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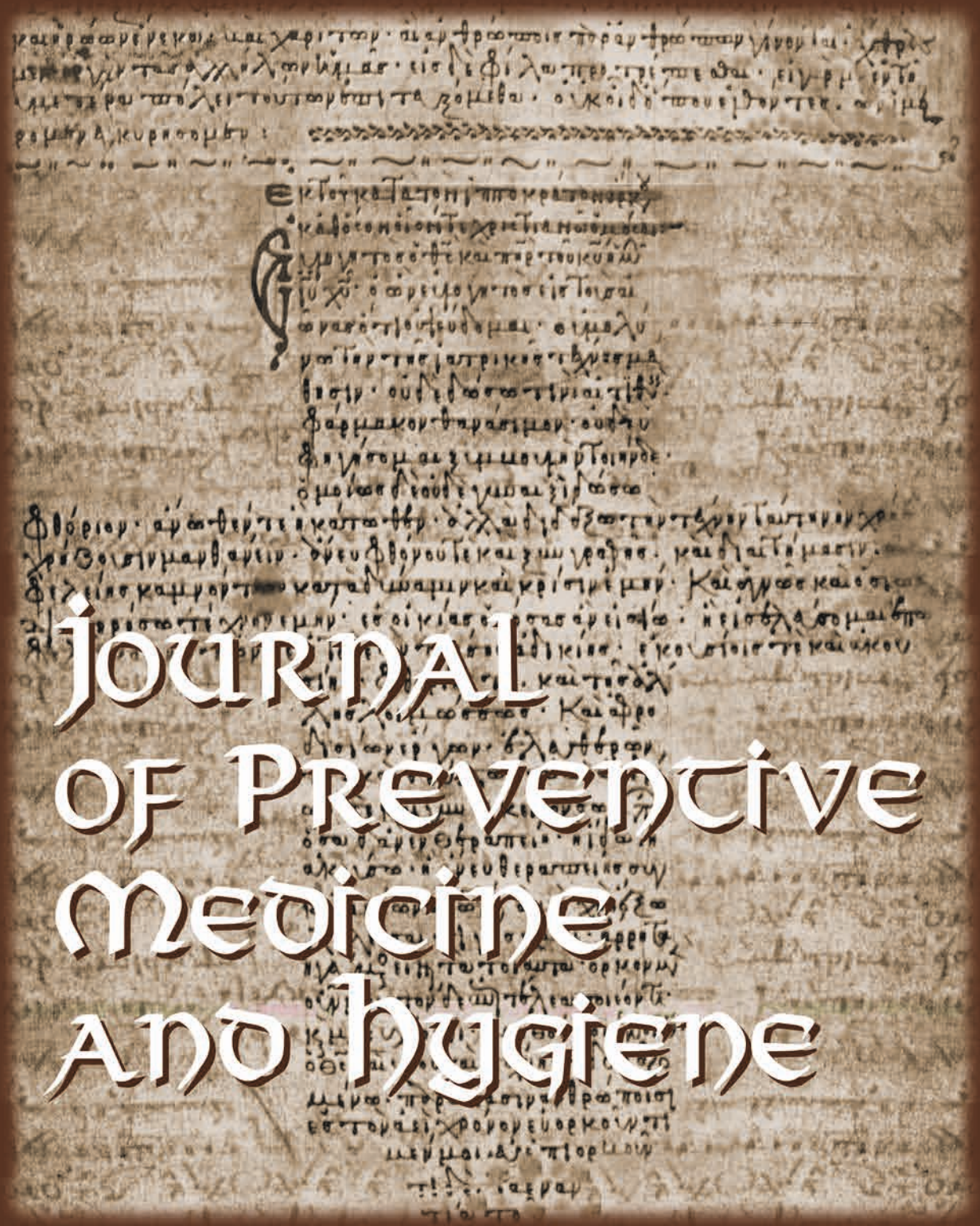

The original document of Hippocrates' oath

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Contents

COVID-19

Vaccine hesitancy in healthcare workers during COVID-19 pandemic: Draw on experience

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Keywords

Healthcare workers • Vaccine hesitancy • COVID-19 • Psychological wellbeing

Summary

Objectives. *The present study aimed to identify factors that affect healthcare workers' (HCWs) vaccine hesitancy and the subsequent changes in psychological well-being.*
Study design. *800 employees (207 M; 14 aged ≤ 25; 145 aged 26-35; 381 aged 36-55; 260 aged > 55 years) were recruited from the San Martino Hospital during the first months 2021.*
Methods. *HCWs were asked to fill in an online survey assessing (a) demographics, (b) having contracted COVID-19 infection, (c) vaccination history (against COVID-19 and influenza), (d) expected changes in psychological well-being, (e) vaccine hesitancy and (f) factors leading to a decision about the vaccine (Information Trust, Information Seeking, Fear for the Self, and Sense of Responsibility).*
Results. *We found that, in vaccinated HCW, years of employment and adherence to the influenza vaccine indirectly affected vaccine hesitancy. These effects were mediated by HCWs' sense of responsibility and information trust. Moreover, while information trust promoted positive changes in psychological well-being, vaccine hesitancy negatively affected it.*
Conclusions. *The present study consistently points to the crucial role of trusting information and having a sense of responsibility on vaccine hesitancy and, consequently, on psychological well-being. We discuss the practical implications for public health of these findings. In the conclusions, we suggest short-term and long-term strategies for improving vaccine adherence.*

Introduction

Vaccine hesitancy is the delay, reluctance, or refusal to get vaccinated despite vaccine availability and involves both vaccinated and non-vaccinated people [1, 2]. Hesitancy was highly affected by vaccine representation as being unsafe and ineffective as well as by negative beliefs regarding the untrustworthiness of the healthcare system [3]. In Italy, vaccine hesitancy is still a topic of interest since it is a major issue that could determine the failure of a vaccination program [4]. The COVID-19 pandemic has highlighted once more the importance of understanding the drivers of vaccine hesitancy. As the virus spread globally, the urgent need for a vaccine to fight against the disease led to a rapid development and approval process. This urgency and concern about the vaccine's safety and efficacy resulted in lower vaccine confidence and uptake rates in the general population [5]. Among others, healthcare workers (HCWs) were not immune to vaccine hesitancy [6-8] and displayed considerable hesitancy toward the COVID-19 vaccine [9]. HCWs' vaccine hesitancy raises significant concerns due to their increased risk of contracting and transmitting the virus leading to increased infections among vulnerable patients and colleagues and due to a possible increase of staff absences when there was a great need [10-12]. Moreover, HCWs' recommendations significantly impact vaccine acceptance in the general population and hesitant professionals were more likely not to recommend vaccination [13-15]. HCWs' attitudes toward COVID-19 vaccination were different from those of the general population that are most investigated [16-19]. Indeed, HCWs are more skillful in seeking healthcare information and can better understand the medical lexicon. An umbrella review synthesized the evidence about barriers and facilitators of HCWs' vaccine hesitancy toward the COVID-19 vaccine spotting several factors affecting vaccine hesitancy, such as sociodemographic, health, social, belief, and information factors [9]. The few empirical investigations on Italian HCWs agreed that their main reasons for accepting vaccination were protecting others and themselves from infection, and the main reasons for opposing vaccination were little or conflicting information and mistrust [20-22]. Moreover, Italian studies suggest a role of several demographic and personal-history-related factors such as age, receiving the influenza vaccination, and receiving a diagnosis of COVID-19 [13, 21-24].

However, these studies did not put all the factors affecting vaccine decisions together to identify the major predictors of COVID-19 vaccine hesitancy and did not consider the emotional effects of vaccine hesitancy. This would be important since enhancing vaccine adherence would, not only, reduce the risk of infection and transmission, but also, allow people to regain a sense of relief and optimism about returning to normalcy [18, 25, 26]. The present study tries to fill these gaps by (a) assessing at the same time all factors affecting vaccine hesitancy and (b) exploring the effects of vaccine hesitancy and related factors on changes in psychological well-being. Thus, the main aim of the present study was to identify factors that affect vaccine hesitancy and the subsequent changes in psychological well-being. Understanding and identifying the key factors that influence hesitancy and psychological well-being changes, especially for newly developed vaccines, like the COVID-19 one, is crucial for developing effective communication strategies that may foster confidence and vaccine acceptance.

Methods

Participants

HCWs were recruited from the San Martino Hospital through the work intranet. In detail, all HCWs were invited through an email in which the nature and consequences of the study were fully explained. The recruitment occurred during the first months of 2021 when the COVID-19 vaccine had just been made available only for HCWs and was not yet mandatory for them. A total of 800 employees (207 M; 14 aged ≤ 25; 145 aged 26-35; 381 aged 36-55; 260 aged > 55 years) agreed to participate and fill in the informed consent and the online survey.

Procedure

Through an online survey, HCWs were asked to answer if they made the COVID-19 vaccine. The survey ended if they can't adhere to the vaccine having contracted COVID-19 90 days before the vaccination, since the Italian ministerial circular drove their decision about the vaccine. All the other participants had to answer further questions assessing (a) demographics, (b) control variables (*i.e.*, having contracted COVID-19 infection, and vaccination history), (c) Changes in psychological well-being, and (d) factors leading to vaccine reluctance/refusal. Finally, for vaccinated HCWs, we also measured vaccine hesitancy and factors leading to COVID-19 vaccine acceptance.

Measures

Changes in psychological well-being

Quality of Life and Work changes. All HCWs were asked to rate on a 3-point Likert scale how they think their Quality of Life (QoL) and Quality of Work (QoW) would change after the vaccination campaign. We derived a QoL index and a QoW index that go from -1 (will get worse) to +1 (will get better).

Changes in positive and negative emotions. All HCWs were asked to think about pandemics and rate on a 3-point Likert scale how their emotions changed after the vaccination campaign. Participants can answer that the written emotion did not belong to them. In this case, the answer was considered as a missing value. We calculated a changes-in-positive-emotions and a changes-in-negative-emotions index from the mean of positive (*i.e.*, calmness and confidence) and negative (*i.e.*, stress, anxiety, anger, helplessness, worry, and fear) emotions items that could range from -1 (Less than before) to +1 (More than before).

Factors leading to a decision about the vaccine

Factors leading to COVID-19 vaccine reluctance/refusal. All HCWs were asked to rate how much information and mistrust in the vaccine affected their decision about the vaccine on a 6-point Likert scale from 0 ("at all") to 5 ("a lot"). We derived an Information-Trust (IT) index and an Information-Seeking (IS) index (see Supplementary).

Factors leading to COVID-19 vaccine acceptance. Vaccinated HCWs were asked to rate how much their sense of responsibility and concerns for their health affected their decision about vaccine adherence on a 5-point Likert scale from 0 (at all) to 5 (a lot). We derived a Fear-for-the-Self (FS) index and a Sense-of-Responsibility (SR) index (see Supplementary).

Vaccine hesitancy

Vaccine hesitancy was measured, like in previous studies, with a single item assessing how many doubts vaccinated HCWs had about vaccine adherence when they knew the vaccine would be available to them [27]. We asked them to rate this index on a 3-point Likert scale from 0 ("no doubts") to 2 ("many doubts").

Statistical analyses

Before testing our main hypothesis, we conducted descriptive statistics, and group comparisons (vaccinated *vs* non-vaccinated HCWs) using χ^2 tests for ordinal and categorical dependent variables, and independent sample t-tests for continuous dependent variables.

We then examined the associations between aspects leading to a decision, vaccine hesitancy, and well-being changes in vaccinated HCWs, adopting a path model where factors leading to decisions (*i.e.*, IT, IS, SF, SR) predict vaccine hesitancy and psychological well-being changes. The model also included the effect of vaccine hesitancy on psychological well-being changes and controlled for age, gender, years of employment, having contracted COVID-19 infection, and vaccination history letting them regress on factors leading to a decision and vaccine hesitancy. Finally, we let error terms covary within constructs (*i.e.*, aspects leading to decision, and changes in wellbeing) to allow for potential residual associations among variables.

The fit of the model tested was evaluated following the

Tab. I. Descriptive statistics among demographic and control variables for each group (vaccinated *vs* non-vaccinated).

	Whole	Vaccinated	Non-vaccinated		
	N	N (%)	N (%)	χ^2	p
Gender				3.23	.072
Male	188	185 (98%)	3 (2%)		
Female	559	534 (96%)	25 (4%)		
Age				4.93	.177
< 25	14	14 (100%)	0 (0%)		
26-35	135	134 (99%)	1 (1%)		
36-55	362	346 (96%)	16 (4%)		
> 55	236	225 (95%)	11 (5%)		
Profession				8.20	.085
Healthcare executive	207	204 (99%)	3 (1%)		
Healthcare professionals	397	375 (94%)	22 (6%)		
Healthcare assistants	28	28 (100%)	0 (0%)		
Residents	52	51 (98%)	1 (2%)		
Amministrative personnel	63	61 (97%)	2 (3%)		
Years of employment				6.61	.037
0-5	123	122 (99%)	1 (1%)		
6-15	123	121 (98%)	2 (2%)		
> 15	501	476 (95%)	25 (5%)		
COVID-19 infection				5.64	.018
Yes	101	93 (92%)	8 (8%)		
No	646	626 (97%)	20 (3%)		
Influenza vaccine				30.92	<.001
Yes	516	510 (99%)	6 (1%)		
No	231	209 (90%)	22 (10%)		

Tab. II. Descriptive statistics among variables of interest for each group (vaccinated *vs* non-vaccinated).

	Vaccinated		Non-vaccinated				
	N	Mean + SD	N	Mean + SD	t	p	g
Changes in QoL	719	0.50 +.51	28	0.18 +.48	3.46	.002	0.63
Changes in QoW	719	0.48 +.51	28	0.18 +.48	3.23	.003	0.59
Changes in PE	699	0.37 +.54	26	-0.52 +.50	8.23	<.001	1.65
Changes in NE	635	-0,42 +.44	25	0.15 +.54	-6.36	<.001	1.28
Information-Seeking	719	1.42 +.93	28	0.36 +.64	8.46	<.001	1.15
Information-Trust	719	2.94 +.75	28	2.46 +.62	3.36	.001	0.64
Fear-for-the-Self	719	1.65 + 1.00	-	-	-	-	
Sense-of-Responsibility	719	2.89 +.95	-	-	-	-	
Vaccine hesitancy	719	0.34 +.56	-	-	-	-	

QoL: Quality of Life; QoW: Quality of Work; PE: Positive Emotions; NE: Negative Emotions.

criteria recommended by Brown [28]: nonsignificant chi-square (χ^2) test, root mean square error of approximation (RMSEA) ≤.08, a comparative fit index (CFI), and a Tucker-Lewis index (TLI) ≥.90.

Results

Preliminary descriptive analyses

Among all participants, 89.9% (N = 719) have made the COVID-19 vaccine, 3.5% (N = 28) actively refuse to get vaccinated, and 6.6% (N = 53) can't adhere to the vaccine since have contracted COVID-19 90 days before the vaccine. In subsequent analyses, we focused only on a subsample of 747 HCWs of which 96% adhere to the vaccine and 4% actively refuse to get vaccinated. Descriptive statistics of the two samples among all study variables are reported in Tables I and II.

Groups comparison

Regarding ordinal and categorical variables, we found differences between groups in years of employment, having adhered to the influenza vaccine, and having contracted COVID-19 before the vaccine (Tab. I). In detail, the percentage of COVID-19 vaccine adherence decreased for HCWs with more years of employment. Moreover, HCWs who contracted a COVID-19 infection showed a lower percentage of vaccination against COVID-19 compared to HCWs who did not contract COVID-19

yet. Finally, HCWs not vaccinated against influenza, compared to vaccinated ones, showed a lower percentage of vaccination against COVID-19. No differences were found for gender, age, and profession (Tab. I).
Regarding variables of interest, results showed a significant difference in IS, and IT (Tab. II). In detail, we found that non-vaccinated HCWs were more alarmed by the availability of the vaccine for them and reported a lower influence of IS and IT on their decision about the vaccine. Moreover, we found a significant difference in changes in QoL, QoW, positive, and negative emotions (Tab. II). In detail, non-vaccinated HCWs referred to expect a lower increase in QoL and QoW as well as an increase in negative emotions, and a decrease in positive emotions.

Associations between aspects leading to a decision, vaccine hesitancy, and well-being changes in vaccinated HCWs

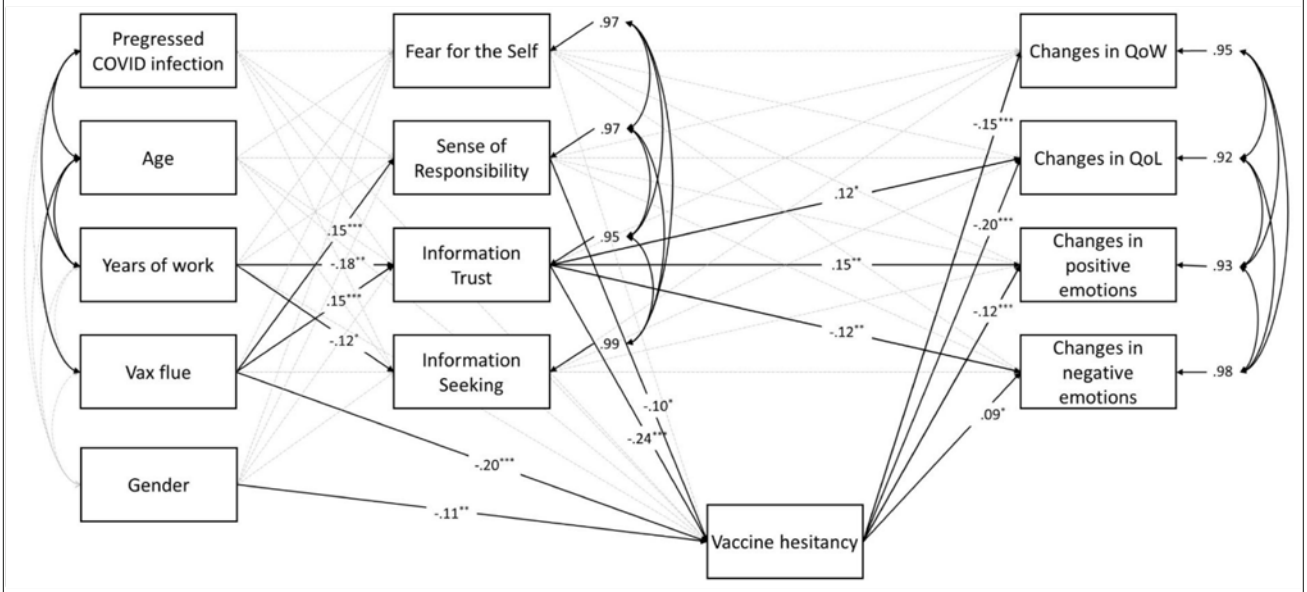
We investigated the effects of aspects leading to a decision on vaccine hesitancy and psychological well-being changes in vaccinated HCWs using the path model previously described. The resulting model exhibited a good fit to the data, $\chi^2(20) = 30.54$, $p = .062$, RMSEA = .03, CFI = .99, TLI = .96. Results are reported in Figure 1 and showed that years of employment affected IT, and IS in the direction that higher HCWs with more years of employment reported less IT and IS. Adherence to the influenza vaccine predicted SR, IT, and vaccine hesitancy. In detail, we found that HCWs who adhere to the influenza vaccine reported more SR and IT, and less vaccine hesitancy. Being male, SR, and IT exerted a negative effect on vaccine hesitancy. IT also predicts changes in negative emotions, QoL, and positive emotions in the direction that HCWs with more IT expect a decrease in negative emotions and an increase in positive emotions and QoL after the vaccine campaign. Finally, we found an effect of vaccine hesitancy on changes in negative emotions, QoW, QoL, and positive emotions. In detail, HCWs with more vaccine hesitancy expect an increase in negative emotions and a decrease in positive emotions and QoL after the vaccine campaign.

Discussion

Preliminary results

We first discuss preliminary results about the percentage of vaccine adherence and the difference between vaccinated and non-vaccinated HCWs.
Results about the percentage of vaccine adherence showed that even if the majority of HCWs adhere to the COVID-19 vaccine a percentage of professionals actively refuse vaccination, in line with national data before the vaccine became compulsory [29].
Regarding differences between vaccinated and non-vaccinated HCWs, we found that HCWs who contracted a COVID-19 infection showed a lower percentage of vaccination against COVID-19 compared to HCWs who had not contracted COVID-19 yet. This fits with evidence showing that HCWs who contracted COVID-19 considered themselves already immune from infection [20]. In addition, we found that the percentage of the COVID-19 vaccine decreased for HCWs not vaccinated against influenza.

Fig. 1. Path diagram depicting relations between control variables, factors leading to a decision about the vaccine, vaccine hesitancy, and changes in psychological well-being.



Paths with p >.05 are shown in grey dotted lines. * p <.05. ** p <.01. ***p <.001. Vax flue: Influenza vaccine; QoL: Quality of Life; QoW: Quality of Work.

This result fits with the literature reporting refusal of the influenza vaccine as a predictor of vaccine hesitancy [13, 17, 21, 24]. Interestingly, regarding the influenza vaccine, we found that the number of HCWs that adhere to the influenza vaccine was very high in line with the increasing trend of influenza vaccination rates following the start of the COVID-19 pandemic [30, 31]. We found that the percentage of the COVID-19 vaccine increased for HCWs with higher years of employment, *i.e.*, those who are more experienced. Thus, they may preferably base their decisions on the intuitive system (*i.e.*, automatic, associative, and fast way of thought) rather than on the analytical system (*i.e.*, logical, reason-based, and relatively slow way of thought) [32]. Being more subjective to heuristics could result in decision cognitive biases [33] that were negatively related to risk perception, information-seeking, and preventive behavior like vaccine adherence [34]. Moreover, we also found that IT and IS are higher in HCWs vaccinated against COVID-19, in line with the higher trust induced by COVID-19 [35] and its role in vaccine acceptance [17-36]. Finally, we found that vaccinated HCWs expect an increase in their QoL, QoW, and positive emotions, and a decrease in their negative emotions. Thus, people who adhere to the vaccine feel it is the ultimate answer to the pandemic that would allow them to return to life as it was and to regain freedom, and normality in social relationships positively impacting emotional well-being [37].

Main results

The main aim of the present study was to identify factors that affect vaccine hesitancy and the subsequent changes in psychological well-being.

We found that higher years of employment predict lower IS and IT which, in turn, predicts vaccine hesitancy. The indirect effect on vaccine hesitancy mediated by IT is in line with the hypothesis that the higher formation about vaccines received during newer healthcare professionals' degree programs leads to a higher trust in vaccines. Thus, HCWs with fewer years of employment are those who have been educated more recently. In the last few decades, healthcare degree programs increased their attention to vaccines' safety and value. Interestingly, studies performed among younger HCWs have shown higher rates of adverse reactions, mild and transient, following the COVID-19 vaccines, further highlighting the need to improve the knowledge concerning these items among this subcategory. These findings could be useful in informing all HCWs to set evidence-based expectations and possibly improving adherence to vaccination campaigns [38-40]. Thus, improving self-rated knowledge about the COVID-19 vaccine was found to be significantly protective against COVID-19 and vaccine hesitancy [23-40].

Moreover, adherence to the influenza vaccine exerted a significant direct and indirect negative effect on vaccine hesitancy. Indeed, during the COVID-19 pandemic, the importance of the influenza vaccine could have been boosted by the co-circulation of the two viruses during flu season. Thus, being vaccinated against influenza could help to disentangle the type of virus contracted [41]. Moreover, the higher perceived level of a health threat could lead people to adopt higher preventive behavior [41]. The indirect effects on vaccine hesitancy were mediated by SR and IT. The mediation of IT highlighted how trust would have reduced hesitancy about the COVID-19 vaccine. Indeed, several studies highlighted the role of trust in the COVID-19 vaccine and science on vaccine acceptance [17, 36, 42, 43]. The mediation of SR on vaccine hesitancy suggests that HCWs vaccinated against influenza are more prone to a sense of responsibility that affects their higher acceptance and lower hesitancy among vaccines in general. The role of responsibility in reducing vaccine hesitancy highlights the importance of getting vaccinated as a collective responsibility to protect the health of patients and family members [44].

Contrary to our expectations, we did not find an effect of IS on vaccine hesitancy and changes in well-being probably because no clear information was already available about SARS-CoV-2 and its vaccines, and people were highly exposed to conflicting or unclear information [9]. Thus, in this period, even HCWs face the challenge of seeking trusting information making IS not a valid strategy to decide about vaccine adherence.

Regarding the effect on changes in psychological well-being, we found that IT has a direct and indirect positive effect. This is consistent with studies showing that living a "common fate" in the face of mortal danger, can improve relationality and prosociality, which, in turn, impacts trust toward others and well-being [45]. Vaccine hesitancy mediates the indirect effects of IT and SR on psychological well-being. Accordingly, the literature showed that lower hesitancy reflects individuals' intention to actively contribute to protecting others (*e.g.*, patients and relatives) and promotes a sense of empowerment positively impacting their emotional well-being [18, 25, 26].

Conclusions

Altogether, our findings consistently point to the crucial effects of IT and SR on vaccine hesitancy and expected changes in psychological well-being. These results have several practical implications for public health pointing to the importance of promoting trust and responsibility among HCWs by using, for example, coherent communication campaigns emphasizing social norms and prosocial behavior [46].

In the short term, it could be useful to directly involve HCWs in small group meetings to explore their attitudes towards vaccines and their possible contradictory thoughts. These focus groups should contribute to (a) improving HCWs' decision-making by increasing their awareness of cognitive dissonances and bias based on heuristics (b) enhancing HCWs' trust by giving them evidence-based information about vaccines, and (c) fostering their sense of responsibility by engaging

them actively in promoting vaccine acceptance among HCWs and more broadly the general population. Future studies should move in this way, planning focus groups to identify HCWs' attitudes and cognitive dissonances towards vaccines.

In the long term, it could be useful to break down erroneous beliefs about vaccines starting from the basics of primary school and prosecuting with specialistic education. In line with this, evidence showed that promoting cognitive information processing alone was ineffective in contrasting the effects of fake news [47]. Indeed, it is necessary to increase the general level of instruction to promote a mature prior belief system that has a role in mistrusting fake news [47]. Accordingly, promoting a culture of critical thinking should be crucial to help people navigate a world full of information and distinguish true from fake information [48]. Moreover, since vaccine acceptance is also an emotional process, education programs should help people in the management of emotional responses to false news [49-50]. Educating about emotion regulation strategies in media literacy may reduce hesitancy by decreasing the reliance on heuristics in decisions about vaccines [51].

Limits

Despite the novelty of this study, it is not exempt from limitations. First, the measures used are not preliminarily validated. Second, the cross-sectional nature of the study prevents us from deriving certain conclusions about the direction of the relationships between factors leading to a decision about the vaccine, vaccine hesitancy, and changes in psychological well-being. Indeed, since changes in emotions are expected, we are not certain that our results replicated when emotional changes were assessed retrospectively.

Ethical approval

The local ethics committee approved the study protocol (N. Reg. 171/2021 - DB id 11335).

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Conflicts of interest statement

The authors have no conflicts of interest to disclose.

Author contributions

FR and ES: conceived the study. PDS: conducted the analysis. PDS, FR, and ES: drafted the first version of the article, and all the authors reviewed the article critically for important intellectual content. All the authors have approved the final version of the article.

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HEALTH PROMOTION

Network Analysis of the HLS_{19}-Q12 Health Literacy Questionnaire: insights from an Italian Pilot Study

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Keywords

Health literacy • Network analysis • Health Literacy Survey Questionnaire • HLS-Q12

Summary

Background. *The widespread use of the internet and social media has transformed how people access health information impacting health literacy. Health literacy, the ability to access, understand, and use health information, is crucial to promote and maintain good health. This study is the first exploring with network analysis the correlation and distribution of the items of the Health Literacy Survey Questionnaire (HLS-Q) 12 short form to verify their correspondence to the principal domains of the health literacy conceptual model proposed by Sorensen et al. in 2013.*
Materials and Methods. *A digital version of the Italian HLS19-Q12 questionnaire was distributed online through social media and informal channels in May 2024. The sample consisted of 352 participants from the metropolitan area of Cagliari, Italy. Network analysis was employed to examine the clustering and relationships between the questionnaire items, via JASP using the Ising Fit method.*
Results. *Key findings include significant difficulties in accessing professional help and understanding medical emergencies. Network centrality measures highlighted the prominence of items related to understanding medical emergencies and making health decisions. Three clusters corresponding to healthcare, disease prevention, and health promotion, were visually identified with the last two closely interconnected. The item "making decisions to improve health" is crucial, acting as a bridge between clusters. Some items traditionally belonging to one domain shifted to another.*
Conclusions. *The network analysis provided a clear depiction of health literacy as complex system, emphasizing interactions. Health literacy involves accessing, evaluating, and applying information, with empowerment playing a key role according to our findings. By addressing identified needs and focusing on prominent items, healthcare professionals and policymakers can enhance health literacy and improve health outcomes for individuals and communities. This pilot study's findings could benefit future research and interventions to improve health literacy.*

Introduction

In recent years, communication and how information is obtained by people in their everyday life have undergone radical changes, affecting various sectors, including healthcare. This shift in the way people get informed is mainly due to the widespread use of the internet and social media across all age groups and the increase in communication channels compared to the past. New platforms can reach segments of the population that were previously inaccessible, allowing for broad-spectrum communication and dissemination. In 2024, the Facebook page of the Italian Ministry of Health had 1.5 million followers (Ministero della Salute, 2024), and its Instagram profile had 646,000 followers (Ministero della Salute, 2024), suggesting that people use these new channels to stay informed on specific topics.
The way people get informed changed, as well as the way of communicating with users, and the interaction between users and healthcare professionals. The modern user relies not only on the guidance of healthcare professionals but seeks information independently, reads, and navigates with more knowledge and awareness of available care and assistance options compared to the past. In this view, health is generated by a synergy of knowledge, behaviors, policies, provisions, social resources, and genetic heritage, which develop in different balances [3]. This vision of well-being emphasizes that health promotion becomes a dialogical exchange between educational, clinical, institutional, environmental, socioeconomic, and family contexts. This vision of well-being emphasizes that health promotion becomes a dialogical exchange between educational, clinical, institutional, environmental, socioeconomic, and family contexts. In this view, health is generated by a synergy of knowledge, behaviors, policies, provisions, social resources, and genetic heritage, which develop in different balances.
Recognizing that enhancing citizens' knowledge and awareness can improve their relationship with the systems they interact with. Recent years have seen increased attention to Health Literacy amidst the institutional and organizational restructuring of the healthcare system. Health literacy refers to the ability of individuals to access, understand, and use information in ways that promote and maintain good health for themselves, their families, and their communities. Although different

definitions are used and health literacy is an evolving concept, there is agreement that the meaning of health literacy goes beyond the simple ability to read brochures, make appointments, understand food labels, or follow doctor's advice. It encompasses citizens' skills in terms of personal abilities and the measure of interactions between groups and their living environment [4]. It also refers to the increase in empowerment, which is the acquisition of self-awareness and control over one's choices, decisions, and actions, both in personal relationships and in political and social life, and capability, which is the ability to do or be what one wants to do or be.

Over the years, the concept of health literacy introduced by Simonds in the '70 [5] has been reworked and expanded, and it is now intended more as an autonomous set of skills and learning processes A high level of health literacy is associated with better health conditions, compliance with treatments, and a conscious and effective use of healthcare services [6]. A low level of health literacy is correlated with poor understanding of health indications, errors in interpreting information, and consequent negative outcomes [7]. Furthermore, healthcare inequality is a key factor affecting disease rates, particularly in impoverished communities. Enhancing health literacy is crucial for reducing these disparities [8]. The Ottawa Charter in 1986 recognized the need to enable people to increase control over and improve their health and well-being, ensuring healthier and more sustainable environments where people live, work, study, and have fun [9]. Therefore, it is essential to monitor and assess the population's health literacy level and try to reduce inequalities.

Several measurement tools were developed to measure health literacy and four of them are frequently used: Newest Vital Sign (NVS), the Short Test of Functional Health Literacy for Adults ((S)TOFHLA), the Brief Health Literacy Screener (BHLS), and the Health Literacy Questionnaire (HLQ) [10]leading to improved health outcomes. Assessment tools should ideally address multiple domains of health literacy, fit to the complex hospital context and have a short administration time, to enable routine assessment. This review aims to create an overview of tools for measuring (digital. They vary in approach and design, but only some have focused on comprehensive health literacy in populations. An example is represented by the European Health Literacy Survey Questionnaire (HLS-EU-Q47), which covers most domains of health literacy: i) access, ii) understanding, iii) appraise, iv) and apply. HLS-EU-Q47 is an innovative and comprehensive tool for measuring health literacy in populations, composed of 47 items [11]. The design process was guided by the conceptual model of health literacy derived from a systematic review of existing definitions and conceptualizations of the concept by Sorensen et al. (2013). Following this definition, the HLS-EU Consortium [12] developed a conceptual framework that outlines the main dimensions of health literacy mentioned in the literature and integrates them into a logical model. This model identifies proximal and distal factors that can impact health literacy with potential consequences regarding health behaviors, health outcomes, and the use of healthcare services. The core is a matrix of 12 areas derived from the intersection of healthcare, disease prevention, and health promotion domains with the key processes of health literacy study related to accessing, understanding, evaluating, and applying health-related information. A short version, HLS-Q12, was established in by HLS_{19} Consortium as a part of the Health Literacy Population Survey 2019-2021 [13]. HLS-Q12 meets the assumptions and requirements of objective measurement and offers a concise health literacy screening tool that is widely used. The aim of this pilot study was to evaluate the correlation and distribution of the items of the HLS-Q12 short form in the three domains, healthcare, disease prevention, and health promotion, to verify their effective correspondence to the conceptual model of health literacy proposed by Sorensen et al. [11]. For this purpose, we used the network analysis to study the clustering of the answers to the items of the Italian version of the HLS-EU-Q12 in a sample of questionnaires collected mostly in the metropolitan area of Cagliari (Italy) in 2024. Network analysis is a set of techniques based on graph theory [14] aimed at describing the main characteristics of a system composed of nodes and connections. Its applications span many fields, such as economics [15], public health [16], neuroscience [17], and social sciences [18]. The use of network analysis is constantly evolving, and an example is the recent exploratory graph analysis approach to the structure of SOC (sense of coherence)-13 questionnaire [19]. Rendering the health literacy questionnaire as a network of interacting elements offers a comprehensive representation of how the items are organized, grouped, or related to each other and how the dimensions are positioned relative to each other in a multidimensional space. To our knowledge, this is the first work using network analysis on health literacy data.

Materials and Methods

Measures

The measures included 12 out of the 47 items HLS-EU-Q47 survey questionnaire, gender, age, and highest level of education completed.

HLS-EU-Q47

Based on their conceptual framework, Sørensen and colleagues [11, 20-22] created the HLS-EU-Q47 items. They recommended using a 4-point Likert scale, with response options ranging from 1 (very easy) to 4 (very difficult); a 'do not know' category was also included to capture spontaneous responses from participants during the telephone interviews and was later re-coded to missing data.

HLS-Q12

Due to the length of the HLS-EU-Q47, shorter forms like the HLS-EU-Q16 and HLS-EU-Q6 were developed

and later validated and applied in several languages and regions [23-26]. The HLS-EU-Q16, although shorter, had some limitations in representing the theoretical model fully. A 12-item instrument was also developed independently of the HLS-EU consortium by different groups [27-30]. However, these Q12 short forms had essential differences regarding methodology, quality of data, sample size and degree of adherence to the underlying model and matrix of comprehensive, general HL. To address these issues, HLS_{19}. Consortium decided to develop a new short form HLS-EU-Q12 [13, 31-33]. This 12-item version is a refined instrument aimed to better represent the theoretical model while being more practical for research purposes and easier to use in diverse research contexts. The HLS_{19} Instrument used in this research was developed within "HLS_{19} – the International Health Literacy Population Survey 2019-2021" of M-POHL (Action Network on Measuring Population and Organizational Health Literacy of EHII – WHO Europe). The Italian National Institute of Health (ISS), which participated in M-PHOL, provided the translation and cultural adaptation of the HLS_{19} questionnaire in the Italian language in collaboration with the University of Florence and the Università Cattolica del Sacro Cuore of Rome. For the purpose of this pilot study, we used the Italian version of HLS_{19}-Q12 short form [31, 34, 35].

Data collection

Using an online form tool (Google form), we distributed an open-to-all digital version of the Italian HLS-EU-Q12 through the most popular social media platforms, such as Instagram, Facebook, and LinkedIn. The questionnaire was also diffused through informal channels such as word-of-mouth among acquaintances and family members of students' population. The questionnaire was sent and disseminated by sharing the online link to invite participants to complete the questionnaire. The home page of the questionnaire displayed an image with keywords related to the topic and provided a brief description of the survey's objectives and detailed information on data processing. A constraint was set, allowing participants to fill out the form only if they were of legal age. We collected 353 questionnaires completed by participants aged 18 or over in May 2024. All participants provided informed consent before participating in the study, and 352 out of 353 consented to the use of data collected for research purposes. No IP addresses were recorded, guaranteeing anonymity, and no sensitive data was requested. Each participant could independently decide whether to provide their email address to receive research updates. This pilot study received the approval of the Territorial Ethical Committee of Sardinia (Italy).

Network analysis

Methods

The data was processed with JASP software (JASP Team (2024). JASP (Version 0.19.3) [Computer software]) using the Ising Fit method through the eLasso procedure [36] for estimating network structures. Ising Fit focuses on binary data and is useful for identifying clusters of highly correlated variables and generating hypotheses about the underlying relationships between the variables. ELasso network estimation procedure is based on the Ising model and integrates l1-regularized logistic regression with model selection using the Extended Bayesian Information Criterion (EBIC). EBIC serves as a fit measure to identify relevant relationships between variables. The resulting network represents variables as nodes and their significant relationships as edges.

Our input

To create the input matrix of binomial data, the answers to each of the 12 HLS-EU-Q items were dichotomized in two categories with two scores, "easy" ("easy" or "very" easy = 1) and "difficult" ("difficult", "very difficult" and "don't know" = 2).

The regularization parameter lambda (λ) was set by default to a value 0.25 to identify the strongest relationships and reduce the risk of overfitting. This parameter controls the sparsity of the network, determining which edges (relationships between variables) are included in the final model and balancing the trade-off between model complexity and fit. A higher λ results in a sparser network with fewer edges, a lower λ includes more edges, potentially leading to overfitting.

Output and interpretation

We obtained a weight's matrix and network plots showing i) the nodes, namely the items presented as questions to participants, ii) the edges, namely the partial correlation between two nodes, and iii) the clusters or sets of nodes connected using undirected network models. Each entry in the weights matrix corresponds to the interaction weight between pairs of binary variables. A positive weight indicates a positive relationship, meaning the variables are likely to have the same value, while a negative weight indicates a negative relationship, meaning they are likely to have different values. The magnitude of the weight reflects the strength of the relationship. The relationship between the weight's matrix and odds ratios could be considered to help move from the mathematical framework of Ising Fit to a more interpretable language. The weights in the matrix represent the log odds ratios between pairs of variables and indicate the strength and direction of the relationship. A positive weight suggests a positive association (variables are likely to have the same value), and a negative one suggests a negative association (variables are likely to have different values). The log odds ratios (weights) are converted to odds ratio with the formula:

$$\text{Odds Ratio} = e^{\text{weight}}$$

Since Ising Fit assumes that the interaction between two variables is symmetric, the weight value (log odds ratio) calculated for the interaction between A and B is identical from B to A and describes the strength and

direction of the relationship. Odds Ratios > 1 indicate a positive relationship, < 1a negative relationship, = 1 no relationship.

Several centrality measures were employed to assess the importance and influence of each node within the network. These measures include betweenness centrality, closeness centrality, strength, and expected influence. Betweenness centrality measures how often a node (in our case, a questionnaire item) lies on the shortest path between other nodes. This can help identify items that act as bridges or connectors within the network, providing insights into the structure and dynamics of the relationships between items. Closeness centrality measures how close a node is to all other nodes in the network. A node with high closeness centrality can quickly interact with all other nodes in the network, indicating its efficiency in spreading information. In the context of an Ising Fit model, the strength of a node indicates the overall level of connectivity or influence that node has within the network. A node with high strength is strongly connected to many other nodes. The expected influence is similar to strength but accounts for the signs of the weights (positive and negative influences), considering both the direct and indirect effects of a node on the network.

A nonparametric bootstrap analysis with 1,000 bootstraps was conducted to assess the stability of the network.

Results

Sample demographics

Of 352 participants, 93% were from the metropolitan area of Cagliari (Italy), 21.6% identified as men, 78.1% as women, and 0.3% preferred not to disclose their gender. Regarding the sample distribution by sex, 77 participants were males and 275 females. The youngest participant was 19 years old, while the oldest was 74 years old. There was a higher participation of people aged between 30 and 40 years. 50% of participants had a university degree, 41% had at least a high school diploma, and 9% had a middle school diploma. None of the participants declared no educational qualifications or an elementary school diploma. See Table I for participants' details.

Questionnaire

Here we present the highlights of the varying levels of difficulty people in our sample experienced in different aspects of health literacy and decision-making:

1. *Difficulty in Obtaining Professional Help:* 51.7% of respondents found it "difficult" to get professional help when unwell, while 30% found it "easy";
2. *Understanding Medical Emergencies:* 57.1% of respondents found it "difficult" to understand what to do in a medical emergency, whereas 23.6% found it "easy";
3. *Evaluating Treatment Options:* 59.9% of respondents found it "difficult" and 17.3% "very difficult" to evaluate the advantages and disadvantages of different treatment options;
4. *Following Medical Instructions:* 72.2% of respondents found it "easy" to follow the doctor's or pharmacist's instructions, with 19.6% finding it "Very easy";
5. *Managing Mental Health Information:* 48.6% of respondents found it "difficult" to find information on managing mental health problems like stress or depression, and 21.6% found it "very difficult";
6. *Understanding Screenings Importance:* 44.3% of respondents found it "easy" to understand why health screenings are necessary, and 34.1% found it "very easy";
7. *Evaluating Health Warnings:* 44.6% of respondents found it "easy" to evaluate the reliability of health warnings, and 35.2% found it "very easy";
8. *Deciding on Disease Prevention based on Media Info:* Opinions were mixed, with 41.8% finding it "difficult" and 36.1% finding it "easy" to decide how to protect themselves from diseases based on media information;
9. *Understanding Health Advice from Family/Friends:* 53.1% found it "easy" to understand health advice from family or friends, while 23.6% found it "difficult";
10. *Finding Information on Healthy Activities:* 54.3% found it "easy" to find information on healthy activities like exercise and healthy eating, and 29.8% found it "very easy";
11. *Evaluating Living Conditions:* 50.9% found it "easy" to evaluate how their living conditions help them stay healthy, followed by 20.2% who found it "very easy". Meanwhile, 21% found it "difficult," and 6.5% found it "very difficult";
12. *Making Decisions to Improve Health:* the sample was divided, with 41.8% finding it "difficult" and 8% finding it "very difficult" to make decisions to improve their health, while 37.2% found it "easy" and 12.2% found it "very easy".

Network

The network consisted of 12 nodes and 18 non-zero edges, resulting in a sparsity of 0.727.

Tab. I. Participants' demographic characteristics.

N. participant	Female	Percentage	Male	Percentage	
352	275	78%	77	22%	
Education level					Total
Middle School Diploma	25	9%	6	8%	9%
High School Diploma	111	41%	34	44%	41%
University Degree	139	50%	37	48%	50%

Tab. II. Weights matrix. Correspondence between HLQ-47 original items and acronyms used for the network analysis (NA).

Items HLQ-47	Items NA	HC1	HC2	HC3	HC4	DP5	DP6	DP7	DP8	HP9	HP10	HP11	HP12
HL-4	HC1	0.000	0.850	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
HL-7	HC2	0.850	0.000	1.174	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.463
HL-10	HC3	0.000	1.174	0.000	0.000	0.751	0.000	0.000	0.479	0.000	0.000	0.000	0.000
HL-8	HC4	0.000	0.000	0.000	0.000	0.000	0.000	0.488	0.000	0.000	0.000	0.000	0.000
HL-18	DP5	0.000	0.000	0.751	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
HL-23	DP6	0.000	0.000	0.000	0.000	0.000	0.000	1.184	0.286	0.000	0.000	0.000	0.541
HL-24	DP7	0.000	0.000	0.000	0.488	0.000	1.184	0.000	0.000	0.811	0.596	0.247	0.000
HL-31	DP8	0.000	0.000	0.479	0.000	0.000	0.286	0.000	0.000	0.911	0.275	0.399	0.000
HL-32	HP9	0.000	0.000	0.000	0.000	0.000	0.000	0.811	0.911	0.000	0.000	0.000	0.444
HL-37	HP10	0.000	0.000	0.000	0.000	0.000	0.000	0.596	0.275	0.000	0.000	0.000	0.440
HL-42	HP11	0.000	0.000	0.000	0.000	0.000	0.000	0.247	0.399	0.000	0.000	0.000	1.025
HL-44	HP12	0.000	0.463	0.000	0.000	0.000	0.541	0.000	0.000	0.444	0.440	1.025	0.000

Tab. III. Centrality measures per item. Correspondence between HLQ-47 original items and acronyms used for the network analysis (NA).

Items HLQ-47	Items NA	Betweenness	Closeness	Strength	Expected influence
HL-4	HC1	-0.980	-1.066	-1.169	-1.169
HL-7	HC2	1.346	0.390	0.665	0.665
HL-10	HC3	0.829	0.048	0.571	0.571
HL-8	HC4	-0.980	-1.683	-1.575	-1.575
HL-18	DP5	-0.980	-1.396	-1.281	-1.281
HL-23	DP6	0.054	0.208	0.130	0.130
HL-24	DP7	0.829	0.581	1.605	1.605
HL-31	DP8	0.054	1.062	0.511	0.511
HL-32	HP9	0.054	0.906	0.306	0.306
HL-37	HP10	-0.980	-0.422	-0.654	-0.654
HL-42	HP11	-0.980	-0.174	-0.249	-0.249
HL-44	HP12	1.734	1.545	1.142	1.142

Weights Matrix

The weights matrix, shown in Table II, indicates the strength of the connections between the variables. Notable connections include HC2-HC3 (1.174), DP6-DP7 (1.184), and HP11-HP12 (1.025).

Centrality Measures

The centrality measures for each variable are summarized in Table III and Figure 1. DP7 and HP12 items exhibited the highest strength values, indicating their significant influence within the network. HC2 and HP12 items had the highest betweenness and closeness centrality, followed by HC3 and DP7, and can be considered key nodes. Furthermore, HC2 and HP12 features suggest they can be considered as bridge nodes, connecting different parts of the network. Variables such as HC1, HC4, and DP5 showed negative values across multiple centrality measures, indicating their lesser influence and potential peripheral roles in the network.

Network plot

The visual representation of the network provides a depiction of the relationships between the items in HLS19-Q12 in our sample (Fig. 2). The edges between nodes vary in thickness, representing the strength of the connections. Strong connections (*e.g.*, HC2-HC3) are depicted with thicker lines, indicating robust associations. Examining the network plot, it is possible to visually identify the presence of two or three clusters within the network.

HC: health care; DP: disease prevention; HP: health promotion. HC1 (HL-4, …to find out where to get professional help when you are ill? (Instructions: such as doctor, nurse, pharmacist, psychologist); HC2 (HL-7, … to understand information about what to do in a medical emergency?); HC3 (HL-10, …to judge the advantages and disadvantages of different treatment options?); HC4 (HL-8,…to act on advice from your doctor or pharmacist?); DP5 (HL-18, …to find information on how to handle mental health problems? (Instruction: stress, depression or anxiety); DP6 (HL-23, …to understand information about recommended health screenings or examinations?); DP7 (HL-24, …to judge if information on unhealthy habits, such as smoking, low physical activity or drinking too much alcohol, are reliable?); DP8 (HL-31, …to decide how you can protect yourself from illness using information from the mass media? (Instructions: *e.g.*, Newspapers, TV or Internet); HP9 (HL-32, …to find information on healthy lifestyles such as physical exercise, healthy food or nutrition?); HP10 (HL-37, …to understand advice concerning your health

Fig. 1. Centrality plot.

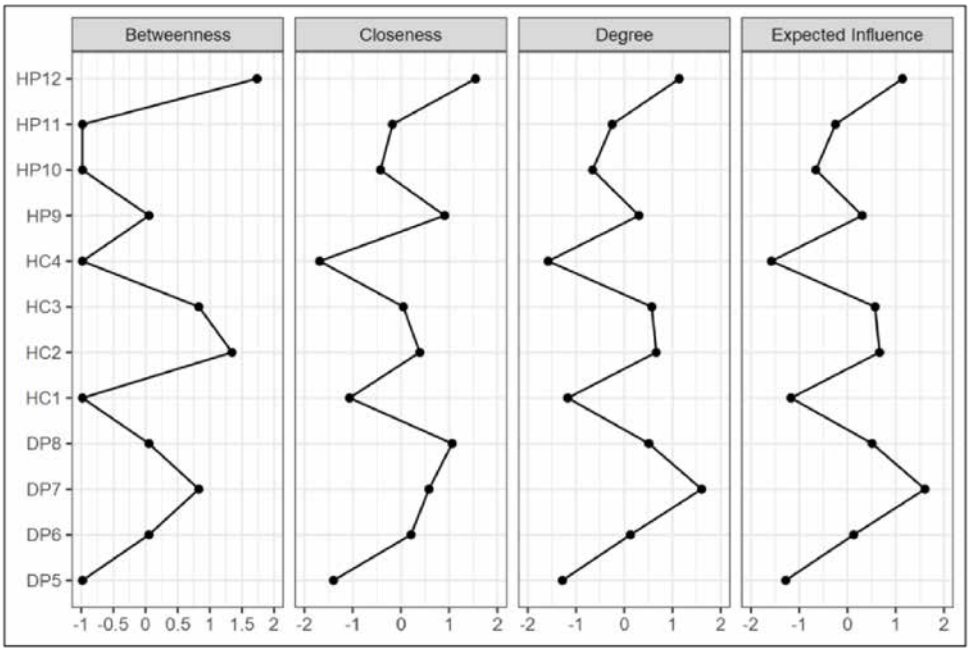
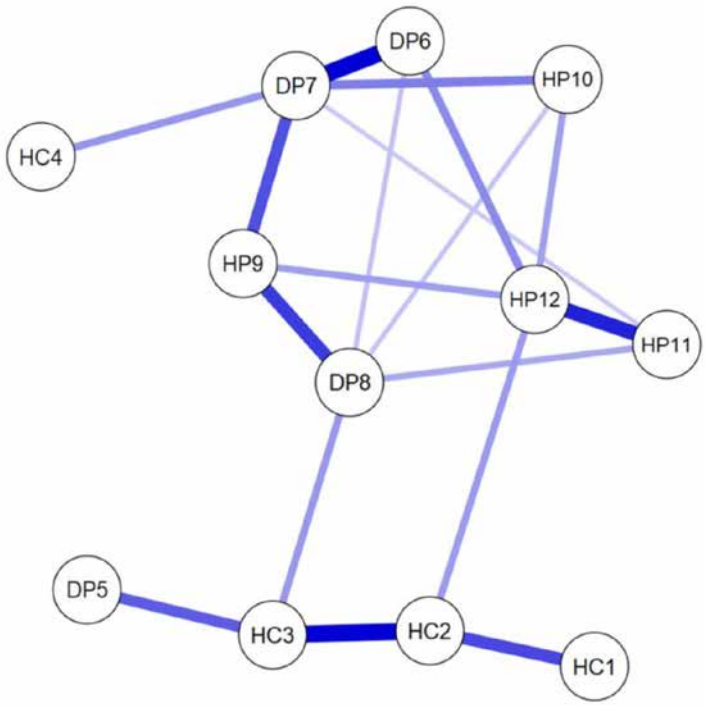


Fig. 2. Network plot.



from family or friends?); HP11 (HL-42, …to judge how your housing conditions may affect your health and well-being?); HP12 (HL-44, …to make decisions to improve your health and well-being?").

The presence of the clusters seems supported by the centrality measures:

Cluster 1) HC1, HC2, HC3, and DP5 appear strongly interconnected, and separated from the other items, with high weights between nodes, particularly between 2HC and 3HC. HC2 is a key bridge node with high betweenness and moderate strength, central to the network. HC3 is significant within the cluster with moderate betweenness and strength. HC1 and DP5 have peripheral roles in the network with negative centrality measures.

Cluster 2) DP6, DP7, DP8, HP9, DP7 and HC4. The item DP7 stands out with high strength and moderate betweenness, indicating its significant influence. DP8 and HP9 are well-connected within the cluster,

particularly through high closeness, although they have lower betweenness and strength. DP6, however, is less central. HC4 is loosely connected with DP7 and has weaker connections compared to other nodes. Its centrality measures indicate HC4 is the least influential in the cluster.

Cluster 3) HP10, HP11, and HP12. This cluster is dominated by HP12, which serves as a key bridge node with the highest betweenness and closeness, highlighting its central role and high influence. In contrast, HP10 and HP11 are more peripheral with negative centrality measures.

While cluster 1 seems to be clearly separated from the other two, with HC2 acting as bridge, clusters 2 and 3 seem way more interconnected, with HP12 acting as bridge.

Bootstrap Analysis

The results indicate that the network structure is stable, with consistent edge and centrality measures across bootstrap samples. See Supplementary for Figure S1 and Figure S2 about edge stability and centrality stability.

Discussion

The questionnaire responses reveal several important insights about health literacy in Cagliari's metropolitan area. Many people struggle to access professional help when unwell, indicating a need for better healthcare accessibility and awareness. Public education on emergency procedures is also necessary, as many find it challenging to know what to do in a medical emergency. There is a significant gap in understanding treatment options and health warnings, highlighting the need for simplified medical information and decision-making support tools. Mental health resources and awareness need improvement, as many have difficulty finding information on managing stress and depression. Public health campaigns on preventive care, such as health screenings, are somewhat effective, but continued efforts are needed. Media literacy is crucial, as mixed responses on disease prevention based on media information suggest. Social support networks play a vital role in health decision-making, with many participants finding health advice from family and friends easy to understand. Public health messages on healthy activities like exercise and healthy eating are reaching people effectively, supporting public health. Awareness of the impact of living conditions on health can be leveraged to promote healthier environments. Finally, the division in responses about making health decisions indicates a need for more personalized decision-making support tools and resources. Providing tools and resources that help individuals weigh their options and make informed choices can improve health outcomes.

Overall, these findings suggest the need for targeted interventions to improve health literacy, accessibility to healthcare, mental health support, and public education on emergency preparedness and media literacy. By addressing these areas, we can help people feel more secure and capable in managing their health and well-being.

The network analysis of the HLS-EU-Q12 items using the Ising Fit method has provided valuable insights into the structure and interrelationships of health literacy components within our sample. The identification of three distinct clusters, each roughly corresponding to the three areas of health literacy according to Sorensen, highlights the multifaceted nature of health literacy and its various dimensions. The healthcare cluster was clearly distinct from the other two clusters and lost item 4HC (following medical instructions), which in turn was loosely connected with the disease prevention cluster. Notably, healthcare cluster included an item traditionally related to disease prevention (5DP) about managing mental health information. Participants seem to consider mental health not as a condition to be preserved with prevention but more as an active problem to be solved when is not good, hence the shift of 5DP to disease prevention cluster. In our opinion, this could be closely related to the cultural Italian context and the approach of politics and healthcare to mental health. The centrality of items such as HC2 (understanding medical emergencies) suggests that these aspects are pivotal for individuals to effectively manage their health. The strong connections within this cluster suggest that improving healthcare literacy could have a significant impact on individuals' ability to access and utilize healthcare services effectively. The disease prevention and health promotion clusters were more interconnected, although their internal structures remained identifiable. We wondered if the overlapping may be linked to the focus of health promotion items on practical aspects (*e.g.,* individual/family management) rather than on broader community and political aspects. The disease prevention cluster encompassed items related to evaluating health warnings and understanding disease prevention measures. The central role of DP7 (evaluating health warnings) within this cluster suggests, again, that the ability to critically assess health information is crucial for making informed decisions about disease prevention. The health promotion cluster, dominated by items related to making decisions to improve health and evaluating living conditions, emphasizes the role of personal empowerment and environmental factors in health literacy. The prominence of HP12 (making decisions to improve health) indicates that health promotion is a key component of health literacy, reflecting the need for individuals to be empowered to make informed health decisions and take proactive steps to improve their well-being. This is in line with its clear inspiration to the Ottawa Charter.

All findings align with the broader understanding that health literacy involves not only the ability to access information but also the capacity to evaluate and apply it in practical contexts and seems to have a lot to do with empowerment. From this perspective, it seems very interesting that "making decisions to improve health (HP12)" is the most prominent item. HP12 represents

a key node and a bridge between clusters, posing health promotion in the position of acting as a glue between the other aspects of health literacy. Skills and behaviors interact with each other, and it is important to identify the key ones that drive the system. In health promotion, we do not think of a measure that completely changes the world, but rather actions that shift the balance and readjust the system. We found that the network model of our analysis depicts the complexity and fine balance of the interactions between all the aspects of health literacy and may help us understand where we can apply a little pressure to readjust the system. Interventions should prioritize central and bridge items. By focusing on these key aspects, interventions can enhance individuals' overall health literacy and their ability to navigate the healthcare system, understand health information, and make informed health decisions. Tailored strategies for different clusters may address synergistically different aspects of health literacy.

Limitations

While the network analysis provided valuable insights related to our sample, there are several limitations to consider. The study was conducted on a sample of 352 participants mostly from the metropolitan area of Cagliari, Italy. The composition of the sample was influenced by the willingness of the population reached through dissemination to complete the questionnaire. Students and their friends and relatives were supposedly more interested in participating. Future research should include a larger sample to enhance the generalizability of the findings. The nature of the study limits the ability to draw causal inferences. We should also consider that the use of the HLS-EU-Q12 short form, while practical, may not capture the full complexity of health literacy.

Conclusion and future steps

The network analysis using the Ising Fit method provided a nuanced understanding of the relationships among health literacy items in our sample, and valuable information about the central items. The network analysis seems very promising in handling health promotion data, just as it was in analyzing salutogenesis data [19]. Classic epidemiology methods lack in encompass the multi-faceted aspects linked to systems made up by complex relationships between elements, such as SOC and health literacy. Going beyond the cause-effect model, the network analysis returned a comprehensible depiction of a complex system giving due importance to the interactions. The findings from this pilot study may be useful for future research and interventions aimed at improving health literacy. The identification of clusters and key and bridge items in a larger and representative sample might offer insights for designing targeted interventions that might influence the overall balance between the areas composing the complex concept of health literacy. By addressing the specific needs identified and focusing on the items that are more prominent, healthcare professionals and policymakers can enhance health literacy and promote better health outcomes for individuals and communities.

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Ethical approval

Ethical approval for this study was obtained from Territorial Ethical Committee of Sardinia [Comitato Etico Sardegna istituito con Decreto N° 18 del 04/05/2023 dell'Assessorato dell'igiene e sanità e dell'assistenza sociale della Regione autonoma della Sardegna] – Deliberazione N. 560 DEL 16.05.2024.

Conflicts of interest statement

The authors declare no conflicts of interest.

Author's contributions

All the authors made substantial contribution to different aspects of the work: SMP, PC: conceptualization; SMP, SM: writing-original draft; SM: data collection; SMP, PC: investigation, formal analysis: PC, SMP, SM, MF, CS, AM: visualization; PC, SMP, SM, MF, CS, AM: results interpretation, PC: project administrator; MF: validation; PC: resources, supervision; SMP, SM, MF, CS, AM, PC: writing -review and editing.

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Supplementary Materials

Fig. S1. Centrality Plot

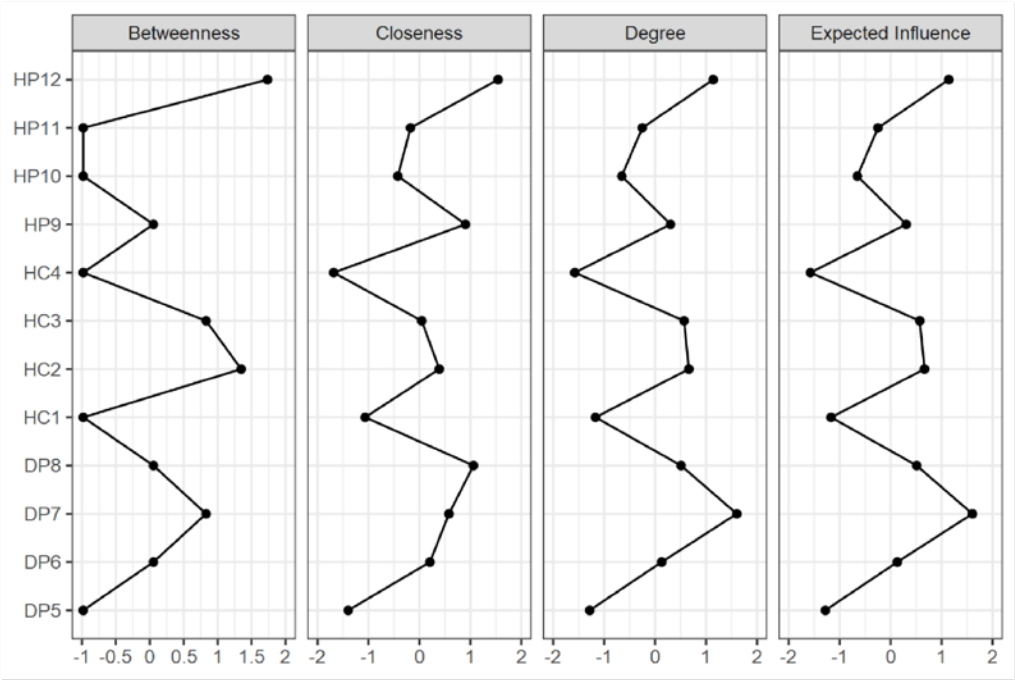
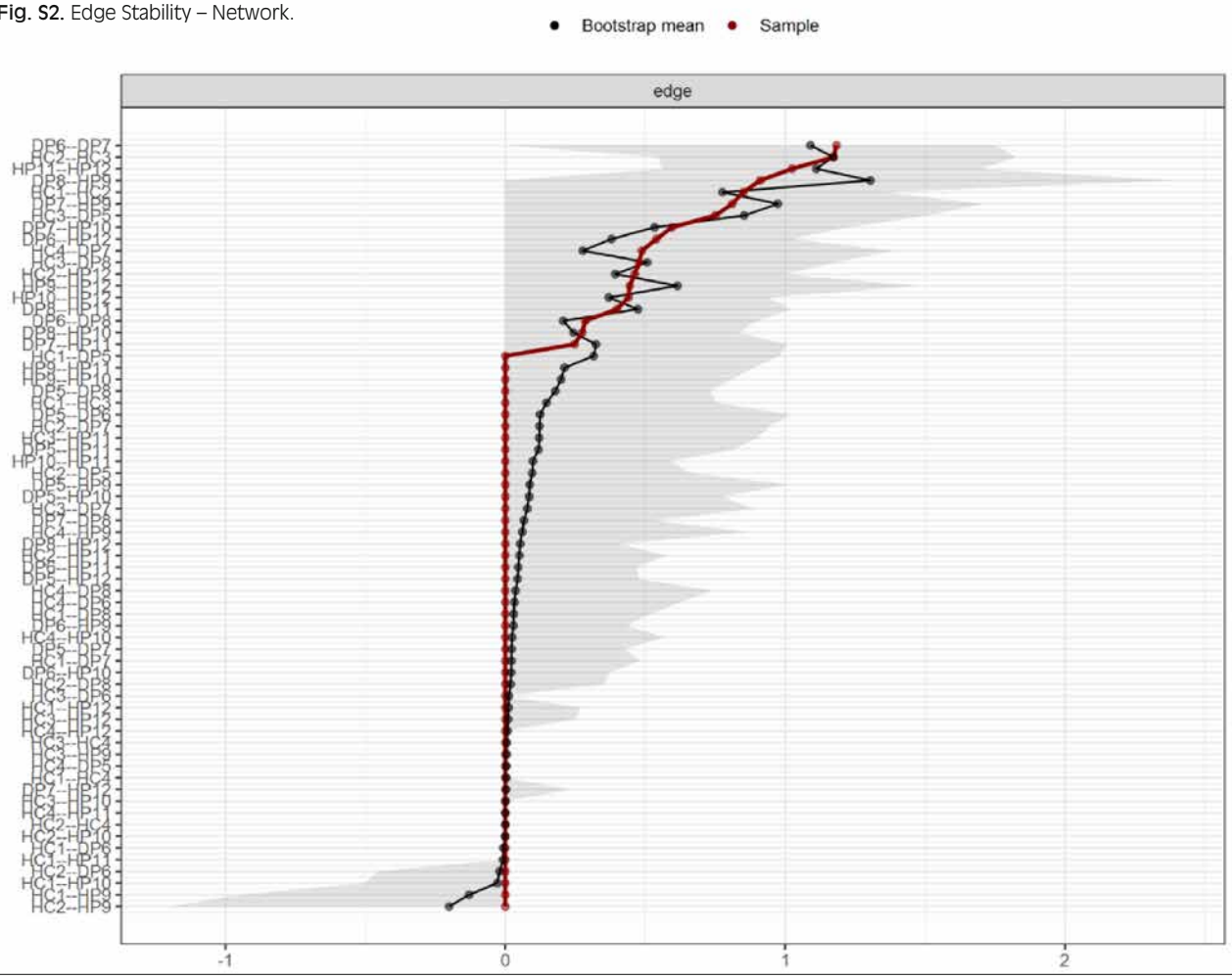


Fig. S2. Edge Stability – Network.



HEALTH PROMOTION

Italian Hygiene and Preventive Medicine Medical Doctor Residents' interest in a Preventive Medicine Physician: a national survey

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Keywords

Preventive medicine • Lifestyle medicine • Public health • Prevention • Prevention physician

Summary

Introduction. *The growing importance of Preventive Medicine is creating a need for specialised professional figures, that are often missing in the actual national and international contexts. This study aimed to assess attitudes, knowledge, and compliance with preventive measures of the Italian physicians specializing in this field, addressing the unrecognized significance of the figure of a prevention expert in Italy and the inadequate training in this Public Health branch.*
Methods. *Between May 1 and May 31, 2023, an online survey was administered to approximately 200 Hygiene and Preventive Medicine Residents (HPMMDR), covering demographic data, health behaviours, training and interests in Preventive Medicine and in undergoing a visit of a "preventive doctor". The collected data were cross-referenced to understand which variables were most related to knowledge and interests in this field. Statistical analyses included parametric tests, hierarchical cluster analysis, and ordered logit regression.*
Results. *Demographically, 57.0% were female, median age 31, with central Italy having the highest representation (52.3%). Analyses revealed associations between demographics, health behaviors, and attitudes. Ordered logit regression showed a significant correlation (OR = 11.3, p = 0.03) between a healthier lifestyle and belief in specialists' usefulness.*
Conclusion. *Despite the lack of recognition and insufficient education, the study unveiled substantial interest and willingness to learn among HPMMDRs in Italy. Findings emphasize the need for recognizing shared priorities and implementing actions for effective Preventive Medicine interventions, guiding future research and policy decisions.*

Introduction

Preventive Medicine, as defined by the American College of Preventive Medicine, is the practice of promoting preventive health care to improve patient well-being, with the ultimate goal of preventing disease, disability, and death [1]. It encompasses a broad range of strategies to reduce the burden of disease by addressing its root causes and risk factors before full-blown illnesses. It shifts the focus from reactive measures to proactive ones, prioritizing prevention over treatment [2].
Examples of Preventive Medicine interventions addressed to small communities or single individuals allowed the collection of evidence of their effectiveness, either for mental health, [3] cardio-vascular diseases [4], diabetes or cancer [5]. Clinical and community-based prevention also has the potential to significantly reduce the economic impact of chronic diseases such as heart disease, cancer, depression, hypertension and type II diabetes [6, 7], and of epidemics, as demonstrated by the recent interventions implemented worldwide to control SARS-CoV-2 spread [7].
The growing importance of Preventive Medicine created a need for specialised professionals. In the field of health and its various determinants, Public Health experts possess the knowledge and insights to formulate policies and programs [8], analysing data, identifying trends, and assessing the potential impact of interventions. Public Health physicians address Public Health crises and promote well-being [9], improving health of communities and environments, striving to diminish diseases and disparities in health [10].
The relationship between individual and population health is often oversimplified, framing them as distinct concepts [11]. However, they are interconnected, and an individual's health is shaped by their life course and environmental factors within the context of a larger society [12]. Unhealthy lifestyle behaviours contribute significantly to the global burden of chronic diseases, resulting in a substantial number of deaths [13]. In recent

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years, there has been a growing interest in examining the advantages of adhering to a "low-risk lifestyle" and ideal "cardiovascular health metrics" [14] but the adoption of such practices remains limited in the population [15].
Moreover, many healthcare workers engage in prevention without clear regulations [16]. Despite the effectiveness of population-level interventions conducted by Prevention Departments of various Italian Local Health Authorities (Azienda Sanitaria Locale, ASL), [17], Public Health education is typically underrepresented in clinical curricula and tends to remain separate from mainstream clinical instruction [18]. Also, many clinicians do not perceive their roles as advocates for Public Health, lacking the required skills [19].
Given the often overlooked role of Preventive Medicine physicians and uncertainty regarding the community's recognition and the areas of maximum benefit [16], we explored the significance of their contributions in prevention at an individual level, fulfilling a role traditionally exclusive to doctors during direct involvement in clinical activities (Riordino Della Disciplina in Materia Sanitaria, a Norma Dell'articolo 1 Della Legge 23 Ottobre 1992, n. 421, 1992). In Italy, resident medical doctors specialising in the Public Health branch are called Hygiene and Preventive Medicine Medical Doctor Residents (HPMMDRs).
This study explores HPMMDRs interest, knowledge, and adherence to preventive measures, as well as the prevalence of prevention-focused activities in their Public Health schools. The findings aim to guide the development of healthcare policies and inform future research in the field.

Methods

Data collection

The study was conducted using a web-based survey on a Google Form and was available for responses from May 1st to May 31st, 2023. Participation in the survey was voluntary and anonymous. Since the data collection for this study aimed to gather insights from HPMMDRs across all regions of Italy, to ensure comprehensive representation, the survey was distributed through the representatives of each Hygiene and Preventive Medicine Residency School (HPMRS) in every region, with the assistance of SItI's *Consulta degli Specializzandi* social networks. The representatives were provided with a direct link to the survey, which they were requested to disseminate among their fellow colleagues using these networks.

Survey development and composition: rapid review of literature

To ensure the accuracy and relevance of our study, a rapid literature review was conducted from January to April 2023 using scientific databases such as PubMed, Web of Science, and Scopus. Grey literature was also explored using Google site search. Specific search strings were formulated for each survey field, with comprehensive strings provided in the supplementary materials.

The questionnaire, consisting of four sections, gathered demographic and medical history data (Section 1), assessed compliance with preventive measures and lifestyle using the Simple Lifestyle Indicator Questionnaire (SLIQ) [20] score in Section 2, examined the perceived importance of Preventive Medicine in Public Health schools (Section 3), and assessed participants' interest in the field (Section 4). The survey included both closed-ended multiple-choice and open-ended questions to capture a comprehensive understanding of respondents' perspectives. Further details on each section are available in the supplementary materials.

SLIQ score

The Simple Lifestyle Indicator Questionnaire (SLIQ) is a tool designed to assess individual lifestyle choices, covering diet, physical activity, sleep, stress management, and substance use. The questionnaire aims to provide a quick evaluation of overall lifestyle, with scores categorized into unhealthy (0-4), intermediate (5-7), and healthy (8-10) lifestyle categories. The total score indicates areas that may need improvement, offering a convenient way to identify and address lifestyle habits.

Exposure variables and outcome

Information about age, gender, living area, internship year, medical history and habits, vaccinations done and vaccine hesitancy were considered as exposure variables, while outcomes were lifestyle (SLIQ score), medical habits; interest, confidence and training received in Preventive Medicine, availability to undergo preventive medicine screenings and impact they are considered to have on health.

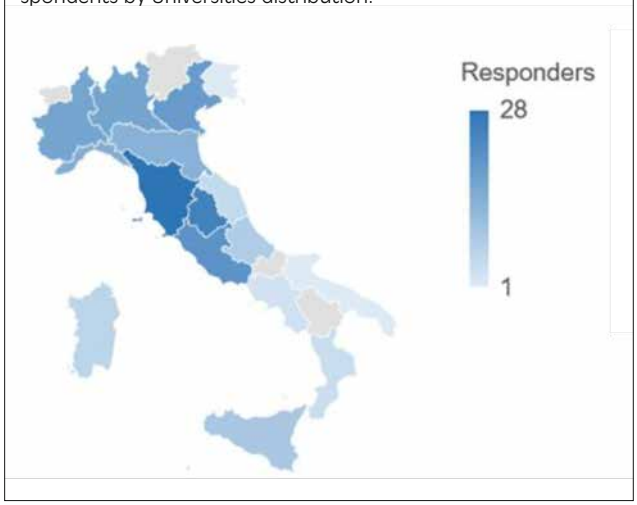
Data collection strategy

After a pretesting phase carried out within the working group to evaluate the questions and the suitability of the variables for statistical analysis, the online questionnaire was published on google web forms disseminated through official and unofficial channels to the hygiene and preventive medicine residents (HPMMDR). The answers collection ended when approximately 200 respondents were reached, which represents approximately 10 percent of the target population, estimated at 2,000 individuals.

Statistical Analysis

A comprehensive statistical analysis used descriptive methods to summarize data. Association analysis employed parametric and non-parametric tests, exploring relationships between variables. The study employed hierarchical cluster analysis to identify patterns in a dataset. Due to the ordered discrete nature of the dependent variable (SLIQ score), ordinary least squares regression was avoided to prevent estimation bias. Instead, an ordered logit model was used to analyze the impact of independent variables on the ordinal categorical dependent variable. Independent variables

Fig. 1. Cartogram representing the regional distribution of respondents by Universities distribution.



included demographics, interest in prevention, training importance, perceived utility of disease prevention, familiarity with risk scores, application of guidelines, and perceived impact on population health. Additionally, a cluster analysis and dendrogram were used to assess distances among responses to "interest on the subject" questions, providing insights into potential groupings based on participants' responses. This dual-method approach aimed to offer a comprehensive understanding of patterns and relationships in the data.

Results

Descriptive analysis

Demographics

A total of 193 HPMMDRs completed the online survey, 57.0% of which identified as female, 40.4% as male and 0.5% as non-binary, whereas 2.1% preferred not to specify their gender. The median age of respondents was 31 years. The majority of respondents attended the second year of internship (36.3%), followed by 3rd year (26.9%), 1st year (24.4%) and 4th year (12.4%), coherently with the total proportion of scholarships funded by the Italian Ministry of University and Research[21]. Although heterogeneously distributed, most respondents attended Central Italy Universities (52.3%), followed by those in Northern Italy (35.8%), Islands (7.8%) and Southern Italy (4.1%) ones (Fig. 1). Most of respondents were originally from Northern or Central Italy (33.2 and 31.6%, respectively), followed by Southern Italy (20.7%), Islands (13.0%) and foreign countries (1.6%) (Fig. 1).

Anamnestic data

Table I shows the anamnestic characteristics of the sample. Most of the respondents reported no previous medical conditions about themselves, but some of them within their families. Around 2/3 of them visited their General Practitioner in the past year and reported receiving two or more non-mandatory vaccination boosters or contracting two or more pathogens for which there is a vaccine (Supplementary Fig. 1) over the past ten years.

SLIQ score

Among the 193 respondents, 48 individuals were classified as having a healthy lifestyle, while 128 fell into the intermediate category. On the other hand, 17 respondents were categorized as having an unhealthy lifestyle.

Universities and Interest in Prevention

University education on prevention showed substantial variability among respondents, with an average score of 3.6 out of 6. 54.4% of the total respondents reported having a personal intermediate level of knowledge on the topic, 19.7% a low one, and 25.9% declared themselves to be well-versed in the subject of prevention. As for the covered topics, the most frequently reported theme is that of infectious diseases, while the least addressed one is alcohol (Supplementary Fig. 2).

The mean interest in prevention and health promotion was 5.17 out of 6. Similar results were reported for the questions "How important do you consider it for a specialist in Hygiene and Preventive Medicine to receive education from their School in concepts and clinical skills

Tab. I. Anamnestic characterisation of the sample.

		N	%
Previous medical condition	0	130	67.4%
	1	45	23.80%
	2+	18	9.30%
Medical conditions of family members	0	36	18.7%
	1	44	22.30%
	2+	113	58.50%
At least one visit by the General Practitioner in the last 5 years	No	68	36.2%
	Yes	120	63.8%
Booster dose of DTaP vaccine (or part of it) in the last 10 years	No	30	3.2%
	Yes	152	16.0%
	Can be	11	1.2%
Volontary vaccines	None	44	24.6%
	Yes	26	14.5%
	Many	109	60.9%
Yearly vaccination against influenza	Never	43	4.5%
	Always	102	10.8%
	Sometimes	48	5.1%
If sometimes, at least once in the last 5 years?	No	33	37.9%
	Yes	54	62.1%
At least one consueling by the travel ambulatory in the last 5 years	No	117	60.6%
	Yes	76	39.4%
Hesitations regarding COVID-19 vaccination	No	177	91.7%
	Yes	16	8.3%

related to prevention?" (5.56 out of 6), "How useful do you consider it for a specialist in Hygiene and Preventive Medicine to be involved in identifying and preventing diseases for which a patient has risk factors?" (5.37 out of 6) and "How useful do you consider it for a specialist in Hygiene and Preventive Medicine to be knowledgeable about and apply risk scores and guidelines dedicated to the prevention of diseases for which a patient has risk factors?" (5.19 out of 6). As for the impact of the general population, the mean score was 4.85 out of 6. Additionally, when questioned "Would you ever seek out a specialist of this kind, if they were affiliated with the National Sanitary System (SSN), to assess your risk and perform targeted screenings?", 71.7% of respondents answered affirmatively, 21.7% "maybe," 6.6% were unwilling to consult this type of health figure. For a specialist not affiliated with the SSN the percentages were 40.8%, 41.3% and 17.9%, respectively. Most respondents (74.6%) suggested a biannual schedule for visits. Almost 91.8% of respondents expressed interest in receiving informational materials on the topic.

Statistical analysis

Major results emerged from the statistical analysis are displayed in Table II. Furthermore, residents living outside Italy showed the median lowest score in both interest in Preventive Medicine and impact considered Preventive Medicine has on health (3 out of 10, vs 5 out of 10 of Northern and Central Italy and 6 out of 10 of Southern Italy and Islands).

Increased vaccination-related variables showed a higher SLIQ score (p = [0.026-0.001]) depending on the variable considered), and more doubts on COVID-19 vaccination.

The sole statistically relevant result of the ordered logit regression was among SLIQ score and "How useful do you consider it for a specialist in Hygiene and Preventive Medicine to be knowledgeable about and apply risk scores and guidelines dedicated to the prevention of diseases for which a patient has risk factors?" (OR = 11.3, p = 0.03). A dendrogram was built to visually discriminate questions categories based on respondents' answers about their interest on "Preventive Medicine Physician". Two main clusters are identifiable in the graph (Fig. 2).

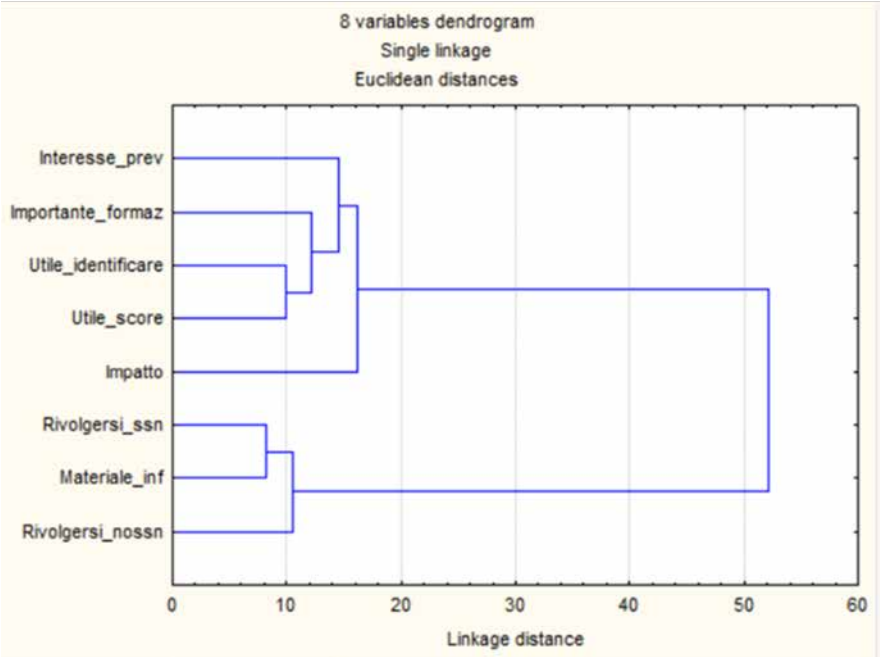
Discussion

Emphasizing the role of surveys in Public Health research [22], particularly in gauging specialists' perspectives, numerous studies have delved into Public Health Residents' interest in prevention, exploring professional goals, profiles, or provided services [23-25]. Our study investigates interest in the "Public Health specialist" role in Italy and its potential correlation with individual lifestyles, acknowledging challenges in recognizing preventive specialists akin to Hygiene Physicians. Despite evidence supporting preventive interventions' effectiveness, global utilization remains low [26-28]. Respondents confirmed limited emphasis by Universities, with around 29% and 50% unable to indicate any prevention interventions planned by their HPMRSs. Additionally, 54.4% and 19.7% respectively indicated intermediate or low levels of knowledge in this field. In 1997, a survey [29] revealed clinicians' underestimation of patient interest in preventive care after general practitioner visits. Assessing patient needs during each visit identified a gap between requests and service delivery, prompting consideration of Clinical

Tab. II. Main associations emerged from the statistical analysis.

Variables		Association/ correlation	p-value
Age	Declared level of education received on prevention	Negative (ρ = -0.151)	p = 0.040
	Availability to undergo targeted screenings affiliated with the SSN	Positive	p = 0.020
Gender	GP visits	Higher in female	p = 0.002
	Interest in Preventive Medicine	Higher in female	p = 0.010
Internship year	SLIQ score	Positive	p = 0.030
Residing in Southern Italy or island regions	Interest in Preventive Medicine	Positive	p = 0.055
	Impact considered Preventive Medicine has on health	Positive	p = 0.008
Being positive for previous medical conditions	Performed a GP visit in the last 5 years	Positive	p = 0.007
	Interest in Preventive Medicine	Positive	p = 0.030
Having performed a GP visit in the last 5 years	Interest in Preventive Medicine	Positive	p = 0.020
Vaccinations undergone	Doubts on Covid-19 vaccination	Negative	p = [0,026-0,001]
	SLIQ Score	Positive	p = [0,014-0.00]
Flu vaccination at least one time in the previous five years	Interest in having a Preventive Medicine counselling outside the SSN	Positive	p = 0.054
Doubts on COVID-19 vaccine	Teaching about prevention	Negative	p = 0.030
	Considering useful the Preventive Medicine physician	Negative	p = 0.020

Fig. 2. Dendrogram of the "interest in the Preventive Medicine Physician" section questions by given interes scores.



Interesse_prev: What is your interest in prevention and health promotion?; Importante_formaz: How important do you consider it for a specialist in Hygiene and Preventive Medicine to receive education from their School in concepts and clinical skills related to prevention?; Utile_identificare: How useful do you consider it for a Specialist in Hygiene and Preventive Medicine to be involved in identifying and preventing diseases for which a patient has risk factors?; Utile_score: How useful do you consider it for a Specialist in Hygiene and Preventive Medicine to be knowledgeable about and apply risk scores and guidelines dedicated to the prevention of diseases for which a patient has risk factors?; Impatto: How much do you believe a professional like this could have an impact on the health of a population?; Rivolgersi_ssn: Would you ever seek out a specialist of this kind, if they were affiliated with the National Health Service, to assess your risk and perform targeted screenings?; Materiale_inf: Would you appreciate having informative materials available on this topic (such as seminars, podcasts, etc.)?; Rivolgersi_nossn: If this specialist were not part of the Public Healthcare system, would you consider seeking their services at least once in your lifetime?

Preventive Medicine to integrate patient care, preventive services, and lifestyle interventions within or beyond established healthcare systems [30]. Our study spotlights HPMMDRs' interest on this topic as well, with a mean reached score for the question "What is your interest in the field of health prevention and promotion" of 5.17 out of 6, confirming what already reported [27].

Furthermore, the adoption of the SLIQ score allowed to investigate any correlations among lifestyle and interest in prevention. Approximately 66% of the survey participants fell into the "Intermediate" category, followed by around 25% of them categorized as "healthy" and 9% as "unhealthy", similarly with previous health specialists data [31] and general population results [20]. Lifestyle related to a high perceived "Importance of Specialist in Public Health and Preventive Medicine's Knowledge and Application of Risk Scores and Guidelines for Disease Prevention for Patients with Risk Factors", ($p = 0.03$) and a weak positive correlation with the perception of the figure's utility. Despite the recognized importance of risk scores [32, 33], their application still faces barriers to diffusion and interpretation, despite focusing on guidelines during medical training to be notably supportive for their further application [34].

Supporting this evidence, a lifestyle medicine curriculum for Preventive Medicine residents, usually results in enhancing residents' personal health habits [35].

Both men and women found the Preventive Medicine Physicians equally beneficial. However, women tended to have a more frequent positive medical history and sought consultations with their General Practitioners (GPs) more often. Previous studies confirm a lower interest in health and less frequent interactions with GPs of men [36], as well as a least pronounced interest in prevention, a higher inclination towards risky health behaviours [37]. Gender disparities in health have been widely investigated in literature. Our homogenous sample might partially mitigate the cultural variable of the matter. Further studies will be needed to investigate this intricate evidence.

Age played a significant role in the willingness to access Preventive Medicine, particularly if funded by the SSN. Younger individuals were more inclined to access it. On the other hand, those who wouldn't access it (21.7% "maybe", 6.6% "unwilling") perceived it as less useful and impactful. Individuals who would seek Preventive Medicine services even fee-based perceived it as highly useful and impactful. This suggests that older age groups might be more interested if cost considerations were not a barrier.

Dendrogram analysis reveals two clusters: one

emphasizing broader themes, societal impact, and the comprehensive role, and the other focusing on individual engagement, preferences for health services, and informational materials. This nuanced segmentation highlights the need for tailored strategies in healthcare policy and research initiatives. Most respondents indicated an intermediate level of knowledge on Preventive Medicine, with an interestingly high number of HPMMDRs reporting their HPMRS not organizing prevention interventions on the general population or students. Individuals who received education on Preventive Medicine, on par with those with silent medical history, tended to consider themselves more knowledgeable about prevention.

HPMMDRs from southern regions and islands showed higher interest in the Preventive Physician figure and its impact. Interestingly, this result might support previous evidence on how populations' dependence on health services might be higher in less-served areas [38]. Italian SSN allows ASL autonomy on prevention programs, resulting in different levels of engagement [39], Older infrastructures, limited professionals hinder preventive interventions [40], with all Regions showing attendance rates below the minimal standards to be in the South and Islands areas [41].

Vaccination-related variables were significantly associated with SLIQ score ($p < 0.001$), indicating greater adherence to vaccinations related to a higher SLIQ score, in line with previous studies [42]. Doubting on vaccines efficacy was associated with receiving less prevention teaching ($p = 0.026$) and considering the Preventive Physician less useful ($p = 0.02$). Data highlighted a link between a positive medical history and attitudes towards vaccination, differently from what similar studies [43] reported. Moreover, those with a positive medical history often had a positive family medical history as well and consulted their GP in the last 5 years. Conversely, those with a positive family medical history tended to have higher vaccination and consultations with Travel Physician rate.

Those who received fewer vaccinations, including boosters and influenza vaccines, expressed more doubts about COVID-19 vaccination, as previously stated in other European studies [44].

Primary Care Specialists play a crucial role in improving health outcomes [45] and trust in healthcare professionals is linked to higher treatment satisfaction and willingness to be treated [46]. COVID-19 pandemic highlighted the importance of active communication between preventive services, primary care providers, and the population [47]. Establishing trust, especially during emergencies, is challenging but essential. Italy's widespread network of GPs played a vital role in promoting COVID-19 vaccination uptake [47], showcasing the impact of physicians' enthusiasm on patients' perceptions of reliability and adherence to therapies [48].

Responses support the significance of acquiring clinical skills in prevention, with the question regarding the importance of Hygiene and Preventive Medicine specialists training in clinical skills receiving the highest average score of 5.6 out of 6. However, a 2022 survey indicated that Public Health physicians encounter difficulties in positioning as Preventive Medicine practitioners [49].

With 92% of respondents expressing interest in informational material on Preventive Medicine, the study suggests the need for ongoing research. It advocates strengthening the identity of Public Health specialists through targeted studies and specialized training for a more impactful contribution to global health systems [50].

Our study offers substantial evidence to support policy decisions, aligning with the emphasis on prevention in Ministerial Decree 77/2022, "New models and standards for Primary Care development in the National Health System" [51] and in the allocation of funds in the National Recovery and Resilience Plan [52].

Strengths and Limitations

This study stands out due to its unique approach, providing a national platform for collaboration among Health Professionals in Preventive Medicine and Medical Doctors in Residency (HPMMDRs). Rigorous survey design, question development, and the application of a validated score ensure reproducibility. The dendrogram distribution confirms internal coherence, and collaboration among health specialists ensures a comprehensive exploration of the subject.

Our study has limitations, including potential participation bias in voluntary surveys and possible selection bias due to online distribution among specific regions. Uneven regional representation may affect generalizability. The survey's length and the need for specific insights may have deterred participation. Additionally, the lack of scientific validation requires further studies for data validation.

Conclusions

Our study reveals a strong interest and willingness to learn, providing a promising foundation for advancing this field in Public Healthcare. The findings emphasize the need to support Preventive Medicine physicians within Public Health services and advocate for the continued development of our "Preventive Medicine Physician" study team. Identifying shared priorities can guide the establishment of standardized objectives, and given the growing recognition of prevention's importance, concrete actions are needed for effective interventions. Further studies are essential to support the development of a robust Preventive Medicine Physician figure.

Ethics approval

Approval for ethical review was not required for this study, as the methods utilized in data collection and analysis ensured the complete anonymity of participants. Furthermore, only aggregated data was presented.

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Consent to participate

Not applicable.

Consent for publication

Not applicable.

Code availability

Not applicable.

Availability of data and material

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Conflicts of interest statement

None.

Authors' contributions

GA: Conceptualization, Methodology, Formal analysis, Investigation, Resources, Data Curation, Writing-Original draft preparation, Writing-Reviewing and Editing, Visualization, Project Administration. AL: Methodology, Resources, Data Curation, Writing - Reviewing and Editing, Visualization. PF: Methodology, Formal analysis, Investigation, Writing-Reviewing and Editing. EL: Resources, Writing-Reviewing and Editing, Visualization. GG: Writing-Reviewing and Editing, Visualization. EL: Writing-Reviewing and Editing, Visualization. MU: Investigation, Writing-Reviewing and Editing, Visualization, Supervision, Project Administration. MCN: Validation, Writing-Reviewing and Editing, Visualization, Supervision, Project Administration.

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Supplementary Materials

Work group

Our work group, established with the aim to precisely define the professional profile of the Preventive Medicine physician, consisted of HPMMDRs and was part of the Italian HPMMDRs network, named Medical Residents' Council (Consulta degli Specializzandi), which is a branch of the Italian Society of Hygiene, Preventive Medicine and Public Health (Società Italiana di Igiene, Medicina Preventiva e Sanità Pubblica, SItI).

Search strings

- Section 2: ("survey" OR "questionnaire") AND (("health behaviours" OR "preventive behaviours") OR ("routine visits" OR "doctor visits") OR ("vaccination history" OR "vaccine compliance" OR "booster doses" OR "vaccine boosters" OR "optional vaccines" OR "recommended vaccines" OR "influenza vaccination" OR "flu shot") OR ("Travel Medicine clinics" OR "travel vaccination")).
- Section 3: ("Preventive Medicine" OR "preventive care" OR "health promotion" OR "public health") AND ("community-oriented" OR "community-based" OR "community health initiatives") AND ("training" OR "education" OR "clinical skills") AND ("Preventive Medicine" OR "hygiene") AND ("education" OR "training" OR "learning" OR "lessons").
- Section 4: ("survey" OR "questionnaire" OR "study") AND ("perspectives" OR "views" OR "attitudes" OR "interests") AND ("training" OR "knowledge" OR "education") AND ("health specialists" OR "health experts" OR "health professionals" OR "interns" OR "medical residents" OR "resident medical practitioner*") AND ("population health" OR "public health").

Survey development and composition

Demographics and Medical History

The survey collected demographic variables, including age, gender, attended Public Health school, internship year, place of origin, personal medical history, and family medical history. These variables provided insights into the characteristics and backgrounds of the participants.

Interest, Knowledge, and Compliance of Medical Residents

The second section focused on HPMMDRs' health behaviours and vaccination history. It gathered information on routine doctor visits, booster doses for vaccines, compliance with optional and recommended vaccines, annual influenza vaccination, travel medicine consultations, and the use of the SLIQ score for lifestyle assessment. These questions highlighted engagement of participants with preventive measures and health promotion.

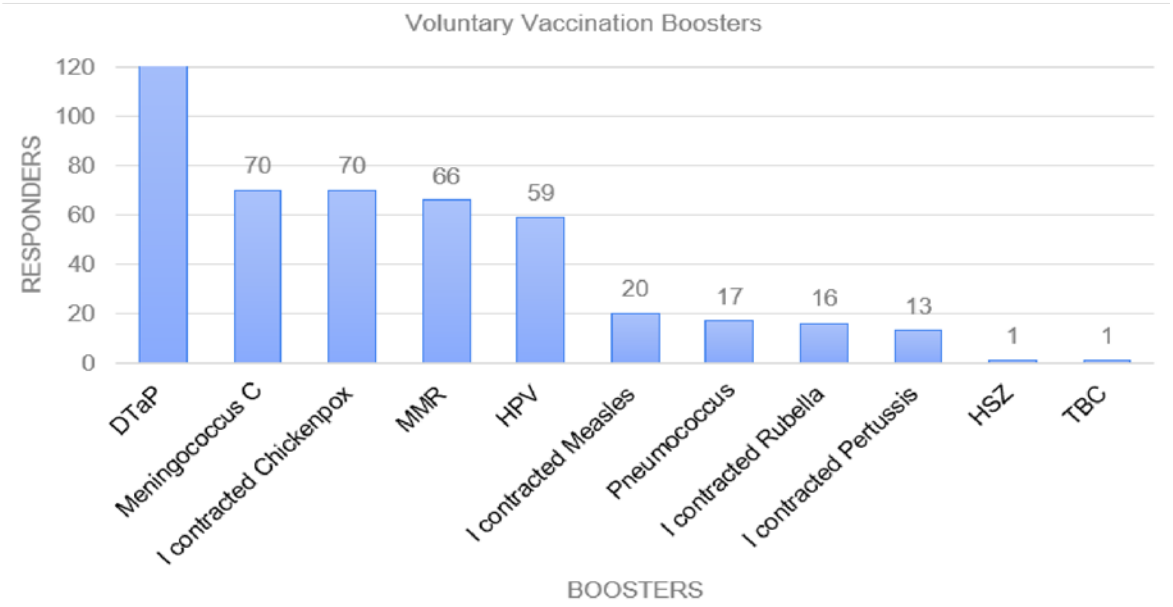
Hygiene and Preventive Medicine Residency Schools' Prevention Interventions

This part explored the preventive and health promotion activities of participants' HPMRSs. It inquired about community-oriented and HPMMDRs-focused initiatives, training on Preventive Medicine, education on prevention-related concepts, and clinical skills for Hygiene and Preventive Medicine specialized physicians. The questions aimed to understand the scope and significance of Preventive Medicine education provided by the universities.

Level of Interest in Preventive Medicine

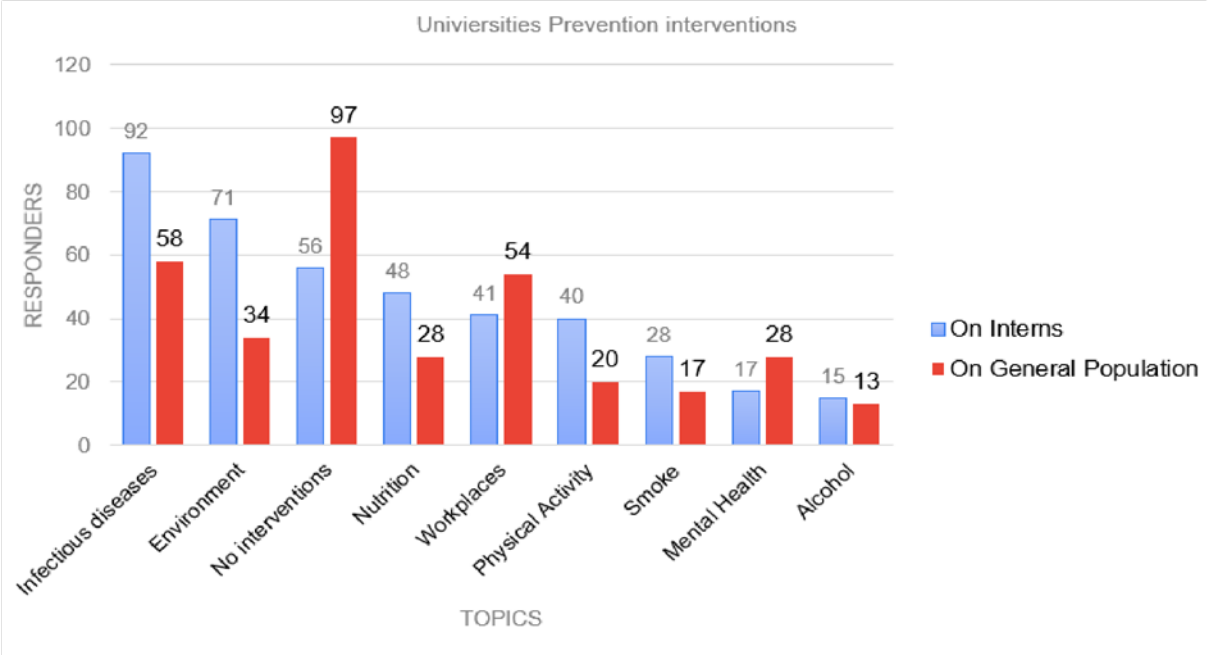
The last section examined HPMMDRs' interest in Preventive Medicine and their perspectives on physicians in Hygiene and Preventive Medicine. It covered self-perceived training, the importance of education, the usefulness of specialists in disease identification and prevention, willingness to seek out specialists within or outside the National Health Service (*Servizio Sanitario Nazionale,* SSN), and the impact of these specialists on population health. The section also addressed participants' interest in accessing informative materials on Preventive Medicine.

Fig. S1. Bar graph illustrating the number of voluntary booster vaccinations administered to the respondents.



DTaP: Diphtheria, Tetanus, and Pertussis; MMR: Measles, Mumps, and Rubella; HPV: Human Papillomavirus; HSZ: Herpes Zoster; TBC: Tuberculosis.

Fig. S2. Bar graph depicting the primary preventive measures implemented for university students and the general population within Italian Universities.



HEALTH PROMOTION

Identification of Community Vaccine Hesitancy: A Descriptive-Cross-Sectional Study

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Keywords

Vaccine • Vaccine hesitancy • Cross-sectional studies • Public health

Summary

Background. *Vaccine hesitancy has become one of the ten global health challenges to be addressed, given its increasing global prevalence.*
Aim. *This study aimed to identify community vaccine hesitancy and the factors influencing vaccine hesitancy in a provincial center.*
Methods. *This descriptive cross-sectional research was conducted with 215 adults seeking care at a family health center for any reason. The data collection instruments included the Descriptive Characteristics Questionnaire and the Vaccine Hesitancy Scale. Determinants of vaccine hesitancy were examined through multiple regression analysis (enter model). The STROBE (cross-sectional research model) guidelines were employed for reporting research data.*
Results. *Among participants, 35.3% had a bachelor's degree or higher, 62.3% were employed, and 76.7% had children. 71.2% of the participants had not received education about vaccines, with only 45.6% considering all vaccines necessary and beneficial. Additionally, 16.2% of the participants with children were identified as having under-vaccinated children. Belief in the necessity and benefits of all vaccines (β = -0.245, 95% CI: -4.715 to -1.453), belief in making vaccination mandatory (β = -0.137, 95% CI: -4.873 to -0.083), receiving the COVID-19 vaccine (β = -0.169, 95% CI: -5.925 to -0.947), and receiving the flu vaccine (β = -0.158, 95% CI: -3.828 to -0.429) were determined to be protective against vaccine hesitancy. These variables explained 24.3% of vaccine hesitancy.*
Conclusions. *The assessment revealed that the community exhibited moderate vaccine hesitancy and did not perceive all vaccines as necessary and beneficial. Considering the impact of vaccines on preventing infectious diseases, reducing disabilities, and preventing deaths, it is recommended to provide information about the seriousness of the diseases prevented by vaccines and the importance of vaccines.*

Introduction

One of the most critical public health practices among primary preventive measures for preserving health, promoting its enhancement, and preventing infectious diseases is vaccination. It is estimated that vaccination prevents 3.5-5 million deaths annually [1]. Despite the recognized significance of vaccination in curbing infectious diseases, global vaccine hesitancy has been on the rise in recent years, leading to a decline in immunization rates. The increase in vaccine hesitancy and the decrease in immunization rates have resulted in a surge in infectious disease cases in many countries, such as the United States, the United Kingdom, Egypt, and India, with notifications of various epidemic diseases, particularly measles [2-6].
In response to the global increase in vaccine hesitancy, the World Health Organization (WHO) established the Strategic Advisory Group of Experts on Immunization (SAGE) [7]. Addressing vaccine hesitancy has been recognized as one of the ten global health challenges [8]. Concerns have been raised that if the current pace of increase in vaccine hesitancy continues, immunization rates may fall below critical levels within the next five years, leading to the resurgence of infectious diseases and potential epidemics and deaths [9]. Recognizing the potential implications of vaccine hesitancy on significant public health issues, SAGE has emphasized the need for further research in this area [10].
Vaccine hesitancy can be influenced by diverse factors, including the level of knowledge and awareness about vaccines, past vaccination experiences, the influence of prominent community figures, the activities of anti-vaccine advocates, and accessibility to healthcare [10]. Notably, in contemporary times, a significant number of individuals have limited exposure to vaccine-preventable infectious diseases, and they focus more on the potential side effects and safety risks of vaccines rather than the severity of vaccine-preventable diseases [11]. The increased use of the internet as a primary source of information has facilitated the rapid spread of 'vaccine injury claims' worldwide, causing vaccine hesitancy and refusals within communities. Moreover, the promotion and marketing of traditional and alternative medicine products such as cupping therapy, acupuncture, honey, pollen, royal jelly, and organic products instead of vaccines have become more widespread, further causing the rise in vaccine hesitancy [12, 13].
In Turkey, similar to the global trend, vaccine hesitancy and refusals are on the rise [14]. Specifically, the

percentage of children who have received all their vaccines has decreased to 67%, and only 50% of 24-35-month-old children have been vaccinated appropriately since 2013 [14]. Examining vaccine hesitancy and its reasons is crucial for preventing infectious and epidemic diseases and safeguarding public health [15]. In the context of this study, it is deemed essential to explore the community's perspectives on vaccination and vaccine hesitancy. A review of relevant literature on vaccine hesitancy in Turkey reveals a predominant focus on investigating parental vaccine hesitancy [15-17]. However, there is a notable dearth of research addressing community-based vaccine hesitancy and identifying its associated risk factors [18], highlighting a significant gap in the existing literature.

Given this background, the primary objective of this study is to assess vaccine hesitancy in a provincial center in Turkey and ascertain its influencing factors, thereby contributing to the existing literature. The research sought answers to the following questions:

1. What is the prevailing community perception regarding vaccination?
2. What is the level of vaccine hesitancy in the community?
3. What are the factors influencing vaccine hesitancy in the community?

Methods

Purpose and Study Design

This research was designed as a descriptive cross-sectional study to determine vaccine hesitancy and the influencing factors among the community in a provincial center in Turkey. The STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines were used in the presentation of the research data [19].

Study Setting and Participants

The population of the study consisted of individuals aged 18 and above residing in the provincial center of Artvin, Turkey. The reason for conducting the study in Artvin was the absence of prior research on vaccine hesitancy in this region, highlighting a gap in the existing literature. The research was conducted at a primary healthcare center frequently utilized by the community for their healthcare needs. During the research process, adults seeking services at the primary healthcare center for any reason were invited to participate, and the research was concluded with the inclusion of 215 adults. For data analysis, multiple regression analysis was utilized. The literature suggests that 10-20 data points are necessary for each independent variable in multiple regression analysis [20]. Consequently, the sample size in this study is considered adequate for conducting the analyses.

Data Collection Tools

The research data were collected using the Descriptive Characteristics Questionnaire and the Vaccine Hesitancy Scale.

Descriptive Characteristics Questionnaire

Prepared by reviewing the literature [15-22], this questionnaire consists of three sections: a) Sociodemographic Information Section, b) Childhood Vaccination Section, and c) Individual Vaccination Practices and Thoughts on Vaccines Section. The Sociodemographic Information Section includes 8 questions on some characteristics of the participants such as age, gender, marital status, and employment status. The Childhood Vaccination Section comprises 12 questions investigating parents' administration of childhood vaccinations and specific vaccines for their children. The Individual Vaccination Practices and Thoughts on Vaccines Section includes 12 questions assessing participants' education on vaccines, the most frequently used source of information about vaccines, following vaccine-related content on social media platforms, receiving vaccinations for COVID-19, Hepatitis A, tetanus, and influenza, as well as thoughts on vaccine benefits and administration.

Vaccine Hesitancy Scale

The scale is a measurement tool developed by the SAGE working group to determine parental vaccine hesitancy regarding childhood vaccinations. It has undergone validity and reliability studies by Shapiro et al. (2018) [23]. The scale, adapted by Luyten et al. (2019) to assess hesitancy towards all vaccines in the community, has been validated for Turkish culture by Yılmaz et al. (2021). The Turkish version of the scale is reported to be a valid and reliable measurement tool for identifying vaccine hesitancy in the community. The scale consists of a total of 9 items rated on a five-point Likert scale (1: strongly disagree, 5: strongly agree). There is no cut-off point for the scale, and the total score ranges from 9 to 45. An increase in the total score on the scale indicates a decrease in vaccine hesitancy. The Cronbach's Alpha for the scale was reported as 0.874 [22]. In this study, the Cronbach's Alpha was calculated as 0.835.

Data Collection Procedure and Inclusion Criteria

The data were collected by the researchers between June 1, 2023, and September 30, 2023. Adults aged 18 and above, seeking services at the family health center for any purpose, were informed about the research theme and procedures, and subsequently, they were invited to take part in the study. Those adults who willingly volunteered to participate were provided with the data collection instruments and subsequently incorporated into the research. The response time for completing the data collection tools was 4-5 minutes, and the research data were collected after obtaining ethical committee and institutional approval.

Data Analysis

The research data were analyzed using the Statistical Package for Social Sciences (SPSS) 25.0 software. Descriptive statistics, including number and percentages,

Tab. I. Sociodemographic characteristics of the participants (n: 215)..

Characteristics	Number	Percentage	Characteristics	Number	Percentage
Level of Education			**Place of residence**		
Primary or middle school	76	35.5	City	170	79.1
High school	63	29.3	Town	31	14.4
Bachelor's degree or above	76	35.3	Village	14	6.5
Perceived income			**Presence of social security**		
Income lower than expenses	35	24.2	Yes	178	82.8
Income equal to expenses	124	57.7	No	37	17.2
Income higher than expenses	39	18.1			
Family type			**Experiencing difficulty in accessing healthcare services**		
Nuclear family	174	80.9	Yes	24	11.2
Extended family	28	13.0	No	191	88.8
Single-parent family	13	6.0			
Employment status			**Presence of children**		
Yes	134	62.3	Yes	166	77.2
No	81	37.7	No	49	22.8

Tab. II. Childhood Vaccination Practices of Parents (n: 166).

Characteristics	Number	Percentage	Characteristics	Number	Percentage
Incomplete Vaccination			**CPV**		
Yes	27	16.3	Yes	146	88.0
No	139	83.7	No	20	12.0
Vaccination card			**MMR vaccine**		
Present	86	51.8	Yes	162	97.6
Not present/lost	80	48.2	No	4	2.4
Special vaccination			**Oral polio vaccine**		
Yes	53	31.9	Yes	152	91.6
No	113	68.1	No	14	8.4
Hepatitis B vaccine			**Tetanus vaccine**		
Yes	155	93.4	Yes	159	96.4
No	11	6.6	No	6	3.6
BCG vaccine			**Hepatitis A vaccine**		
Yes	163	98.2	Yes	157	94.6
No	3	1.8	No	9	5.4
Pentavalent vaccine			**Chickenpox Vaccine**		
Yes	147	91.6	Yes	160	96.4
No	18	8.4	No	6	3.6

BCG: Tuberculosis vaccine, CPV: Conjugate pneumococcal vaccine, MMR: Measles, mumps, rubella vaccine.

were utilized for the evaluation of descriptive data. The distribution of the total scores of the Vaccine Hesitancy Scale was assessed using the Kolmogorov-Smirnov test, and it was determined that the assumptions of normal distribution for the dataset were met, allowing for the use of parametric tests. Multiple regression analysis (enter method) was employed to examine the determinants of vaccine hesitancy. Categorical variables included in the model were transformed into dummy variables (with zero as the reference), and protective factors for vaccine hesitancy were investigated. There were no missing data in the research, and no data imputation methods were employed. A significance level of $p < 0.05$ was considered in the interpretation of all analysis results.

Ethical Considerations

Prior to the research, ethical committee approval (Number: E-18457941-050.99-68822, Date: 01.11.2022) and institutional approval (Number: E-17720518-514.01.02-216530312, Date: 29.05.2023) were obtained. Before initiating the study, participants were informed about the research and its content, and their consent was obtained. This research was conducted in accordance with the principles of the Helsinki Declaration.

Results

Of the participants, 35.3% have a bachelor's degree or higher, 62.3% are employed, and 76.7% have children (Tab. I). The average age of the participants is 41.7 ± 12.4 (Min: 19, Max: 71), and the average number of children is 2.5 ± 1.6 (Min: 1, Max: 5).

Regarding the immunization status of the participants' children, it was found that 16.3% of the children were incompletely vaccinated, 48.2% did not have a vaccination card, and 31.9% had received special vaccinations for their children (Tab. II).

The analysis of the participants' vaccine knowledge and certain vaccination practices revealed that 71.2% had not received any education about vaccines, 33% acquired vaccine information from social media, and

Tab. III. Participants' Sources of Vaccine Information, Thoughts on Vaccines, and Certain Vaccination Practices (n: 215).

Characteristics	Number	Percentage	Characteristics	Number	Percentage
Receiving Vaccine Education			**Willingness to Receive Vaccine Education**		
Yes	62	28.8	Yes	128	59.5
No	153	71.2	No	87	40.5
Obtaining Vaccine Information from Social Media			**Following the Official Accounts of Public Institutions on Social Media**		
Yes	71	33.0	Yes	79	36.7
No	144	67.0	No	136	63.3
Receiving Vaccine Information from Primary Healthcare			**Vaccine Information Source**		
			Doctors and Nurses	100	46.5
Yes	158	73.5	WHO and Ministry of Health	33	15.3
No	57	26.5	Internet and Social Media	46	21.4
			Newspaper, Magazine, TV	36	16.7
Tetanus vaccine			**Flu vaccine**		
Yes	167	77.7	Yes	69	32.1
No	48	22.3	No	146	67.9
Hepatitis A vaccine			**COVID-19 vaccine**		
Yes	111	51.6	Yes	192	89.3
No	104	48.4	No	23	10.7
Thoughts on vaccines			**Thoughts on Mandatory Vaccine Administration**		
All beneficial and necessary	98	45.6			
Beneficial but not necessary	100	46.5	Should be mandatory	185	86.0
Not beneficial and not necessary	7	3.3	Should be optional	30	14.0
I have no opinion	10	4.7			

46.5% considered healthcare professionals, particularly doctors and nurses, as their primary source of vaccine information. Furthermore, 77.7% of participants received tetanus vaccination, and 32.1% were administered influenza vaccination. Regarding vaccine attitudes, only 45.6% believed that all vaccines were necessary and beneficial, while 86% expressed the view that vaccine administration should be a mandatory practice (Tab. III). The participants' mean score on the Vaccine Hesitancy Scale (VHS) was determined to be 30.6 ± 6.3. The determinants of vaccine hesitancy were explored through multiple regression analysis. The belief that all vaccines are necessary and beneficial (β = -0.245) contributed to a decrease of 3.0 points. Additionally, the belief that vaccine administration should be mandatory (β = -0.137) led to a reduction of 2.4 points. Receiving the COVID-19 vaccine (β = -0.169) resulted in a decrease of 3.4 points while receiving the flu vaccine (β = -0.158) contributed to a reduction of 2.1 points. Overall, these factors resulted in a lower total scale score. The model explains 24.3% of the variance in vaccine hesitancy (Tab. IV).

Discussion

Vaccines stand as one of the most effective public health interventions, contributing to numerous successes in the history of medicine. Despite the multitude of achievements attributed to vaccines, coupled with statistically validated outcomes, there is a growing global trend of vaccine hesitancy, resulting in a reduction in vaccination rates [6]. Recognizing that vaccine hesitancy and refusals can result in significant public health issues, the Strategic Advisory Group of Experts on Immunization (SAGE) emphasizes the importance and necessity of further research on the subject [10].

This research, conducted in an urban center, aimed to investigate the community's perspectives on vaccines, vaccine hesitancy, and the factors influencing them. The study revealed that factors such as education level, perceived income, and place of residence did not emerge as determinants of vaccine hesitancy. While existing literature frequently emphasizes the significance of sociodemographic characteristics in vaccine hesitancy [2, 3, 15], the observed disparity in this study's results is attributed to the prevalent and widespread nature of vaccine hesitancy within the community.

The research revealed that getting flu and COVID-19 vaccines is a protective factor against vaccine hesitancy. The literature reports that adults who receive vaccines tend to have lower vaccine hesitancy [2, 4, 24]. The analysis of the SAGE vaccine hesitancy continuity matrix reveals that vaccine hesitancy and vaccine demand are inversely related, indicating that an increase in vaccine hesitancy leads to a decrease in vaccine demand [25]. The research findings indicate that adults who choose to get vaccinated demonstrate increased awareness of the individual health advantages associated with vaccination, leading to reduced vaccine hesitancy and greater acceptance of vaccine applications. Additionally, the optional and fee-based administration of these vaccines in adulthood implies that individuals possess knowledge about these vaccines and their associated benefits. Considering the effectiveness of vaccination in reducing infectious diseases, it is recommended to provide information about the benefits of vaccines and increase awareness about the gains achievable through individual vaccination. Moreover, it is anticipated that such information will be effective in reducing vaccine hesitancy.

Tab. IV. Determinants of vaccine hesitancy (enter model).

Independent variables	Unstandardized Coefficients		β	t	p	95.0% CI
	B	SE				
Level of education (0: Bachelor's degree and above)	-1.379	0.872	-0.105	-1.581	0.115	-3.099 – 0.340
Perceived income (0: Income higher than expenses)	-1.379	1.009	-0.108	-1.742	0.083	-3.749 – 0.232
Place of residence (0: Village)	-0.849	1.583	-0.033	-0.536	0.592	-3.970 – 2.272
Having received training on vaccines (0: Yes)	-1.391	0.909	-0.101	-1.530	0.117	-3.183 – 0.401
Having received COVID-19 vaccine (0: Yes)	-3.436	1.262	-0.169	-2.722	0.007	-5.925 – -0.947
Having received tetanus vaccine (0: Yes)	0.078	1.080	0.005	0.072	0.943	-2.051 – 2.206
Having received Hepatitis A vaccine (0: Yes)	-0.135	0.913	-0.011	0.148	0.883	-1.935 – 1.665
Having received flu vaccine (0: Yes)	-2.128	0.863	-0.158	-2.469	0.014	-3.828 – -0.429
Vaccine practices (0: Beneficial and all necessary)	-3.084	0.827	-0.245	-3.728	< 0.001	-4.715 – -1.453
Thoughts on vaccine administration (0: Mandatory)	-2.478	1.215	-0.137	-1.339	0.043	-4.873 – 0.083

CI: confidence interval; SE: standard error; β: standardized regression coefficient.
Durbin-Watson = 1.943; F = 10.808, p < 0.001; R = 0.517, R2 = 0.268 Adjusted R2 = 24.3%
* The significance level was accepted as p < 0.05.

The current study unveiled that the community acquires information about vaccines through the internet/social media (21.4%) and television/newspapers (16.7%), with a relatively low percentage following official social media accounts (36.7%). These findings highlight deficiencies in accessing reliable sources of information about vaccines within the community. Moreover, the limited number of participants who received education about vaccines implies educational and informational gaps in the community's understanding of vaccines. It is reported in the literature that individuals who receive information about vaccines from sources other than healthcare professionals, and those who use social media and the internet as information sources, tend to have higher vaccine hesitancy [26, 27]. Misinformation and disinformation about vaccines are among the most significant reasons for vaccine hesitancy and refusal among parents and adults [17, 28]. Moreover, false information disseminated through social media and the internet can quickly reach large audiences, posing a greater risk for vaccine hesitancy and refusal [29]. In this context, conducting education and awareness campaigns to ensure that the community receives information about vaccines, supporting the ability to access accurate and reliable information, and providing guidance on how to access reliable information are crucial.

The study revealed that some participants have children with incomplete vaccinations. Several studies in Turkey have identified under-vaccination concerning childhood immunizations [9, 15]. National-level investigations also indicate prevalent cases of under-vaccination in children [14]. To ensure the success of vaccination programs and control infectious diseases, achieving high immunization coverage within the community is paramount. A decrease in immunization coverage jeopardizes community immunity, escalating the risk of infectious diseases. Hence, maintaining adequate immunization coverage is vital for preventing infectious diseases and safeguarding public health [6]. In this context, it is recommended to explore the reasons behind rejected or delayed vaccine applications, assess the factors contributing to vaccine hesitancy, and provide information about the diseases these vaccines protect against, along with potential consequences when vaccines are not administered.

The most significant finding of the study is that the belief in the necessity of vaccines plays a pivotal role in vaccine hesitancy. The findings underscore that the perception that vaccines are both beneficial and indispensable serves as a safeguarding element against vaccine hesitancy within society. Vaccination is one of the most effective public health interventions, and since the discovery of vaccines, the incidence of infectious diseases and related deaths has sharply declined. However, these successful outcomes have led to the paradox of vaccines becoming victims of their own success. In communities that have not experienced infectious diseases and related disabilities and deaths, the perception has emerged that vaccines are unnecessary and not beneficial [21, 30].

Furthermore, misinformation about vaccines shared on social media, along with vaccine opposition narratives disseminated by non-experts and public figures, has contributed to the belief that vaccines are not beneficial or even harmful [27, 28, 31]. The literature suggests that individuals who believe in the benefits of vaccines and exhibit positive attitudes towards vaccinations are less likely to experience vaccine hesitancy [32, 33]. Considering the association between vaccine hesitancy, increasing vaccine refusals, and decreasing immunization rates, providing information about the severity of infectious diseases and the benefits of vaccines and organizing educational programs can be crucial in supporting the belief in the benefits of vaccines. Additionally, highlighting the successes achieved in diseases like smallpox, polio, and rabies through the discovery of vaccines can contribute to reinforcing the belief in the necessity and benefits of vaccines.

Limitations

While this research contributes to the existing literature, it comes with certain limitations. Primarily, the study was confined to a single city center, and data collection was limited to a specific healthcare institution. Another constraint is that the data collection period coincided with the summer, potentially resulting in the absence of residents due to reasons such as holidays. Additionally, the city's tourism resources may attract individuals from different cities and regions, including those who do not reside in the central city. This poses a limitation as the research group may not fully represent the entire population of the city. Consequently, the research findings may not be entirely generalizable to the broader population. Despite these limitations, the results of the research are crucial in shedding light on vaccine hesitancy within the community, the perception that vaccines are harmful and unnecessary despite vaccination achievements, and the necessity for vaccine-related information and education.

Conclusions

In this study conducted in a city center in Turkey to determine the vaccine hesitancy within the community and the influencing factors, it was concluded that the community has a moderate level of vaccine hesitancy. A significant portion of the community was found to believe that vaccines are not beneficial and are harmful. A substantial part of the community, around one-third, has not received any education about vaccines, and a portion of their children is incompletely vaccinated. The study identified that individual vaccine acceptance and the belief that vaccines are beneficial and necessary serve as protective factors against vaccine hesitancy.
The research findings align with existing literature and contribute to the literature. Considering that the belief in the usefulness and necessity of vaccines serves as a protective factor against vaccine hesitancy, it is recommended to increase awareness about the seriousness of infectious diseases and the benefits of vaccines through informative campaigns. Emphasis should be placed on obtaining information about vaccines from healthcare professionals such as doctors and nurses, as well as official organizations like the World Health Organization and the Ministry of Health, instead of relying on information from social media, neighbors, or relatives. Future research could focus on evaluating the impact of vaccine education programs on vaccine hesitancy within the community.

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Artvin Çoruh University (Number: E-18457941-050.99-68822, Date: 01.11.2022).

Data availability statement

Research data are available upon reasonable request from the corresponding author.

Institutional approval

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None.

Authors' contributions

This study is entirely the author's own work and no other author's contribution has been received.

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HEALTH PROMOTION

New integrations in patient care: the role of the pharmacist between couselling and medication adherence

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Couselling • Pharmaceutical care • Pharmaceutical services • Health education • Hharmacies

Summary

The changing scenarios in healthcare in recent years underscore the need to promote diverse, articulated, and complex care approaches capable of paying greater attention to people's vulnerability and responding to multiple care needs. A multidimensional approach to healthcare also suggests a review of the role that pharmacies can assume within the healthcare system, with particular regard to the possibility of creating a relational space with the citizen aimed at strengthening the fiduciary relationship with him or her and promoting greater user empowerment in therapy adherence.
The promotion of this ethically relevant service could yield several benefits: greater protection of public health, rationalization of public spending, and shifts in the demand for healthcare services. This paper aims to illustrate some socially and ethically relevant aspects of collaboration between pharmacists, general practitioners, and pediatricians of free choice.

Introduction

SCIENCE AND HUMANITY

The various health emergencies that periodically occur in our society have highlighted the necessity for effective public health interventions with a global vision, fostering alliances and involving multiple contexts. This requires the utilization of diverse health and non-health skills and professionals, following an intersectoral approach [1, 2].
For some time, medicine has recognized the importance of engaging with and enriching itself through contributions from other sciences. This integration aims to better humanize health services, emphasizing the centrality of the patient in their functional choices and psycho-physical well-being [3, 4].
This acknowledgment has led to a gradual acceptance of the systemic view of the patient and a reevaluation of the role that a strong relationship and effective communication play in the therapeutic context. Notably, in Italy, the significance of attentive, sensitive, and welcoming communication in the care relationship has been explicitly recognized in a national law (Law No. 219 of 2017, "Regulations on Informed Consent and Advance Treatment Provisions").
This law establishes that "communication time is care time," representing a significant innovation by legally endorsing an ethical approach grounded in recognizing the importance of a systemic and comprehensive view of the person, founded on listening, relationship, and proximity, as well as on the recognition of the growing attention towards the will of the minor [5, 6].
Not coincidentally, this principle has been incorpora ed into a provision already existing for years within the Medical Deontology Code [7, 8]. The legal recognition is reinforced by explicit legislative provisions for the specific university training of physicians and health professionals in relationship and communication with patients, aimed at acquiring competence based on specific knowledge and skills.
Similar to physicians, patient education and information represent an essential ethical component of the pharmacist's activity. Given the continuity and consistency of the counseling relationship that often occurs with their clients, pharmacists can play a particularly significant role in promoting proactive health behaviors.
To emphasize the ethical and educational aspects over the commercial side, pharmacists can engage in various practical activities. For example, they can regularly host workshops or seminars focused on patient education, covering topics like disease prevention, proper medication use, and lifestyle changes, thus promoting a more community-oriented and participatory approach to health. Furthermore, offering personalized medication therapy reviews helps patients better understand their treatments, enhancing therapeutic adherence and effectively addressing their specific needs. Another crucial element is active participation in health promotion campaigns, such as vaccination initiatives or preventive screenings, while also providing tailored consultations based on community requirements.
Simultaneously, the complexity of providing adequate responses to the growing demand for health, the

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progressive increase in life expectancy, and the continuous rise of chronic diseases, in the face of limited resources, necessitate the identification of articulated and multifaceted approaches, as well as new models of relationships among different health professionals. This is particularly relevant between general practitioners (GPs) and pharmacists.

In the peculiar situation of vulnerability experienced by individuals facing illness, where discomforts can be exacerbated by multiple contingencies (age, strong emotionality, absence/shortage of family and friend networks, loneliness, comorbidity, etc.), patients need to express requests, doubts, uncertainties, and emotions to competent and easily accessible professional practitioners. These professionals should provide support and guidance in their care, offering clear and understandable information and instructions.

For these reasons, it is crucial to benefit from the support of professionals with solid communicative skills (linguistic, paralinguistic, kinesic, proxemic, performative, socio-cultural, etc.) and relational skills. These professionals can promote and support local community-based medicine capable of addressing and meeting the vulnerabilities and loneliness of a significant portion of the population lacking familial or social support networks. Often, these individuals do not find attention and listening when in need.

In this new multidimensional approach to healthcare, based on the integration of scientific and humanistic expertise, attention has grown towards counseling skills considered essential for ensuring optimal therapeutic outcomes. Simultaneously, counseling plays a crucial role in empowering the patient as the main actor in managing their health, rather than being a passive recipient of treatments.

Rollo May, considered one of the most important representatives of humanistic-existential psychology and, along with Carl Rogers, Abraham Maslow, and Thomas Gordon, one of the founding fathers of counseling, defines the counselor through his goal: "The counselor's task is to assist the client in the search for their true self and then to help them find the courage to be that self" [9]. This non-directive approach is based on the recognition of the latent capacity of the human being, albeit not manifested, to understand oneself to the extent required for solving one's problems. It also acknowledges the capacity to reorganize one's personality to achieve the level of satisfaction necessary for proper functioning.

The counselor's task, therefore, is to foster the development and utilization of the potentialities inherent in the person assisted, using the tools of listening and dialogue. The goal is to accompany the person in self-discovery and aid them in overcoming personality issues that prevent them from fully and freely expressing themselves in the external world.

Counseling finds application in various healthcare settings, particularly in genetic disease centers, oncology facilities, and coronary units [10-12].

Moreover, counseling represents one of the most important services that the pharmacist, freed from a merely technical role, can offer to enhance personal resources, especially for those who are more vulnerable, such as the elderly, disabled individuals, and those who, for various reasons, require special attention and protection.

The increasing role of pharmacists in providing counseling and collaborating with general practitioners has undoubtedly expanded their responsibilities. However, it is essential to recognize that this increased workload, along with the additional time required for counseling and coordination, needs to be adequately compensated [13-15].

Failure to address this aspect could risk undermining the sustainability of these expanded roles within the healthcare system.

To further substantiate the value of pharmacists' contributions, a cost-benefit analysis should be conducted, exploring the long-term economic and health advantages of these services. Such analysis should consider not only the potential cost savings achieved through improved medication adherence and reduced hospitalizations but also the investment needed for the continuous and specific professional development required for pharmacists to stay updated and effective in their roles.

Additionally, recognizing the financial impact of expanded responsibilities on pharmacists' professional commitments is crucial. Adequate compensation and funding for continuous education initiatives are essential to ensure pharmacists can provide high-quality, patient-centered services without facing undue financial or professional strain.

This financial and professional recognition would ensure the sustained integration of pharmacists into the broader healthcare framework, enabling them to provide high-quality, patient-centered services while addressing the challenges associated with their expanded scope of practice.

However, as pharmacists take on a more active role in counseling patients, it is essential to acknowledge the ethical and medico-legal challenges that may arise in this context.

One of the primary concerns is the risk of overstepping professional boundaries, as pharmacists must be careful to provide guidance without encroaching on areas that fall strictly within the physician's domain, such as medical diagnosis or treatment decisions. Without clear distinctions, there is a potential for legal repercussions, making it crucial for pharmacists to adhere to well-defined professional limits. Another significant challenge is ensuring confidentiality during counseling sessions, particularly in open pharmacy settings The increasing role of pharmacists in providing counseling and collaborating with general practitioners has undoubtedly expanded their responsibilities. However, it is essential to recognize that this increased workload, along with the additional time required for counseling and coordination, needs to be adequately compensated. Failure to address this issue could jeopardize the sustainability of these expanded roles within the healthcare system.

To further demonstrate the value of pharmacists' contributions, a cost-benefit analysis should be conducted to explore the long-term economic and health advantages of these services. This analysis should consider not only the potential cost savings achieved through improved medication adherence and reduced hospitalizations but also the investment needed for continuous and specific professional development to ensure that pharmacists stay informed and effective in their roles.

Additionally, acknowledging the financial impact of expanded responsibilities on pharmacists' professional commitments is crucial. Adequate compensation and funding for continuous education initiatives are essential to ensure that pharmacists can provide high-quality, patient-centered services without facing undue financial or professional strain. This financial and professional recognition would facilitate the sustained integration of pharmacists into the broader healthcare framework, enabling them to offer high-quality services while addressing the challenges related to their expanded scope of practice.

As pharmacists take on a more active role in counseling patients, it is important to acknowledge the ethical and medico-legal challenges that may arise in this context. One primary concern is the risk of overstepping professional boundaries. Pharmacists must be careful to provide guidance without encroaching on areas that strictly belong to physicians, such as medical diagnosis or treatment decisions. Without clear distinctions, there is potential for legal repercussions, making it crucial for pharmacists to adhere to well-defined professional limits.

Another significant challenge is ensuring confidentiality during counseling sessions, particularly in open pharmacy settings where private conversations can be inadvertently overheard. Protecting sensitive patient information is fundamental to maintaining trust and complying with privacy regulations.

Pharmacists must also navigate potential conflicts of interest, especially when advising patients on products that may provide financial incentives. Maintaining neutrality and prioritizing patient well-being over commercial interests is essential to uphold the ethical integrity of the profession. To effectively mitigate these risks, pharmacists should adopt standardized protocols that clearly define the scope of their counseling role, helping patients understand the distinction between pharmaceutical guidance and medical consultation.

Additionally, ongoing professional training in ethics, communication, and legal compliance will be vital in helping pharmacists address these challenges with confidence and professionalism. where private conversations can be inadvertently overheard. The ability to protect sensitive patient information is fundamental to maintaining trust and complying with privacy regulations.

Furthermore, pharmacists must navigate potential conflicts of interest, particularly when advising patients on products that may provide financial incentives. Maintaining neutrality and prioritizing patient well-being over commercial interests is essential in upholding the ethical integrity of the profession. To effectively mitigate these risks, pharmacists should adopt standardized protocols that clearly define the scope of their counseling role and ensure that patients fully understand the distinction between pharmaceutical guidance and medical consultation. Additionally, ongoing professional training in ethics, communication, and legal compliance will be vital in helping pharmacists address these challenges with confidence and professionalism.

The Role of Counseling in Pharmacy

In pharmacy, the role of the counselor can be defined as follows: "It means pharmacists talking with patients and listening to them about the medications and the lifestyle modifications they are intended to take, in order to educate them about medications and lifestyle-related issues and to help them get the most benefit from therapy... There are both helping and educational goals of patient counseling in pharmacy..." [16].

In recent years, pharmacists have significantly expanded and diversified the care services offered to users, healthcare companies, and physicians, thereby becoming an increasingly central profession in the multidisciplinary configuration of quality healthcare.

While in the past, the pharmacist's activity was primarily confined to the laboratory for galenic preparation or the sale of drugs and therapeutic products, today, the pharmacist also plays a key role as a consultant in the distribution of medicines, the use of devices, and necessary lifestyle changes. In this context, their activity takes on strong ethical significance, engaging their professionalism and moral responsibility in safeguarding the health of those who seek their assistance.

The increasing clinical focus on the patient, as opposed to a drug-centered approach, has progressively brought the pharmacist into closer contact with both the patient and other healthcare professionals, fostering a relationship of constant interaction. Beyond the perspective of mere commercial activity, the professionalism of the pharmacist necessitates a profound understanding of the patient's personal issues, as well as a commitment to fundamental ethical aspects related to the life and dignity of the human person.

The opportunity to establish a "space of communication" and listening with the citizen, aimed at cultivating an ongoing, relational, and trusting relationship, supports the patient in their pharmacological pathway. This approach aligns with the growing sensitivity towards a care model centered on the individual, emphasizing respect for the person's cultural, social, and belonging background, and, more broadly, advocating for the humanization of care.

In a society characterized by diversity and a plurality of values and cultural references, access to a personalized care and support service for one's therapeutic journey, based on the uniqueness of the relationship, can serve as a crucial tool for overcoming inequalities and promoting well-being.

Indeed, the growing attention to the ethics of care and

a multidimensional view of the person necessitates a network of material and relational support that can establish a territorial medicine of proximity. This approach is closer, more capable of protecting, and providing for care needs through articulated, differentiated, and integrated supports.

In Italy, the Ministry of Education, University and Research, in collaboration with the Ministry of Health, introduced patient counseling during drug dispensing as one of the compulsory professionalizing activities within Hospital Pharmacy. This was outlined in the Interministerial Decree no. 68 dated February 4, 2015, concerning the reorganization of healthcare specialization schools.

Furthermore, international literature provides extensive and significant evidence supporting the importance of counseling in the pharmacist profession, both in hospital and community settings [17].

Similar to the necessity for physicians to integrate "to cure" with "to care," for pharmacists, it is essential to transition from an approach based on compliance to one founded on adherence. This shift aims to achieve therapeutic recognition and reconciliation.

The increasing prevalence of drugs, including generics, the frequent presence of comorbidities, and polypharmacotherapy, often involving multiple healthcare professionals operating in different settings (hospital/private/practice/outpatient) and providing different prescriptions, leads to increased complexity in therapy management. This complexity easily generates doubts and uncertainties. In this context, the pharmacist can be a privileged and competent interlocutor, providing all the necessary and accurate information about prescribed medications, potential side effects, their optimal management, and the adoption of healthy behaviors.

Simultaneously, having access to a space for listening and attention outside the traditional healthcare environment can be perceived as more protected. This can encourage patients to freely express various issues that could impact the correct adherence to therapy.

The pharmacist, when adequately trained in active listening to the patient's needs, values, and cultural background, can effectively integrate with other healthcare professionals. This integration helps in patient care, supporting individuals in making responsible choices regarding their treatment.

Farsaei et al. demonstrated how clinical pharmacist education sessions and medication adherence programs (utilizing pillboxes, diary logs, and follow-up calls) were helpful in significantly reducing average glucose levels in 2011 [18]. Additionally, Ibrahim et al. presented high-quality evidence of the impact of telepharmacy on COVID-19 patients' access to pharmaceutical care and safe medication dispensing [19].

Research indicates that patients suffering from chronic diseases are at a higher risk of medication errors [20]. Non-adherence to medication not only affects their health, leading to reduced desired effects and adverse events such as disease exacerbation, increased hospitalizations, decreased quality of life, and elevated mortality rates, but also impacts healthcare systems through inefficient resource utilization and increased expenditure resulting from the consequences of non-adherence [21-24].

Eliasson et al. demonstrated that in clinical practice, up to 50 percent of patients do not take their medications as prescribed. Non-adherence accounts for up to 48% of asthma deaths, an 80% increase in the risk of death from diabetes, and a 3.8-fold increase in the risk of death in the year following a heart attack [25].

Data from the New England Health Care Institute indicate that 75% of Americans face difficulties taking their medications as prescribed, and this behavior reflects in healthcare costs amounting to billions of dollars [26]. Nonadherence results in approximately 125,000 deaths per year in the United States [27].

According to the AIFA report, the Italian drug agency, therapeutic categories with the highest percentages of nonadherents are uric acid inhibitor drug therapy (57.5%), statin therapy (41.6%), and antidepressant drug therapy (40.1%). Moreover, it has been observed that for treatment with statins, antihypertensive drugs, antiosteoporotic drugs, and antidepressants, both adherence and persistence to therapeutic treatment decrease with increasing age [28].

Multiple factors can contribute to poor medication adherence, including costs that may be inaccessible, difficulty in fully understanding the importance of pharmacological therapy, low health literacy, lack of comprehension of instructions, and challenges in remembering or managing multiple medications or complex regimens. These issues are often compounded by prescriptions from multiple physicians [29].

These data suggest significant opportunities for improvement in medication use, emphasizing the need to enhance patient education and competence, particularly for the most vulnerable patients. An "informed and empowered patient" stands a better chance of understanding their clinical condition, actively participating in decisions, and adhering to treatment, which is a crucial element.

Therefore, collaboration among physicians, nurses, and pharmacists can play a key role in addressing this public health issue. The counseling offered by pharmacists can be particularly valuable for intercepting possible errors in taking therapy and the occurrence of adverse side effects. Pharmacists can provide helpful advice to avoid the risk of interactions and alert the prescribing physician to any event significant for the person's health protection. This monitoring is especially crucial for medications such as innovative drugs, where commitment to adverse event detection is paramount.

Furthermore, the literature highlights the need for patient counseling, particularly in demographic areas with high levels of illiteracy, poverty, and lack of awareness among patients [30]. The literature also identifies multiple reasons why patients seek pharmacist counseling, as well as numerous topics discussed between pharmacists and patients [31].

Italian situation

The current shortage of general practitioners (GPs) in the Italian territory, with numerous areas lacking this professional figure, is generating multiple difficulties in accessing primary healthcare services. This situation has prompted pharmacies to assume an increasingly important role as reference health facilities for the population, thanks to their widespread presence across the territory. In many cases, people turn to pharmacies for basic counseling, advice on the management of common ailments, and the provision of over-the-counter medications. Given the growing importance of pharmacies as a health referral point, it has become necessary to consider innovative strategies to address the challenges related to the shortage of GPs, a situation expected to persist until at least 2026.

In recent years, corrective measures have been introduced to increase the absolute number of GPs, with efforts made from a contractual and organizational perspective to significantly enhance their presence in the territory [32].

Meanwhile, there has been a hypothesis to enhance certain services, such as telemedicine, to enable people to access medical consultations remotely. This approach can help bridge gaps in healthcare coverage and provide more timely access to care, especially in areas with limited medical resources. Additionally, there has been consideration of the opportunity to strengthen counseling services at pharmacies, offering more comprehensive support and information on health-related topics. This can contribute to educating the population about preventive practices, healthy lifestyles, and the management of chronic diseases.

The GP and pharmacist are indeed two indispensable health figures in the provision of primary care and serve as privileged interlocutors for citizens in the territory. The ethical values of both professions are rooted in the principle of respect for life, the protection and promotion of people's physical and mental health, and the relief of suffering. Additionally, both professions are based on the principles of freedom, autonomy, and individual responsibility.

The increasing drive towards innovation and digitalization, the demographic shift resulting in an aging population, and the need for greater patient involvement in the therapeutic alliance, including reducing waste and preventable healthcare costs due to complications and therapeutic failures resulting from poor adherence to therapy, have significantly altered healthcare needs and the context in which GPs and pharmacists operate in their professional roles. Strengthening primary care, involving families in care processes, and providing widespread access to pharmaceutical services are strategic factors in promoting health protection, optimizing resources, and discouraging inappropriate use of emergency room services.

The aforementioned shortage of GPs (and, incidentally, also of Pediatricians of Free Choice) is substantiated by ISTAT 2021 data, indicating that in Italy, an average of 7.12 GPs per 10,000 residents are operating, with a minimum of 6.5 for the Northwest to a maximum of 7.79 for the Islands [33].

The hardship is particularly pronounced in rural hamlets, where citizens often face onerous transfers to reach more populous and equipped healthcare centers. This challenging situation is further compounded by the progressive aging of the population and the limitations of healthcare resources.

In this context, the territorial network of pharmacies provides valuable support to primary health care. Pharmacies are intricately woven into the territory, offering easier accessibility at any time of day and any day of the year. Simultaneously, within the pharmacy, there is often a veritable health services center that provides multiple healthcare services to address the continuous and growing needs of the population, including booking specialist exams, monitoring physiological parameters, and providing health information.

Due to their specialized training, often augmented by post-graduate courses in areas such as nephrology, geriatrics, and outpatient care, pharmacists can identify patients who are non-adherent to prescribed therapies. With their pharmacological knowledge, they can actively participate in developing a therapy that is appropriate and tailored to the patient. Moreover, in collaboration with the GP, they can propose changes to drug dosages for optimal personalized therapy. Possessing specific knowledge about newly approved pharmaceutical products and various guidelines for medication use enables them to serve as a particularly qualified figure in charting the most suitable therapeutic path for specific patients.

Of particular interest are some projects initiated in Italy. For example, at the Policlinico di Bari, a Home Care Program was organized for patients in Pharmaceutical Home Care, centered on counseling and the narration by patients of their disease histories. This approach made it possible to identify a high number of adverse reactions, thus strengthening the active pharmacovigilance system [34].

Another noteworthy project actively involving pharmacists in the oncological care pathway has been initiated by the Oncology Pharmacy of the IRCCS IRST "Dino Amadori" in the Emilia Romagna Region. The pharmacist dedicated to oral therapies conducts direct interviews with patients, providing detailed information about the treatment using drug cards based on health literacy. These interviews, scheduled at each drug pickup, monitor adherence to therapy, evaluate interactions with other medications, and identify any adverse effects. The pharmacist provides a therapy diary to the patient, which is filled out and returned at the subsequent pickup. Information about interactions is transferred to the physician for evaluation. The pharmacist's activities are tracked through a dedicated module in the prescription program, accessible to healthcare providers for integration into the patient's medical record [35].

In the Liguria Region, a pilot project is currently underway, initiated by the Ministry of Health, aimed at creating an algorithm for managing scarce medications—a

critical issue in recent years. This algorithm will enable physicians and pharmacists to interact on the same digital platform, avoiding prescriptions of unavailable drugs and finding alternative solutions. This approach optimizes resources and prevents citizens from having to search for medications.

The integration between GPs/pediatricians of free choice and pharmacists requires substantial changes in mentality and overcoming barriers. Without prejudicing the competencies and prerogatives of each professional, these changes involve preparing articulated, diversified, and complex operational strategies inspired by the identification of the citizen's needs and the objectives to be achieved, rather than rigid compartmentalization of the role of each healthcare professional.

Conclusions

In recent years, the expansion of professional services offered by pharmacies has underscored the pharmacist's role as a crucial element of the healthcare team. Pharmacists are capable of promoting patient care and engaging in a multidisciplinary approach to healthcare by interacting with physicians and patients. Rather than diminishing the importance of the direct doctor-patient relationship, the design of pharmacies oriented towards developing and enhancing relationships and trust with the citizen-user through counseling activities can represent a significant factor in ensuring patient empowerment and therapeutic adherence. This perspective aligns with an authentically ethical approach to integrated healthcare assistance.

The foundation of a comprehensive approach to patient care lies in the synergistic assignment and coordination of skills among various professionals involved. Through a system that allocates different tasks to different professionals, patient safety is promoted, ensuring that each contributes to the patient's well-being with a defined and specific role. In a context where interprofessional collaboration is crucial, especially considering initiatives promoted by the National Recovery and Resilience Plan (PNRR) aimed at both hospitals and communities, doctors, pharmacists, and other healthcare professionals work in harmony, respecting their respective competencies. This multidisciplinary approach not only maximizes the effectiveness of care but also contributes to ensuring a cohesive healthcare system centered on the patient. The convergence of diverse expertise, managed with care and responsibility, becomes an essential pillar for the overall health of the individual suggesting the importance of considering the implementation of shared educational moments where it is possible to address together the discussion of ethical issues [36].

The traditionally exclusive domain of physicians and nurse practitioners, counseling, can thus become an effective tool for providing more efficient healthcare in both health and economic terms. Additionally, it can be part of the solution to the shortage of family physicians.

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Conflict of interest statement

The authors declare no conflict of interest.

Authors' contributions

Both authors conceived the study and contributed to the preparation of the manuscript and approved the final version to be submitted.

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HEALTH PROMOTION

Population-based cross-sectional study of the correlation of physical inactivity and sedentary behaviour with sociodemographic factors among Bangladeshi adults

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Keywords

Sedentary behaviour • Physical activity • Bayesian regression model • GPAQ • Bangladesh

Summary

Background. *Physical inactivity and sedentary behaviour are influenced by various interconnected variables. In Bangladesh, studies on physical inactivity and sedentary behaviour are scarce, regardless of age in the adult population. This study aims to determine the correlates of adults' physical inactivity and sedentary behaviour with sociodemographic factors, including gender, age, residential, educational, and occupational status.*
Methods. *This is a secondary analysis of a cross-sectional survey conducted from February to May 2018 across eight divisions of Bangladesh. Global Physical Activity Questionnaire was used to measure physical inactivity and sedentary behaviour. The data consisted of 8,185 adults aged 18 to 69 years. The Bayesian regression model was used to analyse the correlates.*
Results. *Physical inactivity, including work, active transport, and recreation, males and urban residents were more likely to be inactive than their female counterparts and rural residents. Married adults had greater (Odd Ratio [OR]: 6.6, 95% CI: 5.46 to 7.98) recreation-related physical inactivity. Unemployed adults were more likely to engage in sedentary behaviour (OR: 4, 95% CI: 2.48 to 6.12) and less likely to engage in moderate physical activity (OR: 2.2, 95% CI: 1.43 to 3.39).*
Conclusions. *A notable pattern of insufficient recreational physical activity among adults in Bangladesh was noted. Establishing nationwide surveillance systems to detect physical activity and sedentary behaviour trends to evaluate potential interventions for improving physical activity and reducing sedentary behaviour. Expanding school-based physical activity programs help children and adolescents learn lifelong healthy behaviours. Community sports programs for all ages promote active living.*

Introduction

Physical inactivity and sedentary behaviour are adversely associated with health and quality of life [1, 2]. Inadequate physical activity and sedentary behaviour are major risk factors for non-communicable diseases [3]. Physical inactivity is the fourth leading risk factor for mortality [4]. Globally, physical inactivity is attributed to 3.2 million deaths and 32.1 million disability-adjusted life years annually [4]. Worldwide, the healthcare costs of physical inactivity are estimated at $538 billion, burdening healthcare systems and societies [5]. Similarly, sedentary behaviour accounts for 3.8-5.9% of all deaths due to prolonged sitting time [6-7]. Diseases that correlate with sedentary behaviour cost to the British healthcare system GBP 761.80 million [8] and the Australian $170 million [9]. Several socio-demographic factors have been associated with physical inactivity and sedentary behaviour. Physical inactivity and sedentary behaviour are distinct but interconnected components in developing non-communicable diseases. Most studies attempt to quantify the prevalence of physical activity [10, 11]. Although several studies investigated the relationship between physical activity and socio-demographic factors [12-4], most studies focused on specific population groups, including adolescents and older people, and have a small sample size, which limits the generalizability of the findings [13, 14]. Additionally, previous studies have limited focus on the correlates between different types of physical activity intensity, sedentary behaviour, and sociodemographic factors in adults in Bangladesh using a nationally representative adult population [12, 13]. Forms of physical activity include work, active transportation, recreation, and types of intensity refer to moderate and vigorous physical activity. Besides, a recently published review reported Bangladeshi physical activity and sedentary behaviour, with insufficient evidence of sedentary behaviour [15]. In a recent study, recreation-related activities had the highest frequency of physical inactivity, followed by lack of vigorous

activity, active transport, and work [16]. This study lacks the identification of socio-demographic correlates with physical inactivity and sedentary behaviours among adults in Bangladesh [16]. In addition, the study did not examine whether the results differed by gender, between rural and urban residents, or by level of socio-economic status [16]. Thus, our study aims to: 1) provide the correlates of different types of physical inactivity and sedentary behaviour and 2) how study findings differed by gender, location (rural or urban), or socio-economic status in adults in Bangladesh using nationally representative data from the STEPS Survey 2018. Study findings enable policymakers to design an effective public health policy intervention to improve physical activity levels and reduce sedentary behaviour, reducing the prevalence of non-communicable diseases and alleviating their individual, familial, and socio-economic impacts.

Methods

This study followed the STROBE checklist provided in the supplementary file, Table I.

Participants and public involvement

The study did not involve human subjects. The current investigation comprehensively examined a secondary dataset from the STEPS Survey 2018 [17].

Study design, setting and population

Data collection for the STEPS Survey 2018 was completed from February to May 2018 across eight divisions of Bangladesh. This was a nationwide cross-sectional survey. The primary sampling units (PSUs) of the Bangladesh Bureau of Statistics census used a multistage sampling method. This is a regionally stratified probability-based sampling process. The study population consisted of adults, including older adults aged 18 to 69, who had lived at home for at least six months and were present during the night before the survey. The adults were eliminated from the study if they lived in military bases or group quarters, jails, healthcare facilities, nursing homes, or other similar institutions; if they were deemed fragile, unstable, or physically unfit; or if they were reluctant to engage in the study.

Sample size

The sample size was calculated to ensure the generalizability and reliability of the study findings for the total number of targeted adults in the country. The calculated sample size was adequate to give valid estimates for all variables for males, females, and four age groups (18 to 24, 25 to 39, 40 to 54, and 55 to 69). The sample size was determined by the prevalence of non-communicable disease's risk factors, the relative accuracy rate (20%), and survey practicality.

Based on obesity prevalence, each group needed 472 adults for a successful analysis. The Bangladesh Demographic Health Survey had a 10% non-response rate for individuals, 10% non-coverage rate for households and design effect of 2 were considered. Therefore, the final sample size was calculated with a 20% non-response rate. Initially, 496 PSUs updated in 2017 were examined. One PSU from fieldwork had to be dropped due to inaccessibility. Therefore, 9,900 adults from 495 PSUs comprised the modified sample size.

Sampling frame and Sampling strategy

The Bangladesh Bureau of Statistics' completed list of PSUs – including type of home, location, and anticipated number of households – was included in the sample frame. The study identified 293,533 PSUs: 65,193 urban and 228,340 rural. Bangladesh Bureau of Statistics household lists were used for sampling. Twenty houses from every PSU were randomly assigned either "male" or "female" in an equal ratio. One adult was randomly selected among a household's eligible adults. To avoid bias, preselected families were not replaced during implementation. PSUs were distributed evenly across divisions (62 each), including rural and urban strata (248 each). Household numbers served as the organising PSUs in both urban and rural strata. By using probability proportional to size sampling, each stratum identified 31 PSUs.

Data collection and quality control

A pretested, standard WHO STEPS questionnaire (version 3.2) with all core questions, including several extended and country-specific items, was used to collect data. The Bengali questionnaire was verified by translation and reverse translation. The data was collected in three steps: STEP 1 was face-to-face interviews, STEP 2 was physical measurements, and STEP 3 was blood and urine samples. Android devices obtained data on-site and uploaded it to the cloud using ODK software. Quality control includes daily data review and field monitoring.

Data management and processing

The ODK software was used to input data on personal digital assistants. The ONA database server received the information electronically. The field data collector uploaded daily data to the server. The central office downloaded the data into Microsoft Excel for consistency and validity checks. They combined each adult's personal identification number, and the QR code allowed for integrating data from STEP-1, STEP-2, and STEP-3. The data cleaning process adhered to the WHO STEPS guidelines.

Variables of physical inactivity and sedentary behaviour

The WHO defines physical inactivity as failure to meet the minimum weekly moderate (150 minutes), vigorous (75 minutes), or both exercise requirements [18]. The GPAQ examined three physical activity domains: recreational, work-related, and active transportation-related inactivity. The physical activities were measured

Tab. I. Association of physical inactivity sedentary behaviour with sociodemographic factors for adults in Bangladesh, 2018 (n = 8185).

Characteristics			WHO recommended PA OR (95% CI)	Work-related PA OR (95% CI)	Active transport-related PA OR (95% CI)	Recreation-related PA OR (95% CI)	Moderate PA OR (95% CI)	Vigorous PA OR (95% CI)	Sitting > 8 hours per day OR (95% CI)
Gender	Women	Yes	Ref						
		No	0.86 0.76, 0.98	0.73 0.65, 0.82	0.83 0.76, 0.91	0.78 0.64, 0.85	0.71 0.64, 0.79	0.83 0.76, 0.92	1 0.82, 1.37
	Men	Yes	Ref						
		No	1.1 1.02, 1.30	1.3 1.21, 1.53	1.2 1.08, 1.30	1.3 1.16, 1.55	1.4 1.25, 1.56	1.1 1.08, 1.31	0.95 0.74, 1.19
Age	18-29	Yes	Ref						
		No	0.93 0.81, 1.06	1 0.92, 1.22	1.1 1.01, 1.25	0.95 0.80, 1.11	1 0.93, 1.19	1 0.92, 1.15	0.950 0.69, 1.25
	30-44	Yes	Ref						
		No	0.6 0.86, 1.09	0.97 0.87, 1	0.88 0.80, 0.96	0.99 0.84, 1.14	0.97 0.87, 1.07	0.98 0.89, 1.076	0.85 0.65, 1.08
	45-59	Yes	Ref						
		No	1 0.91, 1.19	0.94 0.83, 1	1 0.94, 1.15	1 0.86, 1.18	0.94 0.84, 1.06	1 0.91, 1.12	1 0.72, 1.32
	60-69	Yes	Ref						
		No	1.2 0.95, 1.54	1.1 0.88, 1.38	0.99 0.82, 1.16	1.1 0.88, 1.45	1.1 0.91, 1.39	0.93 0.77, 1.1	1.8 1.22, 2.63
Residence	Rural	Yes	Ref						
		No	0.99 0.88, 1.12	0.92 0.82, 1.04	0.91 0.83, 0.99	0.98 0.84, 1.12	0.91 0.82, 1.01	0.90 0.81, 0.98	1 0.81, 1.33
	Urban	Yes	Ref						
		No	1 0.89, 1.12	1 0.96, 1.2	1 1, 1.19	1 0.89, 1.18	1 0.97, 1.20	1.1 1.00, 1.21	0.96 0.74, 1.24
Educational status	High School	Yes	Ref						
		No formal education	0.61 0.53, 0.70	0.59 0.50, 0.67	0.90 0.81, 0.99	1.8 1.50, 2.16	0.93 0.83, 1.04	0.48 0.43, 0.53	0.98 0.75, 1.28
	College/ university	Yes	Ref						
		No formal education	0.78 0.64, 0.95	0.93 0.75, 1.14	0.75 0.64, 0.87	1.1 0.84, 1.46	1.1 0.97, 1.36	0.66 0.57, 0.77	0.990 0.63, 1.44
Occupation	Student	Yes	Ref						
		No	0.63 0.47, 0.83	2 1.34, 3.02	1.6 1.24, 2.13	0.86 0.54, 1.27	2.1 1.51, 3.17	1.3 1.04, 1.76	1.4 0.76, 2.39
	Unemployed	Yes	Ref						
		No	1 0.70, 1.4	2 1.29, 3.28	0.89 0.68, 1.17	0.53 0.29, 0.88	2.2 1.43, 3.39	0.71 0.50, 0.97	4 2.48, 6.12
	Employed	Yes	Ref						
		No	1.2 0.99, 1.51	0.52 0.38, 0.68	0.90 0.73, 1.08	1.4 1.04, 2.0	0.52 0.40, 0.67	0.96 0.78, 1.15	0.43 0.30, 0.63
Marital status	Never married	Yes	Ref						
		No	0.91 0.72, 1.14	0.57 0.47, 0.70	2.6 2.08 3.23	0.15 0.12, 0.18	0.78 0.64, 0.96	2.1 1.80, 2.51	1.3 0.84, 2.02
	Married	Yes	Ref						
		No	1.1 0.88, 1.3	1.7 1.41, 2.1	0.39 0.30, 0.48	6.6 5.46, 7.98	1.2 1.04, 1.55	0.46 0.39, 0.55	0.77 0.49, 1.20

PA: Physical Activity; OR: Odds Ratio; CI: Credible Interval, Ref: Reference value.

at a moderate and vigorous level. However, a study reported that sitting for more than 8 hours significantly increased the risk of non-communicable diseases and all-cause mortality [19]. So, in this study, "sedentary behaviour" refers to sitting for more than eight hours per day. Further details of the formulation of physical inactivity variables are provided in the supplementary file, Table II.

Data Analysis

The weighted data accounts for PSU, household, sex, and individuals, as if household member selection probability reflects individual Bangladesh. Missing data was included in the analysis. Therefore, among the target adults of 9,900, 8,185 (82.7%) completed STEP-1 and were included in the study.

Descriptive statistics were utilised to provide an overview of the sample's characteristics. This study used a widely accepted Bayesian regression model. This model offers viable results and yields significant improvements in parameter estimation compared to other statistical models [20]. Therefore, Bayesian linear regression analysis examined the associations between physical activities and sedentary behaviour with sociodemographic characteristics, including gender, age, education level, residence, occupation, and marital status. The degree of correlation was determined using the odd ratio (OR). Outcome measures and group differences were calculated at a 95% credible interval (CI). If the 95% credible interval did not contain 0, then the findings were considered significant. Statistical analysis was conducted in STATA version 17 (StataCorp LLC, College Station, TX, USA).

Results

Physical inactivity and sedentary behaviour

The total number of participants in the study was 8,185. The highest number of participants were assessed as physically inactive considering the recreational (n = 7,331), vigorous (n = 5,708), and active transport-related (n = 3,078) physical activities, as shown in Figure 1. Recreation-related physical inactivity was seen among women in the rural area of Mymensingh district, Bangladesh, as shown in Figure 2.

Physical inactivity and sociodemographic factors

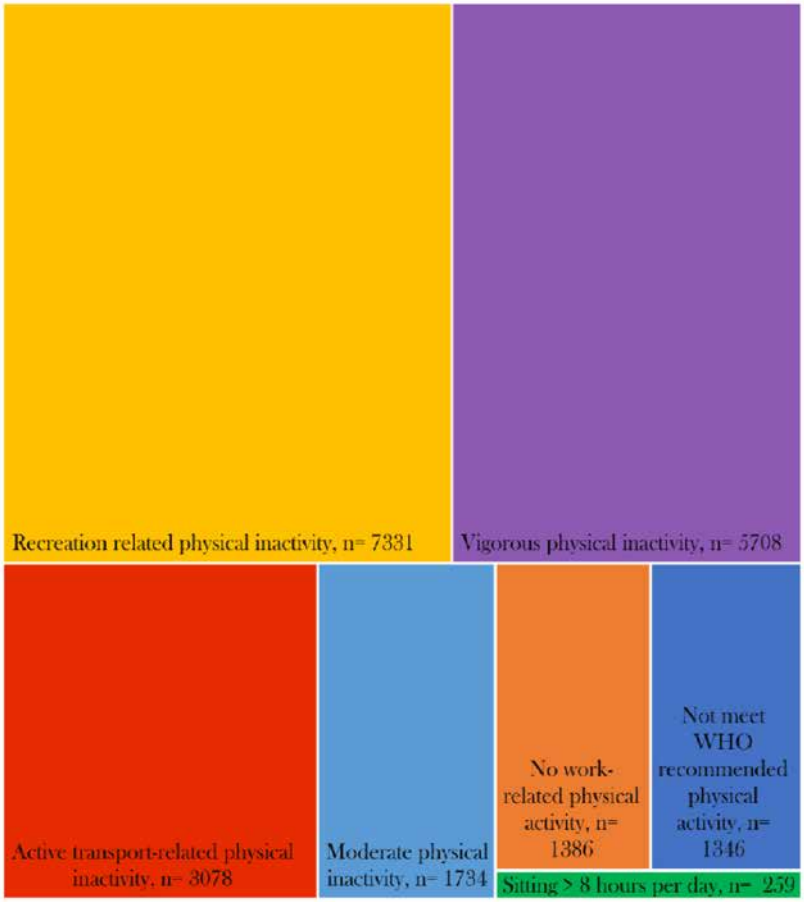
Bayesian linear regression found that inadequate physical activity levels were linked to sociodemographic factors (Tab. I). Across all forms of physical inactivity, including work, active transport, and recreation-related inactivity, males and urban residents were more likely to be inactive than their female counterparts and rural residents. Adults aged 60-69 years were less likely to engage in any physical activity except active transportation-related and vigorous activities such as carrying or lifting heavy objects, engaging in construction work, washing clothes, reaping

Tab. II. Correlates of physical inactivity sedentary behaviour with sociodemographic factors for adults in Bangladesh, 2018 (n = 8.185).

Characteristics			Sitting > 8 hours per day OR (95% CI)
Gender	Women	No	
		Yes	1 0.82, 1.37
	Man	No	
		Yes	0.95 0.74, 1.19
Age	18-29	No	
		Yes	.095 0.69, 1.25
	30-44	No	
		Yes	0.85 0.65, 1.08
	45-59	No	
		Yes	1 0.72, 1.32
	60-69	No	
		Yes	1.8 1.22, 2.63
Residence	Rural	No	
		Yes	1 0.81, 1.33
	Urban	No	
		Yes	0.96 0.74, 1.24
Educational status	High School	No formal education	
		Yes	0.98 0.75, 1.28
	College/ university	No formal education	
		Yes	0.99 0.63, 1.44
Occupation	Student	No	
		Yes	1.4 0.76, 2.39
	Unemployed	No	
		Yes	4 2.48, 6.12
	Employed	No	
		Yes	0.43 0.30, 0.63
Marital status	Never married	No	
		Yes	1.3 0.84, 2.02
	Married	No	
		Yes	0.77 0.49, 1.20

PA: Physical Activity; OR: Odds Ratio; CI: Credible Interval; Ref: Reference value.

Fig. 1. Treemap of physical inactivity and sedentary behaviour of Bangladeshi Adults, 2018.



paddy, and fishing with nets. Active transportation was associated with greater inactivity in the younger (18-29 years) group (Odd ratio [OR]: 1.1; 95% CI: 1.01, 1.25). Insufficient vigorous physical activity was seen among never-married adults (OR: 2.1; 95% CI: 1.80, 2.51). Inadequate participation in recreation-related physical activity was more likely (OR: 1.8; 95% CI: 1.50, 2.16) in those who had completed high school or less than in those with no formal education. Diverse positive relationships were observed among the different occupational groups. Among all other occupations, unemployed adults had a greater odd ratio of moderate physical inactivity (OR: 2.2; 95% CI: 1.43, 3.39). Students were inactive in moderate (OR: 2.1; 95% CI: 1.51, 3.17), work-related (OR: 2, 95% CI: 1.34; 3.02) and vigorous physical activities (OR: 1.3, 95% CI: 1.04; 1.76). Although the positive odd ratio for having all forms of insufficient physical activity increased across marital status, married adults were 6.6 times less likely (95% CI: 5.46, 7.98) to engage in recreation-related physical activity compared to respondents who had never married.

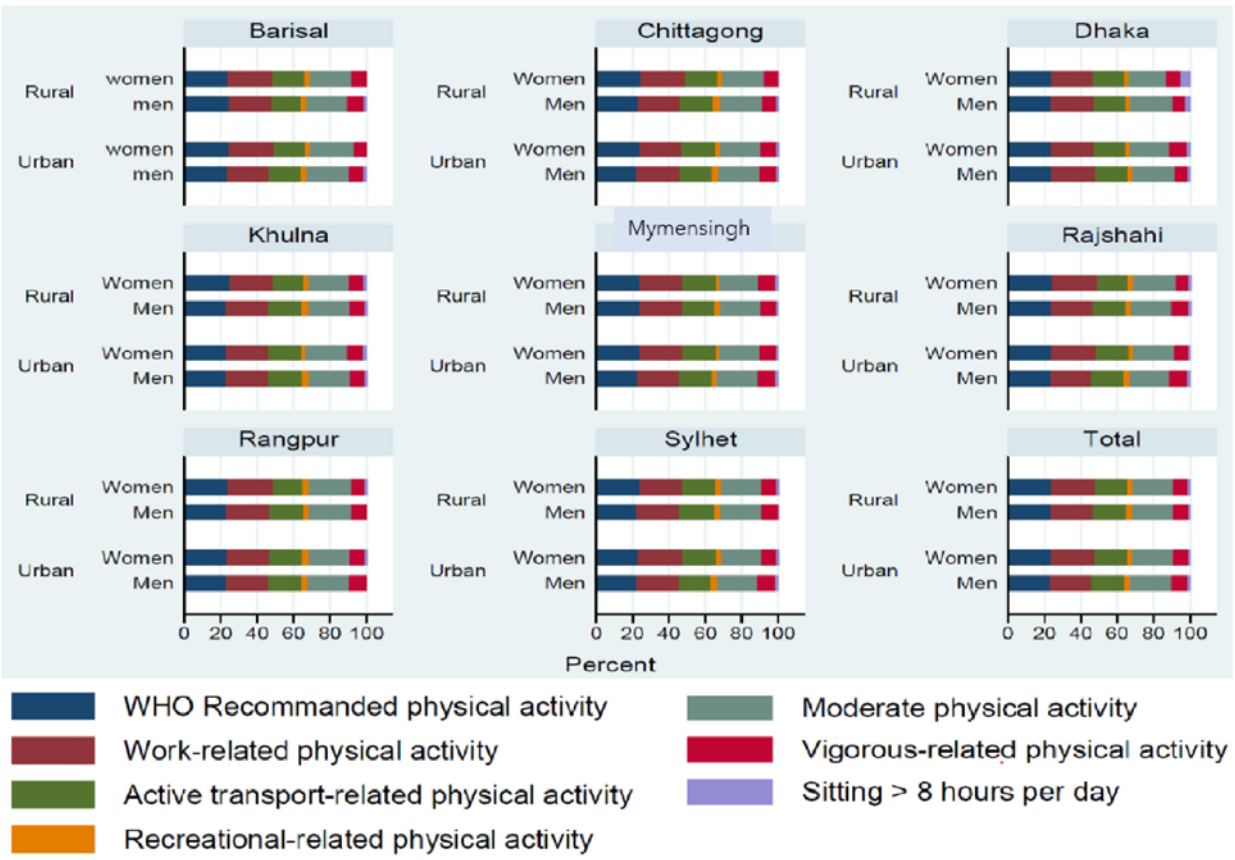
Sedentary behaviour and sociodemographic factors

The findings of a Bayesian linear regression study demonstrated an association between sedentary behaviour (characterised as sitting for more than eight hours a day) and the sociodemographic factors presented in Table II. Overall, adults who self-identified as unemployed were four times (95% CI: 2.48, 6.12) more likely to report higher levels of sedentary behaviour than those who self-identified as employed or students. Aged adults (60–69 years) were found to have 1.8 times (95% CI: 1.22, 2.63) higher sedentary behaviour compared with adults aged 18–59. Never-married adults have higher odds (OR: 1.3, 95% CI: 0.84, 2.02) of spending more than 8 hours sitting per day compared to married ones.

Discussion

This study reports the correlates of different forms of physical activity for different intensity and sedentary behaviour with sociodemographic factors for nationally representative adults in Bangladesh. Overall, insufficient physical activities were found to have positive associations with all sociodemographic factors. Importantly, higher associations were observed in recreation-related physical inactivity among married adults. Subsequently, this study confirmed that unemployed adults were less likely to engage in moderate physical activity. The current study also found that unemployed adults were more likely to be sedentary.

Fig. 1. Treemap of physical inactivity and sedentary behaviour of Bangladeshi Adults, 2018.



Recreational physical activities are less common and familiar in Bangladesh than developed countries. Our study found that married adults were remarkably less active in recreational physical activity. Similar trends were observed among Brazilian married adults [21]. A recent review revealed that the contribution of Bangladeshi adults participating in recreational physical activity was minimal [15]. Previous studies reported that participating in moderate or vigorous recreational physical activity significantly lowered the risk of metabolic syndrome and cardiovascular mortality [22, 23]. In Bangladesh, the prevalence of metabolic syndrome was 30.0%, and the risk of low-level cardiovascular disease was 37.8% [24, 25]. For this reason, efforts are focused on national and regional campaigns to promote the benefits of physical activity and encourage movement in daily life. Investing in infrastructure like bike lanes, walking trails, and parks will make staying active easier and safer [26]. Additionally, partnerships with sports organisations will enhance community engagement in sports [26].

In developing countries such as Bangladesh, unemployment predisposes adults to poor lifestyles and limits physical activity. Concurrent with this, our study found a lack of moderate physical activity among unemployed adults. This finding corresponded to an Irish survey, which found that unemployed adults had a higher association with physical inactivity [27]. The unemployment rate in Bangladesh was 5.3% [28]. Unemployment is also inseparable from demotivation, isolation, and lack of interest and their mental health consequences [29], which could hamper engagement in physical activity. Targeted interventions should promote physical activity among unemployed adults by addressing challenges like demotivation and isolation. Providing social support and accessible exercise opportunities can help reduce the adverse effects of unemployment [30]. Additionally, combining mental health support with these programs may enhance participation and well-being [30].

This study provides evidence that physical inactivity tends to increase with age. Specifically, adults aged 60 and older exhibit lower levels of recreational, work-related, and moderate physical activity than those aged 18 to 59. This trend aligns with findings from low- and middle-income countries, such as Bangladesh [12] and is further supported by cross-sectional and prospective studies conducted in developed nations [31, 32]. Community-based sports initiatives should be launched to improve physical activity across all age groups [30]. These initiatives could include organized events, local sports leagues, and free or low-cost classes held in public spaces, all aimed at encouraging participation from individuals of all ages [30].

Adults with high school education were less likely to be classified as inactive in following to perform recreation-related activities than those with no formal education.

Similarly, a study conducted among university students in the capital of Bangladesh reported a relatively moderate level of recreational physical activity [32]. Furthermore, older adults with secondary education were more likely to meet physical activity recommendations than those with elementary or incomplete education [33]. While higher education increases the likelihood of participating in sports or exercise, it does not significantly impact involvement in recreation-related activities [34]. In addition, studies [34-37] indicated that education level influences the age-physical activity relationship, with educational discrepancies in physical activity widening with age. These findings suggested that effective intervention strategies are needed to promote physical activity from the school-age years [30]. Fostering more physical activity among children and adolescents helps prevent non-communicable diseases and reduces the economic burden on society and individuals [30]. Therefore, expanding school physical activity programs is crucial to provide children and adolescents with regular opportunities for sports and physical activities [30].

Sedentary behaviour, in general, was more likely to be reported among unemployed adults, older adults, and adults who had never married, as confirmed in this study. This study also confirmed that adults with more than a high school education were less likely to adopt sedentary behaviour. Comparable to our study, the unmarried, unemployed, and older Japanese adults were more sedentary behaviour [30]. A meta-analysis reported that being sedentary for more than 6-8 hours per day increases the risk of death from all causes and cardiovascular disease [35]. The findings of this study indicated a relatively significant correlation between employment, age, marital status and sedentary behaviour. Given this finding, if appropriate measures were not taken, there is going to be a potential rise of non-communicable diseases and an increased economic burden among the Bangladeshi population. Therefore, promoting community-based sports programs for all ages, including unemployed adults and adults who have never married, is essential in reducing the time individuals spend sitting and increasing physical activity.

This is the first study to compare a broad form of physical inactivity and its intensity type with sedentary behaviour among Bangladeshi adults. The other strength is the inclusion of a large sample size. The limitations of this study are: 1) it restricted causal inferences concerning the postulated determinants and concomitant physical inactivity behaviour, and 2) the likelihood of inaccurate physical activity information causing recall bias may exist using IPAQ.

Based on the study findings, we have proposed several recommendations. 1) Bangladesh faces a significant gap in its public health infrastructure due to the lack of a comprehensive surveillance policy for tracking physical activity and sedentary behaviour. This absence makes it challenging to accurately assess the physical activity levels and implement effective interventions for healthier lifestyles. The Ministry of Social Welfare should prioritise developing a robust surveillance system to periodically collect data on physical activity across different demographics. This would help policymakers understand the extent of physical inactivity and associated health risks, such as cardiovascular diseases. A surveillance framework would enable the government to track changes, evaluate public health initiatives, and tailor interventions for at-risk groups. In addition, it could facilitate collaboration with international health organisations, aligning Bangladesh's strategies with global best practices. Investing in this system is crucial for promoting a healthier, more active population and improving overall well-being. 2) Developing community-tailored physical activity lifestyle studies involving moderate and vigorous activity. 3) A longitudinal study to further investigate the impacts of physical inactivity and sedentary behaviour on different socio-demographic categories among adults in Bangladesh.

Conclusions

Insufficient recreational physical activity is positively associated with all sociodemographic factors, particularly among married and employed adults. Bangladeshi adults should be more habitual with recreational and vigorous physical activity and lower their sedentary behaviour. A comprehensive approach to this challenge includes key strategies such as establishing national surveillance systems to monitor physical activity and sedentary behaviour, which will help track trends and evaluate interventions. Expanding school-based physical activity programs is crucial for building lifelong healthy habits in children and adolescents. Promoting community sports programs for all ages also fosters a culture of active living.

Acknowledgements

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Ethics approval

Since this study utilized a secondary dataset from the WHO, it was exempt from the need for any kind of ethical review.

Consent to participate

Not applicable.

Consent for publication

Not applicable.

Availability of data and material

Data is available at: https://apps.who.int/iris/handle/10665/332886.

Code availability

Not applicable.

Conflicts of interest statement

The authors have explicitly stated that they have no known financial interests or personal affiliations with third parties that could potentially impact the outcome of this study.

Authors' contributions

MJK: Conceptualization; Data curation; Formal analysis; Investigation; Resources; Software; Validation; Visualisation; Roles/Writing-original draft; and Writing-editing. SJW: Validation, and Writing-review & editing. PK: Validation, and Writing-review & editing. SK: Data curation; Formal analysis; Resources; Software; Visualisation; and Writing-review & editing. BG, MUA and SMMH**:** Validation, Writing-review & editing.

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Supplementary material

Tab. S1. STROBE Statement – checklist of items that should be included in reports of observational studies.

	Item No.	Recommendation	Page No.
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	1
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	2
Objectives	3	State specific objectives, including any prespecified hypotheses	3
Methods			
Study design	4	Present key elements of study design early in the paper	3
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	3
Participants	6	(a) Cohort study—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up Case-control study—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls Cross-sectional study—Give the eligibility criteria, and the sources and methods of selection of participants	3
		(b) Cohort study—For matched studies, give matching criteria and number of exposed and unexposed Case-control study—For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	4
Bias	9	Describe any efforts to address potential sources of bias	
Study size	10	Explain how the study size was arrived at	4
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	6
		(b) Describe any methods used to examine subgroups and interactions	
		(c) Explain how missing data were addressed	6
		(d) Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy	4
		(e) Describe any sensitivity analyses	
Participants	13*	(a) Report numbers of individuals at each stage of study-eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	5
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	
		(b) Indicate number of participants with missing data for each variable of interest	6
		(c) Cohort study-Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	Cohort study-Report numbers of outcome events or summary measures over time	
		Case-control study-Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study-Report numbers of outcome events or summary measures	16

▶

Tab. S1 (follows). STROBE Statement – checklist of items that should be included in reports of observational studies.

	Item No.	Recommendation	Page No.
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	
		(b) Report category boundaries when continuous variables were categorized	
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done-eg analyses of subgroups and interactions, and sensitivity analyses	
Key results	18	Summarise key results with reference to study objectives	8
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	11
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	11
Generalisability	21	Discuss the generalisability (external validity) of the study results	8
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	11

Tab. S2. Questions account for variable formation from Global physical activity questionnaire.

Code	Questions
P1	Does your work involve vigorous-intensity activity that causes large increases in breathing or heart rate like carrying or lifting heavy loads, digging or construction work, reaping paddy, washing clothes, fishing by nets etc, for at least 10 minutes continuously?
P2	In a typical week, on how many days do you do vigorous-intensity activities as part of your work?
P4	Does your work involve moderate-intensity activity that causes small increases in breathing or heart rate such as brisk walking, carrying light loads, washing clothes for at least 10 minutes continuously?
P5	In a typical week, on how many days do you do moderate-intensity activities as part of your work?
P8	In a typical week, on how many days do you walk or bicycle for at least 10 minutes continuously to get to and from places?

HEALTH PROMOTION

A hard-to-heal wound: a case study on the collaboration between nonprofit and Public Health Sector in Southern Italy

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Keywords

Primary Health Care • Diabetic hand infections • Whole-of-health-system approach • EMERGENCY NGO • Italy

Summary

This paper presents a case study of the barriers to care faced by a 44-year-old patient from Ivory Coast who has been living in Italy for 15 years. The patient visited his general practitioner (GP) in his neighborhood in southern Italy, seeking treatment for a complex workplace-related hand injury for which parenteral antibiotic therapy was recommended. During the medical examination, the physician also diagnosed the patient with diabetes mellitus and prescribed specialist examinations (i.e., diabetology, physiatry, surgery). Even if the patient was a regular resident in Italy, he encountered difficulties in navigating the health system to obtain the recommended services (i.e., administration of parenteral antibiotic therapy, serial dressings for the wound, booking several medical appointments). The local office of the Italian non-governmental organization EMERGENCY (EMR) stepped in to support the patient in facilitating the health system navigation and collaborated with his GP on a diagnostic and therapeutic strategy. The course was regular and the patient did not develop any complications (i.e., gangrene, sepsis). The synergy between EMR, the patient, and his GP has resulted in (1) an effective clinical pathway, (2) reduced barriers to access, and (3) increased patient empowerment. However, this approach proved to be extremely resource-intensive. Organizing these resources with more planning and forethought would have granted many more patients access to care. If the SSN were to provide comprehensive healthcare to all patients without relying on the presence of NGOs, outcomes for marginalized individuals would improve significantly, and healthcare resources would be utilized more efficiently and sustainably.

Introduction

Infections of the extremities in diabetic patients are often burdened by a longer healing time and a higher risk of complications and require comprehensive diagnostic and therapeutic management, with a multidisciplinary approach that is not easily achieved in the outpatient setting. Hereby, we report the case of a 44-year-old man with hand infection following a foreign body injury, who was newly diagnosed with diabetes mellitus (DM) and underwent a comprehensive therapeutic course entirely carried out in an outpatient setting in the eastern area of Napoli, Italia.

Despite the high risk of poor outcomes if treatment is delayed or inappropriate, evidence-based data about the correct management setting for diabetic hand infections (DHIs) is scarce. Some studies report that, under specific conditions, DHIs can be managed in the outpatient setting [1].

A multidisciplinary approach, a key factor in DHI management, should include infectious disease and expert hand surgery consultations, as well as ongoing case management (*i.e.,* wound management interventions), diabetes control and functional recovery. From the perspective of a primary healthcare (PHC) approach, all these interventions should be coordinated by the General Practitioner (GP), working together with specialist doctors, nurses and physiotherapists. In real life, several factors besides clinical issues can affect DHI management and outcomes, including barriers to healthcare access due to local context (*i.e.,* availability and affordability of services) or personal background (*i.e.,* limited access to healthcare and/or language barriers). In the eastern part of Napoli, in Campania region, South Italy, some associations and non-governmental organizations (NGOs) work to overcome the barriers to healthcare access. Among those, in 2015 EMERGENCY, an Italian NGO founded in 1994, established an outpatient center for people experiencing difficulties in accessing healthcare services provided by the Italian public National Health System (NHS; in Italian, *Sistema Sanitario Nazionale*, SSN), with the specific objectives of identifying the existing barriers to healthcare access, supporting people in overcoming those barriers, and providing primary healthcare when those barriers persist, with a multidisciplinary, integrated socio-sanitary approach. The overall goal of the organization is to end up integrating these individuals within the Italian National Health System, without providing parallel care, but, rather, to identify the barriers to access to care and the strategies to overcome these, while at the same time providing temporary care to

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people who have been left out of the system or encounter substantial barriers in it. The Italian SSN is organized at the regional level (*Sistema Sanitario Regionale* - SSR) under the supervision of the Ministry of Health. Based on the three pillars of universality, equity and equality, it provides universal healthcare coverage to all citizens and residents. Local health authorities deliver services either free of charge or with a co-payment fee waiver (*i.e.,* ticket*).* Partial or total exemptions are available for individuals with chronic or rare diseases, low or no income, pregnancy, or disabilities. Coverage for non-European nationals is generally valid for the duration of their permit of stay. On the other hand, undocumented non-EU persons can apply for an STP (*Straniero Temporaneamente Presente*) code, which grants access to SSN services for six months and can be renewed as necessary [2, 3]. Over the years, EMERGENCY NGO [4] has forged cooperative relationships with local GPs and other non-profit associations. In the case presented here, positive outcomes were mostly due to a strong networking strategy between social and health providers in the local context, that mitigated the risk of poor outcomes linked to the existing barriers to healthcare access.

Case presentation

On the 11th of February 2023 T.A., a 44-year-old man of Ivorian origin without previously known medical conditions, was admitted to the Emergency Department of a hospital in Naples, Italy, due to a left-hand injury caused by an unknown foreign body (possibly a rusty iron chip) penetrating the skin while working in a farm. On physical examination, the left-hand palm was swollen and painful, especially close to the proximal part of the third and fourth fingers. Oral therapy with amoxicillin/clavulanic acid and a non-steroidal anti-inflammatory drug (*i.e.,* ibuprofen) was prescribed and the patient was discharged. The patient was regularly registered with the public SSN, and after 5 days, given the lack of improvement, the patient presented himself at his GP for consultation. The oedema was spread from the left hand to the elbow, and the wound showed no improvement. Even if the patient was a regular resident in Italy, he encountered difficulties in navigating the health system to obtain the services that were originally recommended (*i.e.,* administration of parenteral antibiotic therapy, serial dressings for the wound, booking the several medical appointments). For this reason, the GP contacted the EMERGENCY NGO outpatient service in the same Napoli area. The aim was to undertake a multidisciplinary approach to care, with both medical and nursing care, including wound management and parenteral antibiotic therapy, if needed. This approach was not available at a standard primary care level in the east area of Naples (suburban neighborhood of Ponticelli) and EMERGENCY NGO offered the possibility to have nursing care and support in health system navigation in a free, quick and easily accessible way. During the evaluation at the EMERGENCY NGO clinic, DM was diagnosed, based on a glycemia of 268 mg/dl (normal values: 60-110 mg/dl) on a finger stick test, and metformin was initiated. Oral antibiotic therapy was initially switched to levofloxacin but, given no evident improvement, a broader spectrum and parenteral approach was adopted, with intravenous infusions and later intramuscular injections performed at the EMERGENCY NGO outpatient service.

Along with antibiotic therapy, bedside wound management interventions with excisional procedures were promptly started on 20th February and were regularly carried out at the EMERGENCY NGO clinic until 29th April (every other day, excluding weekends), monitoring clinical evolution. Figures 1 to 5 show progressive wound improvement from 22nd February to 29th April 2023 with combined pharmacological and wound management (*i.e.,* debridement, disinfection, and dressing). After debridement, disinfection and several days of antibiotic therapy, the forearm swelling was resolved. The initial injury was identified on the palmar surface, close to the proximal part of the third finger. The foreign body likely to be the causative agent

Fig. 1. Left hand lesion on February 22nd (day 2 of IV antibiotic therapy).

Fig. 2. Left hand lesion on 24th February (day 4 of IV antibiotic therapy).

Fig. 3. Left hand lesion on 6th March (day 14 of IV antibiotic therapy).

Fig. 4. Left hand lesion on 20th March 2023 (10 days after substitution of IV with IM antibiotic therapy).

Fig. 5. Left hand lesion on 29th April 2023 (end of wound management treatment).

was not identified in the wound. Purulent drainage from the initial injury and purulent accumulations around appeared early in the wound treatment session, followed by interdigital cutaneous fistulas among the last four fingers (Fig. 3). Regular wound treatment sessions were carried out, with debridement and local application of alginate dressing and, later, polyurethane pads. Antibiotic therapy was stopped on 31st March, due to completion of the therapeutic course and clinical improvement. Left hand ultrasound scan (performed on April 19th in a third sector association that provides free ultrasound scans in the area for people in need) still showed widespread oedema of the intermetatarsal muscles, with some small anechoic collections, and some additional non-homogeneous collections close to the metatarsophalangeal joints. However, a further clinical improvement of the lesions was evident in the weeks after, and on 29th April (Fig. 5) wound treatment sessions were concluded. In the last session, all the lesions appeared closed with no clear signs of active infection but persistent left-hand swelling, hypotrophy of the forearm and hand and finger movement impairment. While local and systemic therapies were performed, a specialist hand surgery consultation was obtained (7th March 2023), but no surgical indication was set at that time. After multidisciplinary consultation at the EMERGENCY NGO clinic, a basic physical therapy approach was initially chosen, and the patient and a friend of his (who acted as his caregiver on several occasions) were trained on active mobilization exercises by the nursing staff.

However, given the persistent movement impairment, in the following months, a hand MRI was performed (2nd May 2023), with evidence of widespread subcutaneous palmar oedema of the hand and fingers, especially involving the third and fourth proximal phalanges. A new hand surgery specialist consultation was performed in the private sector (31st May 2023, sponsored by the patient's employers), which suggested a physical therapy approach. The physiatric assessment was carried out within the public health system in July 2023, followed by physiotherapy and ultrasound therapy, with only partial improvement. The patient underwent a further hand surgery evaluation in December 2023 within the public health system, and eventually a surgery approach was suggested (tenoarthrolysis) to solve the mobility

issues, likely due to post-inflammatory adhesions, not objectified on imaging. The patient is currently on the waiting list for surgical intervention that will be provided by the SSN.

Concerning the new diagnosis of diabetes mellitus, specialist consultation was performed within the SSN. Insulin subcutaneous therapy and oral metformin were prescribed, together with the complete investigation panel to assess the presence of diabetes-related organ damage. Health education about the disease and glycemic control training was provided by the nursing staff of the EMERGENCY NGO clinic. Follow-up is currently ongoing and managed by his GP.

Given some clear difficulties throughout the entire care process in navigating the SSN and the bureaucratic issues related to the incident in the workplace, the patient was supported by the social staff of the EMERGENCY NGO clinic in booking medical appointments, requesting fee waivers (diabetes- and income-related), and in applying for an invalidity pension in collaboration with the patient's GP, with the ultimate aim of a gradual empowerment of the patient.

Discussion

This case study sheds some light on some interesting management aspects. From a clinical point of view, outpatient management of hand infection in diabetes has shown to be feasible and effective under some conditions, according to previous literature [1]. In this case, timely therapy and the combined approach with systemic antibiotic therapy and wound management intervention were crucial elements for the positive outcome. However, several other aspects in addition to the clinical features could have influenced the patient's outcome. Although he has been living in Italy for more than 15 years, is quite fluent in the Italian language, and regularly registered with the Italian SSN, he showed some difficulties in navigating the health system, particularly in booking medical exams and applying for fee waivers, due to poor knowledge about how booking and referral pathways work within the SSN. In addition, the accessibility to the local health system was also impaired by the scarce availability of outpatient services combining the possibility of receiving parenteral antibiotic therapy and wound management services in an outpatient setting. Primary care, as currently organized in the area, has inadequate resources to improve healthcare access and provide appropriate care for cases that need more complex outpatient management.

Taking these barriers into account, and aiming to overcome them, in the case hereby presented we adopted an approach inspired by the PHC model. PHC is a whole-of-society approach to health that aims at ensuring the highest possible level of health and well-being and its equitable distribution, with three main components: 1) comprehensive integrated health services to meet people's needs; 2) multi-sectoral policies and actions to address the upstream and wider determinants of health; 3) engaging and empowering individuals, families, and communities [5]. In addition, multidisciplinary is another key factor of the PHC approach, which has proven to be effective and efficient in terms of health outcomes [6]. Bearing this model in mind, our approach was characterized by:

- multidisciplinary and teamwork: the therapeutic path was coordinated by the patient's GP and involved different professionals, including specialist doctors, nurses, radiologists and social workers, that took charge of the different health and administrative needs;
- networking between the public health provider (*i.e.,* the GP), an NGO (*i.e.*, EMERGENCY) and other non-profit private providers, which led to overcoming the barriers to timely and appropriate health care provision;
- integration between social and health-related interventions that allowed the patient to face both the administrative barriers and those related to healthcare access while receiving appropriate and timely therapeutic interventions;
- involvement of caregivers in health education interventions and patient empowerment, to give the patient adequate tools to improve his health status.

However, our approach presents some limitations. First, barriers to healthcare access were temporarily circumvented, relying on the non-profit private sector, but not solved: in fact, parenteral therapy and wound management activities are still scarcely available in the public sector at the primary care level, as well as radiological services. In addition, the strategy adopted is strictly tailored to the locally available resources and network and not easily generalizable to other contexts. Moreover, other barriers (*i.e.*, language and bureaucratic) are systemic in the SSN and remain, despite the local NGO efforts. This study demonstrates the inefficiency of working without a *whole-of-health system* approach. A clear and established PHC strategy was lacking. Considerable human and material resources were mobilized and deployed for the management of a single case. Traditionally, primary care routes were underutilized or not utilized at all. All of this goes to show the unsustainability of working from a piecemeal perspective, ignoring the need to integrate interventions throughout the health sector. These drastic investments yielded positive results for one patient. However, this outcome could have been multiplied to affect many other health-seekers without further investment, if this PHC strategy, deeply rooted in a whole-of-health system approach, had been formalized.

Conclusions

We presented a clinical and management case providing several starting points for reflection on the potential of a PHC approach applied to a complex clinical case. Currently, in Campania region, the SSR is not yet equipped with a PHC organization as it is in terms

of accessibility to assistance, of comprehensiveness, of consideration of biopsycho-social factors, of coordination between different actors involved in the system, of the temporal-continuity of assistance. The patient's condition required territorial, medical-nursing and administrative management. In these cases, the synergy between public providers and the NGOs can be strategic to improve primary care management in the light of the PHC principles. In this light, NGOs act as temporary support to the SSN, providing health and administrative services and, at the same time, highlight patients' unmet needs and barriers to access basic care. Furthermore, they carry out advocacy actions whose aim is to prompt the SSN to provide needed primary care services. In December 2023 a formal cooperation project between two local GPs and the NGO EMERGENCY was started in Naples, as an experimental form of healthcare provision with a PHC approach. While innovative and promising, this strategic synergy cannot be seen as an end, but as a powerful tool to promote evidence-based advocacy actions to remove the existing barriers to healthcare access at a broader level, with the ultimate goal of public, equitable, accessible and sustainable care for everyone, recognizing and protecting health as a human right.

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Informed consent

Written informed consent was obtained from the patient for publication purposes of his case report and the related images. A copy of the written consent is available for review.

Conflict of interest statement

Authors have no conflicts of interest to disclose.

Authors' contributions

VG conceived and designed the case report. VG and GR drafted the manuscript. SF collected the clinical data and images. EL and ALC critically revised the manuscript for intellectual content. All authors read and approved the final version of the manuscript.

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HEALTH PROMOTION

Virtual Reality as a Tool for Wellbeing in Public Healthcare: Analysis of a Clinical Case

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Keywords

Virtual Reality • Wellbeing • Public Healthcare • e-Health

Summary

Background. *Virtual Reality (VR) is a technology that enables the creation of immersive, interactive, and collaborative environments, with extensive applications in the realm of e-Health.*
Methods. *This study aimed to reduce stress and anxiety in hospitalised patients by employing guided virtual scenarios and non-invasive biosensors.*
Results. *During the initial experimental phase, conducted on 33 patients in a cardiac rehabilitation ward, improvements were observed in stress levels (-11.3%), depression (-4.2%), and anxiety (-3.2%). Supporting these results, a specific clinical case analysis revealed significant improvements in an 82-year-old woman with moderate depression and severe social isolation. Following the VR intervention, the patient experienced a substantial reduction in isolation, heightened motivation for daily activities, and enhanced social interaction quality, with a 35% increase in perceived quality of life. Physiological improvements included reduced sympathetic nervous system arousal and greater heart rate variability stability.*
Conclusions. *These findings underscore VR's potential to promote psychophysical wellbeing and improve healthcare service quality, advocating innovative preventive and therapeutic methods.*

Introduction

Psychophysical wellbeing is a significant challenge in public healthcare, particularly for vulnerable patients in hospital environments. In Italy, where the public health system faces ongoing pressures from an aging population and resource constraints, stress and isolation among hospitalized patients are critical issues. These conditions can severely weaken immune defenses and overall health, increasing the risk of hospital-acquired infections and other complications [1]. The COVID-19 pandemic exacerbated these challenges, highlighting the need for innovative solutions to counteract social isolation and promote mental and physical health [2]. This study explores the use of Extended Reality (XR), encompassing Virtual Reality (VR), Augmented Reality (AR), and Mixed Reality (MR), as an innovative tool to enhance wellbeing and hygiene standards.

The primary objective of the project was to alleviate stress and enhance the quality of life (QoL) of hospitalised patients through:

- emotional engagement and cognitive stimulation;
- mitigating isolation in hospital wards and care homes, positively impacting mental and physical hygiene;
- progress monitoring using specific sensors.

These goals were achieved by integrating techniques such as mindfulness, art therapy, and museum therapy within a multisensory and immersive XR framework [3].

Materials and methods

The project adopted an integrated multidisciplinary approach, combining neuroscience, psychology, and engineering with a particular focus on physical and mental hygiene. The study was conducted in the cardiac rehabilitation ward of Lecce, Italy, from January 2023 to March 2023.

Sample and Setting

A total of 33 hospitalized patients, aged between 45 and 75 years, enrolled in the cardiac rehabilitation program were included in the study. All participants provided informed consent prior to enrollment. The intervention took place in a dedicated therapy room within the hospital, ensuring a controlled and quiet environment.

Intervention Protocol

The intervention extensively utilised Extended Reality (XR) technology, an innovative immersive tool that creates virtual environments capable of inducing relaxing emotional states and stimulating cognitive engagement. Each patient participated in XR sessions that integrated guided virtual scenarios with mindfulness techniques. The intervention protocol was as follows:

- **Frequency and Duration:** patients underwent two sessions per week over a six-week period. Each session lasted approximately 30 minutes;
- **Technologies Used:** patients experienced immersive VR environments through head-mounted displays,

while non-invasive biosensors (such as the Emotiv Epoc for EEG recordings and the Empatica E4 Wristband for measuring electrodermal activity and heart rate) were used to continuously monitor physiological parameters;
- **Objective:** the aim was to foster emotional engagement and cognitive stimulation while facilitating real-time biofeedback, thus supporting targeted psychological interventions.

Physiological Monitoring

Real-time monitoring of physiological data played a pivotal role in assessing the impact of immersive experiences. Biosensors captured measures including electrodermal activity (EDA), heart rate (HR), and EEG signals, elucidating the relationship between emotional states and physiological responses. These data contributed to understanding how immersive XR scenarios can modulate stress-related physiological responses, such as reduced sympathetic nervous system activation, lower skin conductance response (SCR) peaks, and enhanced heart rate variability (HRV).

Clinical Applications and Benefits

The intervention produced numerous benefits spanning various aspects of psychological and physical health:
- **Stress Reduction:** immersive XR scenarios directly influenced physiological stress regulation, evidenced by reduced sympathetic nervous system activation, lower skin conductance response (SCR) peaks, and enhanced heart rate variability stability. These outcomes align with prior studies validating VR's efficacy in improving stress responses [7];
- **Psychological Support:** mindfulness techniques and guided meditation integrated into VR demonstrated significant efficacy in managing anxiety and depression, corroborating prior research on VR's potential to enhance emotional regulation and psychological wellbeing [8];
- **Innovative Therapeutic Practices:** the intervention incorporated innovative therapies such as museum therapy and art therapy, particularly beneficial for patients with chronic stress, dementia, or neurodegenerative disorders. These approaches, promoting awareness and hygiene management, were integrated with XR to enhance attention and cognitive stimulation. A notable example is the MoMA Alzheimer's Project, an initiative by New York's Museum of Modern Art, which demonstrated art's role in mitigating cognitive decline and enhancing life quality for Alzheimer's patients [9].

Data Collection and Statistical Analysis

- **Timing of Assessments:** baseline measurements were collected one week prior to the start of the intervention. Subsequent assessments were conducted immediately after the six-week intervention and at a one-month follow-up to evaluate both immediate and sustained effects.
- **Outcome Measures:** psychological outcomes were assessed using validated questionnaires. The Perceived Stress Scale (PSS) [4] measures the degree to which situations in an individual's life are perceived as stressful, evaluating aspects such as unpredictability, overload, and lack of control over the events of the past month. The Hospital Anxiety and Depression Scale (HADS) [5] is a self-report instrument comprising 14 items divided into two subscales – HADS-A for anxiety and HADS-D for depression – with each subscale scoring from 0 to 21. Higher scores on these scales indicate greater levels of anxiety or depressive symptoms. Both instruments have been extensively validated for clinical and hospital settings, ensuring reliable assessments of psychological distress. Physiological outcomes were quantified through continuous biosensor monitoring, capturing real-time data on **SCR** as an indicator of stress.
- **Statistical Analysis**: the primary outcome, the change in PSS scores, was evaluated by calculating the percentage change from baseline to post-intervention and follow-up. No formal statistical testing was performed to determine statistical significance, as this study was observational in nature. Future studies should consider implementing statistical tests to assess the significance of these changes.
- The project has demonstrated how the integration of neuroscience, psychology, and advanced technologies can not only optimise patients' physiological and psychological responses but also open new avenues for treating mental and physical health conditions, promoting an innovative and highly personalised therapeutic approach.

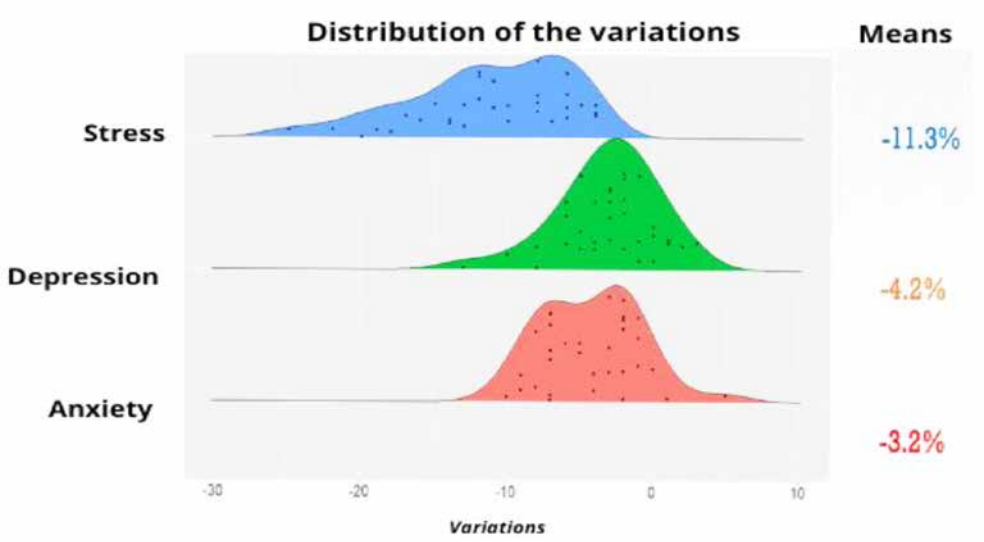
Results

This study involved a total of 33 hospitalized patients in a cardiac rehabilitation ward, who participated in a six-week program that included immersive guided meditation sessions, art therapy, and virtual museum therapy. The key outcomes of the program are described below:

The program resulted in a significant reduction in perceived stress, with an 11.3% decrease in scores on the Perceived Stress Scale (PSS). This indicates a general reduction in stress among the participants, suggesting that the intervention had a positive impact on managing the stress typically associated with cardiac rehabilitation. In terms of mood, a 4.2% reduction in depressive symptoms was observed, as measured by the Hospital Anxiety and Depression Scale (HADS). This reflects an improvement in patients' mood, which may have positively influenced their overall rehabilitation experience and psychological recovery.

Anxiety symptoms also showed a slight but positive improvement, as evidenced by HADS scores (Fig. 1). Although the change was modest, this improvement suggests overall progress in managing anxiety, demonstrating the benefits of the therapeutic interventions. Another important aspect of the program was the

Fig. 1. Differences between the questionnaire scores obtained after the experience and those recorded before the experience.



Tab. I. Study Results on 33 Individuals.

Parameter	Pre-Intervention	Post-Intervention	Percentage Change	Improvement Description
Stress Level (PSS)	50	44.2	-11.3%	Significant perceived stress reduction, supported by SCR peaks decrease
Depressive Symptoms (HADS)	12	11.5	-4.2%	Slight improvement in mood and depressive symptoms
Anxiety Symptoms (HADS)	10	9.7	-3.2%	Slight reduction in anxiety symptoms, indicating overall improvement
SCR Peaks	10	3	-70%	Reduction in galvanic skin response peaks, reflecting decreased physiological stress
Social Satisfaction	3/10	5/10	+40%	Improved perception of social interaction quality and greater participation

increase in socialization. Participants exhibited greater involvement in collaborative virtual experiences, which contributed to a strengthened sense of belonging and social connection. This aspect is further detailed in Table I, which highlights the increased participation in these group activities.

From a physiological perspective, significant improvements in autonomic nervous system function were observed. Specifically, there was a decrease in the peak frequency of the Skin Conductance Response (SCR), along with an increase in heart rate variability (HRV). These results suggest a reduction in sympathetic nervous system activation and an improvement in autonomic balance, indicating that the program also had positive effects on the physiological response to stress.

Finally, quality of life improvements was significantly documented in a detailed case study, which showed notable overall enhancements in one patient's life conditions. This case highlights the potential impact of the program on quality of life, underscoring how innovative therapeutic approaches can contribute to the overall well-being of patients.

Case Study: 82-Year-Old Woman

Among the participants in the study, one case stands out: an 82-year-old woman with moderate depression and severe social isolation, which had significantly limited her quality of life and daily activities. Following the completion of the virtual reality (VR) sessions, several notable improvements were observed in her well-being.

First, the quality and frequency of her social interactions showed remarkable progress. Prior to the intervention, the patient engaged in social interactions only once every two weeks. After the VR sessions, the frequency of social interactions increased to 2-3 times per week, marking a 150% improvement. This significant shift helped to break a long-standing cycle of isolation, contributing to a greater sense of connectedness.

In addition to social engagement, the patient demonstrated enhanced motivation for daily activities. She became more involved in personal and relational activities, including self-care routines and social participation. This increased motivation was indicative of a broader improvement in her overall engagement with life.

Regarding her overall quality of life, significant

Tab. II. Improvements in QoL Domains for the 82-Year-Old Patient.

Domain of Quality of Life (QoL)	Pre-Intervention Score	Post-Intervention Score	Improvement (%)	Description of Improvement
Social Satisfaction	3.0/10	4.2/10	+40%	Increased sense of belonging and reduced loneliness, with greater participation in social interactions
Physical Health	4.0/10	5.4/10	+35%	Improved physical capabilities, more frequent walks, and enhanced self-care routines
Psychological Health	5.0/10	6.3/10	+25%	Reduced depressive symptoms and heightened motivation to engage in daily activities
Autonomy and Independence	3.5/10	5.2/10	+48%	Greater involvement in personal care and daily routines
Overall Wellbeing	4.2/10	6.0/10	+43%	Enhanced perception of psychophysical wellbeing

This table provides a clear and quantitative view of the improvements across various domains of quality of life. The data is organised to highlight the programme's impact on crucial aspects of the patient's wellbeing.

Tab. III. Comparison of Pre- and Post-Intervention Parameters in the Clinical Case.

Parameter	Measurement Method	Pre-Intervention Result	Post-Intervention Result	Increase (%)
SCR Peaks	Physiological measure (SCR)	4-5 peaks per day	2-3 peaks per day	-50%
Heart Rate Variability (HRV)	Physiological measure (HRV)	50 ms	70 ms	+40%
Social Interactions	Self-reports and observations	1 interaction every 2 weeks	2-3 interactions per week	+150%
Motivation	Self-reports and observations	25% of daily activities	60% of daily activities	+140%
Social Satisfaction	Self-reports and observations	3/10	4.2/10	+40%

improvements were noted. The patient's score on the WHOQOL-BREF scale increased from 4.5/10 to 6.8/10, representing a 51% improvement (Tab. II). This positive change reflects a notable enhancement in her perception of her well-being and life satisfaction.

Psychologically, the patient experienced a substantial reduction in perceived stress, with her score on the Perceived Stress Scale (PSS) improving by 45%. This reduction in stress was closely associated with a decrease in depressive symptoms, which were reflected in a 28% improvement in the Hospital Anxiety and Depression Scale (HADS). These results suggest a significant enhancement in her overall psychological well-being, further underlining the potential benefits of the VR intervention for addressing both mental health and social isolation.

These improvements are documented through a combination of objective measurements, such as heart rate variability (HRV) and skin conductance response (SCR) peaks, which reflect the physiological changes related to stress reduction and overall well-being improvement. The measurements were taken using daily monitoring, showing a significant reduction in SCR peaks (-50%) and an increase in heart rate variability (+40%). In parallel, psychological improvements were monitored through self-reports from the patient and direct observations (Tab. III).

This clinical case is not only an example of individual success but also represents a model for public health, demonstrating how innovative and personalized approaches can radically transform the lives of vulnerable patients. Its story highlights the importance of integrating advanced technologies and psychological interventions in the context of cardiac rehabilitation, paving the way for new possibilities in the treatment of chronic anxiety and social isolation.

Discussion

The project has demonstrated how the integration of neuroscience, psychology, and advanced technologies can not only optimise patients' physiological and psychological responses but also open new avenues for treating mental and physical health conditions, promoting an innovative and highly personalised therapeutic approach.

The project yielded promising results, demonstrating the effectiveness of an integrated multidisciplinary approach combining neuroscience, psychology, engineering, and immersive technologies to address stress, anxiety, and social isolation, with positive psychological and physiological impacts. Patient data and experiences suggest that Extended Reality (XR), in conjunction with physiological biosensors, represents a breakthrough in managing psychological disorders and improving general wellbeing.

Implications of Immersive Technologies in Stress Management: The results related to stress reduction, measured through skin conductance response (SCR) and heart rate variability (HRV), corroborate prior studies supporting the effectiveness of VR in enhancing physiological responses to stress. For instance, a study by Freeman et al. (2017) associated virtual

environments with significant reductions in anxiety and stress symptoms, positively influencing emotional regulation [10]. XR appears to activate relaxation mechanisms, decreasing sympathetic nervous system arousal. These results support the use of VR as a therapeutic tool to reduce physiological activation related to acute and chronic stress.

Mindfulness and Meditation as Psychological Support Tools: The integration of mindfulness and guided meditation into the treatment provided significant psychological benefits, reducing anxiety and depression in patients. According to a study by Hofmann et al. (2010), mindfulness has been documented as effective in treating psychological disorders, particularly in reducing symptoms of anxiety and depression [11, 12]. The combination of mindfulness and meditation with VR allowed patients to experience deep relaxation, fostering emotional self-regulation. Although the effects are promising, one aspect to consider is the need for regular, personalized treatment sessions to optimize benefits, taking into account individual variables related to emotional response and patients' concentration abilities.

Music Therapy and Art Therapy in Rehabilitation: The inclusion of music therapy and art therapy in the program brought significant benefits for patients with cognitive disorders, such as dementia and neurodegenerative diseases. The cognitive stimulation derived from art and culture contributed to improving attention, memory, and daily awareness. Research such as that by Civitarese et al. (2016) documented the effectiveness of art therapy in improving cognitive functions in Alzheimer's patients, highlighting a significant improvement in quality of life and disease management [13]. The MoMA Alzheimer's Project experience provided important insights into how art can stimulate memory and reduce cognitive symptoms, with a positive impact on quality of life [9]. However, a critical aspect that emerged is the difficulty of access to such interventions for certain patient groups due to logistical or economic barriers, which can limit the universal applicability of these therapies.

Study Limitations and Future Directions: Although the results obtained are encouraging, our study has some limitations. First, the relatively small sample size may affect the generalizability of the results to a larger population. Another aspect to consider is the limited duration of the intervention, which does not allow for observing long-term effects. Studies by Garrison et al. (2015) and Pina et al. (2020) suggest that the effectiveness of VR and mindfulness techniques could be enhanced with prolonged treatments and regular follow-up to observe long-term benefits [14, 15]. In the future, it would be useful to examine the possibility of combining these interventions with pharmacological approaches to treat complex psychological disorders, such as chronic anxiety, which could benefit from integrated therapy.

Implications for Public Health: The results of this study have important implications for public health, suggesting that the adoption of advanced technologies and innovative therapeutic approaches could be a crucial step toward transforming the treatment of psychological and physiological disorders. The integration of XR, biosensors, and psychological therapies in the treatment of stress-related, anxiety, and social isolation disorders could improve access to and effectiveness of care, reduce healthcare costs, and enhance the quality of life for patients, particularly those with chronic or neurodegenerative diseases. According to evidence from studies like that of Rizzo et al. (2019), the use of VR in psychological rehabilitation is emerging as an opportunity to treat complex psycho-physical conditions efficiently and cost-effectively [16].

These initial findings suggest the benefits to the community from using this type of alternative medicine in hospital settings. There is a need for further experimental campaigns to be conducted on a larger sample in order to obtain statistically significant results.

Conclusions

The study has demonstrated the potential of Extended Reality (XR) as a transformative tool in public health, capable of improving the quality of life for vulnerable patients and supporting the maintenance of high hygiene standards. The integration of XR technologies with traditional therapeutic approaches can represent a breakthrough in healthcare, providing effective tools to reduce stress, improve psycho-physical well-being, and promote proper hygiene practices. Future perspectives include expanding the project to extra-hospital contexts, such as schools and nursing homes, and developing personalized protocols based on machine learning to tailor XR experiences to individual needs, strengthening the link between technological innovation and sustainable public health.

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Ethics approval and consent to participate

This study was exempted from ethical committee approval, with the consent of the Asl Lecce, protocol no. 66, dated 8.10.2021.

Consent for publication

Not applicable.

Availability of data and materials

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

Conflicts of interest statement

The Authors declare that they have no competing interests.

Authors' contributions

FN: contributed to the conception and design of the work, to the interpretation of data, and wrote the first draft of the manuscript. VG: contributed to data interpretation and revised the final version of the manuscript. PL: contributed to the conception and design of the work, to the interpretation of data and substantially revised the manuscript. All Authors revised and approved the final version of the manuscript.

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Infectious Diseases

The burden of Tuberculosis in a province of a low incidence country: epidemiological differences between Italy-born, regular foreigner and irregular foreigner TB cases

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Keywords

Tuberculosis • Surveillance • Epidemiology • Migration status • End TB strategy

Summary

Introduction. *Tuberculosis (TB) represent a serious public health issue even in most developed countries, where TB cases are mostly concentrated in some risk groups, like immigrants from high-incidence TB countries. Aim of the study was to describe the occurrence of TB in Siracusa Local Health Authority (Italy) and to explore its determinants in three different populations: Italy-born, regular foreigner and irregular foreigner.*
Methods. *Cases were classified per patient origin and legal ground: Italy-born (IB); regular foreigners (REF); irregular foreigners (IRF). All the notifications were evaluated and uploaded to the Notification System of Infectious Diseases (PREMAL) by the Epidemiology Unit of the Prevention Department of Siracusa LHA.*
Results. *During the study period, 183 TB cases were detected: 72 (39.3%) were Italy-born, 26 (14.2%) were regular foreigners and 85 (46.5%) were irregular foreigners. Overall, foreign-born cases (regularly and irregularly residents) accounted for 60.7% of all cases. We demonstrated significative differences in epidemiological, demographic and clinical features among the three different groups.*
Furthermore, we registered a decrease in TB notifications of 59.5% among Italy-born patients, 46.0% among regular foreigners and 95.5% among irregular foreigners, who, however, remain the population group with the highest incidence of tuberculosis in Siracusa LHA.
Conclusions. *TB control in migrants is considered key to achieving TB elimination in low TB incidence countries, in accordance with the World Health Organization (WHO)'s End TB Strategy, that set ambitious targets for 2020–2035, including 90% reduction in TB incidence and 95% reduction in TB deaths by 2035, compared with 2015.*

Introduction

Tuberculosis (TB) is one of the oldest diseases known to affect humans and still represent one of major cause of death worldwide [1]. TB, caused by the bacillus *Mycobacterium tuberculosis*, is primarily a pulmonary disease. However, *M. tuberculosis* also infects lymph nodes, the pleura, bone, the central nervous system and other organs. These clinical presentations constitute extra-pulmonary TB. While 10% of those infected develop active disease, the majority of individuals mount an effective immune response leading to successful containment of *Mycobacterium tuberculosis* growth; a condition known as latent TB infection (LTBI) [2].
Despite the UN's resolution of ending tuberculosis infection by 2035, it remains a major public health challenge. Tuberculosis used to be the leading cause of death in infectious diseases and became the second after COVID-19 during the pandemic [1], including among persons living with human immunodeficiency virus (HIV) infection [3].
More than 10 million people continue to fall ill with TB every year. About a quarter of the global population is estimated to have been infected with TB. The reported global number of people newly diagnosed with TB was 7.5 million in 2022. This is the highest number since WHO began global TB monitoring in 1995. Globally in 2022, TB caused an estimated 1.30 million deaths [1].
Geographically, most TB cases in 2022 were in the WHO regions of South-East Asia (46%), Africa (23%) and the Western Pacific (18%), with smaller shares in the Eastern Mediterranean (8.1%), the Americas (3.1%) and Europe (2.2%) [1].
TB epidemiology is strongly influenced by social and economic development and health-related risk factors such as undernourishment, diabetes, HIV infection, alcohol use disorders and smoking. Strictly sense, TB can be considered a social disease [4].
A World Health Organization (WHO) initiative, The End Tuberculosis Strategy, set ambitious targets for 2020–2035, including 20% reduction in TB incidence and 35% reduction in the absolute number of TB deaths by 2020

and 90% reduction in TB incidence and 95% reduction in TB deaths by 2035, compared with 2015 [5-6].
The current TB epidemiological situation in Italy, as in many other industrialized countries, is characterized by an incidence lower than 10 cases/100,000 inhabitants in the general population, a threshold within which the WHO defines Italy as "low endemic country" [7]. In countries with low TB incidence, the cases are mostly concentrated in some risk groups, like immigrants from high-incidence TB countries. In Italy, 2,480 cases of TB have been notified in 2021, with a notification rate of 4 per 100,000. A foreign origin was detected in more than half of all TB cases (57.9%) [8].
Immigrants arriving from high-incidence TB countries may pose a threat to TB control in low incidence host countries. In Italy, a significant positive correlation between TB notification rates and immigration numbers was observed [9]. Besides the immediate morbidity and mortality from any resurgence of TB, there would also be the increased economic cost of treatment of cases, tracing and preventive treatment of contacts, as well as concern over the potential emergence of drug-resistant forms of TB, that are emerging as a greater threat and causing higher mortality rates [9]. TB in migrants from TB-endemic countries can be the result of different processes: arrival in the host country with prevalent active TB, entering the host country with latent tuberculosis infection (LTBI) that reactivates after arrival, new infection in the host country, or infection when travelling back and forth from the host country to the country of origin [10, 11]. TB control in migrants is therefore considered key to achieving TB elimination in accordance with the World Health Organization's End TB Strategy [5, 6].
Aim of the current study was to describe the occurrence of TB in Siracusa Local Health Authority (LHA), Italy, over a ten-year period (2014-2023) and to explore its determinants in three different populations, concerning demographic and epidemiological data, clinical features and risk factors for TB infection and transmission.

Methods

We conducted a ten-year retrospective analysis of all TB notifications in Siracusa LHA, from 1st January 2014 to 31st December 2023. According to ISTAT data, censed foreign born people account for 3.9% of the population (384,866 province population). The presence of regular foreigners in the province of Siracusa is lower than at national level, where migrants represent 8.6% of the resident population [12]. Any official data are available for irregular foreigners. According to an estimation by ISMU Foundation (Initiatives and Studies on Multi-ethnicity), an independent and highly qualified research centre, the estimated number of irregular foreigners is about a mean of 8.1% of regular immigrants through the years 2014-2023 (last available data for the year 2021) [13].
Cases were classified per patient origin and legal ground: Italy-born (IB); regular foreigners (REF); irregular foreigners (IRF) (*i.e.,* foreigners without residence permit, as migrants landed on our coasts).
By law, TB notification is mandatory in Italy, according to Ministerial Decree 15 December 1990 "Information system of infectious and diffusive diseases" (and subsequent amendment in Ministerial Decree 29 July 1998) [14 15]. All the notifications regarding the considered period were evaluated and uploaded to the Notification System of Infectious Diseases (PREMAL) by the Epidemiology Unit of the Prevention Department of Siracusa LHA.
A TB case was defined as all forms of active TB, including pulmonary and extrapulmonary TB. For the distribution between pulmonary and extrapulmonary TB, cases with both pulmonary and extrapulmonary TB were categorized as pulmonary TB. Diagnosis was either microbiologically confirmed or based on clinical and/or paraclinical findings suggestive of TB, prompting TB treatment. Information on how TB cases were detected was not available. There was no systematic TB screening among migrants during the study period.
Cases notified more than one time within 12 months were included using first notification, unless they had an outcome report of treatment completion or TB cure within the same 12-month period.
Number of TB cases and TB incidence (/100,000 population per year) were investigated for the considered period both for the total population and for the three principal population subgroups.
Calculation of TB incidence in the not Italy-born population was made with two different methods and using different data sources: first considering as denominators the data on immigrants regularly registered (subjects who own a regular residence permit) [16] and secondly considering the estimated prevalence of not regularly registered immigrant presence, by an independent research centre [17].
Study variables were analysed differentiating between the three principal subgroups. Comparison between groups were made using the calculation of odds ratio (OR) and its 95% confidential intervals (95% CI). Continuous variables (*i.e.,* age at notification) were compared using the student t-test for unpaired data. Statistical analysis was performed using Stata.

Results

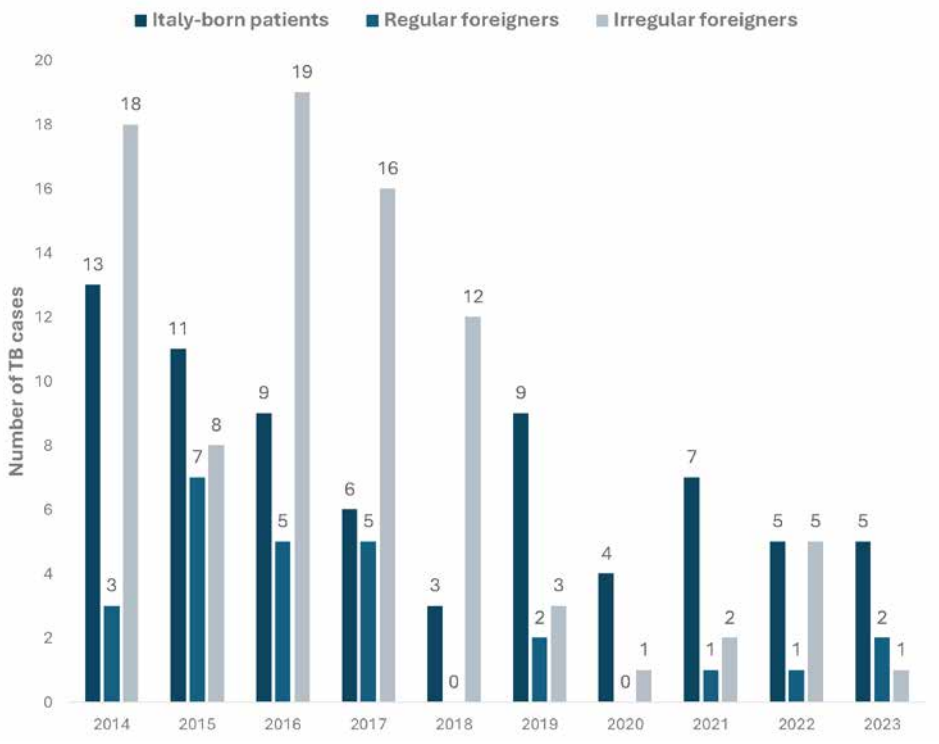
During the ten-year study period, 183 TB cases were detected and included in the study: 136 (74.3%) males and 47 (25.7%) females. Of the total, 72 (39.3%) were Italy-born patients, 26 (14.2%) were regular foreigners and 85 (46.5%) were irregular foreigners. Overall, foreign-born cases (regularly and irregularly residents) accounted for 60.7% of all cases (n = 111), while regularly residents (Italy-born and foreign-born) accounted for 53.5% (72 cases) (Tab. I). Figure 1 shows the distribution of the reported cases in the three groups of patients by year of notification.

Tab. I. Demographic and clinic characteristics of patients.

	TOT		IB		ReF		IrF	
	n	%	n	%	n	%	n	%
N	183		72	39.3%	26	14.2%	85	46.4%
Sex								
Males	136	74,3%	47	65,3%	16	61,5%	73	85,9%
Age								
Mean age (±SD)	38.4 (±22.3)		54.9 (±23.4)		38.8 (± 16.6)		24.4 (± 10.0)	
0-19	46	25,1%	7	9,7%	9	34,6%	36	42,4%
20-39	62	33,9%	12	16,7%	11	42,3%	41	48,2%
40-59	36	19,7%	17	23,6%	3	11,5%	8	9,4%
60-79	26	14,2%	23	31,9%	3	11,5%	0	0,0%
≥ 80	13	7,1%	13	18,1%	0	0,0%	0	0,0%
TB localization[1]								
Pulmonary	75	41,0%	25	34,7%	14	53,8%	36	42,4%
Extra_pulmonary	24	13,1%	5	6,9%	1	3,8%	18	21,2%
Unknown	84	45,9%	42	58,3%	11	42,3%	31	36,5%
TB type[2]								
New cases	63	34,4%	21	29,2%	12	46,2%	30	35,3%
Relapse cases	13	7,1%	8	11,1%	4	15,4%	1	1,2%
Unknown	107	58,5%	43	59,7%	10	38,5%	54	63,5%

[1] Information available for 99 patients. [2] Information available for 76 patients. IB: Italy-born; ReF: regular foreigners; IrF: irregular foreigners.

Fig. 1. Number and distribution of the TB cases in the three study groups reported by year to the Siracusa LHA from 2014 to 2023.



During the study period, TB incidence rate (IR) was 2.4/100,000 inhabitants among regular residents (both Italians and foreigners); specifically, IR in the Italy-born was 1.8/100,000, while in the regular foreigners IR was 17.7/100,000 ($p < 0.00001$). Overall, TB notification rate declined from 3.2/100,000 inhabitants in 2014 to 1.3/100,000 in 2023 in Italy-born group (-59.5%; $p = 0.07$, ns), while in the same period, TB notification rate declined from 24.2/100,000 to 13.1/100,000 in the regular foreigners (-46.0%; $p = 0.22$, ns). Using the estimation by ISMU (as reported in "Methods"), we calculated an IR reduction of 95.5% among irregular foreigners ($p < 0.0001$).

Overall, the median age of all TB patients was 38.4 (±22.3 SD) years, rising from 54.9 (±23.6) years in Italy-born patients to 38.8 ± 16.6 years ($p = 0.0021$)

and 24.4 ± 10.0 years ($p < 0.0001$) in regular foreigners and irregular foreigners, respectively. Among the latter, 93.0% of them was aged between 15 and 44 years old, while this percentage fell to 60.0% ($p < 0.0001$) and 26.4% ($p < 0.0001$) among regular foreigners and Italy-born patients, respectively.

Classification of TB type at the moment of diagnosis was available for 41.5% of patients (Tab. I). Among those 76 patients, a total of 63 (82.9%) were classified as "new cases", 13 (17.1%) as "re-treated cases", either failure or relapses. Regular foreigners were more frequently "new cases" (39.5%; $p = 0.71$, ns), while "relapse cases" status was found more frequently among Italy-born patients (10.5%; $p = 0.70$; ns), although without any statistical significance.

TB localization was available for 54.1% of patients (Tab. I); among them, 75 (75.8%) had pulmonary TB, 24 (24.2%) had extra pulmonary TB. Common extra pulmonary sites included pleura, intestine and peritoneum, which were affected in 4.9%, 3.8% and 3.3% of all TB cases reported, respectively. The likelihood of extra pulmonary TB was more common among irregular foreigners, although without statistical significance.

Regarding the geographical distribution of TB cases origin, Romania was the most represented country among the regular foreigners (44.0%, n = 11 cases), followed by Germany, Morocco and Sud Sudan (8.0%), while Somalia was the most represented country among the irregular foreigners (25.6%, n = 22 cases), followed by Gambia (12.8%, 11 cases), Eritrea and Nigeria (11.6%, 10 cases) (Tab. II). According to WHO Regions [18], a half of all patients (50.5%) came from the African Region, 31.5% from Eastern Mediterranean Region and 17.1% from European Region. Only 1 patient (0.9%) came from South-East Asia Region.

The occupation status was known only for 38.3% of patients, with difference among the three study-groups: 58.3% (n = 42) for Italy-born patients, 28% (n = 7) for regular foreigners and for 24.4% for irregular foreigners (n = 21). 57.1% of them were workers, 21.4% unemployed, 4.3% underage (< 18 y/o), 5.7% housewives, 21.4% retired. Among the workers, there were house cleaners, construction workers, street sellers, caregivers, agricultural day labourers, waiters, and traders.

The TB multidrug-resistant (MDR TB) status was known for only three patients; all of them were from Romania and were regularly resident in Italy.

The risk factors for TB identified in our study were reported for only four patients. They were HIV infection (1 case), HCV infection (1 case), homeless status (1 case) and pregnancy (1 case).

Four patients died from TB during the study period: 2 cases among irregular foreigners, 1 patient among Italy-born patients and 1 case was regular foreigner. Among them, there was 1 case of MDR TB and 2 cases of previously treated patients. The mean age of those four patients was 41,3 years (20 years for irregular foreigners, 43 for regular foreigners and 72 for Italy-born).

Discussion

In this study, we reported the epidemiological updates of TB incidence in Siracusa LHA throughout a 10-year observational study and we analysed the differences among three different study groups: Italy-born, regular foreigner and irregular foreigner patients.

TB still represent a serious public health issue in more developed countries, where has increasingly become a disease for specific population subgroups. Immigrants are an important population group at risk and their presence may affect the epidemiological situation in host TB low-incidence countries [19]. We showed that migrants, both regulars and irregulars, accounted for 60,7% of all TB cases in Siracusa LHA, although they constitute only a small fraction of the entire population. Indeed, during the study period, regular foreigners constituted 3.7% of the population, they accounted for 14.2% of all TB cases and their TB incidence rate was approximately 9.8-fold higher compared to Italy-born patients. Likewise, even if irregular foreigners constituted only 0.7% of the population (according to an estimation [13], they accounted for just under half (46.4%) of all TB cases.

Furthermore, our study demonstrated significative differences in epidemiological, demographic and clinical features among the three different groups. Italy-born patients were older than regular foreigners; 73.6% of Italy-born were > 40 years, while 76.9% of regular foreigners and 90.6% of irregular foreigners were younger than 40 years, respectively. Given the different mean age between the Italian and migrant patients, TB among elderly was mostly detected among the Italy-born group. Also, the proportion of males was different

Tab. II. Geographical origins of not Italy-born TB cases (both regular and irregular foreigners) by World Health Organization (WHO) region.

WHO Region	TOT		IB		ReF		IrF	
Eastern Mediterranean region (WHO-EMRO)	35	19,1%	0	0,0%	3	11,5%	32	37,6%
European region (WHO-EURO)	91	49,7%	72	100,0%	19	73,1%	0	0,0%
South-East Asia region (WHO-SEARO)	1	0,5%	0	0,0%	0	0,0%	1	1,2%
The African region (WHO-AFRO)	56	30,6%	0	0,0%	4	15,4%	52	61,2%

IB: Italy-born; ReF: regular foreigners; IrF: irregular foreigners.

between the three-study groups: males were 65.3% among Italy-born, 61.5% and 85.9% among regular foreigners and irregular foreigners, respectively. The latter were more frequently "new cases" than regular foreigner and Italy-born patients. The "unknown" TB type status was significantly associated with irregular status. Extra pulmonary disease was more common among irregular immigrants. The higher proportion of extrapulmonary TB among irregular migrants (approximately 3-fold higher compared to Italy-born patients) is consistent with previous founding [20-21], and it could be attributed to the large proportion of migrants from Africa countries in our study (approximately one third of all patients and more than 60% of all irregular foreigners) [22]. From a public health perspective, extrapulmonary TB is less important for TB transmission, but extrapulmonary TB is often attributed to reactivation [23], which emphasizes the need to consider latent TB infection (LTBI) screening among migrants. Our data are in accordance with other studies [24-29].

The observed higher TB incidence rate in foreign-born (regular and irregular residents) in our study may had two different dynamics: an increase in the absolute number of foreign-born (regular and irregular residents) TB cases, mainly explained by increased immigration from high TB endemic countries; a decrease TB incidence among native population [30]. According to data, regular and irregular migration increased in Siracusa LHA by 23.4% from 2014 to 2023 [31, 32]. Our results are in accordance with trends at the national level [8].

Migrants are a heterogeneous group, characterised by specific language and cultural identities, with specific health needs. They include undocumented people, asylum seekers, migrants temporarily resettled, or newly resettled during the year.

Among migrants, we observed significative differences in TB risk between regular residents and irregular immigrants, with the former population being more affected. Compared to irregular foreigners, the observed lower TB IR in regular foreigners may be explained by the decreasing risk of TB in the latter group after staying in a low burden country, as well as by the gradual improvement in health care strategies addressing migrants, especially regular ones, from high TB burden countries [33]. However, the legal process for becoming resident (and consequently permanently entitled to health assistance) requires time, a job position and permanent housing, all factors well known to affect the risk of TB reactivation in migrants [33].

There are different drivers of TB in migrants that act along all the migration trajectory: pre-departure (in the country of origin), transit, arrival and early settlement (in the host country), return travel (in the country of origin, again). First, TB burden in the country of origin probably is the most important societal level determinant [34-36]. Secondly, migrants, particularly asylum seekers and refugees, are at high risk of TB due both to the perilous situation they are escaping from, and to the dangerous conditions encountered during migration. Thirdly, risk after arrival is influenced by migrant, social and health policies in the host country [37]. Finally, once resettled, migrants usually travel back to their country of origin without seeking pre-travel advice [34-38].

Overall, provincial TB incidence rate estimation was 4.6/100.000; it was quite lower than other northern and central region [24-27] and in line with the most recent national data (4.2 cases/100.000, from 6.5/100000 in 2017) [8]. For all study-groups, TB notification curve presents a decreasing trend throughout the study period, although with different magnitude between the groups and isolated annual increases. Irregular immigrants presented major fluctuations within the decreasing trend, probably explained by differences and fluctuations in the total number of migrants and their risk profile.

From 2020 a remarkable reduction of TB notifications was observed in every of the three-population groups. Overall, we passed from a mean of 24.3 notifications per year in the pre-pandemic period (years from 2014 to 2019), to a mean of 8.5 notifications per year in the pandemic one (2020-2023). However, the observed reduction was significantly different among the three population groups, with a major magnitude observed in irregular foreigners (from a mean of 12.7 notification per year in the pre-pandemic years, to a mean of 2.5 in the pandemic one; -80.3% notifications per year), followed by regular foreigners (from 3.7 notification/year to 0.8; -78.4% per year) and Italy-born patients (from 8.5 to 5.3; -37.6% per year).

We hypothesized that COVID-19 pandemic played an important role in reducing the observed trend in notifications. Worldwide, the pandemic demonstrated a disproportionate impact on access to essential TB services characterised by pronounced drops in the number of TB cases notified [1, 39], that was likely to reflect two distinct challenges: under-reporting and missed (or delayed) TB diagnosis on a large scale. Decreasing notification could, however, also indicate a real less in TB transmission, due to restrictions and protective measures during the pandemic [39, 40].

Most developed countries, with low TB incidence levels and with the aim to achieve the TB elimination goal, have two major impediments, namely the reactivation of latent TB infection (LTBI) among the elderly population (especially in native population) and among other risk groups, including immigrants from high TB incidence countries [41]. The elderly are considered a large reservoir for *Mycobacterium tuberculosis* infection, especially due to the reactivation of latent infections [42]. Furthermore, aging of the immune system is considered a driver factor for active TB, as well the presence of comorbidities [43].

Due to their vulnerability, it is important to control TB among migrants. Strengthening screening for active TB at arrival can potentially reduce the high TB risk following immigration. However, given the long-term TB risk related to reactivation of TB [28], LTBI screening and treatment could be important tools to reduce subsequent reactivation among the high-risk groups. Furthermore, as many TB cases develop years after arrival, long-term access to preventive health care

should be prioritized so that TB signs can be spotted and diagnostics initiated [44].

The most important strength of our study is taking into consideration the differences among different groups of populations, in terms of the epidemiological, demographic and clinical features. Because tuberculosis is a disease with a strong social connection [4], its understanding demands that the impact of social and economic factors on the individual (including countries of birth, migration status, living conditions), be considered as much as the mechanisms by which *Mycobacterium tuberculosis* cause damage to the human body [45]. In this sense, TB has been considered a marker of social inequities in health [46].

The analysis of data at the local level is another strength of our study. In our view, having in-depth analyses of the local epidemiological situation is extremely useful for putting in place actions targeted to the specific needs of the local context, first and foremost appropriate prevention measures. Leveraging local data sources and integrating them with regional and national data sources will provide more timely and geographically specific analyses to support local insights and specific policy development.

There are some limitations to address. The first is the TB incidence estimation among irregular immigrants, in the absence of any official data regarding the real size of this population, that could lead to a its wrong estimation in this population (see "Methods" section for details).

Another limiting is basing only on notified cases as a unique source of information. Although the surveillance system is considered quite efficient in Italy, it can be hampered by under-reporting and inconsistency.

Another limitation was the lack of some information, such as MDR situation, presence of risk factors (HCV, HBV, HIV, alcohol and drug abuse), type of housing, job description, that were available in a small number of patients. Maintaining data quality and completeness to provide an optimal and efficient report is essential requirement for the establishment of notifiable diseases information system architecture.

Conclusions

This study provides a clear description of the current epidemiology of TB in Siracusa LHA, which will help inform appropriate public health action and health service provision. In this study, we have found an overall decline in TB notifications during the study period, in line with the End TB Strategy milestones. Discontinuation of services due to the COVID-19 pandemic could have contributed to the reduction of notifications in 2020, especially among undocumented immigrants. There is no doubt that the TB constitutes a primary health issue important to the immigrant population, that still represent the group with the highest number of cases. The enhancement of health care strategies directed to immigrants from high TB burden countries should be a priority in the efforts towards global TB elimination.

It is a common misconception that migrants simply 'import' TB from abroad. They "present a tuberculosis picture from the country of origin" and not from the host country where the disease eventually manifests [47]. Indeed, differential pathogen exposure can explain much of the higher incidence of TB among migrants and ethnic minorities, due to both pre-migration residence in high-incidence countries and maintenance of transnational links with the country of birth or ethnic origin. However, positing this as the sole driver fails to address the complex interplay of factors driving the vulnerability of migrant and ethnic groups to infection and progression to active disease. Furthermore, certain migrant and ethnic groups face barriers to accessing treatment including cultural differences in treatment-seeking behaviours, stigmatisation of sufferers, and barriers to healthcare access. TB in ethnic minorities does not occur in isolation but against a backdrop of socioeconomic, political and cultural context that affects their knowledge, attitudes and behaviours. Concordant with increasing interest in the social determinants of health in general, and of tuberculosis in particular, the Sustainable Development Goals and WHO's new End TB Strategy place emphasis on social protection and poverty-alleviation programmes [37-48].

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Conflicts of interest statement

Authors declare no conflict of interest.

Authors' contributions

FC: conceptualization, methodology, statistical analysis, original draft preparation and writing. FC, EDP, CR: acquisition of data. FC, FB EDP, MLC: formal analysis and interpretation of data. FC, FB: writing, review and editing. FC, EDP, MLC: supervision and project administration. All authors have read and agreed to the submitted version of the manuscript.

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Infectious Diseases

Analysis and Impact of Infection Prevention Procedures in Long-Term Care Facilities

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Keywords

Infection control • Prevention procedures • Long-term care facilities • Infection risk management

Summary

Background. *Healthcare-associated infections (HAIs) are a significant healthcare complication, with major implications for public health. In the EU/EEA, up to 2.6 million new HAIs cases occur annually, causing significant burdens and economic costs. In Italy, the prevalence of HAIs is rising due to factors like invasive devices, antibiotic resistance, and poor infection control. The aim of this work is to evaluate the effectiveness of HAIs containment practices in long-term care facilities (LTCF).*

Materials and methods. *This cross-sectional study included eight LTCF inspected by Prevention Technicians of the Local Health Authority Tuscany South-East (LHA-TSE) in 2023. The study evaluated non-compliance in procedures for legionellosis prevention, cleaning and disinfection, laundry management, management of pans, HAIs prevention, healthcare tools disinfection, and hairdressing services. Data were analysed using descriptive statistics and the Mann Whitney test to compare infection rates with procedure compliance.*

Results. *In 2023, 606 infections were reported in the eight enrolled LTCF. The most frequent infections were COVID-19 (19.4%), urinary tract infections (16.9%), pharyngitis (15.6%), and influenza-like illness (ILI) (15%). For the "Laundry Procedure," 3 LTCF were compliant and 5 were not, showing a significant relationship with influenza syndromes (p = 0.02) and surgical site infections (p = 0.04). For the "Cleaning Check" procedure, non-compliance was linked to higher fungal infections (p = 0.01) and gastroenteritis (p = 0.04). The "Disinfection of Health Tools procedure showed non-compliance correlated with higher gastroenteritis (p = 0.04) and conjunctivitis (p = 0.01). Gastrointestinal infections from* Clostridium difficile *were linked to non-compliance with "HAIs Procedures Routes" (p = 0.04), "Pans" processes (p = 0.04), and cleanliness in the hairdressing service (p = 0.04). Herpes simplex or Herpes zoster infections were higher in LTCF with non-compliant hairdressing service rooms (p = 0.02). Two legionellosis cases were recorded in LTCF with reported non-compliance in analytical procedures for Legionellosis.*

Conclusions. *Our analysis showed significant correlations between cleanliness procedures and reductions in fungal infections, gastroenteritis, and ear infections. Compliance in laundry procedures was linked to ILI and surgical site infections. Non-compliance in healthcare tools correlated with higher rates of gastroenteritis and conjunctivitis, highlighting the need for stronger practices. The data suggest that effective prevention measures reduce HAIs, though discrepancies in implementation across facilities call for standardization and continuous monitoring.*

Introduction

Healthcare-related infections (HAIs) are caused by bacteria, viruses, or other pathogens. HAIs are the most frequent complications that occur in all healthcare settings (hospitalization facilities, outpatient facilities, local residential facilities, *etc.*) [1-3].

They can be related to endogenous transmission mechanisms, caused by bacteria within the body. Still, more frequently they are related to exogenous transmission events, from person to person or derived from the environment [4-6]. HAIs also represent a public health problem, as they generate additional treatment costs, a reduction in quality of life and an increase in the risk of morbidity and mortality [3-7].

Every year in the European Union and in the European Economic Area up to 2.5 million new cases of HAIs occur, and the most common HAIs are pneumonia, urinary tract infection, surgical site infection, *Clostridium difficile* infection, neonatal sepsis, and primary bloodstream infection. In addition, the burden of HAIs has been estimated at 501 disability-adjusted life years (DALYs) per 100,000 population [8].

The global report published by the World Health Organization highlights that in Europe HAIs cause 16 million additional days of hospitalization, 37,000 directly attributable deaths and 110,000 deaths for which the infection represents a contributory cause. The direct costs of these infections are approximately estimated at around 7 billion Euros [9].

According to the PPS3 (Point Prevalence Survey) report, published in 2022, the Italian prevalence of HAIs is higher than that reported in PPS2, published in 2016/2017, and the European prevalence [10]. The highly specialized hospitals, where the number of beds and days of hospitalization are greater, are probably more at risk since they are more concentrated on fragile patients with high care intensity [10].

With the general aging of the population, long-term

care facilities (LTCFs) are increasingly needed, and those that already exist are crowded. The elderly who are residents in these facilities have an increased risk of contracting HAIs as they are used to share facilities with other residents, to live in a confined environment, to have risky contact with staff, or with improperly performed procedures [11, 12]. However, the results of a 2017 European survey show a higher prevalence of HAIs in acute hospital settings than LTCFs, while the latter need to pay more attention to the phenomena of antimicrobial resistance (AMR) [13].

A 2019 Dutch study demonstrating the decreasing trend of HAIs in LTCFs participating in a national surveillance network implies that surveillance is a valuable addition to current strategies to optimize infection control [11].

Among the main factors contributing to the increase of HAIs, there is the use of invasive medical devices such as venous catheters, urinary catheters, and ventilators, as well as the extensive use of antibiotics, which has promoted the spread of multidrug-resistant organisms [14, 15]. However, the poor application of environmental hygiene and infection prevention and control measures in healthcare settings cannot be underestimated [16]. Environmental monitoring confirms the persistence of contamination of objects, equipment, and beds placed in rooms of colonized/infected patients [17].

Frequent cleaning of high-touch surfaces is crucial to prevent the spread of infections, while regular cleaning and disinfection of the patient's environment can reduce the contamination and the risk of HAIs [18, 19].

The Italian Regulatory System, which regulates the organization of LTCFs, requires documented procedures for cleaning, waste treatment, laundry/wardrobe management, prevention of water-borne diseases through the internal water network and specific protocols for infectious diseases [20, 21].

These procedures must therefore describe the most suitable methods to carry out the operations and/or the necessary prevention measures to be adopted to contain infections [22].

For these reasons, this work has the aim of investigating the methods of drafting the procedures for the containment of HAIs and of correlating the presence and the compliance to these procedures with the incidence of HAIs LTCFs.

Material and methods

Study population

This is a cross-sectional study conducted in Tuscany (Italy) in 2023. The structures included in the study were monitored by Prevention Technicians of the Public Hygiene and Nutrition Unit of the Local Health Authority Tuscany South-East (LHA-TSE). The included structures were eight. One out of 8 has 325 beds, six have between 40 and 60 beds, one 20 beds.

The population is constituted by frail elderly individuals with chronic conditions and physical and/or cognitive disabilities. These are individuals who are either fully dependent or have a mild level of independence.

This type of control is carried out according to the criteria adopted with the General Director's Resolution no. 546 of 16/05/202312 with which specific check lists for supervisory activities were approved.

Infections evaluated

Each LTCF included in the study received a form for the collection of cases of HAIs diagnosed in its structure in 2023 [23]. The types of infections to be included in the study were extrapolated from the pilot study carried out by University of Turin with the support of the Italian National Institute of Health and the Ministry of Health in 2023 [24].

The list included: urinary tract infections, pharyngitis, Influenza-Like-Illness (ILI), pneumonia, Legionellosis, other lower respiratory tract infections (RTI), COVID-19, surgical site infections, skin infections (cellulitis, soft tissue, wound infection), scabies, *Herpes* simplex or *Herpes* zoster, fungal infection, gastroenteritis, *Clostridium difficile* infection, conjunctivitis, ear infections, sinusitis, oral Infections or Candidiasis, blood infections, Fever of unknown origin (FUO).

Presence and compliance of procedures

The procedures considered in this study are categorized into the following macro areas: prevention of Legionella, cleaning and disinfection of the premises, laundry management, management of pans, procedures for the prevention of HAIs, disinfection of healthcare instruments, and management of the hairdressing service. Each macro area includes specific items, and for each item the Environmental Health and Safety Technicians assess the compliance or non-compliance, as well as the presence or absence of the procedures. For a detailed description of these procedures, see Supplementary Material 1, where each macro area is further described.

For the prevention of legionellosis, reference was made to the 2015 guidelines of the Italian Ministry of Health and to the report of the Italian National Institute of Health "ISTISAN 22/32" where the standards for quality of water in priority buildings were descripted in order to identify the critical points [25, 26].

For the cleaning and disinfection procedures of the premises, reference was made to the guidelines produced by National Association of Hospital Management Physicians (ANMDO) [27].

Statistical analysis

A preliminary descriptive an analysis was conducted. The absolute frequency and percentages to summarize the qualitative variables and median and interquartile range for the quantitative ones were performed.

The number of infections with the compliance at procedures, through the Mann Whitney test was compared. Statistical comparisons were performed only for infections with at least 10 cases. Statistical tests were considered significant with a p-value < 0.05. The analyses were carried out with STATA version 13.0.

Results

Figure 1 shows the 606 infections reported in the eight enrolled structures in 2023. In particular, 118 cases of COVID-19 (19.5), 103 urinary tract infections (17.0%), 95 pharyngitis (15.7%), 91 Influenza-Like-illness (15.1%), 54 Pneumonia (8.9%), 40 fungal infection (6.6%), 32 Conjunctivitis (5.3%), 15 oral infections or Candidiasis (2.5%), 14 skin infections (2.3%), 13 Gastroenteritis (2.1%), 11 Scabies (1.8%), 6 infection of *Herpes* simplex or *Herpes* zoster (1.0%), 5 ear infections (0.8%), 3 *Clostridium difficile* infection (0.5%), 2 cases of legionnaires' disease (0.3), 2 other lower respiratory tract infections (RTI) (0.3%), 2 surgical site infections (0.3). Excluding SARS-CoV-2, the three more prevalent infections were urinary tract infections, pharyngitis, and ILI.

Table I shows the Distribution of infections according to presence and compliance to laundry procedures. In particular, 5 structures of 8 did not have a laundry procedure and 6 were non-compliant to guidelines (Failure to identify dirty clean paths; Failure to label guests' clothing.

Lack of instructions in the procedure on the collection, handling and washing of clothes from infected subjects). Structures with laundry procedures had a significantly lower prevalence of ILI than the structures that had not laundry procedures ($p < 0.05$,0 [0-2] *vs* 30 [13-40]).

Similar results were obtained for the compliance to the laundry guidelines. A significant difference was observed in ILI cases ($p = 0.04$), non-compliant structures had significantly higher rate of ILI (35 [30-40] *vs* 1 [0-6]), and in pneumonia cases, non-compliant structures had significantly higher rate of cases (18 [8-28] *vs* 3 [0-5], $p = 0.04$). Significantly higher presence of non-COVID infections was also observed in structures without laundry procedures ($p = 0.02$, 109 [98-125] *vs* 20 [14-24]) and non-compliant to guidelines ($p = 0.04$, 117 [109-125] *vs* 22 [14-94]).

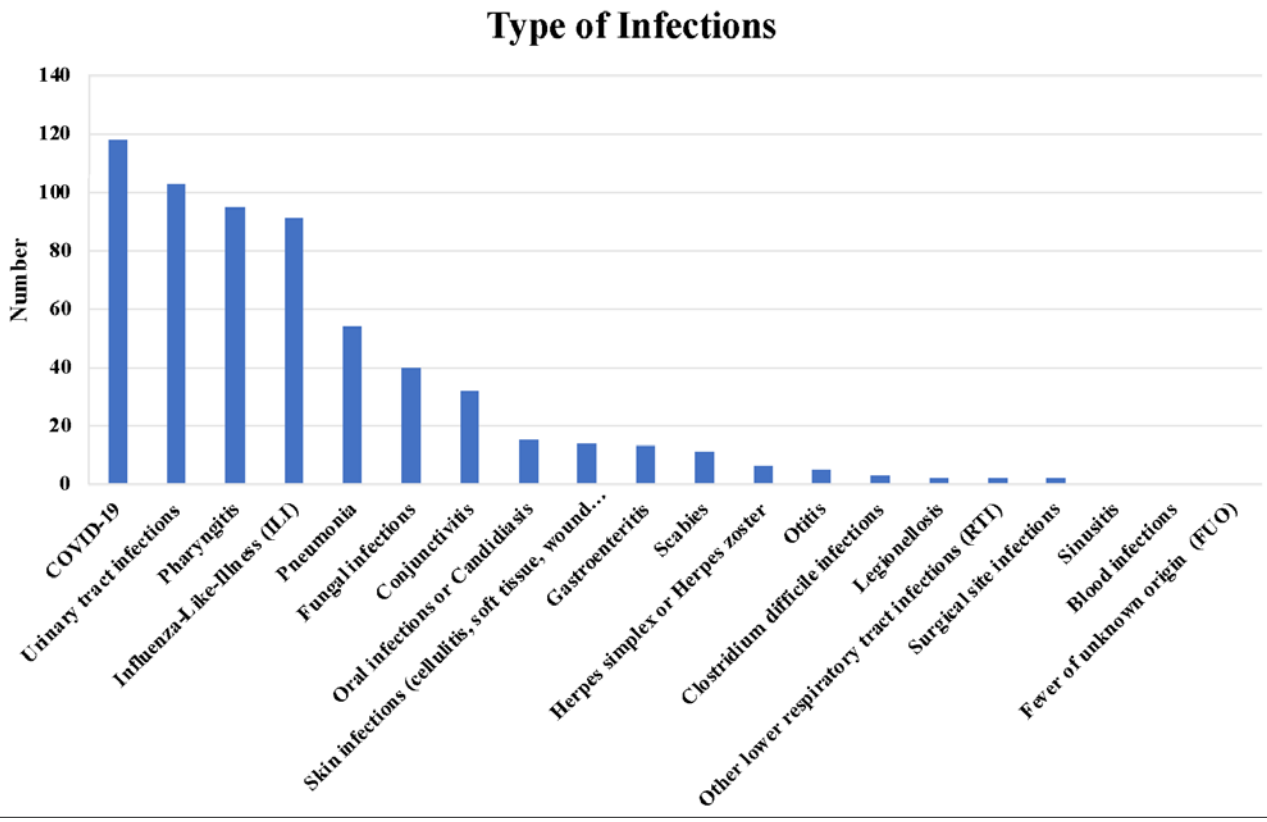
Distribution of infections according to adequacy hairdressing service room were shown in Table II. The rooms set up for the hairdressing service were found to be adequate in 2 structures and not in 6. Non-compliant structures, for professional and/or authorization requirements of the hairdresser compliant with regional legislation and with unavailability of equipment or products for thermal or chemical disinfection of hairdresser's tools, seem to correlate with a greater number of urinary tract infections ($p = 0.04$, 27 [20-34] *vs* 7.5 [2-15]). The same was found for the conjunctivae ($p = 0.03$, 12 [11-13] *vs* 0 [0-3]).

Table III shows the distribution of infections according to the item "Cleaning process verification system" of the macro area "Cleaning and disinfection process of the premises" an "Disinfection of healthcare tools" like:

Urinary and respiratory devices: catheters, syringes, urinary probes, respiratory suction devices

Vital sign monitoring devices: thermometers, blood

Fig. 1. Distribution of most frequent infections according to procedures.



Tab. I. Distribution of infections according to compliance of laundry procedures

	Presence of laundry procedures			Compliance to laundry guidelines		
Compliant	Yes N = 3	No N = 5	p	Yes N = 2	No N = 6	p
Infections	Median [IQR]			Median [IQR]		
Urinary tract infections	6 [2-15]	16 [9-34]	0.17	7.5 [2-15]	25 [16-34]	0.09
Pharyngitis	0 [0-6]	20 [14-30]	0.09	3 [0-20]	22 [14-30]	0.17
Influenza syndrome	0 [0-2]	30 [13-40]	0.02	1 [0-6]	35 [30-40]	0.04
Pneumonia	1 [0-5]	8 [5-28]	0.07	3 [0-5]	18 [8-28]	0.04
Fungal infection	0 [0-2]	1 [0-34]	0.52	1 [0-3]	0.5 [0-1]	0.59
Conjunctivitis	0 [0-3]	5 [0-11]	0.52	1.5 [0-5]	5.5 [0-11]	0.85
Oral infections	0 [0-0]	2 [0-3]	0.39	0 [0-3]	1 [0-2]	1.00
Skin Infection	2 [0-3]	2 [0-4]	0.75	2.5 [0-3]	1 [0-2]	0.38
Gastroenteritis	0 [0-0]	2 [0-10]	0.12	0 [0-1]	5 [0-10]	0.44
Scabies	0 [0-0]	0 [0-0]	0.43	0 [0-0]	0 [0-0]	0.56
Tot. NON COVID-19 infection	20 [14-24]	109 [98-125]	0.02	22 [14-94]	117 [109-125]	0.04

Tab. II. Distribution of infections according to compliance to the hairdressing service room procedures.

	Compliance to the hairdressing service room guidelines		
Compliant	Yes N = 2	No N = 6	p
Infections	Median [IQR]		
Urinary tract infections	7.5[2-15]	27 [20-34]	0.04
Pharyngitis	3 [0-20]	19.5 [14-25]	0.30
Influenza syndrome	1 [0-13]	23 [6-40]	0.17
Pneumonia	3 [0-5]	7.5 [7-8]	0.17
Fungal infections	0 [0-2]	2 [1-3]	0.28
Conjunctivitis	0 [0-3]	12 [11-13]	0.03
Oral infections	0 [0-2]	5 [0-10]	0.44
Skin infections	2 [0-3]	1.5 [0-3]	0.86
Gastroenteritis	0 [0-0]	5.5 [1-10]	0.05
Scabies	0 [0-0]	0 [0-0]	0.56
Tot. NON COVID-19 infection	22 [14-98]	109.5 [94-125]	0.18

pressure cuffs, stethoscopes, pulse oximeters, digital thermometers.

Four structures had failure to adopt a cleaning process verification system and the fungal infections and gastroenteritis are significantly more present in this structure (fungal infections p = 0.01, 2.5 [1.5-18.5] *vs* 0 [0-0]) (gastroenteritis p = 0.04, 1.5 [0.5-6] *vs* 0 [0-0]).

The "Disinfection of health instruments " procedure was found non-compliant in 4 structures due to unavailability of equipment or products for thermal or chemical disinfection of medical instruments.

Non-compliance is correlated with a greater number of gastroenteritis (p = 0.04, 1.5 [0.5-6] *vs* 0 [0-0]). Same thing for conjunctivitis (p = 0.01, 8 [4-12] *vs* 0 [0-0]).

Regarding infections with low incidence (< 5 cases), we found 3 cases of gastrointestinal infections from *Clostridium difficile* in two structures. One structure was not compliant with the identification of horizontal and vertical accesses and routes, structurally and/or functionally distinct, both for people (guests, healthcare workers, GPs, suppliers) and for goods and materials (separation of dirty/clean routes for food, linen, waste) and the other to non-application of physical or chemical disinfection system for the reconditioning of bedpans.

Still regarding infections with few cases, we have recorded two cases of surgical site infection in two facilities, one of which showed no compliance in laundry procedures.

Finally, regarding the two cases of legionellosis, they were recorded in 2 structures where a "Failure to adopt corrective measures following analytical non-conformities detected in self-monitoring" had been reported.

Discussion

Awareness of the importance of basic hospital hygiene is therefore of fundamental importance, together with formal monitoring, feedback to cleaners and surveillance of the main environmental pathogens [16].

Based on the results obtained from the cross-sectional study conducted to evaluate the prevalence and relationships between infection prevention practices and their incidence in some LTCF, some significant conclusions emerge.

As regards the prevalence of infections, the most frequent in the year 2023 were those from SARS-CoV-2, followed by urinary tract infections, pharyngitis, influenza syndromes and pneumonia. Results in line with those obtained from the 2022 report "Prevalence study on healthcare-related infections and the use of antibiotics in non-hospital social and healthcare facilities", which recorded a predominantly respiratory (40.6%) and urinary localization (28.1%) [10]. These results reflect the importance of specific preventive strategies for these pathologies.

Tab. III. Distribution of infections according to cleaning process verification system and compliance to the disinfection of healthcare instruments procedures.

	Cleaning process verification system			Compliance to the disinfection of healthcare instruments		
Compliant	Yes N = 4	No N = 4	p	Yes N = 4	No N = 4	p
Infections	Median [IQR]			Median [IQR]		
Urinary tract infections	10.5[4-15.5]	14.5[5-27]	0.56	8.5 [1.5-15.5]	14.5 [7.5-27]	0.24
Pharyngitis	3[0-18]	17[7-22.5]	0.55	0 [0-15]	17 [10-22.5]	0.23
Influenza syndrome	1[0-16]	9.5[3-26.5]	0.37	0 [0-15]	9.5 [4-26.5]	0.13
Pneumonia	3[0.5-26.5]	6[2.5-7.5]	0.77	3 [0.5-16.5]	6 [2.5-7.5]	0.77
Fungal infection	0[0-0]	2.5[1.5-18.5]	0.01	0 [0-1]	2 [0.5-18.5]	0.16
Conjunctivitis	0[0-1.5]	8[2.5-12]	0.09	0 [0-0]	8 [4-12]	0.01
Oral infections	0[0-1]	1.5[0-6.5]	0.32	0 [0-1]	1.5 [0-6.5]	0.32
Skin infections	2[1-2.5]	1.5[0-3.5]	0.88	1 [0-2]	3 [1.5-3.5]	0.13
Gastroenteritis	0[0-0]	1.5[0.5-6]	0.04	0 [0-0]	1.5 [0.5-6]	0.04
Scabies	0[0-5.5]	0[0-0]	0.31	0 [0-5.5]	0 [0-0]	0.31
Tot. NON COVID-19 infection	22[17-66.5]	96[49-111.5]	0.56	19[9-66.5]	96[57-111.5]	0.24

The analysis highlighted significant correlations between some prevention procedures and the incidence of specific infections. The presence of cleanliness verification procedures has been associated with a reduction of the number of fungal infections, ear infection and gastroenteritis. For the latter, although it has been observed that cleanup alone may not be able to prevent an outbreak, it is critical to reducing its impact [28]. In addition, the surveillance of fungal infection is crucial, in fact this one are increasingly common problems in inpatient settings, and episodes of infection with new and rare species of fungi are becoming more frequent [29, 30].

Similarly, the presence of compliant procedures in laundries is correlated with a lower prevalence of flu syndromes and surgical site infections. However, data are limited regarding the association between tissue characteristics and the risk of surgical site infection [31]. Regular cleaning and disinfection of all laundry areas is necessary to prevent recontamination of washed textiles during post-wash handling processes [32]. This is especially important in healthcare laundry, where textiles meet vulnerable patients and antibiotic-resistant microorganisms are increasingly prevalent. However, there are currently no international standards for validating and monitoring the effectiveness of industrial laundering processes [33]. Alternatively, they might consider using disposable materials where possible and cost allowing [31].

Although further studies are needed, a 2022 systematic review demonstrates a strong relationship between interventions to improve healthcare environmental hygiene and the reduction of both environmental bacterial load and colonization of patients or HAIs [34]. The need to improve specific procedures appears evident, some areas have emerged as critical points that require particular attention. For example, non-compliance in the disinfection of healthcare tools is associated with an increase in gastroenteritis and conjunctivitis, suggesting the need to strengthen these practices. In fact, these two infections are often caused by viruses that can be acquired from healthcare tools [35, 36]. Since their effective disinfection and sterilization plays a key role in preventing morbidity and mortality due to infectious diseases [37].

The importance of the adequacy of procedures in additional services also emerged. Additional services, such as hairstyling services, also require specific procedures to ensure user safety. Lack of local adjustments and instrument cleaning may be related to increased infections; in fact, hairdressing services can be a possible source of cross-contamination [38]. It is therefore necessary to increase awareness about the potential transmission of infections through common tools and products used in hairdressing and cosmetic services [39].

Regarding the 3 cases of *Clostridium difficile*, living in a LTCF is a risk factor for colonization by multi-resistant bacteria. In fact, several characteristics of this bacterium favour environmental survival and transmission of this pathogen. These include the prolonged survival of spores in the environment, frequent environmental contamination, and continued environmental contamination despite relative resistance to germicides [40]. In particular, the presence of common areas and multi-bedrooms, where hygiene procedures are not always respected, could have an impact on the risk of transmission [41]. The two cases of legionellosis, associated with structures where "non-conformity of analytical procedures for legionellosis" was detected, raise concerns about the effectiveness of monitoring and control systems for legionella. This highlights the need to ensure that all structures strictly adhere to established guidelines for the prevention of legionella, as emphasized by several studies showing that effective water management can drastically reduce the incidence of legionellosis [42]. Certainly, the complexity and organizational heterogeneity of prevention services and insufficient coordination between different levels of territorial competence do not act as factors that do not promote infection prevention [9].

Finally, it is important that the different cleaning methods available are used in a complementary way because each one analyses and quantifies different aspects of the operations necessary to achieve adequate environmental cleanliness [43]. All of this is essential to reduce the risk of infection as much as possible.

Limitations

Although the study provides valuable information on the effectiveness of infection prevention procedures, it has some limitations, such as, self-reported number of infections. In addition, the LTCFs that decided to participate in this study are few. Hence the need to confirm the results with a larger sample size.

Conclusions

Our study seems to suggest the effectiveness of prevention measures and a positive impact of their implementation, highlighting a significant reduction in HAIs. This data can be interpreted as an encouraging sign, indicating that sanitation practices are tangibly contributing to improving patient and staff safety in LTCF.

However, the discrepancies observed between different LTCF raise interesting questions regarding the consistency in the implementation of prevention practices. There may be significant variations in the resources available, the protocols followed and the adequacy of staff training, which could influence the results obtained. This raises the need for standardization and continuous monitoring of prevention practices.

Finally, it seems clear that there are still numerous challenges to face to guarantee a uniform level of safety in LTCF. The development of more effective and sustainable strategies for infection prevention will require a continuous commitment to monitoring and updating practices to ensure a safe environment for patients and operators themselves. Adopting a proactive and collaborative approach, involving all stakeholders, is essential to address emerging challenges and to consolidate the progress achieved, in order to ensure high standards of safety and care in LTCF.

The future of infection control lies in the adoption of advanced technologies, the integration of infection control into patient safety initiatives, the promotion of collaboration and the empowerment of patients.

Conflict of Interest statement

The Authors declare that there is no conflict of interest.

Authors' contributions

Conceptualization: RP, GG, NN; Methodology: FV, AC, GG; formal analysis: AC; data Curation: FV, RP; Writing, original draft preparation: FV, RP, GG; Writing, review and editing: FV, AC, RP, GG, NN; Visualization: FV; Supervision: NN; Project administration: FV, GG. All authors approved the final version of the manuscript.

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Supplementary material

Tab. S1. Description of the procedures.

Procedure	Non-compliance
Legionellosis	Lack of risk assessment document
	Failure to appoint a risk management officer
	DVR containing the description of environmental and plant characteristics that do not correspond to those existing in the structure
	Failure to implement the prevention measures provided for in the DVR
	Failure to adopt corrective measures following analytical non-conformities detected in self-monitoring
	No sampling plan in DVR
Cleaning and disinfection of premises	Lack of procedure for cleaning and disinfecting the premises
	Failure to identify the person responsible for cleaning
	Failure to divide environments into risk areas
	Generic procedure without definition of frequencies, equipment and cleaning products
	Lack of training and education for cleaning staff
	Using cloths without colour coding
	Inadequate reconditioning of cloths and rags
	Failure to adopt a cleaning process verification system
	Failure to adopt a performance verification system
Laundry	Lack of procedure for managing the laundry washing process
	Failure to identify dirty clean paths
	Failure to label guests' clothing
	Lack of instructions in the procedure on the collection, handling and washing of clothes from infected subjects
Pans	Lack of procedure for reconditioning of pans
	Failure to apply a physical or chemical disinfection system for the reconditioning of bedpans
Generic hais procedure	Lack of procedure for the management of healthcare-associated infections
	Failure to identify accesses and horizontal and vertical routes, structurally and/or functionally distinct, both for people (guests, healthcare workers, GPs, suppliers) and for goods and materials (separation of dirty/clean routes for food, laundry, waste)
	Failure to prepare a plan for the management of cases or outbreaks of infectious diseases that require isolation
	Lack of training/education of operators for the application of HAIs management procedures
Disinfection of healthcare instruments	Lack of procedure for disinfection of medical instruments
	Unavailability of equipment or products for thermal or chemical disinfection of medical instruments
Hairdresser service	Lack of procedure for managing the hairdressing service
	Professional and/or authorization requirements of the hairdresser not compliant with regional legislation
	Unavailability of equipment or products for thermal or chemical disinfection of hairdresser's tools

Procedure compliance is defined as the presence of the procedure in conjunction with compliance with additional parameters. In the manuscript was evaluated the compliance/non-compliance and presence/absence of the procedure.

Infectious Diseases

Attitudes and knowledge of the adult population on arboviral diseases

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Keywords

Vaccination • Risk perception • Vector-borne diseases

Summary

Background. *Climate change and globalization have heightened the risk of vector-borne diseases (VBDs) in Europe, including Italy. VBDs cause over 1 billion cases and 1 million deaths annually, accounting for 17% of all communicable diseases worldwide. With competent vectors present, effective control measures and surveillance are vital. This study assessed adults' knowledge, attitudes, and practices regarding Arbovirus infections.*
Methods. *An 11-question survey targeting individuals aged 18 and over at the LHU Roma 1 vaccination clinic evaluated knowledge and experiences with Arbovirus diseases. Data were coded and analyzed.*
Results. *Of 308 participants, 58.1% were female, 63.65% had no children, and 84.1% held a degree or higher. Tick-Borne Encephalitis (TBE) was the most recognized disease (65.9%), followed by Zika (52.3%), while West Nile virus risk in Italy was underestimated (20%). Dengue awareness was high (91.6%), but Usutu awareness was low (47.4%). Vaccination was supported by 93.8%, with the 41-50 age group most willing to vaccinate children. Overall, knowledge of Arbovirus diseases was limited.*
Conclusions. *Public awareness of VBDs and preventive measures must improve to support effective risk prevention strategies. Education campaigns are essential to address gaps in knowledge and promote informed decision-making.*

Introduction

In recent decades, viral diseases transmitted by arthropod vectors (insects with articulated legs) such as ticks, spiders, mites and mosquitoes, also known as Arbovirosis (acronym for ARthropod-BOrne virus), have consistently posed a significant threat to both public health and global development [1, 2]. There are currently over 100 viruses classified as arboviruses in nature that can cause disease in humans. [3] Among the main arboviral diseases that are emerging or have now become firmly established in our country, dengue stands out as an autochthonous disease, characterised by particularly deadly haemorrhagic symptoms, affecting around 390 million people and causing about 25,000 deaths each year [4]. Together, these diseases account for more than 17% of infectious diseases and cause more than 1 million deaths each year worldwide [5]. Although in recent years there has been an increase in the number of imported cases of mosquito-borne diseases also in Italy, there is still little public knowledge of this group of diseases.
In Italy, arbovirosis' prevention is mainly focused on disease surveillance and vector control, given the lack of specific vaccinations for most of these infections suitable with regard of epidemiological situation in the country. In fact, there are vaccinations for some arbovirosis that may be recommended for those living in areas where these diseases are endemic or for those travelling to tropical and subtropical areas. Tick-borne encephalitis vaccine is recommended in several endemic regions in Europe, including a limited area in North-East Italy, while dengue and Japanese encephalitis vaccines are recommended for travelers in risk areas. Recently a Chikungunya vaccine has been authorized in Europe and its use is supposed to be also limited to travelers to endemic areas. Vaccination uptake by travelers is influenced by several factors, such as access to vaccination centres, sources of information and knowledge of travel-related risks, as well as social and individual factors such as attitudes and behaviour towards vaccines. Proper knowledge and perception of infectious risk are further important elements in the choice to vaccinate: some travelers' diseases may be considered irrelevant due to their low incidence, but it is important to prevent them due to their potential severity [6].
In this survey, the focus was on analysing the knowledge, attitudes and preventive practices of adults towards infections caused by Arbovirus. In particular, a 11-question questionnaire was constructed and addressed to citizens (target 18 - over 70 years) attending the LHU Rome 1 vaccination clinic, with the aim of measuring experience and knowledge of these diseases. Knowing people's perceptions and opinions on the risk related to mosquitoes' bites and their attitude towards preventing the spread of these vectors is of fundamental importance for designing communication initiatives aimed at risk prevention.

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Materials and methods

This monocentric study was conducted on 308 participants aged 18 and over, recruited from those attending the UOC Vaccinations Outpatient Clinic of LHU Rome 1 during April and May 2024. A purposive and convenience sampling approach was adopted to quickly access a readily available population within the clinical setting; consequently, the sample size reflects the number of eligible participants available during the data collection period rather than being predetermined.

Data were collected using a self-administered questionnaire (Supplementary Material, Tab. S1) distributed via Google Forms, an online survey platform that ensured anonymous responses. The questionnaire was designed to maximize anonymity, with demographic information categorized on an ordinal or nominal scale. To facilitate access, Google Forms generated a unique survey URL that allowed participants to submit their responses anonymously. Within the vaccination clinic, the questionnaire was disseminated through a QR Code displayed on a poster (Fig. S1) at the centre's entrance, in compliance with the ethical authorization from the relevant health facility.

The Department of Experimental Medicine of the University of Salento acted as the data controller in accordance with current data protection regulations (EU Regulation 679/2016), as detailed in the introductory note of the questionnaire.

The study was approved by the Institutional Ethics Committee of LHU Rome 1, in accordance with the applicable ethical and legal standards.

On the first page (section) of the questionnaire, participants received information on the rationale and modalities of the survey. Only after understanding the purpose of the project and accepting the privacy terms were participants allowed to take part in the questionnaire. Respondents were not allowed to change their answers after submitting the questionnaire.

In terms of content, the questionnaire was divided into two sections and the number of questions in each section varied according to the objectives of the survey (questionnaire attached). In the first section of the questionnaire, socio-demographic information was collected; six questions were aimed at defining the characteristics of the sample surveyed (gender, age, family composition, number of children if present, educational qualification, and any specific data in relation to the survey), information that was useful for the final processing of the data.

The second section included 11 questions aimed at assessing the degree of knowledge and attitude the respondent reported having in relation to Arbovirosis diseases.

Results

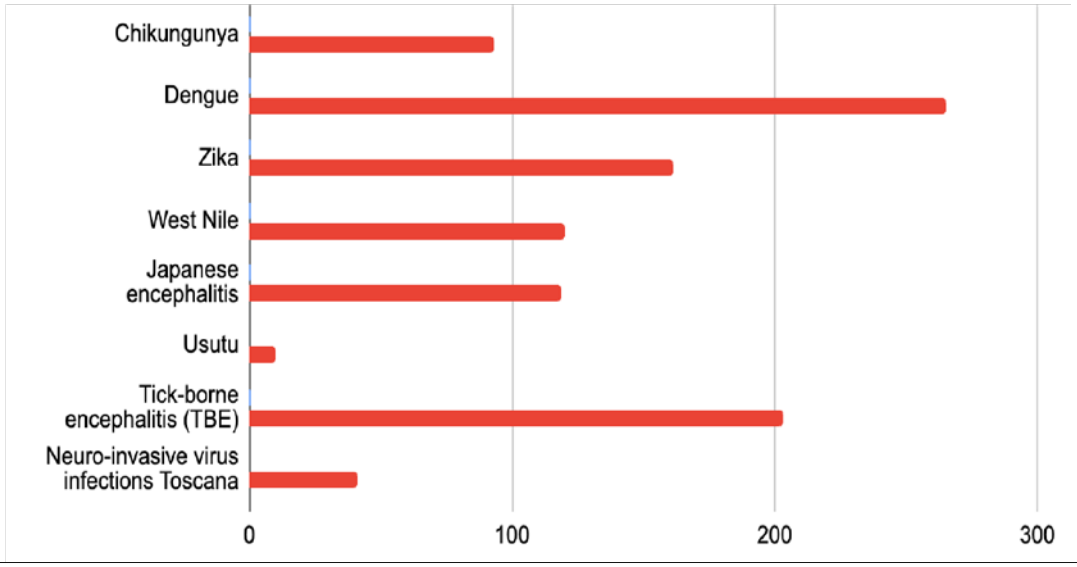
A preliminary univariate analysis was conducted to describe the sample characteristics and distribution of key variables. The results showed that a total of 308 subjects took part in this study, with the most frequent age group being 31-40 years (27.6%) and a higher percentage of females (58.1%) compared to males (41.9%). More than half of the respondents reported not having children (63.65%), and the majority of respondents had a university degree or higher (84.1%) (Tab. I).

The most well-known disease was TBE (65.9%), followed by Zika (52.3%). Usutu was the least known disease. Only 20% of respondents thought they could contract West Nile Virus (WNV) in Italy (21.4%), while there was an overestimation of the risk for TBE (65.3%) (Fig. 1). Although all diseases mentioned can be contracted by travelers, the answers to the question "Which of these diseases do you think could be a risk for travelers?" were heterogeneous. The lowest risk perception was found for Usutu (47.4%) and the highest for Dengue (91.6%) (Tab. II).

Tab. I. Socio-demographic variables of the study population.

Socio-demographic variables	%	Frequency
Number of subjects		308
Gender (%)		
F	58.1%	129
M	41.9%	179
Age		
18-30 years	25%	77
31-40 years	27.6%	85
41-50 years	20.1%	62
51-60 years	17.9%	55
60-70 years	8.8%	27
Over 70	0.6%	2
How many people live in your family, including yourself?		
I live alone	18.5%	57
1-2 members	32.5%	100
3-4 members	41.9%	129
5-6 members	7%	21
> 6 members	0.3%	1
Are you a parent? If yes, how many children?		
No children	63.6%	196
1-2 children	33.1%	102
3-4 children	2.6%	8
> 4 children	0.6%	2
Are you currently pregnant?		
Yes	0	0
No	98.4%	303
I don't know	1.6%	5
What is your qualification?		
No instructions	0.3%	1
Only primary education, *e.g.*, primary school	0.3%	1
Secondary education, *e.g.*, secondary school, middle school	15.3%	47
Tertiary education, *e.g.*, university degree, vocational school	49.7%	153
Post-tertiary education, *e.g.*, master's degree, PhD	34.4%	106

Fig. 1. Frequency of answers to the question "Which of the following disease have you heard of?".



Tab. II. Perception of the risk of contracting arboviral diseases in Italy.

Which of these diseases do you think can be contracted in Italy?	%	Frequency
Chikungunya	16,6%	51
Dengue	55,5%	171
Zika	19,5%	60
West Nile	21,4%	66
Japanese encephalitis	8,4%	26
Usutu	4,5%	14
Tick-borne encephalitis (TBE)	65,3%	201
Neuro-invasive virus infections Toscana	60,7%	187

Univariate analysis showed a general positive attitude towards vaccination, with 93.8% of respondents believing vaccines are important for their health and 64.4% considering repellents insufficient for protection against mosquito-borne diseases (Fig. 2). However, there was limited knowledge regarding arboviral diseases, as only 10 out of 308 respondents answered correctly about diseases that can be contracted in Italy, and no one answered adequately to the question "Which of the following diseases have you heard of?". Furthermore, 40.8% of respondents expressed uncertainty when answering the question "If you had or would have children, would you be willing to vaccinate them against Arbovirosis?" (Fig. 3).

From the statistical analysis, Pearson's chi-squared test revealed significant associations between the participants' age and their willingness to vaccinate children (Contingency Tabs. I, II). Specifically, participants in the 41-50 age group were more likely to

Fig. 2. Frequency of responses to the item: "do you think vaccines are important for your health?".

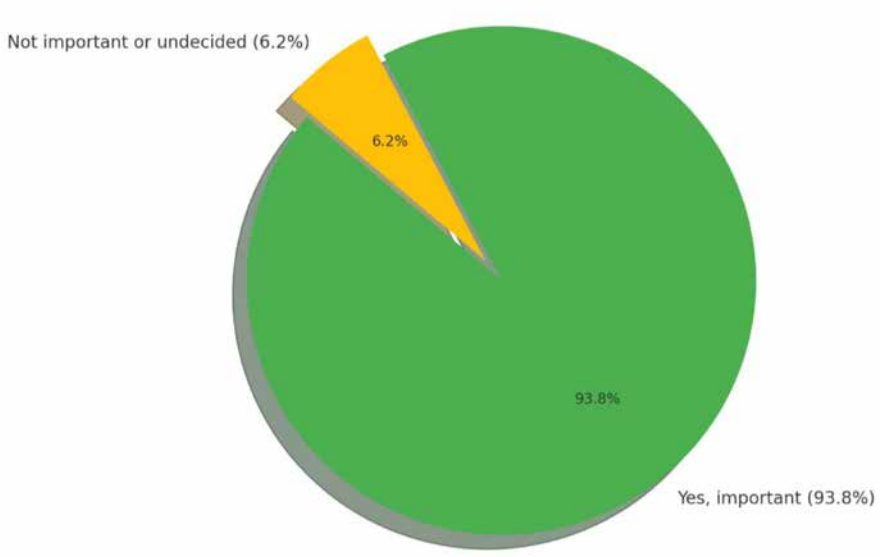
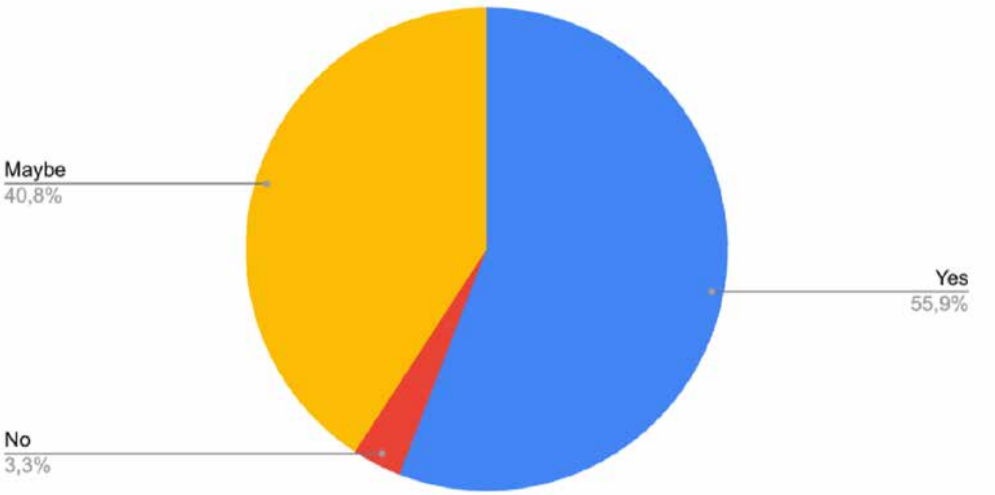


Fig. 3. Percentage of responses to the question: "if you had or had children would you be willing to vaccinate them against Arbovirosis?



vaccinate their children, regardless of whether they had children or not. In contrast, those with less knowledge about the risks were less likely to vaccinate their children. The analysis focused on assessing the independence between variables rather than causal relationships, as per the study's design. Multivariate analysis supported these findings, with associations confirmed through cross-tabulation (Tabs. III-VI).

Discussions

Vaccination acceptance is influenced by several factors including correct knowledge and perception of the infectious risk of diseases [9]. In the post-pandemic era, knowledge and attitudes towards traveler vaccination has not yet been explored [10]. Although some travelers' diseases are to date considered irrelevant due to their low incidence, it is important to recognise and prevent them due to their potential severity. The present study presents the results of a quantitative survey on the knowledge, attitudes and preventive practices of a group of adult users belonging to the vaccination centre of a LHU in Rome, with regard to infections caused by Arbovirus. The use of a convenience sample comprising 308 participants represents a methodological choice driven by the practical constraints of the study period. However, it is important to note that the sampling strategy could have led to oversampling individuals with better knowledge of health-associated issues and higher acceptance of vaccines. Since the sample was selected from individuals attending a vaccination center, these participants were more likely to engage in preventive health behaviors, such as vaccination. While the sample is not representative of the general population, the

Tab. III. Having Children x Age.

Age Group	No	Yes	Total
18-30 years	75	2	77
31-40 years	58	27	85
41-50 years	21	41	62
51-60 years	20	35	55
60-70 years	20	7	27
Over 70	2	0	2
Total	196	112	308

Tab. IV. Having Children x Age, Chi-Square Tests.

Statistic	Value	df	p-value (2-sided)
Pearson Chi-Square	82.546	5	< 0.001
Likelihood Ratio	96.574	5	< 0.001
N of Valid Cases	308		

a.2 cells (16,7%) have expected count less than 5. The minimum expected count is.73.

Tab. V. Knowledge of Arbovirus Risks x Willingness to Vaccinate.

Arbovirosis Risk Knowledge	Maybe	No	Yes	Total
Maybe	0	1	0	1
No	3	90	81	174
Yes	1	43	89	133
Total	4	134	170	308

Tab. VI. Knowledge of Arbovirus Risks x Willingness to Vaccinate, Chi-Square Tests.

Statistic	Value	df	p-value (2-sided)
Pearson Chi-Square	14.032	4	0.007
Likelihood Ratio	14.573	4	0.006
N of Valid Cases	308		

a.5 cells (55.6%) have expected count less than 5. The minimum expected count is.01.

analysis still identified statistically significant trends in risk perception and vaccination intentions among sampled population. Nonetheless, we acknowledge that convenience sampling may introduce selection bias and limit the generalizability of our findings. Future studies would benefit from incorporating a preventive sampling strategy, including an a priori power analysis, to optimize sample representativeness and enhance the robustness of the conclusions drawn.

The analysis of the answers provided by the users to the questionnaires suggested several points for reflection. Despite West Nile being the most widespread arboviral disease in Italy, only a low percentage of the sampled population thought they could contract it without travelling. In fact, since the beginning of June 2022, 236 cases of WNV infection have been reported. Of these, 58 cases were diagnosed as encephalitis and 169 as West Nile fever [11].

On the contrary, the study shows a high perception of risk of TBE, which is, however, considered to be at low risk in Italy, *i.e.,* endemic in a limited area of the country and restricted exclusively to the north-eastern regions of Trentino Alto-Adige, Veneto and Friuli Venezia Giulia, with sporadic reports in Emilia-Romagna, Tuscany and Lazio. With regard to Zika, users also answer the questionnaire by overestimating the risks related to this disease. To date, Italy is to be considered a 'non-endemic area' for ZIKAV as only imported cases have been recorded [12]. Regarding the questionnaire question about the perceived risk of contracting arboviral diseases during travel, although all the diseases listed can be contracted by travellers, the responses were highly varied. This suggests a general lack of awareness about the incidence of arboviral diseases among the respondents. If this finding is confirmed in a larger population, it would highlight the need for strategies to raise awareness, potentially using a range of communication channels to reach a wider audience. In response to these findings, a guide was developed and published on institutional websites, providing general information on methods for preventing and combating arboviral diseases. This guide was drafted with the assistance of ChatGPT to ensure clarity and accessibility of the content (Fig. S2).

In relation to the attitude towards vaccination for arbovirus diseases, a good overall vaccination adherence was noted. Nevertheless, a large number of respondents expressed uncertainty when asked about the willingness to vaccinate their own children against arboviruses. This uncertainty may be partly attributed to the ambiguity of the question, "If you had or will have children, would you be willing to vaccinate them against arboviral diseases?". In particular, some infections, such as Zika, have direct implications for fetal health, which could lead parents to view the risks as more severe, while other infections, like West Nile fever (WNF), may not be perceived as dangerous for children. This distinction likely contributed to the uncertainty regarding vaccination decisions.

In addition, the analysis of the data shows little knowledge of the existence of all arboviral diseases, even though the spread of viruses such as Dengue and Chikungunya has increased in recent years with outbreaks of local transmission even in some European countries, including Italy. Lack of knowledge about the diseases, and therefore a low perception of the related risks, could be among the determinants of the uncertainty to vaccinate their children.

Regarding the questionnaire question about the perceived risk of contracting arboviral diseases during travel, although all the diseases listed can be contracted by travellers, the responses were highly varied. This suggests a general lack of awareness about the incidence of arboviral diseases among the respondents. If this finding is confirmed in a larger population, it would highlight the need for strategies to raise awareness, potentially using a range of communication channels to reach a wider audience. In response to these findings, a guide was developed and published on institutional websites, providing general information on methods for preventing and combating arboviral diseases. This guide was drafted with the assistance of ChatGPT to ensure clarity and accessibility of the content (Fig. S2).

In relation to the attitude towards vaccination for arbovirus diseases, a good overall vaccination adherence was noted. A potential bias towards a general good attitude to vaccination may be due to the convenience sample selected among those attending a vaccination centre. Nevertheless, a large number of respondents expressed uncertainty when asked about the willingness to vaccinate their own children against arboviruses. This uncertainty may be partly attributed to the ambiguity of the question, "If you had or will have children, would you be willing to vaccinate them against arboviral diseases?". In particular, some infections, such as Zika, have direct implications for fetal health, which could lead parents to view the risks as more severe, while other infections, like Dengue, may not be perceived as dangerous for children. This distinction likely contributed to the uncertainty regarding vaccination decisions. In addition, the analysis of the data shows little knowledge of the existence of all arboviral diseases, even though the spread of viruses such as Dengue and Chikungunya has increased in recent years with outbreaks of local transmission even in some European countries, including Italy. Lack of knowledge about the diseases, and therefore a low perception of the related risks, could be among the determinants of the uncertainty to vaccinate their children.

It should be emphasized that, although our study identified some associations between variables, it was not designed to infer causal relationships. The test used only identified correlations between variables, without the possibility of establishing a direct cause-effect link. Therefore, while some associations between risk perception and the intention to vaccinate one's children were observed, these should not be interpreted as evidence of causality. Moreover, the use of multiple-choice variables in the questionnaire may have introduced limitations in the analysis, making it more difficult to accurately interpret participants' responses. Multiple-choice answers can complicate the assessment of individual intentions and

personal perceptions, as they do not always precisely reflect the priority or intensity of each opinion.
This methodological limitation should be taken into account when interpreting participants' knowledge and perceptions of arboviral diseases.
In the questionnaire, most users report having a university degree or higher; being a population with a high level of education, knowledge about arbovirosis has to be considered fragmented. Recent neuropsychological research supports this result, highlighting that individuals with a medium-high cultural level tend to have a low perception of risk. This is because they possess the cognitive tools to navigate the internet and read the information available. However, much of this information is often inaccurate. Paradoxically, it is precisely these individuals who are most exposed to the excessive, contradictory, and risk-laden information about vaccines that circulates online. Moreover, their social status often brings them closer to naturist approaches that tend to be against pharmacological treatments, particularly vaccines [13]. In the questionnaire, most users report having a university degree or higher; being a population with a high level of education, knowledge about arbovirosis has to be considered fragmented. Recent neuropsychological research supports this result, highlighting that individuals with a medium-high cultural level tend to have a low perception of risk. This is because they possess the cognitive tools to navigate the internet and read the information available. However, much of this information is often inaccurate. Paradoxically, it is precisely these individuals who are most exposed to the excessive, contradictory, and risk-laden information about vaccines that circulates online. Moreover, their social status often brings them closer to naturist approaches that tend to be against pharmacological treatments, particularly vaccines [13].
Descriptive statistics (age, gender, level of education, region of residence, *etc*.) were used to obtain the summary of the master data. For statistical analysis, the data was collected according to research ethics standards regarding the protection of personal data and exported from Microsoft Excel to be coded and analysed.
From the statistical analysis of the data, correlating the age of the parents to the willingness to vaccinate their children, a greater intention to vaccinate their children was detected only in the age group between 41 and 50; this data could be due to a greater level of concern among parents with young children, who generally belong to this age group in the Italian population.
The data were analyzed using Pearson's chi-squared test to examine the independence of categorical variables. This statistical test was appropriate for determining whether there were differences between the various classes of the population, as represented by the contingency tables (Tabs. III, IV). Due to the study design, the analysis was limited to identifying correlations between variables, and no causal inferences could be drawn. It is important to note that the use of multiple-choice questions may have introduced some limitations, complicating the interpretation of the participants' intentions and perceptions. This approach could make it more challenging to assess the intensity or priority of individual opinions.
The data collected in this survey suggest the need to bring to light, at least in the context analysed, the doubts and perplexities of users about arboviral diseases, the preventive and contrasting measures available in Italy, to provide clear, complete, up-to-date, personalised information and thus facilitate an informed decision-making process.
Adherence to the vaccine offer must therefore be the result of a conscious choice based on knowledge, supported by adequate communication and attention to the specific information needs of the individual.
Although sources of information, knowledge of the risks of travel or mosquito-borne diseases, as well as social and individual factors such as attitudes and behaviour towards vaccines are at the basis of vaccination adherence, it remains to be considered that, unlike other routine vaccinations, counselling and vaccination services for arboviral diseases are not yet all available, and those that are available are subject to payment and paid for by the user. This element could be one of the factors hindering access to vaccinations, especially for travellers who are obliged to bear the cost of vaccinations even though they are more exposed to the risk of importing and spreading viruses, on their return from their trip, among non-immunised individuals and thus causing damage to public health. In fact, the attitude of Italian travellers to vaccinate themselves seems to be lower than that of other European populations, despite the similar proportion of trips made each year [14].
Furthermore, from the organizational point of view of LHU, the factors that could hinder the consultation process towards travelers are connected both to a delay in the approval of vaccines by pharmaceutical companies due to a probable unavailability of intermediate products, and to healthcare allocation unlimited national directly to avoid repercussions on the clinic due to budget disagreement.
The solution to the problem of travelers' vaccination hesitancy, therefore, needs to enter into the mechanisms of knowledge production, methods and public funding and, not least, the ways of building public opinion.

Conclusions

The survey has helped to provide useful information about the knowledge and attitudes of a sample of adults about vector-borne diseases and the protective behaviours they use.
Given the importance of public understanding of diseases in the adoption of effective protective behaviours, this study has shed light on the value of designing effective communication campaigns aimed at risk prevention, with the dual objectives of improving lay people's understanding of diseases and encouraging community participation in vector control.

Ethics approval and consent to participate

The study has been performed in accordance with the Declaration of Helsinki and has been approved by an independent ethics committee of LHU Rome 1. According to the protocol, the study was designed to be anonymous, and no personal identifiers were collected. Collection of data was performed via an online self-administered questionnaire that posed minimal stress to the participants. Data collected was exclusively related to personal opinion on arboviral diseases. Before accessing the questionnaire, a detailed information page was provided to the participants including ethical standards, privacy statements and assurance of confidentiality and voluntary participation. Access to the questionnaire was granted only after confirming that the information page was read, and consent was obtained by clicking on the checkbox.

Consent for publication

Not applicable

Availability of data and materials

The datasets generated and/or analyzed during the current study are available in the Figshare repository, accessible at the following DOI: 10.6084/m9.figshare.28062866. For additional information, please contact the corresponding author at valeria.gabellone@unisalento.it.

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Conflicts of interest statement

The Authors declare that they have no competing interests.

Authors' contributions

FN contributed to the conception and design of the work, to the interpretation of data, and wrote the first draft of the manuscript. VG contributed to the design of the work, to the analysis and interpretation of data, and substantially contributed to the manuscript. SC contributed to data interpretation and revised the final version of the manuscript. LB contributed to data interpretation and revised the final version of the manuscript. PL contributed to the conception and design of the work, to the interpretation of data and substantially revised the manuscript. All Authors revised and approved the final version of the manuscript.

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Supplementary material

Tab. S1. Questionnaire on Knowledge and Attitudes towards Arbovirosis Diseases.

I understand the purpose of the project and accept the privacy terms - I agree - I do not accept
Gender - Male - Female
Age - Less than 17 years - 17-30 years - 31-40 years - 41-50 years - 51-60 years - Over 60 years old
How many people live in your household, including yourself? By household we mean the number of people (including yourself) living at the same address, sharing a kitchenette and living, sitting or dining area - I live alone - 1-2 members - 3-4 members - 5-6 members - >6 members
Are you a parent? If yes, how many children (under the legal age) do you have? - No children - 1-2 children - 3-4 children - >4 children
Are you currently pregnant? If FEMALE is selected in D1: - YES - No - Don't know
What is your educational qualification? - No education - Only primary education, *e.g.*, primary school, primary school - Secondary education, *e.g.*, secondary school, middle school - Tertiary education, *e.g.*, university degree, vocational school - Post-tertiary education, *e.g.*, master's degree, PhD
Arbivorous diseases:
1. Which of the following diseases have you heard of? a) Chikungunya b) Dengue c) Zika d) West Nile (e) Usutu (f) Tick-borne encephalitis (Tbe) (g) Neuro-invasive infections with Toscana viruses
2. Which of these diseases do you think can be contracted in Italy? a) Chikungunya b) Dengue c) Zika d) West Nile e) Usutu (f) Tick-borne encephalitis (Tbe) (g) Neuro-invasive virus infections Toscana
3. Which of these diseases do you think could be a risk for travellers? a) Chikungunya b) Dengue c) Zika d) West Nile e) Usutu (f) Tick-borne encephalitis (Tbe) (g) Neuro-invasive virus infections Toscana

▶

Tab. S1 (*follows*). Questionnaire on Knowledge and Attitudes towards Arbovirosis Diseases.

4. Did you know that mosquitoes can transmit diseases? a) Yes b) No c) Maybe
5. Do you think repellents are enough to protect you from Arbovirosis? a) Yes b) No c) Maybe
6. If you were offered a vaccine against Arboviral Diseases would you vaccinate? - Yes I have full confidence in vaccines - Yes I have some confidence in vaccines - Yes, but I am hesitant about these new vaccines - I don't know - No, but I am willing to learn about this vaccine - No, I don't think it's necessary - No, I am strongly against having the vaccine
7. If you had or would have children, would you be willing to vaccinate against Arbovirosis? a) Yes b) No c) Maybe
8. Do you know the health risks caused by mosquito-borne diseases other than Arbovirosis? a) Yes b) No c) Maybe
9. Do you consider vaccines important for your health? a) Yes b) No c) Maybe
10. Do you know that there are vaccines approved by AIFA and available in your ASL against certain mosquito-borne diseases? a) Yes b) No c) Maybe

Fig. S1. Leaflet with QR Code available to users of the Vaccination Service.

Fig. S2. Vademecum on Arbovirosis Diseases.

Vademecum on Arbovirosis Diseases

Arbovirosis diseases are caused by viruses transmitted by insects, such as mosquitoes or ticks. Examples include dengue, Zika virus and West Nile virus. To prevent these diseases, it is advisable to use insect repellents, wear protective clothing and avoid infested areas. In addition, it is important to empty containers of stagnant water that can act as breeding grounds for mosquitoes.

Always consult a doctor for specific information on the prevention and treatment of these diseases.

In Italy, the prevention of arboviruses, diseases transmitted by arthropod vectors such as mosquitoes and ticks, focuses mainly on surveillance and reducing exposure to vectors, given the lack of specific vaccinations available for most of these infections. The arboviruses receiving particular attention include Chikungunya, Dengue, Zika, West Nile, Usutu, tick-borne encephalitis (TBE) and neuro-invasive Toscana virus infections, with West Nile being the most widespread. Recommended preventive measures include the use of repellents, protective clothing and mosquito nets, as well as the removal of standing water to limit mosquito breeding【5†source.

Although there are no vaccines available for most of the arboviruses in Italy, there are vaccinations for some tick-borne diseases, such as tick-borne encephalitis (TBE), that may be recommended for those travelling or living in areas where these diseases are endemic. This approach aligns with the National Plan for Prevention, Surveillance and Response to Bluetongue (NAP) 2020-2025, which emphasises prevention through surveillance and vector control measures【7†source】.

For more information on available vaccinations and specific recommendations, it is advisable to consult directly the official sources of the Italian Ministry of Health or local health authorities, as well as the dedicated pages on their websites【6†source】.

Here is a general vademecum for the prevention of arboviral diseases:

1. **Protect yourself from mosquito bites:**

- Use insect repellents containing DEET, picaridin or eucalyptus citriodora oil.

- Wear long-sleeved clothing, long trousers and closed footwear when in mosquito-infested areas. - Use mosquito nets in windows and doors to prevent insects from entering.

2. **Avoid high-risk areas:**

- Find out about geographical areas at risk of arboviral disease transmission and avoid non-essential travel to these

areas during periods of increased mosquito activity.

3. **Eliminating potential mosquito breeding sites:**

- Regularly empty containers of standing water such as pots, buckets or gutters to prevent the proliferation of

mosquitoes.

- Cover or empty outdoor water containers, such as buckets, to prevent them from becoming stagnant.

Nosocomial infections

Health-care associated infections in the two university hospitals of southern Tunisia: a point prevalence survey

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Keywords

Healthcare associated infections • Prevalence • Factors

Summary

Introduction. *Despite advances in the prevention of healthcare-associated infections (HAI) in recent decades, this once-almost-usual adverse event remains relatively common and still has a definite impact on patients and public health. In light of this, this study aimed to determine the HAI prevalence, to describe their main specificities and to identify their associated factors, in Southern Tunisia.*
Methods. *We conducted a cross-sectional study to assess HAI point prevalence in two university hospitals in southern Tunisia. The study was started on February 20th to March 13th, 2023.*
Results. *There were 1.028 patients included in the survey and (47.3%) of them were women (n=486). The median age was 48 years (Interquartile Range (IQR)=[30-65]) years. We noted 86 HAI in the two establishments visited, with a global HAI prevalence of 8.4%. Multivariate analyses showed that independent factors of HAI were immune suppression (AOR=2.5; p=0.004), hospital stay duration ≥ 6 (AOR=4.5; p<0.001), surgery 30 days prior to the study date (AOR=1.9; p=0.021), having central vascular catheter (AOR=2.44; p=0.032) and having intubation or endotracheal tube (AOR=3.5; p=0.002).*
Conclusions. *This study highlighted a relatively high prevalence of HAI in southern Tunisia. Therefore, urgent and ongoing corrective measures should be implemented, maintained and re-evaluated continuously in order to control HAI and promote care safety.*

Introduction

Despite advances in the prevention of healthcare-associated infections (HAI) in recent decades, this once-almost-usual adverse event remains relatively common and still has a definite impact on patients and public health. Undoubtedly, this complication requires efforts to control it at best [1]. HAI are responsible of an increased and a sup-er added morbidity, mortality and healthcare costs as well [2]. In addition to these consequences, HAI are widely known as a factor of prolonged hospital stay, long-term disability and increased antimicrobial resistance [3]. Although all methods and strategies are implemented across the world to prevent and to control HAI, they remain to represent a challenge for the modern medicine [4]. Moreover, fighting this scourge becomes a quality and safety indicator of healthcare in health establishments. Clinically, and according to the diagnosis and the interventions received for patients, HAI most frequent sites were bloodstream infections, urinary tract infections, respiratory tract infections, and surgical site infections [5]. The responsible agent of HAI could be bacterial, viral, or parasitical [6]. Furthermore, the most considerable particularity of HAI was that they are increasingly caused by resistant microorganisms such as *Methicillin-Resistant Staphylococcus Aureus and Carbapenemase-Producing Enterobacteria*. Also, it was estimated that about the one-third of these infections were caused by an antibiotic-resistant bacterium [7].
HAI as previously described, are a global health phenomenon but with unequal distribution depending on the country's development level. In fact, according to the World Health Organization (WHO) out of every 100 patients in acute-care hospitals, seven patients in high-income countries and 15 patients in low- and middle-income countries will acquire at least one HAI during their hospital stay and on average, 1 in every 10 affected patients will die from their infection [8]. Considering the gravity and the importance of this problem, prevention is the most effective strategy to fight HAI complications and repercussions. One of the pillars of this prevention is having an effective surveillance of HAI in order to characterize and to quantify this problem and to reduce it [9]. HAI prevalence was about 5.9% in 28 European countries and about 10% in low-income countries (10.1%) [10]. In Tunisia, the latest surveys dated from 2005 and 2012 where the HAI prevalence was ranged from 6 to 7% [11]. At a regional level, there was local point prevalence surveys conducted in the center east and in the southern regions of the country where the reported HAI prevalence was 17.7% and 9.02% [12-13]. Given this, the evaluation of HAI frequency remains a mandatory and a crucial step before any control action.

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The point prevalence studies of this type of infections are of a major interest in epidemiological surveillance in hospitals given their easily implementation and low cost.
In light of this, this study aimed to determine the HAI prevalence, to describe their main specificities and to identify their associated factors, in Southern Tunisia.

Methods

Study design and settings

We conducted a cross-sectional study to assess HAI point prevalence in the two university hospitals of southern Tunisia. These two referral hospitals of southern Tunisia have complementarity activities. In fact, the first one was a teaching hospital with almost a medical vocation with a maximum capacity of 1000 beds, while the second one has an almost surgical aptitude hosted 562 beds. These two university hospitals are housing patients from Sfax and from neighboring regions in the southern Tunisia.
The study was started in February 20th to March 13th, 2023. The protocol of the world health organization prevalence survey was assumed and validated by a national committee in hygiene and preventive health in order to standardized prevalence surveys between region [14]. All departments in the two hospitals that had a patient hospitalization unit were included. Totally, 21 departments of the medical vocation university hospital and 16 departments of the surgical hospital were eligible. It was a one-day visit per department and the whole prevalence survey lasted for 19 days.

Study population and case definition

All patients of any age hospitalized in the two hospitals were included in the morning on the day of the survey. An exhaustive and updated patients' list was obtained at this time in each department. HAI were defined according to the Center for Disease Control (CDC) criteria as a hospital acquired infections that are typically not present or might be incubating at the time of admission and manifest 48 hours after admission. They are infections acquired during hospital care, which are not present, or incubating at the time of admission [15, 16].

Data collection and study tool

The study tool used was a pretested, structured, uniformed and validated fact-sheet written in English. The investigation was done by pre-trained medical epidemiologist after discussing with the nursing staff and physicians if needed.
Different parameters were collected from patient medical files such as nursing notes, medical notes, temperature charts, drug charts, electronic prescribing systems, surgical notes, laboratory reports, and other relevant charts.
Collected data included sociodemographic and clinical information such as age, gender, ward type, admission date, length of hospital stays, medical history and criteria to investigate different infections. We also noted if the patient had an invasive device, surgical intervention within 30 days, or antibiotic treatment on the day of the survey.
We used the McCabe scale to classify patients according to the severity of their underlying conditions. The McCabe scale provides an objective and structured method to classify the severity of comorbidities. In our study, using this scale allows for a clear categorization of patients, which can help understand how the burden of comorbidities interacts with other risk factors for HAIs. This scale was composed of 3 categories: nonfatal disease (expected survival > 5 years), ultimately fatal disease (expected survival 1-4 years), and rapidly fatal disease (expected death within 1 year) [17]. As for patients that had been operated in the last 30 days, and based on the American Society of Anesthesiologists (ASA) and to the to the surgical wound class patients were classed into grades that ranged from 1-4, and to (clean, clean/contaminated, contaminated and dirty), accordingly [18]. The data were checked for both completeness and accuracy to rule out missing or inconsistent data.

Statistical analysis

For the entry and the statistical analysis, we used SPSS Statistics software version 26. According to the variables type, continuous variables were presented as mean ± standard deviation or median and interquartile range (IQR) giving to the normality distribution tested. As for categorical variables, they were described as numbers and percentages. We used the chi square test in independent samples to assess association between categorical variables. The crude odds ratio (COR) was assessed as well as its 95% confidence interval (CI). Variables statistically associated with HAI were then entered into a multivariate logistic binary regression model backward stepwise, in order to determine HAI independent factors (adjusted odds ratio (AOR) and 95%). A p value < 0.05 was considered as statistically significant.

Results

Description of the study population

There were 1028 patients included in the survey and (47.3%) of them were women (n = 486). The median age was 48 years (Interquartile Range (IQR) =[30-65]) years. In total, 694 participants (67.5%) were hospitalized in the medical vocation hospital. As for patients' main clinical characteristics, 523 patients (50.9%) were hosted for more than 6 days, 154 patients (15%) had previous hospitalization in the last 3 months, and 42 patients (4.1%) were transferred from another hospital (Tab. I).

Characteristics of healthcare associated infections

We noted 86 HAI in the two establishments visited,

Tab. I. Description of the study population.

Characteristics	Number	Percentage
Gender		
Males	542	52.7
Females	486	47.3
Age groups		
Neonates	69	11.1
≤ 2 years	160	15.6
]2-60[years	553	53.8
≥ 60 years	307	29.9
Hospital		
Hedi Chaker University Hospital	694	67.5
Habib Bourguiba University Hospital	334	32.5
Hospital stay duration		
< 6	505	49.1
≥ 6	523	50.9
Previous hospitalization in the last 3 months	154	15
Transfer from another hospital	42	4.1
Ward type		
Medical	631	61.4
Surgical	307	29.9
Intensive care unit	90	8.8
Tobacco use	150	14.6
Alcohol use	57	5.5
Drug use	26	2.5
Medical history		
Surgery since admission		
No surgery	356	68.3
Minimal invasive surgery or non-NHSH surgery	66	12.7
NHSN surgery	95	18.2
Unknown	4	0.8
Surgery in the last 30 days	164	16
ASA score		
1	86	59.7
2	33	22.9
3	19	13.2
4	6	4.2
Surgical wound class		
Clean	96	59.3
Clean contaminated	25	15.4
Contaminated	26	16
Dirty	15	1.5
Antimicrobial preoperative prophylaxis	108	10.5
Comorbidities		
Immunosuppression	106	10.3
Neutropenia	25	2.4
Obesity	69	6.7
High blood pressure	194	18.9
Diabetes	217	21.1
Dyslipidemia	106	10.3
Malnutrition	27	2.6
McCabe Index		
Non-fatal disease	845	82.2
Ultimately fatal disease	144	14
Rapidly fatal disease	39	3.8
Invasive devices in place on the survey date		
Central vascular catheter	49	4.8
Peripheral vascular catheter	573	55.7
Urinary catheter	100	9.7
Intubation or endotracheal tube	64	6.2
Antibiotics prescription	389	45.4

ASA score: American Society of Anesthesiologists.

with a global HAI prevalence of 8.4%. The prevalence of HAI was of 7.6% in the medical vocation hospital, and the department had the highest prevalence was the hematology department (39.3%) (n = 11). As for the surgical vocation hospital, the prevalence was 9.8% and the highest prevalence was noted in the intensive care units (24.1%) (n = 14) (Tab. II).

According to the anatomic site of HAI noted, the most frequent site was the respiratory tract infection (32 cases; (37.2%)), followed by blood stream infections (21 cases; (24.4%)). We noted that in 46.5% of cases a microorganism was isolated (n = 40). Among which, the pathogen isolated was *Klebsiella pneumoniae* in 22.5% of cases (n = 9) (Tab. III).

Associated factors of healthcare associated infections

Results of univariate analysis

For patients' relative risk factors univariate analyses showed that age between less than 2 years or ≥ 60 years was statistically associated with HAI. For comorbidities, immune suppression and neutropenia were statistically associated with HAI. High blood pressure was statistically associated with HAI. Patients with rapidly fatal disease and those with an ASA score ≥ 2 were statistically more frequently affected by HAI.

For extrinsic risk factors, hospital stay duration ≥ 6 days, previous hospitalization in the last 3 months, Surgery 30 days prior to the study date and dirty Surgical Wound Class were statistically associated with HAI. Also, we found that devices statistically associated with HAI were central vascular catheter, peripheral vascular catheter, urinary catheter and intubation or endotracheal tube (Tab. IV).

Results of multivariate analysis

Multivariate analyses showed that independent factors of HAI were immune suppression (AOR = 2.5; p = 0.004), hospital stay duration ≥ 6 (AOR = 4.5; p< 0.001), surgery 30 days prior to the study date (AOR = 1.9; p = 0.021), having central vascular catheter (AOR = 2.44; p = 0.032) and having intubation or endotracheal tube (AOR = 3.5; p = 0.002) (Tab. IV).

Tab. II. Healthcare associated infections according to ward specialty and university hospital.

University hospital/ward specialty	All enrolled patients	Number of HAI	Prevalence of HAI (%)
Total patients	102,8	86	8.4
Medical vocation hospital (total)	694	53	7.6
Adult departments	487	30	6.2
General medicine	290	28	9.7
Hematology	28	11	39.3
Other general medicine departments	262	17	6.5
Genecology and obstetrics	103	0	0
Adult psychiatric unit	94	2	2.1
Pediatric departments	207	23	11.1
General medicine	150	18	12
Neonatology	40	5	12.5
Neuro-pediatrics	3	0	0
Pediatric surgery	12	0	0
Pedopsychiatric	2	0	0
Surgical vocation hospital (total)	334	33	9.8
Surgery	240	17	7.1
Intensive care	58	14	24.1
General medicine (neurology, oncology, radiotherapy)	36	2	5.5

HAI: healthcare associated infections; %: Percentage.

Tab. III. Health-care-associated infections anatomical site and isolated micro-organisms.

HAI site	HAI (N = 86) (n, %)	Micro-organism in question (N = 40) (n, %)											
		Total MO isolated	E.c	K.p	E.f	Other E.	S.a	A.b	P.a	C.N.S	C.a	P.m	Others
All HAI	86 (8.4)	40 (46.5)	3 (7.5)	9 (22.5)	1 (2.5)	3 (7.5)	2 (5)	1 (2.5)	8 (20)	2 (5)	4 (10)	3 (7.5)	4 (10)
Urinary tract	11 (12.8)	9 (81.8)	2 (22.2)	3 (33.3)	1 (11.1)	-	-	-	1 (11.1)	-	1 (11.1)	-	1 (11.1)
Respiratory tract	32 (37.2)	5 (15.6)	-	2 (40)	-	1 (20)	-	-	2 (40)	-	-	-	-
Bloodstream	21 (24.4)	15 (71.4)	-	3 (20)	-	1 (6.6)	1 (6.6)	1 (6.6)	2 (13.3)	1 (6.6)	2 (13.3)	3 (20)	1 (6.6)
Surgical site	11 (12.8)	8 (72.7)	1 (12.5)	1 (12.5)	-	1 (12.5)	1 (12.5)	-	3 (37.5)	-	-	-	1 (12.5)
Eye, ear, nose, throat and mouth	11 (12.8)	3 (27.3)	-	-	-	-	-	-	-	1 (33.3)	1 (33.3)	-	1 (33.3)

* N,n: number; HAI: Health-care associated infections, Pr: prevalence of HAI; E.c: Escherichia coli; K.p: Klebsiella pneumoniae; A.b: Acinetobacter baumannii; P.a: Pseudomonas aeruginosa; S.a.: staphylococcus aureus; E.f.: Enterococcus faecali; Other E: other enterobacteria; C.N.S: coagulase negative staphylococcus; C.a.: Candida albicans; P.m: Proteus Mirabilis.

Discussion

This study pointed-up HAI prevalence and its associated risk factors in tertiary care hospitals in southern Tunisia. Evaluating this indicator was a key outcome in healthcare systems because of the huge impact of HAI on patients and healthcare systems. This study illustrated a global HAI prevalence of 8.4%. This prevalence was slightly lower from two previous studies conducted in our region in 2017 (10.9%) and 2019 (9.02%) [12]. This decrease could be explained by the effectiveness of the corrective measures taken by the preventive medicine and hygiene department in order to fight HAI notably continuous training sessions for healthcare professionals about standard precautions. This percentage was about 17.7% in a center-east Tunisian region with two university hospitals [19]. These findings could be explained by the complexity and invasive interventions administered for patients. By comparing with previous literature from other developing countries, we found a relative disparity between countries and globally HAI frequencies reported were more important than our findings. They were about 11% in Nepal [20] and about 30% in India [21]. In contrast, recent studies conducted in European developed countries reported a HAI prevalence rate ranging from 4.6% to 9.3% [22]. The high prevalence of HAI in low and middle outcomes countries could be reported to the lack of really active HAI prevention and control committee in hospitals. They could be related to the lack of respect of standard precautions given the huge workload and to the lack of financial resources [23].

It was worthy to know that the most important prevalence was noted in the hematology and the intensive care departments. This finding was in accordance with previous similar study [24]. An eventual explanation of this fact could be the invasive interventions delivered

Tab. IV. Factors associated with healthcare-associated infections: results of univariate and multivariate analysis.

	Univariate analysis				Multivariate analysis	
Variables	HAI		COR (95% CI)	p	AOR (95% CI)	p
	No (N,%)	Yes (N,%)				
Patients' relative risk factors						
Gender						
Male	488 (90)	54 (10)	1	0.051		
Female	454 (93.4)	32 (6.6)	0.6 [0.4-1.1]			
Age groups						
[2–60] years	523 (93.2)	38 (6.8)	1			
< 2 years or ≥ 60	419 (89.7)	48 (10.3)	1.6 [1.1-2.5]	0.043		
Habits						
Tobacco use						
No	800 (91.1)	78 (8.9)	1	0.147		
Yes	142 (94.7)	8 (5.3)	0.5 [0.2-1.2]			
Alcohol use						
No	889 (91.6)	82 (8.4)	1	0.705		
Yes	53 (93)	4 (7)	0.8 [0.3-2.3]			
Drug use						
No	918 (91.6)	84 (8.4)	1	0.900		
Yes	24 (92.3)	2 (7.7)	0.9 [0.2-3.9]			
Comorbidities						
Immunosuppression						
No	857 (93)	85 (80.2)	1		1	0.004
Yes	65 (7)	21 (19.8)	3.3 [1.9-5.6]	< 0.001	2.5 [1.3-4.5]	
Neutropenia						
No	923 (92)	80 (8)	1	0.004		
Yes	19 (76)	6 (24)	3.6 [1.4-9.4]			
Obesity						
No	878 (91.6)	81 (8.4)	1	0.728		
Yes	64 (92.8)	5 (7.2)	0.8 [0.3-2.2]			
Hypertension						
No	776 (93)	166 (85.6)	1	0.001		
Yes	58 (7)	28 (14.4)	2.3 [1.4-3.6]			
Diabetes						
No	748 (92.2)	63 (7.8)	1	0.181		
Yes	194 (89.4)	23 (10.6)	1.4 [0.8-2.3]			
Dyslipidemia						
No	847 (91.9)	75 (8.1)	1	0.430		
Yes	95 (89.6)	11 (10.4)	1.3 [0.6-2.5]			
McCabe Index						
Non-fatal disease	783 (92.7)	62 (7.3)	1	0.009		
Ultimately fatal disease	128 (88.9)	16 (11.1)	1.6 [0.8-2.8]	0.123		
Rapidly fatal disease	31 (79.5)	8 (20.5)	3.2 [1.4-7.4]	0.005		
ASA score ≥ 2						
No	79 (91.9)	7 (8.1)	1			
Yes	45 (77.6)	13 (22.4)	3.3 [1.2-8.8]	0.015		
External risk factors						
Admission ward type						
Medical	581 (92.1)	50 (7.9)	1	<0.001		
Surgical	289 (94.1)	18 (5.9)	0.7 [0.4-1.2]			
Intensive care unit	72 (80)	18 (20)	2.9 [1.6-5.2]			
Hospital stay duration						
< 6	488 (96.6)	17 (3.4)	1	<0.001	1	<0.001
≥ 6	454 (86.8)	69 (13.2)	4.4 [2.5-7.5]		4.5 [2.6-8.1]	
Previous hospitalization in the last 3 months						
No	819 (93.7)	55 (6.3)	1	<0.001	1	0.001
Yes	123 (79.9)	31 (20.1)	3.7 [2.3-6.1]		2.6 [1.5-4.4]	

▶

Tab. IV (*follows*). Factors associated with healthcare-associated infections: results of univariate and multivariate analysis.

	Univariate analysis				Multivariate analysis	
Variables	HAI		COR (95% CI)	p	AOR (95% CI)	p
	No (N,%)	Yes (N,%)				
Transfer from another hospital						
No	902 (91.5)	84 (8.5)	1	0.389		
Yes	40 (95.2)	2 (4.8)	0.54 [0.1-2.3]			
Surgery 30 days prior to the study date						
No	800 (92.7)	63 (7.3)	1	0.004	1	0.021
Yes	141 (86)	23 (14)	2.1 [1.3-3.4]		1.9 [1.1-3.4]	
Surgical wound class						
Clean	86 (89.6)	10 (10.4)	1	0.150		
Clean contaminated	22 (88)	3 (12)	1.2 [0.2-4.6]	0.820		
Contaminated	22 (84.6)	4 (15.4)	1.5 [0.4-5.4]	0.484		
Dirty	10 (66.7)	5 (33.3)	4.3 [1.2-15.1]	0.023		
Invasive devices in place on the survey date						
Central vascular catheter						
No	911 (93.1)	68 (6.9)	1	<0.001	1	0.032
Yes	31 (63.3)	18 (36.7)	7.8 [4.1-14.6]		2.44 [1.1-5.5]	
Peripheral vascular catheter						
No	432 (94.9)	23 (5.1)	1	0.001		
Yes	510 (89)	63 (11)	2.3 [1.4-3.8]			
Urinary catheter						
No	863 (93)	65 (7)	1	<0.001		
Yes	79 (79)	21 (21)	3.5 [2.1-6.1]			
Intubation or endotracheal tube						
No	896 (92.9)	46 (71.9)	1	<0.001	1	0.002
Yes	68 (7.1)	18 (28.1)	5.2 [2.8-9.4]		3.5 [1.6-7.4]	

* N: Number; %: Percentage; COR: Crude Odds Ratio; CI: Confidence interval; AOR: Adjusted Odds Ratio; HAI: Healthcare associated infection; ASA: American Society of Anesthesiologist.

and the immunodepression of patients hospitalized in these units.

By anatomic site, the most frequent HAI site was respiratory tract infection. This fact could be related to the change in the emergence of the COVID-19 pandemic. In fact, it was reported that during this pandemic there was a reduction of respiratory tract infections worldwide due to social distancing and the use of barrier gestures [25]. Besides, in the post-pandemic era, a possible increase in the incidence of respiratory infections was expected in the whole world due to the lack of adherence to preventive and distancing measures, the irrational and abusive abuse of antibiotics during the pandemic era, and emergence of multi-resistant respiratory strains [26].

According to the microorganism type the most frequent bacteria isolated was the Klebsiella pneumoniae followed by the Pseudomonas aeruginosa. This result was in line with previous data [12-27]. In fact, these pathogens are the most common isolated pathogens in HAI in the literature (over than 40% of cases) [27, 28].

As for HAI predictive factors, our study showed that the only patients' relative risk factor was immune suppression. In fact, it could be considered as evidence that immunocompromised patients are the mostly at risk to have HAI [29].

For extrinsic predictors, we found that hospital stay duration ≥ 6, surgery 30 days prior to the study date, having central vascular catheter and having intubation or endotracheal tube were independently associated with HAI. Our findings were in accordance with previous studies [11-12-30]. All previous factors cited could be a source of germs transmission for hospitalized patients via direct or indirect route. Invasive devices, such as central catheter and intervention could be an entry point for germs via a direct route by breakage of the skin barrier or closed cavities.

This original study is the first one enlightening magnitude of HAI in south Tunisian university hospitals after the COVID-19 era. The exhaustivity of the data collection gives a clear and exact idea about HAI burden in our region. In addition, the validated protocol used give an added value to the survey. Nevertheless, there were some limitations. Firstly, it was a cross-sectional study which illustrated only association between facts but did not approve the causality. Secondly, other factors apart from the listed could have influenced risk for HAI such as healthcare professional adherence to preventive measures and availability of financial resources in hospitals evaluated. Finally, it was a regional study that should be completed by other researches in different regions of the country in order to dressed HAI profile at a national scale that to be able to control it.

Preventing healthcare-associated infections (HAIs)

requires a robust infection control strategy that prioritizes consistent hand hygiene, appropriate use of personal protective equipment (PPE), and regular cleaning and disinfection of frequently touched surfaces. Healthcare facilities should also emphasize antimicrobial stewardship to combat resistance, ensure the safe management of invasive devices, and perform ongoing surveillance to promptly identify and address infection trends. Continuous training for healthcare workers and patient education on infection prevention are crucial in minimizing HAI risks and enhancing overall patient safety.

Conclusions

This study highlighted a relatively high prevalence of HAI in southern Tunisia. Multiple factors were predictive of HAI specifically invasive devices, surgery, length of hospital stay and fragility of patients.
Considering this, health authorities, hospital direction and healthcare professionals must be aware about the HAI alarming rates. Therefore, urgent and ongoing corrective measures should be implemented, maintained and re-evaluated continuously in order to control HAI and promote care safety.

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None.

Human Ethics and Consent to Participate declarations

Not applicable.

Data Availability Declaration

Not available.

Conflicts of interest statement

None.

Authors' contributions

MB, MBH, HBAM and MBJ: developed the study design and were responsible for the organization and coordination of the study. MB: was the chief investigator and responsible for the data analysis. All authors contributed to the writing of the final manuscript. All members of the healthcare associated infections in the two university hospitals of southern Tunisia: a point prevalence survey contributed to the management or administration of the study.

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Nursing

Validity and reliability of the Home Health Care Survey of the Consumer Assessment of Healthcare Providers and System (HHCAHPS) tool: a multicentre cross-sectional study

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Keywords

Home care services • Nursing • Psychometric properties • Validation study • Satisfaction • Quality of health care

Summary

Introduction. *This study aims to investigate the psychometric properties of the Home Health Care Survey of the Consumer Assessment of Healthcare Providers and System (HHCAHPS) in the Italian context.*

Methods. *This is a secondary analysis of data from the AIDO-MUS-IT study. A total of 9,780 patients cared for by home healthcare services completed the HHCAHPS along with a measure of satisfaction for the care received. Structural validity was assessed with a confirmatory analytical approach (CFA). Construct validity was ascertained via hypothesis testing (convergent validity) by correlating the HHCAHPS scores with the scores derived from the measure of patient satisfaction for care. Internal consistency was assessed with the Omega (ω) coefficient.*

Results. *Structural validity was confirmed, with satisfactory fit indices of the CFA model specified according to the conceptualized three-factor structure ("care of patients", "communication with the providers", and "specific care issues"). Construct validity was confirmed with moderate correlations between the level of satisfaction for care and the factors "communication with the providers" ($r = 0.39$, $p < 0.001$), "care of patients" ($r = 0.34$, $p < 0.001$), and "specific care issues" ($r = 0.19$, $p < 0.001$). Internal consistency was satisfactory for the "specific care issues" factor ($\omega = 0.81$), while it was at the threshold of acceptability for the other factors ($\omega = 0.60$-0.62).*

Conclusions. *This study shows that the HHCAHPS is valid and sufficiently reliable when tested on the Italian population. Therefore, this tool can be supportive for promoting research and designing interventions to promote patient-centered care within home healthcare settings.*

Introduction

Healthcare quality has increasingly attracted the attention of health managers and policymakers worldwide [1, 2]. This expanding focus is largely due to the recognition that improving healthcare quality leads to better patient outcomes, provides a competitive edge, and ensures long-term financial sustainability [2]. In view of the increasing demand for personalized and continuous care outside hospitals, it is especially important to assess and ensure the quality of services provided in home care [3, 4]. This demand is largely driven by demographic changes and shifting epidemiological patterns, which underscores the need for a more tailored, patient-centered approach to care [5].

Although objective indicators such as mortality and morbidity rates remain essential, patients' perceptions also play a crucial role in evaluating the quality of healthcare services [1-6]. Patient experience in particular has become an important quality indicator in various areas of healthcare, as it helps to determine whether services are effectively tailored to patients' individual needs and to assess the extent to which patients are actively involved in their care and recognized as partners [7]. In addition, several

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studies have consistently shown that a positive patient experience is strongly related to clinical effectiveness, patient safety, and health-related behaviors [7, 8]. These behaviors include adherence to prescribed medications, participation in screening programs, and efficient use of health resources across various medical conditions, care settings, and population groups.

Various efforts have been made to develop conceptual models and assessment tools that can be used to measure the multidimensional nature of overall service quality [9]. For example, Brady and Cronin [10] developed a third-order factor model for assessing service quality. This hierarchical model emphasizes that overall service perception is shaped by customer interactions, the environment, and tangible outcomes. Subsequently, Dagger and colleagues (2007) refined the framework by developing and validating a four-domain hierarchical model through a mixed-methods study. In this model, service quality is described as a combination of the interaction between the provider and the user, the provider's technical expertise, the environmental factors that influence both service and consumer perception, and the effectiveness of administrative processes.

Based on these conceptual models, specific tools were developed to assess the perceived quality of healthcare services, including the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS). The HCAHPS is a well-known and internationally validated tool for evaluating patients' experiences with hospital care [12, 13]. The original instrument consists of 33 items distributed into 6 domains: "physician communication," "pain management," "discharge planning," "nurse communication," "physical comfort," and "drug communication." Building on the success of HCAHPS, the Home Health Care Survey of the Consumer Assessment of Healthcare Providers and Systems (HHCAHPS) was developed to assess patient experiences in home care. The instrument was developed by the Centers for Medicare & Medicaid Services (CMS) in collaboration with the Agency for Healthcare Research and Quality (AHRQ) [14] and consists of 34 items designed to assess specific dimensions of care quality, including access to care, communication with healthcare professionals, and interactions with home health agencies (HHAs) and their staff. The survey also includes two global rating measures that evaluate the overall care quality and the willingness to recommend the organization to family and friends. To gain a comprehensive understanding of patient experiences, the HHCAHPS also integrates demographic information and self-reported health conditions.

Home care is increasingly recognized as a key component of healthcare systems worldwide, as a result of demographic, epidemiological, and economic changes [15]. In this context, a standardized assessment tool such as HHCAHPS could play a crucial role in evaluating the quality of home care services. However, despite its widespread use, the psychometric properties of HHCAHPS have not yet been assessed. This gap raises concerns about the applicability and accuracy of the tool in capturing patients' experiences in this specific context.

Therefore, our study aims to investigate the psychometric properties of HHCAHPS in the Italian home care system. Our research can contribute to understanding home care settings by validating a tool to measure patients' perceptions of the quality of care and, thus, optimising care practices and ensuring a more patient-oriented approach to home care. Additionally, a well-validated tool could enable home care providers to identify areas requiring improvement, refine service delivery, and monitor the impact of care interventions over time.

Methods

Study design

This is a validation study of the Home Health Care Survey of the Consumer Assessment of Healthcare Providers and System (HHCAHPS), which has been translated into Italian and adapted to measure the care satisfaction of patients cared for in home care settings. This study is part of the Home Nursing Care in Italy (AIDOMUS-IT) project [4]. In Italy, home care is managed by local health authorities (LHAs). These are public agencies that are responsible for managing and providing health services within designated districts or areas, which typically correspond to provinces. LHAs coordinate primary care services provided by various healthcare professionals (*i.e.,* general practitioners, family nurses, and district nurses). The COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) reporting guidelines were used to ensure accurate and reliable reporting [16].

Data collection

The data used for this validation study comes from the AIDOMUS-IT dataset, collected from April to October 2023. Specifically, an online survey was administered to patients cared for by the participating LHAs at a single point in time. The survey was disseminated by home care nurses on paper or via a web-based questionnaire. For the latter, a QR code was used to access a secure link to LimeSurvey®. When accessing this web application, participants were required to view the informational materials and the respective informed consent. After providing their consent, patients were allowed access to the survey. In case the patient wanted to complete the paper-based questionnaire, a written informed consent was signed before commencing. The questionnaire included an adapted version of the HHCAHPS.

Measurement tool

The original HHCAHPS is composed of 34 items divided into four sections: 1) your home health care; 2) your care from home health providers in the last 2 months; 3) your home health agency; and 4) about you. Moreover, 10 supplementary items are available [14]. This tool can be used to calculate three composite measures: 1) "care of patients" (items Q9, Q16, Q19 and Q24); 2)

"communications between providers and patients" (items Q2, Q15, Q17, Q18, Q22, Q23); and 3) "specific care issues" (items Q3, Q4, Q5, Q10, Q12, Q13 and Q14).

Each item of the first three sections of the HHCAHPS have a dichotomous response (*e.g.,* yes or no, item Q2), a Likert-type response (*e.g.,* from never to always, item Q9) or a numeric rating scale response (*i.e.,* from 0 to 10, item Q20). In the AIDOMUS project, this tool was adapted considering the aim of the project and target population and their specific characteristics. Items of sections one, two and three were referred to nurses' activity instead of the activity related to the agency, as the aim of the AIDOMUS project was to assess the quality of care received by nurses. Section 4 (sociodemographic characteristics) were adapted considering the Italian context (*e.g.,* Q29 was adapted considering the school levels available in Italy). Items Q12, Q30, Q31 and Q32 were not considered as they were not adequate for Italian home care. Moreover, supplemental items S1, S2, S5, and S8 were added to the survey. Items S2 and S8 were revised to include additional response options. Item S2 included the following response options: "after discharge from a hospital"; "after discharge from a private or affiliated nursing home"; "after discharge from a rehabilitation facility"; "upon request by your general practitioner". Item S8 included the following response options: "I am still waiting for the problem to be resolved"; "not satisfied at all"; "somewhat satisfied"; "fairly satisfied"; "satisfied"; "very satisfied". These changes were made to more accurately capture the specific reasons for home care enrollment and to better assess patients' satisfaction with how the nurses resolve their problems. Item Q16 ("How often did nurses from this agency treat you as gently as possible") was removed and replaced with S5 ("How often did you feel that nurses from this agency really cared about you") as Q16 was similar to Q19 (How often did nurses from this agency treat you with courtesy and respect).

After revising the instrument, face and content validity [17] were assessed involving five experts working in the home care setting. Face and content validity were investigated by means of a group of experts through an online survey. Their responses were collected with their sociodemographic, educational, and occupational details. Experts were asked to read each item of the HHCAHPS and to assess its relevance using a Likert scale from 1 (totally irrelevant) to 4 (totally relevant), while comprehensiveness and comprehensibility were assessed through text comments.

Item S8 was used to test convergent validity of each of the three composite measures of the HHCAPS. Responses were transformed in a numeric rating from 1 (Not satisfied at all) to 5 (Very satisfied), excluding the response "I am still waiting for the problem to be resolved". Higher values of item S8 indicated higher levels of satisfaction.

Data analysis

Sociodemographic and clinical characteristics of the sample are described with means (SD) and absolute frequencies (%). Response categories of the items are presented as absolute frequencies (%). The Content Validity Index (CVI) for each item (I-CVI) was calculated to assess content validity. The relevance ratings, originally on a scale from 1 to 4, were grouped into two categories: scores of 1 and 2 (indicating irrelevance) were recoded as 0, while scores of 3 and 4 (indicating relevance) were recoded as 1. The I-CVI for each item was then computed by dividing the number of experts who assigned a relevant score (coded as 1) by the total number of experts. Additionally, the Scale Content Validity Index (S-CVI) was obtained by averaging all I-CVI scores across items. Content validity was considered excellent if S-CVI exceeded 0.90 and I-CVI was greater than 0.78 [18].

Regarding the factorial structure of the tool, it was postulated to be composed of three latent factors, representing the composite measures reported by the HHCAHPS website [14]: "care of patients" (Q9, S5, Q19, Q24), "communication with the providers" (Q2, Q15, Q17, Q18, Q22, Q23), and "specific care issues" (Q3, Q4, Q5, Q10, Q12, Q13, Q14). Item S5 was considered an indicator of the first composite measure as its structure and meaning is very similar to that of item Q16. We used a confirmatory factor analysis (CFA) to investigate the structural validity of the scale. The HHCAHPS was also composed of two global items (Q20 and Q25) representing a rating and a recommendation regarding the home care services. Thus, these items were not included in the CFA. Since the items of the HHCAHPS are ordinal in nature, we used a categorical estimator (ULSMV) to derive the parameters [19]. The following fit indices were used to judge model fit: chi square (χ 2), comparative fit index (CFI; values > 0.90 are considered satisfactory), Tucker-Lewis index (TLI; values ≥ 0.90 indicate satisfactory fit), root mean square error of approximation (RMSEA; values ≤ 0.05 indicate good fit), and standardized root mean square residual (SRMR; values ≤ 0.08 are indicate good fit). Item factor loadings ≥ |0.30| were considered adequate to confirm their related latent factors. Internal consistency reliability was computed with the Omega coefficient (with values ≥ 0.70 considered adequate). This index was computed for each latent or composite factor. Construct validity was assessed by hypothesis testing. Specifically, we hypothesized that each composite measure of the HHCAHPS was positively correlated with the level of satisfaction for the care received (convergent validity). This validity was confirmed if Pearson's correlation coefficient was statistically significant. All the descriptive statistics were computed with SPSS® v. 25 (IBM corp. Released 2017). The CFA was performed with MPlus® v. 8.9 [20].

Results

Content validity

Five experts were recruited for the content and face validity process. The experts were all nurses with

valuable experience in home care, mainly female (n = 4, 80%), had mean age of 47.8 (SD = 7.5) years, mostly had a Master of Science in Nursing (n = 3, 60%), reported a mean number of 24.4 years (SD = 8.6) years of experience in the field and worked mostly as nurses with organizational tasks (n = 4, 80%). Regarding face validity, no comments were reported on comprehensibility. Regarding content validity, I-CVI ranged from 0.80 to 1 with an average S-CVI of 0.93.

Characteristics of the sample

A total of 9,780 patients completed the questionnaire. The patients had a mean age of 75.32 years (SD = 14.61), the majority were male (57.57%), most participants had secondary school education (50.51%), cohabited with a family member or caregiver (80.57%) and almost all patients were Italian (95.84%). Most of patients perceived their health to be sufficient (38.99%), while the majority rated their mental/emotional health as good (38.31%). Home care was most frequently activated upon the request of a general practitioner (49.83%). Satisfaction with home care was generally high, with 57.16% of participants reporting being very satisfied with the service. Table I reports the sociodemographic and clinical characteristics of the sample.

Structural validity and internal consistency

Table II reports the descriptives of the items of the HHCAHPS. In summary, patients predominantly reported that the nurses cared for them in a professional way (the "always" option was endorsed by 70.1% to 91.4% of the respondents). They also reported that the nurses communicated well with them (the "always" option was endorsed by 81.3% to 82.9% of the respondents), and that they discussed with them about medicines, pain, home safety, and information (the "yes" option was endorsed by 60.9% to 91.2% of the respondents, except for Q13 and Q14). Finally, most patients (98.7%) rated their care at least 6 to 10 points, and 78.9% of them wanted to recommend the agency to their family or friends.

The initial CFA performed considering the three composite measures yielded partially satisfactory fit indices: x^2 (120, N = 9,779) = 7,975.32, $p < 0.001$; RMSEA = 0.027 (90% CI = [0.025, 0.029]; p (RMSEA < 0.05) = 1.00); CFI = 0.91; TLI = 0.89; SRMR = 0.089. An inspection of the modification indices showed that the largest index (389.99) pertained to Q2 loading to the "specific care issues" composite measure. Since this loading can be reasonable (*i.e.,* patients are likely to consider the information on care and services as other different aspects of care issues) this modification index was accommodated. After moving Q2 from "communication with the providers" to "specific care issues" composite measure, the fit of the model improved significantly: x^2 (101, N = 9,779) = 589.32, $p < 0.001$; RMSEA = 0.022 (90% CI = [0.021, 0.024]; p (RMSEA < 0.05) = 1.00); CFI = 0.94; TLI = 0.93; SRMR = 0.076. All factor loadings were significant and moderate-to-high in size, except for Q10, which was at the threshold for acceptability (Fig. 1). When the HHCAHPS scores were correlated with the scores of the level of satisfaction, we found that participants with higher satisfaction for care scored also higher on the factors "communication with the providers" (r = 0.39, $p < 0.001$), "care of patients" (r = 0.34, $p < 0.001$), and "specific care issues" (r = 0.19, $p < 0.001$). Internal consistency yielded the following Omega coefficients:

Tab. I. Sociodemographic and clinic characteristics of the sample (N = 9,780).

	n (%) or mean (SD)
Sex	
Male	4,044 (57.57)
Female	5,585 (41.59)
Preferred not to reply	72 (0.74)
Age (years)	75.32 (14.61)
Education	
Primary school	3,671 (37.94)
Secondary school	4,888 (50.51)
Degree or post-degree	572 (5.91)
No formal education	546 (5.64)
Nationality	
Italian	9,373 (95.84)
Other	289 (2.96)
Perceived general health status	
Excellent	260 (2.69)
Good	2,379 (24.59)
Sufficient	3,772 (38.99)
Poor	1,947 (20.13)
Insufficient	1,316 (13.60)
Perceived mental/emotional status	
Excellent	718 (7.43)
Good	3,703 (38.31)
Sufficient	3,161 (32.71)
Poor	1,134 (11.73)
Insufficient	949 (9.82)
Living alone	
Yes	1,881 (19.43)
No	7,801 (80.57)
Need help filling out the survey	
Yes	5,391 (55.58)
No	4,308 (44.42)
Activation of home care	
On request made by the general practitioner	4,852 (49.83)
After discharge from the hospital	3,948 (40.54)
After discharge from a rehabilitation facility	323 (3.47)
After discharge from a private nursing home	202 (2.07)
After the request of the patient	64 (0.66)
After the request for social services	11 (0.11)
Other	338 (3.32)
Satisfaction with home care	
Very satisfied	2,747 (57.16)
Satisfied	1,575 (32.77)
Quite satisfied	347 (7.22)
Not very satisfied	35 (0.73)
Not at all satisfied	7 (0.15)
I'm still waiting for the problem to be resolved	95 (1.98)

"care of patients": ω = 0.62; "communication with the providers": ω = 0.60; "specific care issues": ω = 0.81.

Discussion

This study aimed to investigate the psychometric properties of the HHCAHPS in the context of the Italian home care services. Our results provide evidence of satisfactory validity and acceptable reliability of the scale in a large sample of individuals.

We found that the HHCAPS has satisfactory structural validity, with appreciable factor loadings. However, in our sample, item Q2 loaded onto the "specific care issues" factor, which is different from the authors' original postulation, where the item was conceptualized as an aspect of communication between the patient and provider. This may reflect a characteristic of the Italian population, who probably tend to give more importance to the information they receive instead of communication nuances when approaching the services for the first time because they want to prepare themselves as sufficiently as possible for future care needs. Notably, the right to be informed in Italy is emphasized both legally and ethically and is a constant evolving issue expanding also at a European level [21].

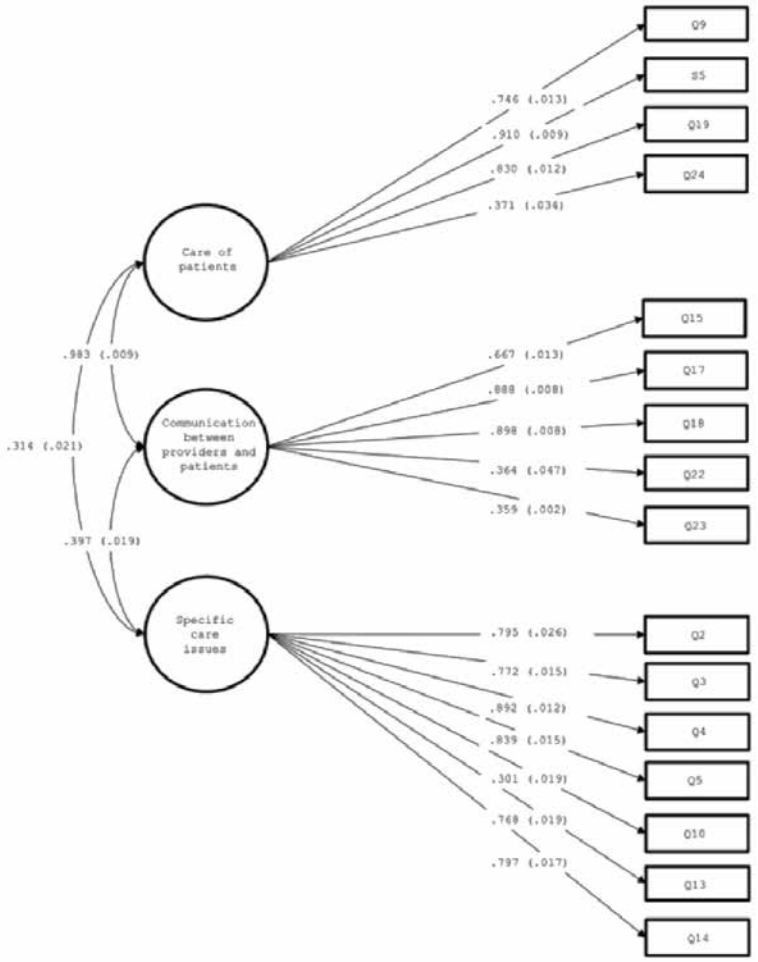
We also found evidence of acceptable internal consistency of the HHCAHPS. The traditional cut-off of 0.70 was not reached for the factors "care of patients" and "communication with the providers". This may be because there are some items loading weaker than the others to their respective factors. Specifically, item 24 loaded just over the threshold for adequacy in the "care of patients" factor, while items 22 and 23 showed the same issue in the communication factor. This may in turn be explained by the fact that such items have a high rate of missing (approximately half of our sample responded to these questions), and exhibit significant floor effects, because the patients mostly gave positive ratings. However, an internal consistency slightly below the threshold, as in our case, may not necessarily be a problem, since it has been discussed that reliability values as low as 0.50 should not seriously impact the validity of a scale [22]. As a result, we believe the scale is still reliable, although we recommend future testing in other populations.

Finally, we found that the HHCAHPS has satisfactory convergent validity given that the scores of the composite measures of "care of patients", "communication", and "specific care issues" were strongly correlated with the levels of satisfaction of the patients. This is not surprising, and reflects that patients mostly judge the quality of the communication with the healthcare provider and the actual care received in order to be

Tab. II. Descriptives of the items of the Home Health Care Consumer Assessment of Healthcare Providers and Systems (HHCAHPS).

Item		Response categories			
Care of Patients	**n**	**Always**	**Usually**	**Sometimes**	**Never**
Q9	8,249	6,851 (70.1)	1,438 (14.7)	309 (3.2)	53 (0.5)
S5	9,699	8,371 (85.6)	1,202 (12.3)	141 (1.4)	25 (0.3)
Q19	9,748	8,943 (91.4)	751 (7.7)	47 (0.5)	7 (0.1)
	n	Yes	No		
Q24	4,790	4,454 (45.5)	336 (3.4)	-	-
Communication between providers and patients	**n**	**Always**	**Usually**	**Sometimes**	**Never**
Q15	9,744	7,994 (81.7)	1,293 (13.2)	358 (3.7)	99 (1)
Q17	9,699	7,951 (81.3)	1,530 (15.6)	218 (2.2)	-
Q18	9,715	8,108 (82.9)	1,400 (14.3)	207 (2.1)	-
	n	Yes	No		
Q22	4,966	4,835 (49.4)	131 (1.3)	-	-
	n	Same day	1 to 5 days	6 to 14 days	More than 14 days
Q23	4,794	3,052 (31.2)	1,587 (16.2)	103 (1.1)	52 (0.5)
Specific care issues	**n**	**Yes**	**No**		
Q2	9,153	8,922 (91.2)	231 (2.4)	-	-
Q3	8,692	7,247 (74.1)	1,445 (14.8)	-	-
Q4	8,247	5,953 (60.9)	2,294 (23.5)	-	-
Q5	8,609	6,859 (70.1)	1,750 (17.9)	-	-
Q10	9,691	6,851 (70.1)	2,840 (29)	-	-
Q13	5,891	3,026 (30.9)	863 (8.8)	-	-
Q14	3,831	2,725 (27.9)	1,106 (11.3)	-	-
Global items	**n**	**0-5**	**6-10**		
Q20	9,728	73 (0.7)	9,655 (98.7)		
	n	**Definitely yes**	**Probably yes**	**Probably no**	**Definitely no**
Q25	9,673	7,715 (78.9)	1,853 (18.9)	61 (0.6)	44 (0.4)

Fig. 1. Confirmatory factor analysis of the Home Health Care Consumer Assessment of Healthcare Providers and Systems (HHCAHPS) scale.



Notes. Numbers near the one-headed arrows are standardized factor loadings. Numbers near the double-headed arrows are correlation coefficients. Standardized residuals are in brackets. Legend. Q, question.

satisfied with the services. In recent decades, there has been a significant expansion of literature focused on healthcare provider-patient communication as a key element of patient-centred care [23-25]. At the same time, there has been a tendency in modern healthcare to value patients' subjective experience of the care received [26]. This paradigm shift is important as it implies an increase in wellbeing and satisfaction, as well as better physical and mental health during the patient trajectory of care [27, 28].

Limitations and strengths of the study

This study has some limitations worth noticing. First, we enrolled a sample who were mostly satisfied with the home care received. Therefore, further psychometric testing of the HHCAHPS is needed for a more heterogeneous population. Second, the rate of missing was high for some items, which, in addition to the floor effects generally exhibited, led to a suboptimal reliability for some factors. Although we did not perform a missing data analysis, future studies should employ more effective ways of data collection to limit missing responses. Finally, this study presented an adapted version of the original scale determined following the specific aim of the AIDOMUS project. Thus, results should be confirmed for the original version of this scale.

This study also has noticeable strengths, including the large sample size, and its multicentric nature, which leads to confidently stating that the individuals enrolled accurately represent the real Italian population cared for by the LHA in their homes.

Conclusions

Overall, this study provides evidence that HHCAHPS is valid and sufficiently reliable when tested on the Italian population cared for by home healthcare services. Therefore, HHCAHPS could be a useful tool for promoting research and assisting healthcare providers develop interventions to promote patient-centred care

within home healthcare settings.

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Ethical approval

Approval for the study was obtained from the Ethics Committee (Liguria Region, n° 675/2022 – DB ID 12844, approved 29/11/2022).

Conflicts of interest statement

The Authors declare that there is no conflict of interest.

Authors' contribution (CRediT)

MDN, PI, IM writing – original draft; AB, RA, LL, DFM, LR, GR, MZ, GC, BM, LS: Conceptualisation, methodology, writing – review & editing; VC, FZ, YL, VV, DC, ABu, PL: writing – review & editing; MDN, PI: Data curation, formal analysis; AB, LS: Supervision.

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Occupational Medicine and Hygiene

Assessment of hygienic knowledge and oral health practices among children under dynamic observation for periodontosis in Aktobe

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Keywords

Periodontal diseases • Oral hygiene • Orthodontic treatment • Dental education • Dentistry

Summary

Introduction. *Oral diseases are a serious global public health problem affecting more than 3.5 billion people, are among the most common diseases in the world, and carry serious medical and economic problems, substantially reducing the quality of life of those affected. Oral diseases undoubtedly represent a global public health problem, with particular concern about their growing prevalence in many countries, which is associated with broader social, economic, and commercial changes. The purpose of the study is to establish the level of hygienic education among schoolchildren undergoing orthodontic treatment in Aktobe.*
Material and methods. *The design of the study is experimental and descriptive. The sample was gathered without pre-selection. It included children from 6 to 18 years old who were on dynamic observation, with a diagnosis of periodontal diseases.*
Results. *According to the data obtained, it was identified that 300 respondents aged 6 to 18 years took part in the survey, the average age of the respondents was 13.75 ± 1.38 years. The survey identified a low level of dental education in hygiene and oral care among children and a lack of motivation to maintain dental health.*
Conclusions. *It is necessary to strengthen educational work with the involvement of dentists, teachers, and parents to increase the low level of knowledge on dental health and oral care among the interviewed schoolchildren.*

Introduction

Oral diseases, particularly periodontal diseases, represent a significant global public health concern, affecting over 3.5 billion individuals worldwide. These diseases have a significant impact on quality of life, causing discomfort and pain and resulting in profound medical, social, and economic implications. A lack of oral health can result in several adverse consequences, including the persistence of pain, sepsis and a reduction in the quality of life experienced by the individual. For children, these effects are particularly concerning as they have the potential to impact their overall well-being, academic performance, and social interactions. Despite the preventable nature of periodontal diseases, they remain prevalent, largely due to insufficient oral hygiene, unhealthy diets, lack of awareness, and limited access to dental care, especially in marginalised communities [1, 2].

Children are particularly susceptible to oral health issues due to their limited comprehension of optimal hygiene practices and the habits they establish during their developmental years. Inadequate oral hygiene and unhealthy dietary habits, such as the frequent consumption of sugary foods and drinks, are significant contributing factors to the development of dental diseases. Those undergoing orthodontic treatment are at an even greater risk, as they often have difficulty maintaining proper hygiene around braces, which can exacerbate periodontal issues. In the absence of adequate education and guidance, these children are at an increased risk of developing severe oral health issues that may persist into adulthood.

Despite the preventability of many oral diseases, oral health education remains inadequate in many regions, particularly among children. A paucity of oral health knowledge frequently gives rise to inadequate hygiene practices and a lack of motivation to maintain oral health. A substantial body of research indicates that the level of hygienic education among children is frequently inadequate. Many children lack awareness of the significance of maintaining optimal oral hygiene and its impact on their overall health. Furthermore, parental involvement in the reinforcement of healthy oral hygiene practices represents a crucial element in the prevention of periodontal diseases in children [3-5].

The objective of this study is to evaluate the extent of hygienic education and oral health awareness among schoolchildren undergoing orthodontic treatment in

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Aktobe. A comprehensive understanding of their current knowledge and the identification of deficiencies in their oral health education will facilitate the development of targeted interventions designed to enhance oral hygiene practices. The objective of this study is to contribute to the development of more effective oral health education programmes for children, with the ultimate goal of improving long-term oral health outcomes and reducing the prevalence of periodontal diseases.

Materials and methods

The study employs an experimental and descriptive design. The sample size was determined on the basis of the statistical power required to detect significant differences in oral hygiene education among schoolchildren undergoing orthodontic treatment. The sample comprised 300 children and adolescents, aged between 6 and 18 years, who had been diagnosed with periodontal disease and were undergoing dynamic observation. The mean age of the respondents was 13.75 ± 1.38 years. Of these, 183 (61%) were female and 117 (39%) were male. The sample was gathered without prior selection, comprising both male and female participants. The study included children with concomitant diseases, such as gastrointestinal and nervous system disorders. The exclusion criteria included adults, children under the age of six, and individuals with oral diseases or tumour-like changes.

A sociological survey was conducted using a validated questionnaire recommended by the World Health Organization. The questionnaire was specifically designed to assess the level of hygienic knowledge among schoolchildren. The reliability of the questionnaire items was confirmed through the calculation of Cronbach's alpha coefficient, which ensured content validation. Furthermore, test-retest validation was conducted to ensure the consistency of responses over time.

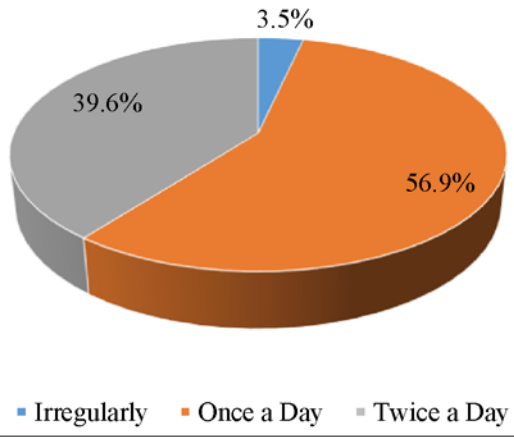
The questionnaire comprised 14 closed or semi-closed questions pertaining to the respondents' self-assessment of their oral health, dental care practices, reasons for dental visits, use of dental care products, dietary habits, and the presence of oral health-related behaviours such as smoking. The questions were designed in such a way as to allow for straightforward and unambiguous selection of responses, thus ensuring the efficient collection of data. The data were then processed using the Statistica 10 program, and descriptive statistics were performed in order to analyse the responses. Furthermore, the study also evaluated the correlation between parental education levels and the children's dental health behaviours, such as the frequency of dentist visits, the condition of the gums, and brushing habits.

The project was approved by the Ethics Commission of the West Kazakhstan Marat Ospanov Medical University, No. 1356. Informed consent to the survey was acquired from the parents of the subjects.

Results and discussion

Substantial differences were obtained when answering the question about personal assessment of the condition of teeth ($p = 0.002$); teeth brushing ($p = 0.003$), and difficulty biting off food ($p = 0.016$). When asked about the frequency of brushing teeth, the following results were obtained (Fig. 1).

Fig. 1. Frequency of tooth brushing among participants.



The majority of children are dissatisfied with the appearance of their teeth, which amounted to 60.25%. The main reasons for dissatisfaction with their teeth are anomalies in the location of teeth – 63.5%, caries processes of the central group of teeth – 24.6%, and insufficiently white enamel colour – 11.9%. For this reason, many children avoid smiling and laughing when communicating, covering their mouths with their palms. According to the results of the survey, the majority of children go to the dentist because of a toothache that has already appeared, which is 54.6%. According to the results of the survey, 25.7% of children undergo routine examination and treatment by a dentist. When questioning children about the consumption of sweet confectionery products and sweet drinks that cause damage to teeth and gums, 71.3% gave a positive answer, tea is drunk with added sugar by 75.8%, several times a day, which is a trigger in the development of dental disease. Children constantly consume easily digestible carbohydrates in large quantities, which in combination with poor oral hygiene leads to deterioration of their dental health. When analysing the section on the education of parents, during statistical analysis of the relationship, a statistically highly reliable correlation was determined between the education of the father and the visit to the dentist. A strong correlation was observed between parental education and dental health outcomes in children. Fathers' and mothers' secondary or higher education levels (97.2% and 97.8%, respectively) were linked to better dental care practices in children, including frequency of dentist visits and oral hygiene maintenance (Tab. I).

Tab. I. Correlation between parental education and dental care.

Parent's Education Level	Frequency of Dentist Visits	Oral Hygiene Practice
Secondary Special & Higher Education	Positive Correlation	Better Hygiene Habits

Periodontal disease in adolescence is affected not only by the state of oral hygiene but also by personal parameters and psychological factors. In school dental health, personal health guidance from a responsible teacher who knows the student well is very important to improve the periodontal condition, along with proper examination and evaluation by school dentists [6]. A positive relationship between periodontitis and hypothyroidism was identified. Further well-controlled prospective clinical and immunological studies are required to confirm this link, measure the strength of any link with the severity of the disease, and establish a causal relationship and the role of one disease in the pathogenesis of another [7].

Putative periodontal pathogens play a crucial role in the onset of the disease and provoking host inflammation, continuing to perpetuate the disease through immune subversion and tissue manipulation [6]. Observations showed that the oral cavity changes considerably due to periodontal disease, indicating potential mechanisms by which viral species can manipulate both bacterial and host processes during disease progression [5, 8]. Factors affecting microbial dysbiosis and periodontal inflammation have gone beyond a simple lack of oral hygiene and now include the person's environmental factors such as psychological stress and diet [9, 10]. Studies among children and adults in the southern region of the Lisbon agglomeration in Portugal show a high burden of periodontitis. Age, level of education, smoking status, and diabetes mellitus were identified as substantial potential risk factors for periodontitis [11, 12]. The model, which includes age, gender, ethnicity, HbA1c (A haemoglobin A1c), and smoking habit, can be used as a reliable screening tool for periodontitis in primary health care institutions to facilitate referral of at-risk patients for periodontal examination and diagnosis.

Based on the presented data, the following recommendations can be made to improve periodontal health and reduce the incidence of periodontitis: well-structured educational programmes on oral hygiene for schoolchildren to develop a positive attitude toward dental care, consolidate knowledge by including oral health and oral hygiene issues in school curricula, and involve teachers in training programmes; implementation of preventive school dental programmes to establish control and prevention of dental plaque; comprehensive screening programmes to assess oral health and treatment needs of schoolchildren [13-15]. These preventive services should be given high priority and started at an early age. Dental services, both preventive and therapeutic, should be widely available to all [16-18]. Thus, the elucidation of the elements of susceptibility to periodontal disease (genetic factors, oral hygiene, smoking) and the family component of this disease is crucial for the development of this disease [19-21].

A potential limitation of this study is the reliance on self-reported data, which may be subject to bias or inaccuracies. Furthermore, the study sample was limited to children from a single region (Aktobe), which may not fully represent the broader population of children undergoing orthodontic treatment. It would be beneficial for future research to expand the sample size and include data from multiple regions in order to gain a more comprehensive understanding of children's oral hygiene education across different demographic groups. Furthermore, the study did not investigate the long-term effects of improved dental hygiene education, which represents an important avenue for future research.

Further research could investigate the efficacy of particular interventions, such as the integration of dental hygiene education into the school curriculum and evaluate their impact on both immediate and long-term oral health outcomes. Furthermore, an investigation into the role of parents, teachers, and healthcare professionals in promoting oral health could provide valuable insights into the most effective methods of fostering better hygiene practices among children.

Conclusions

The study reveals a dearth of knowledge regarding oral hygiene among schoolchildren undergoing orthodontic treatment in Aktobe. It is of paramount importance to prioritise the enhancement of children's dental education, particularly within the context of orthodontic care, in order to guarantee long-term oral health. Furthermore, the participation of parents, educators, and dental professionals is vital to reinforce oral hygiene practices and promote a culture of dental care. The reinforcement of educational programmes and the provision of accessible preventive dental services will assist in addressing the current deficiencies in dental knowledge and improving oral health outcomes for these children. A comprehensive approach, which encompasses both child and family education, is essential for more effective oral health management.

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Ethics approval

The project was approved by the Ethics Commission of the West Kazakhstan Marat Ospanov Medical University, No. 1356.

Conflicts of interest statement

Not applicable.

Authors' contributor

NZ and LY: conceptualization, methodology, data curation, writing-original draft preparation. MU: visualization, investigation, and supervision. SS and GS: software, validation, writing-reviewing, and editing. All authors read and approved the final manuscript.

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HEALTH CARE MANAGEMENT

Performance-based payment systems for general practitioners and specialists in selected countries: a comparative study

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Keywords

Pay for performance • Quality-based payment • Value-based payment • Performance evaluation indicators • Health policy

Summary

Background. *Due to the growing increase in the needs of health systems in the field of financial and human resources management, performance-based payment has been the subject of attention by health and welfare policymakers. This study aimed to compare the components of performance-based payment in selected countries.*

Methods. *This comparative study was conducted in 2021. The selection of countries was based on three measures: the type of health insurance system, the development of the performance-based payment system, and the state of economic development of the countries. The findings were organized using comparative analysis tables. The general framework of performance-based payment systems, including goals, activities and actions, people involved in the program, and the way of encouraging and punishing, was used for analysis.*

Results. *The findings of the study showed that in most of the programs, aspect of clinical quality has the highest weight. Other dimensions include patient experience and satisfaction, physician financial performance, and patients' access to services. In most programs, various risk adjustment methods such as exception reporting, combined payments, payment according to demographic characteristics, were used to reduce provider risk, and clinical service providers were actively involved in the program design progressive.*

Conclusions. *Despite the widespread use of performance-based payment programs in most countries, these programs face limitations and shortcomings. By linking incentives to individual, team, and organizational performance, a performance-based payment program can improve teamwork, and create integrated health care.*

Introduction

Health organizations have a special position in the society due to their duties in the field of prevention, care, treatment and rehabilitation, and any weak performance in their management causes a delay in timely treatment and disease progression or death [2, 1]. Given that in hospitals, human resources play a main role as the core of the organization, inefficient payment systems and insufficient salary or wage has led to some problems, such as absence at work, employee dissatisfaction, conflicts between employees, quitting the job, strike, and complaints [3, 4]. Having a motivated and competent workforce and a performance evaluation system increases the effectiveness and efficiency of services in health care delivery [5, 6]. Performance appraisal seeks to find the most accurate and cost-effective methods for measuring job performance and job satisfaction [7, 8]. Considering that financial incentives are one of the most important factors affecting individual and organizational behavior in the health sector and have many effects on the health system and the quality and quantity of services, health sector managers should consider the powerful effects of motivation on employees' behavior in designing a payment system [9, 10]. According to Steven's study, giving employees 10% more bonuses can be motivated them [11]. Pay for Performance (P4P) is a payment model that attempts to reward measured dimensions of performance and incentivize health service providers to achieve predetermined goals by financial incentives [12, 13]. P4P was created in order to improve quality and efficiency and reduce additional costs by providing financial incentives to payers and service providers to establish a relationship between economic incentives and the quality of their performance [14]. P4P is different from other traditional payment methods. Traditional methods relate income to workload and do not consider paying for quality, while P4P explicitly addresses efficiency and effectiveness [15]. The most

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important advantage of P4P is that they significantly improve the organization's performance without putting additional financial pressure on it [16]. P4P programs intend to improve the system performance and accountability by motivating health workers and increasing their independence in employing available resources [17]. Based on the principal-agent theory, P4P is expected to align payers' and providers' motivations [18]. Motivation, defined as an individual's willingness to try and act towards organizational goals [19]. Other benefits of P4P system include attracting potential job seekers, retaining employees, motivating employees, paying according to legal regulations, curbing organizational costs, and simplifying strategic goal [20-22].The P4P in different countries has different results. For example, implementing this system in the UK, which has one of the most comprehensive P4P programs at the primary care level in the world, has improved uterine screening tests and immunization, as well as improving the quality of the services provided before the introduction of the program [23]. In Turkey, P4P has also led to an increase in the productivity of doctors and a decrease in the number of patients per physician [24]. In general, implementing this system in Turkey has been satisfactory and has led to an increase in the quality of health services [25]. Contrary to the successful experiences in the implementation of this system, in some countries, the implementation of this system has faced problems, the main reasons for this are the costly and time-consuming implementation of the program, the resistance of healthcare workers to change, and the lack of Adequate infrastructure prior to implementation [26, 27]. For example, in Canada, due to the lack of an accurate performance evaluation system in many healthcare organizations, these organizations were not successful in applying performance-based payment methods [28].P4P has been widely implemented in developing countries over the past decade and has shown favorable results despite the existence of little evidence. Evidence has shown that P4P has led to improve chronic disease care [29], reduced hospitalization and mortality [30], improve documented care processes [31] and cost savings [32]. Insurance organizations, as service buyers and custodians of the payment lever in the health system, are obliged to move in the direction of connecting payments with performance quality. If an important reward such as payment cannot be linked with results, it will lead to a decrease in motivation and a drop in performance [33]. On the other hand, deterrents for violators should be designed large enough to encourage providers to invest in order to achieve performance goals [34].Without financial penalties and punitive options (for non-compliant and delinquent providers), P4P will only increase health costs [35]. Considering that P4P is a step towards achieving quality [36], this study was conducted with the aim of comparing the components of the P4P system in selected countries. This study has tried to identify the organization of P4P systems in selected countries to help planners and policy makers in designing a sustainable and effective P4P system.

Methods

Search strategy and selection process

This comparative study was conducted in 2021. In this study, a five-step protocol including determining the countries to be studied, searching for relevant documents, selecting documents, extracting data, and reporting, was used to conduct this comparative review. Searching for electronic resources based on the keywords of "Performance-based payment", "Quality-based payment", "Outcome-based payment", "Value-based payment", "Performance evaluation indicators" and "Quality evaluation indicators" and selected countries was conducted. These keywords were combined with Scopus and PubMed databases, Google Scholar, Google search engine, as well as the websites of the Ministry of Health, the World Bank, OECD, and WHO. The inclusion measures for the study included all articles and documents published between 2000 and 2021, relating to performance - based pay in selected countries.

The measures for entering the countries into the study included the type of health insurance system, the extent of using the performance-based payment system, and the economic development status of the countries. Also, having successful experiences and policies in implementing the performance-based payment system and having valid evidence in the selection of countries were considered. Finally, eight countries, including England (two programs), Taiwan, the United States of America, Canada, Germany, Turkey, France, and Iran, were selected to compare the components of the P4P system.

Comparative review of programs

The selected programs have been examined based on three main questions in accordance with the purpose of the research. In the first question (what is encouraged?), programs were evaluated in terms of performance dimensions and measures, measurement of indicators, provider participation, data collection, and methods used to adjust the risk of providers. In the second question (who is encouraged?), the programs were evaluated in terms of individuals or groups, the characteristics of the providers and the type of their participation (voluntary or non-voluntary). In the third question, in addition to evaluating the basic payments, the type (positive and negative), the amount, the period and the method of calculating the incentive and punitive payments were reviewed.

After reviewing the literature, the P4P system variables were identified, and the data were gathered using a researcher-made checklist based on the P4P framework. The researcher-made checklist contained all the information related to the objectives of the study. The extracted data were classified according to the components of the analysis and were then organized into comparative tables. Three comparative table was completed for the eight selected countries (nine programs). The comparative tables included components such as performance indicators, providers and financing

methods in selected countries. For this purpose, similarities and differences between the countries were compared based on the information extracted from the comparative tables. Framework analysis was used to analyze the data, and the data analysis was performed using comparative analysis tables, which compare the components of P4P system.

Results

In this research, nine programs were selected among the P4P programs in the world, which are: Quality and Outcomes Framework (QOF) and Advancing Quality (AQ) in England, National Health Insurance_Pay for performance (NHI-P4P) in Taiwan, Integrated healthcare association-physician incentive program (IHA-PIP) in the California of US state, Physician Integrated Network (PIN) in Canada, Ergebnis Orientierte Vergütung (ERGOV) in Germany, Family medicine performance based contracting scheme (FM PBC) in Turkey, Rémunération sur Objectifs de Santé Publique (ROSP) in France, and Payment guidelines based on the performance of medical practitioners and faculty members working in university-affiliated hospitals (P&FM-P4P) in Iran.

What is encouraged?

Six programs were initiated by a public purchaser and three by private insurers responsible for managing the care for their enrollees. In the programs targeting multiple dimensions, clinical quality has the highest weight and the most scales were included. Other dimensions include financial performance, patient satisfaction/experience, capacity and access (for example, structural measures referring to administrative and organizational aspects of performance such as receiving training/providing and record keeping). Clinical aspects typically relate to chronic and preventive care, However attention to acute care is considered in some programs such as AQ, FM-PBC, NHI-P4P, QOF and P&FM-P4P. Four programs adopted a set of measures including at least 30 measures pertaining to clinical quality and patient satisfaction/ experience or access.

Various other risk-mitigation methods are used across the programs. Risk adjustment is used in AQ, ERGOV and ROSP for financial purposes. Especially in AQ and ERGOV, risk adjustment appears to be relatively complex, controlling for sociodemographic and morbidity-based risk factors. Not all programs that include outcomes apply risk adjustment. Various other risk mitigation methods are used throughout the programs. For example, in IHA-PIP, performance targets are differentiated based on how current performance is influenced by case mix and population characteristics. In general, although the documents provide limited information on the use of risk-mitigating measures, the results raise doubts about whether differences in risk are sufficiently equalized, especially in PIN and NHI-P4P. In P&FM-P4P, hospitals with low financial performance, add 5% of the hospital's income (Institute share) or the institution's aid from 5% of other hospitals, to the physicians' contribution limit. In most programs, providers actively participate in program design and implementation. The participation of the provider is considered as a critical success factor(37), and is being realized in various ways, including delegating authority to providers (QOF, FM PBC), consensus meetings (AQ, IHA-PIP) and using feedback from providers (QOF, NHI-P4P, FM PBC). Table I evaluate the various performance programs and what is encouraged.

Who are encouraged or punished?

In most programs, payments are mostly provided at the group level. "Targeted groups" vary in structure and size, ranging from hospitals (AQ, FM PBC) to large multispecialty organizations (IHA-PIP) to primary care efforts (QOF, ROSP). In ROSP, payment is provided to the primary care practice for measures for which this does not seem to hold. For example, GPs receive more money for each Pap smear, but if a specified percentage of patients are screened, the physicians receives a fixed amount per patient [67]. In the NHI-P4P, payment is provided to hospitals for cancer and diabetes, but directly to physicians for TB and asthma. However, for many measures included in these program, sample sizes may not be sufficient to generate reliable profiles, particularly for outcomes and resource use [68].This also seems relevant for PIN and QOF, as many physicians still work in small group-practices. For several programs, data state that measures are only included if they are adequately under providers' control and/or if sample size is adequate. However, it is not clear when this is the case. Some programs (*e.g.,* AQ, P&FM-P4P, ROSP) aggregate individual measures into composites, which can increase reliability [69, 70]. In ROSP this resulted in fair reliability, despite that many physicians were duo or solo practices. Although it is difficult to draw conclusions, there are concerns about whether providers can be sufficiently discriminated from each other, and thus whether payment allocation occurs sufficiently. In P&FM-P4P, the performance of each doctor is calculated and paid individually. Participation in this program is non-voluntary and the calculation and payment of the performance of all doctors who have contracts with government health insurances is done under the terms of this plan [71].

In five programs (AQ, FM PBC, ROSP, QOF, P&FM-P4P) the participation rate is virtually 100 percent. In PIN, IHA-PIP and NHI-P4P participation is more than 50%. Low participation in ERGOV may be problematic. In ERGOV, clinics participating in the scheme are known as preferred providers. This may be a strong incentive for clinics to participate, especially if receiving care from unlicensed providers requires large out-of-pocket payments. But participation may still be unattractive because it involves a considerable administrative burden while financial consequences are highly uncertain. To achieve meaningful differences, participation must be increase [54]. Also in NHI-P4P for breast cancer, low

Tab. I. What are the details of the various P4P programs and what is encouraged?

Name of the program/ country/year of commence /number of measures	Performance dimensions (weight)	Performance measures	Development and evaluation method	Methods used to mitigate providers' risk
QOF United Kingdom 2004 134 measures (23, 38-40)	• Clinical (69.6%) • Organizational (16.7%) • Patient experience (9.3%) • Additional services (4.4%)	• Clinical: 86 measures, 20 areas (chronic, acute, prevention, psychological) • Organizational: 36 measures • Patient experience: 3 measures • Additional services: 9 measures	• Evaluation, review and development of Measures by professional organizations • Selection/weights based on negotiations between the government and the British Medical Association • Data collection: uniform electronic medical record managed by General Practitioners, extracted to national database	• Annual inspections by primary care centers, big penalties for fraud • Rejection of some patients by general practitioners. Exception reporting
AQ United Kingdom 2008 At least 30 measures (30, 39, 41)	• Clinical (60%) • Patient experience (20%) • Patient-reported outcome measures (PROMs) (20%)	• Clinical: 27 processes, 3 final outcomes; divided over 5 acute care areas • PROMs: quality of life before and after medical services	• Measures developed within the framework of CMS/Premier Hospital Quality Incentive Demonstration in the US • Self-collected data; goals for completeness/accuracy; centralized support • Endorsed by royal colleges and clinicians.	• Risk-adjustment: survival index for acute myocardial infarction, PROMs • Composite score for each therapeutic and clinical domain
NHI-P4P Taiwan 2004 At least 22 measures (42-46)	• Clinical (100%) Diabetes mellitus, breast/cervical cancer, asthma, tuberculosis • In order to add clinical outcomes, hepatitis B/ C, schizophrenia, and hypertension	• Diabetes mellitus: 2 structures, several processes, 2 intermediate outcomes • BC: 4 structures, processes, 2 outcomes • Asthma: 2 structures, several processes • TB: 4 structures • CC: 2 processes, several processes, 1 final outcome	• Data self-reported by providers and automatically entered into the database • Measures are selected based on disease burden • Intention to increase participation of providers in program development and measure selection	• Requires sample size. • Providers decide which patients to admit. Government increases the number of patients physicians have to admit (in 2010 for DM: 33% of population, ≥ 55 patients)
IHA-PIP America-California 2003 Four main dimensions with at least 25 measures (47-50)	• Clinical quality (50 percent) • Patient experience (20 percent) • Effective use of health information technology (30%) • Appropriate use of resources (without percentage)	• Clinical quality: preventive care, childbirth, cardiovascular, diabetes, musculoskeletal and respiratory • Patient experience: communication with the doctor, coordination of care, timely access, privacy, respect and quality of service delivery, • Appropriate use of resources: utilization of outpatient and inpatient services, referral to the emergency room and prescription of generic drugs	• Measures developed/ negotiated at the national level; Doctors are consulted • The provider payment formula is developed through negotiation with the government and physicians • Separate storage of patient records	75% of payments are determined according to the age and gender of the patient
PIN Canada, Manitoba 2004 37-40 measures (51-53)	• Clinical (100%) • Intention to add ongoing care, access, mental health, and coordination	• 24 processes and 6 areas for chronic care • 14 processes for preventive care • 2 additional processes for depression care	• Selection: expert opinion, consensus meetings • Data system populated via clinics' electronic records	• Measures included if "specific" to clinics and data are valid and Reliable • Checks with registry • Measures adjusted based on feedback

▶

Tab. I *(follows).* What are the details of the various P4P programs and what is encouraged?

Name of the program/ country/year of commence /number of measures	Performance dimensions (weight)	Performance measures	Development and evaluation method	Methods used to mitigate providers' risk
ERGOV Germany, regional 2001 20 item tool (54, 55)	• Patients' ability to perform daily life activities • Quality of outcome of rehabilitation care for stroke patients	• Self-care (7 items), mobility (4), communication skills (4), cognitive activity (5) • 6 types of help in each case	• A quality assessment tool combining items from widely used measurement tools with good psychometric properties • Approved by clinics	• Data is reported online. Checks using self-assessment • Rejection of the patient • ≥100 patients
FM PBC Turkey 2006 35 measures (56-59)	• Clinical (55%) • Services (25%) • Management evaluation (20%)	35 performance measures including: 19 clinical cases Services: 9 items and management evaluation: 7 items	Selection based on experience from other countries, clinical communication and data collection through electronic health records is possible	Creating follow-up or reminder lists for family physician staff as a decision support system
ROSP France 2012 29 measures (60-62)	• Clinical (58%) • Appropriate and efficient versions (24%) • Quality management (17%)	• Chronic disease management and follow-up (9 measures) • Prevention (8 measures) • Appropriate and efficient versions (7 measures) • Office organization and quality of care (5 measures)	• Selection based on disease burden, consensus and available evidence • Development by clinical networks and verification of information by quality measurement. • Information was collected by clinical units	• Actions are only taken if they are sufficiently within the providers' control
P&FM-P4P Iran 2013 27 measures (63-66)	• Clinical measures (46.4%) • Patient satisfaction (32.2%) • Organizational measures (21.4%)	• 13 performance measures for specialist doctors • 9 measures to measure the performance of general practitioners • 6 measures to measure patient satisfaction	• Choosing the weights based on the decisions of Council for planning and supervising the distribution of special income • Data collection: electronic medical records extracted in the database	• Measurements are explicitly selected based on sufficient sample size in each treatment center. • The fixed part of the fee of the program to support the longevity of doctors in deprived areas is not included in the calculation of the professional component

participation appears to be a result of the additional financial risk that participation involves and the fact that hospitals experience survival rates, which determine whether or not they receive a reward, to be largely beyond their control [45].Table II provides more detail on "who is encouraged or punished".

How is encouragement and punishment done?

In AQ, there were no penalties for poor performers, but hospitals that failed to meet targets for data accuracy and completeness received a penalty or were removed from the program. (The current version of AQ involves withholding of payments rather than rewards) [41]. Compared with ERGOV, the financial risk of participation was lower. Also, there was less uncertainty because payments were fixed. Due to the size of the payment, there is much variation across programs. In AQ, in addition to payments for patient-reported outcomes, hospitals could receive a 4 percent add-on to the national tariff for the associated activity. In FM PBC, bonus potential is 5 to 10 percent of the average DRG price. In NHI-P4P, payments per patient are often maximized per year. For cervical cancer, fees may be increased by up to 55 percent. For patients with breast cancer, qualified hospitals receive a bundled payment, which is higher than the regular payments. Hospitals also meeting targets for disease-free survival are qualify for a bonus of up to 8 percent of the bundled payment [44]. In ERGOV, clinics are judged based on their performance relative to the mean. In addition, only three clinics in each of the five clinics that best achieve their own target receive a bonus proportional to the degree of target attainment. Five programs use three or more targets or a sliding scale [55]. FM PBC typically uses five targets per measure with a large difference between levels. A similar approach is used in ROSP, which may well have contributed to the finding that improvements in incentivized measures were typically largest among GPs with medium or low baseline performance [72]. QOF and P&FM-P4P use a sliding scale. Providers in QOF earn

Tab. II. Who are encouraged or punished in the performance-based payment program of selected countries?

Program name	Characteristics of providers	Individual or group?	Type of participation
QOF	• 8,600 primary care practices (almost 100%) • On average 5,500 patients, 3.6 physicians • Gatekeeping and patient enrolment are mandatory	Mostly group, but individual activity is also possible (6% of total in 2008)	Voluntarily
AQ	• All 24 hospitals in the Northwest region of England that provide emergency care • Hospitals can be public or private	• Group • Payments allocated to clinical teams to invest in patient care	Voluntary
NHI-P4P	• Diabetes: Hospitals. (Physicians' participation: 47 percent) • Asthma: pediatricians, internists and general practitioners • Breast/cervical cancer: hospitals • Tuberculosis: hospitals (43% participated in 2006),	• Diabetes, breast/cervical cancer: in groups • Asthma: individual • Tuberculosis: both	Voluntary
IHA-PIP	All 1500 health care clinics	Medical groups	Voluntary
PIN	• Phase 1: typically 15 to 30 physicians (mostly general practitioners, but also specialized physicians and other practitioners) • Currently (phase 2): 14 primary care groups • Measures to participate: electronic medical record, ≥5 GPs, 6,600 patients, access for other general practitioners	• Group, but payment often divided over participating physicians • Primary care groups receive funding from member clinics • Free budget allocation by clinics	Voluntary
ERGOV	• 13 rehabilitation clinics (pilot). • Project with the financial support of clinics • Clinics assess patients at admission and at discharge	• Group	Voluntary
FM PBC	Family doctor units	• Family doctor team	Voluntary
ROSP	72 general practitioners (1.7% of all doctors)	• Individual • Group • Organizational	Voluntary
P&FM-P4P	General and specialist doctors, medical fellowships, dentists, faculty members and assistants included in this directive in the hospital and special clinic affiliated to the university/faculties of medical sciences and health services of the Ministry of Health, Treatment and Medical Education	• Individual • Group	Not voluntary

more bonus for a larger percentage improvement from baseline to the goal. In QOF, each measure has upper and lower targets delineating the scale. Performance improvement were most pronounced for GPs with low scores at baseline, which could have been a result of the sliding scale on which practices are scored [73]. In P&FM-P4P, each performance measure has low and high targets that define the scale [74].

. Providers receive additional revenue for increasing a higher percentage of baseline to service delivery goals. In NHI-P4P provides piece rates for process quality. For example, for breast cancer, hospitals are rewarded for each patient completing recommended cure. This may well have contributed to observed improvements in process quality and the result [45].

Although the performance goals in most programs are different, they follow one or more common goals, including "improving the quality of care", "increasing patient satisfaction" and "improving processes". For example, the main goal in P&FM-P4P, IHA-PIP, QOF and ERGOV programs is to improve the quality of service coverage and improve the individual and team performance of providers. In the NHI-P4P program, ROSP, PIN, improving preventive care is a major goal. Table III provides more details on "how to encourage and punish".

Discussion

The present study provides an international overview of P4P initiatives in health care. The nine identified programs have similar design in several respects. All encourage clinical quality and most of them only use positive incentives, actively involve providers in design, and based on performance, they pay monthly, quarterly or annually. However, there is also considerable heterogeneity regarding the breadth of measure sets, use of risk-mitigating measures, number and type of targets and payment size. there seems to be ample room In most programs to increase incentives for desired behavior and to mitigate incentives for undesired behavior. In particular, shortcomings pertain to number and type of included performance measures, risk adjustment of outcomes and resource use, payment frequency, reliability of measurements, and number of targets.

Different P4P programs in the world consider different dimensions of performance and include different indicators in the program. Experts believe that the indicators of the P4P program should be valid and consider the areas of process and outcome together with each other [75].

Modification seems relevant mainly for ERGOV, FM PBC, and NHI-P4P, but also for other programs there is

Tab. III. How to encourage and punish in the performance-based payment program in selected countries?

Program name	Performance goals	Encouragement or punishment	Incentive size	Basic payments	Payment calculation	Payment frequency
QOF	For each measure: sliding scale within absolute targets (typically 45% and 90%)	Just encouragement	Up to 30% of practice income	Risk-adjusted capitation	• Scores converted into points and then summed (up to 1000 points) • Fixed amount per point (£120), fixed no. Points per measurement	Annually
AQ	• 1st year, clinical: relative, +4% or +2% for reaching top or 2nd quartile of achievement • 2nd year, clinical: relative; attainment (1 target), most improved (1 target), top performance (2 targets)	• Encouragement • Penalty for inaccurate/ incomplete data	• Clinical: 3-5% additional to the tariff (bonuses totaling £3.3M in the first year and £1.7M in the second year) • Outcomes and patient reported experiences: both £1M/year • Max. between £260K-702K/year depending on the size of the hospital	National tariffs for clinical conditions	Hospitals ranked on composite score per clinical area, measures are equally weighted	Annually, often with a delay of 2 or 3 months
NHI-P4P	• Positive scores on structures • For Asthma, DM, BC, TB: enlarged fees for processes • Cervical cancer: number of and monthly growth in Pap smears • Diabetes: relative target for outcome measures • Breast cancer: absolute target for disease-free survival • Tuberculosis: cure rates	•Just encouragement • Financing not from global budgets	• Asthma: NT$1,3K/ patient/year • Cervical cancer: 15-50% add-on to current fees • Diabetes: NT$1,9K/ patient/ year for process measures • Breast cancer: 2, 3, 4, 6 and 8% add-on to bundled payment for 1, 2, 3, 4, and 5 year disease-free survival; on average NT$127K • Tuberculosis: hospitals NT$13K/ case; physicians NT$1,6K/ case; case manager NT$6K (first 6 months $3K, then $550/month)	• Fee-for-service under global budgets. 52 procedures reimbursed through fixed case payments	• Diabetes: outcomes: top 25% on composite • Breast cancer: stage-specific targets for survival, descending targets and ascending payment over the five survival-years • Cervical cancer: 15-50% add-on to current fees based on size of improvement •Tuberculosis: payment varies by 5 treatment stages and is larger if cured earlier	Monthly to annually
IHA-PIP	Medical organizations must operate above 50% of the three main areas of IHA indicators: clinical quality, patient experience and total cost of care	Just encouragement	Depends a lot on size of care / number of patients seen	Each insurance has its own budget and determines the method of calculating bonus amounts to its medical groups	The scores of each medical group in achieving and improving the index are added together, and then the total is multiplied by the corresponding weight.	Annually
PIN	• Phase 1: typically 4 absolute targets/ measure, large range (*e.g.*, 40, 60, 80, and 90%) • Phase 1: only 2 areas of performance measures	Just encouragement	Phase 1: data management: C$5K/ clinic, max. C$5K/ GP, C$360K in total. Group: C$40K/ clinic, max. C$5K/GP, C$370K in total	Fee-for-service	Phase 1: increasing payment per measure if higher goal is reached (*e.g.*, 50, 65, 80, 95, 100% of maximal payment per measure)	After the demonstration period (last quarter of 2008 for phase 1)

▶

room for improvement, notably regarding measure sets, payment size and risk-mitigating methods [76, 77]. For some aspects design seems sufficient in most programs. These include provider involvement in design (seven programs), voluntary participation (eight programs), and type of targets (absolute targets or piece-rates in eight programs). QOF and AQ seem to have been designed particularly well. The effectiveness of QOF has been evaluated in several studies [40, 78]. The most comprehensive program is QOF, which includes more

Tab. III (*follows*). How to encourage and punish in the performance-based payment program in selected countries?

Program name	Performance goals	Encouragement or punishment	Incentive size	Basic payments	Payment calculation	Payment frequency
ERGOV	Quality tournament in which rewards and maluses are determined by relative differences (deviation from mean)	• Both encouragement and punishment • Until now, payments have been virtual	• Depends on how clinic performs relative to other clinics and on size of coefficient (can be adjusted so that clinics do not go bankrupt) • Neutral funding: maluses for low-performers used to finance bonuses for high-performers	Typically a daily or flat payment per patient	• 100 points for each patient • Value at discharge subtracted from predicted value, calculated using admission scores from all patients. The remaining amount per clinic averaged and multiplied by no. of patients to calculate bonus	Quarterly
FM PBC	The contract framework includes two performance levers: • Salary deduction • Warning points	Often punishment	The service credit is calculated in the table that can be adapted to the income of the people and can be considered more than 40% of the basic per capita payment in deprived areas	Per capita	• Losing 20% of the basic payment if you get 50 negative marks (deduction from salary) • Contract termination if 100 or more warning points are obtained during a contract period (warning points)	Monthly and quarterly
ROSP	Preventive care: 3-5 absolute goals per evaluation • Use of services: absolute purpose	Just encouragement	• "A small percentage of the income of general practitioners" • Prevention (registered patients): 6.86 € • Use of services: 18-20 € depending on the rurality of the area	Fee for service	Preventive care: fixed payment per patient, fixed additional payment for achievement of each criterion • Utilization of services: If the provision of services reaches the required number of patients, the payment is fixed	Yearly
P&FM-P4P	• Increasing the quality of treatment • Increasing patients' satisfaction with doctor's performance • Increase assistant performance score	Both encouragement and punishment	• Up to 30% of the income of the professional component	Fee for service	• The treatment quality score is a score between 0 and 100, which is measured individually at least once every 3 months • The level of patients' satisfaction with the doctor's performance is measured based on the standard patient satisfaction measurement form	It is calculated monthly and quarterly

than 131 measures in about 30 areas. Despite this, there is mixed evidence of teaching to the test in the QOF. One study showed neither deterioration nor improvement in unrewarded conditions [79].

Despite the NHI-P4P design seems to be lacking in several respects, several studies have found positive effects of this program [73, 80]. This may seem surprising, but the shortcomings in the design of mainly to aspects that mitigate undesired behavior, including a relatively narrow definition of performance (concern about teaching to the test), limited provider involvement in design (provider support unlikely) and lack of risk adjustment for outcomes (incentives for selection). Unlike most of the programs reviewed in this study, the P&FM-P4P program focuses on all medical groups that contract with insurance organizations. Like most programs, it also focuses on quality aspects of patient care.

Although the data provide limited information on the use of risk-mitigating measures, the results raise doubts about whether differences in (patient) risk are sufficiently equalized, especially in NHI-P4P, FM PBC, ROSP. In view of the relatively large payments in FM PBC and uncertain financial consequences in ERGOV, concerns about teaching to the test are particularly large in these programs. In ERGOV, rewards for high performers are financed by abuse for low performers. Although this contributes to financial sustainability, it may increase the

incentives for gaming theory [54]. To avoid this, clinics are required to supply data via an online tool that enables checks and auditing.

The negative incentives should be taken seriously given evidence that providers do indeed respond to incentives [81]. Many current P4P-programs have shortcomings with respect to design elements that relate to the prevention of undesired behavior (specifically risk selection and teaching to the test), and there is a great diversity in the use of risk-mitigating measures. This shows that buyers though clearly concerned about them, are unsure about how to effectively prevent undesired effects. Therefore because such effects can potentially undermine the entire program, more insight is needed to prevent them. For example, research should continue to focus on developing sufficient risk adjustment than can be applied transparently in practice and on the drawbacks and merits of potentially viable alternatives or supplements such as exception reporting. Second, if P4P is to help to improving patient outcomes, payment allocation must be based on timely, accurate, and reliable performance data. Many shortcomings in the design of current programs, including small measure sets, low payment frequency, lack of risk adjustment, and limited use of outcomes, can be traced back to a lack of data. Efforts should be focused on developing methods for recording, extracting, and processing patient-level data, and the merits of information technology for these purposes should be explored further. MacDonald and Rowland In their study (2009), found that "requiring data entry into the patient's electronic medical record" was intended to reduce eye contact and increase time spent collecting data [82].

Third, breakthrough improvements require alignment of incentives and coordination across disciplines for all providers in the continuum of care. Current programs focus too much on a type of provider (physician groups in primary care) and specific sector. For example, ROSP and PIN specifically target physicians, and payments are mostly made annually [61]. In FM PBC, even though the bonus amount is given to doctors and nurses, the main focus is on the GP program, also the remuneration is paid directly to the family doctors, and then the family doctor decides to divide the amount among other service providers [58]. Consistent incentives require strategies to facilitate inclusion of small practices (*e.g.,* developing methods for collecting performance data) as well as incorporating incentives that encourage coordination. Forms of prospective payment like bundled case rates and customized IT will prove vital in attaining these goals. If structured around patients rather than providers, prospective payment with performance-based elements can both reward providers for effectively coordinating care and reduce the problem of overuse of low-value services [83].

Fourth, it is very important that programs are evaluated using convincing control groups. Of the identified programs, only five have been evaluated, and often only partially. Therefore, studies should not only assess effectiveness but also include assessments of adverse effects and the impact of specific design elements. This not only provides insight in which areas need modification, but also important lessons about program design.

There are two dominant strategies for calculating indicators and paying bonuses among the studied programs, which are "achieving a certain amount of the measures" and "increasing the measures". In the NHI-P4P, ERGOV, FM PBC, ROSP programs, a minimum standard is considered for each measures, and in the payment formula, the individual's performance score is calculated based on the individual's achievement of the standards. On the other hand, in QOF, AQ, IHA-P4P, PIN, P&FM-P4P programs, if the person's performance is more than the target amount, it will be added to his overall score. Applying both types of incentive payment strategies to providers has the potential to improve the performance of service providers with both below-standard and above-standard performance. A study by Ejkanar et al. showed that rewarding providers based on their achievement of predetermined goals may reward high performers, while the greatest improvement was seen in the lowest performing physicians. This means that physicians who had the poorest performance at the beginning of the program achieved the greatest improvement in performance compared to physicians whose performance was above the target level at the beginning of the program [84]. Some critics have also argued that the use of a certain limit of the index cannot motivate providers whose performance is higher than the target level at the beginning of the program. On the other hand, other providers who previously performed poorly have less motivation to improve their performance. Because according to them, the goals are very difficult to achieve [85].

Conclusions

P4P is now widely being used in many healthcare systems and there are no signs that this will change in the near future. However, current evidence suggests that designing an effective P4P-program is a very complex task. Given the limited knowledge about "what works" in P4P, it may not be too surprising that current program design seems to be lacking in several respects and that buyers struggle with developing effective programs. To get the most out of P4P, well-conducted assessments are critical for generating the information needed for fine-tuning P4P to the specific implementation settings. In particular, empirical research is needed to examine the impact of specific design choices in specific settings, as well as insight in the perverse incentives of P4P and how these can be prevented. In parallel, if P4P is to help improve patient outcomes, efforts should be focused on creating easy-to-use and reliable methods for generating comprehensive patient-level (performance) data.

Ethical Approval

This study was approved by the Ethics Committee of Iran University of Medical Sciences (code: IR.IUMS.REC.1399.407).

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Conflict of Interests statement

There are no conflicts of interest.

Authors' contributions

Study concept and design: AA and MEE and HP. Analysis of data: HP and MEE. Drafting of the manuscript: MEE and HP. Performed a search of the literature: HP, MEE, MM**.** Critical revision of the manuscript: MB and HAG and JA. Editing: MB, MM. All authors have read and approved the latest version of the paper for publication.

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HEALTH CARE MANAGEMENT

Designing a performance-based payment model for physicians at outpatient clinics contracted with Iran health insurance: a case study from Iran

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Keywords

Performance-Based Payment • Physician Performance • Health Insurance Organization • Pay-for-Performance (P4P) • Health Policy

Summary

Background. *Providing quality healthcare services relies on capable physicians with high performance levels. A performance-based payment system can enhance physician productivity, clinical service quality, and patient satisfaction. This study aimed to design a performance-based payment model for physicians in outpatient clinics contracted with the Iran Health Insurance Organization, tailored to its specific context and structure.*
Methods. *The study employed a mixed-methods approach, combining quantitative and qualitative data collection and analysis. Through a literature review and expert interviews, 47 performance indicators and 18 selection criteria were identified. These indicators were reviewed in expert panels, and 49 questionnaires were used to prioritize them based on health insurance structures. The final indicators were categorized into current, transitional, and desired statuses, aligned with organizational infrastructures.*
Results. *The study identified 24 key indicators, including 9 for general physicians and 13 for specialized physicians. These indicators covered aspects such as the average number of prescribed medications, electronic prescription usage, per capita diagnostic procedures, timely physician presence, patient complaints, work history, guideline adherence, electronic record completion, patient satisfaction, training participation, and test prescription rates. Each indicator was detailed with a title, formula, standard, data collection method, and source.*
Conclusions. *The proposed performance-based payment model, utilizing the selected indicators, can guide physicians toward achieving organizational goals such as cost reduction, process efficiency, and improved patient satisfaction. By clarifying expe tations and assessing various performance dimensions, the model provides a framework for enhancing physician performance and aligning it with the objectives of the Health Insurance Organization. Policymakers can use this model to drive systemic improvements in healthcare delivery.*

Introduction

Justice is an important principle in healthcare in any country. In a fair health system, financial equity must exist [1]. Investment and optimal allocation of resources lead to development, poverty reduction, and achieving the goal of a healthy population in the country [2]. The payment system is one of the responsibilities of human resource management, which oversees all human resource payments in any organization [3]. An unfair and inefficient payment system leads to increased dissatisfaction among employees, resulting in a negative impact on patient care and a decrease in the quality of services provided to patients. In fact, the performance-based payment system relates to financial and non-financial rewards that are fairly paid to human resources in exchange for their work in the organization [4, 5].

From the perspective of managers and employees, rewarding based on performance outcomes is an important aspect of wage management and one of the key strategies for retaining and nurturing talent, which has become common in performance management [6, 7]. In pay-for-performance (P4P), financial incentives focus on two main objectives: first, creating economic motivation to change provider behavior by encouraging high-quality, evidence-based performance. Second, eliminating the negative effects of existing reimbursement systems that consider the volume of services rather than their value [8, 9].

Traditional payments, such as fee-for-service (FFS), lead to induced demand and overuse of services. In contrast, managed care, such as capitation payment systems, results in underutilization of healthcare services [5]. Studies show that the number of performance-based payment programs in healthcare systems worldwide is increasing (from 37 in 2003 to 174 in 2007) [10]. In the United States, the United Kingdom, Australia, and Canada, P4P is used as a basis for medical payments [11-14].

However, P4P is not without flaws and negative consequences. In some cases, its implementation has led to a reduction in the quality of certain services and the creation of inequality [2]. Major disadvantages of

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this system include inequity in the health sector, some adverse health outcomes, and the potential increase in healthcare costs [15]. Given the necessity and importance of improving the quality, effectiveness, and efficiency of services provided by physicians through the P4P system, designing a practical model for performance-based payment is essential [16, 17]. Therefore, this article aims to examine the current payment situation in Iran and provide a performance-based payment model for physicians in outpatient clinics contracted with the Iranian Health Insurance Organization.

Methods

This research is developmental-applied in terms of its objective and a qualitative and documentary study in terms of methodology. The documentary method is considered one of the unobtrusive and non-reactive measures. In the documentary method, documents are regarded as a social reality. These documents can include statistical data or descriptions of the formal operations of an activity. The difference between the documentary method and "facts recording" is that this collection is conducted based on a theoretical framework. In the documentary method, the unit of analysis can include reports and organizational notes, censuses, official rulings, and so on.

To examine various performance-based payment models in different countries, a review study was conducted. In this search, the review methods and eligibility criteria were predetermined. A checklist was used to prepare the review report. Observational studies, before-and-after studies, time series studies, experimental studies, randomized trials, interpretations, and editorials were excluded from the review. Final keywords were identified and selected through mesh and pilot searches. The search for articles was based on keywords such as "performance-based payment", "quality-based payment", "outcome-based payment", "value-based payment", "performance evaluation indicators" and "quality assessment indicators", These keywords were searched in databases like Scopus and PubMed, Google Scholar, the Google search engine, as well as on websites of the World Bank, the Ministry of Health, OECD, and WHO. The inclusion criteria for the study included all articles and documents published between 2000 and 2023 related to performance-based payment in selected countries. The criteria for countries' inclusion in the study included the type of health insurance system, the extent of performance-based payment system utilization, and the economic development status of the countries.

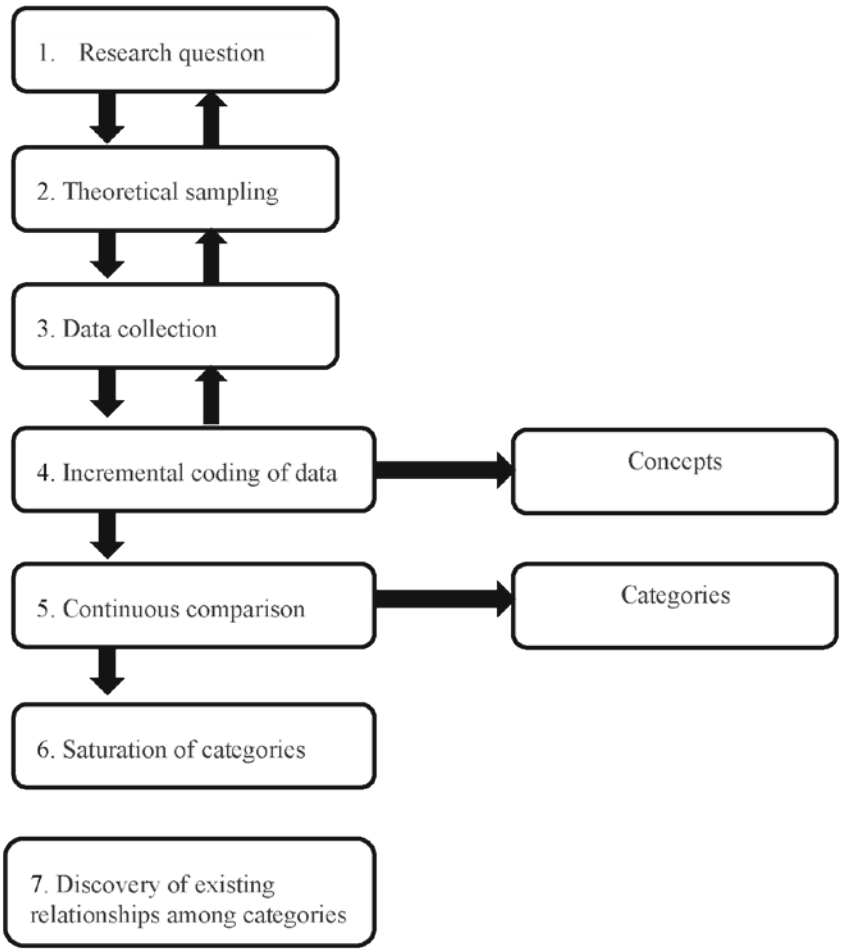
Related articles were screened in two ways: in the first stage, titles and abstracts were independently reviewed by two experts based on the eligibility criteria for the review. In the second stage, the full texts of the articles were screened independently by two experts to identify qualifying articles. Ultimately, data such as study type, context, dimensions and performance criteria, P4P results, and payment strategies were extracted and entered into the data checklist. The statistical population of this research included all managers, policymakers, physicians, and specialists in the field of performance-based payment with at least three years of relevant work experience related to the study's objective. The sample size was determined based on theoretical saturation of the data [18]. In this study, interviews continued until repetitive relationships among components or repetitive elements were established, ultimately achieving theoretical saturation with a sample size of 18 individuals. The sampling method in this research was purposive and incremental, meaning that the researcher gradually performed the coding process from the very first interview after purposefully selecting the samples [19]. The data collection tool was a semi-structured interview with three main specific questions: 1. In your opinion, what indicators should be considered for performance-based payment to physicians in outpatient clinics contracted with health insurance? Which indicators are more important in our country? 2. What criteria should be considered in the final selection of key performance-based payment indicators for physicians? 3. How is the data related to the indicators collected? The implementation method and the stages of information collection were based on several main steps, as shown in Figure 1.

To ensure the validity and reliability of the research, the Lincoln and Guba evaluation method was used [20]. Based on this method, four criteria were considered for assessment: reliability, credibility, transferability, and verification.

The actions taken in the present research to ensure reliability or validity include: 1. Allocating sufficient time for each interview (an average of 45 minutes was dedicated to each interview in this study); 2. Utilizing several experts to validate the research process (the full text of the interviews along with initial coding and categorization was sent to two research method professors and statistical experts, and the full text of two interviews with coding was sent to two specialists in this field. Additionally, throughout all stages of the work, the supplementary opinions of the professors were used for implementation, coding, and extracting initial categories); 3. Employing two expert coders in the field of interviewing to ensure relative consistency of the coders' opinions (the Kappa coefficient obtained for the two codings in this research was 0.0019 = Kappa, 0.771 = Sig, and a suitable agreement coefficient between the two codings was confirmed based on being within the range of 0.6-0.8); 4. Using clear and objective questions (for this purpose, the interview text and extracted codes were presented to the interviewees shortly after, and they expressed their opinions on the accuracy and validity, with discrepancies corrected if necessary).

To facilitate transferability, a clear description of the context, selection method, and characteristics of the participants, as well as the data collection and analysis process, was initially provided so that the audience could apply the findings in other situations. Additionally, by providing detailed findings, efforts were made to

Fig. 1. Qualitative Analysis of Interviews (from Pope C, Ziebland S, Mays N. Qualitative research in health care. Analysing qualitative data. BMJ 2000;320:114-6. https://doi.org/10.1136/bmj.320.7227.114).



increase transferability [21]. For verifiability, a complete description of the research stages, including data collection, analysis, and theme formation, was provided so that the audience could audit the research. The process of conducting the work was also shared with several technical colleagues for verifying the accuracy of the research method.

In this study, three methods were used for reliability: 1. Structured processes (convergent interviewing); 2. Organizing structured processes (systematic recording, writing, and interpreting data); 3. Using a guiding committee to evaluate and conduct interviews (in this research, the opinions of two experts in performance-based payment and qualitative methodology, as well as a statistician in the humanities, were utilized). Nvivo12, a qualitative data analysis software, was used to determine codes and main themes and to provide graphical models. It is worth mentioning that in this research, maintaining the identity and organizational information and ensuring confidentiality in executing the interview content were considered ethical considerations based on the research protocol, along with obtaining informed written consent.

Results

The aim of this study was to identify performance-based payment indicators for physicians, select individuals, and ultimately design a performance-based payment model for doctors. To this end, we first examined various payment models in selected countries and extracted relevant indicators. Then, to complete the indicator forms and identify suitable indicators for Iran, interviews were conducted with experts in this field. After finalizing the indicators, the profile of each indicator was established using a panel of experts. The findings showed that men (77%) participated in the study nearly three times more than women (23%). More than half of the interviewees (experts) were in the age range of 40 to 50 years. Over half of them were in academic management and had more than 10 years of work experience. 83% of the expert group held a doctoral degree or higher and were working in managerial positions, and most had undergone training on performance-based payment systems. The descriptive characteristics of the experts who were interviewed are also presented in Table I. Interviewees were selected from groups of hospital managers, university professors, policymakers, and

Tab. I. Demographic Characteristics of Informed Interviewees.

Research Community Characteristics		Frequency	Percentage
Gender	Male	14	77
	Female	4	23
Education level	Master's Degree	3	17
	Doctorate	3	17
	General Physician	4	22
	Specialist and Sub-specialist	8	44
Job Position	Physician	4	22
	Faculty Member	7	39
	Hospital Director	2	11
	Head of the National Health Insurance Research Center of Iran	1	5
	Deputy of the General Directorate of Treatment of the Imam Khomeini Relief Committee	1	5
	Deputy of the Planning and Policy Office of the Health Insurance Organization	1	5
	Head of Tariff Group, Supreme Council of Insurance Secretariat	1	5
	University Budget Manager	1	5
Work Experience	Under 5 years	1	5
	5-10 years	8	44
	11-15 years	5	28
	Over 16 years	4	22
Organization	Hospital	9	50
	University of Medical Sciences	5	28
	Health Insurance Organization of Iran	1	5
	Imam Khomeini Relief Committee	1	5
	Health Insurance Research Center	1	5
	National Institute for Health Research	1	5

physicians. In total, interviews were conducted with 18 individuals.

Based on a review study of performance-based payment programs in selected countries, as well as the conducted interviews, 47 indicators were extracted as initial payment indicators. Then, in the expert panel, the final indicators were selected using pairwise comparison, and less important indicators and those unsuitable for the current health system in Iran were eliminated. Ultimately, 24 indicators were chosen as the main and influential indicators for the performance-based payment program for physicians. The initial indicators extracted from the articles and interviews are presented in Table II.

Determining Final Indicators and Criteria for Prioritization

After identifying the initial indicators from studies and interviews, a final review, refinement, and specification of the indicators and criteria for prioritization were discussed in the expert panel using a decision-making matrix. In this session, the indicators and criteria derived from previous stages were presented case by case by the researchers, and the opinions of the panel members were collected. By examining the criteria extracted from the literature review and interviews in the expert panel, the criteria were aligned with the CREAM, RAVES, and SMART frameworks. CREAM stands for Clear, Relevant, Economical, Adequate, and Monitorable criteria; RAVES stands for Reliable, Appropriate, Valid, Easy, Accessible, and Sensitive criteria; and SMART stands for Specific, Measurable, Achievable, Relevant, and Time-bound criteria. Ultimately, four criteria were selected with the approval of the panel members, which were relevance, measurability, clarity, and high importance, urgency, and sensitivity (Tab. III). Additionally, it was determined in this session that indicators achieving at least 75% of the total score would be selected as the final performance-based payment indicators for general and specialized physicians.

Finally, after the conducted reviews, the indicators were examined in terms of their relevance to the subject and consideration of local conditions, resulting in 24 indicators entering the next stage for prioritization. After determining the final indicators and criteria for performance-based payment for physicians in the expert panel, a questionnaire was distributed between two separate groups for prioritizing performance-based payment indicators for general practitioners and specialists in outpatient clinics. The questionnaire was sent to 30 individuals from each group, including policymakers, informed individuals, and experts in health insurance, general practitioners, specialists, and professors from medical universities, resulting in a total of 48 completed questionnaires.

The questionnaire contained 24 indicators in rows and 4 criteria in columns, where the score for each indicator was determined based on the specified criteria in this

Tab. II. Indicators Extracted from Articles and Interviews.

Indicators from Interviews	Indicators from Articles	Common Indicators
Number of prescribed medications	Management of chronic diseases and continuity of care	Patient satisfaction
Number of patient referrals to paraclinics	Households covered without tobacco use	Work history
Type of patients based on age	Counseling for smoking and alcohol cessation (lifestyle)	Timely determination of patient status
Location of the clinic or consideration of deprived areas	Optimization of interventions in terms of cost and efficiency	Alignment of diagnostic and therapeutic methods used by the physician with guidelines
Amount of education provided to the patient	Provision of comprehensive care	Number of services provided
Enhancement of the physician's educational level	Quality of on-call service and responsiveness	Duration of consultation and visit
Credentialing of physicians or their ranking	Patient safety	Clinical outcomes
Costs incurred by the patient based on medications	Ability to utilize electronic facilities	Time to access the physician and timely presence
Number of return visits to the physician with the same complaint (pain)	Completion rate of electronic medical records	Promotion of preventive care and primary care
Rate of complaints resolved	Holding professional certifications	Participation in care networks and teamwork
Adherence to professional ethics	Type of services provided	Collaboration in accreditation and quality improvement
Number of complex cases treated		
Facilities and equipment of the clinic		
Monitoring of physician performance		

Tab. III. Description of the Criteria for Selecting Performance-Based Payment Indicators for Physicians.

Row	Criterion Title	Criterion Description
1	Relevance	• The degree of relevance of the indicator to the quality and efficiency of the services provided • The degree of relevance of the indicator to the goals of the Health Insurance Organization
2	Measurability	• The degree of complete and accurate availability of data for the indicator at a reasonable cost (availability of indicator data) • The degree of relative ease in collecting data and measuring the indicator • The degree of ease in analyzing the data of the indicator • Achievable/implementable
3	Clarity, transparency, and comprehensibility	• Being understandable, clear, and evident • Clarity
4	Importance, urgency, and high sensitivity	• Immediate attention is needed from managers and policymakers. • Has a high impact on achieving the goals of the Health Insurance Organization

questionnaire, ranging from 1 to 5. The number 5 indicated the highest alignment of the indicator with the desired criterion, while the number 1 indicated the lowest alignment. To calculate the score given to each indicator, based on the expert panel's opinion, the criterion of relevance was assigned a weight of 1.5, and the other three criteria were assigned a weight of 1. From the total scores given, the score for each indicator was calculated. In Table IV, the prioritized indicators for performance-based payment to general practitioners are presented in order of importance, priority, and based on the average final score.

As previously stated, according to the agreement in the expert panel, indicators that have achieved at least 75% of the total score are selected as final indicators for performance-based payment to general practitioners. Given that the maximum average final score achievable for each indicator is 22.5 points, for performance-based payment to contracted specialist physicians of the health insurance, each selected indicator must achieve a minimum of 16.87 points. Therefore, the 9 specified indicators in Table IV were selected.

According to the agreement in the Expert Panel, the indicators that have earned at least 70% of the total score have been selected as the final performance-based payment indicators for specialized physicians. Considering that the maximum average final score achievable for each indicator is 22.5 points, for performance-based payment to specialized physicians contracted with the Health Insurance, each selected indicator must achieve at least 15.75 points. Therefore, the 13 indicators specified in Table V were selected.

Determining the stage of implementing the indicators

To implement the performance-based payment plan for general and specialized physicians contracted with Health Insurance, the readiness of the necessary

Tab. IV. Final indicators for performance-based payment to general practitioners based on priority.

Row	Indicator	Average final score	Index Selected	Row	Indicator	Average final score	Index Selected
1	Timeliness of the physician's presence at the service location	18.98	✓	13	Ability to utilize electronic facilities	16.79	_
2	Complaints (received) against the physician	18.74	✓	14	Complicated cases treated (*e.g.*, special patients) by the physician	16.73	_
3	Adherence to guidelines in physician decision-making (percentage of unnecessary services)	18.44	✓	15	Quality of services	16.69	_
4	Completion of electronic medical records for the patient	18.14	✓	16	Location of the clinic or consideration of underprivileged areas	16.63	_
5	Patient satisfaction	18.06	✓	17	Percentage of prescribed procedures and medications unrelated to specialty	16.2	_
6	Participation in courses provided by insurance organizations	17.92	✓	18	Average prescription cost per physician	16.08	_
7	Electronic prescriptions recorded and sent on time	17.71	✓	19	Per capita number of procedures	15.82	_
8	Average number of prescribed medications within a specified time frame	17.14	✓	20	Amount of education provided to the patient	15.8	_
9	Physician's work history	17.14	✓	21	Providing systematic explanations in referring patients to other specialties	15.36	_
10	Time allocated for visits	16.86	_	22	Percentage of generic medications to total prescribed medications	14.23	_
11	Average number of tests prescribed within a specified time frame	16.81	_	23	Type of patients visited based on age	14	_
12	Per capita number of services provided by the physician	16.81	_	24	Degree of use of previous diagnoses and opinions from other physicians	11.89	_

infrastructure and facilities is essential. Currently, data and facilities for data collection and implementation of some indicators are available, and for others, they can be provided in the future. For this purpose, in the questionnaire sent to specialists, they were asked to categorize each of the indicators into one of the three stages: current conditions, transitional conditions, and desirable conditions, based on the readiness status of the Health Insurance Organization and the existing infrastructure in the country. The three stages are described in Table VI.

At this stage, based on the determination of the final indicators, the operational model that includes the identification of the indicators was developed using the information obtained from previous stages. The indicator identification includes details such as the title of the indicator, stage of implementation (desirable, feasible, and transitional conditions), standard of the indicator, method of measurement, type, and source of data. To identify the sections of this identification, reports, literature reviews, and interviews conducted with key experts were used. Table VII shows the identification of performance-based payment indicators for general physicians. Table VIII presents the developed indicators for performance-based payment for specialized physicians contracted with Iran's Health Insurance.

Discussion

The implementation of P4P programs in healthcare service delivery has yielded desirable results in most conditions, especially in cost management, preventive care, and increasing the efficiency and quality of services. The adoption of other interventions such as coaching, training, reminders, etc., in line with P4P has recently been welcomed by payers and healthcare providers, and in most cases, it has led to positive outcomes. P4P has been implemented in various ways through different designs, but the results of P4P vary with each design. Therefore, it is not easy to conclude which P4P design is appropriate. P4P has shown encouraging results in most implemented programs.

Various P4P studies worldwide have considered different

Tab. V. Indicators and criteria for performance-based payment to specialist physicians based on priority.

Row	Indicator	Average final score	Index Selected	Row	Indicator	Average final score	Index Selected
1	Adherence to guidelines in physician decision-making (percentage of unnecessary services)	17.86	✓	13	Average number of prescribed medication items	15.92	✓
2	Electronic prescriptions recorded and sent on time	17.74	✓	14	in a specific time period	15.73	_
3	Completion of electronic medical records for the patient	17.74	✓	15	Location of the clinic or consideration of underserved areas	15.59	_
4	Per capita number of prescribed diagnostic procedures (expensive) within a specified time frame	16.86	✓	16	Doctor's work experience	15.51	_
5	Complaints received against the physician	16.78	✓	17	Quality of services	15.48	_
6	Timeliness of physicians' presence at the service location	16.69	✓	18	Percentage of generic medications to total prescribed medications	15.41	_
7	Average number of tests prescribed within a specified time frame by the physician	16.67	✓	19	Percentage of procedures and unrelated medications prescribed	15.17	_
8	Time allocated for visits	16.57	✓	20	Participation in the courses scheduled by the Health Insurance Organization	15.09	_
9	Patient satisfaction	16.45	✓	21	Providing systematic explanations for referring patients to others	14.95	_
10	Per capita number of services provided by the physician	16.23	✓	22	Level of education and communication with patients	14.86	_
11	Complicated cases treated (*e.g.*, special patients) by the physician	16.18	✓	23	Ability to utilize electronic resources	12.98	_
12	Average prescription cost per physician	16.05	✓	24	Type of patients visited based on age	11.59	_

Tab. VI. Description of the three stages for implementing the selected indicators.

Row	Title of the stage	Description
1	Current conditions (Status quo)	Given the existing infrastructure, this indicator can be used in the implementation of the performance-based payment model
2	Transitional conditions (Transient)	The necessary infrastructure for utilizing this indicator in the implementation of the performance-based payment model is being established
3	Desirable conditions (Ideal)	The necessary infrastructure for utilizing this indicator in the implementation of the performance-based payment model is not available but needs to be created

dimensions and performance indicators. Mehrotra Ateev focused on indicators such as reviewing prescribed medications, patient satisfaction surveys, the use of information technology, preventive care, screening, and chronic disease management [22]. The three primary indicators mentioned in this study align with our selected indicators. In examining the performance-based payment scheme in New Zealand conducted by Linda Marie and her colleagues in 2016, service volume, waiting times, the number of acute and chronic patients, patient satisfaction, smoke-free households, and youth access to healthcare services were introduced as selected indicators [23]. Several of the selected indicators and criteria in this study align with our chosen indicators. One common issue in clinics and medical offices is the long waiting time for receiving services, primarily due to physicians not being present on time. Glickman et al., Sika, and Orthok identified waiting time as an impactful indicator for measuring physician performance in their studies [24-26]. In this study, this indicator is also named as the first and most important indicator for performance-based payment.

Habicht et al., identified the use of electronic medical systems as an effective indicator for performance-based payment in their studies [27]. The current study also emphasizes the completion of electronic medical

Tab. VII. Identification of performance-based payment indicators for general physicians in outpatient clinics contracted with Health Insurance.

Indicator title	Index formula	Implementation stage	Standard	Data collection source
Average number of prescribed medication items within a specified time frame	Numerator: Number of medication items prescribed in all prescriptions issued by the physician within a specified time frame Denominator: Total number of prescriptions issued by the physician within a specified time frame	Present	The recommended figure by the World Health Organization is a maximum of 1.8 medication items per prescription	Electronic prescriptions
Electronic prescriptions registered and sent on time	Numerator: Number of electronic prescriptions registered without errors and on time Denominator: Total number of prescriptions by the physician within a specified time frame	Transitive	Range to be determined by the organization (High - Medium - Low)	Creating a suitable dashboard
Per capita number of diagnostic procedures (expensive) prescribed within a specified time frame	Numerator: Number of expensive diagnostic procedures prescribed within a specified time frame Denominator: Total number of patients visited by a physician		Range to be determined by the organization	Electronic prescriptions
Timely presence of the physician at the service delivery location	Average monthly delay time of the physician in arriving at the service delivery location		Range to be determined by the organization	To extract this data from the attendance system (Timex).
Complaints (received) against the physician	Number of complaints registered against the physician within a specified time frame		Range to be determined by the organization	Number of complaints registered in the Medical Crimes Prosecutor's Office, the Organization for the Protection of Medical Professionals, the 1590 system, the 1690 system, and also the number of complaints registered by patients at the treatment center
Physician's work experience	Number of years active as a physician		Range to be determined by the organization	Insurance records
Adherence to guidelines in the physician's decision-making	Numerator: Number of treatment decisions based on guidelines made by the physician Denominator: Total number of treatment decisions made by the physician within a specified time frame	Desirable	Range to be determined by the organization	Creating a suitable dashboard
Completion of electronic medical records for patients	Numerator: Number of electronic records completed by the physician within a specified time frame Denominator: Total number of electronic records that the physician should complete within a specified time frame		Range to be determined by the organization	HIS
Patient satisfaction	Numerator: Number of patients visited with satisfactory consent within a specified time frame Denominator: Total number of patients visited within a specified time frame		Range to be determined by the organization	Questionnaire - System
Participation in training courses provided by insurance organizations	Numerator: Number of approved courses that the physician participated in within a specified time frame Denominator: Total number of approved courses specific to the physician within a specified time frame		Range to be determined by the organization	Continuing education system

Tab. VIII. Identification of performance-based payment indicators for specialist physicians in outpatient clinics contracted with health insurance.

Index Title	Index Formula	Application Stage	Standard	Data Collection Source
Average number of tests prescribed in a given period by a physician	Numerator: Number of tests prescribed by the doctor in a given time period Denominator: Total number of prescriptions by the doctor in a given time period	Present	Cut-off to be determined by the organization	Electronic copies
Complex cases treated (*e.g.*, specific patients) by a physician	Numerator: Number of complex cases treated by the doctor in a given time period Denominator: Total cases visited		Range to be determined by the organization	Electronic copies
Average number of pharmaceutical items prescribed in a given period	Numerator: Number of prescribed medications in all prescriptions issued by the physician in a specified time period Denominator: Total number of prescriptions issued by the physician in a specified time period		The recommended number by the World Health Organization is a maximum of 1/8 of a drug per prescription.	Electronic copies
Electronic prescriptions recorded and sent on time	Numerator: Number of electronic prescriptions recorded without errors and on time. Denominator: Total number of physician prescriptions in a specified time period	Transitive	Range to be determined by the organization	Creating a suitable dashboard
Per capita number of diagnostic procedures	Numerator: Number of expensive diagnostic procedures prescribed in a given time period Denominator: Total number of patients seen by a physician		Range to be determined by the organization	Electronic copies
(Expensive) prescribed in a given period	Average monthly delay time of a doctor in entering the service area		Cut-off to be determined by the organization	To extract this data from the attendance system (Timex)
Timely presence of physicians at the service location	Number of complaints registered against a doctor in a specific time period		Range to be determined by the organization	To extract this data, the attendance system (Timex) should be used
Complaints (received) from the physician	Numerator: Number of services provided by the physician in a specified time period Denominator: Number of visits performed by the physician in a specified time period		Range to be determined by the organization	The number of complaints registered with the Medical Crimes Prosecution Office, the Penal Organization, the Medical System Organization, the 1590 system, the 1690 system, as well as the number of complaints registered by employers and clients in the medical center
Per capita number of services provided by the physician	Numerator: Number of guideline-based treatment decisions made by the physician Denominator: Total number of treatment decisions made by the physician in a given time period	Desirable	Range to be determined by the organization	Electronic copies
Adherence to guidelines in medical decision-making	Numerator: Number of electronic records completed by the physician in a given time period Denominator: Total number of electronic records that the physician must complete in a given time period		Range to be determined by the organization	Creating a suitable dashboard
Completion of patient electronic medical records	Numerator: Number of patients visited with satisfactory satisfaction in a given time period. Denominator: Total number of patients visited in a given time period		Range to be determined by the organization	HIS
Average cost of prescriptions per physician	Deductible: The cost of services, drugs, and equipment issued in all prescriptions prescribed by a physician during a specified period of time Deductible: The total number of prescriptions prescribed by a physician during a specified period of time		Cut-off to be determined by the organization	Electronic copies

▶

Tab. VIII *(follows)*. Identification of performance-based payment indicators for specialist physicians in outpatient clinics contracted with health insurance

Index Title	Index Formula	Application Stage	Standard	Data Collection Source
Average cost of prescriptions per physician	Deductible: The cost of services, drugs, and equipment issued in all prescriptions prescribed by a physician during a specified period of time Deductible: The total number of prescriptions prescribed by a physician during a specified period of time.		Cut-off to be determined by the organization	Electronic copies
Time allocated for visits	Numerator: Total time spent by a doctor visiting patients in a given time period Denominator: Total number of patients visited by a doctor in a given time period.		Specialist: 20 minutes Subspecialist: 25 minutes Psychiatrist: 30 minutes	Questionnaire-System

records as one of the important indicators for payments to contracted physicians under health insurance. Patient satisfaction holds special importance from various aspects. Dissatisfied patients are less likely to follow physician instructions and use medications correctly. Eijankaar, Kraut, and Chalmers, as well as Dennis and Marie and their colleagues, have shown in their studies that patient satisfaction is one of the important indicators for performance-based payment [23, 28-30]. In the present study, this indicator is also listed among the most important indicators.

Work experience, which reflects a physician's experience, indicates the number of years a physician has gained expertise in their specialty. Pali and Jinor found that the clinical efficiency of experienced physicians improves. Mohtashami and Tayebi also used work experience as a practical and effective indicator for performance-based payments to employees in an industrial company in their study [31]. Another finding of this study was participation in training courses related to insurance organizations, aimed at enhancing and updating medical knowledge. A study by Ghaebi et al. aligns with this topic, showing that the evaluation indicator for training courses and curricula received the highest score among other evaluation indicators [32].

Logical prescribing of tests and medications means selecting appropriate tests and medications for the suitable patient. Failure to adhere to logical prescribing can lead to threats such as deviations in the diagnostic and treatment processes, compromising patient safety, increased healthcare costs, and higher morbidity and mortality rates. Therefore, this indicator can effectively control physician prescriptions and reduce unnecessary costs by impacting performance-based payments. According to the World Health Organization, rational drug prescribing means prescribing and using medications that are appropriate to the clinical needs of the patient [10]. A study conducted by Izadi et al. showed that as physicians' experience increases, the cost of prescribing tests and medications also rises [33]. This indicator was also among the important indicators identified by experts participating in this study for the performance-based payment scheme in Iran.

Patient complaints and dissatisfaction with treating physicians due to violations and diagnostic and therapeutic errors in healthcare services are common. Gravel, Peterson, and Habicht identified complaints against physicians as one of the important indicators in performance-based payment systems in their studies [27, 34, 35]. Additionally, Forstater noted that a lack of mutual understanding between patients and physicians is one of the main factors leading to complaints against doctors [36]. The results of these studies and the current study indicate that paying attention to the level of complaints against physicians and reducing these complaints can serve as an important indicator for performance-based payments to physicians in health insurance organizations. Physicians make medical care decisions on behalf of patients; therefore, they may unnecessarily increase patient demand. Physicians do not always fulfill their representative role correctly, and their recommendations can be influenced by personal interests. Behbahani et al. stated in their study that the most important way to reduce physician-induced demand is to fully implement a family physician-based referral system in the country [37]. The results of the current study also indicate the degree of adherence to guidelines in physicians' decision-making and the percentage of unnecessary services induced by physicians to patients as an important indicator for performance-based payment.

Conclusions

Providing financial incentives can be seen as a tool for enhancing motivation for efficiency. Performance-based payment is considered a specific type of strategic purchasing that is exclusively used to reward the achievement of predetermined goals. Policymakers in insurance organizations can utilize payment mechanisms for physicians to encourage desired behaviors aligned with their organizational objectives. Identifying and clarifying the indicators and criteria for payments to healthcare providers can assist stakeholders and responsible parties in implementing their desired programs through these indicators. The identified

indicators should be examined from various aspects and piloted. Introducing these indicators and explaining their importance to target groups regarding the quality of services provided, patient satisfaction, and most importantly, their compensation can play a significant role in the implementation of these indicators. However, it seems that the long-term execution of this program may also lead to unintended consequences. Previous studies have pointed to issues such as neglecting other important duties, reporting changes instead of actual activity changes, individuals becoming dependent on financial incentives, and a decline in intrinsic motivation. To prevent such operational barriers and potential issues related to favoritism, it appears essential to have continuous evaluation and timely feedback. This can be achieved by designing performance evaluation dashboards with defined indicators in hospital information systems and considering these indicators as criteria for assessing the quality of services provided, as well as the performance of physicians, routinely evaluated by hospital officials or external organizations, thereby mitigating such problems.

Ethical approval

This study was approved by the Ethics Committee of Iran University of Medical Sciences (code: IR.IUMS.REC.1399.407).

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Conflicts of interest statement

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Authors' contributions

Conceptual design of the study: HP and MEE. Data analysis: HP and HAG. Drafting the manuscript: MEE and HP and HAG. Performed a search of the literature: HP, MEE, and MM**.** Editing: MB, MM. Critical revision of the manuscript: JA, and MB. All authors have read and approved the latest version of the paper for publication.

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History of Medicine and Ethics

The summer colonies: 'custodians' of the health of the young. Prophylaxis of infectious diseases and educational purposes in the reports of the school medical inspector Benedetto Barni (1893-1970) in the 1950s

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Keywords

Benedetto Barni • Prophylaxis of Epidemic Diseaes • Preventive Medicine • Heliotherapy Colonies • Tuberculosis • Poliomyelitis

Summary

Starting from the 1950s, climatic-prophylactic colonies for children took on characteristics that were partly different from those of their predecessors. From their origins until the years immediately following the Second World War, these facilities had the stated aims of education, prevention and cure for poor and malnourished children. In the mid-20th century, however, a change took place; the colonies no longer catered exclusively for the less privileged and most fragile, but rather for an economically and culturally heterogeneous population, while still maintaining the purpose of health prevention and promotion in childhood and adolescence. The number of agencies involved in organizing the colonies increased, and large companies also participated. Similarly, the annual number of children who spent a period of time in the colonies grew steadily, owing to intense migration towards the cities, increased female employment and holiday closures of large factories during the month of August.

The authors recount this historical transition on the basis of the experience of the Sienese doctor Benedetto Barni (1893-1970) and the unpublished reports that he produced during his time as a school medical inspector. Against the backdrop of the teaching of the great hygienist and initiator of preventive medicine Achille Sclavo, who was Benedetto Barni's mentor, these reports testify to an everyday activity made up of real contacts with the people and with the territory; this enabled Barni to understand the social and healthcare problems facing the country and to try to work out a solution to them from the standpoint of preventative medicine.

Introduction

The summer, or "heliotherapy", colonies were residential institutions situated in locations other than those of their guests' usual residence, where minors were hosted during period of school closure. They were established for social, pedagogical and health reasons:

- *social* because in the initial stages they catered for children of the proletarian classes;
- *pedagogical* because they exploited the stay in another location for educational purposes;
- *health* as they focused particularly on aspects of preventive medicine.

Here, the authors mainly deal with the healthcare aspect, while acknowledging that these different areas are often interconnected.

With the industrial revolution, a new system of production developed in the 19th century, giving rise to the appearance of the proletariat: people who migrated to the cities to work in factories, and who generally lived in the poorest and most insalubrious neighbourhoods. These industrial workers lived in conditions of extreme instability and poverty. Even children were employed in factories for 12 to 14 hours a day in unhealthy and dangerous environments.

Children of the urban lower classes were "deprived of childhood"; they grew up in a world populated by adults who did not recognize that they should have their own space and specific rights.

In the years preceding and following the unification of Italy, the country's health and hygiene situation was extremely precarious and difficult, and it was the children who suffered most. Indeed, scrofula and rickets were rife, affecting the youngest in a population mostly affected by infectious diseases of which the etiology and modalities of contagion are still unknown.

In this scenario, the approach that medicine adopted towards society was changing, in that strategies of social and preventive intervention were implemented in such a way as to reach individual citizens. By the end of the

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century, hygiene had become a highly topical issue, in both medical and political circles, and international conferences on medicine, hygiene and pedagogy were frequently held [1].
One of the main themes on which the attention of the medical class and the government of the time focused was the danger of the spread of infectious diseases, a hazard that was markedly exacerbated by the new structure of the cities, which were overcrowded and insalubrious and lacked water mains and sewers.

The scourge of tuberculosis

Particular concern was aroused by tuberculosis, a very widespread and much feared disease [2-4]. And it was precisely to protect children of the poorest classes from this slow disease – especially in its extrapulmonary form, so-called scrofula (tuberculous lymphadenitis), characterized by enlargement of the neck lymph glands, which tended to suppurate – that seaside hospices were created; these healthcare initiatives were halfway between a hospital model and a holiday camp [5].
One of the first promoters of the idea of a seaside hospice that would not have the character of a hospital was Giuseppe Barellai [6], a doctor at Santa Maria Novella Hospital in Florence and a scholar of forms of tuberculosis prophylaxis. In 1853, he proposed the creation of free facilities for the care of children suffering from scrofula [7], an initiative that gave rise to the *Committee for the foundation of free seaside hospices for indigent scrofula sufferers* [8]. Barellai claimed that there was no "better medicine than sea air and water" for the treatment of scrofula and rickets in children [9, 10].
From their origins until the 1950s, these facilities clearly aimed at prevention and cure for poor and malnourished children. With the advent of fascism, however, an ideological-educational purpose was added, with a view to instilling the principles of the regime into the younger generations. In the mid-20th century, following the end of the Second World War, these summer "colonies" were no longer aimed exclusively at the less privileged and most fragile; rather, they catered for an economically and culturally heterogeneous population, while still maintaining the purpose of health prevention and promotion in childhood and adolescence.
Colonies were a phenomenon that has certainly affected much of Europe and America since the last decades of the 19th century and we must observe that in the context of an evolving concept of childhood, these experiences were presented as an attempt to resolve, through distancing from the urban context and a simultaneous return to nature, the social or health problems typical of the industrial revolution [11-13].
In Europe, France was the country in which the colonies had the greatest diffusion, as evidenced by well-detailed articles written on these experiences, compared to a smaller production in Italy, usually focused on the conquests of the fascist era [14].
It was in a context of tuberculosis epidemic that Brittany became, between the end of the 19th century and the beginning of the 20th century, a real field of health experiments, based on the therapeutic virtues of sea water and the prophylactic qualities of sea air. At the end of the 19th century, the Breton coast became a favorite land for the settlement of colonies.
The recreational aspect only established itself after the Second World War.
As the French scholar Henri Laborde highlighted, summer camps are also closely linked to the collective character of the festival and its timing during a period of school closures. In this regard in 1958 he wrote: "Au sens strict du terme, la colonie de vacances peut être définie comme une œuvre de vacances collettivis qui reçoit, dans un milieu aménagé à cet effet, un groupe d'enfants normaux âgés de 6 à 14 ans, pour des périodes d'étendue variable pendente les congés scolaires" [15, 16].
At the National Medical-Pedagogical Congress in 1953, Agostino Gemelli (1878-1959) stated: "*The doctor is the backbone of the colony, and therefore has a great responsibility on his shoulders. Educators and assistants must refer to the doctor for instructions or advice, which are provided on the basis of the factual data that they present to the doctor. He is therefore the backbone of the colony because its main and fundamental aim is to restore its young guests to a sufficient physiological condition to be able to cope with life; the colony must enable children to return to school in such a physical condition that they can benefit from teaching"* [17]. Thus, the period spent in the colony was regarded as a time to prepare the child or adolescent to return successfully to school. This vision was also stated very clearly by Benedetto Barni (1893-1970), doctor, health officer and school medical inspector in Siena, whose reports, written at the end of the 1950s, prompt the reflections that form the basis of the present article.

School and the colonies in Benedetto Barni's vision of the prevention and promotion of health in childhood and adolescence

Benedetto Barni was born in 1893 into a wealthy family in Montalcino, in the province of Siena. His father, a school inspector, was a dour, dutiful man, and a keen advocate of Maria Montessori's pedagogical ideas. After attending classical high school in Siena, Benedetto enrolled in the Faculty of Medicine and Surgery. However, he was able to pursue his studies only for three years, as he was conscripted into the army in December 1915. Immediately assigned to the military hospital in Florence as an aspiring medical officer, in May 1916 he was sent to the front, where he worked tirelessly to assist the wounded. Having been wounded himself, he was sent on convalescence leave to Siena, and, while still a soldier, was able to complete his medical studies. Immediately after graduating, he was sent to serve as a military doctor at the Gorgòna penitentiary [18].

At the end of the war, he was discharged from the army and returned to Siena, and in 1920 he became a general practitioner in Vagliagli, near Siena.
Thus, for family reasons, he abandoned all ambitions in the academic field, despite his first-rate preparation and the fact that, in the field of Public Health, he had had such great masters as Achille Sclavo (1861-1930) [19] and Giovanni Petragnani (1893-1969).
Achille Sclavo dedicated his life to spreading the principles of hygiene to children and public health by leading numerous health campaigns wanted by the governments of the time. He dealt with preventive medicine and hygiene, applying them to the Sienese territory: it is natural that someone like Barni who worked as a doctor and health officer had a close bond with the great hygienist [20].
In 1937, Barni was transferred to Siena as a general practitioner, and held the position of Health Officer of the Municipality of Siena from 1939 to 1961.
The author of scientific publications on pediatric auxology, Barni left interesting reports on his long healthcare activity. Some of the reports written at the end of the 1950s, regarding his experience as a school medical inspector, reveal the great work of prevention that he carried out on Sienese children and adolescents during the school year, in preparation for their stay in the colony. In particular, he left two autographs, consisting of 167 numbered cards (a draft and the final version), that list the temporary colonies used for the performance of service for the year 1959 [21]. Barni meticulously reported a series of data that were fundamental to providing an up-to-date picture of the health of young people from a preventive medicine perspective. For each colony to which Sienese children and young people were sent, he provided important information on the health of each child: age, weight and height on arrival at the colony, changes in weight and height during the stay in the colony, growth values, and anti-diphteria [22] and anti-poliomyelitis vaccination [23].
These data were correlated with the physical and psychic data collected during the individual visits to school during the year, in line with Agostino Gemelli's observation. As Barni wrote: *"If the summer camps are regarded as the completion of the school year; if the door of the school opens, allowing selected children to reach their pre-defined destinations in the mountains or at the seaside, the current health and hygiene concerns will disappear […]"* [21].
In this regard, Achille Sclavo's report "*Somatic growth and psychic evolution: methods of evaluation – outdoor schools"* [24] is of particular interest. The idea of the outdoor school (Fig. 1) was conceived by Achille Sclavo, in order to create healthy school environments where growth could be integrated with physical education, precepts of hygiene and the principles of the fight against tuberculosis [25].
According to what Barni states in the above-mentioned report, medical examinations of children were frequently carried out during the school year, and all the data collected were carefully noted in personal files.
"*The healthcare assistant collaborates in anti-tuberculosis prophylaxis, which is carried out through the complete radiography of pupils and staff […]. At the same time, an allergy test is conducted by means of an anti-tuberculin reaction patch, and anti-tuberculosis vaccination is carried out if the result is positive. […] The social worker completes health report cards to record, in addition to the mandatory prophylactic vaccinations required by law, smallpox vaccination […], the two diphtheria […] vaccinations and the three polio vaccinations, to which a fourth polio vaccination must be added [...]*" [24, 26].

Fig. 1. The "Achille Sclavo" outdoor school on the bastions of the Sienese Fort (Courtesy of Historical Archive of the Municipality of Siena, Benedetto Barni archival fund).

The data on the percentages of children vaccinated in the five classes of the "Achille Sclavo" outdoor elementary school are interesting: 85% had received the first and second polio vaccine doses, and 73.4% the third dose, while for the fourth they had to wait until the regulatory interval had expired [24]. Data on diphtheria and smallpox vaccinations were also recorded.

Regularity, adequacy, and control: the principles underlying the experience of the colonies

The information provided by Barni suggests that the colonies and the preparation carried out at school during the school year constituted an extremely valuable means of preventing diseases in children and an effective control mechanism. As Barni claimed, "*No child admitted to a colony escaped the third diphtheria booster vaccination*" [21].

Preventive medicine based on the concepts of regularity and constant control.

The work carried out by the colonies owed much to the close collaboration between the Municipal Hygiene Office and the Provincial Anti-Tuberculosis Consortium, which also conducted "*radiographic screening to detect contagious forms and to promptly recognize initial forms before admission to the colony community*" [21].

Medical examination and the checking of vaccination status had the purpose of ascertaining the health of children who were candidates for the colonies, in order to exclude the participation of those suffering from contagious diseases which could prove to be a risk for other children.

These procedures were followed by a thorough social analysis, in order to favor candidates with the greatest economic and family needs.

The primary schools of Siena – Barni wrote in 1959 – *"have been endowed with 6 clinics*", where doctors had been working since the beginning of the school year, their task being to "*prepare pupils for the colony, study them with that purpose in mind, accompany them with all the somatic and physio-psychic information collected from individual examinations* [21]. *"The school doctor certifies that the children leaving for the colony are free from communicable diseases and come from areas where there have been no recent infectious or widespread diseases; he also checks the child's need to be sent to one of the various types of colony"* [21].

In describing the Belcaro colony near Siena, Barni states that: *"During their stay in Belcaro, the children selected and followed during their school life, with their frailty, fatigue, anemia and states of predisposition, which have been scrupulously documented before admission, will have the most suitable physical and mental rest, so that they can then return to school willingly and joyfully. In the colony, healthcare activity takes precedence over teaching activity, this latter being understood only as the assimilation of the norms of health education in the sense of preventive medicine and not curative medicine, since a child who falls ill immediately leaves the collective life of the colony*" [21].

While most of the colonies were at the seaside (Fig. 2), some were located in hilly or mountainous areas (Fig. 3). "*Environments of medium altitude, between 600 and no more than 1000 meters, have a stimulating and tonic effect. As children readily adapt to the mid-mountain climate without great effort, it is considered one of the most suitable climates for childhood prophylaxis, particularly in the summer period […] on account of the*

Fig. 2. Camping at Marina di Cecina - Livorno (Courtesy of Historical Archive of the Municipality of Siena, Benedetto Barni archival fund)

Fig. 3. The mountain colony of San Marcello pistoiese (Courtesy of Historical Archive of the Municipality of Siena, Benedetto Barni archival fund).

lower atmospheric pressure, the dryness and purity of the air and the intensity and longer duration of sunshine, due to the absence of atmospheric dust" [21].

"The Municipality's Hygiene Office is particularly attentive to the needs of children who aspire to benefit from a stay at the summer camps. However, it would be useless to carry out all this activity if the sector made up of managers, auxiliary staff and members of the maintenance and service staff were to be neglected. Indeed, it would be useful, or rather necessary, to provide the members of this sector with a personal booklet in which they can record, in addition to their qualifications and specialization courses attesting to their technical preparation [...], also their physical fitness, in terms of the absence both of infectious or otherwise contagious diseases in progress, and of organic diseases and mental disorders incompatible with life in a childhood community. [...] This must be observed in order to comply with the rules necessary for social safety, according to which vaccination prophylaxis is mandatory; moreover, parenteral vaccination against typhoid, paratyphoid etc. is also mandatory for laundresses and those who handle food and drink, and any healthy carriers must undergo verification by means of laboratory tests" [21].

Conclusions

The reports left by Benedetto Barni provide significant data that help us to reconstruct the organization of an institution, that of the colonies, which accompanied the growth of many generations of Italians for over a century. The colonies remained very popular right up to the end of the 1950s. Indeed, in the summer of 1959, over 3,000 Sienese children and young people – aged 5 to 18 – (on a population of approximately 60,000 inhabitants) attended the seaside and mountain colonies. From the point of view of the age of the children taken in, there isn't in scientific literature a specific position regarding Italy. Sergio Neri, (1937-2000), teacher, educational director, trainer, school inspector, at the end of 1960 refers to a range of age between 6-12 years. If the children were older, it wasn't a colony but a simple stay [16, 27, 28].

It must be said that the structure of the stay in the colony remained substantially the same.

As the colonies were designed to host large numbers of children, who had to be kept under control in large teams, they lacked flexibility and offered their young guests a narrow range of activities. Nonetheless, their value from a medical and preventive point of view is undeniable.

Within this model, the child evidently had a passive role and could not emerge from the anonymous multitude of his peers. At the same time, the educators themselves did not have the freedom to modulate their work according to the children and young people entrusted to them; rather, they had to comply with the directives handed down from above, to respect them and to ensure that the children respected them.

This organization did not change much over time, although the management of the colonies passed from the philanthropic associations of the 19th century to the government in the 20th century (particularly in the fascist period), to finally see the commitment from the 1960s also of important national companies and international.

Continuity between school and colony was extremely close, which prompted Barni to state: "*The school-colony partnership must be maintained without evaluative discontinuity with regard to prophylaxis, which today constitutes a highly social objective*" [21].

This statement reflects the teaching of Barni's mentor, the great Sienese hygienist Achille Sclavo, who devoted much of his life to the prevention of epidemic diseases, particularly those of childhood [29]. Like Sclavo, Benedetto Barni also considered health to be a personal right and a community interest. Barni's writings clearly reveal the foresight of a doctor who devoted his work and his study to the school-age population of the Municipality of Siena.
In this setting, he drew up rules to follow regarding personal hygiene and nutrition; together with vaccines, this approach was instrumental in defeating the many diseases that afflicted the population at the time: tuberculosis, typhoid, polio and diphtheria and which today due to wars, vaccine hesitation and environmental disasters tend to return [30-32]. Barni's professionalism and generosity were such that the Siena colonies were judged to be among the best in Italy.

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Informed consent statement

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Conflicts of interest statement

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Authors' contribution

DO & MM: conceived the study; DO: designed the study; DO, MM: drafted the manuscript; DO, MM, FZ, DP: performed a search of the literature; DO, FZ, DP: critically revised the manuscript; DO, DP: conceptualization and methodology; DO: investigation and data curation; DO, MM: original draft preparation; FZ, DO, DP: review; DO, MM, DP: editing. All authors have read and approved the latest version of the paper for publication.

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History of Medicine and Ethics

Historical and Social Considerations upon Tuberculosis

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Keywords

Antibiotic resistance • History of medicine • Infectious diseases • Medicine • Palaeopathology

Summary

The present article offers a concise perspective on tuberculosis (TB) ranging from antiquity to the present day and highlights the dangerousness of the disease in the light of its historical manifestations and current antibiotic resistance. Reflections on the social and economic impact of tuberculosis are presented together with notes on TB's interplay with malnutrition and the social stigma linked to this disease in modern times. Different types of evidence from palaeopathological to artistic ones are offered and the need for a more comprehensive understanding on the disease's history and evolution is stressed.

Introduction

Understanding tuberculosis

According to WHO statistics, in 2023 a total of 1.25 million people worldwide died from tuberculosis (TB), which explains how TB has now returned to be the main infectious disease killer, after three years in which it was "replaced" by COVID-19, and ranking higher than AIDS [1]-two of the most significant epidemic diseases in the last 40 years capable of breaking the previous pathocoenosis balance [2-4]. For a long time, TB has been a scourge for humankind and currently its dangerousness is associated with multi-drug-resistant strains of *Mycobacterium* spp. Again, the WHO data indicate that in 2023, only 2 out of 5 people with antibiotic-resistant TB accessed treatment [1]. Moreover, despite an estimated 75 million lives saved from TB since 2000, TB still represents a major hindrance factor in the development of nations [1, 5]. The most commonly prescribed antibiotics include isoniazid, rifampin, pyrazinamide, ethambutol and streptomycin [1, 6]. Such drugs need to be administered every day for a period of 4-6 months and a key to the success of the therapeutic strategy is not to stop taking them too early or without medical advice, since this could let TB *Mycobacteria* to survive and become drug-resistant [1, 7].

Economic and Social Impact

Tuberculosis has enormous economic implications for its hosts and society. The financial consequences of tuberculosis may be of two types. The first one, direct, refers to the costs of medical treatment, including drugs, laboratory tests, physician fees, radiological investigations, and hospitalization. These costs to TB patients are high compared to *per capita* income and have also a major impact on the family economy in low- and middle-income countries. The second type of financial burden, indirect one, is related to illness-induced reduction of the earning capacity of the patient and by reducing the demand for labour as a result of death or disease [8]. TB causes large costs in healthcare systems and hospital budgets as well as increased expenses on welfare. There are also substantial revenues that can be realised if full cost recovery from elements of tuberculosis care such as human resources, laboratory investigations, radiology, drugs, etc. is achieved. A study based on a TB-endemic country like India [9], for example, indicated that approximately 24.3% of TB patients experienced both social and economic reverberations, with 75% patients suffering from at least one of them. In addition, "social impact was perceived by more female patients as compared to males (80.7% *vs* 62%)" and "more patients with extra-pulmonary disease (44.4%) and patients belonging to joint families (40.7%) perceived economic impact" [9].

Stigma and Discrimination

Tuberculosis is stigmatised by most communities mainly due to the fear of transmission during contact with infected person, but second important aspect includes its

link with such factors as: "HIV, poverty, low social class, malnutrition, or disreputable behaviour" [10].
As with leprosy (Hansen's disease), tuberculosis is also almost always associated with stigma. In some societies, this can result in consequences such as being abandoned by family or shunned by a community (*e.g.* co-workers, villagers, etc.). In more extreme cases, losing a job might also be an outcome. The social impact of TB is considerable, due to direct or indirect forms of discrimination [11].
The TB sufferer will endure both the physical pain caused by the disease as well as the social sequelae of stigma and discrimination. Perceptions of TB by society in general include negative, and often ill-informed attitudes about the disease. Because tuberculosis is a disease that has been associated with poverty, squalor, poor hygiene, marginalization of certain groups, and even the disintegration of character, it can result in social disregard for TB patients. Much of the prejudice is due to the lack of awareness about tuberculosis [12]. In some cases, health staff hold their own deeply entrenched biases in addition to misinformation.
The stigma associated with tuberculosis (TB) is not only an obstacle to the social acceptance of patients but also has a direct impact on the quality of care and prevention of the disease, hindering the achievement of the World Health Organisation's global goals for TB elimination. Moreover, stigma in healthcare settings compromises access to diagnosis, adherence to treatment and deteriorates therapeutic response. The most effective solutions require an integrated approach that includes educational initiatives, structural reforms and participatory methodologies, involving patients and health professionals in a common goal of reducing stigma at the individual, societal and institutional levels. Such an approach will ensure more accessible, effective and compassionate healthcare, thus contributing to the global TB elimination goals [13, 14].

Tuberculosis and malnutrition

The latest edition of the *State of Food Security and Nutrition in the World* estimates that nearly 690 million people lived in hunger in 2019, which is an increase of 10 million since 2018 and nearly 60 million in five years. Due to high costs and poor accessibility, billions of people do not have a healthy or nutritious diet (*UN World Food Programme -WFP)* [15].
It is now well established that tuberculosis is related to malnutrition both as a predisposing factor for infection and as an effect of the infection itself. This condition has also been associated with a worse prognosis in tuberculosis patients resulting in increased deaths and in a false negative tuberculin test, thus delaying diagnosis [16]. In fact, malnutrition can cause secondary immunodeficiency that makes the individual more susceptible to contracting infection [12, 16]. Tuberculosis reduces appetite, thus lowers total food intake and prevents absorption of nutrients and micronutrients in the gut as well as alters the individual's metabolism [17]. In particular, patients with a severe form of tuberculosis show significant loss of muscle mass, caused by the body's reduced ability to absorb and metabolise protein. In addition, a deficiency of micronutrients such as zinc, selenium, iron, copper, and vitamins (A, C, D, and E) results in an altered immune system [17].
A correlation between vitamin D deficiency and response to therapy has been sought in several studies [17-22]. Low serum vitamin D was observed in patients with active TB and also in multidrug-resistant tuberculosis (MDR-TB) during treatment, which may be one of the important factors responsible for susceptibility to TB in both groups; however, its significance is still being investigated [17-22].
Even before taking into account the indispensable antitubercular drugs, nutrition plays an important role in the treatment of tuberculosis: proper nutrition and an adequate nutritional supplementation may represent a novel approach for fast recovery in tuberculosis patients. Furthermore, raising nutritional status of population may prove to be an effective way to control tuberculosis in underdeveloped regions of the world.

Medical Advances and Future Outlook

Medical advances have made it possible to treat tuberculosis since the advent of antibiotics in the 1940s [23]. Previously, efforts at developing an effective vaccine for tuberculosis date back to the period just after the bacterium that causes the disease, *Mycobacterium tuberculosis*, was identified by Robert Koch (1843-1910) in 1882 [24] and are still ongoing. Preventing the development of tuberculosis from bacterial exposure is thus the focus of vaccination, while therapy aims to free the human body of the pathogen once an active infection has begun to do harm, although these therapeutic and preventive efforts overlap. One current approach to the elimination of tuberculosis involves primarily detecting and treating active cases of the disease to prevent ongoing transmission. There is also a second approach, in which the search for latent infection precedes caring for active infections, has been suggested. All these efforts, based on antibiotics and vaccine strategies, have always been a balance of risk versus benefit, of which disease and pathology are now much better understood [25].
Several vaccines have been developed to prevent TB. However, while Bacillus Calmette-Guérin (BCG) vaccination is the most widely administered vaccine in the globe, it offers limited protection against the most severe presentations of TB. Bacillus Calmette-Guérin vaccination mainly protects young children from miliary TB and other disseminated forms of TB, but it does not consistently protect against pulmonary TB [26]. Injecting a vaccine directly into the blood (intravenous administration) could provide superior protection against the most severe forms of TB, but it will have other technical/regulatory challenges and potentially other adverse events. Furthermore, no new TB vaccine has received WHO prequalification so far or been endorsed by any national regulatory authorities [27, 28].
Shorter, safer, and simpler regimens for both TB prevention and treatment, with improved effectiveness

against drug-susceptible and drug-resistant TB, would also significantly improve the prevention and hence the management of TB infection. Improving the management of the latter could help prevent progression to TB disease. A regimen of a dose of rifapentine and isoniazid (3HP) weekly for three months for treating late TB infection (LTBI) is recommended by WHO since 2020 to improve compliance and adherence by people getting LTBI treatment [29]. The benefits of such weekly therapy are anticipated to have some impact in reducing TB morbidity, especially in low- and middle-income countries. Tests and regimens for managing TB infection (LTBI) for safety, efficacy, shorter therapy, are a "game changer" for avoiding people progressing from TB infection to TB disease.

Some historical remarks

Historically, tuberculosis has been known by various names, ranging from the *White Plague* to *Phthisis*, *Consumption* or *The Great Killer*. Since the discovery of its aetiologic agent in 1882, over one billion people have succumbed to it. Much greater numbers could be hypothesised from previous eras, yet no comprehensive statistics on the disease's prevalence can be collected from the palaeopathological record [30-35], which consists of lesions detected in osteological and mummified remains, data recovered through biomolecular tests as well as literary and artistic sources [33-35]. Nevertheless, as highlighted by other infectious diseases in the past [36, 37], unless a combination of phenotypic and genetic information can be collected (or at least a convincing proportion of such data), no definitive inferences about the actual prevalence of tuberculosis can be effectively made. Hence, the process of tracing back its antiquity must be accompanied by a careful scrutiny of the available sources and greater caution should be used when making strong statements about this aspect. For example, while it was previously thought that no evidence of ancient tuberculosis was present in Sicily [38], recent discoveries effectively pushed the disease's history on the island to the potentially as far back as the 7th-5th centuries BC [39].

Indeed, tuberculosis, together with other infectious lung diseases, represented the leading cause of death in the 18th and 19th centuries, in the pre-antibiotic era, with a peak around 1850 [31], with a 35-40% mortality. It is a disease that develops most in crowded cities due to contagion via the respiratory route showing its most critical periods in the Middle Ages and, above all, during the Industrial Revolution. Despite scientific advances, in 1993, the World Health Organisation (WHO) declared TB a global emergency [31]. A watercolour (ca. 1912) (Fig. 1) by the artist Richard Tennant Cooper (1885-1957) portrayed TB as the angel of death, showing the shape of a human skeleton clutching a scythe and an hourglass, visiting a sickly pale young woman who is sitting on a balcony. Such an image powerfully points to the devastating effects of a disease at the time certainly considered to be a death sentence.

Moving on, in the 20th century, as the nature of TB's aetiologic agent and transmission methods were scientifically clarified, it is worth mentioning a poster (Fig. 2) entitled *Tuberculosis Don't kiss me!: Your kiss of affection - the germ of infection*, which focuses on the disease's impact on the paediatric population. Parents' kisses to their children, though an obvious manifestation of parental love, could turn into a powerfully effective transmission route for *Mycobacteria*, hence parents were advised to show greater caution. The disease was still extremely dangerous, and the first antibiotic strategies were *de facto* in their infancy. Hence, in order to contain

Fig. 1. A sickly young woman sits covered up on a balcony; death (a ghostly skeleton clutching a scythe and an hourglass) is standing next to her; representing tuberculosis. Watercolour by R.T. Cooper, ca. 1912. Attribution 4.0 International (CC BY 4.0). Source: Wellcome Collection. https://wellcomecollection.org/works/vktusgk3

Fig. 2. Tuberculosis Don't kiss me!: Your kiss of affection - the germ of infection / / JD. Poster about tuberculosis in children and methods of transmission, showing a child wearing a bib. [New York]: WPA Federal Art Project, District 4, [between 1936 and 1941]. No known restrictions on publication. https://catalog.loc.gov/vwebv/search?searchCode=LCCN&searchArg=98516354&searchType=1&permalink=y.

Fig. 3. Healthy looks can hide tuberculosis: the x-ray will show it before you know it. Images from the History of Medicine (IHM). [S.l.]: Christmas Seals, [193-?]. https://collections.nlm.nih.gov/catalog/nlm:nlmuid-101451864-img.

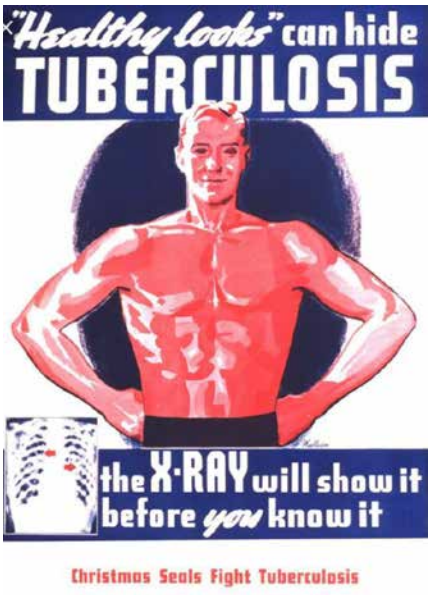
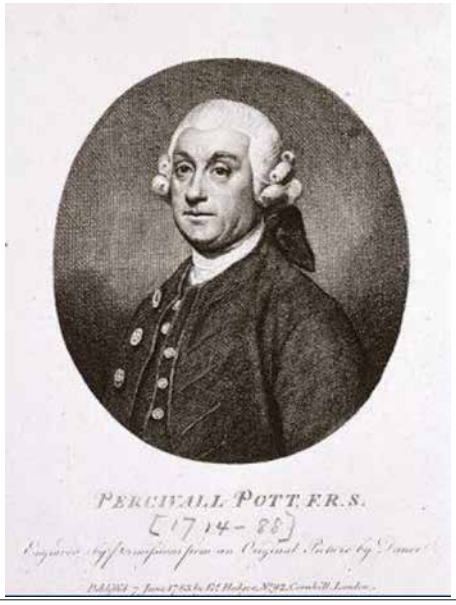


Fig. 4. Sir Percivall Pott, engraving based on an original picture by Nathaniel Dance-Holland, National Library of Medicine. Image in the public domain from Wikimedia Commons: https://en.wikipedia.org/wiki/Percivall_Pott#/media/File:PercivallPottb026992.JPG.



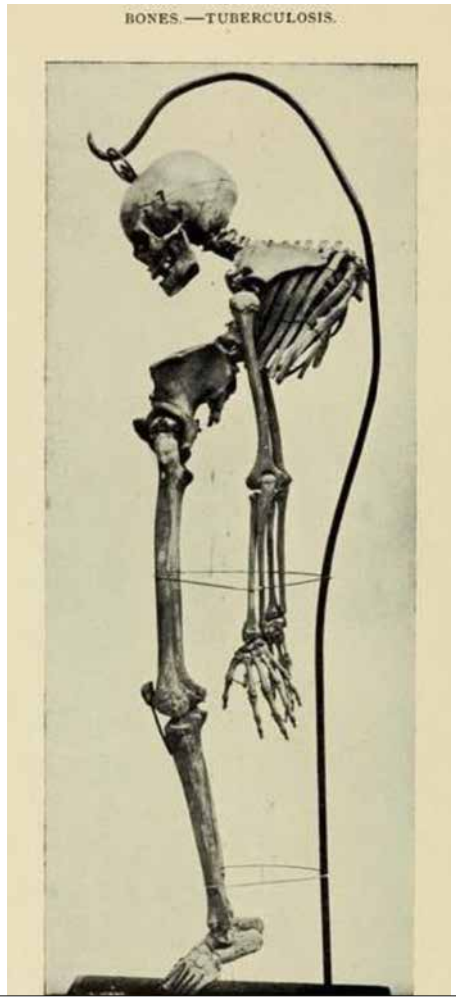
the advancing infectious disease, a disruption of social and family conventions was deemed a necessary sacrifice in order to safeguard the general populace.

Another poster (Fig. 3), *Healthy looks can hide tuberculosis: the X-RAY will show it before you know it*, testifies the advancing preventive strategies to stop the disease and to inform the population about the risks of tuberculosis. After the introduction of X-rays in 1895, chest radiographs started to play a role in the identification of individuals with pulmonary lesions, who, then, since the 1940s onwards, would be selected as candidates for treatment [40]. Indeed, by identifying TB patients who may have not yet developed the typical consumptive external phenotype but who may already have active lung TB, it was possible to detect positive cases and to implement the necessary therapies [40].

As the disease's pathophysiology teaches, when the TB *bacterium* enters the human organism through the respiratory system, it reaches the pulmonary alveoli. Macrophages attempt to counter it and the result of this fight between immune cells and the mycobacteria determines the formation of the characteristic tubercle. In the central portion of the tubercle, caseous necrosis takes place where some *Mycobacteria* persist being dormant [31, 32]. The infection can then, through the haematogenous route, spread from the lungs to the skeletal system, in some cases causing skeletal TB, the spinal column being the most commonly involved district (over 50% of cases). Through the vertebral arteries, the *Mycobacteria* reach the central portion of the vertebral bodies, causing it to be eroded so that a reduction in size and a collapse of the vertebral body's anterior portion ensues. This phenomenon ultimately results in a skeletal condition known as Pott's disease (angular gibbus), most frequently affecting the first lumbar vertebra [32-34]. This specially hyperkyphotic spine is named after Sir Percivall Pott (1714-1788), who, being a surgeon at St Bartholomew's Hospital in London, first described it in 1779 (Fig. 4) [34, 41].

Amongst the most ancient attestations of tuberculous infection, a recent study has proposed that it may have affected Neanderthal individuals from the Subalyuk Cave (Hungary – earliest individual: 39,732-39,076 cal. BP) [42] Moreover, TB in *Homo sapiens* can be traced back to 9,000 years ago in Atlit Yam, off the coast of Israel [43]. Palaeopathological evidence of tuberculosis has been consistently reported from Predynastic Egypt (6000-3150 BC) and has long been described in Ancient Egyptian mummified remains. DNA evidence has also been adduced from the Predynastic era, the Old, Middle and New Kingdoms and has been found in the young and old, from high- and low-status burials [44]. According to Crubézy et al. [44], as well as Zink et al. [45], tuberculosis existed in Ancient Egypt over 5,400 years BP, with a particularly high prevalence in the Predynastic and Late Periods. The scarcity of TB lesions in bioarchaeological material from this region of the planet is, nonetheless, probably attributed to the poor state of preservation of the affected bones. In addition, one should not ignore the fact that, even in contemporary TB patients, skeletal tuberculosis merely accounts for 3-5% of untreated cases. This may thus lead to the conclusion, as introduced aboved, that the true prevalence of TB in the past may be underestimated. In the Italian Peninsula, a very ancient attestation of skeletal TB is represented by the male adolescent skeleton (aged approx. 15 years at the moment of death) from the Neolithic site of Arene Candide (4,000-3,500 BC, Liguria Region). This prehistoric individual's spine

Fig. 5. 19th century skeleton of an unknown young adult woman with Pott's disease, or spinal tuberculosis. John Collins Warren Collection, OnView, accessed September 5, 2024, https://collections.countway.harvard.edu/onview/items/show/13129.



presents pronounced thoraco-lumbar hyperkyphosis with formation of a 90-degree angular gibbus [46]. This type of morphological deformation has preseved its appearance over time and can be appreciated in modern times, as highlighted by a 19th century skeletal preparation of an unidentified young adult female exhibited in the John Collins Warren Collection (Fig. 5, Harvard University).

Finally, once more the figurative arts – as seen in a number of pathological entities, both infectious and non-infectious ones [47, 48] can offer a valuable source of data on the antiquity and morphology of TB infection. As previously reported by some of the author of this article [35], Ancient Egyptian figurines can show the typical morphology seen in Pott's disease. Out of many such representations, one from the National Archaeological Museum of Naples (MANN) stands out (Fig. 6). Belonging to the erotic objects of the MANN's Borgia Collection, it is currently exhibited in the museum's *Secret Cabinet*, potentially an ithyphallic representation of god Harpocrates. The MANN statuette not only shows an angulate morphology of the

Fig. 6. Statuette possibly representing Harpocrates, the Greek god of silence. Ptolemaic Era, 4th-1st century BC, inventory number: #2767, National Archaeological Museum of Naples (MANN).

Photo credits: National Archæological Museum of Naples (MANN).

gibbus but also pectus carinatum, hence indicating a combination of highly incapacitating multiple muscolo-skeletal abnormalities affecting the individual(s) who served as a morphological inspiration for this artistic representation [35].

Conclusions

The antiquity of TB needs to be investigated further if an adequate understanding of its historical trajectory and evolutionary path is to be achieved. In the process, several sources of information should be used, not limiting the investigation only to skeletal remains or historical written sources. Artworks should also play a role in the process and, together with other typologies of information such as the palaeogenetic one, should actively contribute to a comprehensive reconstruction of the pathology's history. This will provide clinicians with a much better-informed background on TB and may catalyse new preventive and therapeutical strategies aimed at terminating this perilous infectious disease [49]. Even in current days we must always detect and highlight that infection prevention, contagion and control measures are crucial in public health services because there is a risk of transmission of the bacterium *Mycobacterium tuberculosis*; the World Health Organization (WHO) developed recommendations according to the methods defined in the WHO handbook for guideline development [50].

Moreover, we should always consider and reflect on one of the most important aspects in this long pathway: a real and successful vaccine. We still have to remember today

that only a really efficacious vaccine will enable us to eradicate TB [51].
Especially at a time of great societal scepticism about and misunderstanding of vaccinations and medical treatments, paradoxically in an era in which the abundance of information should produce, instead, the opposite effect [52].

Note

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Authors' contributions

EV: conceptualisation, original draft-writing, supervision. MM, MV, VV, JMS, RG, FMG and VP: original draft-writing. FMG and VP: supervision.
All authors have read and approved the latest version of the paper for publication.

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