance, acceptable drop-out rate, timing of outcome assessment similar and intention-to-treat analysis. The studies were included also with low quality scores, but it was taken into account when describing the results.

Results

Of 6906 records identified; after removing duplicate records, we selected 34 for full text review (Fig. 1) and, finally, 12 were discussed (Tab. II). The composition of included vaccines was reported in Table III.

Description of studies

Study design and population

All the studies included were randomized trails. Their characteristics are summarized in Table II. Twelve RCT were included in our review; of these, 7 had only 1 control group, 4 had 2 control groups and 1 had 5 control groups; moreover, of the 12 studies included, only 2 regarded co-administration [12, 14], while all were about immunogenicity [11-22]. The studies were conducted among people aged 11-73 years: Tdap1 in subjects aged 14-55; Tdap3 (GSK) in subjects aged 18-73; dTap3 (BNT) in those aged 18-35; and Tdap5 in those aged 11-72. The composition of the vaccines is reported in Table I.

Four studies were conducted in Europe [11, 12, 20, 21], one in Asia [19], one in America [22], seven studies were multi-centre [13, 14, 17, 18, 20, 22], and four were conducted in more than one country [15, 17, 18, 20].

Disease background or exclusion criteria of the studies included were: a history of significant medical illness; the presnce of any progressive or severe neurological disorder, seizure disorder or Guillain-Barre syndrome; immunodeficiency; administration of any diphtheria or tetanus or pertussis vaccine prior to enrolment in the study or history of allergy to any vaccine component; pregnancy or breastfeeding. For details, see Supplementary Table I.

The risk of bias in the studies included is summarized in Table IV.

We excluded 22 studies [23-44] from our analysis because they did not meet any inclusion criteria (Supplementary Tab. I).

Seroconversion, antibody persistence and adverse events in adolescents and adults

The 12 RCT included in our analysis are described below.

Carlsson et al. [11] reported the results of a non-blind RCT (see risk of bias in Tab. III) with two vaccines, a

Tab. I. Research strategy.

Adults^	TS = ((Diphtheria Tetanus Pertussis Vaccine or Vaccine, Diphtheria-Tetanus-Pertussis or DTwP Vaccine or Vaccine, DTwP or DPT Vaccine or Vaccine, DPT or DTP Vaccine or Vaccine, DTP or Di-Te-Per Vaccine or Di Te Per Vaccine or Vaccine, Di-Te-Per or Diphtheria-Pertussis-Tetanus Vaccine or Diphtheria Pertussis Tetanus Vaccine or Vaccine, Diphtheria-Pertussis-Tetanus) and (Case-Control Study or Studies, Case-Control or Study, Case-Control or Case-Comparison Studies or Case Comparison Studies or Case-Comparison Study or Studies, Case-Comparison or Study, Case-Comparison or Case-Compeer Studies or Studies, Case-Compeer or Case-Referrent Studies or Case Referrent Studies or Case-Referrent Study or Studies, Case-Referrent or Study, Case-Referrent or Case-Referent Studies or Case Referent Studies or Case-Referent Study or Studies, Case-Referent or Study, Case-Referent or Case-Base Studies or Case Base Studies or Studies, Case-Base or Case Control Studies or Case Control Study or Studies, Case Control or Study, Case Control or Nested Case-Control Studies or Case-Control Studies, Nested or Case-Control Study, Nested or Nested Case Control Studies or Nested Case-Control Study or Studies, Nested Case-Control or Study, Nested Case-Control or Matched Case-Control Studies or Case-Control Studies, Matched or Case-Control Study, Matched or Matched Case Control Studies or Matched Case-Control Study or Studies, Matched Case-Control or Study, Matched Case-Control or Cohort Study or Studies, Cohort or Study, Cohort or Concurrent Studies or Studies, Concurrent or Concurrent Study or Study, Concurrent or Closed Cohort Studies or Cohort Studies, Closed or Closed Cohort Study or Cohort Study, Closed or Study, Closed Cohort or Studies, Closed Cohort or Analysis, Cohort or Cohort Analysis or Analyses, Cohort or Cohort Analyses or Historical Cohort Studies or Cohort Study, Historical or Historical Cohort Study or Study, Historical Cohort or Cohort Studies, Historical or Studies, Historical Cohort or Incidence Studies or Incidence Study or Studies, Incidence or Study, Incidence or Vaccinations or Immunization, Active or Active Immunization or Active Immunizations or Immunizations, Active or Intervention Study or randomized controlled trial or Clinical Trial, Phase 4) NOT ("ANIMALS" NOT "humans").
Adolescents	TS = ((Diphtheria Tetanus Pertussis Vaccine or Vaccine, Diphtheria-Tetanus-Pertussis or DTwP Vaccine or Vaccine, DTwP or DPT Vaccine or Vaccine, DPT or DTP Vaccine or Vaccine, DTP or Di-Te-Per Vaccine or Di Te Per Vaccine or Vaccine, Di-Te-Per or Diphtheria-Pertussis-Tetanus Vaccine or Diphtheria Pertussis Tetanus Vaccine or Vaccine, Diphtheria-Pertussis-Tetanus) and (Case-Control Study or Studies, Case-Control or Study, Case-Control or Case-Comparison Studies or Case Comparison Studies or Case-Comparison Study or Studies, Case-Comparison or Study, Case-Comparison or Case-Compeer Studies or Studies, Case-Compeer or Case-Referrent Studies or Case Referrent Studies or Case-Referrent Study or Studies, Case-Referrent or Study, Case-Referrent or Case-Referent Studies or Case Referent Studies or Case-Referent Study or Studies, Case-Referent or Study, Case-Referent or Case-Base Studies or Case Base Studies or Studies, Case-Base or Case Control Studies or Case Control Study or Studies, Case Control or Study, Case Control or Nested Case-Control Studies or Case-Control Studies, Nested or Case-Control Study, Nested or Nested Case Control Studies or Nested Case-Control Study or Studies, Nested Case-Control or Study, Nested Case-Control or Matched Case-Control Studies or Case-Control Studies, Matched or Case-Control Study, Matched or Matched Case Control Studies or Matched Case-Control Study or Studies, Matched Case-Control or Study, Matched Case-Control or Cohort Study or Studies, Cohort or Study, Cohort or Concurrent Studies or Studies, Concurrent or Concurrent Study or Study, Concurrent or Closed Cohort Studies or Cohort Studies, Closed or Closed Cohort Study or Cohort Study, Closed or Study, Closed Cohort or Studies, Closed Cohort or Analysis, Cohort or Cohort Analysis or Analyses, Cohort or Cohort Analyses or Historical Cohort Studies or Cohort Study, Historical or Historical Cohort Study or Study, Historical Cohort or Cohort Studies, Historical or Studies, Historical Cohort or Incidence Studies or Incidence Study or Studies, Incidence or Study, Incidence or Vaccinations or Immunization, Active or Active Immunization or Active Immunizations or Immunizations, Active or Intervention Study or randomized controlled trial or Clinical Trial, Phase 4) NOT ("ANIMALS" NOT "humans") and (Adolescence, Adolescents, Adolescents, Female - Adolescents, Male Teenagers, Teens and Youth).

^ In accordance with guidelines, no age restriction was used; to avoid limiting search results, we did not use the word "adult" to screen references.

Tdap5 and Tdap1 [5, 7]. Briefly, children born in 1994 were invited to participate in booster studies of immunogenicity and reactogenicity on two separate occasions: a booster study of the DTaP5 vaccine in 1999 at age 5 years, and a second one with the same Tdap5 and a monocomponent (Tdap1) vaccine in 2009 at age 14-15 years [11]. Both studies used an open, randomized, parallel-group multicentre study design with blinded seroanalyses. The lower and upper limits of anti-PT after Tdap5 and Tdap1 were similar; regarding reactogenicity, fever, moderate or severe headache and moderate to severe swelling ≥ 2.5 at the injection site were reported more often after Tdap1 than Tdap5 (RR 2, 1.4 and 1.5, respectively).

Embree et al. [12] evaluated sierological assays (pre-vaccination, at 1 month, and 3-5-10 years after immunization) and co-administration (see co-administration section for description).

At 1-month post-vaccination, the seroprotection rates were comparable between the groups and remained high for up to 10 years post-vaccination for diphtheria, tetanus and poliomyelitis, but subsequently returned to pre-vaccination levels. Anti-pertussis Geometric Mean Titers (GMTs) declined over time: anti-PT displayed the lowest percentage of participants with detectable antibodies after 10 years (74.1%) while the percentages of the other three antigens were higher. No serious adverse events were reported.

Halperin et al. [13] showed that the proportion of participants displaying a booster response to Tdap5 vaccination was similar in the naïve group and the repeat-dose group, demonstrating that a second dose of a five-pertussis-component Tdap in adults was safe and immunogenic in comparison with adults in the naïve group. A solicited adverse event was reported by just over 92% of recipients of Tdap and there were no differences in rates of any adverse events.

Tab. II. Studies included in systematic review.

First author's last name	Year of publication	Study design	Total n. of participants	Age range	Gender	Arm 1	Arm 2
Carlsson	2015	RCT	230	14-15	Both	114 (Tdap5)	113 (Tdap1)
Embree	2015	RCT	236	11-14	Both	144 (Tdap5 -Polio) HepB 1 month later	132 (Tdap5-Polio) HepB concurrently
Halperin	2012	RCT	769	20-72	Both	407 (Naive Tdap)	362 (Repeat dose group Tdap5)
McNeil	2007	RCT	720	19-64	Both	359 (Tdap5 concomitant administration with flu)	361 (Tdap5 sequential administration with flu)
Halperin	2000	RCT	1207	12-60	Both	Adolescents^ Adults^^	Adolescents^ Adults^^
Halperin (Vaccine)	2000	RCT	749	12-55	Both	151* (Td)	449* (TdaP5)
Halperin	2019	RCT	1330	18-65	Both	1002 (Tdap5)	328 (Td)
Sirivichayakul	2017	RCT	60	18-35	Both	20° (Tdap5)	20° BNA'S Tdap3
Van der Wielen	2000	RCT	299	18-73	Both	96$ (Tdap3)	98$ (Td)
Thierry-Carstensen	2012	RCT	802	18-55	Both	401 (Tdap1)	401 (Td)
Jahnmatz	2014	RCT	230	14-15	Both	Tdap1	Tdap5
Pichichero	2005	RCT	4480	11-64	Both	3053 (Tdap5)§	1427 (Td)§

Note: ^ Adolescent cohort 1: Td-IPV at visit 1 and aP at visit 2; cohort 2: TdaP-IPV
^^ Adults: cohort 1: Td at visit 1 and aP at visit 2; cohort 2: TdaP at visit 1 and IPV at visit 2; cohort 3: TdaP at visit 1 and aP at visit 2; cohort 4: TdaP-IPV.
* Cohort 3: n = 149 aP (5 components)
° Cohort 3: n = 20 BNA's aP (3 components)
$ cohort 3: n = 96 aP (3 components)
§ Adolescent cohort 1: n = 1232 TdaP5; cohort 2 :n = 821Td
Adults: cohort 1:n = 1821 TdaP5; cohort 2:n=606 Td

Tab. III. Composition of dTpa vaccines analyzed.

Antigen	dTpa (1) AJ Vaccines	dTpa (3) GSK	dTpa (5) Sanofi Pasteur	dTpa (3) Bionet
Diphtheria toxoid	Not less than 2 UI	Not less than 2 UI	Not less than 2 UI	Not less than 2 UI
Tetanus toxoid (TT)	Not less than 20 UI	Not less than 20 UI	Not less than 20 UI	Not less than 20 UI
Pertussis toxoid (PT)	20 µg	8 µg	2,5 µg	5 µg
Filamentous hemagglutinin (FHA)	---	8 µg	5 µg	5 µg
Pertactin (PRN)	---	2,5 µg	3 µg	2.5 µg
Fimbriae type 2/3	---	---	5 µg	-

McNeil et al. [14] performed a study on the concomitant administration of Tdap and trivalent inactivated influenza vaccines or influenza vaccine followed (in 4-6 weeks) by Tdap. For this purpose, they enrolled 720 healthy subjects aged 19-64 years. Regarding diphtheria and tetanus, seroprotection rates and post-vaccination GMTs were non-inferior in the concomitant administration group compared with the sequential administration group. A trend towards lower antibody responses to *Bordetella pertussis* antigens PT, FHA and FIM was observed after concomitant administration, and in the case of PRN, this difference failed the non-inferiority criteria. Halperin et al. [15] performed an RCT to evaluate the safety of and antibody response to a single dose of an adult formulation of a Tdap5 and inactivated poliovirus vaccine (Tdap-IPV) in adolescents and adults, and

Tab. IV. Risk of bias in included studies.

First author's name and year	Jadad score	Cochrane^
Carlsson, 2015 [11]	3	6/10
Embree, 2015 [12]	3	7/10
Halperin, 2012 [13]	1	4/10
McNeil, 2007 [14]	3	7/10
Halperin, 2000 [15]	5	9/10
Jahnmatz, 2014 [16]	1	4/10
Halperin, 2000 [17]	5	9/10
Halperin, 2019 [18]	3	6/10
Sirivichayakul, 2017 [19]	3	9/10
Van der Wielen, 2000 [20]	5	7/10
Thierry-Carstensen, 2012 [21]	2	6/10
Pichichero, 2005 [22]	5	9/10

^ We reported the number of domains fitted by the study (ten domains were analyzed: randomization method, allocation concealed, similar baseline, patient blinded, provider blinded, assessor blinded, co-intervention avoided, acceptable compliance, acceptable drop-out rate, timing of outcome assessment similar and intention-to-treat analysis).

to assess the response to a second dose of the acellular pertussis vaccine in a subset of the adults. The antibody response against *Bordetella Pertussis* antigens was vigorous in all groups, although adults given the Tdap-IPV vaccine had lower antibody titers against filamentous hemagglutinin, pertactin, diphtheria and tetanus toxoids than those given Tdap vaccine. Similarly, adolescents given TdaP-IPV had lower antibody titers against *Bordetella pertussis* toxin, filamentous hemagglutinin, fimbriae and agglutinins than those given Td-IPV and aP alone. A second dose of acellular *Bordetella pertussis* vaccine was not associated with increased adverse events in adults, but raised antibody titers above the level achieved by a single dose only against pertussis toxin.

Jahnmatz et al. [16] described a study on 230 adolescents (aged 14-15 years) in an open-label, randomized multicenter study without a control group and with blinded analysis. Both vaccine groups had significant increases in *Bordetella pertussis* toxin-specific serum IgG levels, and the 5-component group had significant increases in filamentous hemagglutinin- and pertactin-specific memory B-cell and serum IgG levels; these were not seen in the 1-component group, as expected.

Halperin et al. [17] measured antibody levels before and one month after immunization and investigated adverse events (at 24 h, 72 h and 8 to 10 days). They did not find statistically significant differences in tetanus and diphtheria antitoxin levels between recipients of Td and Tdap, and the antibody response against *Bordetella Pertussis* antigens was vigorous in all groups. Adverse events were reported with similar frequency among the three vaccine groups. Moderate pain at the injection site was reported less frequently in the aP group than the Tdap group (RR = 0.4) and chills were reported less frequently after Td than after Tdap (RR = 0.4).

Halperin et al. [18] found a robust antibody response to each *Bordetella pertussis* antigen in the Tdap-vaccinated group, while post-vaccination geometric mean concentrations of tetanus and diphtheria antibodies were similar in the Tdap and Td groups with seroprotection rates > 99%. A solicited adverse event was reported by 87.7% of Tdap and 88.0% of Td vaccine recipients. No significant differences in the rates of local and systemic reactions between the vaccine groups were found.

Sirivichayakul et al. [19] enrolled only 60 subjects in 3 cohorts randomized to receive one of the vaccines in study, as reported in the Table II. Safety follow-up was performed for one month, while immunogenicity was assessed at the baseline and at 7 and 28 days after vaccination. One month after vaccination, seroresponse rates of anti-PT, anti-FHA and anti-PRN IgG antibodies exceeded 78% in all vaccine groups. Although the authors concluded that, in this clinical study, PTgen-based BioNet's aP and Tdap vaccines showed similar tolerability and safety profiles to those of Tdap5, the sample size was very small and moreover, follow-up was too short.

Van der Wielen et al. [20] evaluated responses to a Tdap3 vaccine. In all groups, severe reactions were infrequent and no serious adverse events were reported during the study; the incidence of local and systemic reactions following the administration of Tdap or Td vaccine was comparable. One month after vaccination, a similar percentage of subjects in the Tdap and Td groups had anti-diphtheria, anti-tetanus, anti-FHA and anti-PRN antibodies, while the anti-PT vaccine response rates were 96.8 and 100.0%, respectively, for Tdap3 and aP.

Thierry-Carstensen et al. [21] showed antibody responses (anti-PT) in adults aged 18-55 years in 92% of cases. The frequencies of solicited local adverse reactions were low and comparable between TdaP and Td vaccinees. In the TdaP group, 30.7% reported pain, 4.2% swelling and 2.0% erythema at the injection site. The most frequent solicited general symptoms were headache (20.4%), fatigue (17.0%) and myalgia (10.0%).

Pichichero et al. [22] showed that Tdap5 elicited robust immune responses to *Bordetella pertussis*, tetanus, and diphtheria antigens in adolescents and adults, while exhibiting an overall safety profile similar to that of a licensed Td vaccine; these data support the potential routine use of this Tdap vaccine in adolescents and adults. Indeed, 94% of Tdap recipients had protective antibody concentrations of at least 0.1 IU/mL against diphtheria and tetanus. Geometric mean antibody titers against the five antigens of *Bordetella pertussis* used exceeded (by 2.1 to 5.4 times) levels in infants following immunization with DTaP at 2, 4 and 6 months. The safety profile was similar in the Tdap and Td groups.

Co-administration

Two studies [12, 14] evaluated the co-administration of dTap5 with flu and with hepatitis B vaccines in adolescents and adults.

In the study by Embree et al. [12], no clinically relevant interference was observed on co-administration of Tdap5-IPV and HepB. Participants achieved seroprotective levels against tetanus (100%) and diphtheria (98.6% of group 1 and 100% of group 2). The *Bordetella pertussis* antibody seroresponses 1 month after Tdap-IPV vac-

cination were comparable in groups 1 and 2, as measured by 4-fold increases in PT, FHA, FIM and PRN.
McNeil [14] did not observe clinically relevant between-group differences (Tdap5 with flu or Tdap5 followed 1 month later by flu) in terms of safety; injection-site pain was the most commonly reported adverse event (66.6% concomitant administration group *vs* 60.8% sequential administration group), showing the possibility of concomitant administration.
In our analysis, we identified several studies on the co-administration of reduced-antigen content vaccines indicated for boosters in adults (Tdap3 and Tdap5), while no evidence emerged to support the co-administration of the Tdap1 vaccine with others one (such as HBV , flu, etc.).

Discussion and conclusion

In our systematic review, we observed that all vaccines were immunogenic but, as expected, the contents and concentrations of antigens influenced the responses.
In the study by Jahnmatz et al. [15], the authors found that the 1-component vaccine induced higher levels of PT-specific memory B cells than the 5-component vaccine, which could be explained by the higher concentration of antigen in the 1-component vaccine.
The 5-component vaccine, on the other hand, produced broader responses, with increases in both FHA- and PRN-specific memory B cells. Furthermore, this vaccine also elicited PT antibodies [11-18, 22, 31, 32].
It is important to establish the optimal antigen contents and concentrations to include in a booster dose, as we have shown here that these factors influence the extent of the vaccine response.
Regarding the immunogenicity and tolerability studies of Tdap vaccines, the authors of the Halperin studies [31] amply demonstrated that, on administering a booster dose of Tdap vaccine in adult subjects five years after the first vaccination, 100% and 95% of participants had protective levels of antibodies against tetanus and diphtheria, respectively). Furthermore, with regard to Bordetella pertussis, a post-vaccination antibody threshold of ≥ 50 IU/mL was seen in 82.1% (pertussis toxoid), 96.7% (filamentous haemagglutinin), 95.6% (pertactin) and 99.8% (fimbriae); this showed that a second dose of Tdap vaccine was immunogenic in adolescents and adults and was well tolerated (in fact, adverse events were slightly more frequent than after the initial dose) [31]. In the immunogenicity, reactogenicity and safety study by Asatryan et al. [32], one month after the administration of a single dose of Tdap vaccine all subjects (> 99.0%) enrolled were seroprotected against diphtheria and tetanus, and > 96.0% of the participants were seropositive for *Bordetella pertussis* antibodies. Furthermore, only one serious adverse event occurred, and this was not causally related to the vaccine under study.
With regard to the persistence of antibodies at 3, 5 and 10 years, there is a lack of long-term studies on the efficacy of the 1-component Tdap vaccine; such studies on the 3-component and 5-component Tdap vaccines are, however, available [11-22].
Below, we report the results of two robust follow-up studies: the first one evaluated antibody persistence after a single dose of Tdap vaccine (tetanus, diphtheria and acellular *Bordetella pertussis* 5-component vaccine) in a follow-up study of 3 RCTs [43] involving both adolescents and adults; this study amply demonstrated the presence of protective antibodies against diphtheria (99%) and tetanus antitoxin (100%). Seropositivity for one or more *Bordetella pertussis* antigens also persisted for 10 years in most of the subjects enrolled, and antibody levels remained high in nearly all adults. The second study, a follow-up study of 1 RCT, was conducted 1, 3, 5 and 10 years after immunization [44]; almost all adolescents and 91% of adults had diphtheria antibody levels > 0.01 IU/mL before receivingTdap or Td vaccines. One month after vaccination, nearly all adolescents and 94% of adults in both study groups had diphtheria antibody levels > 0.1 IU/mL; this percentage decreased slightly to 95% at 5 and 10 years. Almost all adolescents and adults always had high levels of tetanus antibodies during the entire follow-up period. GMC antibodies against each *Bordetella pertussis* antigen contained in the Tdap vaccine decreased 1 month after vaccination but remained higher than baseline levels at all follow-up times, with the exception of anti-PT after 5 and 10 years, which declined to near pre-vaccination levels in both adolescents and adults. The persistence of pertussis antibodies in adolescents followed a similar pattern to that observed in adults.
Therefore, the robustness of the data on antibody persistence in adults who receive vaccines with reduced antigen concentration is evident from the analysis of the present studies. This evidence is provided by RCTs and their related follow-up studies, which constitute an essential tool for monitoring the decay rate of antigens over time. However, we found a lack of follow-up studies on the persistence of antibodies against diphtheria-tetanus and *Bordetella pertussis* with regard to the 1-component Tdpa vaccine.
Thus, according to the follow-up studies conducted to date on adults, it can be concluded that there are substantial differences regarding the possibility of administering booster doses in the different age-groups; this finding must guide the regulatory authorities.
On the basis of the RCTs included in our analysis and of the indications for use reported in each "Summary of Product Characteristics", we briefly analyzed the age limits at which the vaccines can be administered. Indeed, the 1-component Tdpa vaccine is authorized for use in subjects aged up to 55 years (however, the short period of follow-up prevented the evaluation of long-term response) [16]. By contrast, studies on the persistence of antibodies elicited by the 3-component and 5-component Tdpa vaccines [11-22] have involved subjects up to 76 and 79 years of age, respectively. Moreover, the CDC recommends these vaccines for all subjects over 65 years of age [45].
In our analysis, we identified several studies, both in

children and in adults [12,14], involving the co-administration of reduced-antigen content vaccines indicated for boosters in adults (Tdap3 and Tdap5) with other vaccines, such as hepatitis B, influenza, pneumococcal, meningococcal vaccines and HPV vaccines; however, there is a lack of evidence to support the co-administration of the Tdap1 vaccine with others one. Furthermore, vaccines with reduced antigen content display adequate immunogenicity, as demonstrated by non-inferiority studies, without yielding a clinically significant increase in reactogenicity [12, 14, 46-48].

A further problem noted in our review is the paucity of studies evaluating long-term immunogenicity and long-term persistence of antibodies elicited by the 1-component Tdap vaccine.

When a new treatment is studied, it is important to perform well-designed clinical trials; in particular, randomization, blindness, research duration and sample size calculation are key features to evaluate [49]. In our review, we noted some shortcomings in this area (as shown by bias evaluation) with regard to studies on the 1-component Tdpa vaccine [11, 21].

In conclusion, we can confirm that few RCTs with a low risk of bias are currently available to guide us in choosing the best vaccine. However, the broadest antibody response is elicited by the 3- or 5-component vaccines; the presence of antibody persistence, as demonstrated by the studies analyzed in this review, should prompt public health authorities to choose a vaccine with multiple *Bordetella pertussis* components (Tdap3 or Tdap5).

Although there is a lower content of *Bordetella pertussis* toxin in 2 out of 3 of the vaccines described, several studies support their use as vaccines during booster sessions in adolescence and/or in adults, and those with more components are generally ,considered more effective than a vaccine/Pa that contains only PT or even FHA [50]. Finally, as changes in circulating *Bordetella Pertussis* strains may affect vaccine efficacy, the incidence and transmission of *Bordetella pertussis* deserve to be closely monitored. In conclusion, although 3-component and 5-component vaccines contain a lower dose of antigen, they are more effective than 1-component vaccines in the prevention of diphtheria-tetanus and *Bordetella pertussis*, owing to the persistence of the antibodies elicited and the feasibility of their co-administration. The robustness of the data and the analytical tests support the use of vaccines with reduced antigen concentration for decennial booster sessions in adolescence and adulthood.

The Tdap vaccine remains of fundamental importance throughout life. Not only does it protect children through the “cocoon strategy” and immunize them in their early years, it also protects subjects subjects who are at risk because of their working conditions or chronic diseases. Moreover, it can effectively be administered to all people every 10 years, given the demonstrated need for booster doses [51]. Finally, in order to protect infants in the postpartum period, the immunization of pregnant women is of paramount importance and is recommended in the third trimester of each gestation, regardless of the woman’s vaccination history and the time that has elapsed since the previous gestation [52]. However, if women are not vaccinated during pregnancy, administration of the dTpa vaccine remains important. Indeed, the Advisory Committee on Immunization Practices recommends that all adolescents and adults who have, or who anticipate having, close contact with an infant younger than 12 months (siblings, parents, grandparents, child care providers and health care workers), and who have not previously undergone vaccination with the Tdap vaccine, should receive a single dose of Tdap at least 2 weeks before coming into close contact with an infant [53].

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Conflict of interest statement

The authors declare no conflict of interest.

Author's contribution

All authors carried out a systematic review to identify all scientific publications. Screening was carried out independently by the two authors (RS, CG). Any disagreement about eligibility between reviewers was resolved by discussion. The two authors extracted data from included papers using a data extraction form reviewed by each other. The two reviewers (CG and RS) identified potentially relevant articles, collected the data and independently assessed the quality of individual studies included.

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Supplementary Tab. I. Disease background and exclusion criteria of included study.

First author's last name	Disease background and exclusion criteria
Carlsson	a. Serious chronic illness (cardiac or renal failure, failure to thrive, progressive neurological disease, uncontrolled epilepsy, infantile spasm) b. immunosuppression c. Previous culture-confirmed pertussis.
Embree	a. Any substantial underlying chronic disease (including malignancy; known impairment of neurological function or a seizure disorder of any etiology) b. Immunodeficiency, immunosuppression, or receipt of high-dose steroids; c. Receipt of any pertussis-, diphtheria-, tetanus-, or poliomyelitis-containing vaccines or HBV vaccine within the previous 5 years; history of physician-diagnosed or laboratory-confirmed pertussis disease within the previous 2 years; receipt of blood products or immunoglobulins within the previous 3 months; receipt of any vaccine within 2 weeks of any study vaccine administration; or daily use of non-steroidal anti-inflammatory drugs d. Known or suspected allergy to any vaccine components in the study.
Halperin	a. Pregnant or nursing b. Allergic to Tdap vaccine or any of its constituents or to latex
McNeil	a. Any significant underlying chronic disease (malignancy, neurological disease or seizure disorder requiring medication b. Primary disease of the immune system or use of immunosuppressive therapy or daily non-steroidal anti-inflammatory therapy, c. Received any Tdap vaccines within 5 years prior to enrolment, influenza vaccine during the current year, blood products or immunoglobulins within three months of enrolment, or if they had a history of physician-diagnosed or laboratory-confirmed pertussis disease within 2 years prior to enrolment. d. Known or suspected allergy or previous adverse events to any of the vaccines or vaccine components being used in the trial e. Pregnant or breast feeding or unwilling to use effective contraception during the study
Halperin	a. Significant underlying chronic illness and seizure disorder b. Known or suspected diseases of the immune system or immunosuppressive therapy, receipt of a blood product in the previous 3 months, c. Receipt of any pertussis-, polio-, diphtheria- or tetanus-containing vaccine in the previous 5 year d. Allergy to a vaccine constituent, physician-diagnosed pertussis in the previous 2 years e. Pregnancy or planned pregnancy during the study period
Halperin (Vaccine)	a. Significant underlying chronic illness, seizure disorder b. Known or suspected diseases of the immune system or immunosuppressive therapy, receipt of a blood product in the previous 3 months c. Physician-diagnosed pertussis in the previous two years, or receipt of any pertussis-, diphtheria- or tetanus-containing vaccine in the previous 5 years d. Allergy to a vaccine constituent e. Pregnancy or planned pregnancy during the study period
Halperin	a. Had a chronic illness or medical condition b. Suspected congenital or acquired immunodeficiency or had received blood or blood-derived products in the previous 3 months; had received any vaccine within 30 days before receiving study vaccine (except for flu vaccine, which was allowed up to 15 days before the study vaccine) or had plans to receive another vaccine before the second study visit; had participated in another interventional clinical trial; had reported seropositivity to HIV, HBV or HCV; thrombocytopenia or a bleeding disorder that would be a contraindication for an intramuscular injection c. Received any dtp vaccine since receipt of the qualifying dose of Tdap vaccine 8 to 12 years earlier or had physician-diagnosed or laboratory-confirmed pertussis in the previous 10 years d. Hypersensitivity or previous severe reaction to a pertussis-, tetanus-, or diphtheria-containing vaccine; Guillain-Barré syndrome; moderate or severe illness at the time of vaccination e. Pregnancy or breastfeeding
Sirivichayakul	a. History of significant medical illness or individuals with any progressive or severe neurological disorder, seizure disorder or Guillain-Barré syndrome; b. Immunodeficiency c. Having received any Diphtheria or Tetanus or Pertussis vaccine within 5 years prior to enrolment in the present study d. History of allergy to any vaccine component or history of serious adverse event or neurological adverse event after injection with DTP vaccine e. Pregnant or breastfeeding women f. History of alcoholism and/or intravenous drug abuse

Van der Wielen	a. Administration of immunosuppressive/ immune-modifying drugs b. Previous vaccination against either diphtheria or tetanus within 5 years or vaccination against pertussis since childhood; a known history of diphtheria or tetanus; known exposure to diphtheria or pertussis within the previous 5 years; or a known history of non-response to diphtheria, tetanus or pertussis vaccination. c. History of allergic disease or reactions likely to be exacerbated by any component of the vaccine; or previous record, following DTP vaccination, of any serious adverse reaction or precautionary indication for DTP vaccination d. Administration of vaccines not foreseen by the protocol (one month before or after the start of the trial), of immunoglobulins and blood products (3 months prior or during the trial)
Thierry-Carstensen	a. Progressive neurological disease, uncontrolled epilepsy, progressive encephalopathy b. Immune deficiency or administration of immune-modulating drugs ≤3 months before inclusion c. Tetanus, diphtheria, or pertussis vaccination or infection ≤5 years before inclusion d. Known hypersensitivity to any of the vaccine components e. Pregnancy f. vaccination with any vaccine ≤1 month before inclusion
Pichichero	a. Malignancy, significant underlying disease,neurological impairment,acute respiratory illness b. Any immunodeficiency or daily use of oral nonsteroidal, anti-inflammatory drugs; receipt of blood products or immunoglobulins within 3 months c. Receipt of any DTP vaccine within 5 years; diagnosis of pertussis within 2 years d. Allergy or sensitivity to any vaccine component, including previous vaccine reactions e. Pregnancy

Supplementary Tab. II. Characteristics of excluded studies.

Study	Reason
Barkoff, 2012 [22]	Single-arm study evaluating the antibody response induced after booster vaccination and infection
Gustafsson, 1996 [23]	RCT evaluating serological response in child at 2, 4 and 6 months of age (range of age out of the aim of the study)
Ohfuji, 2015 [24]	Multicentre case-control study comparing the history of DTaP vaccination between 55 newly diagnosed pertussis cases and 90 age- and sex- matched controls.
Keijzer-Veen, 2004 [25]	Observational study of reactivity of acellular pertussis vaccine in 4-year-olds
Hanvatananukul, 2020 [26]	Cross-sectional study to determine the seroprevalence of antibodies against DTP among Thai adolescents
Afari, 1996 [27]	RCT study of acellular DTP in southern Ghana on children under 5 years of age and women of fertile age
Halperin, 1995 [28]	RCT study of acellular pertussis vaccine as a booster dose for 17- to 19-month-old children previously immunized at 2, 4 and 6 months of age
Fortner, 2018 [29]	RCT study on pregnant and non-pregnant women
Halperin, 2011 [30]	Open-label, non-randomized, multicentre study in which participants in three previous randomized, controlled trials of Tdap received a second dose of Tdap vaccine
Asatryan, 2020 [31]	Phase III, open-label, non-randomized study
Cherry, 2010 [32]	Described other study performed in the 1980s and 1990s
Collins, 2004 [33]	RCT on immunogenicity and reactivity of two combined low-dose DTaP vaccines in children aged 3-3.5 years
Hori, 2016 [34]	RCT of two dtap vaccines in Ghana in 89 infants
Knuf, 2004 [35]	A controlled open-labelled double-blind trial with Biken acellular pertussis vaccine
Langley, 2005 [36]	RCT on children 4-6 years old
Schmitt, 1996 [37]	Blinded prospective follow-up of immunized children
Pichichero, 1996 [38]	RCT on 190 infants
Meyer, 2008 [39]	RCT on immunogenicity and reactivity in 4- to 6-year-old children
Trollfors, 2006 [40]	Open study on 502 10-year-old children
Tiru, 2000 [41]	Post hoc analysis
Tomovici, 2012 [42]	Follow-up study of 3 RCT
Pool, 2018 [43]	Follow-up of an RCT at 1, 3, 5 and 10 years post-vaccination

Letter to the Editor

Improving quality in school canteens: *Un fiore in mensa (A flower in canteen)* project from ATS Val Padana (Italy)

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Keywords

Children • Health behavior • School • Food • Quality

Dear Editor,
It is known that dietary behaviors in childhood track into adulthood and are predictive of future chronic disease [1-3]. For this reason, the WHO recommends the implementation of food and beverage policies as a strategy to improve the nutrition of children [4, 5]. Children usually spend many hours at school each day, including lunchtime, so the school environment could be considered an important out of home setting where children consume at least one main meal a day. Given the influence that the environment can exert on students' food choices, it is crucial to create a healthy food environment in schools that facilitates students to choose healthy food products. In this way, students are enabled to develop healthy eating habits from which they can benefit the rest of their lives [6-8].
The foods offered in school canteens have an increasingly important role to ensure that children could have a consistent opportunity to choose healthy foods [9].
In Italy several children bring their lunch from home, but the majority of schools (especially primary, and middle schools) have a canteen; this phenomenon is also described in other parts of the world [10].
The project called *Un fiore in mensa* (*A flower in canteen*) was conceived by ATS (Agenzia di Tutela della Salute - Health Protection Agency) Val Padana as an acknowledgment given to the quality of the school catering service that could contribute to:

- improve the quality level of school catering service;
- stimulate teachers to live the meal at school as an educational moment;
- actively involve children by educating them in a healthy and correct diet;
- achieve children's autonomy;
- stimulate local administrators, or private managers to achieve a common goal which is the psycho-physical well-being of children.

The aim of the project is to assign an award – *The Flower* – on the basis of the evidences emerged from an inspection. The inspection should be performed at school (without any notice) by health personnel during lunch. Each room, tackle and food should be examined as well as the entire lunch (from preparation of meal to the consumption).
In particular the health personnel should evaluate:

1. quality of the menu;
2. organization and cleaning of the kitchen and/or other locals;
3. collaboration of the teachers;
4. general presentation of the refectory (cleanliness, brightness, furnishings, tables…);
5. collaboration between all the personnel during lunch;
6. children's behavior.

During the inspections, the health personnel should use a questionnaire divided in 6 sections (see Appendix), assigning different scores for each item (max 10 points for each section).
It is necessary to reach at least 30 points to have the "flower", but these points should be achieved in 3 essential sections (and therefore "petals"):

1. quality of the menu;
2. organization and cleaning of the kitchen and/or other locals;
3. collaboration of the teachers.

The complete flower (with 6 petals) could be reached with 60 points (corresponding to 4 - general presentation of the refectory; 5 - collaboration between all the personnel during lunch; 6 - children's behavior).
At the end of the inspection, a brief report should be written and sent to the local administrators (e.g. mayors) or private managers involved in school catering.
In the first edition of the project (school year 2014-2015) 17 on 28 schools (60.7%) obtained the flower.
In particular: one school obtained a 3-petals certificate; 5 schools obtained a four-petals certificate (4 obtained the petal 4, 1 obtained the petal 5); four schools obtained a five-petals certificate(2 obtained the petals 4 and 5, 1 the petals 4 and the 6 and 1 obtained the petals 5 and 6); seven schools met all the requirements and obtained the complete six petals certificate.
Among the 17 schools that obtained the flower, nine were kindergartens and eight elementary schools. Moreover, five had an internal kitchen and twelve the refectory only.
81.8% (9 out of 11) kindergartens and only 47% (8 out of 17) of elementary schools obtained the flower. 83.3% (5 out of 6) of schools with internal kitchens and only

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54.5% (12 of 22) of schools with the refectory obtained the flower.

It is pivotal to say that these results are limited to the schools sited in the territory of ATS Val Padana (situated in Northern Italy) and certainly studies on larger areas, involving a greater number of schools could confirm or deny what we observed.

However, in our experience, we observed in the schools with an internal kitchen several problems: the locker rooms and the toilets dedicated to the canteen personnel were often unsuitable (dirty, or with lockers insufficient for all the workers); in the pantry we often found unsuitable foods such as wine, non iodized alt, bouillon cubes, snacks, precooked foods. In some cases we found a poor collaboration of the teachers.

The better results reported by the kindergartens could be partially explained by their general management: they were often small schools, with a limited number of children and the most of them had a private management.

In the first edition of the project we observed, during the year, a progressive improvement in canteens quality and a progressive growth in the awareness about the project. Some schools that have not received the full flower contacted us to try to resolve some critical aspects and this is certainly an important confirmation of the utility of the project that we encourage to use also in other realities.

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Conflict of interest statement

The authors declare no conflict of interest.

Authors' contributions

GT wrote the article, MS had the idea of the project, MLC had the idea of the project, EF contributed to the data collection, AMF helped to conceptualize the ideas, VC helped to conceptualize the ideas.

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Appendix

Questionnaire used during the inspection

(Failure to comply with even one of the requirements will result in failure to attribute the petal)

1. Quality of the menu: • validation of the menu by ATS with distinction between winter and summer menus and special diets for clinical reasons (2 points); • variety and quality of menu (type of used foods, presence of seasonal fruit and fresh products) (2 points); • quality of special diets (variety and possibility of substitutions) (2 points); • compliance with the planned menu and the presence of bread with a reduced salt content (1.7% salt) (2 points); • portions appropriate to age, pleasant tasting, correct use of condiments, attention to the use of salt (iodized and in appropriate quantity) (2 points).
2. Organization and cleaning of the kitchen and/or other locals: • absence of previous inspections with a negative result by ATS or fulfillment of the changes imposed by ATS (3 points); • adequate space and equipment in the kitchen, in the refectory and in the pantry (2 points); • hygiene of workers, hygiene of spaces and hygiene of equipment (cookware, stove, oven…) (3 points); • presence and application of the self-control plan (HACCP) (2 points).
3. Collaboration of the teachers: • behavior of the teachers during the meal (they eat with the children or with each other, they encourage the tasting of food, they behave in a polite and kind way with the children) (4 points); • meal management as an educational moment (4 points); • vigilance on special diets (2 points).
4. General presentation of the refectory (cleanliness, brightness, furnishings, tables…): • brightness, furniture and adequate spaces of the refectory (2 points); • table setting (2 points); • use of non-disposable plates and cutlery (1 point); • presentation of dishes (1 point); • relationship between the diners and the workers who distribute the meal (2 points); • punctuality of the served meal and duration of the meal (2 points).
5. Collaboration between all the personnel during lunch: • communication and collaboration during the meal (for example clearing away with the help of children, reporting some problems relating to the meal…) (3 points); • consumption of the same meal by teachers and children (4 points); • general harmony during the meal (peaceful atmosphere, respect for roles, etc.) (3 points).
6. Children's behavior: • table education (2 points); • correct use of cutlery (2 points); • acceptance of the meal (tasting of unwelcome foods) (2 points); • correct consumption of bread (2 points); • correct consumption of fruit (preferably mid-morning) (2 points).

ORIGINAL ARTICLE

Exploring the nutritional beliefs of pregnant women in Yazd city

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Keywords

Pregnant women • Nutrition during pregnancy • Culture • Beliefs

Summary

Introduction. *During the pregnancy, a woman as a healthy person grows another human being in her body and needs more cares due to changes in psychological and physical needs. This study aimed to explore the nutritional beliefs of pregnant women in Yazd city.*

Methods. *This was a qualitative study conducted with a conventional content analysis approach. A total of 12 participants were selected from women referred to the community health centers in Yazd, Iran, by the purposeful sampling method. Data were collected through recorded semi-structured interviews that were transcribed verbatim and analyzed by the Lundman and Granheim's content analysis method.*

Results. *In this study, after analyzing the data, 10 main categories and 26 subcategories were extracted. The codes were 446 cases with no overlap, which was reduced after careful review and integration of similar items. Topics of categories included: The concept of nutrition during pregnancy, Nutrition limitations during pregnancy, Myths about food during pregnancy, Doubts about nutrition during pregnancy, Pregnancy food style, Sources of nutritional information in pregnancy, Positive Consequences of Healthy Nutrition in Pregnancy, Consequences of inappropriate pregnancy nutrition, Religious Beliefs in Pregnancy Nutrition, social support.*

Conclusion. *The results indicated that the women were committed to their own nutritional beliefs that derive from their culture and this study provided a clear picture of the cultural beliefs of Yazdi women regarding pregnancy nutrition. According to the results, it is necessary to design the education process based on the culture of the community in order for that process to be effective.*

Introduction

A woman, as a healthy person, nurtures another person in her womb during pregnancy and due to the psychological (anxiety and depression) as well as physical (weight gain and cardiac problems) changes which occur during pregnancy, she will be needing more care. Taking care of the woman's health directly affects the health of her unborn child [1, 2]. Maintaining the mother's health through prenatal care is the main guarantee of giving birth to a healthy baby. It is also the most cost-effective intervention method to reduce maternal (infant) mortality and complications before and after birth [3].

Proper nutrition is one of the determining factors of pregnant mother's health. Maternal nutrition during pregnancy should be balanced. Having a healthy diet during pregnancy is a reliable guarantee for a good pregnancy and childbirth. Proper nutrition also plays an important role in preventing and alleviating some pregnancy problems such as constipation, heartburn, anemia and urinary tract infection [4].

Pregnancy and lactation require proper nutrition and special attention, which is due to the body's need for nutrients and the important role nutrition plays for the fetus and infant. It is important to emphasize the necessity of achieving and maintaining a proper diet for maternal health during pregnancy and lactation. A variety of foods, such as milk, yogurt, cheese, meat, eggs, all kinds of grains and fresh vegetables, and fruits are recommended during this period. Maternal nutritional needs in different periods of pregnancy vary according to fetal growth and the mother's conditions. An ideal diet will provide not only for the usual day to day needs of the mother, but for the needs of the developing fetus as well as the future breastfeeding [5].

If pregnant women do not have the perfect knowledge of nutrition, it causes malnutrition during pregnancy which will have very bad effects on the fetus [6]. Pregnant women are highly vulnerable to malnutrition due to hormonal, metabolic and physical changes that increase their nutritional needs for nutritious foods. Inadequate nutrition leads to delayed intrauterine growth, miscarriage, preterm delivery, especially low birth weight (LBW) [7] and diseases such as non-insulin dependent diabetes, renal disease, hypertension and cardiovascular disease in adulthood [8].

Dietary superstitions are known in almost all human societies and may be found in various forms around the world. Pregnancy is seen as a critical period in the lives of women and is usually affected by food superstitions in order to save their lives and their babies [9]. In many small communities, pregnant women have unreliable dietary superstitions, which are believed to lead to a lack of access to vital nutrients [10]; Women in developing countries suffer from nutritional deficiencies, but social and cultural factors, including superstitions and taboos that may be related to malnutrition, have not been well studied [11].

Nutritional patterns and behaviors of pregnant women have strong cultural backgrounds and cultural beliefs which can determine the types of foods consumed, bans, and superstitions during pregnancy. Health care providers must be aware of these beliefs in order to target their performance in society, and those beliefs that are useful to pregnant women and their babies should be supported by scientific explanations. Vice versa, those beliefs that have a poor scientific base should be put aside by educating people in the community [12].

Based on what was said above, studies in Iran have limited information gaps in the analysis of pregnant women's beliefs about nutrition that are precisely based on the culture of their community and require conducting more qualitative studies. It is possible that the extraction and identification of women's perceptions and experiences about pregnancy nutrition could be of interest to health educators in designing and implementing appropriate educational programs and would provide the basis for promoting Iranian women's health. Therefore, the present study has aimed to explain the nutritional beliefs of pregnant women in Yazd.

Methods

The present study was conducted between April to August 2019 to explore the beliefs of pregnant women in a qualitative study using conventional content analysis approach. Women who met inclusion criteria such as being pregnant, willing to participate in the interview, being native to Yazd, age range of 18-49 years, having a file at a health center near their place of residence, were considered as participants. Exclusion criteria included a history of underlying disease and psychological illnesses during pregnancy. Participants (12 pregnant women) were selected through theoretical and purposeful sampling and textual data collection continued until data saturation.

The researcher first obtained the telephone number of eligible pregnant women from the health department of the city health center. During the phone call with women and explaining the purpose of the study, they were asked about the appropriate time and place of interview. In this study, semi-structured in-depth interviews were used. Interviews with women took place in three session of focus group discussions. In group meetings, the group dynamic rules were used to guide the discussion and the participants were encouraged to share their experiences and knowledge of nutritional beliefs during pregnancy. Pregnant women were first asked to introduce themselves and state their pregnancy rating. Then there are questions like "What foods do you eat during pregnancy?" or "What traditional Yazdi foods (common in Yazd) do you eat during pregnancy?" It should be noted that during the interview, some in-depth questions such as "give an example, explain more, and what do you mean?" was used to expand and deepen the findings. Personal information such as age, education, occupation and pregnancy rating were also asked in addition to the main questions. The group interview was conducted in a calm and confidential environment. Interviews attempted to minimize interference with the interview process and at the same time preventing the diversion of the interview route. Also, with the follow-up questions, the interview process was guided to cover the research objectives. Focus group discussion sessions continued until no new data emerged and in other words data were saturated. The approximate duration of focus group discussion sessions was 30-45 minutes. Interviews were recorded with the prior permission of the participants, using a voice recorder; then the textual data were handwritten first and then typed.

After completing the stage of transcribing the group interviews and reaching the information saturation, a qualitative content analysis was performed. They were all coded according to conventional content analysis method and themes were extracted. The process of analyzing the data was based on the Granheim and Landman method in 2004, which include: 1. Conducting interviews and reviewing them several times in order to gain a proper understanding of all written materials, 2. Extracting semantic units and their classification as compact units, 3. Summarizing and classifying semantic units and selecting the appropriate label for them, 4. Sorting the subgroups by comparing similarities and differences in subgroups, 5. Selecting the appropriate title that can cover the created categories.

To evaluate and increase the scientific robustness of the findings and codes, categories were revised and compared with the data again. The method of review was used by the research colleagues to ensure the objectivity of the data. After coding and classifying the codes, the researcher provides the semantic units, codes, subcategories, and extracted main categories to the research team members to reach a general consensus. Interviews were re-reviewed if part of the research process was not approved by the team and referrals were made to the interviewers if necessary.

The ethical considerations of the present study included obtaining permission from pregnant women and their spouses as well as completing an informed consent form for women to record audio and ensure that their recorded information and voice were protected and that they volunteered to participate in or withdraw from the study. This study was approved by the Ethics Committee of Shahid Sadoughi University of Medical Sciences, Yazd-Iran under the code: IR.SSU.SPH.REC.1397.02.

Results

The demographic data of 12 pregnant women participating in the focus group discussion are summarized in Table I. In this study, data were extracted by analyzing 10 main categories and 26 subcategories (Tab. II). The codes were 446 cases without overlap, which was reduced to 120 codes after closer examination and integration.

This section examines each of the categories and subcategories extracted. It was composed of four subcategories, namely "Definition of Prenatal Nutrition", "Importance of Prenatal Nutrition", "Healthy Nutrition" and "Unhealthy Nutrition". Pregnant women in this study defined the nutrition of pregnancy as dos and don'ts and consumption of healthy foods. For example, the participant 1 stated that "nutrition during pregnancy means the dos and don'ts during pregnancy". Pregnant women should also consume healthy foods and care for their nutrition due to the growth of their fetus. "At least during pregnancy, I tried to eat healthy because it had an impact on the baby" (P2). Regarding healthy eating subcategories, participant 4 stated, "In our opinion - Yazd people- meat, barbecue and Gormeh are nutritious and tonic foods; I ate these a bit more during my pregnancy; Now I have severe anemia so I am eating them again". Almost all of the participants believed that unhealthy nutrition means eating fast-food, soft drinks and junk food. "Soft drinks, hot dogs, sausages and a variety of foods that may be allergic and may have a negative impact on

Tab. I. Study participants demographic features.

Age of pregnancy	Job	Education	Rank of pregnancy	Age	Code
15 w	Housekeeper	High school	1	18	1
12 w	Employee	Student	2	27	2
14 w	Housekeeper	Diploma	2	33	3
21 w	Employee	Bachelor	3	39	4
10 w	Teacher	Bachelor	3	45	5
15 w	Housekeeper	Bachelor	1	27	6
32 w	Worker	Diploma	2	36	7
28 w	Teacher	Bachelor	2	31	8
20 w	Employee	Bachelor	2	37	9
17 w	Housekeeper	Associate	1	26	10
30 w	Housekeeper	Associate	2	34	11
18 w	Worker	Diploma	1	40	12

Tab. II. Categories and subcategories extracted from the analysis of focus group interviews.

N	Main category	Subcategory
1	The concept of nutrition during pregnancy	Defining nutrition in pregnancy The Importance of Nutrition in Pregnancy Healthy nutrition Unhealthy Nutrition
2	Nutrition limitations during pregnancy	Prohibition of Nutrition in Pregnancy Obstacles to proper nutrition in pregnancy
3	Myths about food during pregnancy	Feelings about pregnancy nutrition Selective tendency Forced / voluntary use
4	Doubts about nutrition during pregnancy	Nutritional ambiguities in pregnancy food superstitions in pregnancy
5	Pregnancy food style	Pay attention to food units and calories Changing diet before and during pregnancy Observe the diversity in food consumption Consume local food and herbal medicine in pregnancy Supplements in pregnancy
6	Sources of nutritional information in pregnancy	Important others Trust / distrust to advices from important others
7	Positive Consequences of Healthy Nutrition in Pregnancy	Delivery facilitators Inhibitors of neonatal jaundice
8	Consequences of inappropriate pregnancy nutrition	Causes of neonatal jaundice Physical problems of pregnant woman
9	Religious Beliefs in Pregnancy Nutrition	The Influence of Food on the Narrative View Religious practices
10	Social support	Spouse supportive behaviors Supportive behaviors of mother / mother-in-law

the fetus. I put them in the unhealthy diet category"(P2). It was divided into two subcategories, entitled "Nutrition Prohibitions in Pregnancy" and "Prohibition of Proper Nutrition in Pregnancy". Concerning dietary restrictions, participants stated that consumption of sheep's liver, carrot juice, honey, saffron, and barberry can lead to miscarriage, especially during the first months of pregnancy. So these items were removed from their food basket. "I didn't drink too much carrot juice; I didn't even eat sheep's liver "(P1). "They said I should not eat some things. For example, they said I should not consume saffron or honey too much and I should not eat hot foods too much as well" (P7). According to the pregnant women in the present study, barriers to nutrition may include lack of proper nutrition, inappropriate economic status, occupation of mother, and longing of pregnant women. "Foods are expensive and this in itself prevents proper nutrition, but one has to get the food they need in pregnancy" (P7). "Now, because craving bothers me, I tend to eat less" (P10).

This category was composed of three subcategories naming "feelings about nutrition during pregnancy", "food choice in pregnancy" and "forced / voluntary consumption of food in pregnancy". In this study, pregnant women expressed their inner feeling about eating or not eating: "I can't eat the dried apricot, almond and any other dried goods. They say it's good, but I can't eat, so I don't feel good about eating"(P4)." The things that make me feel good, I love to eat. The rest I felt bad as I looked at them such as meat" (P1). Pregnant women would choose foods based on their desire for certain foods. That is, in pregnancy they would interpret their particular desire to "have a craving" for certain foods. For example, participant (1) said "Now I eat whatever I crave. If I don't crave something, I can't eat it, there is not so much else to do" (P1). "After all, a mother in her pregnancy hates many things she has loved before, and loves some things she used to hate, for example, at this moment I do not like sweets at all" (P3). Pregnant women have to consume some foods due to their nutrition and positive impact on their physical condition and fetal development, and on the other hand, some foods have to be avoided. "Well I feel like I have to eat some foods during pregnancy. Just because they are good for my health" (P3). "Pregnant women have to consume some nutrients during pregnancy" (P7). There were some doubts about whether or not some foods were consumed by pregnant women. For example, they doubted if they should consume tomatoes or fish because they believed that consuming too much tomatoes or fish would cause malfunction and decrease infant's IQ level. It was composed of two subcategories with "nutritional ambiguities in pregnancy" and "prenatal nutrition superstitions". Pregnant women had doubts as to whether or not to eat certain foods during pregnancy. An example of the ambiguities of pregnant women is: "I have heard in recent months that we should eat liver. I do not know why, but I am going to do it" (P5). Some superstitions have long been prevalent among pregnant women but our participants despite their knowledge, did not adhere to those superstitions. "For example, they say that if you drink seawater, the color of infant's eyes will turn blue. It is superstitious. I do not accept anything like this." Pregnant women believe that the dietary style of pregnancy is different from that of pre-pregnancy. This is composed of 4 subcategories: "Paying attention to food unit and calorie", "Pre-pregnancy diet change", "Variety in food intake", "Local food consumption and herbal medicine in pregnancy" and "Supplements In pregnancy". Pregnant women participating in the present study emphasized the importance of the unit and amount of food consumed during pregnancy. "It's good for a pregnant woman to know what she's eating - how much protein she's eating - but well, it's hard for us to calculate especially now that we don't have the expertise." (P2). "Some foods should be consumed less while excessive consumption of certain foods is not good" (P3). According to pregnant women participating in the study, diet should be different from before pregnancy. "I had no interest in consuming sweets before I got pregnant but now I eat a lot of sweets" (P7). "One cannot eat anything like when she was not pregnant, but the amount of my food is lower than before "(P6). The participants acknowledged that the principle of diversity should be respected during pregnancy. For example, participant # 8 stated: "There is no need to eat special foods during pregnancy. Everything has to be eaten and I eat everything." Or another participant stated, "The doctor said, eat everything, but don't eat too much, and I eat everything"(P7). Concerning the subcategory of consumption of local food and herbal medicine in pregnancy some pregnant women believed that herbal medicine should not be used during pregnancy. For example, participant 1 acknowledged "gynecologist said that herbal medicine should not be used too much. The doctor said you could not take herbal medicine".

The perception of pregnant women participating in the study about the usefulness of supplements in pregnancy is significant. "I have a very severe anemia and I take iron pills now" (P4).

Pregnant women in the present study acknowledged that they gained information about their pregnancy nutrition through their surroundings and cyberspace. It consisted of two subcategories under the heading "Important Others" and "Trusting or not trusting the recommendations of important others". "Important others" in the present study are mother, mother-in-law, spouse, internet, cyberspace, friends, neighbors and books. For example, participant number one stated, "I use the Internet for my nutritional information."

"Older people were also recommending us to eat local bread and so we would" (P8). Some pregnant women trusted information, and some did not trust information from "important others".

"I am very attentive and act on the advice of my spouse, mother and mother-in-law" (P7).

"I listened to everyone around me and trusted them" (P8). "My mother-in-law doesn't do much for me. They don't say anything special about pregnancy. Of course, they used to say a lot about my previous pregnancy, but I didn't trust them very much and I didn't act" (P2). This

was composed of two subcategories, namely "neonatal jaundice inhibitors" and "delivery facilitators". Some pregnant women found the effect of consuming cool foods to prevent infant's jaundice. "I started consuming chicory tea right now to prevent my baby's jaundice. I use jujube as it is cool, so my baby doesn't get jaundice" (P7). "In the ninth month of my previous pregnancy, I always drank chicory tea which had a cool nature so that my baby would not get jaundiced" (P6). Pregnant women also believed that some foods such as saffron, rose water, barberry, etc., would facilitate delivery. "I believe vegetables would make delivery easier" (P7). "I have heard that eating saffron, barberry and honey and carrot in the last months will make your delivery easier" (P5). This part was composed of two subcategories which were "causes of neonatal jaundice" and" physical problems of pregnant women ". Some pregnant women saw the effect of warm-natured foods as a cause of neonatal jaundice. My first child had jaundice that was said to be due to eating warm-natured foods during pregnancy" (P5). Pregnant women reported some physical problems during pregnancy such as gastric bloating, weight gain and inactivity. "For example, when I eat too much, I get bloated or heavy in the stomach and I get hurt" (P6). "I have heard that we should not eat yogurt alone because yogurt alone can increase appetite and increase weight and lead to obesity" (P5). This part was composed of two subcategories, entitled "The Influence of Food from the Narrative View" and "Religious observance". Pregnant women found some foods to be effective on the baby's physical beauty and its intelligence. "I eat apples and peaches because I have heard them say that if you eat apples and peaches the baby will become beautiful" (P7). "I have read in the narratives that eating "Quince fruit" increases "the intelligence of a child" (P2). Pregnant women considered attending Quranic teachings and practicing hadiths effective during their pregnancy. "I read in the narrations that if I had ablution during my pregnancy, my baby would be quiet and in peace when born. So I am always with ablution" (P2). "I used to read surahs of the Quran during my pregnancy. I also read Quranic verses on fruits and then ate them" (P8). The theme consisted of two subcategories, namely "supportive behaviors of the husband" and "supportive behaviors of the mother or mother-in-law". Pregnant women stated that their husbands' support for nutrition during pregnancy was needed. "My husband urges me to consume fish, shrimp and sea food in general for their phosphorus." (P11). "My husband insists on not eating fast food and soft drink during pregnancy" (P4).

Supportive behaviors of mother/mother-in-law

Pregnant women stated that they were supported by their mother or mother-in-law and that the support they received, especially from their husbands, was found to be effective in helping to calm the heart. "One of the main people to tell me what to eat was my mom" (P2). "My mother-in-law advised me on the use of herbal medicine in pregnancy" (P12).

Discussion

In this study, Yazdi pregnant women share their experiences and perceptions about the dietary style of pregnancy, definitions of the concept of pregnancy nutrition, dietary restrictions, superstitions, information and trust sources, religious beliefs, social support, etc.

Sedaghati et al. argue that the importance of pregnancy is that maternal health directly influences the life of another person [2] In this regard, the participants emphasized the importance of healthy nutrition during pregnancy and considered it necessary to consume healthy foods; Kamalifard writes that proper nutrition is an important part of a healthy pregnancy and proper nutrition education can play an important role in promoting maternal and child health [13] which was consistent with the findings of the present study.

The perceptions of women participating in the study about unhealthy foods in pregnancy were consumption of leftover and multiple heated foods, fast foods and sauces. Sehati and colleagues acknowledge that the type of maternal nutrition of pregnancy affects the weight and birth of the infant [14], indicating the importance of consuming the necessary nutrients during this time. In this study, participants were also aware of the impact of eating healthy and adequate food during this time. Pregnant women in this study cited barriers to nutrition during pregnancy, such as poor economic status, unwanted pregnancy, not having enough time to cook because of employment, welfare, insufficient study, and lack of knowledge about proper nutrition. For a safe pregnancy, pregnant women should buy and consume food in an appropriate way. Women with poor economic status may face restrictions that may affect their pregnancy. In the study of Yadegari et al. (2017), 30.9% of pregnant women did not have food security; they stated that food security is related to socioeconomic factors of the family, monthly income and monthly cost of food supply [15]. Working women who participated in this study stated that they did not have enough time for cooking and preparing proper nutrition for themselves during pregnancy and therefore felt deficient in themselves; In this regard, Jong (2017) and colleagues in their study found that energy, protein, vitamin B2, vitamin C, calcium and potassium levels were significantly lower in working pregnant women [16]. The present study also emphasized unwanted pregnancy as a barrier to proper nutrition in the group discussion. Yazdkhasti et al. (2015) reported that about 40 percent of pregnancies in Iran are unwanted, with a greater percentage ending in miscarriage which can cause serious irreparable harm to the mother and also affect the quality of life [17]. Another obstacle to proper nutrition in pregnancy is the high prevalence of Hyperemesis gravid arum known as craving among pregnant women in the present study. Gabra (2018) emphasizes the psychological and brain complications and malnutrition and craving of pregnant women [18]. Having enough knowledge about pregnancy nutrition can have beneficial consequences for pregnant women, as Lee et al. (2018) concluded in their study that preg-

nant women did not have sufficient information about pregnancy nutrition and received inadequate nutritional information from healthcare providers [19] Karimi et al. (2017) study also showed that only 26% of pregnant women in Saveh had good knowledge about pregnancy nutrition [11]. Pregnancy dietary restrictions for women include foods that should not be eaten during pregnancy (for example, consumption of honey and carrot juice during the first months of pregnancy) and women fear and had a particular apprehension about consuming such foods in pregnancy. Therefore, in order to raise awareness, attitude, practice and reduce the concern of pregnant women regarding proper and inappropriate nutrition during pregnancy, it is recommended that educational programs based on dietary patterns appropriate to their beliefs and cultural behaviors be held for them before and during pregnancy. In a focus group discussion, most pregnant women stated that despite their strong interest in fast food, they did not eat it because it was harmful to their fetus and were part of their dietary restrictions. The results of a recent study on fast food consumption in pregnancy showed that repeated fast food consumption in pregnancy is associated with an increased risk of asthma and rhinitis in children [20].

Pregnant women in this study had to consume some foods because of their properties and even despite their high cost and had to avoid certain foods despite their interest. This topic is called the Voluntary / Forced Tendency Subcategory within the category "Mental Imagination about Pregnancy Nutrition". Concerning the above category, pregnant women reported a change in tastes and a pleasant feeling about some foods, which is in line with the results of Reyes et al.'s (2013) study [21]. In this study, despite women's high awareness of nutritional superstitions during pregnancy, they did not adhere to them and did not practice them. This finding was consistent with the study by Ugwa et al. [22] but was not consistent with the study of Demissie et al due to the high prevalence of food superstitions [23]. Concerning the description of the prenatal nutrition categories, extracted in the present study, in this study, a number of women during pregnancy had increased consumption of red meat due to vigorous anemia and relieving anemia and physical endurance compared to pre-pregnancy, which was not consistent with the study by Zerfu et al. (2016). Because they believed that a vegetarian diet based on the consumption of fruits and vegetables in pregnancy would make delivery easier [24]. Another finding of this study was that the majority of participants believed that due to the fetus's need for nutrition during pregnancy, the number of maternal meals should be increased and the amount of food consumed reduced, which was consistent with the study of Ugwa et al (2016) [22]. But it is not consistent with the results of the study by Ojofitimi et al. (1982) [25]. According to pregnant women in the present study, the principle of diversity should also be observed during pregnancy. During the day, in addition to food, other things such as fruits, vegetables and nuts should be eaten. In the view of the participants, all the food was of value. Balance means consuming sufficient quantities of food and diversity means consuming the types of foods that are in the food groups. In each food group, the nutritional value of the ingredients is approximately the same and suitable substitutes can be used [26]. According to research by Burrowes et al. (2006), physiological changes in pregnancy require more energy to deal with increased blood volume, maternal body tissue growth, fetal growth and development, and maternal readiness for breastfeeding, which can be supplied from a variety of foods [27]. This is an affirmation of the principle of diversity in pregnancy nutrition. Also, in this study, women tried to avoid excessive use of herbal remedies and, if necessary, had enough and used it with a doctor's prescription. This finding contrasts with the study by Forster et al. (2006) who used herbal remedies such as ginger and chamomile during pregnancy [28]. In this study, most pregnant women obtained their nutritional information through their physicians and healthcare providers, books, media, mothers, and mother-in-laws. Celia et al. (2016) stated in their study that the sources of knowledge of pregnant women included healthcare providers in healthcare, social settings, and mass media, which was consistent with the present study [29]. In addition, pregnant women identified their mother as one of the most important sources of information that they have high confidence in. Martel (1990) concludes in his study that when a girl becomes pregnant, intimacy between her and her mother increases, with girls receiving more help from their mother [30]. In another study by Hromi et al. (2016), family dietary recommendations have been considered an important factor in increasing fruit and vegetable consumption by pregnant women [31]. Another potential issue raised by the research units of this study was the role of facilitators of delivery. Pregnant women and their spouses in this study considered consuming rose water, saffron, and vegetables in the last months as a convenient delivery method; in a study by Lennox et al. (2017), eating less food was considered as a facilitator for childbirth [32]. In the study of Martin et al. (2015) having a Dietary Approaches to Stop Hypertension (DASH) diet was known to be a contributing factor to preterm delivery [33], which was in line with the positive outcomes of nutrition in pregnancy in the present study. The results of this study showed that a limited number of participants experienced physical problems during pregnancy such as gastric bloating, nausea, vomiting, weight gain and sedentary behavior. This finding is in line with the study by Yeasmin et al. (2016), in which some women reported having nausea and vomiting during pregnancy [34]. Pregnancy is typically considered a period of vulnerability for women and one of the major risk factors for maternal health is the lack of social support [35]. Spouses' support in this study was reported to provide the pregnant woman with food despite the high cost and psychological support. In the study of Ugwa et al (2016), about 53% of women had the support of their husbands, which was more effective than the support of others [22]. From the perspective of the women in this study, religious teachings have a significant effect on the type of food consumed by women during pregnancy and

lactation. Participants in this study found that halal eating during this time was effective; they also believe in that prayers such as Ziarat-e-Ashura, Ayat al-korsi, spiritual rituals, Qur'anic verses, and hadiths to calm and even enhance infant's memory. One of the most important factors that can have a profound effect on the human spirit and education is the issue of "eating the lawful and forbidden" and in this way he must make every effort to obtain a halal and not to eat but halal food. Nutrition is lawful and forbidden by the Creator. The effect of the halal food also affects the fetus in the mother's womb. The Prophet (peace be upon him) says: Raise your children in the womb of their mothers. How is this possible, or Prophet Muhammad? They said: by eating halal food to their mothers [36]. In general, it can be deduced that the women in the present study were bound to their own nutritional beliefs that derive from their culture, and this study was able to provide a clear picture of the cultural beliefs of Yazdi women regarding nutrition during pregnancy.

Conclusions

Health education experts should identify and explain qualitative approaches to pregnant women's nutrition beliefs during pregnancy and subsequently use culture-based approaches to minimize dietary misconceptions. It is suggested that proper education be provided to improve the nutrition of pregnant women.

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Conflict of interest statement

The authors declare no conflict of interest.

Authors' contributions

SSMM involved in the conception and designing the study. SS. wrote the manuscript and acted as corresponding author. MKH performed the data analysis and interpretation. SSMM, MKH, AN and HF supervised the development of work, helped in data interpretation and manuscript evaluation. SSMM helped to evaluate and edit the manuscript.

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ORIGINAL ARTICLE

Prevalence of rubella antibodies: comparison between women with pregnancy induced by infertility treatments and those with spontaneous pregnancy

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Keywords

Rubella antibody titer • Prevalence • Infertility treatments • Japan

Summary

Widespread rubella epidemics have sometimes occurred in Japan. We compared the prevalence of rubella antibodies in women who had conceived after infertility treatments and in those who had conceived spontaneously. We reviewed the obstetric records of nulliparous Japanese women who had conceived after infertility treatments and whose babies had been born at the Japanese Red Cross Katsushika Maternity Hospital from 2014 to 2018. No significant differences in the rates of women with rubella antibody titers < 8 or < 32 emerged between those who had been treated and those who had not (titer < 8: 4.1 vs. 3.4%, p = 0.58; titer < 32: 17.3 vs. 15.3%, p = 0.45, respectively). It is necessary to thoroughly implement pre-conception care concerning the risk of congenital rubella infection for women undergoing infertility treatments, especially in Japanese obstetric clinics.

Introduction

Infections can impact the reproductive health of women and hence may influence pregnancy-related outcomes for both the mother and the child. Rubella is usually a mild infectious disease, often accompanied by rash. In pregnant women, however, rubella infection can result in miscarriage, stillbirth and a series of disabilities known as congenital rubella syndrome (CRS) [1]. In developed countries, rubella vaccination programs have reduced the incidence of rubella and CRS [2, 3]. However, widespread rubella epidemics have sometimes occurred in Japan. For example, an outbreak of rubella and CRS among adult males occurred between 2012 and 2014, and a rubella outbreak among adult males has been rekindling since 2018 [4, 5]. Indeed, in October, 2018, the US Centers for Disease Control and Prevention (CDC) issued the following Practice Enhanced Precautions: Travelers to Japan should make sure they are vaccinated against rubella with the MMR (measles, mumps, and rubella) vaccine before travel, and pregnant women who are not protected against rubella through either vaccination or previous rubella infection should not travel to Japan during this outbreak [6].

Screening and vaccination for rubella infection should be a component of pre-conception care, as there is convincing evidence that vaccination against the infection before pregnancy prevents neonatal infections [7, 8]. In Japan, more than 5% of all pregnancies are the result of the implementation of assisted reproductive technology (ART) [9]. The period of infertility treatments also offers an opportunity for pre-conception care. In Japan, infertility treatment is mainly carried out by obstetricians, some of whom, however, may not be aware of the importance of CRS prevention during pre-conception care. In Japan, rubella antibody titers are measured in all pregnant women by means of the hemagglutination inhibition (HI) test during the first perinatal examination, the cost being borne by the national health service. We compared the prevalence of rubella antibodies in women who had conceived after infertility treatments and those who had conceived spontaneously.

Methods

The study protocol was approved by the Ethics Committee of the Japanese Red Cross Katsushika Maternity Hospital. Informed consent to the retrospective analysis of data was obtained from all subjects. Our institute is one of the main perinatal centers in Tokyo, Japan, and does not carry out any infertility treatments.

In Japan, all women undergo rubella antibody measurement at public expense during early pregnancy. We reviewed the obstetric records of all nulliparous Japanese women who had conceived after infertility treatments and whose babies had been born at the Japanese Red Cross Katsushika Maternity Hospital from 2014 to 2018. Age-matched nulliparous women who had conceived spontaneously and whose first prenatal examination had been carried out on the closest date were selected as controls. In this study, we compared the prevalence of rubella antibodies in the nulliparous women who had conceived after infertility treatments with those measured in the control group. Rubella antibody titers < 32, as measured by the HI test, were considered low, in accordance with

a previous report by Ozaki et al. [10]. Data are presented as numbers (percentage: %) or averages ± standard deviation. Statistical analyses were carried out by means of the statistical software SAS version 8.02 (SAS Institute, Cary, NC, USA).

Results

No differences in socio-demographic characteristics emerged between the 2 groups ($p > 0.07$), as shown in Table I. Table II shows rubella antibody titers, as measured by the HI test. There were no significant differences in the rates of women with rubella antibody titers < 8 or < 32 between the 2 groups: women who had conceived after infertility treatments and those who had conceived spontaneously (titer < 8: 4.1 vs. 3.4%, $p = 0.58$; titer < 32: 17.3 vs. 15.3%, $p = 0.45$, respectively).

Discussion

In terms of rubella antibody titers, this study did not reveal any effect of pre-conception care concerning CRS in infertility treatment facilities. During the period considered, the 411 nulliparous pregnant women who had undergone infertility treatment were referred from 38 ART facilities; however, the results of pre-pregnancy rubella antibody tests were reported only in the documents provided by two facilities (5.3%). Even though these women had attended pregnancy-related medical facilities, they did not seem to have benefited in comparison with women who had only undergone complete first examination. It must be pointed out, however, that some of these latter women have recently begun to undergo voluntary rubella testing because of the fear of rubella infection during pregnancy. Nevertheless, it is very disappointing that obstetricians, who are familiar with the risk of CRS, had failed to perform pre-conception care regarding rubella infection. There may be various explanations for this.

In our previous study, ART was seen to be associated with a lower prevalence of Chlamydia trachomatis (CT) infection before pregnancy [11]. Indeed, women who require ART may sometimes have a history of CT infection. However, women may not be checked for a history of rubella infection because this is not associated with the causes of infertility. Moreover, the fact that the information leaflet accompanying the rubella vaccine carries a warning that 'women of childbearing age should be careful not to get pregnant for about 2 months after vaccination' [12] might also have led ART facilities to refrain from checking for a history of rubella infection. Finally, neither health education nor a past history of vaccination were considered in the study, which is a major limitation.

Conclusions

Because doctors who treat infertility are also obstetricians, we expected women who received infertility treatment to have a higher prevalence of rubella antibodies. However, the results showed no difference in

Tab. I. Women socio-demographic features.

	Women who conceived after infertility treatments (n, %)	Women who conceived spontaneously (%)
Nulliparity	411 (100)	411 (100)
Maternal age (years)	37.0 ± 2.1	37.0 ± 2.1
Living in Tokyo	342 (83)	361 (88)
Economic difficulties*	0 (0)	4 (1)
Total	411	411

* Economic difficulties are defined according to the Japanese hospitalization assistance policy system [13].

Tab. II. Rubella antibody titers in nulliparous women who conceived after infertility treatments (n = 411) and those who conceived spontaneously (n = 411).

Rubella antibody titer* (%)	Women who conceived after infertility treatments (%)	Women who conceived spontaneously (%)
< 8	17 (4.1)	14 (3.4)
8	18 (4.4)	15 (3.6)
16	36 (8.8)	34 (8.3)
(< 32)	71 (17.3)	63 (15.3)
32	106 (26.8)	91 (22.1)
64	114 (27.7)	126 (30.7)
128	69 (16.8)	81 (19.7)
256	36 (8.8)	29 (7.1)
> 256	15 (3.6)	21 (5.1)
Total	411	411

* Rubella antibody titer measured by hemagglutination inhibition test.

rubella antibody titers between the two groups. Given that rubella epidemics have frequently occurred in Japan, it is necessary to thoroughly implement pre-conception care concerning the risk CRS for women undergoing infertility treatments, especially in Japanese obstetric clinics. We believe that this is the duty of the obstetrician, who is most familiar with the risk of CRS.

Availability of data and materials

The datasets are not open to the public.

Ethics approval and consent to participate

This study was carried out in accordance with the Declaration of Helsinki. Informed consent for data analysis was obtained from all subjects. The protocol was approved by the ethics committee of the Japanese Red Cross Katsushika Maternity Hospital.

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Conflict of interest statement

The authors declare no conflict of interest.

Authors' contributions

YH: collected the data and wrote and reviewed the manuscript. SS: designed the report, analyzed the data, wrote and reviewed the manuscript, and approved the final draft.

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ORIGINAL ARTICLE

Risk factors associated with serious bacterial infections among newborns with high body temperature

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Keywords

High body temperature • Fever • Newborns • Serious bacterial infection • Dehydration • Hyperthermia

Summary

Introduction. *Recognizing the importance of serious bacterial infections (SBIs), study aimed to identify factors associated with high body temperature in newborns.*
Methods. *A convenience sample of 54 newborns admitted to our hospital in Iran (March-July 2015) with rectal temperature > 38°C (100.4°F) were examined for clinical signs, blood cultures, complete blood counts, platelets, Erythrocyte Sedimentation Rate (ESR), C-reactive protein (CRP), renal function, chest/abdominal x-rays, spinal tap, and history of maternal infections.*
Results. *Newborns had either fever due to infections, or hyperthermia due to dehydration and/or extreme warm environment. Bacterial infections (37%) included: sepsis (15%) (coagulase-positive or coagulase-negative Staphylococci, Enterobacter, Klebsiella, Escherichia coli), meningitis (13%), and 3.5% UTI, 3.5% pneumonia, 2% cellulitis, and 2% omphalitis. Degrees of dehydration experienced by 55.6% included 37% of cases associated with hyperthermia caused by warm clothing/environment, while in 18.6% dehydration was secondary to fever. Viral infections (11%) included upper respiratory infections, gastroenteritis, while in remaining 13% cause of high body temperature was unknown. The group with SBIs had higher chance of having history of PROM (premature rupture of membrane) ($p = 0.023$), positive CRP ($p = 0.041$), and abnormal platelets count ($p = 0.021$) comparing all others.*
Conclusions. *High body temperature in newborns needs careful evaluation to identify fever due to SBIs. In sepsis cases, antibiotics should cover prevalent bacteria including Staphylococci and Enterobacter. Dehydration was prevalent among newborns with high body temperature due to hyperthermia or secondary to infections. To avoid hyperthermia, parents should know how to clothe their newborns appropriate for environmental temperature. Newborns' SBIs associated with positive CRP, abnormal platelet count, and maternal PROM.*

Introduction

High body temperature in newborns may be identified as either fever or hyperthermia.
Fever is caused by hyper-metabolism due to infection or stress. However, hyperthermia is caused by extreme warm environment. Fever in infants under three months old should be considered an emergency and receive appropriate treatment [1]. References have indicated that bacteremia develops in 2.2% to 5% of febrile infants under three months old [2, 3]. Premature babies born earlier than 37 weeks of pregnancy are 10 times more likely to develop sepsis. In premature babies who develop unstable temperatures or hypothermia rather than fever, these signs may be masked by incubator which holds the neonate. The need to increase the incubator's temperature may suggest that hypothermia is present [4, 5].
Hyperthermia as the result of dehydration during the second or third day of birth is prevalent, especially in breastfed neonates who are usually prone to receiving insufficient milk. Other causes of hyperthermia secondary to dehydration in newborns usually include warm environments such as an incubator, blankets covering the newborn, proximity to heat sources like heating radiator, or exposure to sunlight. Several differential diagnostic signs between hyperthermia due to dehydration versus fever caused by infections are the dehydration signs such as reduction in urine volume, reduced elasticity of skin, and fontanelle closure which is bulged inward. Neonate is eager to drink liquids and is not as ill as a neonate who is suffering from an infection. In that case, feeding the neonate with milk or liquids or providing parenteral liquid therapy as well as reducing the temperature of the baby's environment will help in reducing the baby's body temperature and improving baby's health. Untreated dehydration may develop hypernatremia that may cause convulsion [6]. In addition to infections and hyperthermia/dehydration, other reasons for development of high body temperature include central nervous system dysfunctions, hyperthyroidism, familial dysautonomia, and ectodermal dysplasia [5].
A publication from Greece in 2005 showed that half of the studied neonates with fever had a systemic bacterial infection while the other half had a viral infection [7].
Meanwhile, regardless of the cause of fever and hyperthermia in babies, it is important to correct any water and electrolytes imbalances.

Objectives

This study evaluated the factors associated with high body temperature in neonates admitted to our hospital

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in Iran while focusing on identifying serious bacterial infections.

Methods

In a prospective observational case-series study in an academic hospital in Iran, from March to July in 2015 neonates who had developed high body temperatures and were consecutively admitted to our hospital entered a pilot study.

A convenience sample of 54 recruited neonates had rectal temperatures over 38°C (100.4°F) or an axillary temperature over 37.5°C (99.5°F) at the time of admission [1]. Neonates were examined for causes of high body temperature to differentiate fever (due to infections) from hyperthermia. Both pre-mature and term newborns with high body temperature including newborns with fever due to early-onset sepsis (blood or cerebrospinal fluid (CSF) infections within the 3rd to 7th days of birth) and late-onset sepsis entered the study [8].

Samples from blood, urine, and CSF were collected before starting antibiotic therapy. Blood or urine culture, complete blood count (CBC), platelets (Plts), estimated sedimentation rate (ESR), C-reactive protein (CRP), renal function tests, chest or abdominal X-rays, and CSF tests were performed. The recorded data included family history, history of fever and maternal infections, and the results of clinical and laboratory evaluations.

Statistical analysis

Continuous data were averaged and compared between groups through t tests. Dichotomous data were presented as numbers and percentages and compared through chi-squared tests. All newborns were divided into two groups: serious bacterial infections (SBIs) and non-bacterial causes. Chi-square statistics compared those two categories.

No patient had any missing data. IBM SPSS Statistics 20 was used for statistical analysis. P values less than 0.05 defined statistical significance.

For seven patients who left the hospital earlier than their discharge date, their cultures came in afterward and their results were also included in the study.

Tables A-C in the Appendix explain the methods used to diagnose the etiologies for high body temperature in admitted newborns as well as show specific criteria for diagnosing SBI.

The study was approved and funded by our University based on prevailing ethical principles. Informed consents from the newborns' parents were obtained.

Results

We studied 54 newborns admitted to our hospital. Newborns' rectal temperatures at the admission time averaged 39.1°C (102.38°F), range of 38°C (100.04°F) to 41.5°C (106.7°F).

The average for baby's weight at the time of admission was 2,908 grams (1,650-4,600 grams range). Tables I and II show the numbers and percentages of attributes found in newborns.

Tables III and IV show the comparisons between newborns with and without SBIs.

Serious bacterial infections included sepsis (*coagulase-positive* and *coagulase-negative Staphylococci*, *Enterobacter*, *Klebsiella* and *Escherichia coli*), meningitis, urinary tract infections (UTI), pneumonia, cellulitis, and omphalitis. One newborn had both UTI and sepsis (positive culture). Mortality was 4 (7.4%).

Viral infections included upper respiratory infections and gastroenteritis. Different degrees of dehydration were experienced by 55.6% of newborns when dehydration was present secondary to infections in 18.6% of newborns but in 37% of newborns, dehydration was present due to warm clothing/environment which associated with hyperthermia (Tab. II; Fig. 1).

All viral/bacterial sepsis cases (8 or 14.8%) were preterm (two of them with positive culture), i.e., all preterm babies (8 or 14.8%) had sepsis.

Our data showed the group with SBI had higher chance of having history of premature rupture of membrane (PROM) ($p = 0.023$), positive CRP ($p = 0.041$), and abnormal platelet count ($p = 0.021$) compared to the rest of newborns (Tab. III).

T tests comparing the averages for absolute numbers of WBCs and polymorphonuclears among bacterial infections and non-bacterial cases showed no statistical significance (Tab. IV).

Tab. I. Attributes of neonates with high body temperature. .

Attributes	Percent	Frequency	Notes
GA (term babies) *	85.2%	46	Another 8 babies were pre-term
Sepsis	15%	8	All sepsis cases were pre-term (2 were culture positive)
PROM in mothers	5.6%	3	Longer than 24 hours
Presence of infection in mother	9.3%	5	
Presence of viral infection in family	9.3%	5	
Breast feeding	98.1%	53	

*Based on sonography findings, term newborns had gestational age range between 37 to 41 weeks with average of 38 weeks and 5 days. Preterm newborns had gestational age range between 33 weeks and 5 days to 36 weeks and 4 days with average of 35 weeks and 2 days. GA: gestational age; PROM: premature rupture of membranes. However, to avoid complexity, the overlaps of attributes in each newborn are not presented in this table (n = 54)

Tab. II. Findings in newborns with high body temperatures.

Findings in newborns with high body temperature	Percent	Number
Asphyxia	5.6%	3
Cerebral bleeding	3.7%	2
Kernicterus	0%	0
Dehydration of the neonate	55.6%	30
History of maternal hyperthyroidism in mother	0%	0
History of diabetes insipidus in mother	0%	0
Hyperglycemia in mother	3.7%	2
Blood culture		
Sterile blood culture	81.5%	44
Staphylococcus coagulase negative (2 contamination)*	7.4%	4
Staphylococcus coagulase positive	3.7%	2
Enterobacter	3.7%	2
Klebsiella	1.9%	1
Escherichia coli	1.9%	1
Positive urine culture	3.7%	2
Lumbar puncture (no cerebrospinal fluid smear was tested, all sterile cultures)		
Positive cerebrospinal fluid culture	0%	0
Abnormal cell counts, glucose, and protein levels	13%	7
Cultures performed based on the suspicion of local infection		
Positive eye secretions	9.3%	5
Positive peri-umbilical secretions	1.9%	1
Positive for pseudomonas aeruginosa (secretions from intubation tube)	1.9%	1
Abnormal urinalysis (includes 2 UTIs from above)	16.7%	9
Abnormal creatinine for the age of newborn	24.1%	13
Abnormal urea	31.5%	17
CRP		
Normal	83.3%	45
+	7.4%	4
++	1.9%	1
+++	3.7%	2
++++	3.7%	2
CBC		
Leukopenia	1.9%	1
Leukocytosis	3.7%	2
Platelet counts (normal)	90.7%	49
Thrombocytosis	1.9%	1
Thrombocytopenia	7.4%	4
ABG		
Normal ABG	68.5%	37
Acidosis	29.6%	16
Alkalosis	1.9%	1
Abnormal ESR	14.8%	8
Sodium		
Normal	83.3%	45
Hyponatremia	1.9%	1
Hypernatremia	14.8%	8
Main complaint at admission time		
Poor feeding	25.9%	14
Respiratory (distress, tachypnea, apnea, wheezing)	25.9%	14
Irritability	14.8%	8
Being ill, lethargic, poor health condition	13%	7
Dehydration and diarrhea	11.1%	6
Convulsion	11.1%	6
Icterus	9.3%	5
Fever only	3.7%	2
Others	16.7%	9

*Blood culture: if the laboratory results came positive for coagulase negative staphylococcus, the diagnosis was performed based on the clinical condition of the patients to identify the false positive cultures due to contamination. This row includes 2 newborns having contamination. PROM (including preterm or pre-labor): when the sac containing the fetus and the amniotic fluid develops a hole or bursts prior to the start of labor. UTI: urinary tract infection; CRP: C-reactive protein; CBC: complete blood count; ABG: arterial blood gas; ESR: erythrocyte sedimentation rate. However, to avoid complexity, the overlaps of attributes in each newborn are not presented in this table (n = 54).

Tab. III. Descriptive and comparative results for causes of high temperature in neonates (N = 54).

Factors	Attributes	Serious bacterial infections (N = 20)	Non-bacterial causes (N = 34)	Chi-square	P value
GA (Gestational Age)	Term Pre-term	90% (18) 10% (2)	82.4% (28) 17.6% (6)	0.58	0.441
PROM (Premature Rupture of Membranes)	Positive history Negative history	15% (3) 85% (17)	0% (0) 100% (34)	5.40	0.023*
Maternal infection	Positive history Negative history	10% (2) 90% (18)	8.8% (3) 91.8% (31)	0.02	0.890
Rectal temperature	≥ 39°c < 39°c	60% (12) 40% (8)	67.6% (23) 32.4% (11)	0.32	0.571
APX (Asphyxia)	Positive history Negative history	5% (1) 95% (19)	5.9% (2) 94.1% (32)	0.02	0.891
ESR (erythrocyte sedimentation rate)	Normal Abnormal	75% (15) 25% (5)	91.2% (31) 8.8% (3)	2.61	0.112
CRP (C-Reactive Protein)	Positive Negative	30% (6) 70% (14)	8.8% (3) 91.2% (31)	4.07	0.041*
PLT (Platelet Count)	Thrombocytopenia Normal PLT Thrombocytosis	20% (4) 80% (16) 0% (0)	0% (0) 97.1% (33) 2.9% (1)	7.79	0.021*
CBC (Complete Blood Count)	Leukopenia Normal leukocyte Leukocytosis	5% (1) 90% (18) 5% (1)	0% (0) 97.1% (33) 2.9% (1)	1.91	0.384
ABG (Arterial blood gas)	Normal Abnormal	75% (15) 25% (5)	64.7% (22) 35.3 % (12)	0.62	0.432
Creatinine	Normal Abnormal	70% (14) 30% (6)	79.4% (27) 20.6% (7)	0.61	0.433
Urea	Normal Abnormal	65% (13) 35% (7)	70.6% (24) 29.4% (10)	0.18	0.671

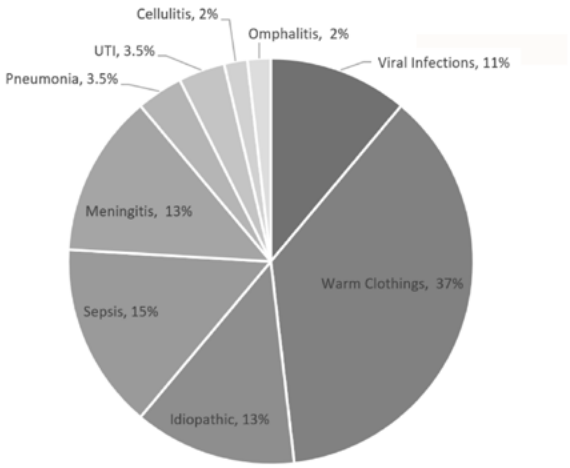
*P values less than 0.05 are statistically significant, in 2x2 tables with degree of freedom of 1, the X2 values higher than 3.84, and in 2x3 tables with degree of freedom of 2, X2 > 5.99. In the above cases, the p values < 0.05 were considered significant to address 95% confidence level. However, if the confidence level decreased to 90%, the difference between ESR levels between the two groups showed that high level of ESR was correlated with the presence of bacterial infection in neonate (p = 0.11).

Tab. IV. Differences in white blood cell and neutrophil counts between bacterial and non-bacterial cases of high body temperature in neonates (n = 54).

	Serious bacterial infections mean (SD)	Non-bacterial cases mean (SD)	T value	P value
WBC	11,042.50 (5,095.23)	11,070.59 (513.045)	0.02	0.985
Neutrophil	5,748.35 (3,235.35)	8,279.70 (8,521.27)	1.27	0.210

Degree of freedom (DF) is 52, p values less than 0.05 and t values higher than 1.68 are significant. SD: standard deviation; WBC: white blood cell.

Fig. 1. Diagnosed factors which were associated with high body temperature in newborns (n = 54). Bacterial infections comprised 20 (37%) of total patients. One newborn had both urinary tract infection and sepsis. Cases diagnosed as sepsis included three categories: 2 were certain sepsis, 5 were probable sepsis, and 1 was clinical sepsis. Viral infections included upper respiratory infections 5 (9.3%) and gastroenteritis 1 (1.8%).



Discussion

This study described the factors that associated with high body temperature among 54 newborns. Since infections are one of the most important causes of mortality in newborns [9], we prioritized the detection of SBIs among newborns to start proper treatment. However, dehydration and/or hyperthermia were the most prevalent factors associated with high body temperature in our patients. Cases diagnosed as fever included bacterial sepsis (*coagulase-positive* and *coagulase-negative Staphylococci*, *Enterobacter*, *Klebsiella*, and uro-sepsis due to *Escherichia coli*), meningitis, viral infections (upper respiratory infections and gastroenteritis), urinary tract infections, pneumonia, omphalitis, and cellulitis. Secretions from an intubation tube came positive for pseudomonas aeruginosa. In 7 cases (13%) no reason for fever was identified.

Our data showed the group with SBIs had higher chance of having history of PROM, positive CRP, and abnormal platelets count [10] compared to the rest of newborns with high body temperatures.

Similar to our results, other studies have shown PROM is a risk factor for developing bacterial infection such that the incidence of sepsis in newborns following PROM longer than 24 hours increased to 8.1% in another study [11-13].

Among the bedside tests for predicting the occurrence of serious bacterial infections, when no source of infection was identified, blood procalcitonin (PCT) and CRP performed better than interleukin 6 (IL-6), WBC, and/or band count in a study in Geneva on febrile children younger than 36 months old [14].

Another study showed that compared to CRP level and the ratio of pre-mature neutrophils to the total neutrophil count, ESR level had less specificity for diagnostic purposes [13]. False positive ESR tests in hemolysis and false negative response in DIC have been observed [15].

Baby's physiologic responses to warm environment include vasodilation of blood circulation in the surface skin and perspiration to lose heat. Although in premature neonates, perspiration system may not be fully functional. When there is a fever developed due to hypermetabolism caused by either infection or some stimulating drugs, the rectal temperature will be higher than the skin temperature. In this case, since vasoconstriction reduces blood circulation in lower extremities, the feet will be more than 3°C colder compared to the skin temperature in the abdominal area. However, if the body's high temperature is due to staying in warm environment, the rectal temperature will be lower compared to the skin temperature while the temperatures of feet and abdominal skin are close [16].

Other researchers have reported that frequency of SBI is about 10% among newborns, 5% among infants under 3 months old, and between 0.5 to 1% among older infants and toddlers [16]. The mortality of SBI among newborns is about 10%. The degree of concern of either the parents and/or the physician is important warning signs for SBI. Clinical signs of SBI include tachypnea, cyanosis, impaired peripheral perfusion, petechiae, and a rectal temperature above 40°C. Antipyretic drugs can be used only in special, selected situations [16]. More than 40% of cases of fever of unknown origin (FUO) are due to infections. For over 30% of cases, the cause of fever is never determined [17].

Due to the importance of timely diagnosis of SBI, it is essential that the newborn having fever receives repeated physical examinations. Parent counseling in addition to making sure that medical and nursing staff have received education about the warning signs for SBI are important aspects in management of fever in newborns [18].

In this study, 37% of neonates had fever caused by SBIs which shows a higher rate compared to other studies reporting 10% prevalence of bacterial infections in hospitalized febrile neonates [5]. In another study, in febrile infants younger than three months old, pathogen bacteria were found in 27% of those cases [4]. A study in France showed that in febrile infants younger than three months old, SBIs including meningitis, osteoarthritis, cellulitis, UTI, pulmonary infections, and gastroenteritis comprised 10% of the cases while two third of fever cases were reported to be due to viral agents [18].

Our results showed higher prevalence of SBIs in febrile neonates compared to research results from the Western countries. However, our results were close to research results in Taiwan which is an Asian country and showed higher rates of sepsis among neonates [19].

Yet, fever can be a sign rather than an illness since it may even benefit the body in battling against the infections. Providing cold environment to bring down the body's temperature has been proved to benefit the neonates who have developed high body temperature due to exposure to hot environments. However, it is less clear if cooling down methods can similarly benefit neonates that have developed fever due to sepsis or other internal stresses.

Since the incidence of meningitis in neonatal period is higher compared to any other period of life, a neonate with septicemia should be evaluated for meningitis also. Less than one third of septicemia cases in neonates are due to meningitis. Neonatal fever due to pneumonia may develop following aspiration in birth canal during delivery, transferred germs from mother (trans placental), or acquired from the environment. Also, in 3% of pre-term and 1% of term neonates fever may develop due to urinary tract infections [20].

Limitations

Since data collection was not through randomized-controlled trial, factors associated with high body temperature were identified rather than factors causing it. Also, larger sample size may increase the power of the statistical calculations.

Stratification of the neonates according to their age could have provided more information. Also, as other researchers have reported the presence of fungal infections in Neonatal Intensive Care Units (NICUs), we missed to test and to look for possible fungal infections [21].

Conclusions

In newborns with high body temperature identifying bacterial fever is urgent. Dehydration was prevalent due to either hyperthermia or secondary to an infection. To reduce neonatal hyperthermia/dehydration, parents should learn how to clothe their newborns appropriate for the temperature in their environment.

For sepsis, antibiotics should cover prevalent bacteria (*Staphylococci* and *Enterobacter*).

SBIs in neonates associated with having history of PROM, positive CRP, and abnormal platelet count.

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Conflict of interest statement

The authors declare no conflict of interest.

Authors' contributions

AN and NTT both contributed to designing the study and writing the manuscript.

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Appendix

Tab. A. Methods defining diagnostic criteria (n = 54).

Diagnostic criteria followed in this study to identify different disease conditions.	
Definite septicemia	Clinical signs, positive blood culture, with/without changes in CBC, ESR, and CRP
Probable septicemia	Clinical signs, negative blood culture, abnormal CBC, ESR, and CRP
Clinical septicemia	Strong clinical signs, negative blood culture, normal CBC, ESR, and CRP
Definite meningitis	Abnormal CSF and positive CSF culture
Probable meningitis	Abnormal CSF and negative CSF culture
Pneumonia	Clinical signs and positive chest X-ray
UTI	Positive urine culture collected through suprapubic aspiration method
Hyperthermia	Is the status when body's peripheral temperature is either the same or higher compared to body's central temperature. Hyperthermia associated with dehydration. Causes included the high temperature of the environment and/or wearing too warm clothing. There were no signs of sepsis/infections
Viral infections	The diagnosis was based on the presence of the signs for common cold, coryza, the history of recent viral infection in the family, or a mix of all above, or gastroenteritis with negative stool smear and culture for bacteria. The work up for sepsis was negative
Idiopathic high body temperature	When no clinical and para-clinical reasons for high body temperature were found
PROM	When membrane ruptures before the start of labor

ESR: erythrocyte sedimentation rate; CBC: complete blood count; CSF: cerebrospinal fluid; CRP: C-reactive protein; UTI: urinary tract infection; PROM: premature rupture of membrane.

Tab. B. Factors for identifying different states to diagnose disease conditions (n = 54).

Infection in mother	Fever around the time of delivery, signs of chorioamnionitis (maternal fever, tenderness of uterus, fetal tachycardia), or maternal urological infection towards the end of pregnancy and around the delivery, the history of viral infection (i.e. common cold or coryza) in the family
APX	The history of neonatal asphyxia at delivery reported by mothers (the timing of first cry, presence of cyanosis in baby, baby's breathing status) and/or presence of low Apgar number recorded in the birth card were evaluated
Kernicterus	Diagnosed based on clinical signs and high levels of serum bilirubin
Staying in a warm environment	Determined based on the parents' attitude towards the room temperature and evaluating their judgement
Clothing	The presence of too many layers or thickness of clothing were evaluated
Hyperglycemia	Serum glucose levels above 180 mg/dl in addition to glycosuria and dehydration were counted as hyperglycemia
WBC count	Between 4,000 to 25,000 per microliter during the first days after birth and after that period, the normal range based on baby's age were evaluated. The values above normal were counted as leukocytosis and the values below normal were considered leukopenia
PLts count	Between 100,000 to 450,000 per microliter were considered normal range. Less than 100,000 was considered thrombocytopenia and above 450,000 was considered thrombocytosis
Estimated ESR	The normal range for ESR was determined in relation to the baby's age based on number of days plus number 3, to the maximum number of 15
ABG	PH between 7.35 and 7.43 was considered normal. PH below 7.35 was considered acidosis and PH above 7.43 was considered alkalosis
Hypernatremia	Was determined when serum sodium level was above 150 mEq/L and hyponatremia was determined when it was below 130 mEq/L
Meningitis	Meningitis cases were diagnosed based on changes in cells, glucose, and proteins in CSF (all CSF cultures were negative and CSF smear was not tested due to limited logistics)

APX: asphyxia; WBC: white blood cell; PLts: platelets; ESR: erythrocyte sedimentation rate; ABG: arterial blood gas; CSF: cerebrospinal fluid.

Tab. C. Criteria to diagnose sepsis (n = 54).

Clinical examination
Increase or decrease in blood neutrophil count
Increase in band cell count
Increase in ESR and/or CRP
Blood culture of at least 1 milliliter blood sample from peripheral vein (and not from intravenous catheter)
Lumbar puncture to test cerebrospinal fluid
Urinalysis to detect bacterial antigens (urine was collected through suprapubic aspiration to avoid external contamination of sample)
Chest X-ray, simple abdominal X-ray
Granulocytopenia indicates that the body antimicrobial system is exhausted

ESR: erythrocyte sedimentation rate; CRP: C-reactive protein.

ORIGINAL ARTICLE

Factors influencing flu vaccination in nursing students at Palermo University

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Keywords

Surveys and questionnaires • Nursing students • Sicily • Cross-sectional study • Influenza vaccine

Summary

Introduction. *The purpose of this study was to ascertain the determinants of nursing students' compliance with flu vaccination.*
Methods. *In this cross-sectional study, an anonymous paper questionnaire was administered to students attending the 3-year nursing course at the University of Palermo. Adjusted Odds Ratios (aOR) are presented.*
Results. *403 nursing students (65% female) completed the questionnaire (response rate 98.5%). The average age of the respondents was 22.0 years (SD ± 3.04). The dependent variable: "In the next season, do you intend to be vaccinated against flu? Yes", displayed a statistically significant association with the following independent variables: "year of study: second" (aOR 2.66), "year of study: third" (aOR 1.72), "Perceived health status: medium-high" (aOR 6.61), "Did you get vaccinated against seasonal flu last year? Yes" (aOR 22.47).*
Conclusions. *Although nursing students are not yet health professionals, they spend part of their time in health facilities for their clinical training and will be the health workers of the future. Involving nursing students in influenza vaccination campaigns can also help them take better care of themselves and their patients.*

Introduction

In a period in which the sustainability of health systems is at risk, disease prevention is of fundamental importance and constitutes a valid "investment" in health. Vaccinations are the most effective and safe public health interventions for the primary prevention of infectious diseases, and their impact goes well beyond health [1]. Indeed, the infectious diseases for which vaccination is available have been drastically reduced and remarkable results have been achieved, such as the eradication of smallpox and, in most countries, of polio. Determining the burden and the resulting economic costs attributable to influenza viruses is critical to directing decisions regarding public health programs. The burden of influenza disease can vary widely and is determined by a number of factors, including the characteristics of circulating viruses, the timing of the influenza season and the number of people who are vaccinated. Seasonal influenza imposes a yearly disease burden in terms of morbidity and mortality. It causes illnesses that range in severity and sometimes lead to hospitalization and death. The World Health Organization (WHO) estimates that seasonal influenza may result in 290,000-650,000 deaths each year due to respiratory diseases alone [2].
In Italy, in accordance with the provisions of the 2017-2019 National Vaccine Prevention Plan, flu vaccination is actively recommended and offered free of charge to certain groups of people whose professional exposure or health conditions place them at higher risk [3]. The "ideal" vaccination coverage objective is 95%, while the "minimum" target is 75%.
However, influenza vaccination coverage in both the global population and at-risk categories is far below these targets. In the 2017-2018 season, coverage was 15.3% in the general population, while in the period 2014-2017, the average coverage among people aged 18-64 with at least 1 chronic disease was 20.3%, ranging from 15% to 29% according to the specific pathology and the region considered [4]. Influenza prevention, control and preparedness are vital to ensuring the sustainability of national programs, which constitute an investment in healthcare systems and improve pandemic preparedness. As the resources available for health promotion and disease prevention are limited, one reason to increase influenza vaccination is to reduce the impact of virus-associated morbidity and mortality in the population, especially in the groups at greatest risk (elderly, children, patients with chronic medical conditions and pregnant women). Protecting subjects at risk also involves implementing policies to increase the immunization of healthcare workers (HCWs), who are at increased risk of contracting infections and further transmitting them to colleagues and patients [5]. While immune HCWs act as a barrier against the spread of infections, vaccine uptake rates in HCWs have often been low [5]. Therefore, the aim of this study was to ascertain the determinants of vaccination uptake in nursing students.

Methods

This cross-sectional descriptive study was approved by the Ethics Committee of the Paolo Giaccone University

Hospital in Palermo, Minutes No. 07/2019 (No. 25) of July 17, 2019. In May 2019, a survey was administered to students attending mandatory daily lectures on the 3-year nursing science course at the University of Palermo. Informed consent was provided by all participants. The questionnaire was adapted from another study [6] by the authors and consisted of three sections. The first section gathered socio-demographic information. In the second section, participants were asked if they had been vaccinated during the previous flu campaign, if they intended to be vaccinated during the next campaign and if, as health workers, they felt more at risk of contracting infectious diseases. In the third section, respondents were asked to indicate the single main reason why they were or were not vaccinated during the previous vaccination campaign. A multivariable logistic regression analysis was performed, in which the dependent variable was: "Do you intend to be vaccinated against the flu during the next season? Yes", in order to evaluate the role of the variables in the questionnaire. The statistical significance level chosen for the entire analysis was 0.05. For all the qualitative variables, absolute and relative frequencies were calculated. Results are expressed as adjusted Odds Ratios (aOR) with 95% Confidence Intervals (CI). The data were analysed by means of the STATA statistical software version 14 [7].

Results

A total of 403 nursing students took part in the survey, 65.01% of whom were females; all participants were born in Italy, and their mean age was 22.02 (SD ± 3.04) years. All students attending the 3-year nursing course at the University of Palermo received a questionnaire and an informed consent form. The total number of students enrolled in the nursing degree course was 409; the response rate was therefore 98.53%.

Almost 38% of respondents were attending the first year of the nursing science course. A description of the sample is shown in Table I: 82.88% of respondents perceived themselves as having a medium-high economic status and 95.04% perceived their health status to be medium-high; 62.53% consider themselves to have a higher risk of contracting infectious diseases owing to their future profession, but only 21.09% had been vaccinated against seasonal flu the previous year. Table II show the reasons why flu vaccination was/was not carried out.

The results were somewhat contradictory: 37.65% of participants underwent vaccination because they considered themselves to be at greater risk of infection, and 36.47% in order to protect their family and the general population from the flu virus. By contrast, 35.54% did not have flu vaccination because they did not consider themselves to be at greater risk of infection, and 26.11% because it was not strongly recommended during their studies.

Table III shows the results of the multivariable logistic regression and Adjusted Odds Ratios. Considering as a dependent variable: "During the next season, do you intend to be vaccinated against flu? Yes", the independent variables showing a statistically significant association were: "year of study: second" (aOR 2.66, 95%CI 1.45-

Tab. I. Sample description.

		N (%)
Gender	Female	262 (65.01)
	Male	141 (34.99)
Country of birth	Italy	403 (100.00)
	Other	0 (0.00)
Off-site, on-site or commuter students	Off-site	112 (27.79)
	Commuter student	106 (26.30)
	On-site	185 (45.91)
Year of study	First	153 (37.97)
	Second	115 (28.54)
	Third	135 (33.50)
Perceived economic status	Medium-high	334 (82.88)
	Low	69 (17.12)
Perceived health status	Medium-high	283 (95.04)
	Low	20 (4.96)
Do you have chronic diseases (more than 6 months)?	No	363 (90.07)
	Yes	40 (9.93)
Considering your future profession and your state of health, do you consider yourself to have a higher risk of contracting infectious diseases?	No	151 (37.47)
	Yes	252 (62.53)
Were you vaccinated against seasonal flu last year?	No	318 (78.91)
	Yes	85 (21.09)
Do you intend to be vaccinated against flu during the next season?	No	215 (53.35)
	Yes	188 (46.65)
Age	22.02 (SD ± 3.04)*	

*mean (Standard Deviation)

Tab. II. Reasons why flu vaccination was/was not carried out.

I decided to get vaccinated because:	N (%)
I consider myself to be at greater risk of infection	32 (37.65)
To avoid infecting my family or other people	31(36.47)
To avoid infecting patients	17(20.00)
It was strongly recommended by the facility where I study or do my internship	5 (5.88)
I decided not to get vaccinated because:	**N (%)**
I don't consider myself to be at greater risk of infection	113 (35.54)
It wasn't strongly recommended by the facility where I study or do my internship	83 (26.11)
I forgot to be vaccinated	52 (16.36)
I do not think it is an effective vaccination	32 (10.02)
I do not consider myself to be a source of infection for my family or others	29 (9.13)
I do not consider myself to be a source of infection for patients	9 (2.84)

4.90, p = 0.002), "year of study: third" (aOR 1.72, 95%CI 1.13-3.14, p 0.010), "Perceived health status: medium-high" (aOR 6.61, 95%CI 1.15-37.86, p = 0.034), "Did you get vaccinated against seasonal flu last year? Yes" (aOR 22.47, 95%CI 9.28-54.39, p < 0.001). Each independent variable is adjusted for all the other independent variables (based on 403 observations) in Table III.

Discussion

Among young university students, the quality of information, the modes of communication and the development of critical skills towards a non-imposed choice of lifestyles and behaviors in line with public health policies are important [8, 9]. Nursing students are future healthcare professionals and, as such, will have a major influence on patients' health choices. Reducing the influenza burden is important and the most effective means of achieving this is influenza vaccination [10].
According to the European Centre for Disease Prevention and Control, the term "determinants of vaccination" covers barriers to and enablers of vaccination uptake, reasons for refusing vaccination, beliefs and attitudes towards vaccination, and system design-mediated factors [11]. The SAGE Working Group "Model of determinants of vaccine uptake" categorized [12] these determinants as contextual, individual and group influences and vaccine- and vaccination-specific issues. Contextual influences include the historic, social, cultural, environmental, economic, political and institutional factors which might influence vaccine hesitancy. Individual and group influences include personal percep-

Tab. III. Multivariable logistic regression. Adjusted Odds Ratio are presented. Each independent variable is adjusted for all the other independent variables. Based on 403 observations.

		Dependent variable: during the next season, do you intend to be vaccinated against flu? Yes		
Independent variables		**aOR**	**95% CI**	**p-value**
Gender	Female	1		
	Male	0.68	0.41-1.15	0.150
Are you an off-site, on-site or commuter student?	Off-site	1		
	Commuter student	1.11	0.59-2.08	0.739
	On-site	1.17	0.66-2.08	0.601
Year of study	First	1		
	Second	2.66	1.45-4.90	0.002
	Third	1.72	1.13-3.14	0.010
Perceived economic status	Medium-high	1.29	0.67-2.48	0.450
	Low	1		
Perceived health status	Medium-high	6.61	1.15-37.86	0.034
	Low	1		
Do you have chronic diseases (more than 6 months)?	No	1		
	Yes	0.61	0.27-1.38	0.237
Considering your future profession and your state of health, do you consider yourself to have a higher risk of contracting infectious diseases?	No	1		
	Yes	1.03	0.62-1.71	0.911
Did you get vaccinated against seasonal flu last year?	No	1		
	Yes	22.47	9.28-54.39	< 0.001
Age	As unit increase	1.04	0.96-1.15	0.332

tions of, or beliefs about, vaccines and influences from the social environment. Vaccine- and vaccination-specific issues include risk and benefit (scientifically based), vaccination schedule, mode of administration, introduction of new vaccines or new formulations, role of healthcare professionals and costs. We therefore decided to investigate only some of these determinants, which are shown in Table II.
Of the 403 students who took part in our survey, only 21% stated that they had undergone flu vaccination; this is a fairly low percentage, but is in line with the percentages found in other similar studies, which have reported coverage rates ranging between about 10% and 50% [13, 14]. The results reported in Table II are worrying, in that almost 36% of students declared that they had not been vaccinated because they did not feel that they were at greater risk than the general population; this is a misconception, as demonstrated by Lietz et al. [15] who have estimated that health professionals have about a 6% higher occupational risk of influenza infection. There are several factors that influence vaccination uptake among health professionals; according to a previous Italian study, one of these factors was whether these subjects considered themselves at greater risk of infection [10]. Although 63% of our respondents considered themselves to be at higher risk, this did not emerge as a statistically significant factor in the multivariable analysis. Students in the second and third course years displayed a significantly higher probability of being vaccinated during the next vaccination campaign; this was probably because the knowledge and experience acquired during their course raised their awareness of the importance of vaccination as a public health tool [16, 17]. Contrary to what one would expect, those who reported a perceived medium-high state of health were more likely to be vaccinated in the next vaccination campaign than those with a perceived low state of health. A similar result emerged from a previous study [18], in which a perceived low state of health made subjects more inclined to be afraid of vaccinations and therefore less likely to be vaccinated. In our study, other factors were also seen to favor vaccination uptake, such as having been vaccinated in the previous vaccination campaign; this is in line with the results of other studies [19]. The findings in this study are subject to at least three limitations. Firstly, as it was a cross-sectional study, it was not possible to draw any conclusions about causal relationships of the results. Secondly, as vaccination status was self-reported, it might have been subject to recall bias. Finally, this study yielded a general overview of the behavior and attitudes of these specific nursing students, and should not be regarded as providing a complete description of the behavior of nursing students at other universities. Thus, although our results are in line with those reported in the literature, they should not be generalized to all university students.

Conclusions

Implementing comprehensive evidence-based intervention strategies is important, in order to ensure that future healthcare personnel and patients are protected against influenza. Although nursing students are not yet health professionals, they spend part of their time in healthcare facilities for their clinical training and will be the health workers of the future. Educating nursing students in active immunization should be an essential step in promoting vaccination in the general population. Involving nursing students in influenza vaccination campaigns can also help them take better care of themselves and their patients. The scientific literature shows that it is relatively easy to educate medical or nursing students with regard to the importance of vaccination is [20]. Indeed, universities can, with minimal resources, implement education programs to improve vaccination adherence and inculcate a positive attitude toward influenza prevention in future healthcare workers.

Ethical approval

The study was approved by the Ethics Committee of the Paolo Giaccone University Hospital in Palermo, Minutes No. 07/2019 (No. 25) of July 17, 2019.

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Conflict of interest statement

The authors declare no conflict of interest.

Authors' contributions

AF, SP, OES conceived, designed, coordinated and supervised the research project. AF, SP, OES collected samples. OES, SP performed the data quality control, optimized the informatics database, performed the statistical analyses and evaluated the results. OES, SP wrote the manuscript. All authors revised the manuscript and contributed to improving the paper. All authors have read and approved the final manuscript.

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ORIGINAL ARTICLE

Behavioural risk factors for non-communicable diseases among undergraduates in South-west Nigeria: knowledge, prevalence and correlates: a comparative cross-sectional study

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Keywords

Non-communicable diseases • Behavioural risk factors • Undergraduates • Nigeria

Summary

Low- and middle-income countries are experiencing a transition from a preponderance of infectious to Non-Communicable Diseases (NCDs). Many of the behaviours that produce these risks often commence in late adolescence. The study assessed the prevalence and knowledge of the major risk factors for NCDs among undergraduates in Ibadan Metropolis. This was a comparative cross-sectional study using a systematic random sampling technique. Data were collected using the WHO STEPs questionnaire and were entered and analysed using SPSS version 21. Data were analyzed with descriptive statistics, Chi-square test, and logistic regression at p < 0.05. Of 1,200 undergraduates, 646 (53.8%) were male and 1062 (88.5%) were aged 15-24 years; mean age was 20.4 (+/-3.5) years; 673 (56.1%) lived on campus. Only 3.1% of the respondents were current tobacco smokers. Also, 51.3% of respondents currently take alcohol with 11.2% classified as having excess alcohol use (> 6 standard drinks in one sitting in the last 30 days). About three quarters (70.6%) of respondents were classified as having unhealthy diets based on fruit/vegetable servings per day. Only 29.3% had adequate physical activity. Moreover, 48.3% were classified as having poor knowledge of the risk factors for NCDs. Overall, 99.3% of respondents had at least one behavioural risk factor. Public university undergraduates were more likely to have good knowledge of these risk factors OR 1.485 (95% CI: 1.485-2.398, p < 0.001). Behavioural risk factors for NCDs were prevalent among these undergraduates. Knowledge of NCD risk factors was average and those who attended public universities were more likely to have good knowledge of the risk factors for NCDs.

Introduction

Non-communicable diseases (NCDs) remain an important group of disease conditions [1, 2] – medical conditions that are mostly non-infectious and non-transmissible that increasingly contribute to the overall morbidity and mortality in humans worldwide [3-5]. NCDs are characterized by complex aetiology, multiple risk factors, and a long latency period [6]. They usually have a prolonged course of illness that may result in functional impairment and disability [7]. The major NCDs which are of priority to the World Health Organization (WHO) are cardiovascular diseases, diabetes, cancers, and respiratory diseases because of their public health significance [3]. In 2012, NCDs contributed to more than 60% of deaths globally [1]. The majority (82%) of these deaths, were among those younger than 70 years, with most (75%) occurring in low- and middle-income countries (LMICs) [2, 3]; a significant increase from 66% reported in 2005/2006 [4]. Consequently, the disproportionate rise in NCDs among LMICs worsens the developmental challenges associated with a double burden of communicable and non-communicable diseases [3, 5]. Furthermore, there are predictions that by the year 2020, NCDs will cause 70% of deaths in LMICs [5].

Although NCDs are mostly prevalent in middle to late adulthood, most behavioural and dietary risks are initiated during adolescence and young adulthood (15-24 years) [8]. NCDs are a result of a combination of modifiable and non-modifiable risk factors [8]. The WHO has targeted four major modifiable risk factors for NCDs: poor diet, physical inactivity, tobacco use, and harmful alcohol use [8]. These factors have also been identified by the Lancet NCD Action group and the NCD Alliance as priority intervention areas [9] and the modifiable risk factors can lead to metabolic/physiologic changes. The most common metabolic changes include increased blood pressure, elevated cholesterol levels, elevated glucose levels, and obesity [7, 10]. These risk factors for NCDs can occur in isolation or co-exist in an individual, however, the co-existence of two or more risk factors in an individual further increases the risk for NCDs [11]. The incidence of the above-mentioned risk behaviours is increasing among young people globally [8, 9]. About 40% of adolescents and young persons' use alcohol and about 50% of this continue to do so into adulthood [8, 9].

The increasing participation of young people in risk behaviours and their importance to the economic development of nations around the globe makes them critical to all efforts directed at the prevention and control of NCDs

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worldwide. However, perhaps due, to the low prevalence of these diseases among young people as compared to older populations, the former seems to be ignored in the discussions of NCDs. The major focus of government interventions in developing countries among young persons is on communicable diseases; rightly so, but to curb and reduce the burden of NCDs, it is important to consider behavioural modification interventions among adolescents and young people. Focusing attention on risk behaviours among young people is conceivably a smart investment to address the preventive morbidity and mortality associated with NCDs.

While studies exploring risk factors of NCDs are available [10-11, 13-18] especially in Nigeria [10, 14, 15] most of these studies have focused on adults [16] or adolescents [11]. Very few, have been conducted among university undergraduates [15-17] and even fewer comparing public and private universities in Nigeria [18]. Most of these studies cited here also assessed the risk factors either in isolation or in pairs. However, this study explores the four main behavioural risk factors simultaneously among undergraduates in Nigeria. This is so, as the university environment offers the opportunity to provide a package of targeted interventions to the students in either public or private universities for the 4-6 years spent learning. Also, this phase of life offers opportunities for the adoption of both protective and adverse risk behaviours. This study intends to fill some gaps in research, regarding the knowledge and occurrence of the major risk factors, and potential translation of this evidence to inform appropriate interventions that can be adopted by University Health Services and aid policy development in Nigeria.

Methods

Study area

The study was conducted in Ibadan, Oyo State. Ibadan is the capital of Oyo State which is situated in the south-western geo-political zone of Nigeria. Ibadan is currently home to an estimated population of 3.6 million people, as projected from the 2006 census which had an estimated 2.5 million people, according to the National Population Commission [19]. Regarding educational institutions in Ibadan, there are 1,576 public primary schools and 324 secondary schools [20]. Also, there are three other higher institutions in Ibadan: School of Nursing and Midwifery and the College of Hygiene and Health Technology [20]. Furthermore, there is an estimated 1,252,424 youth (15-24 years) in the town [20].

Two universities with full-time academic programs, operating for more than 5 years in Ibadan were selected for the study. The study was conducted in one public and one private university. The choice of the institutions strategically reflects diversity in terms of both institutional types, ownership, and student characteristics, thereby ensuring representativeness.

The University of Ibadan is the first in Nigeria, founded in 1948, and is a major centre for undergraduate and postgraduate education in Nigeria [21] The population is drawn from a heterogeneous pool of students who come from all over the country and from some neighbouring countries to access education [21] Lead City University was founded in 2005 and also provides undergraduate and postgraduate education [22] to students from all around Nigeria and some neighbouring countries.

Study design

This study was a comparative cross-sectional study that utilized a quantitative data collection method.

Study population

The study was conducted among undergraduates at a public and private university.

Inclusion criteria

- All consenting undergraduates in the public and private university.
- Undergraduates who had spent at least one full academic session on full-time programs in both universities.
- Undergraduates who were in the selected departments and faculties.
- Students who had valid university identification cards.

Exclusion criteria

- Undergraduates who were critically ill were excluded from the study.

Sample size determination

The sample size was determined using the formula for comparing two proportions [23]. Using prevalence (P1) of alcohol use among undergraduate of 72% from a previous study [11], assuming a 10% difference and adjusting for 10% non-response, the minimum sample size calculated was 571 in each group, giving a total of 1,142 respondents.

Sampling technique

This study adopted a systematic random sampling technique.

- Stage 1 - Selection of faculties: a list of all faculties in both schools was obtained and stratified into three categories: Science-related, Education, and Art-related faculties [17]. 1 faculty from each of these three was then chosen.
- Stage 2 - Selection of Departments: three departments were randomly selected from selected faculties by balloting. Proportional allocation was used to determine the number of respondents that were to be chosen in each of the selected departments.
- Stage 3 - Selection of students: within each of the selected departments, a sampling fraction was determined after which the first respondent was selected using a table of random numbers.

The first student was pre-selected from the list using a systematic sampling approach; using a table of random

numbers. The next students were selected as the nth number from the first. In situations when a pre-selected student was not available, the next nth student was picked**.** To get the sampling fraction, = n/N (sample size/ total number of students) was used.

Study instrument

Data was collected using interviewer assisted semi-structured questionnaire. The questionnaire was adapted from the WHO STEPS Questionnaire for chronic disease surveillance and was already validated for use in Lagos, Nigeria [24].

Data collection methods

At each level, the class representatives were approached for a class list in 2018. Training of 8 research assistants (with minimum BSc qualification) was conducted over 2 days. Research assistants (RA) were trained on the content and method of administration of the questionnaire as well as maintenance of ethical standards of confidentiality, beneficence, non-maleficence by the principal investigator. Paper flashcards were used in the training of RA to demonstrate a standard measure of fruits/ vegetables and alcoholic drinks. The research assistants were supervised daily and filled questionnaires were checked daily to ensure the quality of data collection.

Assessment of outcome variables

The dependent (outcome) variable was the behavioural risk factors while the independent variables were the socio-demographic characteristics of the respondents. This was assessed using the questions on tobacco use, alcohol use, unhealthy diets, and physical inactivity.

Knowledge of risk factors for NCDs was scored, wrong answers were scored 0 and right answers scored 1. Mean knowledge scores were computed. The expected maximum score was 10. Knowledge scores were converted to percentages and cut off points used to determine poor knowledge and good knowledge. Those with scores above 70% were classified as having good knowledge, and those with 69% and less were classified as having poor knowledge. Risk behaviours are as specified by the WHO STEPS handbook [24].

Current cigarette smoking: This was defined as any respondent who had smoked at least one cigarette in the last 30 days preceding the survey.

Alcohol use: male respondents who report an average daily alcohol consumption of more than 2 drinks. Female respondents who report an average daily alcohol consumption of more than 1 drink. Also, respondents who reported 6 or more alcoholic drinks at a sitting were classified as having excessive alcohol use [24, 31].

Physical inactivity: respondents who report no physical activity in form of a formal exercise regimen and who mostly sit, or stand were classified as sedentary [24, 31], those who had less than 5 days of < 60 minutes moderate-to-vigorous physical activity in the past 7 days preceding the survey were identified as being physically inactive. Physical activity included walking or riding a bicycle to school, playing football, running, and jogging.

Unhealthy diet: was defined as the lack of daily intake of fruits and/or vegetables (raw or cooked) and/or the daily intake of high fat or high sugar meals- consuming pastries or soft drinks at least once daily). This was determined by the recall of vegetable/fruit consumption in the last 1 week. Respondents who had less than five servings of fruits and vegetables on any of the days in the last 7 days preceding the survey were classified as having poor diets or less than once a day [24, 31].

The prevalence of risk factors was reported singly and also as a cluster, and clustering was defined as the presence of two or more risk factors in a respondent.

Data management

Data were entered and analysed using SPSS version 21. Means and standard deviations were used to summarize quantitative variables. Summary statistics were generated and presented appropriately. All categorical variables were compared using the chi-square test while quantitative data were compared using the t-test. Variables significant at 10% on bivariate analysis as well as variables believed apriori to be related to the outcome variables were selected and fit into multivariate logistic regression models to identify predictors of these risk factors. Crude and adjusted odds ratios and 95% confidence intervals were reported. The significance level for all statistical tests was set at 5%.

Ethical considerations

Ethical approval was obtained from the Oyo State Ethical Research Committee (AD 13/479/694). Permission was obtained from the school authorities, and written informed consent from each participant. Each participant was informed of their right to decline or withdraw from the study at any time without adverse consequences.

Results

A total of 1,254 respondents were approached to participate in the study of which 1200 (public: 50 %; private: 50%) completed the study, giving a response rate of 95.7%. The sociodemographic characteristics of the study participants are shown in Table I. Of a total of 1,200 respondents, 47.8% were aged 15-19 years, male (56.3%), never married (96.7%), Christian (82.7%), and Yoruba by tribe (79.4%). Overall, the highest proportion (60.6%) of respondents were 200 level students and a higher proportion (56.0%) lived on campus. A significantly higher proportion (48.4%) of the respondents from the public university were from science-related faculties compared with 41.9% of those from the private university ($p < 0.001$). More students from the public university (69.5%) than private (42.5%) lived on campus ($p < 0.001$). The variables that showed statistically significant differences between students of the public and private universities were age ($p < 0.001$), sex ($p < 0.001$), marital status ($p < 0.001$), fathers' ($p < 0.001$) and mothers' levels of education ($p < 0.001$). A higher proportion (52.8%) of respondents from the private university

Tab. I. Respondents sociodemographic characteristics.

Characteristics	Public university (N = 600) n (%)	Private university (N = 600) n (%)	Total (N = 1,200) n (%)	X^2 value	P-value
Age groups (in years)					
15-19	257 (42.8)	317 (52.8)	574 (47.8)	6.073	0.014*
20-24	280 (46.7)	208 (34.7)	488 (40.7)		
25-29	55 (9.2)	54 (9.0)	109 (9.1)		
30-34	8 (1.3)	21 (3.5)	29 (2.4)		
Mean age	20.6 ± 3.0	20.1 ± 3.9	20.4 ± 3.5	20.622#	< 0.001*
Sex					
Male	373 (62.2)	273 (45.5)	676 (56.3)	3.224	< 0.001*
Female	227 (37.8)	327 (54.5)	554 (43.7)		
Marital status					
Ever married	9 (1.5)	31 (5.2)	40 (3.3)	12.517	<0.001
Never married	591 (98.5)	569 (94.8)	1,160 (96.7)		
Religion					
Christianity	502 (83.7)	491 (81.8)	993 (82.7)	0.706	0.401
Others	98 (16.3)	109 (18.2)	207 (17.3)		
Tribe					
Yoruba	484 (80.7)	469 (78.2)	953 (79.4)	1.147	0.284
Others	116 (19.3)	131 (21.8)	247 (20.6)		
Fathers' educational level					
Never attended	0 (0.0)	0 (0.0)	0 (0.0)	5.126	< 0.001*
Primary	35 (7.8)	23 (4.2)	58 (7.0)		
Secondary	122 (20.6)	86 (14.9)	208 (17.3)		
Tertiary	254 (42.7)	187 (31.9)	441 (36.8)		
Postgraduate	173 (28.9)	294 (49.0)	467 (38.9)		
Mothers' educational level					
Never attended	19 (3.1)	17 (2.8)	36 (3.0)	3.853	< 0.001*
Primary	42 (7.0)	30 (5.0)	72 (6.0)		
Secondary	136 (22.7)	105 (17.5)	241 (20.1)		
Tertiary	280 (46.7)	228 (38.0)	508 (42.3)		
Postgraduate	123 (20.5)	220 (36.7)	343 (28.6)		

Others: Ijaw, Urhobo, Efik; #: independent t-test; *: significant association; X^2: Chi square.

were aged between 15-19 years compared to 42.8% of the public university students. Also, a higher proportion (54.5%) of respondents from the private university were females compared to 37.8% from the public university.

Regarding the knowledge of the behavioural risk factors for NCDs, excessive alcohol intake was the most often identified behaviour among respondents from both universities (public: 80.5%; private: 69.3%) shown in Figure 1. A significantly higher proportion of the students from the public university had good knowledge of risk factors or behaviours for NCDs 364 (60.7%) compared with 257 (42.8%) of the students from the private university ($X^2 = 38.201$; $p < 0.001$).

Respondents who were aware of a school policy on alcohol were 60.8% and 46.6% in the public and private university respectively ($X^2 = 24.254$; $p < 0.001$).

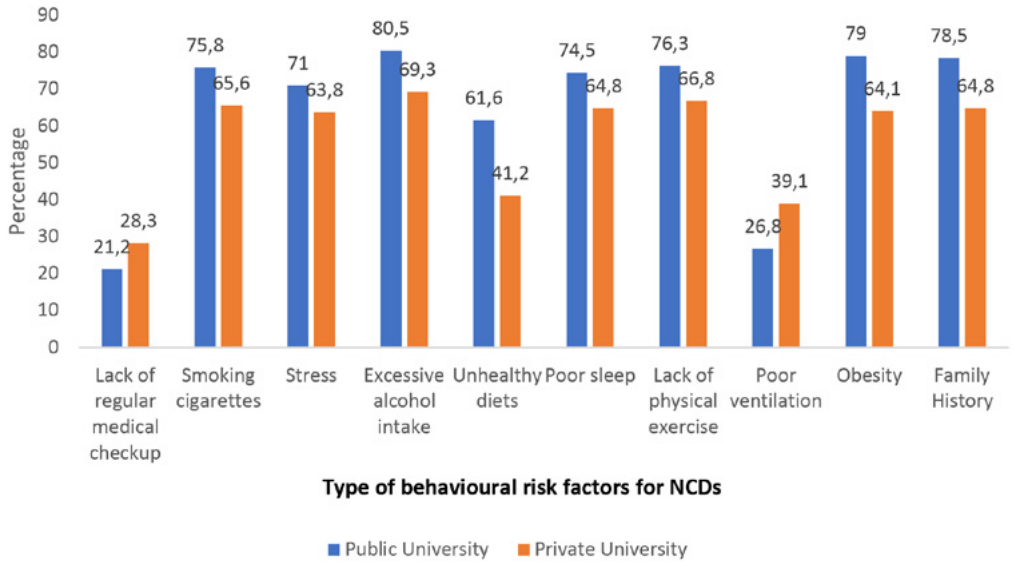
Only 31.5% and 23.9% of respondents from the private and public university, respectively had ever attended a seminar or program on NCDs prevention/management ($X^2 = 8.708$; $p = 0.003$). Those who had heard about NCD risk factors on the University radio were 26.5 and 21.7% from the private and public university, respectively ($X^2 = 4.834$; $p = 0.089$).

Table II shows the prevalence of risk factors for NCDs among respondents in both universities. Overall, 68.3% had unhealthy diets and 70.6% were classified as being physically inactive. Only, 3.1% were current smokers and 51.3% reported alcohol use. A significantly lower proportion of respondents from the public university (66.0%) had unhealthy diets, compared to 70.6% of respondents from the private university ($X^2 = 29.97$; $p < 0.001$).

Overall, 99.3% of all respondents had at least one behavioural risk factor. In total, only 8.5% of all the respondents had 3 risk behaviours. About 44.5% of respondents from the public university and 46.3% from the private university reported 2 risk behaviours each shown in Figure 2.

However, regarding private university respondents, when reported risk behaviours were disaggregated by gender, females had a higher prevalence of unhealthy diets (55.2%) compared with males (44.8%). Also, physical inactivity was higher in females (53.3%) compared with males (46.7%) as shown in Table III. In the public university, physical inactivity was also higher in females (50.3%) than in males (49.7%).

Fig. 1. Proportion of respondents with correct answers to questions on risk behaviours by university.



Tab. II. Prevalence of behavioural risk for NCDs between respondents in a private and public university.

Variables	Public university N = 600 n (%)	Private university N = 600 n (%)	Total N = 1,200 n (%)	X_2 value	P-value
Unhealthy diets					
Yes	396 (66.0)	424 (70.6)	820 (68.3)	29.97	< 0.001*
No	204 (34.0)	176 (29.3)	380 (31.7)		
Physical activity					
Yes	187(31.2)	165 (27.5)	352 (29.3)	7.085	0.008
No	413 (68.8)	435 (72.5)	848 (70.6)		
Current smoking					
No	582 (97.0)	581 (96.8)	1,163 (96.9)	0.636	0.425
Yes	18 (3.0)	19 (3.1)	37 (3.1)		
Alcohol use					
No	201 (33.5)	383 (63.8)	584 (48.6)	0.314	0.575
Yes	399 (66.5)	217 (36.2)	616 (51.3)		
Overall behavioural risk factor					
No risk factor	2 (0.3)	6 (1.0)	8 (0.7)		0.287^
Has risk factor	598 (99.7)	594 (99.0)	1,192 (99.3)		

*: significant association; ^: Fisher's exact reported.

In the public university, males had a higher prevalence of alcohol use (88.2%) compared to females (11.8%) and current smoking (94.4%) compared to 5.6% among females. Similarly, males in the private university recorded a much higher gender difference in the prevalence of alcohol use (89.4%) compared to 10.6% in females and current smoking (78.9%) compared to 21.1% in females ($X^2 = 10.32$; $p = 0.001$).

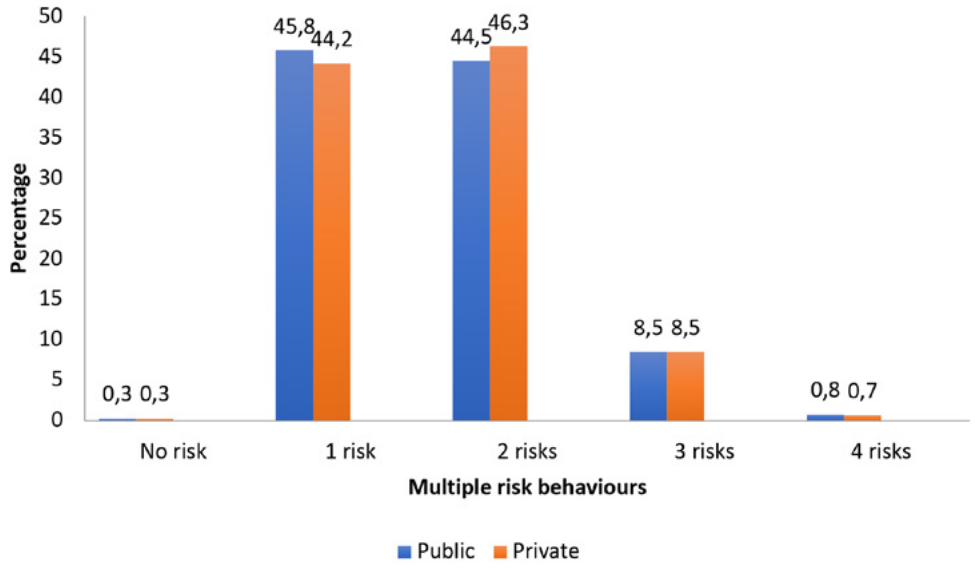
Table IV shows the association between socio-demographic variables of respondents and behavioural risk factors for NCDs. No socio-demographic variable/family-related characteristic varied significantly with the behavioural risk factors among respondents from both universities.

In the private university, more females (99.4%), more young people [aged 15-24 years (99.0%)], more 200 level students (98.7%), who resided off campus (98.8%) and whose fathers completed more than secondary school 476 (99.0%) had any/at least 1 of the behavioural risk factors for NCDs. None of these were statistically significant.

Similarly, among respondents from the public university, more males (99.5%), more young people (aged 15-24), (99.6%), more 200 level students (99.7%), who resided on campus (99.5%) and whose fathers completed more than secondary school (99.5%) had any of the behavioural risk factors for NCDs. None were statistically significant.

This regression model included the type of university, sex, and place of residence which were factors significant at 10% and bivariate analysis. The predictors of

Fig. 2. Prevalence/clustering of multiple behavioural risk factors for NCDs.



Tab. III. Sex-specific prevalence of individual behavioural risks of NCDs among respondents in a private and public university.

Variables	Private university		Public university	
	Male	Female	Male	Female
Unhealthy diets	**(N = 424)**		**(N = 396)**	
Yes	190 (44.8)	234 (55.2)	283 (71.5)	113 (28.5)
	X^2 = 1.672; p-value = 0.196*		X^2 = 1.043; p-value = 0.307	
Physical activity	**(N = 435)**		**(N = 413)**	
Inadequate	203 (46.7)	232 (53.3)	205 (49.7)	208 (50.3)
	X^2 = 10.321; p-value = 0. 001*		X^2 = 8.609; p-value = 0.003*	
Current smoking	**(N = 19)**		**(N = 18)**	
Yes	15 (78.9)	4 (21.1)	17 (94.4)	1 (5.6)
	X^2 = 0.029; p-value = 0.864		X^2 = 5.273; p-value = 0.022*	
Alcohol use	**(N = 217)**		**(N = 399)**	
Yes	194 (89.4)	23 (10.6)	352 (88.2)	47 (11.8)
	X^2 = 0.943; p-value = 0.331		X^2 = 2.962; p-value = 0.085	

*: significant association.

prevalence of the behavioural risk factors for non-communicable diseases among respondents from both universities are shown in Table V. Those more likely to have behavioural risk factors for NCDs were females OR = 1.28 (CI = 1.034-1.946) and this was statistically significant (p = 0.025).

Discussion

This study was conducted to assess the prevalence of the major modifiable behavioural risk factors for non-communicable diseases among undergraduates We also assessed their knowledge of these risk behaviours. Regarding knowledge, about sixty percent of students in the public university and about forty-two percent in the private university had good knowledge of the risk factors for non-communicable diseases. Knowledge scores less than seventy percent was categorized as poor, for this study. They also reported alcohol use most commonly as a risk factor for non-communicable diseases. These findings are similar to findings from studies done among undergraduates in other countries, Myanmar and Malaysia, among medical and pharmacy undergraduates, respectively who had fair to good knowledge of NCD risk factors [25, 26]. In contrast, studies among rural adolescents in Nigeria and India revealed only 0.3% had a good level of knowledge regarding the lifestyle risk factors for NCDs and 62.6% were not aware of the prevention of NCDs [14, 27]. Reasons for these findings may include access to health information on the internet, contact with health care workers in clinics when registering in school or when they present when ill. This may also be due to preponderance of health information on all forms of media, IEC materials, health programs organized by non-governmental organizations or faith-based organizations, or the school during the academic session. These findings among adolescents in rural areas may be due to

Tab. IV. Association between socio-demographic variables and behavioural risk factors among respondents I.

Variables	Private university (n = 600)		Public university (n = 600)	
	Any behavioural risks for NCDs		Any behavioural risks for NCDs	
	Has risk n (%)	No risk n (%)	Has risk n (%)	No risk n (%)
Sex				
Male	269 (98.5)	4 (1.5)	371 (99.5)	2 (0.5)
Female	325 (99.4)	2 (0.6)	227 (100.0)	0 (0.0)
	X^2 = 1.095; p-value = 0.419^		X^2 = 1.221; p-value = 0.529^	
Age group				
	(N = 594)			
15-24 years	520 (99.0)	5 (1.0)	535 (99.6)	2 (0.4)
> 24 years	74 (98.7)	1 (1.3)	63 (100.0)	0 (0.0)
	X^2 = 0.096; p-value = 0.553^		X^2 = 0.253; p-value = 1.000^	
Level				
200	391 (98.7)	5 (1.3)	330 (99.7)	1 (0.3)
300	140 (100.0)	0 (0.0)	147 (99.3)	1 (0.7)
400	54 (98.2)	1 (1.8)	119 (100.0)	0 (0.0)
500	9 (100.0)	0 (0.0)	2 (100.0)	0 (0.0)
	X^2 = 2.153; p-value = 0.314#		X^2 = 0.936; p-value = 0.817#	
Residence in school				
	(N = 594)			
On-campus	254 (99.2)	2 (0.8)	415 (99.5)	2 (0.5)
Off-campus	340 (98.8)	4 (1.2)	183 (100.0)	0 (0.0)
	X^2 = 0.216; p-value = 1.000^		X^2 = 0.881; p-value = 1.000^	
Father's educational level				
	(N = 594)		(N = 598)	
Less than Secondary	33 (100.0)	0 (0.0)	51 (100.0)	0 (0.0)
Secondary level	85 (98.8)	1 (1.2)	122 (100.0)	0 (0.0)
Tertiary level	476 (99.0)	5 (1.0)	425 (99.5)	2 (0.5)
	X^2 = 0.364; p-value = 0.707#		X^2 = 0.813; p-value = 0.506#	
Knowledge of risk factors				
	(N = 594)		(N = 598)	
Poor knowledge	339 (98.8)	4 (1.2)	236 (100.0)	(0.0)
Good knowledge	255 (99.2)	2 (0.8)	362 (99.5)	2 (0.5)
	X^2 = 0.223; p-value = 1.000^		X^2 = 1.301; p-value = 0.522^	

^: Fisher's exact reported; #: likelihood ratio reported.

Tab. V. Predictors of prevalence of behavioural risk factors for NCDs among respondents.

Variable N = 1,200	Odds ratio	95% Confidence Interval		P-value
		Lower	Upper	
Type of university				
Public Private	1 0.82	0.640	1.873	0.192
Sex				
Male Female	1 1.28	1.034	1.946	0.025*
Place of residence				
On-campus Off-campus	1.23 1	0.835	1.819	0.293

less exposure to media or opportunities to interact with health communication materials which may be available in urban areas. While the challenge may be more acute in rural areas and among less-educated youths [26], variable gaps in knowledge have been reported among in-school youths. For example, in a 2017 study, over 30% of undergraduates did not know any preventive measure for diabetes mellitus in a tertiary institution in a south-western state in Nigeria [17]. The findings in the universities enrolled for this study buttresses the fact that a good number of undergraduates have some knowledge of the risk factors for NCDs, however, more still needs to be done to improve both knowledge of and prevention of these risk factors.

Also, the study observed that knowledge of the risk factors was significantly higher among students from the public university. The reason for this difference is unknown but may be due to the increased presence and participation of students from public universities in organizations that provide awareness programs on a wide range of issues. No relationship was found between knowledge and demographic variables except age. This indicates that the pattern of exposure to information about the risk behaviours or factors for NCDs is similar for the different demographic groups in both school categories. The university radio and in-school seminars were some of the routes through which students access information about risk factors for NCDs. Some other studies have also cited friends, family members, the media, and social media -which is very popular among undergraduates- as avenues where young people can learn about these behavioural risk factors [16].

Our study revealed a widespread prevalence of various risk factors for non-communicable diseases in both universities. Regarding gender differences, females had a higher prevalence of unhealthy diets (in the private university) and physical inactivity in both universities. While males had a higher prevalence of alcohol use and current smoking compared to the females in both schools.

The most prevalent risk factors were physical inactivity and unhealthy diets in both universities. The high prevalence of poor diet (89.5%) and physical inactivity (85.9%) was also corroborated in the study among adolescents in South-west Nigeria [14]. Also, physical activity was assessed in another study in the school area during leisure time, and about four-fifths of the students were sedentary in school with a little over two-thirds reporting physical activity outside school time, corroborated by a study among undergraduates in two countries [16, 25]. This may be possibly due to prolonged sitting in classes for lectures and convenience eating which is popular among undergraduates. Similar to the evidence from other regions, respondents were generally not committed to regular physical activities even when aware of the importance. Some of the reasons given were lack of motivation, lack of time, distance from their rooms to places of exercise, and lack of social support [25]. Interestingly, the built environment of the universities provides the opportunity for targeted interventions that encourage physical activities (by improving knowledge and linking it to action) among undergraduates resident in and around the university environment.

The prevalence of tobacco smoking was 3.0 and 3.1% respectively in the public and private university, similar to the findings of another study among undergraduates in Ibadan done in 2010 [13]. This is much lower than what was recorded across other developing countries like Burma (12.6%) to Bangalore India (70%). However, consistent with findings from other studies, males and those slightly older had higher smoking rates [17]. Apart from cigarettes, some of these respondents also smoked hookah/shisha, pipe, and e-cigarettes. Tobacco smoking is generally more easily accessible, can be bought online, in restaurants, and increasingly, females (though less than males) are also engaging in this behaviour [17]. Alcohol use by respondents in this study was lower than rates from some other countries. Similar to other local and studies conducted outside Africa, more males than females reported excessive use of alcohol [9, 25]. This is probably explained by maybe higher alcohol tolerance and social acceptability of the drinking culture among males [31].

No respondent consumed the recommended five fruit and vegetable servings per day, despite the expanded definition used for this study. Seasonal variations in fruit supply and sometimes the occasional prohibitive costs of some fruits may be possible contributors. In addition to the inadequate intake of fruits and vegetables, many respondents also had unhealthy eating habits of daily consumption of soda/soft drinks, and other diets high in sugar and fats. In this study, more males than females consumed unhealthy diets in the public university as opposed to what was observed in the private university; the former contrasting with findings from 2 universities in the same southwestern region of Nigeria, where more females consumed unhealthy diets corroborated by findings in the private university [18, 29].

Overall, 99.3% of all respondents had at least one behavioural risk factor. In total, only 8.5% of all the respondents had 3 risk behaviours. About 44.5% of respondents from the public university and 46.3% from the private university reported 2 risk behaviours each. These findings are corroborated by the study among adolescents in South-west Nigeria which explored the clustering of risk factors for non-communicable diseases [16]. This finding underscored the observation that risk behaviours tend to cluster in population groups [16].

The prevalence of multiple risk factors was substantial in this study irrespective of the university type. Less than 1% of all respondents had no behavioural risk factor at all. This is a very important finding necessitating urgent steps taken in line with national guidelines to address the NCD epidemic in Nigeria. Furthermore, less than 10% of all the respondents reported themselves having self-perceived risks for NCDs. It may be this lack of self-awareness that has prevented many from commencing or sustaining healthy lifestyles.

Limitations of the study

This study has a few limitations. First, the cross-sectional design did not allow inferences to be drawn regarding causal relationships among variables. Secondly, the study sample is only representative of undergraduate students in the University community and findings may not be generalizable to other urban settings or out of school youth in Nigeria. Second, risk behaviours were self-reported and not validated by objective measures, respondents might tend to give answers that would convey more favourable behaviours, such as understating alcohol/tobacco use (social desirability bias). Recall bias was a potential limitation because many incidents brought up had taken place, weeks previously. This was minimized by using both standardized and recheck questions. De-

spite these limitations, the study provides insight into the risk profile of multiple lifestyle behaviours as a useful source of evidence to quantify behaviour and health at the population level especially among age groups where behaviours adverse to health are best targeted.

Conclusion

Our lifestyle choices shape our health status and most of these are imbibed from a young age.
While the environment and family history play significant roles, risky health behaviors such as alcohol use and unhealthy diets continue to contribute to the occurrence of NCDs. Many of the respondents had individual risks for NCDs. There is a need for continued surveillance of NCDs and their risk factors to provide data-driven targeted interventions for prevention for relevant population segments.

Recommendations

Therefore, there is a need for continued surveillance of NCDs and their risk factors to provide data-driven targeted interventions for NCD prevention for relevant population segments.
Tertiary institutions alongside their health services units can also implement campus-wide programs to encourage healthy behaviour such as bans on tobacco or alcohol sale within campuses and routine distribution of IEC materials.

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Conflict of interest statement

The authors declare no conflict of interest.

Authors' contributions

OFO, AMA, OAP contributed to the conceptualization, OFO collected the data, OFO, AMA, OAP contributed to data analysis, the write up and the draft submitted.

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ORIGINAL ARTICLE

Socioeconomic-related determinants of asthma in the elderly

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Keywords

Asthma • Elderly • Prevalence • Socioeconomic factors

Summary

Introduction. *As the population ages, the impact of asthma in the elderly is expected to be enhanced over the forthcoming decades. We investigated the prevalence of asthma and its socioeconomic factors in the elderly, Shiraz, Iran.*
Methods. *In this population-based study, 1527 subjects older than 60 years were selected based on the stratified random sampling method. The data on asthma symptoms, current asthma, physician diagnose asthma, and allergic rhinitis were collected using the translated ECRHS (European Community Respiratory Health Survey) questionnaire. Information on individual socioeconomic status was derived from the participants' self-reported educational level and their occupation, income, and residence. A p-value of less than 0.05 was considered to be statistically significant.*
Results. *The prevalence of asthma, current asthma, physician diagnose asthma, and allergic rhinitis was found to be 8.97, 6.81, 4.78 and, 23.51%, respectively. The most common asthma symptoms were nocturnal chest tightness (15.52%, n = 237/1,527). In univariate analysis, the prevalence of asthma was higher in illiterate patients (12.7%), subjects with the lowest income level (10.6%), and patients living in urban areas (24.1%). Having age more than 80 (OR = 2.01; 95% CI = 1.10-3.65), being a current smoker (OR = 2.76; 95% CI = 1.69-4.51) and living in a sub-urban area (OR = 3.01; 95% CI = 1.20-7.50) were significant predictive factors for asthma in the regression model.*
Conclusions. *Asthma and allergic rhinitis in the elderly should be more focus in the southwest of Iran. Moreover, our findings highlighted the effect of socio- economic status, disparities and inequality on community health.*

Introduction

With demographic changes, rapid aging of the global population, the impact of asthma in the elderly is expected to be enhanced over the forthcoming decades [1-6]. Mortality, hospitalization, medical costs and health-related quality of life are significant components of asthma burden in this age group [2, 3, 5,7,8].
Nevertheless, asthma in the elderly is still under-diagnosed and epidemiologic data are mainly about childhood asthma; recent studies have indicated that asthma is highly frequent in the elderly population, with its prevalence ranging from 4.5 to 12.7% [1, 3, 9-11]. Moreover, there is a fourfold greater mortality, as reported by Tsai et al., in this age group than younger adults [12].
In Iran, like other developing countries, epidemiologic observational studies are scarce. Our knowledge about the prevalence of asthma in the elderly is incomplete. Therefore, it is an imperative task to recognize our current situation and set future plans for outcome improvements in the elderly with asthma.
The Shiraz Adult Respiratory Disease Study (SARDS), 2015 providing population-based data for the prevalence of chronic obstructive respiratory diseases (CORDs) and its socioeconomic determinants in the population of Shiraz, Iran [13]. The current study aimed to investigate the prevalence of asthma in the elderly group and determine the association between the prevalence of asthma and socioeconomic factors.

Methods

Setting and sampling

SARDS, a population-based study, was conducted from June to October 2015 among adult subjects from the general population of Shiraz, Iran. Shiraz city is the capital of Fars province, in southwest of Iran. The 2011 census recorded the Fars region's population as 4.59 million, 1.7 million of whom are living in Shiraz city and its suburbs [14] . The sampling frame was individuals of the urban and suburban zones of the Shiraz. Using the formula $N = (z1 - \alpha/2)^*p\ (1 - p)/d^2$, a minimum sample of 5,593 subjects was required based on the Z = 1.96 (the desired level of confidence 95%), margin of error = 0.75% and P = 9%. Accordingly, the study included 6,152 non-institutionalized inhabitants aged 20 and over 20 years old from the nine municipal districts of Shiraz, Iran. The sample was selected based on the stratified random sampling method proportionate to the number of municipal districts and strata. The sample consisted of 0.5% of the 1,219,237 total inhabitants aged ≥ 20 years in the survey area. The SARDS' methodology has been described in de-

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tail elsewhere [13]. From the total of 6,152 subjects, 1,527 were older than 60 years and their data were analyzed in the current study.
This study was approved by the Ethics Committee of Shiraz University of Medical Sciences (IR.SUMS.MED.REC.1398.094). Verbal informed consent was obtained from all the participants and the confidentiality of all personal data was considered.

Questionnaire and definitions

The translated ECRHS (European Community Respiratory Health Survey) questionnaire was administered by a group of trained interviewers and face to face interview. The validity and reliability of the Persian version of the questionnaire were evaluated previously (Cronbach's alpha = 0.854) [15].
Asthma was defined as a positive answer to all the three following questions in the preceding 12 months: 1) Have you had wheezing or whistling in your chest?; 2) Have you been breathless at all when the wheezing noise was present?; and 3) Have you had this wheezing or whistling when you did not have a cold? Current asthma was defined as a positive answer to each of the following questions: 1) Have you had an attack of asthma in the last 12 months?; or 2) Are you currently taking any medicine (including inhalers, aerosols or tablets) for asthma? [16]. A feeling of tightness, by an attack of shortness of breath and an attack of coughing in one's chest at any time in the last 12 months were considered as respiratory symptoms.
Information on individual SES was collected from the participants' self-reports on the level of education, occupation, income, and residence (urban or suburban). Educational levels were rated as bachelor's degree or higher, high school graduate, middle school graduate, or less. The self-reported education level of the research subjects was combined into a single variable. This composite variable contained four categories of illiterate, primary, secondary/high school, and academic. Occupations were collected with an open-ended question and then categorized into four groups of non-manual, manual, jobless, and unspecified. Subjects who were unable to work, retired persons, and those with an unknown job were classified as having an unspecified occupation. The income earned was the total income received by households for one year. The classification was based on the average income of all households in Iran [14]. Income was divided into four categories ranging from less than $ 3,500 to more than $ 7,000 per year.

Statistical analysis

Data were entered into the Statistical Package for the Social Sciences software version 15.0 (SPSS Inc., Chicago, IL, USA) by a trained operator and double-checked by an investigator. In addition to descriptive statistics, chi-square test was used to find the associations between asthma and socioeconomic factors and group differences. To derive predictive socioeconomic factors, we entered all variables of interest with a p-value less than 0.05 in univariate analysis into the multiple logistic regression models to estimate the adjusted odds ratios and 95% confidence intervals (CI). A p-value less than 0.05 was considered to be statistically significant.

Results

In this population-based study, a total of 1,527 subjects aged older than 60 years completed the study. Forty-seven out of 1,574 (2.9%) potential participants were not willing to complete the interview process and were considered as a non-respondent in this study. Frequency analysis of their demographic characteristics did not show a substantial difference from respondents.
The mean age of the participants was 69.32 ± 6.70 years. Considering the total respondents, 53.8% were male, 79.1% lived with family, and 11.9% were current smoker. In socioeconomic variables, 42.4% had a primary school education, 44.7% had a manual job, 71.8% earned ≤ $ 3,500 per year, and 98.1% lived in an urban area (Tab. I).

Prevalence

The prevalence of asthma, asthma symptoms, current asthma, physician diagnose asthma, and allergic rhinitis in total population are summarize in Table II. Accordingly, the prevalence of asthma was found to be 8.97% (137/1,527), (95% CI = 7.59-10.52%). The most common asthma symptoms were nocturnal chest tightness (15.52%, n = 237), nocturnal cough (10.22%, n = 156), and nocturnal dyspnea (9.76%, n = 149). The prevalence of current asthma, physician diagnose asthma and allergic rhinitis was 6.81% (95% CI = 5.60-8.19%), 4.78% (95% CI = 3.77-5.97%), and 23.51% (95% CI = 21.40-25.72%), respectively.
Table I illustrates the prevalence of asthma by sociodemographic and socioeconomic variables. The prevalence of asthma among the subjects older than 80 years was significantly higher than the younger (61-80) participants (P = 0.005). We found no statistically significant association between the asthma prevalence and gender, BMI or living situation. The prevalence of asthma was 16, 8.6, 10.1, and 7.6% among current, ex-, passive, and non-smokers, respectively (p = 0.003).
Among socioeconomic factors, the prevalence of asthma was higher in illiterate patients (12.7%), subjects with the lowest income level (10.6%), and patients living in urban areas (24.1%). All of these differences were statistically significant (P = 0.009, P = 0.008 and P = 0.004).

Predictive factors

An adjusted logistic regression model was used to identify the predictive factors for asthma (Tab. III). Being more than 80 years old (OR = 2.01; 95% CI = 1.10-3.65), being a current smoker (OR = 2.76; 95% CI = 1.69-4.51), and living in a suburban area (OR = 3.01; 95% CI = 1.20-7.50) were significant predictive factors for asthma in the regression model.

Tab. I. Asthma prevalence among the elderly by demographic and sociodemographic data, univariate analysis.

Variables		Asthma (n = 137)	Non-asthma (n = 1,390)	Total (n = 1,527)	P-value
Age groups	61-70	88 (8.6%)	931 (91.4%)	1,019 (66.7%)	0.005
	71-80	31 (7.6%)	376 (92.4%)	407 (26.7%)	
	> 80	18 (17.8%)	83 (82.2%)	101 (6.6%)	
Gender	Male	82 (10.0%)	739 (90%)	821 (53.8%)	0.13
	Female	55 (7.8%)	651 (92.2%)	706 (46.2%)	
BMI	Under weight	7 (10.4%)	60 (89.6%)	67 (4.4%)	0.69
	Normal weight	57 (8.6%)	608 (91.4%)	665 (44.1%)	
	Overweight	45 (8.7%)	472 (91.3%)	517 (34.3%)	
	Obese	28 (10.9%)	230 (89.1%)	258 (17.1%)	
Living situation	Alone	27 (8.5%)	291 (91.5%)	318 (20.9%)	0.72
	With family	110 (9.1%)	1,095 (90.9%)	1,205 (79.1%)	
Smoking habits	Current smoker	29 (16%)	152 (84%)	181 (11.9%)	0.003
	Ex-smoker	9 (8.6%)	96 (91.4%)	105 (6.9%)	
	Passive-smoker	18 (10.1%)	161 (89.9%)	179 (11.7%)	
	Non-smoker	81 (7.6%)	981 (92.4%)	1,062 (69.5%)	
Occupation	Manual	63 (9.3%)	616 (90.7%)	679 (44.7%)	0.86
	Non-manual	11 (8.6%)	117 (91.4%)	128 (8.4%)	
	Jobless	7 (11.3%)	55 (88.7%)	62 (4.1%)	
	unspecified	55 (8.5%)	595 (91.5%)	650 (42.8%)	
Education level	Illiterate	55 (12.7%)	378 (87.3%)	433 (28.4%)	0.009
	Primary	54 (8.4%)	592 (91.6%)	646 (42.4%)	
	Secondary	16 (6.0%)	251 (94%)	267 (17.5%)	
	Academic	12 (6.8%)	165 (93.2%)	177 (11.6%)	
Income (per year)	Less than 3,500 $	116 (10.6)	981 (89.4%)	1,097 (71.8%)	0.008
	3500 to 4,750 $	17 (5.2%)	312 (94.8%)	329 (21.5%)	
	5250 to 7,000 $	3 (4.8%)	59 (95.2)	62 (4.1%)	
	More than 7,000 $	1 (3.0%)	32 (97.0%)	33 (2.2%)	
Residency	Suburban	7 (24.1%)	22 (75.9%)	29 (1.9%)	0.004
	Urban	130 (8.7%)	1,357 (91.3%)	1,487 (98.1%)	

BMI: body mass index.

Tab. II. Prevalence of asthma, asthma symptoms and allergic rhinitis in the elderly based on ECRHS questionnaire.

Parameters	Prevalence	95.0% Confidence Interval	
		Lower	Upper
Asthma (wheezing + dyspnea + absence of a cold)	8.97% (137)	7.59%	10.52%
Asthma symptoms			
Awake with chest tightness	15.52% (237)	13.74%	17.44%
Awake with dyspnea	9.76% (149)	8.32%	11.36%
Awake with cough	10.22% (156)	8.74%	11.85%
Current asthma (attack of asthma/ taking asthma medication)	6.81% (104)	5.60%	8.19%
Physician diagnose asthma	4.78% (73)	3.77%	5.97%
Allergic rhinitis	23.51% (358)	21.40%	25.72%

Discussion

The burden of asthma in the elderly has remained high globally. Although it is a multifactorial issue, identifying the epidemiological data of asthma in this age group and the related socio-economic factors is crucial to set future directions, especially in developing countries with rapid aging of population [3, 7-9]. The current study examined the prevalence of asthma in the elderly and related sociodemographic and socio-economic factors based on the 2015 SARDS.

The prevalence of asthma, current asthma, physician diagnosis asthma, and allergic rhinitis was 8.97, 6.81, 4.78, 23.51% in urban and suburban non-institutionalized elderly inhabitants of Shiraz, Iran. The prevalence of asthma in the elderly was higher significantly among the subjects older than 80 years, smokers, illiterate subjects, and individuals with the lowest annual income, and those who lived in suburban areas. In a multivariate logistic regression model, those with advanced age, current smokers, and those living in suburban are-

Tab. III. Predictive factors of asthma prevalence in the elderly based on OR and 95% CI using multiple logistic regression analysis.

Variables	B	SE	Adjusted OR (95% CI)	P-value
Age groups				
61-70	Baseline	-	-	-
71-80	-0.15	0.22	0.86 (0.55-1.33)	0.50
More than 80	0.69	0.30	2.01 (1.10-3.65)	0.02
Smoking habits				
Non-smoker	Baseline	-	-	-
Current smoker	1.01	0.25	2.76 (1.69-4.51)	000
Ex-smoker	0.09	0.38	1.09 (0.51-2.31)	0.80
Passive smoker	0.23	0.28	1.26 (0.72-2.18)	0.40
Residency				
Urban	Baseline	-	-	-
Sub-urban	1.10	0.46	3.01 (1.20-7.50)	0.01
Education				
Academic	Baseline	-	-	-
Illiterate	0.32	0.38	1.38 (0.65-2.96)	0.39
Primary	-0.11	0.36	0.89 (0.43-1.84)	0.76
Secondary	-0.27	0.40	0.76 (0.34-1.69)	0.50
Income				
More than 7,000 $	Baseline	-	-	-
Less than 3,500 $	1.00	1.04	2.72 (0.35-21.06)	0.33
3,500 to 4,750 $	0.38	1.05	1.47 (0.18-11.61)	0.71
5,250 to 7,000 $	0.49	1.18	1.64 (0.16-16.65)	0.67

B: beta; SE: standard error; OR: odds ratio; CI; confidence interval.

as significantly predicted the prevalence of asthma in the elderly.

There are no epidemiologic data or population-based study about asthma prevalence in older population of Iran. Only two large population-based studies reported the prevalence of asthma in the age group of older than 60 years. Idani et al. in 2018 reported the rates of asthma-like symptoms, current asthma, physician diagnosis asthma, and allergic rhinitis 26.8, 11.3, 8.7 and 23.9% respectively in the 45-65 year old population of Khuzestan Province [17]. Advanced age was a significant predictive factor of asthma in this study. Specific condition of Khuzestan province regarding more exposure to micro-waste, industrial and non-industrial pollutants can be explained by this higher rate. In another population-based study conducted in the north-east of Iran, the prevalence of asthma symptoms had an increasing trend and was highest in older age groups: 7% in 60-64 years, 8.4% in 65-69 years, and 8.4% 70-104 years [18].

In the recent national survey, the prevalence of asthma was 8.9%, current asthma 4.7%, physician-diagnosed asthma 3.7%, and the history of allergic rhinitis 21.1% in 20-44 year old population in Iran [15]. Varmaghani et al. in a meta-analysis reported the pooled prevalence of asthma ever and physician diagnose asthma 2.5% (95% CI; 1.98-3.10%) and 1.9% (95% CI; 1.26-2.61%) in the population aged over 18 years in Iran [19]. In the first study from SARDS, the prevalence of adult asthma was 7.8 % in urban and suburban non- institutionalize inhabitants of Shiraz, Iran [20]. According to the mentioned rates, it is confirmed that asthma prevalence in the elderly is high, like many other developed and developing countries [2, 4, 21-24].

In the study of Nejjari et al., cumulative asthma prevalence was reported 6.1% in the French elderly [4]. This rate was significantly higher among manual workers. The prevalence of current asthma was 6.3% in the elderly population of West Texas [25]. In the multiple logistic regression analysis, low income (OR = 1.84; 95% CI = 1.04, 3.27) and history of smoking cigarettes (OR = 1.48; 95% CI = 1.03, 2.14) were among the independent risk factors for current asthma. The lack of national studies and the methodological heterogeneity in international studies made achieving the desirable comparison difficult, especially in socioeconomic areas.

Strengths and limitations

To the best of the authors' knowledge, this is the first population-based study evaluating the asthma prevalence in the elderly and its related socioeconomic factors in Iran. To increase the response rate, the questionnaires were completed by a team of trained interviewers. This study had at least two limitations. First, a validated ECRHS questionnaire was used to facilitate international comparisons; however, this questionnaire was used more in the age range of 20-44 years, and some variability in asthma symptoms was reported in 90 elderly subjects. Another limitation was that using self-reported income as an indicator of socioeconomic status does not essentially imply the real income; it is associated with underreporting because of social undesirability of this variable in our cultural setting [26].

Conclusion

The findings provide helpful information to develop targeted interventions in order to reduce the burden of asthma in the elderly especially among vulnerable groups; active smokers, and those living in suburban areas. Moreover, this study highlighted the effect of socio- economic status, disparities and inequality on community health.

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Conflict of interest statement

The authors declare no conflict of interest.

Authors' contributions

Conception of study: HM, SS. Study design: HM, SM, SS. Acquisition, analysis, and interpretation of data: HM, SM. Drafting of manuscript: HM, SS. Critical revision: SM. Final approval of manuscript: HM, SS, SM.

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ORIGINAL ARTICLE

Cervical cancer and screening: knowledge, awareness and attitudes of women in Malta

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Keywords

Cervical cancer • Cervical screening • Knowledge • Attitudes

Summary

Objectives. *This study comes at an opportune time due to recent introduction of the National Cervical Cancer Screening programme in Malta. It aims to assess the knowledge of 25-64 year-old females on cervical cancer and attitudes towards screening.*
Study design. *A cross-sectional, telephone-based, quantitative survey conducted in 2017.*
Methods. *The survey tool was based on the Cervical Cancer Awareness Measure questionnaire and was carried out among a random stratified sample of females of 25-64 years, resident in Malta. Multivariate logistic regression models were applied.*
Results. *407 females (85% response rate) were interviewed. Knowledge of cervical cancer risk factors and symptoms was found to be significantly higher in women with a higher level of education ($p < 0.001$). Cervical screening was attended every 3 years by 69% of respondents. Regular attendees were more likely to have children ($p = 0.001$), have experienced cancer in a close family member ($p = 0.002$), and were between 35-44 and 45-54 years old ($p < 0.001$). The main reasons for non-attendance were embarrassment, fear of the test and fear of the result.*
Conclusion. *This research provides a better understanding of who are the vulnerable groups with respect to cervical cancer knowledge and screening attendance. Improving health literacy and implementing health promotion campaigns will improve early symptom recognition, risk factor knowledge and attendance for screening.*

Introduction

Cervical cancer (CC) is an important public health challenge. It is the fourth and sixth most prevalent cancer in females, worldwide and in Europe, respectively [1]. This cancer is most common in women between 35-45 years [2, 3], a period of time where women are most active and productive. Therefore, it leads to significant psychological, social and economic strain on the affected individual, their family and the community [4].
CC can be avoided through primary prevention which is the Human Papillomavirus (HPV) vaccination and by engaging in secondary prevention by attending for cervical screening (CS) [5]. There are disproportionate variations in the incidence and survival rates of CC, with women of lower socioeconomic status (SES), those from ethnic minority groups and those living in developing countries being affected more than others [3, 5]. Providing education and awareness of CC risk factors, symptoms and preventive services availability, reduces this inequality gap since CC can be detected earlier [5].
The European Union (2015) recommends that screening is offered through a population-based, organised programme which should start between 20-30 years and is to continue up to 60-65 years, at 3-5 year intervals [5]. Currently, there are 22 Member States implementing, piloting or planning for a population-based CS programme [6]. Moreover, the HPV vaccination should also be delivered through a population-based organised programme which targets females before they become sexually active [5].
CC incidence and mortality rates have remained relatively stable over the past 20 years in Malta with local rates being lower than the rates of Europe and the European Union [7, 8]. However, the 5-year relative survival rate of CC cases (2000-2007) for Malta was 54.73%, which ranks Malta as having the second worst 5-year survival rate in the 29 represented European countries [9]. However, results should be interpreted with caution as the confidence interval for Malta is wide due to small numbers of CC cases and deaths.
Locally the importance of increasing the knowledge of cancer symptoms and risk factors, and tackling any possible negative views on cancer screening was emphasised in the National Cancer Plan for the Maltese Islands 2017-2021 (NCP) [10]. The national CS programme was launched in 2016, prior to this, females in Malta attended for opportunistic screening both in the public and the private sector. The current organised programme is targeting women aged 27 to 39 years and is conducted via Liquid-based cytology and if results are abnormal and the woman is above 30 years of age, the HPV test is conducted as well. The participation rate for 2019 was 25% for the organised screening programme, however many attend for opportunistic screening. In the European Health Interview Survey 2014/2015, 82.3% of females between 27 and 37 years answered that they attended for CS in the public or private sector within the 3 years prior to the survey [11]. Females of 40-64 years

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are still being screened through opportunistic screening. An HPV vaccination programme was introduced in 2012 and provides the vaccine for 12-year-old girls.
Through this study the researchers wanted to assess the level of knowledge of cervical cancer symptoms and risk factors amongst the Maltese female population and their awareness of preventative services available at the National Health Systems. This study also aimed at obtaining a comprehensive picture on the attitudes towards cervical screening and on barriers identified by females who are not getting screened.

Methods

Study population

The target population was females of 25 to 64 years residing in Malta during the previous year. A random, representative sample of 800 females stratified by 10-year age groups and the 6 regions of Malta was taken from the Maltese Identity Card Register. Considering a 95% confidence level, the sample needed to have an accuracy of at least +/-5%, would be of at least 384 respondents. When accounting for a 20% loss of participants due to inability to find their contact number and an approximate response rate of 60% for telephone interviews, the size of the sample needed was inflated up to 800 females. The Identity Card register was used as the reference population for Malta.
Females, who did not have a registered contact number in the National Screening Unit database or in the online directory, had hearing or cognitive problems or were abroad during the fieldwork, were excluded.

Development of research tool

The Cervical Cancer Awareness Measure questionnaire developed by the University College London, Health Behaviour Research Centre, was culturally adapted to Malta and used as the basis of the research tool [12]. The Cervical Cancer Awareness Measure covers questions regarding awareness of the symptoms and risk factors of CC, the public knowledge on National Cervical Screening and HPV vaccination programme, and demographic information. Questions on uptake of CS and any possible barriers were taken from another two studies and added to the research tool [13, 14] after relevant permissions were sought and obtained. Psychometric evaluation of the tool was then conducted. The tool was tested for validity, reliability and then piloted on 50 females, to produce the final research tool which was used during the fieldwork.

Data collection and analysis

Data was collected in 2017 using a telephone-based interview. Informed consent was given by the participant over the phone prior to the interview. The participants' anonymised answers were then inputted into a spreadsheet. The socio-demographic variables were grouped before data analysis: 1) age was categorised in 10-year age groups; 2) locality of residence was categorised to the 6 regions of Malta; 3) the level of education was grouped in International Standard Classification of Education (ISCED) levels 0-2, 3-4, 5-8; 4) employment was split in "Gainfully employed" and "Not gainfully employed"; 5) the last time the smear test was done was grouped in "Smear test done less than 3 years ago", "Smear test done more than 3 years ago" and "Smear test was never done".
A score was formulated for the CC symptom knowledge and the CC risk factor knowledge. For the symptom knowledge questions, respondents were given 1 mark for every "Yes" and 0 marks for every "No" and "Don't Know" they answered. For the risk factor knowledge question respondents were given 1 mark for "Agree" and "Strongly Agree" and 0 marks for "Strongly Disagree", "Disagree" and "Don't Know" answers given [15].
The data was analysed using Statistical Package for Social Sciences (SPSS) version 20. Univariate analysis using Chi-squared test, Fisher's Exact Test and Analysis of Variance (ANOVA) was undertaken to assess the association between the identified dependent and independent variables. The independent variables which were significantly associated with the dependent variables were used to create models using multivariate logistic regression technique for the following dependent variables:

- Model 1: unprompted identification of any cervical cancer risk factors;
- Model 2: awareness of an organised cervical screening programme at the National Screening Unit;
- Model 3: awareness of the HPV Vaccination programme on the National Immunisation Schedule;
- Model 4: when was the last smear test done (less than 3 years, more than 3 years, never).

Results

Response rate

From the original sample there were 474 subjects who met the inclusion and exclusion criteria. A response rate of 85.86% was obtained (407 respondents). There was no statistically significant difference between the age and region characteristics of the responders, the non-responders, the non-eligible females and the Identity card register population and therefore the study sample population was considered to be representative of the target population for the variables compared.

Socio-demographic characteristics

The socio-demographic characteristics of the 407 females who participated in this study are summarised in Table I. The mean age of the participants was 42.49 ± 11.85 years (range: 25-64 years).

Symptoms and risk factors knowledge

74.94% (n = 305) of the participants were able to identify more than 3 symptoms when prompted, with the most identified symptoms being post-menopausal bleeding, persistent pelvic pain and weight loss (Fig. 1). The

Tab. I. Participants socio-demographic features.

Variable	Category	Frequency (n = 407)	Percentage (%)
Age group	25-34	122	29.98
	35-44	106	26.04
	45-54	88	21.62
	55-64	91	22.36
Country of birth	Malta	375	92.14
	EU country	9	2.21
	Non-EU country	23	5.65
Region	Gozo and Comino	33	8.11
	Northern	72	17.69
	Northern Harbour	137	33.66
	South Eastern	56	13.76
	Southern Harbour	61	14.99
	Western	48	11.79
Civil status	Single	104	25.55
	Married/ registered relationship	266	65.36
	Separated	26	6.39
	Widowed	4	0.98
	Divorced	3	0.74
	Refusal	4	0.98
Have children	No	122	29.98
	Yes	285	70.02
ISCED level	0-2	186	45.70
	3-4	74	18.18
	5-8	147	36.12
Employment	Gainfully employed	281	69.04
	Not gainfully employed	126	30.86

Fig. 1. Correctly identified cervical cancer symptoms.

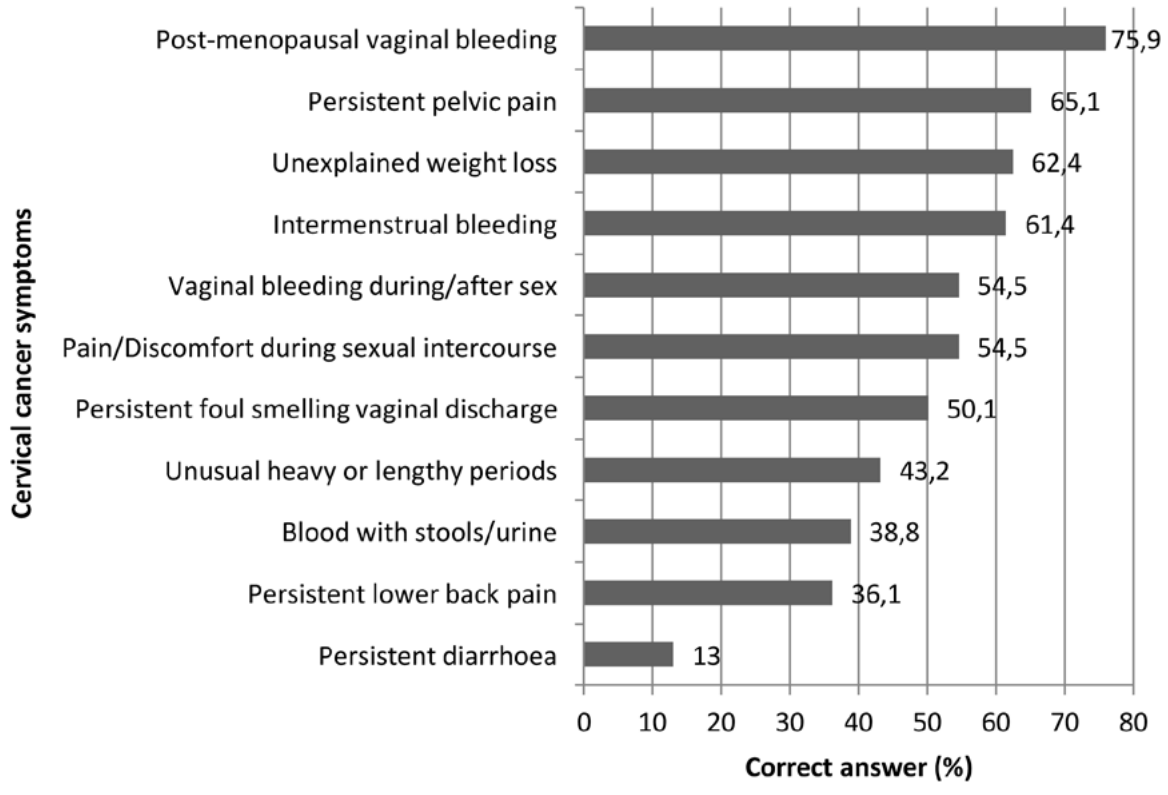
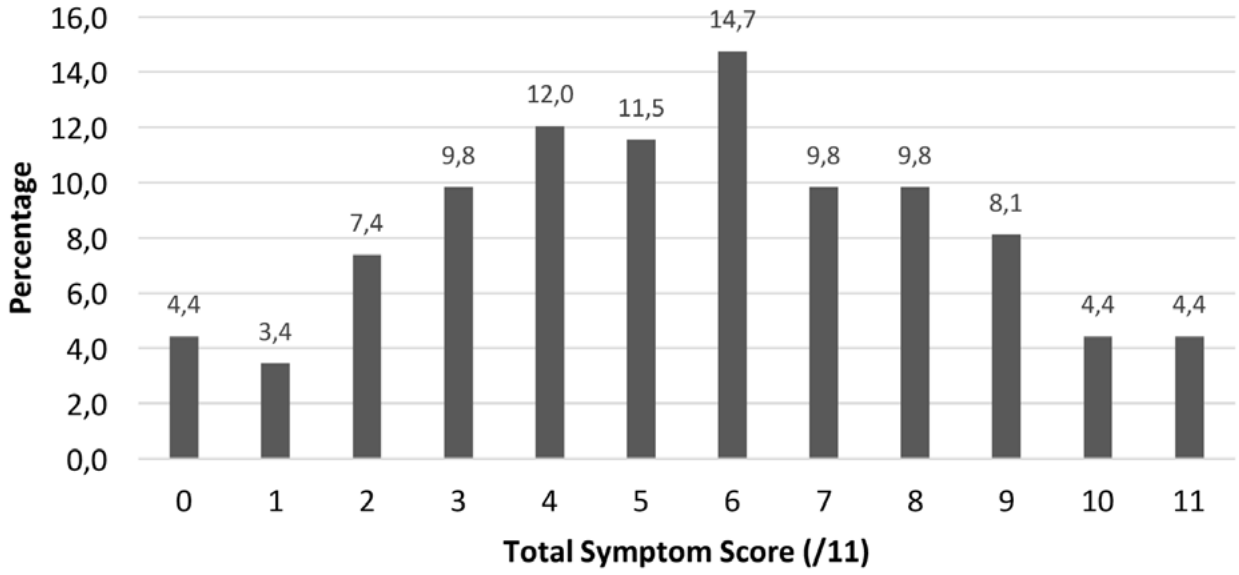


Fig. 2. Total score for the number of symptoms positively identified.



mean total symptom score attained was 5.55 ± 2.82 (range: 0-11) out of maximum score of 11 (Fig. 2).

Participants were also asked to identify any CC risk factors unprompted. 46.44% (n = 189) were unable to identify any risk factors, while only 10.32% (n = 42) of participants were able to correctly identify the two most important factors which are multiple sexual partners and HPV infection. Only 38.1% (n = 155) of the research population knew that HPV infection is a risk factor (prompted). The mean total risk factor score was 4.71 ± 2.70 (range: 0-10) out of a maximum score of 10. Women with a higher level of education were significantly more likely to be aware of risk factors (Mean Difference between ISCED level 0-2 and ISCED level 5-8: -0.72, 95% CI = -1.43, -0.01; p = 0.040) and symptoms associated with cervical cancer (Mean Difference between ISCED level 0-2 and ISCED level 5-8: -1.27, 95% CI = -2.00, -0.53; p < 0.001). For the unprompted identification of risk factors, none of the participants who were between 55 and 64 years were able to identify two or more risk factors. Unemployed women (OR = 0.27, 95% CI = 0.10-0.71; p = 0.014) and women with a low level of education (OR = 0.24, 95% CI = 0.11-0.52; p < 0.001) were significantly less likely to be aware of any risk factors while females who had a past diagnosis of HPV infection were more likely to mention 2 risk factors unprompted (OR = 3.89, 95% CI = 1.29-11.69; p = 0.036) .

Knowledge on available preventative services

When asked about the National CS Programme, 50.86% (n = 207) of the participants were aware of its existence but only 38.46% (n = 80) of these, identified the correct age cohort which is currently being invited. Awareness was significantly higher amongst females who were from the youngest age groups (p < 0.001), 25-34 years (OR = 2.71, 95% CI = 1.55-4.75) and 35-44 years (OR = 2.68, 95% CI = 1.50-4.77). Women with a high level of education, ISCED level 5-8 (OR = 1.94) were significantly more (p = 0.044) aware of the National CS Programme when compared to ISCED level 0-2 (OR = 0.72, 95% CI = 0.47-1.11) On the other hand women who are unemployed (OR = 0.472, 95% CI = 0.307-0.72; p = 0.010), have children (OR = 0.54, 95% CI = 0.35-0.83; p = 0.011) and were married in the past (OR = 0.66, 95% CI = 0.418-0.99; p = 0.029) were significantly less aware of the National CS Programme.

Regarding the HPV vaccination programme, 56.27% (n = 229) of participants were aware of this service with nearly half of these (n = 111) knowing the correct age when the vaccine is given. Awareness of this service was significantly higher within the two youngest age groups (p < 0.001). The OR of the 45-54years age group (OR = 0.74, 95% CI = 0.41-1.34) falls outside the ORs and CIs of the 25-34 years (OR = 1.67, 95% CI = 0.96-2.91) and 35-44 years (OR = 1.75, 95% CI = 0.99-3.10) age groups. Participants with a lower level of education (OR = 0.57, 95% CI = 0.37-0.89; p = 0.043) and who were unemployed (OR = 0.55, 95% CI = 0.36-0.84; p = 0.031) were significantly less aware of the vaccination programme.

Attendance for cervical screening

Respondents were also asked about their screening practices. 69.04% (n = 281) of respondents claimed to have attended for CS in the 3 years prior to the interview, with 72.28% (n = 203) of these attendees claiming that they go for screening more often than the recommended 3-yearly interval. The majority (84.78%) of those that have attended screening at least once in their life (n = 368) said that they attend for screening in the private healthcare sector. Among those participants who never attended screening or attended more than three years ago, the most common barriers mentioned were embarrassment,

fear of the test and fear of the result (Fig. 3). Regular attendees to CS (every 3 years) were significantly more likely to have a higher level of education (OR = 1.36, 95% CI = 1.10-1.78; p < 0.001), be married or separated (OR = 2.48, 95% CI = 1.56-3.94; p < 0.001), be in the 25-34 (OR = 2.36, 95% CI = 1.35-4.15; p = 0.003), 35-44 (OR = 4.90, 95% CI = 2.57-9.54; p < 0.001) or 45-54 (OR = 3.20, 95% CI = 1.70-6.02; p < 0.001) age groups, have children (OR = 1.63, 95% CI = 1.045-2.56; p = 0.007) and have a close family member with a history of cancer (OR = 1.72, 95% CI = 1.11-2.67; p = 0.012).

Multivariate logistic regression model

Models (Tab. II) were computed for the outcome variables which reached the level of significance in the univariate analysis, mentioned above. In Model 1, the explanatory variables that remained statistically significant after adjusting the model for the other variables were:

- level of education (ISCED level): risk factor identification increased with increasing level of education;
- females who had a past positive diagnosis of HPV infection were significantly more knowledgeable than those who had not.

The outcomes of the second model which assessed the awareness of organised CS programme and the third model on the awareness of the national HPV vaccination programme (Tab. II) gave similar results. Females in the younger age groups (25-34 and 35-44) were significantly more aware of the presence of an organised CS programme at the National Screening Unit and the HPV vaccination programme.

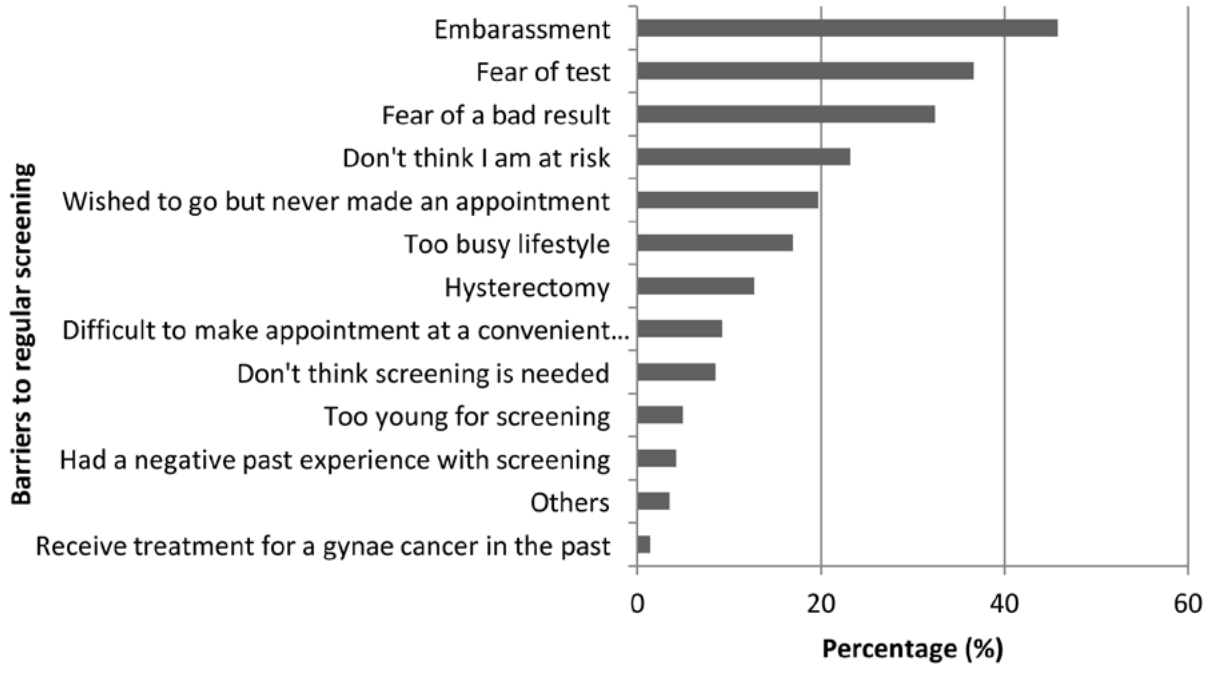
Model 4, assessed when the last smear test was done (less than 3 years, more than 3 years, never). The model resulted in three independent variables remaining statistically significant. Females who attended screening regularly were from the younger age group (especially the 35-44 age group), had children and had a close family member who suffered from cancer in the past (Tab. II).

No models were done for the outcome variables Total Symptom Score and Total Risk Factor score since they were only statistically significant associated with one variable – level of education.

Discussion

This study found moderate overall knowledge of CC symptoms which differed from local research regarding breast cancer symptoms where it was found that women in Malta were highly knowledgeable [16]. This may imply greater health promotion and health education on breast cancer compared to CC. The most recognised CC symptoms were post-menopausal bleeding, persistent pelvic pain and unexplained weight loss. Pain and weight loss are general symptoms of most cancers; participants might have acquired information on these symptoms from other cancer information campaigns. Health promotional messages in England were focused on increasing the knowledge of the three earliest CC symptoms: post-menopausal vaginal bleeding, post-coital bleeding and persistent foul smelling vaginal discharge [2, 14]. There is a need to increase the knowledge of these three symptoms in Malta, to help in their early recognition by the public and thus early referral to a health professional. Knowledge of CC symptoms increased with increasing level of education which was a common finding in the literature [2, 14] and may be attributed to people with higher level of education having a higher health literacy [17].

Fig. 3. Identified barriers for not attending cervical screening regularly.



Tab. II. Results of the multivariate logistic regression models.

	Variables	Univariate p-value	Multivariate p-value	Category p-value	Odds ratio (95% CI)
Model 1	ISCED	< 0.001		0.001	
	ISCED level 0-2		0.001		0.443 (0.273-0.719)
	ISCED level 3-4		0.887		0.955 (0.508-1.797)
	ISCED level 5-8 (reference)				1.000
	HPV infection in the past	0.036	0.023	0.023	
	Yes				1.66 (1.074-2.560)
	No (Reference)				1.000
	Age (25-34, 35-44, 45-54, 55-64 years)	0.001			
	Employment (gainfully employed or not)	0.014			
Model 2	Age group	< 0.001		<0.001	
	25-34 years		< 0.001		3.174 (1.745-5.772)
	35-44 years		< 0.001		3.122 (1.692-5.761)
	45-54 years		0.419		1.306 (0.683-2.497)
	55-64 years (reference)				1.000
	ISCED (ISCED level 0-2, 3-4, 5-8)	0.044			
	Employment (gainfully employed or not)	0.010			
	Civil status (married in the past or not)	0.029			
	Having children (yes or no)	0.011			
Model 3	Age group	< 0.001		0.002	
	25.34 years		0.018		2.015 (1.129-3.598)
	35-44 years		0.016		2.088 (1.150-3.791)
	45-54 years		0.611		0.851 (0.456-1.586)
	55-64 years (reference)				1.000
	ISCED (ISCED level 0-2, 3-4, 5-8)	0.043			
	Employment (gainfully employed or not)	0.031			
Model 4	Having children	0.007		0.001	
	Yes		0.001		2.705 (1.470-4.976)
	No (reference)				1.000
	Past history of cancer in a close family member	0.012		0.002	
	Yes		0.002		2.155 (1.332-3.488)
	No (reference)				1.000
	Age group	< 0.001		< 0.001	
	25-34 years		0.001		3.503 (1.667-7.362)
	35-44 years		< 0.001		4.302 (2.137-8.661)
	45-54 years		0.001		3.234 (1.570-6.662)
	55-64 years (reference)				1.000
	ISCED (ISCED level 0-2, 3-4, 5-8)	< 0.001			
	Civil status (married in the past or not)	< 0.001			

CI: confidence interval.

The most recalled unprompted CC risk factor (43.24%) was sexual promiscuity which was again confirmed in the prompted questions. This finding was also prevalent in the literature where sexual behaviour was the most commonly recalled and recognised risk factor [2, 15, 18]. This study highlighted a very low awareness of HPV, also found by local and international studies conducted in England, France and Germany [2, 14, 19-24]. Despite having a national HPV vaccination programme and an organised CS programme, the knowledge of HPV remains low. This might indicate that both programmes are not being promoted effectively and fail to educate the public on the role of HPV in CC aetiology. It is important to highlight the role of HPV, different sexual partners and smoking in the aetiology of CC as these are three important modifiable risk factors. Educational material on CC tends to deemphasise the mode of transmission of HPV to avoid associating CC to a Sexually Transmitted Disease. It is important not to cause an increase in the stigmatisation of CC which can be a barrier for screening attendance but females have a right to know the exact pathophysiology of CC in order to be empowered in taking decision regarding their sexual life [5, 18, 25, 26].

The first model showed that level of education and past HPV infection were the only two variables which remained statistically significantly associated with knowledge of risk factors. The positive effect of the level of education on the knowledge of CC risk fac-

tors was also documented in British and Italian studies [14, 15, 18, 27]. Low et al. (2012) and De Vito et al. (2014) found that females who received a result of an abnormal smear in the past where more knowledgeable as they had received advice and education from health professionals who delivered the diagnosis. An abnormal result might also have pushed them to seek more information on their condition.

When assessing the awareness of nationally available CC preventative services, this was low compared to England [2]. Of those who were aware of the programme there were a lot of misconceptions on who is currently being invited and at what frequency. Model 2 and Model 3 showed that age was the most significant variable, with the two younger age groups 25-34 years and 35-44 years, that is those who are currently being targeted by the screening programme, being significantly more knowledgeable. In studies conducted in England and France a positive effect of education on the overall knowledge of preventative services was also found [2, 23] but this was not found locally. This highlights the lack of promotion of these services, as both highly educated females and those with low level of education had low awareness of these services.

When it comes to CS practices 69.04% of the participants attended CS within the three years prior to the study with the majority of these attending within intervals less than the recommended three years [5] and in the private sector. This is a very similar figure to the European Health Interview Survey 2014 where 69.6% of the participants attended opportunistic CS within three years [11]. Therefore, if the national screening programme is to be extended to other age groups and kept at the recommended 3-year interval, the public should be educated on the benefits of screening and on the harms of over-screening such as over-treatment and increased psychological distress (anxiety). Discussions should also be conducted with health professionals who tend to recommend excessive use of screening in women with normal levels of risk factors [25].

Model 4 showed that regular attendees were more likely to be young, have children and have a close family member with a past history of cancer. Various literature works in Spain, Switzerland, Germany, Greece and the Netherlands also found that younger age groups attend for regular screening more because they are at the child-bearing age and therefore come into contact with gynaecological services more [28-32]. The same effect is therefore seen in women who have children. During these consultations they can be advised on the benefits of CS and given information on CC risk factors [28, 30-34]. Chorley et al. (2017) and Fylan (1998) also argued that post-menopausal women attend screening less as they might erroneously think that they are no longer at risk of CC. The systematic review conducted by Chorley et al. (2017) also agreed with the finding that females who have a close family member who suffered from cancer attend for CS more. Fear that close relatives of a cancer patient are more at risk of developing any type of cancer themselves might explain such finding and therefore these relatives are more prone to engage in preventative services.

The most mentioned barriers for CS were embarrassment, fear of test and fear of bad result. Embarrassment of CS was attributed to the fact that pelvic examination is considered as intimate by women [2, 23, 35]. Fear of test resulted from lack of knowledge on the procedure itself and fear of pain. Fear of bad result comes from the common public perception that a cancer diagnosis is fatal and lack of believe that if diagnosed early it is more treatable [2, 23, 35]. The inclusion of an information leaflet with the CS invitation letter, explaining the procedure and highlighting the benefits of screening will reduce the fear of the test itself and incentivise women to attend for screening. There is also the need to increase the awareness that CS usually detects lesions which are pre-cancerous or non-invasive cancers, to decrease the fatalistic perceptions towards screening.

The results of this study should be interpreted in the light of this study's limitations: 1) although respondents and non-respondents, and respondents and the Maltese population had a similar distribution in terms of age and region of residence there might still be a selection bias in terms of other socio-demographic characteristics; 2) screening practices were based on self-reported data which might be susceptible to recall bias and also over-reporting due to social desirability; and 3) the cross-sectional methodology does not allow for causality to be determined. Nonetheless, it is the first national representative study with a high response rate that provided a picture of the local knowledge, awareness and attitudes on cervical cancer and screening.

Conclusion

In conclusion the outcomes of this study provide important information on the knowledge, awareness and attitudes of females in Malta on CC and CS. Through this study, various gaps in the knowledge of CC symptoms and risk factors were identified. This information should be used when planning future health promotion campaigns on CC, with the aim of increasing the knowledge on the role of HPV in CC and also to increase the ability of early symptoms recognition. These campaigns should especially target females of screening age with a specific focus on females having a low level of education. The identified attitudes and barriers towards CS should also be utilised and addressed in future health services planning. The implementation of such recommendations can empower females in Malta to prevent CC by reducing the risk of HPV infection and by attending regularly for screening services.

Key points

- To our knowledge, this is the first national representative study that provides information on the local knowledge, awareness and attitudes on cervical cancer and screening which can be of use in planning

health promotion campaigns and in health service planning particularly in further development of the national cervical cancer screening programme.
- The findings of this study infer that there is a moderate overall knowledge of cervical cancer symptoms and risk factors amongst 25-64-year-old females in Malta with females having a low education level being less knowledgeable.
- There was low awareness on preventative services available locally including the organised cervical screening programme and the availability of the HPV vaccine on the National Immunisation Schedule.
- A cervical screening rate of 69.04% was found, with many not following European guidelines.
- Participants who regularly underwent cervical screening were more likely to be young, have children and have a close family member with a past history of cancer.

Ethical approval

This study was approved by the Research Ethics Committee of the University of Malta.

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Conflict of interest statement

The authors declare no conflict of interest.

Authors' contributions

Authors contributed equally to this research work.

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ORIGINAL ARTICLE

Awareness and risk burden of diabetes mellitus in a rural community of Ekiti State, South-Western Nigeria

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Keywords

Awareness • Knowledge • Risk-factors • Diabetes • Rural community

Summary

Objective. *In recent times, Diabetes Mellitus (DM) has had a rapid increase in developing countries as a result of changing lifestyles among the people. This study was therefore aimed to investigate the level of awareness of DM and its associated risk factors in Afao: a rural community located in Irepodun/Ifelodun Local Government Ekiti State, Nigeria.*
Design. *The study was descriptive cross-sectional in design. A multi-stage sampling technique was applied to recruit respondents who are residents in the community. Two hundred and one individuals were involved in this community-based study. Information was obtained using a modified WHO STEPwise approach to chronic disease risk surveillance. The questionnaire included questions that assessed socio-demographic characteristics, diabetic risk factors and anthropometric measures of respondents.*
Result. *Of the 134 (66.7%) respondents aware of DM, only an average of 43.9% had knowledge of its risk factors. Respondent's body mass index was significantly associated ($P < 0.01$) with knowledge of overweight/obesity as overweight (52.9%), grade 1 obese (62.5%) and morbid obese (100%) respondents had no knowledge of their status as risk factors for DM. Also, respondent's blood pressure status showed a significant association ($P = 0.099$) with respondent's knowledge of high blood pressure, 62.5% of those unaware of their blood pressure status had no knowledge of high blood pressure as a diabetes risk factor. Respondent's age ($P = 0.024$) and diet; daily vegetable servings ($P = 0.015$) and cooking oil ($P = 0.05$) showed significant association with the occurrence of the disease in 14.4% respondents previously diagnosed.*
Conclusion. *This study shows a need to improve on the level of awareness of diabetes risk factors in Afao. Routine measurement of blood glucose levels for adults, community health education and enlightenment strategies through the ministry of health on the awareness of diabetes are highly recommended for the Afao community.*

Introduction

Diabetes Mellitus (DM), a non-communicable disease, is one of the core universal health problems. Over the past four decades, there has been so much talk about this disease and knowledge about it has increased in many regions of the world. However, in many developing countries, especially the rural areas, the level of awareness of diabetes and its risk factors is still very low. Statistically, about 50% of people with diabetes remain undiagnosed and approximately 20-30% patients usually have already developed complications before being diagnosed [1].
Moreover, it has been documented that 75% of people with diabetes reside in low-and middle-income countries [2]. Records from the World Health Organization (WHO) reveal that Nigeria; the most populous black Nation in the world, has the greatest number of persons living with diabetes in Africa [3] The prevalence of diabetes in Nigeria varies from 0.65% in the rural (North) to 11% in the urban (South.) [4].
In a recent study of a rural community in southern Nigeria, a prevalence of 8% and two major risk factors were observed; misuse of alcohol and physical inactivity. "The major risk-factors identified point to a likely change from an active lifestyle that was characteristic of rural farming communities to a less active lifestyle characteristic of urban populations which have been exposed to westernization" [5].
Hence, the main objective of this study is to assess the level of awareness of diabetes mellitus in Afao: a rural community in South Western Nigeria. The specific objectives are:

- to assess the respondents knowledge of diabetes risk factors;
- to determine those with previously diagnosed diabetes in the study population;
- to find out the risk factors which significantly associates with knowledge and occurrence of the disease among the respondents.

Methods

Study location

The study was conducted in Afao, a small rural community located in Irepodun/Ifelodun Local Government Area of Ekiti State. It is about 19.4 km from Ado-Ekiti (the State capital) and 3.4 km to Are-Ekiti by road. At

the time of conducting the study, the human population of Afao was estimated at 10,879 [6]. Afao comprises of ten settlements namely: Odo-Ode, Kajola, Oke-Uro, Temidire, Olorunfemi, Aba-Igbira, Ikefun, Aba-Fulani, Ogbon-Aarin and Oloruntedo. The community has fairly developed basic infrastructure e.g. primary schools, secondary schools, a private hospital and a Government Health centre. Afao is inhabited by the Yoruba speaking people of South-western Nigeria.

Study population

Inclusion criteria: any adult (irrespective of sex and previous diagnosis of diabetes) who lives in the area was eligible to participate.
Exclusion criteria: pregnant women, breast-feeding mothers, and non-consenting adults were excluded from the study.

Study design

The study was descriptive cross-sectional in design.

Sample size

The minimum sample size, for the study was determined using the formula [7] for a single population proportion. Z is normal deviant at the portion of 95% confidence level = 1.96, 2.3% is the prevalence of DM from a previous study in a rural community southern Nigeria [8], is margin of error acceptable = 3%. Non-response rate of 5% and a multiplication factor of 2 was further utilized to compensate for design effect. The minimum sample size obtained was 201.

Sampling technique

Multi-stage sampling technique was used to recruit adults who are residents in the community. Three stages were involved: Stage one: Simple Random Sampling (SRS) was used to select four out of the ten settlements; Stage two: two streets were then selected from each of the four settlements to give eight streets by systematic sampling; Stage 3: 201 respondents (1 per household) were finally selected from households within the 8 selected streets by cluster sampling.

Data collection instrument

Data collection was done using interviewer assisted questionnaire method and physical examination. The questionnaire was a modified WHO STEP wise approach to chronic disease surveillance. Using only STEP 1 and STEP 2 for low resource countries. STEP 1 gathered information on socio-demographic features and risk factors such as smoking, alcohol use, fruit/vegetable intake, physical activity etc. STEP 2 included objective data collection by physical measurements of physiological attributes of human body such as weight and height [9]. Measurements were taken with the aid of calibrated equipment using standard techniques. Subjects were weighed in kilograms to the nearest kg. Height was measured using a stadiometer as respondents stood on barefoot with minimal/essential dressing and the results were recorded to the nearest 0.5 cm. Body mass index (BMI) was estimated as the ratio of weight in kilograms to the square of height in meters{weight (kg)/heights (m^2)}. Waist circumference was measured by placing a plastic tape to the nearest centimeters (cm) horizontally, at the midpoint of the lower margin of the 12^{th} rib and the upper margin of iliac crest along the midaxillary line.

Data analysis

The data collected for the study were first of all checked for errors, cleaned and then analyzed using the Statistical Package for Social Sciences (SPSS), version 23. Descriptive analysis of socio-demographic variables, respondent's perception, risk practices and so on were presented in frequencies and percentages using tables. The Chi-square test was used to test for significance of association between the variables.

Ethical consideration

Ethical clearance was obtained from the Research and Ethics committee of the Afe Babalola University Ado-Ekiti. With due respect to respondent's privacy, oral consent was obtained from each participant before data collection. In addition, respondents were informed of their right to voluntarily participate or withdraw from the study at any stage without adverse consequences. Confidentiality was also observed as the questionnaire bore no name of respondent or any identifying information.

Results

Socio-demographic characteristics of respondents

A total of 201 respondents were interviewed out of which 44.3% were male while 55.7% were female, giving a male to female ratio of 0.8:1. The mean age was 36.9 ± 1.053 years, the median age was 33 years while the minimum and maximum ages were 17 and 93 years respectively. The respondents comprised largely of people in the age-group 17-40 years (70.7%). Majority of the respondents were; married (59.7%), of the Yoruba tribe (81.6%), Christians (85.6%) traders (67.2%). Also, most respondents (42.8%) had only primary education while a majority (54.7%) earned an average monthly income lesser than or equal to 15,000 Naira (39$).

Awareness and source of information about diabetes mellitus

Participants were asked if they knew what diabetes mellitus was and were scored on their responses about the nature of DM. Most 134 (66.7%) of the participants thought that DM was a result of partial or complete reduction in insulin secretion. Respondents who had never heard of the disease and those that felt it was through excess eating of sweet foods were scored as 'not aware'. Majority (70.1%) of those aware of DM got to know about the disease from health care workers.

Tab. I. Respondents socio-demographic features.

Variables		Frequency	Percent
Sex	Male	89	44.3
	Female	112	55.7
Age	17-40	142	70.7
	41-60	41	20.4
	Above 60	18	9.0
Marital status	Married	120	59.7
	Divorced	-	-
	Widowed	15	7.5
	Separated	3	1.5
	Never married	59	29.4
	Cohabiting	4	1.9
Ethnicity	Yoruba	164	81.6
	Hausa	5	2.5
	Igbo	5	2.5
	Others	27	13.4
Religion	Christianity	172	85.6 13.4
	Islam	27	
	Traditional	1	0.5
	Others	1	0.5
Occupation	Farming	23	11.4 8.5
	Artisan	17	
	Commercial cyclist	11	5.5
	Taxi driver	9	4.5
	House-wife	6	3.0
	Trading	135	67.2
Highest education	Non-formal	65	32.3 42.8
	Primary	86	
	Secondary	37	18.4
	Tertiary	13	6.5
Average monthly household income	< $5	33	16.4 12.9
	$5-$13	26	
	$13-$26	22	11.0
	$26-39$	29	14.4
	>$39	91	45.3

Tab. II. Awareness and source of information about diabetes mellitus.

Awareness of Diabetes	Frequency	Percent
Aware	134	66.7
Not aware	67	33.3
Total	201	100.0
Source of information		
Media	93	69.4
Healthcare worker	94	70.1
Friends/Relatives	83	61.9
Books, Lectures, Flyers	51	38.1

Tab. III. Respondents' knowledge about risk factors of diabetes mellitus (N = 134).

	Yes	
Risk factors	**Frequency**	**Percent**
Smoking	44	32.8
Stress	56	41.8
Lack of exercise	62	46.3
Poor diet	72	53.7
Overweight/obesity	59	44.0
Alcohol misuse	62	46.3
High blood pressure	57	42.5

Respondents' knowledge about risk factors of diabetes mellitus (N = 134)

Of the 134 respondents who were aware of diabetes, most (53.7%) perceived poor diet as the major diabetes risk factor followed by lack of exercise and alcohol misuse (46.3%). Smoking (32.8%) was the least perceived diabetes risk factor. On the average, only 43.9% had knowledge of diabetes mellitus risk factors.

Tab. IV. Risk practices of diabetes mellitus among all respondents.

Risk practices	Frequency	Percent
Currently smoke tobacco	26	12.9
Currently use smokeless tobacco	13	6.5
Total	39	19.4
Duration of smoking		
< 1 year	4	10.3
2-4 years	10	25.6
≥ 5 years	25	64.1
Currently consumes alcohol daily	46	22.9
Average bottles taken per day		
1 bottle	12	26.1
2-5 bottles	27	58.7
6 bottles	2	4.3
> 6 bottles	5	10.9
Consumed alcohol in the past	64	31.8
If yes, how long did you stop?		
1 year or less	6	9.4
2-4 years	12	18.8
5 years	16	25
No response	30	46.9
Daily fruit servings		
None	25	12.4
1-2 servings	91	45.3
3-4 servings	50	24.9
5 servings	35	17.4
Daily vegetable servings		
None	8	4
1-2 servings	114	56.7
3-4 servings	49	24.4
5 servings	30	14.9
Oil mostly used for cooking		
Palm oil	170	84.6
Vegetable oil	22	10.9
Coconut oil	3	1.5
Others	6	3
Weekly walk/bicycle ride(30 mins)		
None	51	25.4
2-4 days	39	19.4
5-6 days	11	5.5
Everyday	100	49.7
Sports (30 mins. minimum daily)		
Yes	75	37.3

Risk practices of diabetes mellitus among all respondents

Smoking/Alcohol intake: Most (64.1%) of the 39 smokers had been smoking for over 5 years. Majority (58.7%) of the 46 who took alcohol drank an average of 2-5 bottles daily. Of the 31.8% respondents who used alcohol in the past, 25% had stopped drinking over 5 years earlier.
Fruits/vegetables consumption: 12.4% of the respondents did not take any kind of fruits while only 17.4% took about 5 servings daily. More than half of the study group took only 1-2 servings of vegetables daily.
Oil used for cooking: More than four-fifth (84.6%) of the participants use saturated fat (palm oil) for cooking.

Tab. V. Previous measurements among all respondents.

	Yes	
Previous Measurements	Frequency	Percent
Measured blood pressure	105	52.2
Measured blood sugar	60	29.9
Previously diagnosed with high blood pressure	17	8.5
Previously diagnosed with diabetes mellitus	29	14.4

Exercise/Sport (*Weeklywalk/Bicycle* ride): While over a quarter (25.4%) of the respondents do not engage in exercise which includes at least a 30 minutes daily walk or bicycle ride 62.7% do not engage themselves in any sporting activity.

Previous measurements among all respondents

About 52.2% of the study population had gotten their blood pressure measured while 8.5% had been previously diagnosed with high blood pressure. About 60 (29.9%) respondents had gotten their blood sugar level measured while only 29 (14.4%) had been previously diagnosed with diabetes mellitus.

Anthropometric measurements among all respondents

With respect to body mass index of the respondents, most (40.3%) were overweight while 32 (15.9%) were obese. Furthermore, 81.1% of the total respondents had a normal waist circumference while 18.9% had an abnormal waist circumference.

Knowledge of risk factor and its associated risk among respondents (n = 134)

Tab. VII looks at the association between knowledge of diabetes risk factors (Tab. III) and the risk factors/practices of respondents aware of DM. Respondent's

Tab. VI. Anthropometric measurements among all respondents.

Body mass index		
Category*	Value (kg/m²)*	Frequency (percent)
Underweight	<18.5	10 (5.0)
Normal	18.5-24.9	78 (38.8)
Overweight	25.0-29.9	81 (40.3)
Grade 1 obesity	30-34.9	23 (11.4)
Grade 2 obesity	35-39.9	6 (3)
Morbid obesity	≥ 40	3 (1.5)
Waist circumference		
Category*	Value (cm)*	Frequency (percent)
Normal male	< 102	86 (52.8)
Normal female	< 88	77 (47.2)
Total		163 (81.1)
Abnormal male	≥102	3 (7.9)
Abnormal female	≥ 88	35 (92.1)
Total		38 (18.9)

*Guidelines on overweight and obesity [10].

Tab. VII. Knowledge of risk factor and its associated risk among respondents (n = 134).

Risk factor	Knowledge of risk factor				*p* value
	No	Yes	Don't know	χ^2	
Have high blood pressure	**High blood pressure**				
No	53 (54.1)	42 (42.9)	3 (3.1)	7.816	**0.099***
Yes	3 (25)	7 (58.3)	2 (16.7)		
Don't know	15 (62.5)	8 (33.3)	1 (4.2)		
Smoke tobacco	**Smoking**				
No	75 (64.1)	36 (30.8)	6 (5.1)	1.912	0.384
Yes	8 (47.1)	8 (47.1)	1 (5.9)		
Consume alcohol daily	Alcohol abuse		0.181	0.913	
No	50 (49)	48 (47.1)	4 (3.9)		
Yes	17 (53.1)	14 (43.8)	1 (3.1)		
Daily fruit servings	**Poor diet**				
Less than 5	49 (45.4)	55 (50.9)	4 (3.7)	2.338	0.311
5 and above	9 (34.6)	17 (65.4)	0(0)		
Daily vegetable servings	**Poor diet**				
Less than 5	52 (45.6)	58 (50.9)	4 (3.5)	2.818	0.244
5 and above	6 (30)	14 (70)	0 (0)		
Cooking oil	**Poor diet**				
Unsaturated oil	10 (41.7)	14 (58.3)	0 (0)	1.006	0.605
Saturated oil	48 (43.6)	58 (52.7)	4 (3.6)		
Body mass index	**Overweight/Obesity**				
Underweight	3 (60)	2 (40)	0 (0)	33.221	**< 0.01****
Normal	29 (50.9)	27 (47.4)	1 (1.8)		
Overweight	27 (52.9)	23 (45.1)	1 (2.0)		
Grade 1 obesity	10 (62.5)	6 (37.5)	0 (0)		
Grade 2 obesity	1 (25)	1 (25)	2 (50)		
Morbid obesity	1 (100)	0 (0)	0 (0)		
Sport	**Lack of exercise**				
No	35 (46.1)	38 (50)	3 (3.9)	0.566	0.754
Yes	27 (46.6)	30 (51.7)	1 (1.7)		
Weekly walk	**Lack of excercise**				
Everyday	34 (52.3)	30 (46.2)	1 (1.5)	4.158	0.655
2-4 days	13 (46.4)	14 (50)	1 (3.6)		
5-6 days	2 (28.6)	5 (71.4)	0 (0)		
None	19 (55.9)	13 (38.2)	2 (5.9)		

χ^2: Chi-square test; *: *p* value < 0.1; **: *p* value < 0.01

blood pressure status showed a significant association (P = 0.099) with respondent's knowledge of high blood pressure as a risk factor of DM. Most (62.5%) of the participants who did not know their blood pressure status were not aware that high blood pressure is a risk factor of diabetes. Furthermore, a significant association (P < 0.01) was observed between respondent's body mass index and overweight/obesity as a risk factor of DM. Majority of the respondents who were overweight (52.9%), grade 1 obese (62.5%) and morbid obese (100%) were not aware of overweight/obesity as risk factors of diabetes mellitus.

Association between risk factors and previous diagnosis of diabetes

Respondent's age (P = 0.024), daily vegetable servings (P = 0.015) and cooking oil (P = 0.05) showed significant association with previous diagnosis of diabetes. Furthermore, diabetes was more predominant in: age-group 17-40 (62.1%), those who consume less than five daily vegetable servings (100%) and those who mostly used saturated oil for cooking (72.4%).

Discussion

Evidence has shown over the years that attention be given to ensuring adequate knowledge of diabetes [11-13]. Of the 134 (66.7%) respondents aware of DM, only an average of 43.9% had knowledge of its risk factors. Lack of adequate knowledge of DM does not come as a surprise since Afao is a rural community with about 75.1% of the respondents having no formal education or a primary school education. Moreover, 70.1% of the respondents got information about the disease from community health care workers. Community health workers have shown to develop and support connections between the health care system and their own community through

Tab. VIII. Association between risk factors and previous diagnosis of diabetes.

Variable	DM Present n (%)	DM Absent n (%)	χ^2	*p* value
Age				
17-40	18 (62.1)	124 (72.1)	72.875	0.024*
41-60	9 (31)	32 (18.6)		
above 60	2 (6.9)	16 (9.3)		
Currently smoke tobacco				
no	27 (93.1)	148 (86.0)	1.097	0.295
yes	2 (6.9)	24 (14)		
Consume alcohol daily				
no	22 (75.9)	133 (77.3)	0.03	0.862
yes	7 (24.1)	39 (22.7)		
Daily vegetables servings				
less than 5	29 (100)	142 (82.6)	5.946	0.015*
5 and above	0 (0)	30 (17.4)		
Daily fruits servings				
less than 5	27 (93.1)	139 (80.8)	2.606	0.106
5 and above	2(6.9)	33 (19.2)		
Oil mostly used for cooking				
unsaturated fat	8 (27.6)	23 (13.4)	3.844	0.05*
saturated fat	21 (72.4)	149 (86.6)		
Weekly walk/bicycle ride				
Everyday	20 (69)	80 (46.5)	6.255	0.1
2-4 days	2 (6.9)	37 (21.5)		
5-6 days	2 (6.9)	9 (5.2)		
None	5 (17.2)	46 (26.7)		
Body mass index				
underweight	1 (3.4)	9 (5.2)	0.792	0.978
normal	12 (41.4)	66 (38.4)		
overweight	12 (41.4)	69 (40.1)		
grade 1 obesity	3 (10.3)	20 (11.6)		
grade 2 obesity	1 (3.4)	5 (2.9)		
morbid obesity	0 (0)	3 (1.7)		

χ^2: Chi-square test; *: *p* value < 0.05

health-related awareness and education [14, 15]. Despite their merits, research has shown the need to develop diabetes competencies and evaluative tools as a way to standardize health workers diabetes trainings in local communities [16].

There is limited evidence on whether having risk factors for diabetes, ensures greater knowledge of risk factors important for motivating preventive behaviours [17]. This present study reveals that respondent's body mass index was significantly associated with knowledge of overweight/obesity as overweight (52.9%), grade 1 obese (62.5%) and morbid obese (100%) respondents had no knowledge of their status as risk factors for DM. These findings is in congruence with previous studies that have associated obese respondents with poor awareness [17, 18]. Also, most (62.5%) of the participants who were unaware of their blood pressure status had no knowledge of high blood pressure as a risk factor of DM. Routine blood pressure monitoring is very crucial and needful for adults. This is because high blood pressure has been associated with an increased risk of diabetes [19-22].

Also, in this study, two risk factors which significantly relates with the occurrence of the disease among previously diagnosed respondents have been documented by researchers who identified age [23-25] and poor diet [26-29] as risk factors for DM.

Conclusion

This study concludes that one-third of the study population were unaware of diabetes, more than half of those aware of the disease had no knowledge of its risk factors while well over a tenth had been previously diagnosed with the disease. Most overweight and obese respondents had no knowledge that they were at risk of having diabetes. Respondents unaware of their blood pressure status also had no knowledge of high blood pressure as a risk factor for diabetes. The risk factors which significantly relates with the disease occurrence among previously diagnosed respondents were age and poor diet, respectively. Thus, this study shows a need to improve on the level of awareness of DM and its risk factors in Afao. Routine

measurement of blood glucose levels for adults, community health education and enlightenment strategies through the Ministry of Health on the awareness of DM are highly recommended for the Afao community.

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Conflict of interest statement

The authors declare no conflict of interest.

Authors' contributions

ARD and AIOE contributed in the study design, training and supervision of data collectors. ARD designed the questionnaire. AIOE analyzed the data with the contribution of AEO. AIOE drafted the manuscript with the contribution of AEO, ARD and IOA. All authors reviewed and approved the final version of the manuscript.

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ORIGINAL ARTICLE

A theory of planned behavior-enhanced intervention to promote health literacy and self-care behaviors of type 2 diabetic patients

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Keywords

Diabetes • Self-care behavior • Health literacy • Attitude • Behavior change

Summary

Background. *Improved health literacy and awareness could help type 2 diabetic patients to control the disease complications.*
Objective. The current study aimed to evaluate the impact of theory-based educational intervention on health literacy and self-care behaviors of type 2 diabetic patients in Tonekabon city.
Methods. *This randomized controlled trial study was conducted at health care centers in Tonekabon city, Iran, from April 5, 2017, to October 22, 2018. Using multistage random sampling, 166 patients with type 2 diabetes divided into two groups: theory-based intervention (n = 83) and custom education (n = 83). The data collection tools consisted of demographic information, Theory of Planned Behavior (TPB) measures, health literacy for Iranian adults (HELIA) and summary of diabetes self-care activities (SDSCA). The five 45-minute group training sessions based on the baseline assessment and model constructs along with the targeted pamphlet and m-health strategy were designed for the experimental group. Data were analyzed using chi-square, independent and paired t-test and Analysis of covariance (ANCOVA).*
Results. *After controlling for pre-test effect, there was a significant difference between the two groups in terms of mean scores of attitudes, subjective norms, perceived behavior control and intention in post-test ($P < 0.001$). Also, after controlling for the pre-test effect, the results showed a significant difference in the self-care domain in the post-test ($P < 0.001$). Finally, after controlling for the pre-test variable effect, covariance analysis reflects significant difference in total health literacy score and its dimension at posttest ($P < 0.001$).*
Conclusions. *Applying TPB based education is suggested to maintain and improve self-care behaviors and health literacy in type 2 diabetic patients and other chronic diseases.*

Background

Type 2 diabetes and its consequences

Diabetes, a chronic metabolic disorder and one of the major public health concerns, is regarded as a global epidemic [1]. The risk factors contributing to the development of type 2 diabetes (T2D) are comprised of age 45 years and older, obesity and overweight, sedentary lifestyle, polycystic ovary syndrome, high blood pressure, impairment in lactose tolerance test, unhealthy diet and cigarette smoking [2]. Complications associated with diabetes are comprised of visual impairments, kidney dysfunction, cardiovascular disease, impaired wound healing, diabetic foot ulcers and eventually death. Moreover, the rate of diabetic patient's hospitalization is said to be nearly 4.2 times more than other chronic diseases and patients' life expectancy be five to fifteen years shorter than other people's [3].
Having numerous complications, T2D adversely affects quality of patients' lives. Besides, with regard to non-communicable and chronic nature of T2D as well as imposing heavy financial burden on families and health care system, it is essential to take serious heed of the disease outcomes [4, 5].

Prevalence of type 2 diabetes worldwide and in Iran

Yearly, more than 7 million people worldwide suffer from diabetes, which would lead to nearly 3.8 million death related to it. Furthermore, every 10 seconds equates to a diabetic patient death. It is expected that the number of diabetic patients will approximately double by 2030 if no intervention is considered, developing countries to encounter with a 69% increase in diabetes prevalence [6]. In addition, estimations suggesting that 14% of Iranian population aged over 30 are diabetic, which their number will rise to 9 million by 2021 [7].
Considering the increasing trend of diabetes all around the world, World Health Organization (WHO) has regarded it as a hidden epidemic and requested all countries to deal with it. Therefore, given the lack of a certain cure for diabetes, what could play a key role in preventing its sever complications is to concentrate on appropriate cares such as regular blood sugar control and maintaining it in an optimum level [8].

Self-care and its role in diabetes control

Studies have shown that maintaining blood glucose level in a normal range may cause eye and renal complications to delay by 8 and 6 years, respectively. There is no

denying that patients' responsibility in controlling blood sugar and effective management of the disease are an integral part of self-care behaviors [9].

Generally, self-care is an evolutionary process on enhancing knowledge and awareness through learning that improves life quality and leads to patient's better adaptation to stress, despite the complex nature of diabetes. Self-care comprises all the actions that each individual performs to take care of their health relying on knowledge, skills and capacities [10]. As a result, one of the changeable and effective risk factors in the incidence of T2D is the lack of adherence to self-care behaviors. Moreover, no adherence to self-care principles is the momentous underlying cause of mortality in individuals with diabetes. Several studies have reported that self-care can lead to longevity increasing, decreasing the incidence of disease complications or postpone it, and improving the quality of life (QOL) of diabetic patients [11, 12].

Despite the importance of self-care, research findings indicate that only 16.2% of diabetic patients adhere to self-care behaviors [9]. In addition, the results of Vosoghi et al. (2012) study revealed that 68.5% of patients with T2D have poor self-care ability [13]. Similarly, Parham et al. found that 53.5% of the patients do not perform self-care behaviors [14].

Health literacy and its relationship with self-care

Self-care is influenced by a set of knowledge, personal beliefs and attitudes, as well as the values and sociocultural characteristics. Among these, the role of knowledge about the nature of the disease and its preventive strategies strongly affects the control of the disease [15]. In contrast, patients should not only be able to obtain sufficient information about the disease and the necessary care skills but also to take advantage of their knowledge in different circumstances. Patients' skills to access, understand and use information from various sources will have an impressive effect on their behavior and health condition. Such skills are termed health literacy. Indeed, health literacy refers to an individual's capacity to gain access to, interpret, and understand the basic information, which is integral to make effective health related decisions [16]. Low health literacy could lead to patient's poor performance in activities such as blood glucose monitoring, medicine intake adjusting, consumed carbohydrate calculating [17].

WHO has identified health literacy as one of the greatest health determinant [18]. It is less probable that individuals with limited health literacy could perceive written and spoken information given by health experts [19]. Limited access to health care, self-care deficit, less adherence to treatment, continual hospitalization, and lack of confidence to health experts are of consequences of low health literacy [20]. Results of the latest national study in the United States demonstrated that 36% of adults have limited health literacy (adequate or borderline health literacy) [21]. Additionally, findings of Tehrani et al. indicated that 56.6% of the individuals undergoing treatment have inadequate health literacy [22].

The effect of education on self-care and health literacy

Education, improved health literacy and awareness could help diabetic patients to control the disease conditions, reduce the level of perceived stress, and apply effective coping strategies. WHO has considered education as the foundation of diabetes treatment, and identified attitude change, self-care promotion and increased awareness as the key goals of diabetes education [23]. Appropriate education could lead to a decrease in diabetes complications up to 80% [24].

Theoretical framework of educational intervention

Despite the importance of education and improving health literacy in diabetic patients, previous studies on behavior changing have revealed that elevating knowledge is not sufficient to achieve it and is required to address other behavior determinants such as attitudes, social norms and environmental factors. In fact, the value of health education programs depends on the effectiveness of them, and subsequently the capacity of such programs to change behavior depends largely on the application of health education models. Moreover, most of the interventions using behavior change models have been more successful in achieving their goals [25]. The Theory of Planned Behavior (TPB), one of the social-cognitive models introduced by Ajzen and Fishbein in 1988, provides a useful framework for predicting and understanding of health-related behaviors. From the perspective of TPB, optimal behavior could be predicted by behavioral intention. Intention is the main indicator by which it can be understood how much people are willing to do things and try to plan for implementation of a particular behavior. It is, for its part, the result of attitude (positive or negative evaluation of the behavior), subjective norm (whether the significant individuals confirm the behavior or not) and perceived behavioral control or PBC (the expanse that individuals believe could control the behavior performance). Perceived behavioral control, additionally, could anticipate a behavior directly, which occurs when the behavior is not fully under individual's intention. Review studies have emphasized that the TPB is the most comprehensive and appropriate theory for studying diverse behavior [26-29].

Summary and purpose of the present research

Despite this, the application of this theory for designing interventions and assessing the degree of changes in behavioral psychology's predictions has not been well investigated. Moreover, there are limited studies on the educational interventions' assessing with the purpose of promoting health literacy and self-care in diabetic patients simultaneously, and most of research have focused only on the prediction and description of self-care determinants and correlation between the variables, or measured the effect of intervention on one of the self-care behaviors such as physical activity or foot care,

separately. To this end, the current study was undertaken to determine the effect of educational intervention based on TPB on the self-care behaviors and health literacy of T2D patients.

Material and methods

Setting and sampling

The present study was a randomized controlled trial (RCT) conducted from March 2018 to April 2019. The purpose of this study was to determine the effect of theory-based education on health literacy and self-care behaviors in patients with T2D in Tonekabon, Mazandaran province, Iran.

The research society consisted of all T2D patients who referred regularly to 4 Tonekabon urban health care centers. The method of multistage random sampling was used for the sample selection. Firstly, through the 13 healthcare centers located in different parts of the city, 4 of them were randomly selected. Afterwards, among the volunteer patients of each center, eligible Participants were randomly selected on the basis of random numbers table.

Sample size was calculated based on previous studies, the confidence interval of 95%, test power of 80% and using G*power software about 66 patients. Due to simple random sampling, the effect size of 0.50 and probability of 20% drop in participants, 83 patients were considered for each of the experimental and control groups, finally.

Inclusion criteria were comprised of reading and writing ability, the history of at least six months of diabetes definite diagnosis, the history of drug therapy, living in the city up to a following year later, the lack of suffering from grade 2 diabetic foot ulcers and higher (based on Wagner's criteria and the confirmation of clinic specialist) and voluntary participation. While Inclusion criteria consisted of suffering from gestational diabetes, mental and physical disorders and uncontrolled underlying disease as high blood pressure (160/90 mmHg) despite taking medicine.

All participants signed an informed consent form before participation. The study protocol was approved by the University of Alberta Research Ethics Board and Alberta Health Services.

Data collection

Data in the present study were gathered with the use of self-administered questionnaire including the following sections.

Demographic questionnaire

This questionnaire includes age, gender, education, employment status, marital status, economic status, history of having diabetes, medicine utilization, weight, and length.

Theory of Planned Behavior (TPB) constructs-related items

According to the of Fishbein & Ajzen (2010) Questionnaire Design guidance, a semi structural interviewing was carried out from 10 T2D patients, and silent belief related to constructs were extracted. Subsequently, the first version of the items was designed on the basis of the extracted beliefs and previous studies. Then, an expert panel (including 2 health education assistants, 2 internal specialists, 2 nutrition experts, 2 public health expert) assessed the content validity of the questions and confirmed Content Validity Index (CVI) and Content Validity Rate (CVR). The values of 0.83 and 0.86 in CVI and CVR, respectively indicated the content validity of the scales. Then, in order to determine the reliability by the method of test retest reliability and also measure face validity, the questionnaire was completed by a sample composed of 10 T2D patients, with two weeks interval. In addition, Cronbach's alpha coefficient was used to determine the internal consistency. At last, the following scales were applied to measure the TPB-related structures:

- *subjective norms (5 items)*: patients were asked to express their agreement with each item on a 5-point Likert scale from 1 (completely disagree) to 5 (completely agree). The responses ranged from 5 to 25, and the higher was the score, the stronger was the social support for self-care. The Cronbach's alpha coefficient of 0.83 indicated good internal consistency, and the test-retest coefficient of 0.93 confirmed the reliability of the scale;
- *attitude (8 items)*: it was measured based on the 5-points Likert scale ranging from 1 (completely disagree) to 5 (completely agree). The scores ranged from 8 to 40, and the lower were the grades, the weaker were the attitude and vice versa. Moreover, the values of $r = 0.79$ and $\alpha = 0.76$ were the confirmative of internal consistency and acceptable reliability;
- *PBC (5 items)*: it was evaluated on the 5-points Likert scale ranging from 1 (not sure at all) to 5 (completely sure). The responses ranged from 5 to 25, and the higher was the score, the more was the intentional perceived control of patients on the desired behavior. Finally, the internal consistency and reliability of the questions of this scale were confirmed by Cronbach's alpha coefficient and test-retest;
- *behavioral intention (5 items)*: patients were requested to answer questions based on the 5-point Likert scale from 1 (completely disagree) to 5 (completely agree). The scores ranged from 5 to 25, and the lower were the scores, the weaker were the targets and vice versa. The Cronbach's alpha coefficient of 0.83 and the test coefficient of 0.93 indicated an internal consistency and a good reliability of the scale, respectively.

Short Test of Functional Health Literacy in Adults (STOHFLA)

This test is used to assess the health literacy of diabetic patients. The questionnaire is one of the most common and comprehensive general standard instruments in health literacy appraisal. The number of questions in

this questionnaire is 33, with the first 27 questions being answered based on the 5-point Likert scale from 1 (never) to 5 (ever). Answering to the rest of questions (the 7 remained ones) is done by means of Likert scale ranging from completely easy to completely hard. The questionnaire consisted of five dimensions as follows: *reading skills* (6 questions), *information accessibility* (6 questions), *information comprehension* (6 questions), *information analysis* (6 questions), and *decision making and information behavior* (9 questions). The final score of health literacy is considered between 33 and 165. Eventually, the scores are divided into three levels including inadequate literacy (77-33), borderline (122-78), and adequate health literacy (165-123). Validity and reliability of the questionnaire have been emphasized in previous studies [31, 32].

The Summary of Diabetes Self-Care Activities (SDSCA)

The questionnaire is composed of 15 questions on diet, physical activity, blood glucose monitoring, foot care and medication use. Each question is given a score from 0 to 7 in terms of the number of days in the last week that a person has performed self-car behaviors. As example, eight questions are related to nutritional behaviors with the range of scores from 0 to 56 dividing into undesirable (0-16), somewhat desirable (17-32) and desirable (33-56). Moreover, the total score of self-care is divided into the following levels: poor self-care (0-37), moderate self-care (38-71) and good self-care (72-105). The validity and reliability of the questionnaire has been confirmed in previous studies [33].

Data collection process

After initial coordination and allocation of patients to experimental and control groups, they were asked to complete the questionnaires in the health centers in two stages of before and 2 months after the theory-based intervention. To this end, according to a pre-prepared timetable agreed upon by patients, they were requested to complete the research tool after receiving the health services. The questionnaires were filled out at approximately 45 minutes in the presence of one of the researchers. The researchers attended not only to answer possible questions, explain the method of completing scales, and make ensure from responding to all questions, but also to elucidate on the way of answering to the questions and emphasize on providing honest responses. In addition, they stressed on the anonymity and confidentiality of the contained information in the questionnaires.

Theory based education

After analyzing the patients' responses to the questionnaires in the first phase, the patients assigned to the experimental group participated in a multi-part training program. Participants in the intervention group consisting of 7-15 T2D patients were involved in five 45-minute training sessions. The goals of each session were determined by TPB constructs as well as first phase response analysis. A set of educational strategies tailored to the purpose of each session was used such as lecture, role playing, focus group discussion, Q&A methods, brain storming and practical implementation of skills. Moreover, a 10-minute educational film, targeted pamphlet and educational booklet were given to the experimental group patients was used to remind the educational content presented at each session.

With regard to the capabilities and access of patients to the use of cyberspace and online social networking information, all the provided information in educational package were presented to all T2D patients involved in the experimental group with the use of m-health strategy and based on the WhatsApp application. Detailed information on the content and purpose of the training sessions is provided in Table I.

Data analysis

SPSS software (version 23) was applied for data analysis. Data normality was confirmed based on Kolmogrov-Smirnov test. Descriptive statistics including mean and standard deviation, along with analytic statistics tests were used for data analysis. Moreover, the data were subjected to parametric tests as paired and independent t-test, chi-square and one-way analysis of variance (ANOVA). The significance level was considered of 5%. The present investigation was approved by the ethics committee of Qazvin University of Medical Sciences (IR.QUMS.REC.1396.354). Moreover, in order to respect for human dignity, after collecting the second stage data, all patients in the control group participated in an intensive educational course including two 60-minute training sessions. In addition, all the educational provision presented to the experimental group was also provided to T2D patients in the control group.

Results

The findings of Table I show the demographic and background characteristics of the patients participating in the study. The mean age of the patients was 57.3 ± 9.5 years and frequency of patients older than 50 years was higher than other age groups. Also, the mean BMI of patients was 27.5 ± 4.5 and approximately 50% of patients in both groups had BMI of 25-30. Moreover, half of the patients had primary education and almost 10% had a university education. In addition, about 2/3 of patients are retired and 12.05% of patients in the experimental group and 15.67% of the control group were housewives. The results of Chi-square test didn't show significant difference between the two groups in terms of demographic variables. Further results are shown in Table II.

The results of comparing the mean of self-care domains between the two groups before and after the educational intervention are shown in Table III. Results of independent t-test showed that there was no significant difference between the two groups in terms of mentioned variables before intervention. However, the mean of all self-care domains such as Diet, Blood Glucose Control, Regular Physical Activity, Medication Adherence and Foot Care increased significantly in the experimental

Tab. I. Details of the training program presented in the experimental group.

Session	Specific objective	Educational strategies	Training material	Instructional technology
Informing and awareness	• Explain the blood sugar and its indicators, symptoms and T2D mechanism • Identify the risk factors for T2D • Describe the consequences of T2D • Explain the relationship between risk factors and prevention of the consequences of T2D	Lecture, Q&A	Tailored pamphlet, CD, booklet	Data projector, white board
Health literacy and self-care	• Have access to appropriate information about foot care • Have sufficient information about how to measure and interpret blood glucose • Can learn how to properly evaluate physical activity status • Patients understand the importance of taking medicines in a timely manner and in accordance with the physician's instructions • Patients know how to measure the calorie content of different foods and are able to determine the amount of calories they need in meals	Lecture with Q&A	Educational booklet and tailored pamphlet	Data projector and white board
Attitude change	• Patients know that the consequence of the disease is preventable • Patients know that the consequences of diabetes can be severe • Patients know that self-care is the best way to maintain good health • Patients emphasize the role of self-care and personal behaviors in comparison to environmental factors, luck, and appreciation • Patients know that the consequences are likely to occur for them • Understanding and evaluating the importance of self-care in preventing the consequences of diabetes	Focus group discussion	Fear appeals photos and videos of diabetic foot ulcer patients	White board
Increase self-efficacy	• Identify the physical barriers to implementing and maintaining self-care behavior • Identifying individual potentials and capacities • Identify environmental and external opportunities and facilities • Examine available solutions for to implement and maintain self-care behavior • Dividing tasks into smaller executable and more practical and easier steps • Psychological and personal commitment to perform self-care tasks • Implement self-care behaviors, group encouragement, and verbal persuasion	Teamwork and role playing, individual counseling	-	White board
Practical skills	• Practical display of blood glucose measurement and comparison with standards • Practical display of foot examination & care • A practical method for evaluating breathing and heart rate during physical activity • A practical method for calculating food calories and comparing healthy and unhealthy foods • Repeat and practice self-care skills and provide feedback	Teamwork, practical presentation, individual counseling	Tailored pamphlet, educational booklet, CD	Data projector, white board

group after the intervention ($P < 0.001$). Despite this, the results of paired t-test did not show a significant change in the mean of these domains in the control group. Further results are shown in Table III.

The results of covariance analysis showed that the difference between the pre-test and post-test scores of the two groups was significant for the mean of attitude construct ($F = 621.77$, $P < 0.001$). Also, the eta coefficient indicates that Theory based educational intervention is able to explain 31.5% of the variance of attitude constructs in

Tab. II. Distribution of demographic characteristics of T2D patients in experimental and control groups.

Variables		Intervention (n = 83)		Control (n = 83)		P value
		Number	Frequency	Number	Frequency	
Age (years)	Less than 45	2	2.41	2	2.41	P = 0.39 χ^2 = 0.512 df = 118
	46-50	7	8.43	6	7.23	
	51-55	14	16.9	13	15.66	
	56-60	19	22.9	18	21.69	
	60-65	20	24.1	24	28.92	
	More than 65	21	25.3	20	24.1	
	Total	83	100	83	100	
BMI	Less than 25	20	24.1	21	25.31	P = 0.436 χ^2 = 0.271 df = 118
	25.1-30	43	51.81	45	54.22	
	More than 30	20	24.10	17	20.48	
	Total	83	100	83	100	
Education	Elementary	43	51.81	41	49.4	P = 0.193 χ^2 = 6.079 df = 4
	Middle school	17	20.49	19	22.9	
	High school	14	16.87	13	15.67	
	University	9	10.85	10	12.05	
	Total	83	100	83	100	
Job status	Housewife	10	12.05	13	15.67	P = 0.690 χ^2 = 2.249 df= 4
	Retired	58	69.88	56	67.47	
	Employed	15	18.08	14	16.87	
	Total	83	100	83	100	

Tab. III. Comparison of mean and standard deviation of self-care and related dimensions in diabetic patients in experimental and control groups before and after educational intervention.

Self-care dimension		Intervention (n = 83)	Control (n = 83)	P value between two group
		Mean ± SD	Mean ± SD	
Physical activity	Before	1.80 ± 0.78	1.75 ± 0.75	0.41
	After	3.60 ± 0.52	1.82 ± 0.77	P < 0.001
	P value pre-post	P < 0.001	0.19	
Nutrition	Before	26.18 ± 3.9	26.39 ± 3.4	0.53
	After	41.30 ± 10.1	26.33 ± 3.91	P < 0.001
	P value pre-post	P < 0.001	0.53	
Foot care	Before	7.14 ± 3.72	6.93 ± 3.67	0.26
	After	18.38 ± 2.16	7.10 ± 3.72	P < 0.001
	P value pre-post	P < 0.001	0.20	
Medication adherence	Before	5.43 ± 0.94	6.21 ± 0.85	0.11
	After	10.09 ± 0.47	6.35 ± 0.91	P < 0.001
	P value pre-post	P < 0.001	0.16	
Blood glucose control	Before	2.40 ± 0.76	2.30 ± 0.85	0.18
	After	3.90 ± 0.54	2.24 ± 0.72	P < 0.001
	P value pre-post	P < 0.05	0.47	
Total self-care	Before	31.11 ± 3.47	30.74 ± 4.07	0.13
	After	63.05 ± 5.18	31.35 ± 3.22	P < 0.001
	P value pre-post	P < 0.001	0.63	

T2D patients (F = 67.75, P < 0.001). Moreover, the results of Table IV show there was a significant difference between the groups in terms of the subjective norms in the post-test (F = 52.26, P < 0.001). Also, Eta coefficient indicates that 26% of the variance of subjective norms is explained by theory based educational intervention. In addition, results showed that after controlling for pretest effect, there was a significant difference between the two groups in terms of PBC in post-test (F = 23.69, P < 0.001). According to Eta coefficient, it can be deduced that 13.9% of the variance of PBC is described by theory based educational intervention. Finally, after controlling for pretest effect, the results of covariance analysis showed a significant difference in posttest regarding behavioral intention (F = 23.69, P < 0.001). Also, Eta coefficient indicates that 27.3% of the variance in behav-

Tab. IV. Covariance analysis of the effect of theory-based educational intervention on mean of Theory of Planned Behavior (TPB) constructs in diabetic patients.

TPB constructs	Source	Sum of squares	df	Mean square	F	Sig	Partial eta squared
Attitude	Pre-test	3388.64	1	3388.64	621.771	0.82	0.809
	Group	369.24	1	369.24	67.750	0.000	0.315
Subjective norms	Pre-test	7.83	1	7.83	6.34	0.013	0.041
	Group	64.58	1	64.58	52.26	0.000	0.262
PBC	Pre-test	1095.56	1	1095.56	2684.72	0.138	0.948
	Group	9.67	1	9.67	23.69	0.000	0.139
Intention	Pre-test	6.99	1	6.99	22.198	0.097	0.131
	Group	17.36	1	17.36	55.106	0.000	0.273

Tab. V. Covariance analysis of the effect of theory-based educational intervention on self-care domains in diabetic patients.

Self-care domains	Sources	Sum of squares	df	Mean square	F	Sig	Partial eta squared
Physical activity	Pre-test	74.45	1	74.45	34.96	0.048	0.192
	Group	198.97	1	198.97	93.44	0.000	0.389
Diet	Pre-test	319.1	1	319.1	31.91	0.46	0.178
	Group	238.59	1	238.59	23.86	0.000	0.140
Foot care	Pre-test	5.782	1	5.782	0.703	0.003	0.005
	Group	1639.32	1	1639.32	199.31	0.000	0.576
Medication adherence	Pre-test	18.21	1	18.21	2.12	0.160	0.092
	Group	1002.26	1	1002.26	116.85	0.000	0.85
Glycemic control	Pre-test	0.11	1	0.11	0.007	0.035	0.001
	Group	1908.37	1	1908.37	119.34	0.000	0.88
Total self-care	Pre-test	146.48	1	146.48	12.9	0.042	0.381
	Group	749.89	1	749.89	66.1	0.001	0.76

ioral intention is explained by theory based educational intervention. Further results are shown in Table IV.

The findings are listed in Table V show the result of One-way covariance analysis regarding the effect of theory based educational intervention on self-care domains in patients with type 2 diabetes. After removing the pre-test effect, there was a significant difference between the mean scores of physical activity in the post-test ($F = 93.44$, $P < 0.001$, $\eta^2 = 38.9$). In addition, Eta coefficient indicates that 38.9% of variance in physical activity domain is predicted by educational theory-based education. Moreover, after controlling for the pre-test effect, the results showed a significant difference in the nutrition domain in the post-test ($F = 23.86$, $P < 0.001$, $\eta^2 = 14.0$) and Eta coefficient also indicates that 14% of the variance in nutrition domain is explained by theory-based education. Finally, after controlling for the pre-test variable effect, results of one-way ANCOVA reflect significant difference in foot care ($F = 199.31$, $P < 0.001$, $\eta^2 = 57.6$), medication adherence ($F = 116.85$, $P < 0.001$, $\eta^2 = 8.5$), blood glucose control ($F = 119.34$, $P < 0.001$, $\eta^2 = 8.8$) and total self-care ($F = 66.1$, $P < 0.001$, $\eta^2 = 7.6$) in posttest. In addition, theory-based educational intervention was able to describe 57.6, 5.8, 8.8 and 7.6% of the variance in foot care, medication adherence, glycemic control, and self-care behaviors, respectively ($P < 0.05$). Further results are shown in Table V.

The results of Table VI are related to the mean and standard deviation of the total health literacy score and its dimensions in the experimental and control group patients before and after the educational intervention. Results of independent t-test before the intervention did not show any significant difference between the two groups in terms of the mentioned variable and its dimensions. However, the mean scores of reading skills, accessibility, comprehension, analysis and decision making significantly improved in the experimental group after the intervention ($P < 0.001$). Also, the mean score of total health literacy in the experimental group increased significantly after the educational intervention ($P < 0.001$). Table VII shows the results of the analysis of covariance regarding the effect of theory-based educational intervention on health literacy dimensions and its total score in T2D patients in the experimental and control groups. The findings indicate that after controlling the pre-test effect, there was a significant difference between the mean of reading skills in the post-test ($F = 65.49$, $P < 0.001$, $\eta^2 = 0.76$). Eta coefficient also indicates that 76% of the variance of reading skill dimension is predicted by educational intervention. In addition, after controlling for the pretest effect, the results indicated a significant difference in the mean score of information accessibility ($F = 28.82$, $P < 0.001$, $\eta^2 = 0.50$), Information Comprehension ($F = 96.16$, $P < 0.001$, $\eta^2 = 0.78$), information analysis ($F = 85.87$, $P < 0.001$, $\eta^2 = 0.80$), decision making and information behavior ($F = 105.48$,

Tab. VI. Comparison of the mean and standard deviation of different dimensions of health literacy and its total score in diabetic patients in experimental and control groups before and after the theory based educational intervention.

Health literacy dimension	Number of items	Range of score	Follow-up time	Group		Sig
				Control (n = 83) Mean ± SD	Intervention (n = 83) Mean ± SD	
Reading skills	6	6-30	Baseline	16.83 ± 4.42	17.57 ± 4.13	0.542
			2 months after	17.15 ± 4.28	26.22 ± 3.41	P < 0.001
			P value*	0.611	P < 0.001	
Information accessibility	6	6-30	Baseline	15.31 ± 3.52	16.09 ± 4.11	0.307
			2 months after	16.45 ± 2.81	24.76 ± 3.51	P < 0.001
			P value*	0.264	P < 0.001	
Information comprehension	6	6-30	Baseline	13.94 ± 4.27	15.00 ± 3.92	0.097
			2 months after	15.55 ± 3.73	24.80 ± 4.33	P < 0.001
			P value*	0.831	P < 0.001	
Information analysis	6	6-30	Baseline	16.82 ± 3.55	17.19 ± 2.90	0.733
			2 months after	18.1 ± 3.05	25.76 ± 2.64	P < 0.001
			P value*	0.229	P < 0.001	
Decision Making and information behavior	9	9-45	Baseline	24.66 ± 5.25	25.10 ± 4.83	0.561
			2 months after	26.02 ± 4.66	35.6 ± 4.68	P < 0.001
			P value*	0.188	P < 0.001	
Total score of health literacy	33	33-165	Baseline	92.86 ± 11.89	93.27 ± 12.72	0.108
			2 months after	94.33 ± 12.64	132.14 ± 13.81	P < 0.001
			P value*	0.429	P < 0.001	

P value*: significant value pre-post intervention.

Tab. VII. Covariance analysis of the effect of theory-based educational intervention on the dimensions of health literacy in diabetic patients.

Health literacy dimension	Sources	Sum of squares	df	Mean square	F	Sig	Partial eta squared
Reading skills	Pre-test	1.34	1	1.34	0.076	0.78	0.004
	Group	1161.8	1	1161.8	65.49	0.001	0.760
Information accessibility	Pre-test	42.22	1	42.22	6.31	0.01	0.19
	Group	945.37	1	945.37	28.82	0.001	0.50
Information comprehension	Pre-test	284.38	1	284.38	10.13	0.009	0.21
	Group	769.36	1	769.36	94.16	0.001	0.78
Information analysis	Pre-test	102.97	1	102.97	5.88	0.024	0.22
	Group	1501.38	1	1501.38	85.87	0.001	0.80
Decision making	Pre-test	4.99	1	4.99	0.43	0.521	0.020
	Group	1237.26	1	1237.26	105.48	0.001	0.83
Total score of health literacy	Pre-test	137.25	1	137.25	6.93	0.370	0.21
	Group	1911.42	1	1911.42	91.41	0.001	0.84

$P < 0.001$, $\eta^2 = 0.83$) in the post-test. Also, Eta coefficients associated with each dimension showed that theory-based intervention was able to describe 50, 78, 80 and 83% of the variance in the information accessibility, comprehension, analysis and decision making dimensions, respectively. Finally, after controlling for the pre-test variable effect, covariance analysis reflect significant difference in total health literacy score at post test and theory-based education was able to explain 84% of the variance in total score of health literacy in diabetics patients ($F = 91.41$, $P < 0.001$, $\eta^2 = 0.84$).

Discussion

The purpose of present study was to determine the effect of a theory-based educational intervention on health literacy and self-care behaviors in T2D patients. Generally, the findings showed that the intervention based on TPB could improve the health literacy and self-care behaviors in the participated patients. In accordance with the current study, in a meta-analysis conducted on the effect of diabetes self-care interventions with a focus on health literacy, positive changes were obtained in cognitive-psychological health, along with desirable health outcomes and self-care improvement [34]. Furthermore, the results of a systematic review of Berkman et al. (2011) indicated a health literacy intervention has a significant effect on prevalence of disease, knowledge, self-efficacy and medication adherence [35]. The findings of the study by Zhao et al. (2015) are consistent with the results of the present study [36].

One of the major results of this study was the score enhancement of all domains and the total score of health literacy among experimental group after intervention. Health literacy is the capacity of individuals to acquire, process, and understand basic health services and information in order to make appropriate health decisions [16]. Limited health literacy is influenced by complex mechanisms that affect health and health outcomes including reduced access to health care, poor interactions between patient and health care providers, and a lack of proper self-care under specific circumstances, all of which are crucial to the diabetes management [37]. In fact, inadequate health literacy refers to the patients who are incapable of acquiring, interpreting, and understanding health-related information, which is of paramount importance for making correct decision in health care system. As a result, they need to be informed and educated in a different way than others. Given the findings of present study, most of the patients in experimental group had insufficient health literacy before intervention, and the number of those with borderline and adequate health literacy was low, respectively, which was in line with the results reported by Esfahrood et al. (2016), and Fransen et al. (2012) [38, 39]. After the educational intervention, the number of patients whose health literacy was improved significantly increased and it is reasonable to expect a significant decrease in the percentage of T2D patients with low levels of health literacy. Similar results in consistent with ours have been reported on the enhancing of health literacy as a function of theory-based education impact [40, 41]. Some studies have emphasized the necessity of designing and implementing educational interventions equal to the level of health literacy of patients, and shown that the determinants of health behaviors in patients with various levels of health literacy significantly differ; to this end, the same interventional strategies shouldn't be designated. In addition, the following strategies could be employed to improve health literacy in patients: simple and understandable communication, gradual presentation of information and an emphasis on information curtailment, limiting information provided at each patient referral, repeating information in various ways, repeatedly receiving feedback and refining the education process, encouraging patients to be curious, and focusing on simple media utilization [42, 43]. Overall, it is recommended that health care experts be familiar with the concept and strategies of health literacy, and apply these skills while educating patients in order to better returnee's perception of represented information in addition to the enhancement of effectiveness of educational interventions.

Another important finding of the present study was that the TPB theory constructs comprising attitude, subjective norms, PBC, and behavioral intention improved significantly after intervention in the experimental group. This is in accordance with the results obtained by Beiranvand et al. (2016), Taha et al. (2016) and Reisi et al. (2017) [44-46]. Also, a review of 20 RCT by Zhao et al. (2017) revealed that theory-based self-management educational interventions on patients with T2D were able to significantly improve patients' self-efficacy, diabetes knowledge and other psychological variables [47]. So, the multidimensional nature and complexities associated with self-care behaviors justify the necessity of using theories and patterns of behavioral change to describe factors influencing the foregoing behavior. The association between TPB constructs and self-care behaviors in diabetic patients has been well predicted in various studies. Identification of psychological factors affecting self-care behavior is an indispensable and undeniable step in the design of interventions [48].

Amongst the TPB constructs used in this study, the mean score of attitudes of the experimental group significantly improved after the intervention, which is in agreement with the results of previous investigation [44, 45]. Generally, adopting health behaviors in diabetic patients will arise from an individual's evaluation of positive and negative consequences of the recommended behavior, perceived benefits and barriers, understanding the outcomes of not following the advised behavior, the severity of the complications, and the perceived risk [49]. It could be hypothesized that the reason for the improvement of attitude and self-care behaviors is considering attitude as one of the principal components of the educational program. Particular concentration on perceived threats and sensitization to various complications of a disease, being negligible before the educational intervention, promises the effectiveness of education in designing educational content. Developing a positive attitude in diabetic patients could cause adherence to self-care behaviors. Besides, there is a positive correlation between attitude and the level of health literacy in diabetic patients. Therefore, patients' health literacy enhancement could in turn affect attitude changes positively. It is recommended that health experts reinforce positive attitudes and reduce negative beliefs using techniques such as qualitative interviewing, and effective intervention strategies like focus groups.

Moreover, to attitude change, the experimental group achieved significantly higher mean score in subjective norms after the intervention, which is in line with previous research findings [49-51]. Song et al. (2017) after reviewing 28 interventional studies concluded that there was a moderate and significant relationship between social support and self-care in diabetic patients [52]. In this regard, research has revealed that the level of psychological vulnerability of individuals with higher social support is lower than others. Social support could be effective in controlling diabetes through two major processes: the direct impact of social support via health-related behaviors such as encouraging healthy behaviors, and the shield effect of social support that contributes to the adjustment of acute and chronic neurotic stress effects on health, as well as increased adaptation to diabetes neurotic pressure [53, 54]. In fact, the relationship between social support and improvement in behaviors controlling disease, diet adherence and self-management in diabetic patients has been approved. Whenever stress levels were high, diabetic patients who received more social support would have better glycemic control. Also, family sup-

port is the momentous predictor of adherence to treatment in patients with type 2 diabetes, whereas family's non-supportive interactions predict poorer adherence to diabetes self-care program. Consequently, forming small groups and participating in focus group discussions, expressing the barriers of self-care by other patients, the presence of family members and their involvement in education, along with building up the sense of care, being loved, self-esteem, and feeling valued would lead to improvement of self-care behaviors [55]. Thus, special places should be considered for engagement of family members' participation in self-care education programs. The present study also found a significant improvement of mean score for PBC after educational intervention in the experimental group. These results are in consistence with those obtained by Beyranvand et al. (2016) and as well as other researchers [44, 45, 50]. With regard to the results of investigations, a strong comprehension of disease controllability is likely to be accompanied by stronger self-regulatory behaviors.

Moreover, individuals with higher self-efficacy expect better outcomes, and consider barriers to self-care as overcoming challenges. Previous studies have reported a significant and positive correlation between patients' level of health literacy and PBC and identified health literacy as the predictor of PBC [48, 49, 56]. Hence, it could be speculated that such improvement in PBC is due to the focus of the educational program on promoting health literacy in the first place. It is also worth noting that strengthening social support, along with improving self-efficacy, could contribute to increasing of the perception of disease controllability and the potential for behavior change [56]. Overall, given the significant impact of self-efficacy on self-care, its reinforcement with proprietary strategies should be amongst the particular goals of interventions.

The most momentous finding in our study was changes in self-care behaviors of diabetic patients in experimental group after theory-based educational intervention, which is line with those obtained by Al-Hashmi et al. [57] and Mohammadi et al. [58]. Diabetic patients may have diverse plans for controlling their disease and use various tactics unconsciously; yet irregular and unplanned utilization of control guidelines to overcome temptation, different social pressures, as well as lack of motivation due to low self-efficacy would result in loss of self-care [59]. In such circumstances, education and intervention will be needed to make self-care behaviors part of their daily routine. Consequently, patients' mental capacity to accept the recommended changes will increase.

Following self-care behaviors regularly is a highly complex process influenced by a variety of factors and changing these behaviors requires a comprehensive theory- based approach. Accordingly, considering the nature of self-care behaviors in diabetic patients and the role of personal beliefs, as well as the predictive feature of personal beliefs in adherence to self-care behaviors, the choice of TPB theory could be one of the main points of the present study.

It is worth noting that due to the complicated nature of health behaviors, none of theories of behavior change can independently describe and predict all aspects of health behaviors. And applying a combination of theories and models is needed to ameliorate significantly the efficiency and effectiveness of educational interventions. Thus, following studies can implement other models to enhance the effectiveness of interventions and design more effective pamphlets such as Transtheoretical Model, Pender's Health Promotion Model, Health Action Process Approach Model, Health Belief Model, Social Cognitive Theory, and/or Stage of Change Model.

Study limitation

The current study had several limitations, including: first, due to budget constraints and time of project implementation, the findings of experimental group were compared merely with the results of a control group, which makes it difficult to judge the effectiveness of the TPB based intervention as compared to other models of behavior change. So, in order to increase the ability to evaluate the impact of theory-based intervention it is essential that a traditional training group and a group receiving training based on other behavior change included in the intervention design. Second, it is proposed to focus on a specific behavior such as regular insulin injection or foot care instead of focusing on a complex set of behaviors or complex behaviors such as healthy eating. Third, lots of environmental and external factors affect patients' adherence to self-care behaviors, which are changing constantly; therefore, it should not be expected that a brief educational program by itself solve the problems. Changing behaviors is a continuous process influenced by a chain of behavior change techniques that is gradually provided by different channels. Continuing the education process, maintaining a healthy relationship with the audience, and providing reminders can reduce relapse. In addition, education through mass media, Community-Based Intervention and Online education can maintain behavioral change. Fourth, in the current study follow-up was performed only 2 months after Theory based education, and obviously, decision-making about the stability of education would require several follow-ups. It is recommended that future studies use either a Washout design or one- and two-year follow-up. And lastly, self-report and self-administered questionnaires were applied for collecting data in this study that will be accompanied by bias although the validity and reliability of this method have been confirmed in studies. Hence, it is recommended that future research apply other direct measuring methods of behavior such as the laboratory (HbA1c and FBS measurement) or anthropometric indices (BMI).

Conclusions

The results implied that educational intervention based on the constructs of TPB can considerably elevate the level of health literacy, attitude, subjective norms, PBC, and behavioral intention in patients with T2D. Further-

more, the effectiveness of theory-based education in promoting self-care behaviors such as regular adherence to the prescribed medication, foot care, regular physical activity, healthy diet, and blood glucose self-monitoring were confirmed. Therefore, applying this model of behavior change is suggested to maintain and improve self-care behaviors in both T2D patients and other chronic diseases.

Ethical approval

The study protocol was approved by the Ethics Committee of Qazvin University of Medical Sciences (IR.QUMS.REC.1396.354- January 2016).

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Conflict of interest statement

The authors declare no conflict of interest.

Authors' contributions

IMZ was involved in the study concept, design, analysis, interpretation of data, and drafting of the manuscript. HM and HAO supervised the conduct of the study.

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ORIGINAL ARTICLE

Joint effect of high blood pressure and physical inactive on diabetes mellitus: a population-based cross-sectional survey

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Keywords

Joint effect • Blood pressure • Physical inactivity • Diabetes mellitus • Indonesia

Summary

Introduction. *The relationship of high blood pressure and physical inactivity to diabetes mellitus is well known, but not many studies have known the joint effect of the two in causing diabetes mellitus. This study aims to evaluate the joint effect of high blood pressure and less physical activity against Diabetes Mellitus (DM) in Indonesia.*
Methods. *This is a cross-sectional study. Subjects in this study were the age group ≥ 21 years old who were followed by the interview. We investigated factors related to DM in Indonesia associated with blood pressure and physical activity by controlling other confounding variables. Statistical analyses were conducted using logistic regression. Age, sex, education level, marital status, occupation, body mass index, residence area, stress, fruit, and vegetable consumption were adjusted for in the multivariate model.*
Results. *The prevalence of DM was 3.86% among respondents. Multivariate analysis showed that people who had hypertension and less physical activity had a risk of 3.68 (95% CI, 2.43-5.34) times having DM. People who had hypertension and enough physical activity had a risk of 2.33 (95% CI, 1.65-6.43) times having DM. While people who do not have hypertension and had less physical activity had a risk of 1.81 (95% CI, 1.34-3.62) times.*
Conclusions. *People with hypertension and less physical activity have the greatest risk of developing DM.*

Introduction

In 2014, according to WHO there were 422 million adults aged over 18 who lived with Diabetes Mellitus (DM) [1]. Prevalence of DM in Indonesia has continued to increase, from 5.7% in 2007, to 6.9% in 2013, and increased again to 8.5% in 2018 [2-4]. Indonesia is the 4th country with the highest prevalence of DM in the world. Even the number of people with DM continues to increase from year to year. WHO data estimates that the number of people with DM in Indonesia will increase significantly to 21.3 million in the next 2030 [5].
Lifestyle factors and clinical factors are among the other factors that have a major influence on the incidence of DM. According to the study from Coldberg (2016) and Williams (2013) high blood pressure and less physical activity were the main predictor factors that trigger an increase in blood sugar levels. So, the two factors must be controlled as prevention efforts [6].
Based on these data it can be seen that the prevalence of DM patients increases every year in Indonesia and the joint effects of blood pressure and physical activity in influencing DM events have never been done. In previous study by Hanafi and Prihartono (2018), a similar study was carried out with different study outcomes [7]. This study aims to find the joint effects of blood pressure and physical activity with DM by controlling other variables such as age, sex, marital status, education level, occupation, residence area, body mass index, stress, vegetable consumption, and fruit consumption.

Methods

Ethical considerations

The IFLS-5 survey procedures had been approved by Institutional Review Boards (IRBs) in the United States at Rand Corporation, Santa Monica, California and in Indonesia at Ethics Committees of Gadjah Mada University.

Study design

This study uses a cross-sectional design using data from the Indonesian Family Life Survey-5 [8]. The survey collected information on individual, household and community level data using multistage stratified random sampling. IFLS is a longitudinal household survey involving both questionnaire and anthropometric measurements, and which was collected under the supervision of the Rand Corporation. IFLS-5 was conducted in 13 provinces in Indonesia [9].
IFLS-5 was conducted in September 2014-March 2015 on 50,148 individuals. The study population was the population who became the subject of IFLS-5 research

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in 2014. While the sample was the age group ≥ 21 years who followed the interview and had questionnaire data on important variables [10].

Study variable

We include demographic information, individual characteristics and behavioral factors as confounding. We categorize the level of education completed by respondents to low (under Senior High School), middle (Senior High School) and high (College or University), while marital status was classified as single, married, separated, live divorced, death divorced. Occupations were categorized as working and not working.

Physical activity was assessed through a series of questions a brief form modified from the International Physical Activity Questionnaire (IPAQ) on the type and time of physical activity involved in, in all parts of life: work, home and exercise and then classified as enough and less physical activity [11].

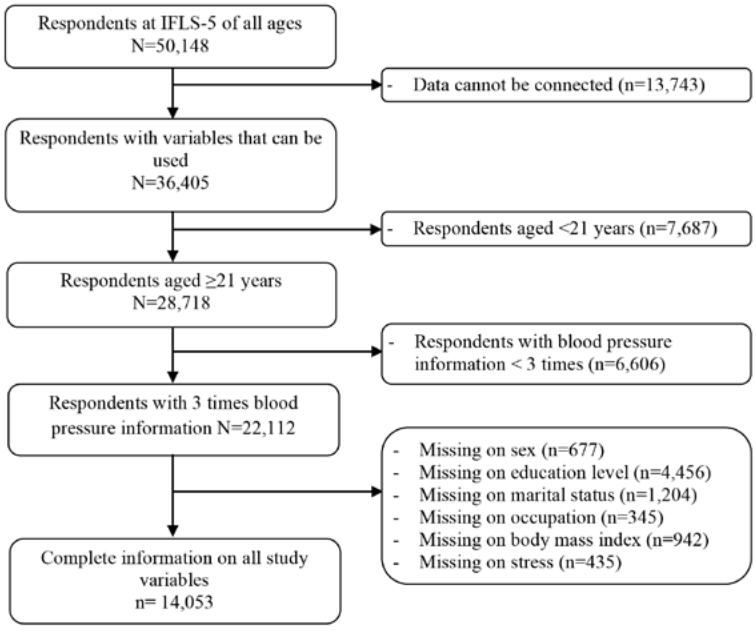
DM is assessed through questions ever diagnosed or not done by doctors or paramedics. We also measured respondents' fiber consumption in the past week, which was seen from the consumption of fruits and vegetables. Body mass index (BMI) < 27 kg/m^2: normal weight; and ≥ 27.0 kg/m^2: obesity derived from the height and weight measured during the physical examination, these criteria were determined based on the Ministry of Health of the Republic of Indonesia in 2013. Height measured by the Seca plastic height board model 213 and weight was measured using Camry model EB1003 scale. In this study the measurement of body weight and height was carried out by the interviewer or enumerator who was competent in their field and had received previous training.

Blood pressure was measured 3 times at an individual, using Omron meter HEM 7203. The first measurement was done at the beginning of the interview with the next two steps taken during the interview. The average of the 3 measurements was used for the current analysis. According to the JNC 7 blood pressure was categorized into 4 levels, namely normal (< 120/80 mmHg), prehypertension (120-139/80-89 mmHg), hypertension stage 1 (140-159/90-99 mmHg), and hypertension stage 2 (≥160/100 mmHg). We classify respondents as hypertension if their blood pressure ≥ 140/90 mmHg based on the criteria of JNC 7. Blood pressure measurement was carried out by the interviewer or enumerator who was competent in their field. Only respondents with complete information and blood pressure measurements were taken 3 times included in the analysis. After processing the data all of our study variables continued by making the joint variable of blood pressure and physical activity into one variable. The joint variables are divided into 4 categories, namely groups of people who are not hypertensive and have enough physical activity, groups of people who are not hypertensive and have less physical activity, groups of people who are hypertensive and have enough physical activity, and groups of people who are hypertensive and have less physical activity.

Statistical analysis

Logistic regression was performed to calculate the risk in all age groups. This study includes age, sex, education level, marital status, occupation, body mass index, residence area, stress, fruit and vegetable consumption and as potential confounders variables by including them in multivariable analysis between blood pressure and physical activity to DM. If there is a difference of more than 10% between POR crude and POR adjusted then these variables were considered as confounding variables and not included in the next model. The same procedure was used to estimate adjusted odds ratio (and 95% CI) for DM [12]. Finally, the joint effect (and 95% CI) of hyper-

Fig 1. Selection of study sample flowchart.



tension and physical activity, individual effect of hypertension among people with enough physical activity, and effect of people with less physical activity among non hypertension on DM were evaluated (Fig. 1).

Results

The description of each study variable can be seen in Table I. Of the 14,053 respondents, the proportion of DM in Indonesia was 3.86%. While the proportion of hypertension and less physical activity was 18.50% and 21.20%, respectively.

Table I shows that the majority of respondents were 21-44 years old (62.61%), women (54.52%), married (78.70%), low education (85.76%), working (81.80%), living in rural areas (54.79%), not hypertensive (81.50%), not obese (73.81%), enough physical activity (78.80%), not stressed (62.72%), consuming vegetables 7 days/week (48.39%), and consuming fruits 7 days / weeks (39.86%). The results of joint variables of blood pressure and physical activity showed that most respondents were in the category of non-hypertensive and enough physical activity (64.93%) and the least in the hypertension and less physical activity group (4.63%).

Based on Table II shows that the proportion of DM is highest in the 45-59 year age group (51.48%), women (55.54%), married people (83.76%), low education (74.17 %), people who live in urban areas (67.16%), obese people (54.61%), people who have enough physical activity (62.18%). Variables of age, sex, education level, marital status, residence area, blood pressure, body mass index, physical activity, fruit and vegetable consumption were significantly associated with DM with p value < 0.05. While the occupation and stress variables do not show a significant relationship with a p value > 0.05.

Based on the joint variable blood pressure and physical activity the proportion of the highest diabetes mellitus is indeed in the group of people who are not hypertension and have enough physical activity (33.95%). However, this is due to the fact that the proportion in this group is the highest, namely 64.93% (Tab. II). Interestingly, the group with the second and third highest proportion of DM was a group of people with hypertension and enough physical activity (28.23%) and groups of people with hypertension and less physical activity (19.93%). While the group of people without hypertension and less activity the least proportion of DM. So, it can be concluded that hypertension is a significant factor in influencing the proportion of DM than physical activity (Tab. III).

Table IV shows that the highest risk of DM is in the group of people who have hypertension and less physical activity which is 3.68 times, while those in hypertension and less physical activity risky 2.33 times, in groups of people who are not hypertension and have less physical activity risky 1.81 times greater with a group of people who are not hypertension and have enough physical activity as a reference.

Tab. I. Respondents features.

Characteristic	Total	Percentage
Diabetes mellitus		
Yes	542	3.86
No	13,511	96.14
Age (years)		
21-44 (adults)	8,799	62.61
45-59 (middle)	3,543	25.21
60-74 (elderly)	1,498	10.66
75-90 (old)	213	1.52
Sex		
Male	6,392	45.48
Female	7,661	54.52
Marital status		
Single	1,598	11.37
Married	11,060	78.70
Separated	80	0.57
Live divorced	297	2.11
Death divorced	1,018	7.24
Education		
High	1,503	10.70
Middle	498	3.54
Low	12,052	85.76
Occupation		
Yes	11,496	81.80
No	2,557	18.20
Residence area		
Rural	7,700	54.79
Urban	6,353	45.21
Blood pressure		
Non-hypertension	11,453	81.50
Hypertension	2,600	18.50
Body mass index		
Normal	10,372	73,81
Obesity	3,681	26,19
Physical activity		
Enough	11,074	78,80
Less	2,979	21,20
Stress		
No	8,814	62.72
Yes	5,239	37.28
Vegetable consumption		
7/week	6,800	48.39
4-6/week	3,725	26.51
1-3/week	3,058	21.76
Never	470	3.34
Fruit consumption		
7/week	5,601	39.86
4-6/week	3,919	27.89
1-3/week	3,464	24.65
Never	1,069	7.61
Joint variable of blood pressure and physical activity		
Non-hypertension + enough	9,125	64.93
Non-hypertension + less	2,328	16.57
Hypertension + enough	1,949	13.87
Hypertension + less	651	4.63

Tab. II. Frequency of diabetes mellitus according to individual characteristics.

Characteristics	Diabetes mellitus		Non-diabetes mellitus		P value	POR	95% CI
	N = 542	%	N = 13,512	%			
Age (years)							
21-44 (adults)	180	33.21	8,619	63.79		1	1
45-59 (middle)	279	51.48	3,264	24.16	< 0.001	1.68	1.21-2.15
60-74 (elderly)	80	14.76	1,418	10.50	< 0.001	2.70	2.06-3.53
75-90 (old)	3	0.55	210	1.55	< 0.001	4.09	3.37-4.95
Sex							
Male	241	44.46	6,151	45.53		1	1
Female	301	55.54	7,360	54.47	< 0.001	1.04	0.87-1.24
Marital status							
Single	17	3.14	1,581	11.70		1	1
Married	454	83.76	10,606	78.50	< 0.001	3.98	2.44-6.47
Separated	1	0.18	79	0.58	0.011	1.17	1.05-8.95
Live divorced	14	2.58	283	2.09	0.045	4.60	2.24-9.43
Death divorced	56	10.33	962	7.12	0.005	5.41	3.12-9.37
Education							
High	98	18.08	1,405	10.40		1	1
Middle	42	7.75	456	3.38	0.035	2.02	1.60-2.53
Low	402	74.17	11,650	86.23	0.004	2.66	1.91-3.71
Occupation							
Yes	11,135	82.41	361	66.61		1	1
No	2,376	17.59	181	33.39	0.051	2.34	1.95-2.82
Residence area							
Rural	178	32.84	7,522	55.67		1	1
Urban	364	67.16	5,989	44.33	< 0.001	2.56	2.14-3.08
Blood pressure							
Non-hypertensive	281	51.85	11,172	82.69		1	1
Hypertensive	261	48.15	2,339	17.31	< 0.001	2.22	1.18-3.26
Body mass index							
Normal	246	45.39	10,126	74,95		1	1
Obesity	296	54.61	3,385	25.05	< 0.001	2.31	1.46-3.67
Physical activity							
Enough	337	62.18	10,373	79,47		1	1
Less	205	37.82	2,774	20,53	< 0.001	1,76	1,01-3,06
Stress							
No	322	59.41	8,492	62.85		1	1
Yes	220	40.49	5,019	37.15	0.066	1.15	1.07-1.37
Vegetable consumption							
7/week	257	47.42	6,543	48.43		1	1
4-6/week	154	28.41	3,571	26.43	< 0.001	1.19	0.69-2.04
1-3/week	116	21.40	2,942	21.77	< 0.001	1.30	1.16-2.28
Never	15	2.77	455	3.37	< 0.001	2.11	1.17-2.86
Fruit consumption							
7/week	246	45.39	5,355	39.63		1	1
4-6/week	158	29.15	3,761	27.84	< 0.001	1.31	0.90-1.93
1-3/week	105	19.37	3,359	24.86	< 0.001	1.44	1,09-2,12
Never	33	6.09	1,036	7.67	< 0.001	2.44	1.89-3.08

Tab. III. Frequency of diabetes mellitus according to joint variable of blood pressure and physical activity.

Characteristics	Diabetes mellitus		Non-diabetes mellitus		POR	95% CI
	N = 542	%	N = 13,512	%		
Non-hypertension + enough	184	33.95	8,941	66.18	1	1
Non-hypertension + less	97	17.90	2,231	16.51	1.85	1.17-3.53
Hypertension + enough	153	28.23	1,796	13.29	2.52	1.86-5.27
Hypertension + less	108	19.93	543	4.02	3.82	2.54-9.35

Tab. IV. Final model of joint variable of blood pressure and physical activity against diabetes mellitus.

Joint variable of blood pressure and physical activity	Diabetes mellitus		Non-diabetes mellitus		POR (95% CI)
	N = 542	%	N = 13,512	%	
Non-hypertension + enough	184	33.95	8,941	66.18	1.00 (reference)
Non-hypertension + less	97	17.90	2,231	16.51	1.81 (1.34-3.62)
Hypertension + enough	153	28.23	1,796	13.29	2.33 (1.65-6.43)
Hypertension + less	108	19.93	543	4.02	3.68 (2.43-5.34)

Adjusted by age, sex, education, occupation, residence area, body mass index, and fruit and vegetable consumption.

Discussion

The starting point for healthy living with diabetes is an early diagnosis, the longer a person lives with undiagnosed and untreated diabetes, the worse the health outcome. For those diagnosed with diabetes, a series of interventions can reduce the risk of bad prognosis diabetes, regardless of what type of diabetes they may have. These interventions include blood pressure control, blood glucose, through a combination of diet, physical activity and, if necessary, treatment, to facilitate early control [1].

Our study shows that (48.15%) people with DM have hypertension. Most people with DM were female. This is in line with several other studies that show that women suffer more from DM [13-17]. Most respondents have low education and working [18, 19]. This study also shows that most people with DM are adults (21-44 years) and married. This is in line with several other studies. The results of the same study were also mentioned by other studies [18].

This study shows that in non-diabetes mellitus patients have enough physical activity than less physical activity. Other studies suggest that physical activity can improve blood sugar control [20].

This cross-tabulation analysis also shows that the variables of age, sex, education level, marital status, residence area, blood pressure, body mass index, physical activity, fruit and vegetable consumption are significantly associated with DM. While the occupation and stress variables do not show a significant relationship.

Physical activity includes all movements that increase energy use. Exercise improves blood glucose control in DM, reduces cardiovascular risk factors, contributes to weight loss, and improves well-being [21, 22]. Enough physical activity can prevent or delay the development of diabetes [23]. Regular exercise also has considerable health benefits in people with diabetes (e.g., increased cardiovascular fitness, muscle strength, insulin sensitivity etc. [24]. Challenges related to blood glucose management. Insulin in the muscles and liver can be modified immediately by physical activity and regular physical activity [25]. Aerobic exercise increases muscle glucose up to 5-fold. After exercise, glucose uptake remains increased by insulin-independent (2 hours) and insulin dependent (up to 48 hours) [26].

Physical activity is not the only trigger factor for DM in the equation below explained about the joint effects of blood pressure and physical activity on the occurrence of DM. The pathophysiological mechanism that explains the relationship between hypertension and the incidence of DM is not yet clear. However high blood pressure has been shown to induce microvascular dysfunction, which can contribute to the pathophysiology of the development of diabetes [27, 28]. Endothelial dysfunction associated with insulin resistance is also associated with hypertension, and biomarkers of endothelial dysfunction are predictors of DM [29].

Elevated blood pressure values are a common finding in patients with DM and are thought to reflect, at least in part, the impact of the underlying insulin resistance on the vasculature and kidney [30]. On the contrary, accumulating evidence suggests that disturbances in carbohydrate metabolism are more common in hypertensive individuals [31, 32]. Thereby indicating that the pathogenic relationship between DM and hypertension is actually bidirectional.

In the multivariate analysis of joint variables of blood pressure and physical activity was found that hypertension had a greater effect of 2.33 times in causing DM than less physical activity ie 1.81. However, the risk of DM increases significantly, which is 3.68 times when hypertension and less physical activity appear together. In the above results, the percentage of the increased risk of DM events can be calculated when hypertension and less physical activity appear together as follows:

- (3.68-1) = (2.33-1) + (1.81-1);
- 2.68 = 1.33 + 0.81;
- 2.68 = 2.14;
- 2.68 > 2.14;
- 2.68-2.14 / 2.68 = 20.14%.

This means that the risk for developing DM will increase by 20.14% when hypertension and less physical activity appear simultaneously due to the interaction of both.

This study has limitations, because this is a Cross-Sectional study, so it cannot determine causal relationships. Longitudinal studies are needed to assess the joint effect of blood pressure and physical activity on DM to draw strong conclusions about the causal pathways of this relationship.

Conclusions

The proportion of DM in Indonesia who became respondents in IFLS-5 is 3.86%. The combination of hypertension and less physical activity have a risk of 3.86 times to suffer from DM compared to those who not hypertension and have enough physical activity. Hypertension and less physical activity together show a greater

association with DM than hypertension or less physical activity alone. The continued increase in DM prevalence makes it necessary to increase health promotion efforts including the addition of nutrition counseling and counseling as well as joint sports activities (gymnastics) in integrated coaching activities. Communities, especially those classified as high-risk (hypertension and less physical activity) can realize the importance of independently performing DM screening in this case was blood pressure, blood glucose level, general obesity of body weight and height.

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Conflict of interest statement

The authors declare no conflict of interest.

Authors' contributions

NS: conceived of the presented idea, collect the data, performed the analysis. ASH: conceived of the presented idea, conceived and designed the analysis, contributed data or analysis tools, performed the analysis, contributed to the interpretation of the results. DS: verified the analytical methods, designed the model and the computational framework, other contribution. M: developed the theory and performed the computations, performed the analysis, derived the models and analyzed the data, wrote the paper. All authors discussed the results and contributed to the final manuscript.

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ORIGINAL ARTICLE

Assessment of the operation of a pilot program of preventive medicine for adults in three primary care centers of Athens and Piraeus: a cross-sectional study

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Keywords

Patient satisfaction • Screening program • Health visitor/nurse • Greek Healthcare System • Program of Preventive Medicine for Adults

Summary

Objective. *To evaluate the operation of the pilot Program of Preventive Medicine for Adults (PPMA) from the provision of healthcare services in three primary health care centers of Athens and Piraeus (Greece).*
Design. An observational, cross-sectional study was undertaken. A structured questionnaire was used to collect data.
Setting. *Three public primary health centers of Athens, Greece.*
Participants. 142 participants, 40-55 years of age, with no previously identified/diagnosed health issues (overall healthy) that should not have undergone any type of screening in the past 12 months.
Measures and results. *The majority of participants were female (75.4%), aged 40-45 years (43.7%), Greek nationals (88%), employed (62.7%) and high school graduates (52.8%). 68.3% of participants scheduled an appointment in the first two days and 58.9% waited up to 5 minutes in the waiting room. The paramedical personnel scored higher evaluation (4.94) than the doctor (4.61), but all health care centers received a very high general evaluation (4.87). Multiple linear regression showed significant association between the evaluation of the pilot PPMA, the evaluation of health visitor/nurse (B = .240) and the communication of results to participants (B = .245).*
Conclusions. *Findings show an extremely positive evaluation of the pilot PPMA, a result that can be used by healthcare managers for the expansion of the screening program to the general population.*

Introduction

In Greece evidence shows that metabolic syndrome (MetS) affects 20-30% of the adult population [1], meanwhile 98 per 100,000 persons die each year from chronic heart disease and 200 per 100,000 persons die from malignant neoplasms [2]. Lifestyle and family history have been shown to contribute to the development of both acute and chronic disease [3]. Health Screening Programs are the most important aspects of prevention, representing basic tools of modern public health, aiming at early detection of disease [4].
Several screening programs have been implemented over the years worldwide for targeting risk factors and specific populations at risk [5, 6]. Preventive medicine and screening have gained a growing interest in Greece with the Ministry of Health launching in 2008 the National Plan of Action on Public Health, aiming at the effective protection and health promotion, through measures, programs, structures and new prevention strategies [7]. In Greece there are organizational barriers in the provision of screening services, with only a small percentage of the Greek population receiving screening [8]. There are only few nationwide screening programs for cancer or chronic diseases [9-13] and few more local programs in rural areas [9, 11], so preventive screening uptake is low, making timely treatment problematic.

Due to the lack of a nationally organized invitational screening programs, screening is carried out mostly on the advice of general practitioners (GP) or based on the individual's request. In this context, in 2009 the pilot Program of Preventive Medicine for Adults (PPMA) was established by the National Organization for Healthcare Provision (EOPYY) providing primary health care to citizens aged 40-55 years. The program aims to raise awareness among citizens regarding annual screening for the early diagnosis of diseases such as heart disease, malignant neoplasms, metabolic syndrome and their effective management.
To our knowledge, no national or international study to date has evaluated the operation of the PPMA and aimed to analyse which from the health services offered within this primary health care program of EOPYY are important for its evaluation. Program evaluation permits to identify program strengths, weaknesses, and areas for improvement.

Materials and methods

Design

An observational, cross-sectional study was undertaken to evaluate the operation of the pilot PPMA. The study

took place in primary health care centers of Athens and Piraeus (primary health care centers of Kallithea and Peristeri in Athens and Agia Sofia in Piraeus), densely populated districts of the capital and the largest seaport of Greece, covering approximately 300,000 citizens (according to the 2011 census). A questionnaire was specifically developed for data collection.

Ethical considerations

The study was approved by the Department of Prevention and Health Promotion of EOPYY (protocol number 3917).

Description of pilot Program of Preventive Medicine for Adults (PPMA)

Each primary health care center had a physician or a cardiologist, a midwife and a health visitor (healthcare professional who deals mainly with the protection and promotion of health for the most vulnerable population groups) or nurse. The midwife and health visitor or nurse worked mainly by protocol. The doctor met with participants for counselling and health promotion activities, with the exception of the Kallithea health care center where the physician had minimal involvement unless a medical problem occurred. The program offers participants annual screening including clinical assessments and laboratory tests. Eligible participants should be between 40-55 years of age, overall healthy and should not have undergone any type of screening in the past 12 months. Exclusion criteria were a recorded diagnosis of hypertension, diabetes, cardiovascular disease, thyroidopathy, hyperlipidaemia, prostatitis and anaemia. Participants who met the inclusion criteria were scheduled to undergo the recommended screening tests which included: Cell Blood Count (CBC), urine analysis, erythrocyte sedimentation rate (ESR), thyroid stimulating hormone (TSH), lipid panel screening, urea, fasting blood sugar and electrocardiogram. Women also received a mammography and Pap smear and men received a prostate-specific antigen test (PSA). Demographic characteristics, anthropometric, clinical data and test results for all participants were obtained by a health visitor/nurse then registered on the participant's medical record so that the doctor could make a medical evaluation. If during the screening a medical problem was discovered the participant was referred to the appropriate specialty for further evaluation and treatment (Fig. 1).

Participant Recruitment

The target population comprised participants who were already taking part in the program and had completed the entire screening process. Participants were informed about the program only through announcements in the primary health care centers or through relatives and friends. Assuming an effect size (f^2) = 0.2, α error probability = 5%, statistical power = 95% and number of predictors = 6, an a priori power analysis using the G power software (version 3.1) [14] revealed that data would have to be collected from N = 111 participants. Overall 149 people had verbally consented to participate in this

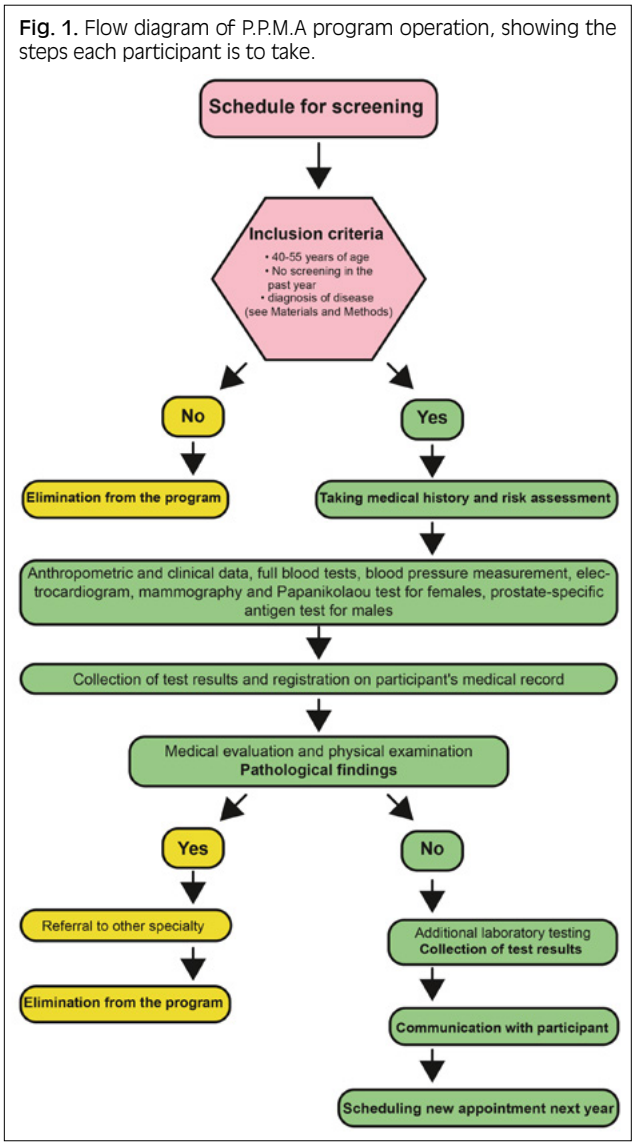

Fig. 1. Flow diagram of P.P.M.A program operation, showing the steps each participant is to take.

study, 7 participants left the questionnaires incomplete. In total, 142 respondents, 50 participants from Kallithea, 50 from the Peristeri health care center and 42 from Agia Sophia, who completed the questionnaire were included in quantitative analysis. The overall response rate was 95.3%.

Procedure and Data collection

A structured questionnaire for patients was developed to evaluate primary care in a number of key areas ranging from the access to care, the helpfulness of visitors/nurses, the doctors' communication skills and overall program evaluation on validated questionnaires used in primary care in Greece, UK, US and Europe [15-17].
To increase confidence a pre-study evaluation of the questionnaire (with 5 patients, 2 nurses and 1 physician) was performed to test validity in terms of language and understanding. The questionnaire consisted of 37 questions and was divided into four sections: socio-demographic features, ease of access to the program, attitude of health care personnel and general program

evaluation. The majority were closed-ended questions using five-point Likert scale, ranging from 1 (very dissatisfied), 2 (dissatisfied), 3 (undecided), 4 (satisfied), 5 (very satisfied), so that higher scores indicate greater satisfaction. The remainder were in yes/no format and multiple choice questions based on guidelines reported in other studies [16, 18]. Evaluation of health visitor/nurse and evaluation of doctor is defined as the participant's opinion about the existence of good communication, courtesy and concern of the health visitor/nurse and the doctor with participant's questions/worries. The evaluation of the pilot PPMA is defined as the participant's opinion about organizational structure, accessibility to the program, physical environment, ease of arranging appointment(s) and good service attitude. Each participant who had completed the entire screening process was interviewed after visiting the physician. The interviews took 10 to 15 minutes on average to complete and were scheduled on specific days. The primary author (T.M) of this study collected the data independently. No monetary benefit was given to the respondents for participation in this study.

Statistical analysis

Statistical analysis was carried out with SPSS (Version 22.0. Chicago: SPSS Inc.). A descriptive analysis for categorical variables was carried out using Pearson's Chi-square test, to evaluate the associations between each health care center. The results are presented as counts and percentages. Continuous variables were expressed as means and standard deviation (SD) using analysis of variance (ANOVA) for measuring the difference between means. To identify which variable(s) is the best predictor of the evaluation of the pilot PPMA, a standard multiple linear regression analysis was performed including variables whose association were significant at a value $P < 0.2$. After excluding collinearity, the best subset of variables was selected. The predictor (independent) variables for this study were demographic characteristics (age and gender), attention and interest of health visitors/nurse, evaluation of doctor, communication of results to participants and evaluation of health visitor/nurse. The evaluation of the pilot PPMA was the dependent variable. The statistically significant threshold was set at .05 probability value.

Results

Characteristics of the participants

Most participants were female (75.4%), aged 40-45 years (43.7%), Greek nationals (88%), married (78.2%), employed (62,7%) and high school graduates (52.8%). In addition, we found a significant association between the 3 primary health care centers and participant characteristics: nationality ($X^2 = 19.918$, $p < .001$, Cramer's V = .375), age ($X^2 = 14.289$, $p = .006$, Cramer's V = .224) and gender ($X^2 = 8.086$, $p = .017$, Cramer's V = .239) (Tab. I).

Concerning access to the program, 68.3% of participants scheduled an appointment in the first two days, while 58.9% declared a waiting time in the waiting room of up to 5 minutes. Moreover, all participants totally agreed (100%) that they will continue undergoing screening and that they will recommend the program to family and friends. The majority of participants (66.4%) learned about the program through friends and relatives, while a smaller number of participants (9.4%) were informed by their doctor (Tab. 2). With regards to the counselling, the participants declared that they preferred the doctor to perform health promotion counselling (43.7 %), where it was available (see discussion) or health visitor/nurse (48.6%) (Tab. II). Moreover, we found a significant association between the 3 primary health care centers and the amount of waiting time ($X^2 = 16.687$, $p < .001$, Cramer's V = 0.342) and the health promotion counselling ($X^2 = 45.806$, $p < .001$, Cramer's V = .401).

Concerning the attitude of the health care personnel, analysis of variance showed greater satisfaction with the health visitor/nurse of Kallithea and Peristeri. Participants stated that they received more attention and interest and that the health visitors/nurses in these centres were more capable, available and helpful compared to the health professionals at Agia Sofia (Tab. III). The doctor of Agia Sophia received the highest score (4.90) in the doctor's evaluation and the doctor of Peristeri the lowest (4.32). There was no statistically significant difference in the general evaluation of the pilot PPMA between the primary health care centers. Allhealth care centers received very high evaluation showing impressive satisfaction rates from the operation of the pilot PPMA.

Multiple linear regression was used to identify independent determinants of the evaluation of the pilot PPMA (Tab. IV). The results of linear regression revealed attention and interest of health visitors/nurse, evaluation of doctor, gender and age not to be statistically significant predictors to the model ($p > .05$). However, the results of multiple linear regression analysis revealed a statistically significant association between communication of results to participants and evaluation of health visitor/nurse ($R2 = .355$, adjusted $R2 = .326$, $F(6, 135) = 12.381$, $p < .001$).

Discussion

The aim of the current study was to evaluate the operation of the pilot PPMA organized by EOPYY in 3 primary health care centers of Athens and Piraeus. To the best of our knowledge, the present study is the first to evaluate the operation of the program. The results of our study demonstrate great evaluation of participants regarding access to the program. Most participants were informed about the program from family and friends with only a small number referred by their doctor. Research has shown that Greek doctors have limited awareness of screening [19] so it is crucial to educate physicians in using effective strategies for the implementation of prevention [13]. Also, protocols and guidelines should be established to improve doctors screening attitudes [20].

Tab. I. The sociodemographic characteristics of the participants of the pilot Program of Preventive Medicine for Adults (PPMA) in the 3 different Primary health care centers, N (%).

Demographic characteristics		Primary health care centres						
		Kallithea	Peristeri	Agia Sophia	Total	*p*-value[a]	X^2-value	*Cramer's V* -value
Gender						.017	8.086	.017
	Male	19 (13.4)	7 <(4.9)	9 (6.3)	35 (24.6)			
	Female	31 (21.8)	43 (30.3)	33 (23.2)	107 (75.4)			
Age in years						.006	14.289	.224
	40 - 45	15 (10.6)	21 (14.8)	26 (18.3)	62 (43.7)			
	46 - 49	21 (14.8)	19 (13.4)	11 (7.7)	51 (35.9)			
	50+	14 (9.9)	10 (7.0)	5 (3.5)	29 (20.4)			
Nationality						<.001	19.918	.375
	Greek	36 (25.4)	50 (35.2)	39 (27.5)	125 (88.0)			
	Other	14 (9.9)	0	3 (2.1)	17 (12.0)			
Educational level						.342	8.995	.178
	Read and write	3 (2.1)	3 (2.1)	3 (2.1)	9 (6.3)			
	Elementary	6 (4.2)	5 (3.5)	7 (4.9)	18 (12.7)			
	High school graduates	29 (20.4)	28 (19.7)	18 (12.7)	75 (52.8)			
	University/college graduates	8 (5.6)	11 (7.7)	5 (3.5)	24 (16.9)			
	Master or PhD	4 (2.8)	3 (2.1)	9 (6.3)	16 (11.3)			
Occupational status						. 091	4.796	0.183
	Employed	37 (26.1)	30 (21.1)	22 (15.5)	89 (62.7)			
	Unemployed[b]	13 (9.2)	20 (14.1)	20 (14.1)	53 (37.3)			
Marital status						.207	3.142	0.148
	Married	35 (24.6)	42 (29.6)	34 (23.9)	111 (78.2)			
	Not in relationship[c]	15 (10.6)	8 (5.6)	8 (5.6)	31 (21.8)			

All respondents agreed that they will continue undergoing screening and that they will recommend the program to family and friends. Research findings show substantial benefits from undergoing annual examinations especially with patients receiving lipid screening and gynaecological screening [21, 22]. Communication of health results and health promotion could be performed by nurses or health visitors due to the confidence, proximity and comfort participants feel for them [23]. Our study revealed a higher satisfaction rate for the health visitors/nurses than with doctors. Participants stated that they received more attention and interest from the paramedical personnel (midwives, health visitors and nurses). The negative rating of the doctor's evaluation could possibly be attributed to the lack of time due to part-time occupation and/or lack of interest.

Despite the relatively low evaluation of the program's doctor in our study, participants gave great evaluation for the operation of the pilot PPMA as a whole in all three primary health care centers. This is attributed to the courtesy of personnel, the provision of free screening tests and ease of appointments. The latter confers with findings from other studies showing that participants will evaluate health care services with high scores provided they are satisfied with the organizational structure, the waiting room, the waiting time and the behaviour of the health care personnel [24, 25]. Importantly, using a multiple linear regression analysis in order to identify variables important for the evaluation of the program, demonstrated that the communication of results to participants and evaluation of health visitor/nurse were associated with higher general evaluation of the PPMA from the participants.

The present study has certain limitations. The survey

Tab. II. Different parameters of the pilot Program of Preventive Medicine for Adults (PPMA) in the different Primary health care centers, N (%).

Parameters		Primary health care centers						
		Kallithea	Peristeri	Agia Sophia	Total	*p*-valuea	X^2-value	*Cramer's V* -value
Access to the program						.311	2.337	0.128
	0-2 days	31 (21.8)	38 (26.8)	28 (19.7)	97 (68.3)			
	More than 3 days	19 (13.4)	12 (8.5)	14 (9.9)	45 (31.7)			
Waiting time						<.001	16.687	0.342
	Up to 5 minutes	27 (19.1)	21 (14.9)	35 (24.8)	83 (58.9)			
	More than 5 minutes	23 (16.3)	28 (19.9)	7 (5)	58 (41.1)			
Continue screening and recommend the program						-	-	-
	Yes	50 (35.2)	50 (35.2)	42 (35.2)	142 (100)			
	No							
Information for the program's operation						.257	5.3021	0.143
	Relatives/ friends	32 (25)	35 (27.3)	18 (14.1)	85 (66.4)			
	Internet/ public health social media campaigns	12 (9.4)	11 (8.6)	8 (6.3)	31 (24.2)			
	Doctor	4 (3.1)	2 (1.6)	6 (4.7)	12 (9.4)			
Health promotion counseling						<.001	45.806	.401
	Doctor	5 (3.5)	15 (10.6)	42 (29.6)	62 (43.7)			
	From the health visitor/ nurse	44 (31)	25 (17.6)	0 (0)	69 (48.6)			
	From both	1 (0.7)	10 (7)	0 (0)	11 (7.7)			

was conducted in only 3 of the 6 primary health care centers where the program runs including non-randomly selected participants. The selection of the health care centers was made taking into account the attendance rate in each health care center and the long-distance travel from Athens due to funding constraints. The participants were interviewed on a scheduled day when the rate of appointment was higher. Due to the lack of random selection it is difficult to generalize findings. Bias also may arise from the gratitude and satisfaction participants feel towards the health care personnel resulting in skewed values. We must also consider the probability of bias arising from the participants that were eliminated from the program, due to the inclusion/exclusion criteria, that may change the general evaluation rate. Despite these limitations this study is the first to evaluate the operation of the pilot PPMA and it is worth mentioning the really high rate of positive response. In Greece implemented prevention focuses mainly on cancer screening programs. The operation of this program is innovative due to the coverage of a wider range of diseases, so the benefit for citizens is greater. Additionally, in the current years of economic crisis, free of charge screening is considered a blessing for low- and middle-class population. These findings are valid and should be taken into account for the implementation of the program in larger general population groups.

Conclusion

The findings of the current study demonstrate high evaluation both for the operation of the pilot PPMA and the health care personnel in the all health care centers and the desire for continuation of the screening program on a general basis. In Greece the attendance rate in screening programs is extremely low due to the lack of centralized invitation system, guidelines and protocols and the reduced interest of primary care doctors for prevention. The results of our study can be used to inform preventive medicine program managers about the benefits of the program for the general population so it could lead to nation-wide implementation providing free or low-cost screening and should emphasize the contribution of health visitors and nurses in the successful operation and its acceptance.

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Tab. III. Comparison of mean and standard error of participants' satisfaction in the 3 different Primary health care centers.

Attention and interest of health visitors/nurse					
	N	Mean	SD	F	*p*-value
Kallithea	50	4.94	.240	6.788	.002
Peristeri	50	4.92	.274		
Agia Sophia	42	4.69	.517		
Total	142	4.86			
Capability of health visitors/nurse					
	N	Mean	SD	F	*p*-value
Kallithea	50	4.92	.274	3.222	.042
Peristeri	50	4.84	.370		
Agia Sophia	42	4.71	.508		
Total	142	4.83			
Availability and helpfulness of health visitor/nurse					
	N	Mean	SD	F	*p*-value
Kallithea	50	4.94	.240	5.521	.004
Peristeri	50	4.88	.328		
Agia Sophia	42	4.69	.517		
Total	142	4.84			
Evaluation of health visitor/nurse					
	N	Mean	SD	F	*p*-value
Kallithea	50	4.98	.141	0.798	.452
Peristeri	50	4.90	.416		
Agia Sophia	42	4.93	.342		
Total	142	4.94			
Evaluation of doctor					
	N	Mean	SD	F	*p*-value
Kallithea	50	4.66	.772	5.793	.004
Peristeri	50	4.32	1.115		
Agia Sophia	42	4.90	.370		
Total	142	4.61			
Evaluation of the pilot P.P.M.A					
	N	Mean	SD	F	*p*-value
Kallithea	50	4.96	.198	1.924	.150
Peristeri	50	4.82	.482		
Agia Sophia	42	4.83	.437		
Total	142	4.87			

Tab. IV. Multiple regression of evaluation of the pilot P.P.M.A.

Predictor (IV)	B [95% CI]	β	Sr^2
Attention and interest from health visitors/ nurse	.053 [-0.130, 0.236]	.050	.002
Age	.007 [-0.006, 0.021]	.077	.008
Gender	.096 [-0.030, 0.222]	.106	.016
Evaluation of Doctor	-.007 [-0.030, 0.222]	-.034	.019
Evaluation of health visitor/nurse	.240 [0.150 ,0.330]**	.429	.171
Communication of results to participants	.245 [0.065, 0.425]**	.230	.051

Note: B and β indicate Unstandardized and Standardised Regression Coefficient, respectively. sr^2 indicates Squared Semi-Partial Correlations. CI = confidence interval
*p < .05. **p < .01.

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Conflict of interest statement

The authors declare no conflict of interest.

Authors' contributions

TM and AA conceived of the presented study. TM design the questionnaire and collect the data. AA performed the computations and supervised the findings of this work. All authors discussed the results and contributed to the final manuscript.

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ORIGINAL ARTICLE

A management model for Hospital Hygiene Unit: evidence-based proactive surveillance of potential environmental sources of infection in order to prevent patient's risk

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Keywords

Preventive Medicine • Environmental surfaces • Water safety • Food safety • Patient safety

Summary

Introduction. *The aim of this study is to describe a proactive surveillance system of food, water and environmental surfaces, in order to avoid Healthcare-Associated Infections (HAIs) from hospital environment.*

Methods. *It is a retrospective descriptive study. The surveillance system consists of two integrated phases: pre-analytic and post-analytic. The activities are distinguished in ordinary control activities, performed after scheduled and shared surveys, and compliance activities, performed when it is necessary to establish the adequacy of the destination use, for example opening a new ward.*

Results. *A total of 1,470 Samples were collected and 539 Reports were generated across the five-year study period. Water for human consumption procedure: a statistically significant trend was found only in the total number of Samples collected ($p < 0.001$). Legionella spp. infection water risk procedure: all Samples and Reports, with the exception of Compliance Report Samples, showed a statistically significant trend ($p < 0.001$). Pseudomonas aeruginosa water risk procedure: only Ordinary Reports and Compliance Report Samples trend were statistically significant ($p = 0.002$ and $p = 0.028$ respectively). Effectiveness of surface sanitization procedure: no trend was statistically significant ($p < 0.05$). Hospital catering and food surfaces procedure: Samples and Reports yearly number was constant, no trend analysis was performed. HAIs prevalence was never over 5% in the hospital under study.*

Conclusions. *This surveillance system of water, food and environmental surfaces represents an innovative way of approaching hospital safety for patients and personnel because it overcomes the limitations due to a classic approach limited to a laboratory analytic phase only, according to the best available scientific evidence.*

HIGHLIGHTS

- Highlights 1: Healthcare-Associated Infections (HAIs) still represent a major Public Health problem.
- Highlights 2: we describe a proactive surveillance with regard to water, food and environmental surfaces, in order to prevent and avoid HAIs, according to the best available scientific evidences.
- Highlights 3: the described surveillance system of food, water and environmental surfaces is a proactive surveillance system because it is systematically performed, according to a predetermined periodicity and not only in case of epidemic events or hospital infections.
- Highlights 4: the described surveillance system of food, water and environmental surfaces is an innovative way of approaching hospital safety for patients and *healthcare personnel* because it consists both of a pre-analytic and of a post-analytic phase integrating the analytic one.

Introduction

Healthcare-Associated Infections (HAIs) are infections that occur while receiving care in a hospital or other healthcare facility, that first appear 48 hours or more after hospital admission, or within 30 days after having received treatments such as prosthesis [1].

About 1 in 31 hospital patients has at least one HAI per day. In a 2015 survey 3% of hospitalized patients had one or more HAI. There were an estimated 687,000 HAIs in U.S. acute care hospitals in the same year and about 72,000 hospital patients with HAIs died during their hospitalizations [2].

Environmental contamination and contaminated surfaces may predispose to the development of HAIs because they act as a reservoir if cleaning and disinfection procedures are not correctly known and applied.

In Italy, in the time-period 1st December 2015 - 29th February 2016, a descriptive study was carried out in a hospital in Milan to verify the knowledge and adherence to prevention and control of HAIs procedures by nurs-

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ing staff. Questionnaires with anonymous self-reporting method were administered; inspections in the wards using observational grids were carried out. The Authors found the greatest knowledge gap as regards cleaning, disinfection and sterilization, with a number of incorrect answers approaching 50% [3].
Water exposure in healthcare settings can cause infections by water-related organisms such as *Legionella* and *Pseudomonas aeruginosa* (*P. aeruginosa*) and can potentially lead to outbreaks.
Nine to 20% of infections caused by *P. aeruginosa* take place in Intensive Care Units (ICU) and Hematology which are therefore classified as at risk wards. Healthcare facilities should therefore develop and implement water management programs to limit the growth and spread of water-related organisms [4].
Moreover, some HAIs have been related to the consumption of contaminated foods in hospital settings, too. For example, some cases of hospital-acquired listeriosis have been described in recent years [5-7].
Moreover, *P. aeruginosa* poses a significant threat to patients within the healthcare system because its intrinsic and acquired resistance mechanisms significantly limit the choices for antimicrobial therapy, prompting an increase in the research and development of antibacterial agents with enhanced activity against multidrug-resistant (MDR) *P. aeruginosa*. Patients with MDR *P. aeruginosa* infections have extremely limited and often toxic antibiotic options and resistance to all of these agents will likely emerge, so MDR *P. aeruginosa* has to be considered a major Public Health concern and a perpetual therapeutic challenge [8].
Last, regarding to environmental surfaces, it is known that the contaminated surface environment in hospitals plays an important role in the transmission of *Methicillin-Resistant Staphylococcus aureus* (MRSA), *Vancomycin-Resistant Enterococcus* spp. (VRE), *Clostridium difficile* (*C. difficile*), *Acinetobacter* spp., and norovirus [6].
Infection prevention and control is considered a priority for patient safety and should involve healthcare workers (HCWs) at all levels with programs planned by multidisciplinary groups taking into account local guidelines, following a multimodal intervention strategy that emphasizes hands-on training, and be regularly assessed, and adjusted if necessary [9].
The aim of the present study is to describe the proactive surveillance carried out in a large Italian Hospital, with regards to food, water and environmental surfaces, in order to prevent HAIs.

Methods

The number of environmental Samples stratified for year and procedure was matched with the number of Reports stratified for year, procedure and report typology. More specifically data from the procedures named A1, A2, A3 stratified across 2014-2018 were analyzed. In this period, data regarding the number of Samples from environmental monitoring were collected. Below are shown report typology names, their meaning and the Areas in which the Hospital Hygiene Unit is organized and environmental matrices surveyed are placed:

- *OR (Ordinary Reports)* drawn up after scheduled and shared surveys;
- *OCR (Ordinary Control Reports)* deriving from an OR with the presence of non-compliance and the implementation of corrective actions decided by a focus group;
- *CR (Compliance Reports)* arises when it is necessary to establish the adequacy of the destination use, for example opening a new ward;
- *CCR (Compliance Control Reports)* is produced after a non-compliant CR;
- *A Area - Water safety*: A1: drinking water; A2: *Legionella* spp. infection risk from hospital water system; A3: *P. aeruginosa* infection risk from hospital water system;
- *B Area*: hospital catering and food surfaces;
- *C Area (C3 Procedure)*: effectiveness of surface sanitization procedures.

A Area

A1 procedure: water for human consumption

The purpose of this procedure is to ensure quality and safety of cold water for human consumption in the water system, water from tubs, taps and toilets is monitored through the evaluation of microbiological and chemical-physical parameters as indicated by Italian law.
Sampling, sample transportation, storage and sample frequency planning are carried out according to proper regulation as well.

A2 procedure: Legionella infection risk from hospital water system

The purpose of this procedure is to perform a systematic environmental surveillance of *Legionella* spp. colonization in the water system of the Hospital.
The Italian National Guidelines establish a quarterly sampling for the High Risk (HR) wards and a semi-annual sampling for Incremented Risk (IR) wards. This surveillance plan involves a systematic sampling of the water system (including each hot water tank) in all of the buildings: a quarterly sampling for the HR wards and a yearly sampling for the IR wards. Since each building contains some IR and some HR wards, most of the water system of each building is in fact monitored multiple times a year. According to the Italian National Guidelines [10], whenever a sample results positive for *Legionella* spp. the colonized area is subjected to decontamination procedures and then sampled again after 1, 3 and 6 months.
Each sampling is composed of a minimum number of 6 Samples from the hot water tanks and return loop and at least 4 Samples from distal outlets (including showerheads, faucets etc.).
In all HR wards, point of use (POU) filters are installed on water taps and replaced every 30 days, according to

the manufacturer's specifications. The Samples in these distal points are carried out without the filters so as to analyse the possible colonization of the water plant.
Our sampling method involves two types of sampling: "pre-flush" sampling and "post-flush" sampling. "Pre-flush" sampling indicates water quality at point of use, it cannot refer possible detections specifically to the water system, the terminal part of the tap or both. This is the method routinely used. "Post-flush" sampling indicates water quality at water system level, it is obtained after flushing water for three minutes. These methods are used in combination whenever a significant detection is made.
Temperature, pH, residual chlorine, hardness and conductivity of the sampled water are also determined at the time of collection according to Italian National Health Institute Technical Report [3].
A microbiological analysis is performed on each sample in accordance to ISO standard [11].

A3 procedure: P. aeruginosa infection risk from hospital water system

The purpose of this procedure is to perform a systematic environmental surveillance of *P. aeruginosa* colonization in the water system of the Hospital.
It consists in periodic monitoring of the points of use (tubs and/or taps) to promptly assess the presence of *P. aeruginosa*, which is a potential pathogen in immunosuppressed patients and an indicator of colonization by Gram-negative Bacteria (some of which show antibiotic resistance) and to indicate, whenever possible, the proper course of action.
The methods in use are based on Public Health England Guidelines [12], Health Technical Memorandum [13] and Health Protection Surveillance Centre Guidelines [14].
Our sampling method involves two types of sampling: "pre-flush" sampling and "post-flush" sampling.

B Area: hospital catering and food surfaces

In order to ensure food safety in hospital, every three months food and food surfaces are checked.
Before sampling foods and food surfaces, a visual inspection of the hospital canteen is carried out, using a structured check-list.
Two ready-to-eat foods are sampled. Sampling is carried out using sterile packages transported to the laboratory in a refrigerated thermic bag, in order to avoid bacterial proliferation.
Total bacterial load and the following indicator organisms are routinely identified: *Salmonella* spp., *Listeria monocytogenes*, *Escherichia coli* (*E. coli*), *Enterobacteriaceae* and *Staphylococcus aureus* (*S. aureus*) [15, 16].
Moreover, since the beginning of the "Cook and Chill" system, *Bacillus cereus* and *Clostridium perfringens* (*C. perfringens*) have been added.
For the microbiological quality of ready-to-eat foods, the "Guidelines for the microbiological quality of some ready-to-eat foods sampled at the point of sale" of the Public Health Laboratory Service are applied [17].

As far as concern food surfaces, sampling of environmental surfaces is carried out to demonstrate the efficacy of cleaning and disinfection procedures. Three food surfaces are sampled each three months, though sterile swabs and Petri-style contact plates, filled with a suitable culture medium, using the RODAC-WEIGHT system.
Total bacterial load and the following indicator organisms are identified: *Salmonella* spp., *Listeria monocytogenes*, *E. coli*, *S. aureus* and Yeasts.
For the microbiological quality of surfaces, the "Microbial limits used for various types of food process surfaces based on case study evaluations" by Wirtanen and Salo (2011) are applied [18].

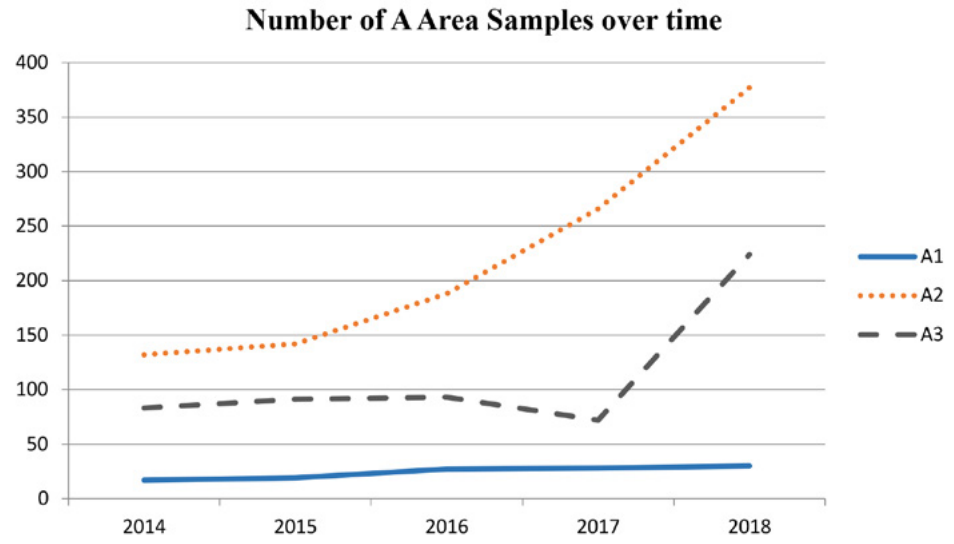
C Area (C3 procedure): effectiveness of surface sanitization procedures

The purpose of the procedure is to verify, "at rest" condition, the effectiveness of the surface sanitization hospital procedures through the evaluation of the microbiological parameters indicated in the Health Protection Agency Guidelines (December 2010) and to establish a continuous surveillance system in order to promptly detect the presence of pathogenic bacteria and take appropriate corrective actions.
The "High Risk" wards subject to the application of the procedure are identified through Scientific Literature consultation, shared with the Health Department and according to most recent evidence. The *high hand-touch* surfaces subject to controls are those most likely to be in contact with the patient and the operator, such as: beds, lamps, bedside tables, chairs, tables, cabinets, handles and doors, phones, assistance call remote control, bathroom faucet knobs, light switches, etc. [19, 20].
Parameters identified as indicators of correct sanitization are total bacterial load, *Acinetobacter baumanii, C. difficile, CRE (Carbapamen-Resistant Enterobacteria), MRSA, Multiresistant P. aeruginosa* and VRE, also potentially causes of HAIs.
For surface sampling, the use of contact plates (Contact Plate, RODAC) combined with "RODAC-WEIGHT" system is more reproducible in order to avoid the subjectivity of the operator.
The surfaces are sampled through the application of a Petri-style contact plate (i.e. surface of the plate against surface to be monitored), filled with a suitable culture medium, using the RODAC-WEIGHT system on the surface to be monitored. The standard duration of the application is 10 seconds.
Microbiological surface sampling with sterile disposable cotton swabs is performed by sampling residual microbiological vital cells with the top of a swab on a defined surface area (conventionally 100 cm^2) and the subsequent count of the colonies, derived from cells eluted from the tip of the swab and then cultured, in suitable culture media.
The Samples are transported to the laboratory in a refrigerated container (1-4°C) for subsequent analysis within 4 hours from collection.

Tab. I. *A Area - Water safety.* A1, A2, A3 Samples stratified by the typology of report they were generated from, across 2014-2018.

A1 Samples	2014	2015	2016	2017	2018	P-value
OR	17	18	15	16	22	0.824
OCR	0	0	0	0	8	0.091
CR	0	1	3	9	0	0.802
CCR	0	0	9	3	0	0.876
Total	17	19	27	28	30	< 0.001
A2 Samples	2014	2015	2016	2017	2018	P-value
OR	96	133	149	176	191	< 0.001
OCR	9	2	27	55	127	< 0.001
CR	27	7	12	25	41	0.184
CCR	0	0	0	10	18	< 0.001
Total	132	142	188	266	377	< 0.001
A3 Samples	2014	2015	2016	2017	2018	P-value
OR	58	81	55	52	76	0.960
OCR	7	1	27	4	58	0.119
CR	17	9	11	16	35	0.028
CCR	1	0	0	0	55	0.091
Total	83	91	93	72	224	0.243

Fig. 1. Number of A Area Samples collected over time (2014-2018) by procedure.



Statistical analysis

An autoregressive integrated moving-average model was used to evaluate trend analysis. The statistical significance level was set at $p < 0.05$ and all the analyses were carried out by using software "Stata IC 13 for Mac"(Stata Corp, Lakeway, USA).

Results

A total of 1,470 Samples were collected and 539 Reports were generated across the five-year study period.
As reported in Table I and Figure 1, the number of Samples collected from the procedures A1 and A3 shows a non-homogenous trend among the five years.

A1 procedure - Drinking water

As shown in Table I and Figure 1, a total of 104 Samples were collected across 2014-2018.
From 2014 to 2017 we found a fluctuating trend in the number of Samples generated from OR followed by a slight increase from 2017 to 2018. In the same period (2017-2018) we registered a clear reduction in both the number of CR and CCR and in the number of Samples they generated. We registered a great increase in the number of both OCR and the Samples they generated from 2017 to 2018. A statistically significant trend was found only in the total number of Samples collected ($p < 0.001$).
With regards to Reports generated, no trend of statistical significance was found ($p > 0.05$). As shown in Figure

2, the number of OR registered a decreasing trend from 2014 to 2017 and a great increase from 2017 to 2018. In addition, we detected a slight increase in the number of OCR from 2017 to 2018 and a decrease in the number of CR and CCR from 2017 to 2018.

A2 procedure - Legionella spp. infection risk from hospital water system

As shown in Table I and Figure 1, a total of 1,105 Samples were collected across 2014-2018.
With regards to Reports generated, as shown in Figure 2, we observed an increasing trend for all collected Samples. We found a general increase in the number of Reports generated from 2014 to 2018 as well, as shown in Table II.

A great increase was found in the number of OR, OCR and the number of Samples this Reports generated from 2015 to 2018. In contrast, we registered only a slight increase for CR, CCR and the number of Samples this Reports generated from 2016 to 2018.
All Samples and Reports, with the exception of the Samples generated from CR, showed a statistically significant trend over time ($p < 0.001$; $p = 0.025$ for CR Reports; $p = 0.003$ for CCR Reports).

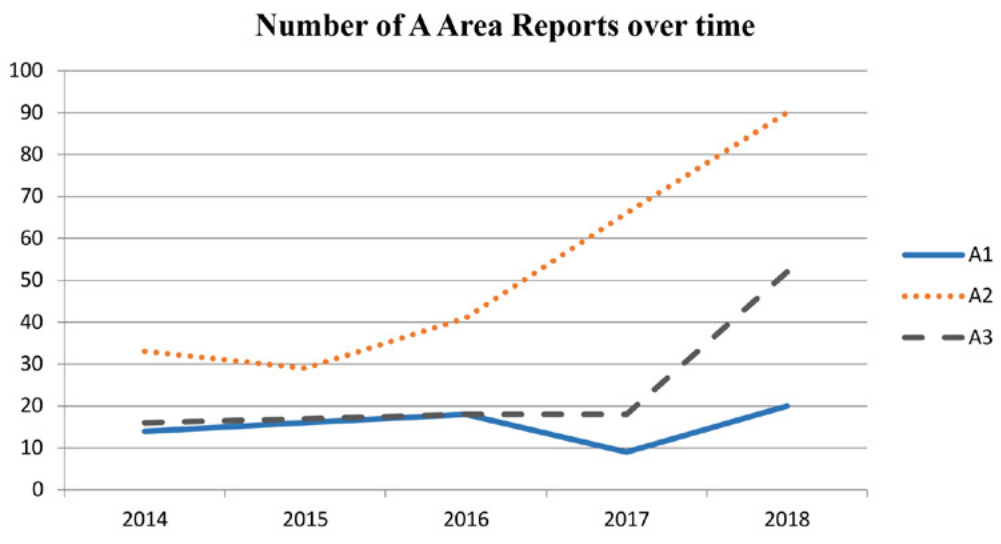
A3 procedure – P. aeruginosa infection risk from hospital water system

As shown in Table II and Figure 1, a total of 563 Samples were collected across 2014-2018.
From 2015 to 2017, we found a decrease in the number

Tab. II. A1, A2, A3 Reports stratified by typology across 2014-2018.

A1 Reports	2014	2015	2016	2017	2018	P-value
OR	14	15	12	7	18	1.000
OCR	0	0	0	0	2	0.091
CR	0	1	2	1	0	1.000
CCR	0	0	4	1	0	0.907
Total	14	16	18	9	20	0.861
A2 Reports	2014	2015	2016	2017	2018	P-value
OR	21	26	27	34	36	< 0.001
OCR	7	1	11	24	41	< 0.001
CR	5	2	3	6	10	0.025
CCR	0	0	0	2	3	0.003
Total	33	29	41	66	90	< 0.001
A3 Reports	2014	2015	2016	2017	2018	P-value
OR	9	12	12	12	16	0.002
OCR	4	1	4	2	15	0.064
CR	2	4	2	4	11	0.617
CCR	1	0	0	0	10	0.100
Total	16	17	18	18	52	0.068

Fig. 2. Number of A Area Reports generated over time (2014-2018) by procedure.



of Samples generated from OR, an increase followed by a decrease in the number of OCR Samples and a slight increase in the number of CR generated Samples. In the end, a general increase in the number of all Samples from 2017 to 2018 was registered.
With regards to the Reports generated, as shown in Figure 2, we registered a fluctuating trend in the number of both OCR and CR generated with a clear increase from 2017 to 2018. CCR increased from 2017 to 2018.
We found a statistically significant trend in the number of generated OR Reports ($p = 0.002$), with an increase from 2014 to 2015, a plateau from 2015 to 2017 and a final increase from 2017 to 2018, and in CR Samples ($p = 0.028$).
As shown in Tables I and II, all other trends regarding Samples and Reports were not statistically significant ($p > 0.05$).

B Area - Food Safety

As far as concern the food safety, during the time-period of five years 40 Samples of ready-to-eat foods have been collected (8 each year, no trend analysis was performed); regarding to food surfaces, 60 sanitized surfaces have been sampled, 12 each year. Yearly, both for food-safety and sanitized surfaces control, 4 Samples were collected and 4 Reports were generated. No OCR have been produced in the analyzed time-period.

C Area (C3 Procedure) - Environmental surfaces

From the general data, a coherence in number of Samples performed for all the years from 2015 to 2018 can be observed. The procedure "Sanitized surfaces" was not active in the year 2014.
Data have been then stratified by extrapolating those related to compliance controls (construction sites) from the ordinary ones. It is clear that in 2015 and 2016 only the data related to the ordinary procedure were sampled, while in 2017 approximately 45% of the data sampled are related to compliance activities. In 2018 compliance activities have tripled with respect to the ordinary work, in fact 60 ordinary Samples and 137 compliance Samples were performed.
Trend analysis performed both on the total number of collected Samples and generated Reports was not statistically significant across the five-year study period ($p > 0.05$).
Looking at the number of Samples related to compliance, we can observe that in recent years, in addition to a constant surveillance of high-risk departments related to ordinary work, the Health Care Management requires an expertise of the staff of the Hospital Hygiene Unit, during the construction site phases in the hospital and specifically, during the return of the premises before they are allocated to health activities.

Discussion

With regards to the increment of the number of Samples related to A area, it can be determined by not conformed OR and consequently the generation of more OCR as it in the case of the new operating settings.
More specifically the results shown for A2 Procedure are justified by the application (from January 2016) of the new International Guidelines which prescribe at least 6 Samples per sampling. This caused a growth in the number of Samples produced as a higher number of Samples increases the chance of detection. Furthermore, these Guidelines prescribe a follow-up at 1, 3 and 6 months after the detection of a positive sample and moreover every new control might turn out to be positive, generating a new series of follow-up controls. In addition, every control turning out to be negative still counts as another OR generated.
There has been an increase of CR and consequently of CCR due to the start of "construction and/or renovation working sites" monitoring.
Results shown for A3 Procedure are justified by the application of the new HPA British Guidelines.
In the previous years, however, Reports did not match with the number of Samples as we know that there is not always a linear correlation between the two. This heterogeneity is dependent upon the different ward's risk level. (e.g. a high risk ward such as ICU might cause a higher number of Samples generated by the same ordinary surveillance activity or it might cause a higher number of CR and thus more Samples than an augmented risk or a "normal" risk one).
There has also been an increase of CR and consequently of CCR due to the start of "working sites" monitoring.
As far as concern A1 Procedure, it did not register many changes and, for this reason, our results did not register many changes as well. It does follow, however, the general increasing trend common to all procedures from 2017 up to 2018. In addition, there is not an increase in CR because this is not a procedure used to monitor "construction and/or renovation working sites". This is due to the fact that construction and renovation activities tend to cause the environmental colonization of the bacteria such as *Pseudomonas* spp. or *Legionella* spp. which are already monitored through other procedures, rather than *E. coli* and other faecal bacteria which are the ones checked for by this Procedure.
No compliance activities (Conformity Reports) were needed relatively to this Area.
With regards to the trend analysis performed, as shown in the Results, a statistically significant trend across the five-year study period was found in the total number of Samples collected both for A1 and for A2 Area ($p < 0.001$); the same statistically significant trend was also found for the total A2 Reports ($p < 0.001$).
In addition, as far as concern study limitations, we would like to report that sample size is quite limited for both B and C3 Procedures. Even though the number of Samples and Reports could be enlarged by extending the observation period, this is not to be seen as a true limitation. Instead, the limited number of collected Samples and generated Reports shows that minimal compliance activity is needed as this surveillance system is effective in preventing infections caused by the hospital environment.

Furthermore, we are aware that many confounding factors could affect a proactive surveillance system of food, water and environmental surfaces. For example, the particular typology of food preparation (Cook and Chill system, Cook and Freeze system, mixed system); the choice of a specific disinfectant and its concentration for the surface sanitization; the disinfection method used for *Legionella* infection risk in hospital water system and so on. Anyway, for scientific correctness we would like to underline that none of these variables has been measured as potential confounding factors, because the only measured data are the ones related to the applied Procedures of the Hospital Hygiene Unit.
Lastly, the infectious disease epidemic does not affect the data in this study, because all the collected and reported data are related to the time-period 2014-2018. Also the epidemiology of notified foodborne diseases does not affect the study as it is based on standard epidemiological indicators.
Concerning B Area, it is important to have effective and reliable food safety management systems in place and the correct application of Hazard Analysis and Critical Control Point (H.A.C.C.P.). Safety assurance must be extended to include the whole process up to the point at which food is served to the patients or operators. Many food manufacturers choose to adopt a programme of routine microbiological monitoring as an added measure of quality and this has often been of value in identifying unforeseen problems at an early stage. No compliance activities (Conformity Reports) were needed relatively to this Area.

Conclusions

The final aim of the described system is to avoid HAIs from hospital environment. The hospital environment is subject to targeted and sustainable surveillance in relation to the size and complexity of the same hospital, based both on epidemiological criteria and on scientific evidences. The activities were performed by the Hospital Hygiene Unit (HHU) in a Teaching Hospital of about 1,500 beds in which the prevalence of HAIs was never over 5% during the study period 2014-2018 (data collected yearly, applying the latest ECDC Point Prevalence Survey Protocol) [21].
In conclusion, it is important to underline that this particular approach, primarily set to ensure patient safety, also provides an added value as far as concern a legal-medical point of view for the healthcare professionals, demonstrating the existence and implementation of a proactive environmental surveillance plan in order to know the risk coming from hospital environment and to take it safe as much as possible.

Ethical approval

Ethical approval was not required for this work as no new empirical data were collected.

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Conflict of interest statement

The authors declare no conflict of interest.

Authors' contributions

PL formulated the original idea and provided scientific supervision to the paper. GD provided scientific supervision to the paper. GQ, DILM, MW, SV and FP provided the data and contributed to the writing of the paper. MDP contributed to data collection and to the writing of the paper.

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ORIGINAL ARTICLE

Dental professionals' knowledge and behavior towards utilization of gloves: a cross-sectional survey

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Keywords

Dental education • Gloves • Protective • Infection control • Infectious disease

Summary

Introduction. *Dental practitioners are at risk of developing infections due to nature of their occupation which can be prevented by following proper infection control protocols, including proper use of gloves. Hence, the purpose of this study was to assess the perception and beliefs of dental healthcare providers towards usage of different type of gloves.*

Methods. *A self-administered questionnaire was distributed among a total of 241 participants out of which 198 participants (77 interns, 58 dental post-graduate students (PG) and 63 dental faculty members) returned completed questionnaire (response rate of 82.15%). The questionnaire comprised of questions on dental professionals' preferences for certain types of gloves and the reasons for these preferences, as well as determining their knowledge, beliefs and behavior concerning the use of dental gloves as a means of barrier protection. Data obtained was analyzed using chi-square test.*

Results. *Dental faculty members had a better knowledge regarding use of gloves as compared to dental PG students and interns. Most of the study participants preferred certain types of gloves for the purpose of better protection followed by comfort. Most of the participants believed that gloves provide full protection as long as there is no visible tear (interns 70.1%; PG students 50%; faculty members 60.3%). Most of the interns (42.9%) and PG students (41.4%) did not know about the fact that petroleum based products affect the integrity of the gloves. 2.6% interns, 29.3% PG students and 20.6% faculty members reported that they would not change gloves during an uninterrupted three-hour long procedure.*

Conclusion. *Most of the interns and PG students had poor knowledge regarding usage of gloves which calls for an action on the part of educators to educate and train dental professionals regarding proper infection control practices.*

Introduction

Healthcare professionals, especially dentists, are at increased risk of developing infections because of the nature of their work. Dentists routinely come in contact with sharp instruments, some of which are operated at very high speeds and primarily work in the oral cavity which consists of contaminated oral fluids such as saliva and occasionally blood. Several studies have shown that dentists and dental assistants are at increased risk of infections with hepatitis B virus (HBV) and hepatitis C virus (HCV) [1]. The emergence of these infections along with others has led to development of Infection Control Guidelines by American Dental Association (ADA) [2]. These standard precautions emphasize on the use of personal protective barriers such as gloves, masks, eyewares, head caps, etc. to prevent cross-contamination during examination or clinical procedures.

The primary purpose of wearing gloves during examination or clinical procedures is to prevent the risk of cross infection from healthcare professionals to patients and vice versa. Gloves are also used for reducing the contamination of the hands of healthcare professionals due to micro-organisms which can be transferred from one patient to another and to protect the users' hands from blood and other body fluids. A number of studies in the past have demonstrated the efficacy of gloves in preventing contamination of healthcare professionals' hand and reducing the transmission of microbes [3-6].

Dentists usually prefer latex gloves; however, allergy to latex has given rise to other materials such vinyl or nitrile gloves [7]. Each type of glove differs from others in some properties such as durability, barrier protection, elasticity and puncture during use and resistance to tear [7-14]. Quality of the gloves gets affected due to prolonged use and contact with materials like disinfectants, alcohol, etc. which results in increased permeability [15, 16]. These limitations have resulted in the use of double gloving technique. Double gloving technique resulted in reduced incidence of perforations in the inner gloves which in turn reduced hand contamination [17].

Though standard protocols are routinely followed by dentists to minimize cross-infections, there is dearth of literature showing understanding of the dentists in terms of using certain types of gloves and their perceptions towards using gloves as a mode of protection. Hence, the present study was undertaken with an aim to assess the perception of dental under-graduate students (Interns), dental post-graduate (PG) students and dental faculty

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members (MDS staff) towards the effectiveness of gloves as a part of infection control in dentistry.

Material and methods

The present cross-sectional study was conducted on entire population of dental under-graduate students (Interns), dental post-graduate (PG) students and dental faculty members (MDS staff) of a dental institute in Maharashtra State, India. The study was conducted over a period of two months from November 2018 to December 2018. Ethical clearance for the study was obtained from the Institutional Ethical Committee (Ref No. 2800/ ACPMMC/Dhule). A written informed consent was obtained from the participants after explaining them the purpose of the study.

Questionnaire

Data was collected through self-administered anonymous questionnaire. The questionnaire was a modified version of previously used questionnaire by Kanjirath et al. [18]. Permission to use the questionnaire was obtained from the authors. Questionnaire was modified by adding a section on double gloving technique and effect of petroleum products on gloves and omitting questions based on use of gloves by the dental professionals during cold sore. Rest all the questions were used as per original questionnaire. The questionnaire was piloted on the experts (2 faculty members, 1 intern and 1 PG student) who gave their feedback concerning the face validity of the questionnaire and accordingly, the changes were made. The questionnaire was administered to a group of 15 subjects (5 interns, 5 PG students and 5 faculty members) twice at an interval of 10 days to check for test-retest reliability. The kappa coefficient value obtained was 0.76 which is good.

Each participant was given sufficient time (on an average 1 hour) to fill the questionnaire. Authors tried to limit the response bias by avoiding leading questions in the questionnaire, not recording any identifiable data and requesting participants to avoid any discussion with other participants while filling the questionnaire.

Statistical analysis

Data was collected, compiled and analyzed using SPSS version 16. $P \leq 0.05$ was considered to be statistically significant. Descriptive statistics were employed to describe the responses of the participants. Comparisons were made for responses between Interns, PG students and faculty members using chi square test and fisher exact test (where one of the cells has less than five observations).

Results

The questionnaire was distributed among a total of 241 participants out of which 198 participants (77 interns, 58 PG students and 63 faculty members) returned completed questionnaires. Response rate was 84.61% for interns, 72.5% for PG students and 90% for faculty members respectively. All the participants reported using disposable gloves.

Table I shows that the participant groups differed in the frequencies for the reasons for wearing certain type of gloves. Protection was the most frequently reported reason by all the participants (98.7% interns; 100% respectively PG students and faculty members; $p = 0.454$). Allergy to latex gloves were least reported factors for preferring certain types of gloves (15.6% interns; 8.6% PG students and 6.3% faculty members; $p = 0.177$). Around 92.1% of the faculty members and 84.5% of the PG students reported using certain type of gloves for comfort; whereas only 58.4% of the interns preferred certain type of gloves for comfort. This overall difference in preference for certain type of gloves among three groups was significant ($p = 0.001$). Pairwise comparison of preference of gloves for comfort showed that difference between interns and PG students ($p = 0.001$) and difference between interns and faculty members was significant ($p = 0.001$).

Table II shows that most of the respondents knew which type of glove provides the best protection i.e. latex gloves (80.5% interns; 87.9% PG students and 77.8% faculty members). The overall difference in their responses were statistically significant ($p = 0.032$). Pairwise comparison of type of gloves showed that difference between interns and PG students ($p = 0.012$) and difference between PG students and faculty members was significant ($p = 0.024$). Table III shows that 24.7% interns, 48.3% PG students and 84.1% faculty members reported that gloves protect against most of the bacteria and viruses. 54.5% interns reported that gloves provide full protection which shows their lack of knowledge. Out of total faculty members, 7.9% faculty members had no idea about the level of protection offered by gloves. This overall difference was statistically significant ($p = 0.001$). Pairwise comparison of degree of protection showed that difference be-

Tab. I. Reasons for preferring certain types of gloves n (%).

Group	Comfort	Protection	Allergy to latex	Cost
Interns	45 (58.4)	76 (98.7)	12 (15.6)	12 (15.6)
PG students	49 (84.5)	58 (100)	5 (8.6)	11 (19)
Faculty members	58 (92.1)	63 (100)	4 (6.3)	12 (19)
P value	0.001*	0.454	0.177	0.827

Chi-square test; * indicates significant at $p \leq 0.05$; the percentages add up to more than 100% because the respondents could choose more than one reason.

Tab. II. Best protection is provided by n (%).

Group	Vinyl	Nitrile	Latex	Don't know	P value
Interns	2 (2.6)	10 (13)	62 (80.5)	3 (3.9)	0.032*
PG students	6 (10.3)	1 (1.7)	51 (87.9)	0 (0)	
Faculty members	3 (4.8)	6 (9.5)	49 (77.8)	5 (7.9)	

Fisher exact test; * indicates significant at $p \leq 0.05$.

tween interns and PG students (p = 0.001), difference between interns and faculty members (p = 0.001) and difference between PG students and faculty members was significant (p = 0.001). 71.4% interns, 63.8% PG students and 81% faculty members reported that gloves do not provide sufficient protection against HIV/Hepatitis B viruses. Almost all the respondents (95.9% total) agreed upon the effectiveness of double gloving technique in reducing transmission of infection. (p = 0.122) Large proportion of responders (70.1% interns; 50% PG students and 60.3% faculty members) believed that gloves provide adequate protection as long as there is no visible tear. Few of interns (14.3%) and PG students (22.4%) reported that gloves are unsafe after 30 minutes of usage. 14.3% of faculty members didn't know about the length of time that gloves provide adequate protection. These differences in responses were significant (p = 0.038). Pairwise comparison of period of protection showed that difference between interns and faculty members was significant (p = 0.025). Almost all the faculty members (90.5%) knew about the effect of petroleum products in quality of gloves as compared to 57.1% interns and 58.6% PG students (p = 0.001). Pairwise comparison of effect of petroleum products showed that difference between interns and faculty members (p = 0.001) and difference between PG students and faculty members was significant (p = 0.001). Almost all the respondents reported using separate gloves for separate patients. However, 10.4% interns, 12.1% PG students and 3.2% faculty members reported use of same gloves for more than one patient. (Tab. IV). Most of the respondents from each group (64.9% interns; 36.2% PG students and 49.2% faculty members) reported changing the gloves after 1 hour of procedure for an uninterrupted three-hour procedure (Tab. IV). 29.3% of PG students and 20.6% faculty members reported continuous use of same gloves for uninterrupted 3-hour procedure which shows their lack of knowledge regarding durability of gloves. The overall difference in responses was statistically significant (p = 0.001). Pairwise comparison of change of gloves showed that difference between interns and faculty members (p = 0.007) and difference between PG students and interns was significant (p = 0.001). Also, when asked about the practice of contaminating gloves by touching non-sterile items, almost all the respondents denied of touching non-sterile items with gloved hands (p = 0.895) (Tab. IV).

Tab. III. Beliefs concerning the way gloves provide protection n (%).

Question	Interns	PG students	Faculty members	P value
What degree do gloves prohibit passage of bacteria and viruses through the glove material?				
Full prohibition	42 (54.5)	4 (6.9)	1 (1.6)	0.001*
Protection against most bacteria and viruses	19 (24.7)	28 (48.3)	53 (84.1)	
Prohibit bacteria, but not viruses	1 (1.3)	11 (19)	4 (6.3)	
Little to no protection	1(1.3)	8 (13.8)	0 (0.0)	
Don't know	14 (18.2)	7 (12.1)	5 (7.9)	
Are the gloves sufficient to provide effective protection against HIV/Hepatitis B patient?				
Yes	22 (28.6)	21 (36.2)	12 (19)	0.054
No	55 (71.4)	37 (63.8)	51 (81)	
Is double gloves technique effective in reducing transmission of infection?				
Yes	73 (94.8)	51 (87.9)	55 (87.3)	0.122
No	4 (5.2)	7 (12.1)	8 (12.7)	
How long do gloves provide adequate protection?				
No visible tear	54 (70.1)	29 (50)	38 (60.3)	0.038*
30 minutes	11 (14.3)	13 (22.4)	5 (7.9)	
1-2 hours	4 (5.2)	9 (15.5)	11 (17.5)	
More than 2 hours	3 (3.9)	1 (1.7)	0 (0)	
Don't know	5 (6.5)	6 (10.3)	9 (14.3)	
Do petroleum based products affect the integrity of the gloves?				
Yes	44 (57.1)	34 (58.6)	57 (90.5)	0.001*
No	33 (42.9)	24 (41.4)	6 (9.5)	

Chi-square test; Fisher exact test; * indicates significant at $p \leq 0.05$.

Tab. IV. Practices of professionals about using gloves n (%).

Question	Response	Interns	PG students	Faculty members	P value
Usage of same gloves for more than one patient	Yes	8 (10.4)	2 (3.5)	2 (3.2)	0.072
	No	69 (89.6)	56 (96.5)	61 (96.8)	
If you were involved in an uninterrupted three hour procedure, how often would you change gloves?	After 30 mins	15 (19.5)	16 (27.6)	11 (17.5)	0.001*
	After 1 hr	50 (64.9)	21 (36.2)	31 (49.2)	
	After 2 hrs	10 (13)	4 (6.9)	8 (12.7)	
	Never	2 (2.6)	17 (29.3)	13 (20.6)	
Do you touch non-sterile items with gloves?	Yes	5 (6.5)	3 (5.2)	3 (4.8)	0.895
	No	72 (93.5)	55 (94.8)	60 (95.2)	

Chi-square test; Fisher exact test; * indicates significant at $p \leq 0.05$.

Discussion

Dental health care professionals should not forget the risks associated with treating patients with infectious diseases. Dental professionals are at increased risk of developing infections because of exposure to pathogenic micro-organisms residing in oral cavity as well as in respiratory tract of the patients. These microbes can be transferred directly to dental professionals by direct contact with patient's blood, saliva or oral secretions or indirectly through sharp injuries or droplet infections. Hence, it is mandatory for dental healthcare professionals to be properly equipped with personal protective barriers while treating every patient. Wearing gloves, one of the recommended protective barrier, helps prevent contamination of the operator's hands due to blood or saliva and also helps in prevention of transmission of infection from operator's hand to the patient [3-6].

In the present study, all the participants reported using disposable gloves while doing surgical procedures. Almost all the participants reported using certain types of gloves for the protection which shows awareness regarding usage of personal protective barriers among them. However, a study conducted by Kanjirath et al. [18] showed that only 40.5% of the professionals, 21.2% of 3rd and 4th year dental students and 37.1% of the graduate students used certain types of gloves for protection purpose. The present study showed increasing number of participants using certain types of gloves for the purpose of comfort from interns (58.4%) to PG students (84.5%) and faculty members (92.1%). This might be due to the fact that as the students step into post-graduate world from internship, they need to perform more complex procedures. Performing complex procedures requires more fine motor skills which can be acquired only when operator has a better sense of judgment about the type of gloves which gives him/her best fit and allow them to perform dental surgical procedures better. Tight fitting gloves may cause irritation by rubbing against the skin [19] and loose fitting may not allow for the proper grip of the instrument.

Almost all the participants believed that latex gloves provide best protection as compared to other two types. 10.6% of the participants reported using non-latex gloves, owing to latex allergy and the rest of the participants (90.4%) preferred latex gloves for routine procedures and might have never used non-latex gloves. Hence, they might have believed that latex gloves provide best barrier protection. However, literature shows that latex and nitrile gloves provide best protection in terms of barrier performance as compared to vinyl gloves [8-14]. Contrasting responses were seen in the previous study done by Kanjirath et al. [18] where mixed responses were observed for the type of gloves providing better protection.

54.5% of interns believed that gloves provide full protection against the passage of bacteria or viruses as compared to 6.9% PG students and 1.6% staff members, which is similar to study by Kanjirath et al. [18] This shows that more experienced health professionals had better knowledge. Literature also shows that continuous use compromised the integrity of the gloves [9, 20]. Responses to a follow-up question about protection against HIV/Hepatitis B patient showed that, 81% of the staff members and 63.8% of PG students believed that gloves do not provide effective protection against HIV/Hepatitis B patients. However, only 28.6% of the interns believed that gloves provide effective protection against HIV/Hepatitis B patients which was in contrast to the response to previous question regarding passage of bacteria or viruses through gloves. Most of the participants knew that double gloving technique is effective in reducing transmission of infection. The respondents were also assessed for how long they believed that they were protected by gloves. Majority of the participants in each group believed that gloves can be worn for a procedure as long as they show no visible tear. However, 14.3% of faculty members and 10.3% PG students had no idea about how long gloves provide sufficient protection as compared to only 6.5% of interns which raises concerns over their understanding of infection control protocols.

Previous study done by Kanjirath et al. [18] reported more number of participants stating that they did not know about how long gloves provide sufficient protection as compared to the present study. Almost half of the interns and PG students did not know about the effect of petroleum based lubricants on the integrity of the gloves which shows their poor knowledge towards usage of gloves.

The participants were asked about their gloves' changing practices to assess their own behavior. Few of the

participants reported using same gloves for more than one patient which is a serious practice requiring urgent rectification. This supplements the wrong practice in ensuring protection against infections i.e. the protection of only the healthcare providers, but not the patients. Reason reported for using same gloves for more than one patient was excessive workload which did not allow for the sufficient time to change the gloves in between multiple patients. Participants were also asked about frequency of changing the gloves when involved in uninterrupted three-hour procedure. Majority of the participants in each group reported changing their gloves after 1 hr which was contradicting to the response about the question regarding duration for which gloves provide protection where only few participants believed that gloves provide sufficient protection for 1-2 hrs. 29.3% PG students and 20.6% faculty members never changed gloves during such uninterrupted procedures which might put them and their patients at an increased risk of acquiring infections.

The results of the present study suggest lack of understanding of basic infection control protocols among interns and to some extent PG students too. Faculty members had a good knowledge and showed acceptable practices regarding usage of the gloves. This clearly shows that perception regarding the usage of gloves improves with increase in clinical experience. Based on the literature available, healthcare providers should keep in mind following things while using gloves: 1) use of disposable gloves, 2) using gloves that fit best to your hands, 3) use of latex or non-latex gloves depending upon need, 4) use of double gloving technique since gloves do not provide complete protection against all bacteria and viruses, 5) change of gloves after every hour in case of an uninterrupted three-hour procedure, 6) avoiding application of petroleum based products to gloves, 7) avoiding use of same gloves for more than one patient.

Limitations

The results are only representative of the population from which they were sampled; therefore, it is not possible to generalize the results to external population.

Conclusions

The findings of the study suggest poor perception of interns and PG students towards the usage of gloves of different types. It is the responsibility of the educators to provide students with adequate knowledge and training regarding infection control protocols, which will subsequently lead to prevention of infectious diseases.

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Conflict of interest statement

The authors declare no conflict of interest.

Authors' contributions

AD developed the original idea. HJ and RN carried out the literature search. HJ, AD and RN collected the data. MK carried out the statistical analysis and drafted the manuscript.

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ORIGINAL ARTICLE

Knowledge, attitude and practice of hygiene and sanitation among food-handlers in a psychiatric hospital in Indonesia - a mixed method study

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Keywords

Food-handler • Hygiene and sanitation • Psychiatric hospital • Knowledge • Attitude and practice

Summary

Introduction. *In a psychiatric hospital that also provides nutritional service, food hygiene and sanitation is considered as an important factor to prevent infection. This study aimed to describe knowledge, attitude, and practice of hygiene and sanitation and the contributing factors in food-handlers of a psychiatric hospital.*
Methods. *A mixed method study was conducted in a referral mental health hospital in Central Java, Indonesia. To obtain the quantitative data, 37 food-handlers were recruited through a purposive sampling. A self-administered questionnaire was distributed to measure knowledge and attitude, while hygiene and sanitation practice was observed directly using a checklist. In-depth interview was carried out with food-handlers as well as supervisors of food production and distribution at the Nutrition Unit. Rank Spearman correlation and Kruskal Wallis test with content analysis were utilized for data analysis.*
Results. *A total of 33 (89%) and 31 (84%) subjects had respectively good knowledge and attitude regarding hygiene and sanitation. However, more than one third (38%) of food-handlers performed poor hygiene and sanitation practice. No correlations were found between knowledge, attitude, and practice regardless of any combination between two factors ($p > 0.05$). Possible causes of unfavourable hygiene and sanitation practice included person-related factors and human resource management. Further analysis indicated that training received by food-handlers had an association with their practices ($p < 0.05$).*
Conclusion. *Knowledge and attitude on hygiene and sanitation are generally good among food-handlers in the psychiatric hospital. There is a need to improve the practice through training programs.*

Introduction

A psychiatric hospital is essentially a health service facility for patients with mental illnesses [1]. Similar to regular hospitals, a psychiatric hospital provides inpatients nutritional service to prevent malnutrition. Patients in psychiatric hospitals may have nutritional risks which could be affected by insufficient dietary intake and their long-term hospitalizations [2]. Provision of foods in the psychiatric hospital is also expected to fulfill patient rights in obtaining quality health services through adequate food-handling standards, yet issues around meals are frequent. A study conducted in two mental health facilities in South Africa found that the poor quality and quantity of hospital food as well as unhygienic condition of the wards caused much frustration and dissatisfaction among patients [3].
Food service in the hospital should be given particular attention as foods can act as transmission vehicles for infection, causing foodborne disease outbreaks in the vulnerable population. Health workers can transmit infections through direct contacts, air, or foods given to patients [4]. One of the prominent attributes of hospital outbreaks is that psychiatric wards and elderly-care wards (including psychogeriatric wards) are likely to be most seriously affected [5]. Fatal foodborne outbreak occurence at a state psychiatric hospital in Lousiana (USA) underlines the need for strict guidelines regarding food preparation at psychiatric inpatient facilities [6].
Hygiene and sanitation is an aspect that needs to be maintained in all activities that take place in the hospital to protect patients, health workers, and visitors from risks of infection [7]. According to Indonesia's Ministry of Health Decree No. 1096 of 2011, food catering facilities are required to meet the hygiene and sanitation regulatory standard specified for every type of establishment in order to prevent adverse health effects [8]. Studies have pointed out that the majority of foodborne disease outbreaks were caused by improper food-handling practices [9, 10] and directly linked to food-handlers [11-13]. WHO identified five food-handling factors associated with foodborne disease outbreaks: improper cooking, temperature mishandling during food storage, cross contamination, poor sanitation and hygiene, and the use of unsafe water and raw materials [14], most of which are closely related to the work activities of food-handlers. To ensure that food-handlers practicing the right way of handling foods, knowledge and training are crucial as part of their job [15].
"Prof. Dr. Soerojo" psychiatric hospital is one of national referral hospitals for mental health. It occupies a rela-

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tively large area of 41 hectare of land and applies decentralized kitchen system where meals are produced in the main kitchen and transported to various locations near customer (pantry wards) for the meal assembly. Thus, challenges in the hygiene and sanitation implementation may present due to double handling of food and supervision at many pantries throughout the facility. Several studies have been conducted on knowledge, attitude and practice of hygiene and sanitation among food-handlers of mental health facilities in Indonesia, but none of them were performed using a qualitative method to better understand the variables in question [16, 17]. The aim of our study was to describe knowledge, attitude, and practice (KAP) regarding hygiene and sanitation, the relations among these factors and the contributing factors in food-handlers of a psychiatric hospital.

Methods

The study was conducted in "Prof. Dr. Soerojo" psychiatric hospital, a national referral hospital situated in Magelang, Central Java Province, Indonesia, during February until March of 2018. Having had a large number of food service workers performing food production and distribution tasks in the main kitchen and pantry wards, the hospital was able to provide a sufficiently large sample size (greater than 30) for our study. We applied mixed method or a combination of qualitative and quantitative approach to examine KAP among food-handlers. The cross-sectional design was used in the quantitative study to identify the level of knowledge, attitude and practice of hygiene and sanitation and to analyze the relations among these factors. Subsequently, a qualitative case study was conducted to support results from the quantitative study and to explore the contributing factors for KAP in food-handlers.

Thirty-seven food-handlers were recruited as samples of the quantitative study through purposive sampling. These respondents were staffs of the hospital's Nutrition Unit who performed direct contacts with foods during food-handling processes, including food receiving, production, distribution and service. A self-administered questionnaire was distributed to measure food-handler's knowledge and attitude, while hygiene and sanitation practice was observed directly using a checklist. The checklist and questionnaires used in this study were adapted from a previous published research article [18]. Instruments' validity and reliability were tested on a group of food-handlers (n = 20) at another psychiatric hospital, resulting in all questionnaire items as being valid and reliable (Cronbach's alpha > 0.6). Variables of KAP were categorized as good (a score between 76 and 100%), fairly good (a score between 56 and 75%), and poor (a score < 56%) [19].

Qualitative data were collected by the researchers through in-depth interviews, participant observation, and document analysis on the Standard Operating Procedures or SOPs, as a means of methodological triangulation. Participants for the in-depth interview were food-handlers who participated in the quantitative survey or staffs of the Nutrition Unit; all of whom had to show willingness to share their insights through an audio-taped interview. A total of 11 participants, consisting of 2 cooks, 1 kitchen staff who was in charge of food storage, 6 food service assistants who performed food distribution, and 2 nutritionists/dietitians who were appointed as supervisors of the food production and distribution, were interviewed until data saturation was reached. The interview was carried out in Indonesian language and in accordance with in-depth interview guides which comprised open-ended questions about personal protective equipments (e.g. aprons, gloves, masks) as well as the food service system and facilities related to knowledge, attitude and practice of the food-handlers. On completion, the interview tapes were transcribed verbatim by the researchers. To ensure that the participants' meanings had not been modified during analysis process, all transcripts were checked by the study supervisor.

Tech's approach of open coding was used to analyze the qualitative data [20, 21]. Themes and categories were sorted manually and then overall thematic descriptions were developed in regard to food-handler's views on hygiene and sanitation in the context of hospital food service. All coding and interpretation in the present study were discussed among research team. For quantitative data, statistical analyses were performed by using SPSS (Statistical Package for the Social Sciences) software. Descriptive statistics were presented in the forms of frequency distribution (%) and the Rank Spearman correlation test was undertaken to identify the relationship between two KAP variables. Additionally, Kruskal Wallis tests were employed to determine individual characteristics that had an association with food-handler's practice of hygiene and sanitation.

This study was approved by Ethics Committees of the Faculty of Medicine, Public Health and Nursing Universitas Gadjah Mada (Ref. KE/FK/0427/EC/2018) and "Prof. Dr. Soerojo" psychiatric hospital (Ref. TEC/001/III/2018). Approval and signing of informed consent were also sought from all respondents.

Results

Food service in the "Prof. Dr. Soerojo" psychiatric hospital

"Prof. Dr. Soerojo" psychiatric hospital implemented a decentralized food distribution system in which the main kitchen became an area where food production took place and was supervised by a nutritionist as the chief of production. Then, food assembly was carried out at the small kitchen of each ward (pantry) located at different buildings. Foods were distributed by some cooks to the pantry wards using distribution cars. At general wards, food assembly and distribution to patients were performed by food service assistants or waiters under the supervision of a nutritionist as the chief of service. At the psychiatric ward, however, once the food containers reached the entrance, they were received by the patients.

There were no food service assistants appointed at this particular ward. Instead, mental health patients would assembly and distribute foods under the supervision of a nutritionist and nurses. Every mental health patient staying in this hospital was scheduled to take turn in the food apportioning at their wards as a therapy to have an outcome of independent living.

Characteristics of respondents

Of the 37 food-handlers, 21.6% were a college graduate and the majority of respondents (n = 27 or 73%) never received any training related to hygiene and sanitation (Tab. I).

Knowledge, attitude, and practice of food-handlers

Table II shows that the proportion of food-handlers who had good scores of knowledge and attitude about hygiene and sanitation was 89.19 and 83.78%, respectively. However, hygiene and sanitation practice were classified as poor for more than one third (37.84%) of the respondents, while the other 27.03% were categorized as fairly good. Table III presents no significant correlation between knowledge and attitude, knowledge and practice, as well as attitude and practice of food hygiene and sanitation (all p-values were larger than 0.05).

In agreement with the finding of the quantitative study which shows a relatively high level of knowledge, the study participants indicated that they had awareness of regulations and SOPs that had been set for the implementation of hygiene and sanitation during food service operations:

- *"Yes, there are SOPs. When portioning foods, we should use PPE (personal protective equipment) ... masks, aprons and gloves. To cover the hair, male workers wear uniform hats and female workers had worn headscarves in the first place"* (food service assistant/waitress-female, 18 years of work experience).
- *"The standard in our kitchen is that a personnel wears boots, an apron, orange clothes (uniforms), a hat and a mask*" (cook-male, 10 years of work experience).

Another participant was able to demonstrate comprehension in hygiene and sanitation standard by explaining its details:

- *"There are supervision of the temperature and inspection of food ingredients in terms of quantity discrepancy, specifications and expiry date. There are also standards for the size of (kitchen) facilities. For instance, a food shelf should have a distance with the wall and the height is at least 15 cm from the floor (according to the Ministry of Health decree)"* (kitchen staff-male, 35 years of work experience).

Participants in the study also expressed positive understandings on proper use of PPE when delivering foods to patients as they realized its importance for the patients' and their own safety:

- *"There are no specific instructions (to use PPE during food distribution). But, if I look at the patient's condition, I usually use PPE (because) it is safer … (just) for my own safety"* (food service assistant/waitress-female, 18 years of work experience).
- *"Even though we serve mental health patients, the standard (to be followed) is similar (to serving general-ward patients). We still have to wear masks, especially for staffs who have direct contacts with patients"* (cook-male, 3 years of working experience).

Tab. I. Respondents features.

Characteristics	n = 37	%
Age (years)		
19-30	7	18.9
31-50	20	54.1
51-70	10	27.0
Sex		
Male	22	59.5
Female	15	40.5
Education level		
Primary school	3	8.1
Secondary school	26	70.3
Higher education	8	21.6
Job position		
Cook (production unit)	25	67.6
Food service assistant or waiter (distribution & service unit)	11	29.7
Kitchen staff (in charge of food storage facilities)	1	2.7
Length of work experience		
< 6 years	4	10.8
6-10 years	13	35.1
> 10 years	20	54.1
Training received (in food safety, hygiene and sanitation, or prevention and infection control)		
Yes	10	27.0
No	27	73.0

Tab. II. Food handlers' knowledge, attitude, and practice (KAP) in hygiene and sanitation.

KAP level	Knowledge		Attitude		Practice	
	n	%	N	%	n	%
Good	33	89.19	31	83.78	13	35.14
Fairly good	2	5.41	6	16.22	10	27.03
Poor	2	5.41	0	0.00	14	37.84

Tab. III. Correlation among knowledge, attitude and practices level of subjects (n = 37).

Variable's correlation	r	p
Knowledge-attitude	-0.153	0.366
Attitude-practice	0.073	0.667
Knowledge-practice	-0.118	0.486

r: Rank Spearman's correlation coefficient; p: p-value (significant at p < 0.05).

However, a number of participants perceived the use of PPE during food distribution process as being unnecessary. One participant remarked:

- *"If the patient is not from the isolation ward or having a special condition such as tuberculosis (infection), it is fine to not wear the PPE*" (food service assistant/waitress-female, 7 years of work experience).

The nutritionists as managers of the food production and distribution stated that the Nutrition Unit had created standard operating procedures for food service activities. However, they acknowledged challenges in the implementation of hygiene and sanitation within food service processes, especially in the use of personal protective equipment, possibly caused by several factors. Firstly, there were differences in perceiving a single SOP by food-handlers who worked in different positions, as was described by this participant:

- *"(The procedure is) when the workers come to the kitchen, they have to wash their hands, wear masks and cover the head for men and women (everyone). When portioning foods and washing utensils, the workers have to wear an apron. However, in the distribution process, (wearing an apron) is not required ..."* (chief of service/nutritionist-female, 10 years of work experience).

The difference in the SOP interpretation between cooks and food service assistants might affect their hygiene and sanitation practice, in which cooks did not wear an apron when they did the dishes in the kitchen as their waiter counterparts did not wear one either.

The next factor that could hinder the implementation of hygiene and sanitation was the improper use of PPE by food-handlers which was still tolerated by supervisors. The key informants suggested that not wearing PPE was tolerable under certain circumstances, including not wearing mask in the kitchen when the temperature is too hot or during a food distribution process when the food-handlers had a face-to-face time with patients:

- *"Ideally, food-handlers have to wear masks and head covers. But, sometimes we do have some tolerance for mask wearing, if the weather is really hot and as long as they do not talk too much during cooking. To minimize food contamination, they are asked to not talk too much* (when they are working in the kitchen)" (chief of production/nutritionist-female, 25 years of work experience).
- *"During the distribution process, food service assistants are not obliged to wear a mask. (Actually), it is the patients who are expected to wear mask, as in a medical situation if someone is sick, then they are the ones who are supposed to wear protective equipments like masks. Also, we do not consider it as very polite for food-handlers to wear a mask (which covers their face) during the food distribution"* (chief of service/nutritionist-female, 10 years of work experience).

Another factor that can cause challenge in the implementation of food hygiene and sanitation is the issue of human resource management and person-related factors, including the traits and age of an individu. Participants in the study felt that the managers had constraints in the supervision of personal protective equipment use in many food service workers, especially senior food-handlers:

- *"Not all food-handlers wear masks and head cover when they cook. So, usually we are (only) recommended to not have too long hair. But, sometimes the older employees seem unwilling to comply with the inputs given by the younger staffs"* (cook-male, 3 years of work experience).

Another remark confirmed that food-handlers' practice was not perfectly good and personal characters might correspond to hygiene practices:

- *"Every day we check the use of PPE (in food-handlers). The problem is, here, we have so many food service workers with different personal characters. The practice of wearing uniform and head cover has already been good (among food-handlers), but we remain struggling with the mask. Frankly, we have to remind food-handlers to wear their masks very often, but it is rather difficult because everyone has a different character. Some individuals may put on their masks (after being reminded by the supervisor), but they remove it shortly after they wear it* (chief of production/nutritionist-female, 25 years of work experience).

Individual characteristics and practice of hygiene and sanitation

As indicated by several participants in the interview, individual characteristics might correspond to one's hygiene practice. Further analysis was performed to identify an association between individual characteristics and food-handler's practice.

Table IV outlines the significant difference of hygiene and sanitation practice between groups of food-handlers who received and did not receive training related to hygiene and sanitation ($p = 0.024$; $p < 0.05$). The group that never received any traning had the largest number of individuals with poor hygiene and sanitation practice ($n = 13$). Hence, the high proportion of respondents in the poor practice category could be attributed to the lack of hygiene and sanitation training.

Participants in the current study reported that formal trainings related to hygiene and sanitation, whose topics included personal hygiene and use of personal protective equipment, had not been received by all food-handlers:

- *"Not all food-handlers (in this hospital) received training on food safety or hygiene and sanitation. These included the majority of food service assistants. Only the nutritionists received (formal) training on Prevention and Infection Control*" (chief of service/nutritionist-female, 10 years of work experience).

Despite the large percentage of respondents who never received formal training on hygiene and sanitation, they attended staff briefing sessions arranged by the Nutrition Unit frequently. The information meetings were mostly delivered by staffs from the Prevention and Infection

Tab. IV. Differences in the practice of hygiene and sanitation based on individual characteristics.

Individual characteristic		Practice								p
		Poor		Fairly good		Good		Total		
		n	%	N	%	n	%	n	%	
Age	19-30	0	0	3	8	4	11	7	19	0.117
	31-50	10	27	2	5	8	22	20	54	
	51-70	4	11	5	14	1	3	10	27	
Education level	Primary school	2	5	0	0	1	3	3	8	0.171
	Secondary school	9	24	6	16	11	30	26	70	
	Higher education	3	8	4	11	1	3	8	22	
Length of work experience	< 6 years	0	0	1	3	3	8	4	11	0.162
	6-10 years	6	16	3	8	4	11	13	35	
	> 10 years	8	22	6	16	6	16	20	54	
Training received	No	13	35	7	19	7	19	27	73	0.024*
	Yes	1	3	3	8	6	16	10	27	

*: p-value (significant at $p < 0.05$).

Control (PIC) Unit of the hospital, as was described by the Chief of Production:

- *"PIC training has yet to be organized (for all staffs). However, PIC staffs come here quite often to provide guidances and short counsellings about hygiene, sanitation, handwashing, motivation for always wearing PPE (personal protective equipment) and banning smoking in the production area".*

Discussion

Food-handlers have a significant role in food safety as poor food-handling practices may lead to food poisoning. Food-handlers may introduce pathogens into food in the course of its preparation, production, and distribution [22]. The current study attempted to quantitatively and qualitatively describe food-handlers' knowledge, attitude and practice in the food hygiene and sanitation.

The majority (more than 80%) of the subjects in this study were in the good knowledge and good attitude category. This concurs with the result of a previous quantitative study in hospital food service settings in Jordan [23], whilst differs from findings of studies conducted in India [24] and Ghana [25]. In terms of hygiene and sanitation practice, about one third of the subjects were in the unfavorable category and the items not complied by most food-handlers were about the use of personal protective equipment during dishwashing and wearing masks when handling foods, among others. This result accords with the findings of a previous study, demonstrating that 33.33% of food-handlers had poor practice in using gloves, mask and cap [24].

Ideally, if the knowledge and attitude of food-handlers related to hygiene and sanitation is classified as good, so is the hygiene and sanitation practice. Such condition will present a positive unidirectional relation among those variables [25, 26]. However, in the present study, it was found that knowledge among food-handlers had no significant correlation with attitude and practice ($p > 0.05$). Likewise, no significant relationship was observed between attitude and practice ($p > 0.05$). A total of 83.78% of food-handlers had good hygiene and sanitation attitude and there was not a single person who had poor attitude. A previous study reported that participants of the hand hygiene campaigns were not effectively translating their knowledge into practice [27]. The absence of the relation between knowledge and attitude can be explained through participants'responses from the interview. Although in general food-handlers had good understanding regarding food hygiene and sanitation, a number of participants perceived the use of personal protective equipment was only necessary when performing food distribution for patients with tuberculosis or infectious diseases and at the isolation ward.

This study has also highlighted that knowledge does not translate into rigorous practice among food-handlers, as was in another study which showed that increased knowledge of food hygiene practices does not always result in a positive change in food-handling behavior [28]. The study participants stated 3 possible factors that might prevent the optimum implementation of food hygiene and sanitation practice, including differences in the SOP interpretation among food service staffs, tolerances from managers in PPE use under some circumstances, and personal characteristics which becomes constraints faced by managers who performed inspection function. Based on the observation, food-handlers had been working by following SOPs accordingly except for wearing masks, a procedure which often overlooked by supervisors due to the unbearably hot temperature in the kitchen. A study among food-handlers at primary schools in Malaysia indicated that the government should bring attention to the importance of wearing a mask and practicing proper hand washing through hands-on training [29]. With regard to managerial function, the pre-emptive–training and the need to develop age-aware human resource policies and practices are suggested as some of the most effective actions to sustain older workforces and their employability in the workplace [30].

The current study put emphasis on the training received by food-handlers as a factor that impact good pratices ($p < 0.05$). There were only 27% of the subjects who received training related to hygiene and sanitation and

this was confirmed by the qualitative result. The Chief of Service reported that it was difficult to organize training for all food-handlers at once as it can cause disruption of food services. Therefore, food-handlers had to take turn participating in a training. Moreover, food-handlers who did not understand the principles of hygiene and sanitation were asked to learn from their colleagues whom already received relevant information or training, so exchanging knowledge among the trained and non-trained workers would help to increase their knowledge and, in turn, improve their practice in hygiene and sanitation. This perspective can thus serve as a barrier that prevent the institution from arranging a formal food safety training for their employees. In this case, sharing knowledge among food-handlers themselves may not be too effective either because of influences of personal factors including employee's age and seniority in the department. The hospital had, in fact, made efforts to provide routine briefings conducted by PIC staffs whose topics include basic principle of hygiene and sanitation, although it did not reach out to all food-handlers. Despite varied results in previous studies regarding the effect of food safety training on food-handler's KAP [31-33], structured training on food hygiene and sanitation is still recommended to be implemented towards food-handlers in the current study. As it was found that 73% of the food-handlers never received any formal training, educating and training of food-handlers is expected to encourage positive attitude and provide the opportunity for food-handlers to put their knowledge into practice. Besides, first hand training will address the issue of SOP application, in that it was performed differently by various food-handlers. A previous study which investigated the efficacy of hygiene training of food-handlers at a teaching hospital underlines the importance of periodic trainings on food hygiene to both keep the level of knowledge high by preventing the information from being forgotten as well as to improve the level [33]. Another study at several Korean hospitals supported the idea that good knowledge of hygiene and sanitation does not guarantee adequate practice performed by a food-handler. Thus, repeated training and inspection are required to implement hygiene and sanitation principles at the workplace [34].

Finding of this study also adds to the literature which stated that differences in inspection scores of hygiene were caused by a wide variety of factors, most remarkably management culture [35]. Participants' remarks in the present study imply that there remains a need in continually improving the capacity of managers in charge of enforcing compliance and inspection of the food hygiene and sanitation to maintain the good quality of foods served in the hospital.

This study is the first to employ a mixed-method approach in a study of food- handlers at a psychiactric hospital setting. It comprises both a survey and qualitative techniques that can comprehensively depict food-handlers' sights on food hygiene behaviors as well as the contributing factors and barriers for properly implementing hygiene and sanitation principles. To determine food-handlers' practice, we also use a direct observation by the researcher rather than a self-reported measure. On the other hand, the study was limited to 37 food-handlers working in a certain hospital, which may not be generalized to describe the condition of knowledge, attitude and practice of food-handlers working in all psychiatric hospitals. In addition, the fact that in the psychiatric hospital patients acted as food-handlers who peformed food assembly and service for other patients may represent a further cause of concern in the monitoring of food hygiene and sanitation in this kind of hospital. However, such problem cases has not been addressed in this study.

Conclusions

Knowledge and attitude of hygiene and sanitation are generally (> 80%) good among food-handlers, although more than one third (38%) of them are in the unfavourable category of practice. No correlations are found among knowledge, attitude, and practice regardless of any combination between two factors ($p > 0.05$); indicating that knowledge does not necessarily transfer into practice among food-handlers. The majority (73%) of food-handlers never receive any formal training related to hygiene and sanitation and this individual characteristic significantly correlates with their practices ($p < 0.05$). Possible causes of poor hygiene and sanitation practice include person-related factors and human resource management, mainly the manager's capacity in imposing regulations and monitoring the staffs' compliance with SOPs. Results of the study strongly emphasize the need for regular formal trainings on hygiene and sanitation to improve food-handlers' practice.

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Conflict of interest statement

The authors declare no conflict of interest.

Authors' contributions

IRP developed research methodology, contributed in data collection and analyses, and wrote the manuscript. RPF contributed in data collection and analysis and

wrote the manuscript. FAU contributed in data analysis and manuscript's writing and translation.

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ORIGINAL ARTICLE

Non-auditory effects of industrial chronic noise exposure on workers; change in salivary cortisol pattern

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Keywords

Noise • Salivary cortisol • Worker

Summary

Background. *Noise has different auditory and non-auditory effects on human. In noisy environments, noise as a non-specific stressor can activates the hypothalamic-pituitary-adrenal axis (HPA, cortisol). The aim of this study was to evaluate the effect of chronic exposure to noise on salivary cortisol on industrial workers.*
Methods. *This cross-sectional study had a case/control design. 136 male workers (68 workers were exposed to chronic industrial noise, and 68 other workers were exposed to background noise) voluntarily enrolled in the study. The equivalent noise level was measured at workstations and salivary cortisol for both case and control groups was measured at the beginning (6 AM) and also at the end of work shift (4 PM). The amount of change in the average of the values of the two groups were compared with each other.*
Results. *The measured Leq_{8h} (equivalent continuous sound level) in case and control groups were 87.43 dB-A and 67.6 dB-A, respectively. Comparison of salivary cortisol levels change in groups shows a significant differences in control groups for salivary cortisol in the morning and in the evening samples ($p < 0.05$); but not in the case group ($p = 0.052$). Also, comparison of salivary cortisol levels changes with noise exposure experience in the case subgroups revealed no significant difference ($p > 0.05$).*
Conclusion. *This study showed that chronic exposure to industrial noise can lead to a change in pattern of salivary cortisol secretion especially in the evening (at the end of the work shift), in a way that instead of its normal decrease, an increase happened.*

Introduction

Noise is a stressor and an important contaminant in our environment that has remained largely unknown [1]. The prevalence of over-exposure to noise is increasing in industries throughout the word. Although control measures to reduce noise have been effective in many industries, but noise is still a common occupational hazard in the workplace [2, 3]. It is estimated that about 600 million workers worldwide have been exposed to noise [4]. Many studies reported that exposure to noise levels above 80 $dB\text{-}_A$ in industrial settings is quite widespread [5-7]. Earlier, most studies focused on noise in office environments and its psychological effects, such as job satisfaction, and less studies have been done on the chronic exposure to noise in industrial environments such as manufacturing sites and etc. [8]. Metal industries are part of the main industries that has been developing over the last 100 years and have many noise generating sources, including large fans for ventilation, electrical transformers, rolling processes etc. [9]. To investigate the epidemiological effects of noise, in addition to the direct method of assessing hearing loss, in an indirect way, it can be focused on stress hormones such as cortisol and risk factors including hypertension and its prominent diseases. In other words, measuring blood pressure and cortisol hormone are good indicators for studying the relationship, mechanism and interaction between exposure to noise and its health outcomes [10]. Cortisol hormone can be measured in urine, serum and saliva. Since salivary cortisol reflects free and physiologic activity cortisol in blood circulation, it is a good indicator for assessing exposure to noise in the industry [11, 12]. The aim of this study was to assess: 1) changes in salivary cortisol among industrial workers (case and control groups); 2) feasibility of saliva cortisol application in assessment of chronic exposure to noise.

Methods

This cross-sectional study had a case/control design. A total of 136 male workers from a steel factory participated voluntarily in this study (68 workers were exposed to chronic industrial noise (the job tasks included furnace operator, molding equipment, and rolling and finishing machines operators), and 68 other workers (working in a quiet office) were exposed to background noise). The Morgan's table was used to determined sample size. Participants had more than two years of job experience. The information about the goals of the study was explained to the participants. They were free to leave the study whenever they wanted to. Then the General Health Questionnaire (GHQ-28) was completed by workers.

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Noise measurement

To measure the equivalent exposure level of noise for each participant according to ISO 9612 [13], the B & K model noise dosimeter equipment, type 4436, both a dosimeter and a sound level meter, were used. The equipment was calibrated before noise measurement and internal standard was set in ACGIH mode. Noise pattern in workstations was continues.

Saliva sampling and analysis

Electrochemiluminescence (ECL) method was used to measure salivary cortisol concentration. Since this method is fast, reliable and convenient, it has been suggested as a technique for measuring salivary cortisol [14]. The 5 ml Maxwell sampling vial was used to get salivary cortisol samples. The participants were asked to take 2 ml of saliva sample in the morning before brushing and eating or drinking (between 6:00 and 7:00 AM), as well as at the end of the work shift (4:00 PM). These saliva samples were frozen in a freezer at -18 °C and finally transferred to the laboratory for testing. Analysis of saliva samples was done in the Cobas radioimmunoassay kit (IBL International GmbH, Hamburg, Germany) using the ECL method and the Elecsys 2010 analyzer device. The mean (CV%) intra- and inter-assay precision were 1.1 (6.2%) and 1.95 (8.7%), respectively. Finally, the amount of salivary cortisol concentration at the beginning of the shift in the two groups, as well as the amount of changes in cortisol concentration. (Salivary cortisol concentration at the end of the work shift minus salivary cortisol concentration at the beginning of the shift shift) was compared in the two groups. The statistical analyzes were performed by SPSS software Version 19. In this study, the Kolmogorov-Smirnov test was used to examine the variables'normality. Also, t-test and linear regression were used to the data analysis. The significance level was considered at $p < 0.05$.

Ethical considerations

This study is based on a research project approved by the Ethics Committee of Ahvaz Jundishapur University of Medical Sciences (Research Ethics Code: IR.AJUMS.REC.1394.242).

Results

There were 136 participants in this study, 68 workers were exposed to chronic industrial noise and 68 employees worked in administrative departments (without industrial noise exposure). Table I shows the demographic data of study participants. According to the results, the groups did not have a significant statistical difference in terms of job experience ($p = 0.83$). The mean of general health score in the exposed group, was 21.5 ± 9.28 and in the control group 20.91 ± 8.49, which had no significant statistical difference ($p = 0.84$). The mean of the equivalent exposure level in the case group and in the control group were 87.43 ± 3.9, 67.16 ± 4.93 dBA, respectively; which had a significant statistical difference ($p = 0.001$). Table II presents comparison of salivary cortisol levels change in groups. There were significant differences in control groups for salivary cortisol in the morning and in the evening samples and similarly between two groups ($p < 0.05$). But in the case group, near significant differences for salivary cortisol in the morning and in the evening, samples was observed ($p = 0.052$). Linear regression coefficients for exposed to noise and salivary cortisol levels are shown in Table III. The results show that the noise exposure ($Leq_{8h} > 80$ dBA) and saliva cortisol levels in the end of work shift are statistically significant ($p < 0.001$). Table IV shows comparison between salivary cortisol in case group which is classified about noise exposure experience. Results shows a significant change in normal salivary cortisol secretion pattern in the case group. Although the amount of noise exposure experience is different between subgroups, the percentage of difference was very close for subgroups and comparison between these subgroups revealed no significant difference ($p > 0.05$) as the decrease of cortisol levels in the end of shift work with respect to the start of shift work is not significant in all classifications.

Discussion and conclusion

In this study, the mean cortisol concentration in workers exposed to noise was higher at the start of the work shift compared to the control group, which was statistically significant. Also, similarly results were observed for the end of work shift between two groups. These findings indicate that chronic exposure to industrial noise leads to an increase in salivary cortisol levels in exposed individuals. In other words, the differential amount of morning and evening salivary cortisol concentration was lower in case group when compared to control group. The incremental changes in the concentration of salivary cortisol at the end of the work shift compared to the beginning of the shift was statistically significant. Overall, the findings of this study showed that due to the higher salivary cortisol Concentration at the beginning of the shift work in the exposed group, as well as significant increase in salivary cortisol concentration after exposure to noise than the control group, exposure to industrial noise (as a stressor) of

Tab. I. Demographic data of study participants.

Groups	Age (year)	Height (cm)	Weight (kg)	Job experience (year)	Leq_{8h} (dBA)
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD
Case (n = 68)	37.3 ± 5.8	174.1 ± 5.2	76.2 ± 8.2	8.53 ± 5.14	87.43 ± 3.9
Control (n = 68)	36.6 ± 5.2	174.2 ± 4.9	77.3 ± 9.4	8.10± 4.74	67.16 ± 4.93
P value	0.701	0.890	0.238	0.843	0.000

Tab. II. Comparison of salivary cortisol levels change between groups.

Groups	Salivary cortisol levels (µg/dL)			
	Before work shift (morning)	End of work shift (evening)	Before and end differences	P value*
	Mean ± SD	Mean ± SD	Mean ± SD	
Case (n = 68)	5.21 ± 4.58	3.92 ± 2.98	1.29 ± 1.7	0.052
Control (n = 68)	3.37 ± 2.13	1.77 ± 1.06	1.61 ± 1.07	0.001
P value**	0.041	0.001	0.121	

*Comparison between morning and evening in each group; **comparison between two groups.

Tab. III. Linear regression coefficients for exposed to noise and salivary cortisol levels.

	Salivary cortisol					
	Before work shift (morning)			End of work shift (evening)		
Leq_{8h} (dB)	N	Coefficient (95% CI)	P*	N	Coefficient (95% CI)	P*
< 65	148	0.32 (0.27 to 058)	0.415	12	-0.11 (-0.21to0.42)	0.324
≥ 65 to ≤ 80	20	0.77 (-1.3 to 1.9)	0.420	56	0.85 (0.66 to 1.04)	0.062
> 80	-	-	-	86	4.16 (1.29 to 6.11)	0.001

*P value < 0.05.

Tab. IV. Comparison of salivary cortisol levels change with noise exposure experience.

		Salivary cortisol levels (µg/dL)			
Noise exposure experience	N	At begging of work shift (mean ± SD)	At end of work shift (mean ± SD)	% difference*	P value**
2-4	7	3.99 ± 2.38	3.01 ± 1.78	32.5	0.112
4-6	20	5.24 ± 3.11	4.07 ± 2.33	28.7	0.193
6-8	16	6.87 ± 4.68	5.21 ± 2.28	31.8	0.091
8-10	13	6.91 ± 2.89	5.48 ± 2.03	26.1	0.327
> 10	12	7.12 ± 2.08	6.02 ± 3.19	18.3	0.471

*The percentage of difference was calculated by dividing begging and end difference by end concentration; **p value (paired sample t-test) < 0.05.

more than 80 dB can lead to stimulation of the hypothalamic-pituitary-adrenal axis and eventually trigger cortisol hormone secretion. Also, the results demonstrated that increased noise exposure experience in workers causes decrease in the differential amount of cortisol secretion in morning and evening samples. In other word, normal pattern of cortisol secretion in workers with chronic noise exposure, changes accordingly and faces fluctuations. Our findings on the effect of noise on salivary cortisol concentrations are confirmed by some other studies. In a study by Green at al. salivary cortisol levels were reported to increase in daytime regarding chronic exposed to noise [15]. Also, the results of the study by Dehaghi et al. showed that there is a significant relationship between exposure to industrial noise higher than 85 dBA and salivary cortisol increase [16]. In another study by Hebert et al. In 2009, the effect of short exposure to noise on salivary cortisol, mental stress, and tinnitus intensity in a laboratory environment was investigated. The results showed that exposure to noise even within the standard range (80 dB) and for 20 minutes, affects the HPA axis (hypothalamic-pituitary-adrenal), which is responsible for secretion of cortisol and mental stress [17]. In a study by Gitanjali et al. serum cortisol level increased significantly on the morning of the day after acute exposure to noise [18]. Some studies that investigated cortisol concentration in blood serum and urine, reported increase in cortisol levels after noise exposure [19-21]. There exist some controversial studies that reported no fluctuation in cortisol secretion due noise exposure [22, 23]. These different findings can arise from: study design, study population (gender, age, job, etc.), noise emission pattern, noise exposure duration and noise levels differences. The aim of this study was to survey the non-auditory effects of noise exposure. In other words, the relationship between exposure to occupational noise and physiological variables such as increasing stress hormone secretion was studied. It should be noted that noise levels above 80 dB increased salivary cortisol. One of the limitations of this study can be stated as; while selecting the sampling site, only one industrial setting was achievable from a wide variety of industries with high level of exposure to chronic noise. A larger population size could make it more feasible for statistical extrapolation. This study revealed that chronic exposure to industrial noise can lead to a change in pattern of salivary cortisol secretion especially in the evening (at the end of the work shift), in a way that instead of its normal decrease, an increase happened. Also testing salivary cortisol is a feasible tool in assessing the effects of chronic noise exposure.

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Conflict of interest statement

The authors declare no conflicts of interest.

Authors' contributions

BFD conceived the study and drafted the manuscript. FK collected the data and drafted the manuscript. KAA carried out the statistical analysis.

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