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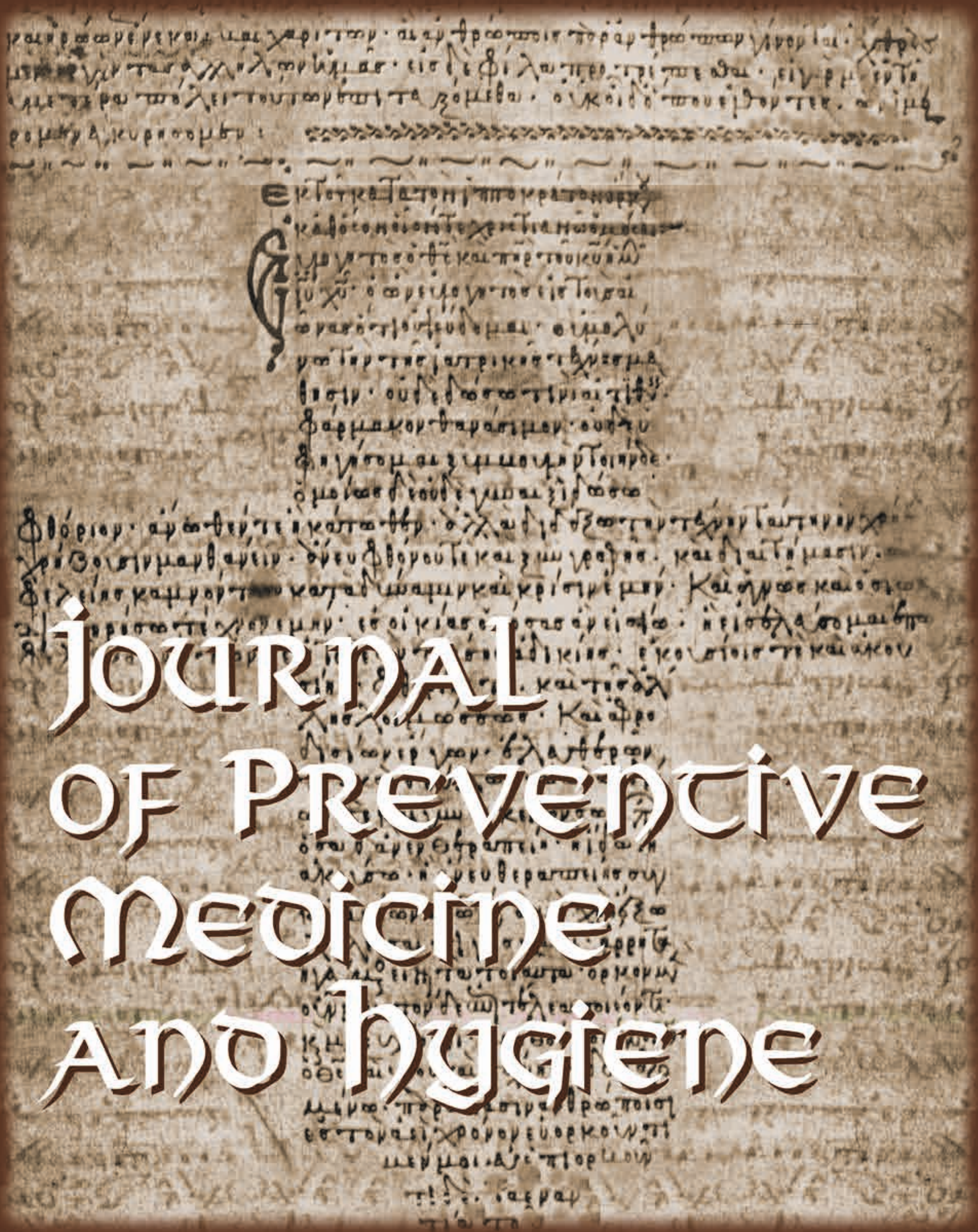

Journal of Preventive Medicine and Hygiene

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Interuniversity Research Centre on Influenza and Other Infections (CIRI-IT), University of Genoa, Italy

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Managing Editor: Patrizia Alma Pacini

Publisher: Pacini Editore Srl, Via Gherardesca 1, 56121 Pisa, Italy
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info@pacinieditore.it - www.pacinimedicina.it

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HEALTH PROMOTION

Impact of an Educational Intervention Video in HPV Prevention among Tunisian Female Students: A before-and-after Study

NADIA BOUCHHIMA[1], MARIAM AMMAR[1,2], MOHAMED KSENTINI[1,2], KHALED ZGHAL[1,2], AHMED HAKIM[1,2], LOBNA BEN MAHMOUD[1,2]
[1] The Regional Pharmacovigilance Service of Sfax, Department of Pharmacology, Faculty of Medicine, University of Sfax- Sfax, Tunisia; [2] Research Laboratory: LR19ES10 "Acute Medicine, Pharmacology, and Toxicology of Xenobiotics", University of Sfax, Sfax, Tunisia

Keywords

Educational intervention video • Cervical cancer • HPV vaccine •, Tunisian Medical School

Summary

Background. *Cervical cancer is the second most common gynecological cancer in Tunisia. The HPV vaccine is a crucial tool for preventing and controlling this disease. Training healthcare providers and equipping them with adequate knowledge is essential. This study aimed to evaluate the effectiveness of an educational intervention video (EIV) on the knowledge and perceptions of HPV, cervical cancer, and the HPV vaccine among Tunisian female students.*

Methods. *A quasi-experimental study involving a single interventional group was conducted among 158 female students. Participants were interviewed before and after watching the EIV. The chi-square test using McNemar's method assessed variations between pre- and post-intervention responses. A p-value <0.05 was considered statistically significant.*

Results. *The average age of participants was 19.74±1.7 years. The EIV had a positive impact on the scores for knowledge and perceptions related to HPV and cervical cancer. A significant difference was observed between the intention to receive the HPV vaccine and perceived severity of HPV, perceived benefits of vaccination, and perceived barriers. Notably, 50.6% of female students believed the HPV vaccine should be available upon request and covered by health insurance, while 46.2% thought it should be included in the Tunisian vaccination schedule.*

Conclusion. *The EIV improved students' knowledge and perceptions about HPV, cervical cancer, and the HPV vaccine. Tailored educational strategies may enhance vaccine acceptance, especially when integrated early in academic training.*

Introduction

Cervical cancer is one of the most common malignancies of the female reproductive tract. It occurs when abnormal cells in the lining of the cervix grow uncontrollably and may progress to invasive cancer if left untreated [1]. This malignancy ranks as the fourth most frequent cancer in women worldwide, both in incidence and mortality, despite the availability of prevention methods for over 70 years [2]. Current estimates show that each year, 604,127 women are diagnosed with cervical cancer, and 341,831 die from the disease [3].

In Tunisia, cervical cancer is the second most common gynecological cancer, following breast cancer, with an incidence rate of 5.8 per 100,000 women corresponding to around 250 to 300 new cases annually [2, 4]. This rate remains significantly higher than in many countries of the Global North, where organized screening and widespread HPV vaccination have reduced incidence to fewer than 10 cases per 100,000 women annually [5]. Recognizing the significant burden of this preventable disease, the Global Strategy to Accelerate the Elimination of Cervical Cancer as a Public Health Problem (2020-2030) has set targets for 2030 [6], aiming to reduce the incidence to fewer than 4 cases per 100,000 women [6]. Most cervical cancers (95-100%) are caused by persistent infection with human papillomavirus (HPV). Two high-risk types, HPV16 and HPV18, are responsible for nearly 70% of cases globally. In Tunisia, the combined contribution of these types reaches 69.5% (61% from HPV16 and 8.5% from HPV18) [3, 7]. HPV vaccination, cervical screening (using either the Papanicolaou smear to detect cytological abnormalities or the HPV-DNA test to identify high-risk HPV infections), and treatment of precancerous lesions are proven and cost-effective strategies for prevention [8, 9]. Currently, three types of HPV vaccines are available [10]. The bivalent vaccine (Cervarix) targets HPV types 16 and 18. It is given in two doses (5 to 13 months apart) for individuals aged 9-14 years, and in a three-dose schedule (at 0, 1-2.5 months, and 5–12 months) for those aged 15 years and older [11]. The quadrivalent vaccine (Gardasil) covers HPV types 6, 11, 16, and 18. It is administered in two doses (6 months apart) for individuals aged 9-13 years, and in three doses (at 0, 2-3 months, and 6-7 months) for those aged 14 years and older [11]. The nonavalent vaccine (Gardasil 9) provides additional protection against five more high-risk types (31, 33, 45, 52, and

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58) along with the four types covered by the previous vaccines. It is recommended for individuals aged 9–14 years in a two-dose schedule (9-13 months apart), and for those aged 14 years and older in a three-dose schedule (at 0, 1-2 months, and 4-6 months) [11].

Although women carry a disproportionately higher burden of HPV infection, men are also impacted by the virus. A 2023 systematic review found that nearly one in three men aged 15 or older were infected with at least one type of HPV, and one in five had one or more high-risk HPV types [12]. HPV-16, the predominant type of HPV, is known to infect the anogenital tract in men as well as the epithelium of the oral cavity, oropharynx, and larynx [13].

Tunisia is in a favorable position to implement broad HPV vaccination. The Tunisian Society of Gynecology and Obstetrics (STGO) is actively advocating for its inclusion in the national immunization schedule [14]. A Tunisian study suggests that introducing the HPV 16/18 vaccine could reduce cervical cancer cases by two-thirds [15]. In 2025, the Ministry of Health plans to introduce the HPV vaccine in the national school vaccination program, targeting girls in the 6th year of primary school (typically aged 11 to 12 years in Tunisia) [16].

Acceptance of the HPV vaccine depends on multiple factors, including knowledge and understanding of HPV infection, perceived risk of cervical cancer, trust in vaccine safety and efficacy, cultural or religious beliefs, and recommendations from healthcare providers [17-19]. A systematic review identified limited knowledge about HPV and its link to cervical cancer as a key barrier to vaccination among individuals aged 9 to 26 [17]. Moreover, a meta-analysis revealed that parental concerns, particularly fears that vaccination might encourage sexual activity, can negatively influence acceptance [18]. In contrast, strong recommendations from trusted healthcare professionals remain one of the most effective motivators for vaccine uptake [19]. As future healthcare professionals, medical and health sciences students will play a key role in the success of vaccination programs. It is therefore necessary to assess whether they have sufficient knowledge to deliver accurate information and guide informed public choices.

The present study was conducted to evaluate (i) the effectiveness of an educational intervention on the knowledge and perceptions of HPV, cervical cancer, and HPV vaccination among female students at the Higher School of Sciences and Technology of Health in Sfax, as well as (ii) their acceptability of the HPV vaccination.

Methods

STUDY POPULATION AND SAMPLING

A prospective quasi-experimental study involving a single interventional group was conducted among female medical students aged 18-23, enrolled at the Higher School of Sciences and Technology of Health in Sfax (Tunisia) during the 2023-2024 academic year.

This study was approved by the Ethics Committee of the Faculty of Medicine of Sfax, Tunisia (Reference: 28/25, dated 21 May 2025). Informed consent was obtained from all participants prior to data collection.

Participants were selected using cluster random sampling. No formal sample size calculation was performed. The number of participants was determined based on available classroom sessions, the total number of eligible female students, and logistical feasibility during the academic calendar. All sections were first grouped by academic level: 1st, 2nd, and 3rd year. Then, using a random number generator [20], two class groups were selected from each group, resulting in three random sub-samples. The selected class groups were: Radiology Imaging and Midwives for the first year; Midwives and Anaesthesiology and Resuscitation for the second year; and Operating Instrumentation and Medical Biology for the third year. The sampling frame included all female students enrolled in these six selected class groups.

Male students were excluded, as the study focused on females due to the direct relevance of HPV-related diseases and vaccination to this population. This allowed the study to address sex-specific health concerns more accurately.

Random sampling across academic levels (first-, second-, and third-year students) was used to ensure diversity in educational background and enhance the representativeness of the study population.

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EDUCATIONAL INTERVENTION

The Health Belief Model (HBM) was used as the theoretical framework on which the interventional study was centered. It aids in explaining and predicting health behaviours and is used in assessing health behaviour interventions by focusing on the attitudes and beliefs of individuals.

This psychological model includes several key concepts: perceived susceptibility, perceived severity, perceived benefits, perceived barriers, cues to action, and self-efficacy. The HBM has been extensively applied to examine beliefs and behaviors related to vaccination, helping to identify participants' perceptions of both diseases and vaccines [21-23].

In this study, the HBM guided both the construction of the questionnaire and the design of the educational video. The questionnaire explored four core constructs of the HBM, and the video was developed to target the same dimensions: it provided information on HPV risks and complications (severity), highlighted the prevalence of HPV infection (susceptibility), emphasized vaccine effectiveness and public health recommendations (benefits), and addressed concerns related to safety, stigma, and accessibility (barriers).

The HBM assumes that health-related action depends on the simultaneous occurrence of perceived susceptibility, perceived severity, perceived benefits, and low perceived barriers, in addition to cues to action and self-efficacy [24]. This framework is widely used in public health to design and evaluate interventions that aim to influence attitudes and health behaviors, particularly vaccination uptake [24, 25].

An educational intervention video (EIV) on HPV and cervical cancer was selected and adapted for use in this study. The original video, titled "Cervical Cancer: Prevention and Control," was published by the World Health Organization (WHO) in 2022 and accessed via the official WHO YouTube channel [26]. It was selected by the research team for its scientific accuracy, visual accessibility, and alignment with public health guidelines. The video addressed HPV transmission, the link between HPV and cervical cancer, preventive strategies, and the importance of HPV vaccination. The original language was English. French subtitles were added, and slides were integrated at the end to include Tunisian epidemiological data (cervical cancer incidence and HPV type distribution in Tunisia). These modifications were guided by national data published by the Tunisian Society of Gynecology and Obstetrics and the Ministry of Health, as reported by Bruni et al. [27].

The final version lasted 2 minutes and 28 seconds. It was projected in the classroom prior to a regular lecture session. A brief standardized oral introduction (less than one minute) was given by a member of the research team to introduce the video and encourage attention. No discussion or debriefing occurred after the video to avoid biasing the post-intervention questionnaire responses.

The choice of a short video was based on its low cost, reproducibility, and ease of dissemination, particularly in resource-limited settings.

QUESTIONNAIRE

A structured questionnaire was designed to collect data. The questionnaire was adapted from previously published questionnaires, based on the study's objectives [28, 29]. It consisted of three parts. The first part included sociodemographic information (age, academic level). HPV vaccination status was not included as all participants were unvaccinated, given that the HPV vaccine was not yet available in the national immunization schedule at the time of data collection.

The second part comprised 35 items representing knowledge regarding HPV, cervical cancer, and HPV vaccination (items 1-9) as well as the four dimensions of the HBM (items 10-35): 'perceived severity' (six items), 'perceived susceptibility' (three items), perceived general benefits' (nine items), and 'perceived general barriers' (eight items).

The third part consisted of two closed questions on the intention to vaccinate and the place of the vaccine in the future, whether it should be included in the vaccination schedule or only available on request.

The questionnaire was pretested in a group of 15 female students who were not included in the final analysis. The pretest, conducted two weeks before the main data collection, aimed to assess clarity, comprehension, and structure of the items. Minor modifications were made to improve wording and formatting. Internal consistency of the HBM-related items was assessed using Cronbach's alpha.

Completion time was not limited but usually took less than 10 minutes.

RECRUITMENT

The questionnaires were distributed to the female students at the beginning of the lectures. Participants were informed of the purpose of the study. Each student was interviewed before and after the EIV using the same questionnaire. Each participant gave written consent to participate in the study. The recruitment period started in November 2023 and ended in May 2024.

OUTCOME VARIABLES

The knowledge statements regarding HPV, cervical cancer, and the HPV vaccine were presented as multiple-choice responses (five items) and true or false responses (four items).

Knowledge was scored with 1 point per correct answer and 0 for incorrect ones. When two answers were correct, each was awarded 0.5 points. Perceptions of severity, benefits, and barriers were measured using a 7-point Likert scale (1-3: strongly disagree; 7: strongly agree), with item-specific scales for items 19 and 32 ("very unlikely" to "very likely") and item 29 ("not expensive" to "very expensive"). Perceived susceptibility was rated on a 0-100% scale, in 30% intervals.

STATISTICAL ANALYSIS

Data were entered in Excel 2013 and analyzed using SPSS 23.0. Qualitative variables were expressed as

Tab. I. Distribution of included female students by academic year and selected class group.

Academic Year	Class groups	Included (n)	Total Enrolled (n)	Participation Rate (%)
Ast Year	Radiology Imaging	28	28	100
	Midwives	27	39	69.2
2nd Year	Midwives	33	34	97.1
	Anaesthesiology and Resuscitation	19	19	100
3rd Year	Operating Instrumentation	26	41	63.4
	Medical Biology	25	28	89.3
Total		158	548	28.8

proportions and percentages. Quantitative variables were presented as means and standard deviations, as normality was verified.

For item-level analysis, only matched pre- and post-intervention responses were included. Missing answers were treated as missing data without imputation.

For dichotomous variables, McNemar's chi-square test was used to assess changes between pre- and post-intervention responses. For continuous or scored data (*e.g.,* knowledge scores, perception scores), paired t-tests were performed. Normality of distributions was verified prior to analysis. A p-value < 0.05 was considered statistically significant.

Results

SOCIO-DEMOGRAPHIC CHARACTERISTICS

Among the 548 eligible female students enrolled during the academic year, 189 were randomly selected for inclusion. Of these, 31 were excluded due to absenteeism, resulting in a final sample of 158 participants. Most participants were aged 18-20 years (n = 118; 74.7%), while 40 participants (25.3%) were aged 21-23 years.

Table I presents the distribution of participants by academic year and selected class groups. Thirty-eight percent of participants were enrolled in midwifery programs within the health science (n = 60; Tab. I).

A few responses were missing for certain items at either time point. As such, only paired responses were retained for the comparative analyses (Tab. II).

EFFECT OF EDUCATIONAL INTERVENTION VIDEO ON KNOWLEDGE

The knowledge score was significantly increased after EIV from 4.23 ±1.64 to 6.16 ±1.48 (paired t-test, $p < 0.001$) (Fig. 1). There was a significant difference between the items assessing knowledge pre-EIV and post-EIV (Tab. II). Most of the female students understood that "cervical cancer is the biggest problem related to HPV", "HPV infection prevented by vaccination", and "HPV vaccine prevents cervical cancer" with a significant increase in correct responses after EIV, indicating a 33.2%, 26%, and 36.7% rise in correct responses (Tab. II). The proportion of female students who answered "yes" to the questions "HPV only affects women?", "HPV can be asymptomatic?", "Is HPV one of the most common sexually transmitted infections?" and "The cervical smear can detect the HPV virus" was decreased after the EIV (Tab. II).

EFFECT OF EDUCATIONAL INTERVENTION VIDEO ON PERCEPTIONS AND ATTITUDES

Perceived severity of HPV

The perceived severity of HPV score was significantly increased after EIV from 26.31 ± 5.58 to 28.59 ± 5.28 (paired t-test, $p < 0.001$) (Fig. 1B). EIV positively impacted the perceived severity of HPV (Table II). After EIV, many respondents perceived HPV infection as a serious condition with potential impact on long-term partner relationships ($p < 0.001$), physical health ($p = 0.022$), and mental health ($p < 0.001$) (Tab. II).

Perceived susceptibility of HPV vaccine

The perceived susceptibility of HPV vaccine score was significantly increased after EIV from 1.45 ± 0.58 to 1.94 ± 0.62 (paired t-test, $p < 0.001$) (Figure 1C). After EIV, many female students perceived the HPV vaccine as essential in preventing HPV, cervical cancer, and genital warts (Tab. II).

Perceived general benefits of HPV vaccine

The perceived general benefits of the HPV vaccine score were significantly increased after EIV from 39.95 ± 8.06 to 43.82 ± 7.35 (paired t-test, $p < 0.001$) (Fig. 1D). As illustrated in Table II, female students had a positive opinion that the HPV vaccine was effective in preventing HPV, genital warts, cervical cancer, and certain types of oral cancer.

Perceived general barriers to HPV vaccine

The score of perceived general barriers to the HPV vaccine did not differ between before (27.94 ± 6.28) and after EIV (27 ± 7.21) (paired t-test, $p = 0.191$) (Fig. 1E). However, there was a significant difference in the items "the vaccine is likely to cause significant side effects" and "i'd be embarrassed if other people knew I'd had the vaccine" between pre-EIV and post-EIV, showing an 18.3% and 4.4% decrease, respectively for correct responses (Tab. II).

Detailed item-level results are available in Supplementary Table I.

Tab. II. Effect of educational intervention video on knowledge, perceptions, and attitudes related to HPV.

Number	Items	Pre-intervention N (%)	Post-intervention N (%)	*p*-value
Items assessing knowledge				
I1	**What is the most problem related to HPV?**			
	Cervical cancer/ heart disease/ HIV/ Genital warts/ I don't know	105/0/0/40/0 (66.5)/(0)/(0)/(25.3)/(0)	165/0/0/73/0 (98.7)/(0)/(0)/(46.2)/(0)	< 0.001
I2	**How is HPV spread?**			
	Cough or sneeze/ Sexual contact/ Blood and body fluid contact/ I don't know	0/75/0/0 (0)/(47.5)/(0)/(0)	0/114/0/0 (0)/(72.2)/(0)/(0)	< 0.001
I3	**How can HPV infection be prevented?**			
	Abstinence/ Antibiotics/ Condoms/ vaccinated/ I don't know	11/2/0/107/0 (7)/(1.3)/(0)/(67.7)/(0)	24/0/0/148/0 (15.2)/(0)/(0)/(93.7)/(0)	< 0.001
I4	**The HPV vaccine can prevent:**			
	Genital warts/ Cervical cancer/ HIV/ herpes/ I don't know	38/92/0/0/0 (24.1)/(58.2)/(0)/(0)/(0)	77/150/0/0/0 (48.7)/(94.9)/(0)/(0)/(0)	< 0.001
I5	**What is the main side effect of the HPV vaccine?**			
	Vomiting/ Pain at blow site/ Headache/ Joint pain/ I don't know	0/68/0/0/1 (0)/(43)/(0)/(0)/(0.6)	0/91/0/0/0 (0)/(57.6)/(0)/(0)/(0)	< 0.001
I6	**HPV affects only women?**			
	Yes / No	130/28 (82.3)/(17.7)	97/61 (61.4)/(38.6)	< 0.001
I7	**The HPV can be asymptomatic?**			
	Yes / No	52/106 (33)/(67)	25/133 (15.8)/(84.2)	< 0.001
I8	**Is HPV one of the most common sexually transmitted infections?**			
	Yes / No	64/94 (40.5)/(59.5)	32/126 (20.2)/(79.8)	< 0.001
I9	**The uterine cervix smear can detect the HPV virus?**			
	Yes / No	53/105 (33.5)/(66.5)	22/136 (13.9)/(86.1)	< 0.001
Items assessing perceived severity				
I10	**Is HPV embarrassing?**			
	Strongly disagree (1 to 3)/ Agree (4 to 6)/ Strongly agree (7)	62/80/16 (38.6)/(49.4)/(9.5)	59/76/23 (37.5)/(48.3)/(14.2)	0.136
I11	**Could HPV prevent a woman from getting pregnant?**			
	Strongly disagree (1 to 3)/ Agree (4 to 6)/ Strongly agree (7)	46/89/23 (28.8)/(56.5)/(14.7)	33/105/20 (20.9)/(66.5)/(12.5)	0.062
I12	Could HPV damage relationships with short-term partners?			
	Strongly disagree (1 to 3)/ Agree (4 to 6)/ Strongly agree (7)	53/86/19 (33.5)/(54.5)/(19)	42/95/21 (26.6)/(60.1)/(13.3)	0.187
I13	Could HPV interfere with long-term partner relationships?			
	Strongly disagree (1 to 3)/ Agree (4 to 6)/ Strongly agree (7)	46/91/21 (28.7)/(57.8)/(13.5)	25/104/29 (15.8)/(65.8)/(18.4)	< 0.001
I14	Could HPV cause long-term damage to a woman's physical health?			
	Strongly disagree (1 to 3)/ Agree (4 to 6)/ Strongly agree (7)	24/94/40 (15.2)/(59.5)/(25.3)	9/107/42 (5.7)/(67.7)/(26.6)	0.022
I15	Could HPV affect a woman's mental health?			
	Strongly disagree (1 to 3)/ Agree (4 to 6)/ Strongly agree (7)	64/71/23 (40.5)/(44.9)/(14.6)	39/88/31 (24.4)/(56)/(19.6)	< 0.001
Items assessing perceived susceptibility				
I16	What is the risk of HPV infection without the HPV vaccine?			
	30%/60%/100%	46/81/31 (29.1)/(51.3)/(19.6)	24/45/89 (15.2)/(28.5)/(56.3)	< 0.001
I17	What is the risk of developing cervical cancer without the HPV vaccine?			
	30%/60%/100%	44/70/44 (27.8)/(44.3)/(27.8)	17/47/94 (10.8)/(29.7)/(60.5)	< 0.001
I18	What is the risk of getting genital warts without the HPV vaccine?			
	30%/60%/100%	50/74/34 (31)/(46.2)/(20.9)	26/54/78 (16.5)/(34.2)/(49.3)	< 0.001

▶

Tab. II *(follows)*. Effect of educational intervention video on knowledge, perceptions, and attitudes related to HPV.

Number	Items	Pre-intervention N (%)	Post-intervention N (%)	*p*-value
Items assessing perceived general benefits				
I19	Is it likely that the benefits of the vaccine outweigh the potential side effects?			
	Very unlikely (1 to 3)/ Likely (4 to 6)/ Very likely (7)	43/105/10 (27.2)/(66.5)/(6.3)	34/109/15 (21.5)/(69)/(9.5)	0.053
I20	Is the HPV vaccine effective in preventing HPV infection?			
	Strongly disagree (1 to 3)/ Agree (4 to 6)/ Strongly agree (7)	23/114/21 (14.5)/(72.2)/(13.3)	11/109/38 (7)/(69)/(24)	< 0.001
I21	Is the HPV vaccine effective in preventing genital warts?			
	Strongly disagree (1 to 3)/ Agree (4 to 6)/ Strongly agree (7)	49/101/8 (31)/(63.9)/(5.1)	25/101/22 (15.8)/(70.3)/(13.9)	< 0.001
I22	One of the benefits of the vaccine is the feeling that I've done everything I can to protect myself from HPV.			
	Strongly disagree (1 to 3)/ Agree (4 to 6)/ Strongly agree (7)	34/100/24 (21.5)/(63.3)/(15.2)	18/100/40 (11.4)/(63.3)/(25.3)	< 0.001
I23	Is the HPV vaccine effective in preventing cervical cancer?			
	Strongly disagree (1 to 3)/ Agree (4 to 6)/ Strongly agree (7)	31/108/19 (19.7)/(68.4)/(12)	17/109/32 (10.8)/(69)/(20.2)	< 0.001
I24	Is the HPV vaccine effective in preventing certain types of oral cancer?			
	Strongly disagree (1 to 3)/ Agree (4 to 6)/ Strongly agree (7)	118/36/4 (74.7)/(22.8)/(2.5)	100/55/3 (63.3)/(34.8)/(1.9)	0.007
I25	Is the HPV vaccine effective in preventing the spread of HPV to partners?			
	Strongly disagree (1 to 3)/ Agree (4 to 6)/ Strongly agree (7)	51/92/15 (32.3)/(58.2)/(9.5)	34/105/19 (21.5)/(66.5)/(12)	0.051
I26	Is the HPV vaccine important for your health?			
	Strongly disagree (1 to 3)/ Agree (4 to 6)/ Strongly agree (7)	24/81/53 (15.2)/(51.3)/(33.5)	14/94/50 (8.9)/(59.5)/(31.6)	0.292
I27	One of the benefits of vaccination is peace of mind.			
	Strongly disagree (1 to 3)/ Agree (4 to 6)/ Strongly agree (7)	37/91/30 (23.5)/(57.6)/(19)	17/103/36 (10.8)/(65.2)/(24)	0.006
Items assessing perceived general barriers				
I28	Is it difficult to request the vaccine because it is associated with a sexually transmitted disease?			
	Strongly disagree (1 to 3)/ Agree (4 to 6)/ Strongly agree (7)	57/86/15 (36.1)/(54.4)/(9.5)	50/97/11 (31.7)/(61.4)/(7)	0.614
I29	How much do you think the vaccine costs?			
	Not expensive (1 to 3)/ Expensive (4 to 6)/ Very expensive (7)	35/103/20 (22.2)/(65.2)/(12.7)	38/106/14 (24)/(67.1)/(8.9)	0.587
I30	Is it a waste of time to receive several doses of the vaccine?			
	Strongly disagree (1 to 3)/ Agree (4 to 6)/ Strongly agree (7)	80/75/3 (50.7)/(47.5)/(1.9)	82/69/7 (51.9)/(43.7)/(4.4)	0.516
I31	Is the vaccination painful?			
	Strongly disagree (1 to 3)/ Agree (4 to 6)/ Strongly agree (7)	81/72/5 (51.3)/(45.6)/(3.2)	80/70/8 (50.6)/(44.3)/(5.1)	0.585
I32	Is the vaccine likely to cause significant side effects?			
	Very unlikely (1 to 3)/ Likely (4 to 6)/ Very likely (7)	69/83/6 (43.7)/(52.5)/(3.8)	98/57/3 (62)/(36.1)/(1.9)	< 0.001
I33	I'd be embarrassed if my partner knew I'd had the vaccine.			
	Strongly disagree (1 to 3)/ Agree (4 to 6)/ Strongly agree (7)	101/54/3 (63.9)/(34.8)/(1.9)	99/55/4 (62.6)/(34.8)/(2.5)	0.400
I34	I'd be embarrassed if other people knew I'd had the vaccine.			
	Strongly disagree (1 to 3)/ Agree (4 to 6)/ Strongly agree (7)	106/47/7 (67.1)/(28.5)/(4.4)	113/41/4 (71.5)/(26)/(2.5)	0.045
I35	Vaccination goes against my beliefs.			
	Strongly disagree (1 to 3)/ Agree (4 to 6)/ Strongly agree (7)	118/40/0 (74.7)/(25.3)/(0)	122/34/2 (77.2)/(21.5)/(1.3)	0.758

p-values were calculated using McNemar's test for paired categorical data. Slight discrepancies in sample sizes between pre- and post-intervention responses are due to unanswered items. Only paired responses were included in the statistical analysis for each question.

Tab. III. Intention to receive the HPV vaccine before educational intervention video

		Intention to receive the HPV vaccine			*p*-value
		No	Yes	No response	
Knowledge level	Low	17	28	2	0.44
	Medium	20	60	4	
	High	7	20	0	
Perceived severity of HPV level	Low	15	29	0	0.002
	Medium	25	49	1	
	High	4	30	5	
Perceived susceptibility of HPV vaccine level	Low	12	30	1	0.09
	Medium	27	47	2	
	High	5	31	3	
Perceived general benefits of HPV vaccine level	Low	17	23	3	< 0.001
	Medium	20	61	3	
	High	7	24	0	
Perceived general barriers to HPV vaccine level	Low	6	33	3	< 0.001
	Medium	24	51	2	
	High	14	24	1	

p-values were calculated using McNemar's test for paired categorical data.

Tab. IV. Changes in knowledge scores before and after EIV stratified by academic year.

	Educational background	Pre-intervention	Post-intervention	*p*-value
Knowledge score (±ET)	1st year	3.6 (± 1.6)	5.5 (± 1.7)	< 0.001
	2nd year	4.7 (± 1.3)	6.3 (± 1.2)	0.087
	3rd year	4.3 (± 1.6)	6.8 (± 1.1)	0.031
Perceived severity of HPV score (±ET)	1st year	25.7 (± 6.1)	28.5 (± 5.6)	< 0.001
	2nd year	27.3 (±)	29.7 (± 5.8)	< 0.001
	3rd year	25.5 (± 5.3)	27.6 (± 4.1)	0.011
Perceived susceptibility of HPV vaccine score (±ET)	1st year	1.5 (± 0.4)	2 (± 0.5)	0.001
	2nd year	1.6 (± 0.6)	2.1 (± 0.6)	< 0.001
	3rd year	1.2 (± 0.5)	1.8 (± 0.6)	0.003
Perceived general benefits of HPV vaccine score (±ET)	1st year	39.8 (± 7.8)	44.1 (± 6.5)	< 0.001
	2nd year	44.5 (± 6.5)	46.4 (± 7.4)	0.015
	3rd year	35.7 (± 7.4)	41.7 (± 6.5)	0.005
Perceived general barriers to HPV vaccine score (±ET)	1st year	29.6 (± 6.7)	29.2 (± 7.8)	< 0.001
	2nd year	27.1 (± 6.3)	25 (± 7.2)	< 0.001
	3rd year	27.1 (± 5.7)	26.7 (± 6.1)	< 0.001

p-values were calculated using paired t-tests.

Impact of academic level on response shifts

To examine the influence of academic level on EIV effectiveness, score changes were analyzed by year of study (Tab. IV). All groups showed improvements in knowledge and perceptions. First-year students recorded the highest score increases across most domains.

Participants' acceptability of the HPV vaccine before educational intervention video

108 (68.4%) participants intended to receive the HPV vaccine in the future if made available in Tunisia.

A significant relationship was found between the intention to receive the HPV vaccine and the levels of perceived severity, perceived general benefits of the HPV vaccine, and perceived general barriers to vaccination (Tab. III). However, no statistically significant difference was found with knowledge or perceived susceptibility levels (Tab. III).

Student attitudes toward HPV vaccine availability are summarized in Supplementary Table II.

The place of the HPV vaccine in Tunisia as perception of female students

50.6% of female students believe that the HPV vaccine should be available upon request and reimbursed, while 46.2% think it should be included in the Tunisian vaccination schedule.

Students suggested alternatives to the HPV vaccine, including well-established awareness campaigns aimed at educating younger generations about sexually transmitted diseases (STD) at an early age, along with providing information on prevention methods.

Discussion

This study assessed the impact of an educational video (EIV) on the knowledge, perceptions, attitudes, and acceptability of HPV vaccination among female students at the Higher School of Sciences and Technology of Health in Sfax. The intervention was based on the Health Belief Model (HBM). To our knowledge, this is the first Tunisian study to evaluate such an intervention.

Although HPV vaccination is primarily recommended during adolescence, our target population included women aged 18 to 23. Many in this age group may have missed earlier vaccination opportunities. The vaccine remains beneficial in this age range and can still prevent HPV-related diseases. Assessing the views of this population helps guide future public health strategies.

The results show a significant improvement in knowledge and vaccine acceptability after exposure to the EIV. Beliefs related to HPV, cervical cancer, and attitudes toward HPV vaccination were evaluated using a structured self-administered questionnaire based on the five dimensions of the HBM. This instrument was administered both before (pre-test) and after (post-test) the intervention. The proportion of correct answers increased significantly between the pre- and post-intervention assessments.

Item-level analysis revealed substantial gains on questions related to HPV transmission, its link to cervical cancer, and vaccine effectiveness. These findings suggest that the video effectively addressed major misconceptions. However, more limited progress on items concerning HPV screening and its asymptomatic nature highlights areas for improvement in future educational tools.

Knowledge scores increased significantly after the intervention. This suggests a positive impact of the video. However, the absence of a control group limits causal interpretation. Other factors, such as prior exposure to related information or testing effects, could also explain part of the improvement.

Most students understood that the HPV vaccine prevents infection with a virus strongly linked to cervical cancer. Similar improvements were reported in other intervention studies [30–34].

In Africa, various educational and multicomponent strategies have been implemented to promote HPV vaccination [30]. For example, a study conducted in South Africa found high HPV vaccine acceptance among a well-educated cohort of Master of Business Administration students in KwaZulu-Natal [31]. Similarly, Redd et al. showed that educational tools effectively increased HPV vaccine intention in a Christian population in the US [32].

The EIV also reduced common misconceptions. Fewer participants believed that HPV is asymptomatic, affects only women, or can be detected through a cervical smear. Our results are consistent with those mentioned by Drokow et al., who observed that educational videos improved understanding of HPV and cervical cancer among Ghanaian adults [33]. In contrast, Ampofo et al. reported limited change in knowledge following a similar video intervention among high school students in Ghana [34]. This discrepancy may be due to differences in participants' age, educational background, or the format and content of the video used.

Correcting such misconceptions likely contributed to improved knowledge and perception scores. Eliminating false beliefs about HPV symptoms or gender restriction may have increased perceived susceptibility. A better understanding of vaccine efficacy may have reinforced perceived benefits and acceptability.

One factor that may explain the high baseline knowledge in certain areas is the academic background of participants. Thirty-eight percent were enrolled in midwifery programs within–the health science. These students may have had prior exposure to key concepts such as cervical screening, which could explain the relatively high performance on related questions.

The EIV significantly impacted HBM-related scores, especially in perceived severity, susceptibility, and general benefits. However, not all items within the severity dimension improved. Only two items showed statistically significant change. This suggests that participants may have already recognized the seriousness of HPV-related disease before the intervention. Future educational efforts may benefit from shifting focus away from severity and toward misconceptions, perceived susceptibility, and barriers to vaccination. These elements may have greater potential to influence decision-making. Public health actors in Tunisia should consider these insights when designing HPV awareness campaigns.

After the EIV, students showed stronger beliefs in HPV prevention. Scores related to perceived susceptibility and severity also increased. According to the HBM, these two factors combine to form the perceived threat [24].

Adolescents often show heightened awareness of sexually transmitted infections, especially males, and may engage in more risk-taking behaviors [35, 36]. The increase in perceived threat among female students is a positive sign. It may influence future choices related to sexual health. Similar patterns were reported in Egypt [37] and Sweden [38], where educational programs improved perceptions of susceptibility, severity, and benefits.

Subgroup analysis by academic year showed that first-year students gained the most in knowledge and perception scores. These students may be more receptive to structured content. This suggests that timing and tailoring interventions to the student's academic stage could increase impact.

Regarding perceived barriers, scores remained largely unchanged after the EIV. This contrasts with findings by Ebrahim Mahmoud et al., who reported significant improvement in all HBM dimensions after an intervention in Egyptian nursing students [39]. The lack of change may be due to the limited scope of our video. It emphasized disease burden, transmission, and benefits of vaccination. It did not focus on practical or emotional barriers, such as fear of side effects, vaccine access, or social norms. These elements may need to be better addressed in future materials.

Regarding HPV vaccine acceptability, 68.4% of participants reported an intention to receive the vaccine if it becomes available in Tunisia. A previous Tunisian study from 2016 reported a higher acceptability rate of 90% among adolescents and young adult women [40].

We found a significant relationship between the intention to receive the vaccine and three HBM dimensions: perceived severity, perceived general benefits, and perceived general barriers. These associations are in line with other findings [41-46]. Despite these results, our study did not assess whether the changes in knowledge and perception would lead to actual vaccination. Measuring vaccine uptake over time requires longitudinal research. Future studies should explore the long-term behavioral impact of this type of intervention. For example, Kahn JA et al. showed that a higher likelihood of vaccination was linked to greater perceived severity and fewer practical barriers [42]. Our study is the first in Tunisia to examine the relationship between intention to receive the vaccine and perceived benefits among college-aged women. Previous research focused on adult women and parents [43, 44].

We did not find a statistically significant link between knowledge level and vaccination intention. This aligns with earlier studies [45, 46]. This result was expected because intention was measured before exposure to the educational video. In contrast, Jones M and Cook R reported that students who correctly answered two or more knowledge questions were up to eight times more likely to accept the vaccine [41]. Our intervention focused on immediate knowledge gain. We did not assess knowledge retention. Future research should include delayed follow-up to examine whether increased awareness persists and influences long-term decision-making.

Half of the female students in our study believed the HPV vaccine should be available upon request and covered by insurance. Additionally, 46.2% supported its inclusion in the Tunisian national vaccination schedule. These results differ from those of Gamaoun et al., who reported that 90% of adolescents and young adult women favored the inclusion of the HPV vaccine in the national immunization program [40]. The lower support observed in our study may reflect differences in awareness, perceived risk, or attitudes toward vaccination among older students. A more tailored educational model addressing the specific concerns of this age group may improve understanding and acceptance. Future studies should explore targeted interventions adapted to adult women's needs and reservations.

Strengths and Limitations

Our findings suggest that integrating structured educational interventions into academic programs can improve students' knowledge about HPV and its prevention. This can inform broader health education strategies. To our knowledge, this is the first randomized, school-based, face-to-face intervention in Tunisia assessing students' knowledge of HPV and cervical cancer prevention.

Despite the novelty of this study, it is not exempt from limitations. First, it included only female students from a single medical faculty and used a non-interactive video format, limiting the generalizability of the results. Broader studies, including participants from diverse socio-cultural and educational backgrounds, and using more engaging approaches, such as workshops or face-to-face sessions, to improve understanding and retention. Second, the study relied solely on quantitative data. Incorporating qualitative methods, such as focus groups or interviews, could help explain the reasoning behind participants' responses. These approaches would offer deeper insight into beliefs, attitudes, and social factors influencing vaccine acceptance and awareness. Finally, due to logistical and resource constraints, no control group was included. This limits the ability to attribute changes solely to the intervention. Although we observed statistically significant changes, the lack of a comparison group restricts the interpretation of efficacy. Future studies should include control groups to isolate the effects of educational interventions and account for confounding variables.

Conclusion

The EIV improved knowledge, corrected misconceptions, and increased HPV vaccine acceptability. Educational interventions based on health behavior models should be integrated into academic curricula to improve awareness and guide prevention strategies.

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Conflict of Interest statement

The authors declare that they have no conflict of interest.

Authors' contributions

All authors contributed to the design and implementation of the research, to the analysis of the results, and to the writing of the manuscript.

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Correspondence: Lobna Ben Mahmoud, Department of Pharmacology, Faculty of Medicine, University of Sfax- Sfax, Tunisia. Research Laboratory LR19ES10. E-mail: benmahmoud_lobna@medecinesfax.org.

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Supplementary material

Tab. S1. Breakdown of Item-Level Changes in Perceived General Barriers to HPV Vaccination (Pre- and Post-EIV)

Barrier Item	Pre-EIV (n, %)	Post-EIV (n, %)	% Change (Correct Response)
The vaccine is likely to cause significant side effects	89 (56.3%)	60 (38.0%)	↓ 18.3%
I'd be embarrassed if other people knew I had received the vaccine	34 (21.5%)	27 (17.1%)	↓ 4.4%
The vaccine is too expensive	99 (62.7%)	101 (63.9%)	↑ 1.2%
I don't know where to get the vaccine	75 (47.5%)	73 (46.2%)	↓ 1.3%
The vaccine is not effective	41 (25.9%)	29 (18.4%)	↓ 7.5%

Tab. S2. Students' Attitudes Toward HPV Vaccine Availability Post-EIV

Statement	Agreement (n, %)
The HPV vaccine should be available upon request and covered by health insurance	80 (50.6)
The HPV vaccine should be included in the Tunisian vaccination schedule	73 (46.2)
I would be willing to receive the vaccine if it became available	108 (68.4)

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HEALTH PROMOTION

Psychometric Evaluation of Iranian Version of Beliefs about Third-Hand Smoke Scale (BATHS-T) in Pregnant Women

MAHSA KHODAYARIAN[1], NOOSHIN YOSHANY[1], SARA JAMBARSANG[2], ZAHRA POURMOVAHED[3],
ZOHREH KARIMIANKAKOLAKI[4]
[1] Department of Health Education and Health Promotion, Social Determinants of Health Research Center, School of Public Health, Shahid Sadoughi University of Medical Sciences, Yazd, Iran; [2] Center for Healthcare Data Modeling, Departments of Biostatistics and Epidemiology, Shahid Sadoughi University of Medical Sciences, Yazd, Iran; [3] Department of Nursing, Research Center for Nursing and Midwifery Care, Non-communicable Diseases Research Institute, School of Nursing and Midwifery, Shahid Sadoughi University of Medical Sciences, Yazd, Iran; [4] Social Determinants of Health Research Center, Shk.C., Islamic Azad University, Shahrekord, Iran

Keywords

Beliefs • hird-hand smoke • Passive smoking • reliability and validity • Smoking prevention • Pregnant women

Summary

Introduction. *Exposure to third-hand smoke (THS) is hazardous for human health, especially for pregnant women. This study aimed at psychometric evaluation of the Iranian version of "Beliefs about Third-Hand Smoke Scale" (BATHS-T) in pregnant women.*

Aims & Methods. *The data collected from 364 pregnant women referring to Yazd health centers. The BATHS scale was translated into Persian, and the stages of adaptation of the BATHS scale in Persian were evaluated with CVR=0.87 and CVI=0.88. Confirmatory factor analysis (CFA) was performed to analyze the construct validity of the scale. Besides, the correlation test was used to evaluate the correlation of categories and subcategories of the scale.*

Results. *The BATHS structural equation model showed a favorable fit as RMSEA value was less than 0.05 and* X^2/df *varied between 2 to 5. Moreover, other indices such as CFI and NFI were more than 90%, indicating the optimal fit of the present model. The correlation between the overall scale of BATHS and its two subcategories was 0.843 (*$p < 0.001$*) and the correlation between health and stability subcategories was 0.886 (*$p < 0.001$*). Since there was a positive and highly significant correlation, the fitted BATHS scale was considered to be structurally consistent with its subcategories. The reliability of the whole scale was 0.86 using Cronbach's alpha coefficient.*

Conclusion. *The Iranian version of the BATHS scale is reliable and valid. This scale provides the required prerequisites for further research and education on third hand smoke exposure. It can also be possibly used in similar studies.*

Implications. *The BATHS scale has innovative aspects based on the real beliefs of participants concerning third-hand smoke. The favorable validity and reliability of the scale makes it possible to use it in similar studies. Hence, a reliable scale of THS beliefs may be a criterion for measuring the desire to reduce exposure to SHS and THS at homes or other private spaces such as cars. Additionally, examining the results among different populations may be useful in identifying high-risk groups to ward off exposure to THS, and groups that are likely to respond positively to interventions that emphasize THS damage.*

Introduction

Smoking is an important risk factor for health and development, and humans are never safe from cigarette smoke [1, 2]. In addition to the high prevalence of smoking as a health problem, the threats caused by cigarette smoke for people exposed to it is a double problem to be contemplated on. Contact with second-hand cigarette smoke (SHS) includes inhalation of cigarette smoke caused by the burning of the cigarette itself and inhalation of smoke exhaled by the smoker [3, 4]. The term Third Hand Smoke is a relatively new concept. This term, first used in 2006, was introduced by Winickoff et al. in 2009 [5]. Third-hand smoke is the residue of nicotine and other chemicals that remain on surfaces and dust for a long time after smoking and are released into the air through reactions with oxidants and other compounds inhaled into the body [6, 7]. Although third-hand smoke has a lower concentration than second-hand smoke, it remains on surfaces for a longer time [7, 8]. In this way, a person is also exposed to third-hand smoke through the skin [9]. Exposure to third-hand smoke is caused by dust and surfaces, inhalation, ingestion, digestion, and dermal absorption of cigarette residues in addition to air inhalation [10, 11]. Dermal absorption is another important method of exposure to dust-bound pollutants [10]. Neonates and young children are more exposed to the effects of third-hand smoke due to playing, crawling, and touching surfaces and floors and touching their mouth [12, 13]. More than 40% of children, 33% of male non-smokers and 35% of female non-smokers are exposed to cigarette smoke round the globe [14-16]. In Iran, exposure to second-hand cigarette smoke was reported as 23% in Mazloumi et al.'s study [17]. In the

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study by Ozmir et al., the belief about third-hand smoke in pregnant smokers was weaker than non-smoker pregnant women, and high education level reduced exposure to third-hand smoke. Believing in third-hand smoke is an important factor in pregnancy [9]. Exposure to cigarette smoke can predispose to ischemic heart disease, respiratory infection, asthma, and lung cancer [15]. Exposure to cigarette smoke is associated with adverse pregnancy outcomes, *i.e.,* complications that attenuate their lifelong health [18]. Chemicals in second-hand smoke damage DNA and contain carcinogens. Animal studies indicated a link between exposure to environmental second-hand smoke and conditions such as prediabetes, asthma, attention deficit hyperactivity disorder (ADHD), asthma, metabolic syndrome, and low birth weight. Third-hand cigarette smoke can cause harmful effects at the gene level and is dangerous for neonates [9]. Pertinent studies have suggested that smoking indoors for just one day exposes people to tobacco toxins for days or even months [19, 20]. THS accumulated in smokers' homes was able to persist even after these homes were left empty for 2 months and then cleaned [21, 22]. The existence of a smoker among the family members [23], lack of knowledge about the effects of contact with cigarette smoke on the fetus and false beliefs are important factors of exposure of pregnant women to cigarette smoke [24]. Studies have demonstrated that education concerning exposure to environmental tobacco smoke is effective in increasing health beliefs in pregnant women and their husbands and reducing exposure to environmental tobacco smoke [25, 26]. Having accurate information regarding THS and its adverse effects can help create a smoke-free environment [27-29]. Nonetheless, there are still very few studies that have examined awareness and attitudes about THS.It is assumed that the "Beliefs about Third-Hand Smoke Scale", *i.e.,* BATHS, can assess the belief in the harmful effects of THS more accurately, and this assessment may be effective in smoking cessation [28]. Haardorfer et al. (2017) conducted a study entitled: "The development of instruments concerning the third-hand smoke beliefs (BATHS). They designed and psychometrically evaluated the 9-item BATHS scale and presented it to researchers as a valid and reliable tool to evaluate THS beliefs [28]. Pregnant women are among the most vulnerable populations when it comes to tobacco smoke exposure, including third-hand smoke (THS). The physiological sensitivity of the fetus, combined with the mother's increased health awareness during pregnancy, makes this group uniquely important. Exposure to THS during pregnancy has been linked to adverse outcomes such as low birth weight, preterm delivery, and developmental disorders [30, 31]. Additionally, pregnancy is recognized as a window of opportunity for behavior change, making this stage ideal for interventions that aim to raise awareness and reduce tobacco-related risks." Since this questionnaire has not been investigated in Iran so far and pregnant women are considered one of the high-risk groups against cigarette smoke, hence, this study aimed at translating and psychometrically assessing properties of Beliefs about Third-Hand Cigarette Smoke Scale on the population of pregnant women as one of the vulnerable groups to promote public and community health in Yazd.

Methodology

The ethical approval of this study (IR.SSU.REC.1402.072) was obtained from the Committee of Ethics in Human Research in School of Health at Shahid Sadoughi University of Medical Sciences.

Participants

The study sample in this methodological study consisted of pregnant women referring to the health centers of Yazd. This study aimed at adapting the THS scale to the Iranian community. Participants were selected with convenient sampling method. The sample size is recommended to be 10 times the number of items in factor analysis [32]. The BATHS scale consists of 9 items. Considering possible subject attrition, data gleaned from 364 people were considered as sufficient for data analysis. After explaining the purpose of the study and obtaining informed written consent, the qualified participants entered the study based on the inclusion criteria. Participants were selected using a convenience sampling method from health centers in Yazd. While this approach facilitated access to the target population, it may have introduced selection bias. Therefore, the findings should be interpreted with caution, as they may not be fully generalizable to all pregnant women in Iran.

Inclusion Criteria

These were: referring to Yazd health centers, absence of smoking cigarettes or tobacco, being in the second trimester of pregnancy onward (This cutoff was chosen for two key reasons: (1) the higher rate of spontaneous miscarriages in the first trimester increases the risk of sample loss, and (2) pregnant women typically begin more regular prenatal care visits during the second trimester, which facilitates participant access and follow-up. This stage also reflects a more stable psychological and physical condition for questionnaire completion), absence of risky pregnancy, residence in Yazd, being a Persian speaker, absence of any speech and hearing disorder, and a willingness to participate in the study.

Exclusion Criteria

These were: termination of pregnancy, smoking cigarettes or tobacco, unwillingness to continue participation in the study, and lack of Iranian citizenship.

Adaptation of BATHS scale to Persian

The Belief about Third-Hand Smoke Scale was developed and standardized by Haardörfer et al. [28]. The Turkish version of this scale has been psychometrically evaluated by Çadırcı et al. [33]. The questionnaire entails 9 items designed with a 5-point Likert scale (completely disagree, disagree, indifferent, agree, & completely agree). The 9-item scale was confirmed with excellent internal consistency using factor analysis. The BATHS scale offers a valid and reliable instrument to the researchers for evaluating THS beliefs (28). The first step in the protocol is translation. Nineitems in BATHS have two categories (health and stability) and use a 5-point Likert scale. First, the instrument was translated into Persian by two English and Persian language experts who were blind to each other; subsequently, the two translations were converted to one version via comparing and adapting them and selecting the most appropriate diction and wording.In the second stage, *i.e.,* the back-translation, the Persian translation was translated again into English by two fluent English native speakers who were blind to each other without knowing the original version of the scale. Then, the two versions were compared and adapted. The best diction and wording were selected to convert them to one version. In the third stage, a collective review was performed where in the review and investigation of the final translation was carried out through consulting with professionals who were skilled in the field of instrument development, psychometric evaluation, obstetric health and midwifery, tobacco, health education and promotion, reproductive health, and addiction studies to better understand the original instrument. After the translation process was completed, the face validity and content validity of the tool were established. For the qualitative (psychometric stage) face validity, the tool was given to 10 pregnant women; of course, these women cooperated with the study only to establish validity. They expressed their opinions on grammar, eligibility, and understanding the items. The required corrections were made. The quantitative and qualitative content validities were established by 20 experts familiar with psychometric evaluation of instruments. To determine the quantitative content validity, the questionnaire was provided to the panel of experts. They were asked to give their opinions concerning content validity ratio (CVR) in three options (it is necessary; it is useful but not necessary, and it is not necessary) and also concerning the qualitative content validity index (CVI) of the questionnaire in four options (not relevant, somehow relevant, relevant, and completely relevant) based on the research goals. Moreover, the qualitative content validity (observance of grammar, the use of appropriate diction and wording, *etc.*) was also examined by 10 experts and finally CVR = 0.87 and CVI = 0.88 were obtained.To evaluate the qualitative face validity, the questionnaire was provided to 10 experts and 20 pregnant women similar to the target group to study it and to assess the items in terms of "simplicity and fluency", "relevance or specificity", and "clarity or transparency". For the content validity stage, a panel of 20 experts was selected using purposive sampling. These experts were selected based on their academic background and research experience in fields such as psychometric evaluation, obstetrics and midwifery, tobacco control, health education and promotion, and addiction studies. They were asked to evaluate each item in terms of necessity (for CVR) and relevance (for CVI) using standard rating scales. For the face validity stage, two groups were involved: **10 pregnant women** from the target population were consulted for qualitative face validity to assess clarity, simplicity, and comprehension of the items. **10 experts** with backgrounds in health education and psychometrics were also asked to review items qualitatively for fluency, clarity, and cultural appropriateness. All suggestions and feedback were integrated before the confirmatory factor analysis stage.

CONFIRMATORY FACTOR ANALYSIS OF BATHS

Confirmatory factor analysis was used to determine the construct validity of Beliefs about Third-hand Smoke Scale (BATHS) using AMOS-24. Furthermore, the correlation between the overall scale of BATHS and its two subcategories and correlation between the subcategories 'health and stability' were also assessed. Then, the reliability coefficients of all scales and categories were calculated with IBM-SPSS22 in terms of internal consistency using Cronbach's alpha for reliability analysis.

ANALYSIS OF DEMOGRAPHIC VARIABLES BASED ON BATHS SCALE

Using the BATHS scale, data collected from 364 participants were explored based on the demographic variables. The correlation between demographic variables and belief and categories was examined. Given the significant correlation between demographic variables and these categories, the homogeneity of the sample for the validity and reliability of the questionnaire was evaluated. Considering the researcher's goals, the score obtained from the BATHS scale was the dependent variable and the "socio-demographic characteristics of participants" was considered as independent variable. Also, participants' beliefs about third-hand smoke were investigated according to independent variables. Given that the socio-demographic variables consist of two groups, independent sample t-tests were used. Additionally, in cases where independent variables consisting of more than two groups were classified, one-way analysis of variance (ANOVA) was performed. Since these analyses are based on parametric tests, parametric test assumptions were examined.

To assess the construct validity of the BATHS scale, confirmatory factor analysis (CFA) was conducted using AMOS 24. The model fit was evaluated using multiple indices including RMSEA, CFI, NFI, and χ^2/df. According to widely accepted criteria, an RMSEA value less than 0.08 indicates an acceptable fit, and values below 0.05 suggest a good fit. Similarly, CFI and NFI values greater than 0.90 are generally considered indicative of a good model fit [32, 34]. In the current study, the RMSEA was 0.076, and both CFI and NFI were above 0.90, indicating that the model demonstrated an acceptable to good fit based on these thresholds. During the CFA, modification indices suggested correlating some of the error terms between items within the same subscale. Such modifications were made cautiously and

Tab. I. Comparison of BATHS scores (Persistence, Health, Total) across demographic variables.

Demographic Variable	Subgroup	Outcome Variable	Mean ± SD	p-value
Education (Women)	Literacy	Persistence	14.88 ± 2.35	0.137
		Health	17.59 ± 3.04	
		Total Score	32.47 ± 4.55	
	Diploma	Persistence	14.73 ± 2.41	0.024
		Health	18.08 ± 2.51	
		Total Score	32.81 ± 4.27	
	College and above	Persistence	15.31 ± 2.72	0.031
		Health	18.67 ± 3.18	
		Total Score	33.99 ± 5.16	
Education (Men)	Literacy	Persistence	14.91 ± 2.32	0.015
		Health	17.70 ± 2.68	
		Total Score	32.61 ± 4.75	
	Diploma	Persistence	14.58 ± 2.58	0.001
		Health	17.61 ± 2.63	
		Total Score	32.18 ± 4.56	
	College and above	Persistence	15.43 ± 2.56	0.001
		Health	19.00 ± 2.97	
		Total Score	34.43 ± 4.68	

Tab. II. The amount of exposure to indirect cigarette smoke.

Items		n = 364	
		n	%
Do you allow others to smoke in your home?	Full ban	164	45.1
	No ban	71	19.5
	Partial ban	129	35.4
Do you smoke yourself?	Yes	31	8.5
	No	333	91.5
Does your spouse smoke?	Yes	86	23.6
	No	278	76.4
How many cigarettes does he smoke in a day and night?	Null	38	10.4
	1	16	4.4
	2-5	54	14.8
	6-10	29	8.0
	>10	30	8.2
How many cigarettes does he smoke in a day and night inside the house or in the car and near you?	Null	28	7.7
	1	17	4.7
	2-5	18	14.9
	6-10	15	4.1
	>10	51	14.0

only when theoretically justified. Specifically, error co-variances were added between items that shared similar content or wording, reflecting possible overlap in meaning or participant interpretation. According to Byrne (2010) and Kline (2016) [32, 35], correlating error terms is acceptable if items measure closely related constructs or if the shared variance is due to similar phrasing or content proximity, which is often the case in psychometric tools assessing attitudes or beliefs. In our model, these adjustments improved overall fit without violating the underlying theoretical structure of the BATHS scale, which consists of two conceptually coherent subscales ("persistence" and "health").

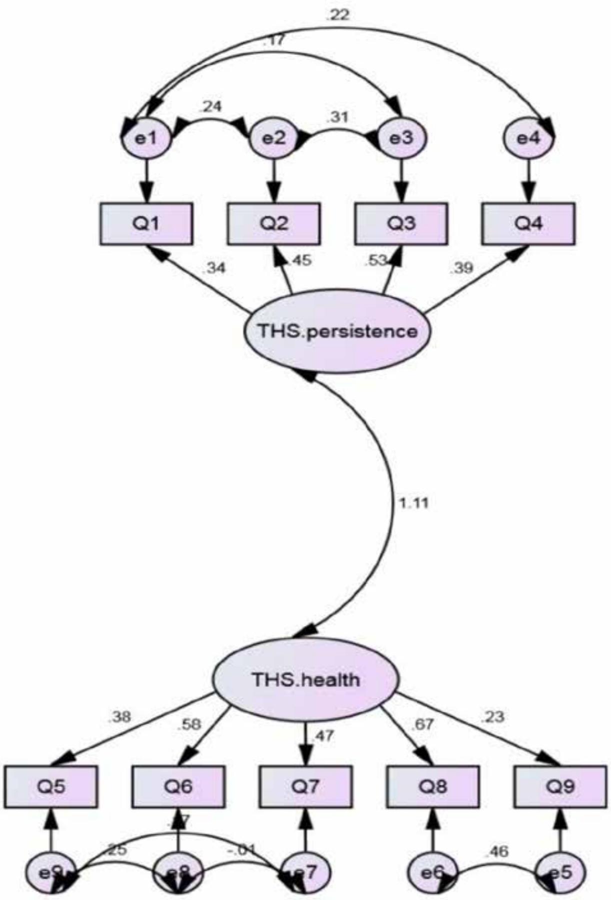
ETHICAL APPROVAL

Ethics approval for this research was granted by Research Ethics Committees of School of Public Health- Shahid Sadoughi University of Medical Sciences, Yazd-Iran (Approval ID: IR.SSU.SPH.REC.1402.072).

Results

In this study, 364 pregnant women aged 14-54 years were examined with the mean age of 28.26 years and a standard deviation of 6.423. The mean and the standard deviation of the age of their husbands was 32.84 ± 6.871. The correlation between "demographic variables" and "belief and its categories" was examined. Due to the absence of any significant correlation between most demographic variables and these categories, it was inferred that a homogeneous sample was intended for establishing the validity and reliability of the questionnaire (Tab. I). The information on the amount of exposure to indirect cigarette smoke is displayed in Table II. Subsequently, confirmatory factor analysis was used to determine the construct validity of Beliefs about Third-hand Smoke Scale (BATHS) using Amos24. Based on the information presented in Table III, it is observed that in all correlations, the determined loads are approved on the general factor. All regression weights of the items were significant. Examination of the model fit indices suggested that some indices have obtained the required quota for the model's fit; yet some of the indices did not obtain the required quota with very subtle difference. Although the software suggests the correlating of the items error without considering the subscale, nonetheless, to observe the factorial structure of the questionnaire, only the common items and a subscale were correlated, reasoning that some of these items may share and assess common concepts (Fig. 1). Thus, due to the model modification indices and the addition of some covariance statements between the error variables, all indices obtained the required quota for the model fit, and the modified factor analysis model acquired good fit. Based on the results, the BATHS structural equation model showed good fit because the RMSEA value was less than 0.05 and the χ^2/df was between 2 to 5. Besides, other indices such as CFI and NFI should be more than 90%, indicating the favorable fit of the present model (Tab. III). The results revealed that the correlation between the overall BATHS scale and its two subcategories was 0.843 ($p < 0.001$) and the correlation between the subcategories of health and the stability was 0.886 ($p < 0.001$). Since there was a positive and significant statistical correlation, the BATHS scale was structurally consistent with its subcategories. The total reliability of the scale was 0.86 using Cronbach's $_{\alpha}$ coefficient. The internal correlation of the first category was 0.745 and that of the second category was 0.81. The values obtained were above 0.70 and showed a statistically positive and significant correlation ($p < 0.001$).

Fig. 1. Confirmatory factor analysis of a scale assessing Beliefs about Third-Hand Smoke (BATHS).



Summary of Psychometric Properties of the BATHS Scale:

- Internal Consistency: the Cronbach's alpha coefficient for the overall scale was 0.86, indicating good internal consistency. The alpha values for the two subscales were 0.745 (Persistence) and 0.81 (Health), both above the acceptable threshold of 0.70;
- Factor Structure: Confirmatory Factor Analysis (CFA) supported the two-factor model of the BATHS scale (Persistence and Health). The model demonstrated acceptable fit indices: RMSEA = 0.076, CFI = 0.941, NFI = 0.918, and χ^2/df = 3.10, all within recommended thresholds (34,35);
- Inter-correlations: the correlation between the two subscales was 0.886 ($p < 0.001$), and the correlation between each subscale and the total score was also high (0.843, $p < 0.001$), indicating strong structural coherence within the scale.

Discussion

Smoke-free air policies are still being implemented in private and public spaces in different communities. Having a proper perception of third-hand smoke and its impact on individual health can play an important role in warding off cigarette smoke damage. Thus, this study aimed at translation and psychometric evaluation of "Beliefs about Third-hand Cigarette Smoke Scale" on the population of pregnant women as one of the vulnerable groups in promoting public and community health in Yazd.While earlier research used a specified item to measure beliefs about third-hand smoke [5, 36-38], yet, based on a review of related literature, it is inferred that BATHS can be used as a valid and reliable document [28]. Haardörfer et al. (2017) conducted a study entitled: "Development of Beliefs about Third-hand Cigarette Smoke Scale". A list of 19 cases related to THS was produced by an expert panel and tested in an experimental study.Based on the results of exploratory factor analysis, two factors emerged: the persistence of THS in the environment and the impact of THS on health; also, the scale was reduced to 9 items, indicating that it made no difference; the BATHS scale offers a valid and reliable tool to the researchers for evaluating THS beliefs [28]. In this study, the authors gave BATHS to pregnant women in the Iranian community to perform its psychometric evaluation and cultural adaptation and then assessed the construct validity of the instrument. The results of construct validity using confirmatory factor analysis demonstrated that the scale developed had a good fit in Iranian community. The study by Çadirci et al. (2021), aimed at determining the validity and reliability of the Turkish version of the BATHS using confirmation factor

Tab. III. Model fit indices and items' regression weight after modification of the model.

			Estimate	Standard Regression Weight	S.E.	C.R.	*p*	Model Fit Indexes
Q1	→	THS.persistence	1.000	.336				
Q2	→	THS.persistence	1.341	.449	.242	5.534	***	CMIN/DF: 3.102
Q3	→	THS.persistence	1.768	.534	.316	5.600	***	CFI: 0.941
Q4	→	THS.persistence	1.410	.393			***	RMSEA: 0.076
Q9	→	THS.health	1.000	.227	.274	5.143		NFI: 0.918
Q8	→	THS.health	2.793	.668	.713	3.915	***	
Q7	→	THS.health	1.503	.472	.467	3.220	.001	
Q6	→	THS.health	2.111	.582	.633	3.334	***	
Q5	→	THS.health	1.402	.382	.458	3.062	.002	

analysis, is consistent with the results of the present study [33]. In this study, Cronbach's α coefficient was reported for the whole scale as 0.9, indicating that the internal validity of the Persian version of BATHS was high.The results indicated that regarding the correlation between the whole scale of BATHS and its two subcategories and correlation between subcategories "health and stability", the BATHS scale was structurally consistent with its subcategories, since there was a statistically very positive and very significant correlation.The correlation values between the categories "health and stability" were over 0.70 and were statistically positive and significant ($p < 0.001$). This instrument has been used in various studies due to its validity. For instance, in the study by Özpinar et al. (2022) aimed at investigating pregnant women's beliefs about third-hand smoke and exposure to tobacco smoke in Turkey, the mean score of the BATHS-T scale was 859.0 ± 79.3. There was a significant relationship between the mean score obtained from the BATHS-T scale and variables such as education and smoking status. As the level of education increased, exposure to third-hand smoke decreased ($p < 0.05$). The mean score of pregnant female smokers obtained from the BATHS-T scale was less than non-smoker pregnant women [9]. In the present study, it is concluded that most of the participating samples were homogeneous due to absence of any significant correlation between demographic variables with categories of BATHS scale. As it is displayed in Table I, merely education level of husbands showed a significant correlation with BATHS categories; this is consistent with the results of other studies [9, 28]. Furthermore, the results of a descriptive cross-sectional study by Xie et al. (2021) aimed at determining the beliefs and behaviors of elementary children's parents about third-hand smoke using BATHS in Shanghai, China, showed that women, younger people, and people with higher income and higher education believed more than others that third-hand smoke exerted some effects on the health and continued smoke in the environment.Participants whose children suffered from respiratory diseases in the past six months gained higher scores of BATHS scale. The results also showed that when smokers lived together more frequently, they gained a lower score than BATHS [39]. In a cross-sectional descriptive study by Köksoy et al. (2023) aimed at investigating the views of parents with disabled children and parents with healthy children about third-hand smoke, the results revealed a statistically significant difference in the mean BATHS Health and BATHS Persistence between the two groups.The mean scores of BATHS Health and BATHS Persistence in parents with disabled children were lower than parents with healthy children. Presence of laws banning smoking in the environment in which they live was such that there was law for 62 people (63%), there was relatively law for 10 people (10%), and there was no law for 27 people (27%). More than half of the research community observed the laws of the use of tobacco in their place of residence. The authors stated that, in particular, the opinions of parents with disabled children about THS should be integrated with basic public health approaches and sufficient information on this issue ought to be provided to them [40]. Previous studies have shown that THS is present on the clothing, skin and hair of smokers as well as on home surfaces such as walls, beds, benches, rugs and tables. Therefore, exposure to THS is not without risk. In addition to non-smoker adults, children are more susceptible to THS because they spend more time indoors and hand-to-mouth behavior increases leading to their enhanced chances of exposure [41]. In this regard, the results by Shehab et al. (2021) aimed at exploring parents' beliefs about cigarette smoke and its association with home smoking laws in Kuwait suggested that most participants believed that being exposed to THS damages children (67.2%) and adults (60.6%) and that the THS residue can remain in the environment for days (58.9%). The prevalence of severe cigarette ban at home increased with total increase in THS (APR_{q4} *vs* Q1=1.48; 95% CI: 1.12-1.96), Health (APR_{Q4} *vs* Q1 = 1.22; 1.02-1.45), and persistence (APR_{q4} vs Q1=1.55; 1.17-2.05) [42]. Based on results of the above studies, it is important to note that pregnant women's awareness of this issue has been increased and that training measures to promote smoke-free homes are designed and implemented. This is because understanding the vulnerability and constant beliefs of parents about THS is accompanied by a severe ban on cigarette smoking at home, thereby providing a safer environment for children and non-smokers. People's beliefs about second-hand and third-hand smoke in Iran are influenced by several cultural, social, and religious factors. In recent years, Iran has implemented strict regulations to reduce tobacco consumption, including bans on cigarette advertising and restrictions on smoking in public places. These policies can increase public awareness of the dangers of tobacco smoke and influence people's perceptions (2). Smoking is considered an accepted behavior in certain social groups, while among others – especially women – it is less common. These social differences can affect the level of acceptance of the risks associated with second-hand and third-hand smoke. Some Islamic teachings emphasize the importance of individual and public health and regard smoking as a harmful practice. This perspective can contribute to reducing tobacco consumption and increasing sensitivity to the dangers of second-hand and third-hand smoke. The concept of third-hand smoke is still unfamiliar to many people; however, studies have shown that public awareness is gradually increasing. The expansion of research and awareness campaigns can help change people's beliefs over time [43].

We have compared the findings of the Iranian version with the original and Turkish versions of the BATHS scale to assess its compatibility within the Iranian population. In our psychometric and statistical analyses, some minor differences were observed between the Iranian and Turkish versions, which may be attributed to cultural and linguistic variations. Specifically, certain beliefs regarding third-hand smoke in Iran might be influenced by public health policies, social norms, and religious teachings, which could explain these differences. To analyze these variations, reliability and validity tests were conducted. Additionally, mean score comparisons across different samples were performed to determine whether these differences are statistically significant. Given the observed differences, we suggest further research into the cultural and social influences on beliefs about third-hand smoke in Iran to achieve a more comprehensive understanding of this phenomenon.

Conclusion

Generally speaking, according to the findings of the present study, the BATHS scale has innovative aspects based on the real beliefs of participants concerning third-hand smoke. The favorable validity and reliability of the scale makes it possible to use it in similar studies. Nevertheless, further studies need to be conducted to strengthen the psychometric aspects of the questionnaire. Hence, a reliable scale of THS beliefs may be a criterion for measuring the desire to reduce exposure to SHS and THS at homes or other private spaces such as cars. Additionally, examining the results among different populations may be useful in identifying high-risk groups to ward off exposure to THS, and groups that are likely to respond positively to interventions that emphasize THS damage. Physicians can use this scale to conceptualize intervention experiences to increase understanding of how THS works in smoke-free homes, which can diminish carcinogenic agents in environments where smoking or SHS invasion is still a problem.

Limitations of the Study

The limitations of the present study can be mentioned as follows: since this study was carried out only on pregnant women, so the findings cannot be generalized to other age and sex groups. Moreover, conducting a study in a traditional society makes it difficult to generalize the results to a more modern community. This issue deserves special attention. Another point is that the researcher-made instruments are usually compared with similar available tools to clarify its discriminative and evaluative power. Yet, as there was no similar tool available in this study with acceptable validity and reliability, so the predictive validity and concurrent validity were not established.

The limitations section has been expanded to include a discussion on social desirability bias and the limitations of self-report measures. Since smoking during pregnancy is a sensitive topic, some participants may have adjusted their responses based on social norms or cultural expectations (social desirability bias). This issue has been acknowledged as one of the study's limitations. Self-reporting tools may lack accuracy, as some individuals tend to underreport their actual smoking behavior. To mitigate this limitation, efforts were made in the study design to create an environment where respondents felt more comfortable and encouraged to provide honest responses. It is suggested that, in addition to self-report questionnaires, biochemical methods such as measuring nicotine levels in saliva or blood be incorporated to obtain more precise data. The use of mixed-method approaches for accurately assessing beliefs and behaviors related to third-hand smoke – especially among sensitive groups such as pregnant women – could lead to more reliable findings. *Due to the use of convenience sampling, the study sample may not represent the broader population of pregnant women in Iran. This limitation could affect the external validity of the results.*

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Ethics approval and consent to participate

Ethics approval for this research was granted by Research Ethics Committees of School of Public Health- Shahid Sadoughi University of Medical Sciences, Yazd-Iran (Approval ID: IR.SSU.SPH.REC.1402.072).

Consent for publication

The manuscript contains no individual person's data in any form.

Data availability statement

Statistical data will be available upon request. The data used in this manuscript are not openly available due to restrictions set by the institutional ethics board. The design and analysis plans for the experiments were not preregistered. The list of questions and coding manuals isn't openly available for download. All materials used in the study aren't openly available for download.

Conflict of Interest statement

None declared.

Authors' contributions

MKH, NY, ZP, ZK: project development, and manuscript writing. SJ: data collection and analysis.

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Correspondence: Zhoreh Karimiankakolaki, Social Determinants of Health Research Center, Shk.C., Islamic Azad University, Shahrekord, Iran. E-mail: Zohrehkarimian68@gmail.com.

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HEALTH PROMOTION

What strategic actions may be implemented to reach high immunisation coverage for clinically vulnerable individuals? A process for achieving regional consensus using World Cafè methods

ELISA GABRIELLI[1], VALERIA GABELLONE[2], FABIANA NUCCETELLI[2], PIER LUIGI LOPALCO[2]
[1] Department of Prevention, Local Health Authority, Lecce, Italy;
[2] Department of Experimental Medicine, University of Salento, Lecce, Italy

Keywords

Clinically vulnerable individuals • World Cafè methods • Immunisation coverage • Consensus process • Vaccination programs

Summary

Background and Study Design. *Clinically vulnerable individuals, including the elderly, are at increased risk of adverse health outcomes following infections, due to immunosenescence, chronic inflammation, or underlying medical conditions. Despite measures such as the National Immunisation Prevention Plan and Regional Laws, immunisation coverage for herpes zoster, pneumococcus, and COVID-19 in the Apulia Region has declined in recent years. This study outlines strategic actions to improve vaccination coverage for clinically vulnerable individualss in the region, using methods like the World Café (WoCa) to achieve regional consensus.*

Methods. *On 31st May 2023, a working group of Apulian researchers and healthcare workers, supported by the Regional Immunisation Committee, conducted a workshop. The WoCa method facilitated structured discussions across five thematic domains to generate innovative solutions for enhancing immunisation rates.*

Results. *Key actions included active vaccination reminders in all formats of informed consent and during healthcare visits; improved training for healthcare workers conducting outreach; involving pharmacies in patient guidance alongside general practicioners (GPs) and public health operators; establishing vaccination clinics near specialist centres and employing mobile units; launching media campaigns to counteract misinformation using authoritative voices; providing vaccinology and scientific communication training for professionals; implementing a hub-and-spoke logistics system under the governance by the Department of Prevention (DP); and ensuring seamless communication between digital platforms for vaccine data reporting and monitoring.*

Conclusion. *The findings demonstrate the value of WoCa in achieving regional consensus to enhance immunisation for frail individuals. Collaboration among healthcare professionals, institutions, and the public is vital to raise awareness, improve accessibility, and address logistical challenges, ensuring equitable access to vaccination for vulnerable populations.*

Introduction

Frailty is a clinical syndrome characterised by a decline across multiple physiological systems, leading to reduced homeostatic reserve and heightened vulnerability to adverse health outcomes. While it is especially prevalent among older adults, with estimates indicating that 21% of those over 65 living in the community are frail and another 48% pre-frail, frailty-related mechanisms such as immunosenescence and chronic inflammation can also affect younger individuals with chronic or debilitating conditions. These clinically vulnerable individuals face increased susceptibility to infections, severe disease complications, long-term disability, and mortality [1, 2].

The increased health risks faced by clinically vulnerable individuals represent a significant challenge for public health, particularly for the National Health Service [3]. Primary prevention through immunisation is key to preventing infectious diseases and associated complications in frail individuals [4].

Frail individuals are eligible for specific vaccines aimed at reducing the risk of vaccine-preventable diseases. The National Immunisation Prevention Plan (NIPP) 2020–2025 mandates the provision of free immunisations to cohorts at risk due to health conditions or age. Immunisations recommended for frail individuals include vaccines for herpes zoster, pneumococcus, and COVID-19 [5].

In the Apulia Region, the herpes zoster vaccine was introduced through Regional Law n.885 of 7th June 2017, titled "Piano Nazionale Prevenzione Vaccinale 2017–2019 (PNPV)." This law introduced the live-attenuated virus vaccine (ZVL) for cohorts over 50 years old with specific diseases or health conditions, and for people over 65 years old.

Later, the adjuvanted recombinant vaccine (RZV) was introduced under Regional Law n.1589 of 5th October 2021, titled "Approval of the New Vaccination Calendar for Life of the Apulia Region – edition 2021," aimed at immunocompromised individuals or those

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with other conditions for whom the ZVL vaccine was not recommended. Regional Law n.885 of 7th June 2017 also introduced sequential pneumococcal immunisation with the 13-valent conjugate vaccine (PCV13), followed by the 23-valent polysaccharide vaccine for the elderly and frail individuals at risk of complications. The target was to achieve an immunisation coverage rate of 75%. With the adoption of Regional Law n.1589 of 5th October 2021, this active vaccination offer (PCV-PPV23) was extended to susceptible cohorts aged 6 to 64 years and all individuals over 65 years. Frail individuals were also prioritised in the COVID-19 immunisation campaign. According to the Ministry of Health Circular of 1st January 2023, titled "Measures in place to manage the circulation of SARS-CoV-2 during the 2022–2023 winter season," an additional COVID-19 vaccine dose was guaranteed for individuals aged over 65 and frail individuals with specific diseases.

Despite these measures, immunisation coverage for herpes zoster, pneumococcus, and COVID-19 in the Apulia Region has been declining, reflecting the national trend. After more than five years of recommendations and operational measures aimed at increasing immunisation coverage, acceptance of the ZVL vaccine remains low [6]. Additionally, pneumococcal immunisation coverage is similar to that for influenza, around 30% [7]. COVID-19 immunisation coverage reached 85% in the first booster dose campaign, but only 18% in the second booster dose campaign [8].

The aim of this study is to describe how the process of reaching regional consensus can lead to concrete strategies for improving vaccination coverage among clinically vulnerable people in Apulia Region, using the participatory method of the World Café.

Methods

On 31st May 2023, a spontaneous working group composed of Apulian researchers and healthcare workers, supported by the Regional Immunisation Committee, organised a workshop aimed at developing a Regional immunisation programme specifically for clinically vulnerable individuals, focusing on Herpes-zoster, Pneumococcus, and COVID-19. The participants included a wide range of healthcare professionals, such as Medical Doctors, General Practitioners, Pharmacists, as well as representatives from professional bodies, political institutions, and trade unions. A total of thirty-four participants were divided into groups to take part in the World Café (WoCa) methodology.

The WoCa is an innovative collaborative method designed to facilitate dynamic, informal discussions on complex topics, encouraging open dialogue and idea generation [9]. This approach encourages participants to explore solutions in a relaxed yet structured environment, stimulating creativity, shared learning, and co-creation. Participants gather around small round tables, each dedicated to a specific topic. Each table is moderated by facilitators who guide the conversation, while ideas and insights are recorded on sheets of paper. After each round of discussion, participants rotate to new tables, allowing them to build upon the ideas generated by previous groups. This rotation process stimulates diverse thinking and helps to connect various perspectives, enriching the overall discussion. The WoCa methodology is particularly effective in engaging a variety of participants, promoting collaboration across different disciplines, and reaching consensus on shared goals [9].

In the context of this workshop, the WoCa provided a productive and inclusive space for participants to collaboratively explore strategies for improving immunisation coverage among clinically vulnerable individuals. The methodology facilitated an in-depth exchange of ideas, leading to the identification of key actions and the formulation of a shared vision for enhancing vaccination efforts within the region.

The participants of the WoCa were divided into five groups to discuss five specific domains, each assigned to a different table. Each thematic table was moderated by two facilitators, with one reporter responsible for recording the ideas and concepts that emerged. The tables were round and equipped with sheets of paper and pencils to allow participants to jot down thoughts, considerations, and ideas during the discussions. Five rounds of discussion were held, each lasting 20 minutes, with participants rotating between tables after each round. The total duration of the activity was 1 hour and 40 minutes. Each group had the opportunity to contribute to discussions on all five domains.

The domains discussed during the workshop were as follows:

- **Domain 1**: How can we improve the offer of active immunisation for clinically vulnerable individuals, ensuring patient identification while respecting privacy policies?
- **Domain 2**: How can we increase immunisation acceptance among clinically vulnerable individuals using institutional communication strategies?
- **Domain 3**: Where can we administer vaccines? Expanding vaccination settings to improve coverage.
- **Domain 4:** How can we increase immunisation acceptance among clinically vulnerable individuals through individual counselling?
- **Domain 5**: Vaccine management, from logistics of distribution and storage to data collection.
- The WoCa methodology created an atmosphere that encouraged spontaneous and informal discussions, in an environment similar to that of a café, where participants could freely exchange ideas and perspectives [9].

Every concept that emerged during the discussions was recorded and integrated with ideas from other groups. At the end of the workshop, the concepts were further discussed, and a final consensus document was drafted, shared by all participants. This document captured the collective insights and strategies developed during the meeting. The data collected from the discussions were transcribed into a document and analysed using ATLAS.ti software, which employs artificial intelligence methodologies to provide a qualitative analysis of the content. The software allowed researchers to modify, delete, or create new themes based on the analysis, ensuring a comprehensive understanding of the results [10].

Results

ATLAS.ti categorised transcripts of the dialogues with artificial intelligence into 5 total codes and 24 subcodes (Tab. I). Ultimately, with a corrective manual manager, the following 5 macro-categories were identified and analysed:

- authority,
- communication,
- engagement,
- logistic management,
- vaccinal pathways.

AUTHORITY CATEGORY

The authority category is described as: "*Identification of an authoritative figure in the field to be the face of the informational campaigns*" and "*Informational campaign through national and local TV channels, especially news programs, with a unified direction at the institutional level*".

COMMUNICATION CATEGORY

The communication category is described by the institutional communication "*Identification of an authoritative figure in the field to be the face of the informational campaigns*" and "*Informational campaign through national and local TV channels, especially news programs, with a unified direction at the institutional level*", also shared between stakeholders "*Advertising campaign (TV, radio) previously shared with representatives of the relevant categories of doctors (GPs and specialists)*", by social media "*Use of advertisements on social networks based on target groups (e.g., age, pathology, and place of origin)*", by positive communication in contrast with vaccine hesitancy as *"Spread positive news about vaccinations to counterbalance information regarding side effects"*, by identify professional communicator in public health *"Identify certified communicators who can disseminate information at a national level"* who knows *"The drivers for effective communication"*. Moreover, it is necessary to use *"specific training on effective communication is necessary for the operators"*.

ENGAGEMENT CATEGORY

The engagement category describes "*The specialist could actively propose vaccination, as the patient views them as their primary physician rather than the general practitioner*" and "*Activate a synergy, a system (general practitioners, specialists, pharmacies, etc.) to surround the vulnerable patient and inform them about vaccinations*". Moreover, "*Utilize the call*

Tab. I. Domains, research questions, and discussion points identified through the analysis of dialogues using ATLAS.ti. The table summarises the five macro-categories and their corresponding questions and discussion points, providing insights into optimising vaccination strategies and communication.

Domain	Research Questions	Discussion Points
Authority	*- Who is the most suitable authoritative figure to represent informational campaigns?* *- Which media channels ensure unified and authoritative communication?*	- The need to identify authoritative figures as the faces of campaigns. - Use of institutional channels (TV, news programmes) for coordinated communication. - Ensuring consistency in messaging through national and local campaigns.
Communication	*- How to design effective communication campaigns?* *- How to counter vaccine hesitancy through social media?* *- What is the role of professional public health communicators?*	- Creation of targeted advertising campaigns (TV, radio, social media) for specific groups. - Dissemination of positive news about vaccines to counter misinformation and hesitancy. - Training on effective communication techniques for healthcare professionals and communicators.
Logistics Management	*- What are the main logistical challenges in vaccine management?* *- How to optimise the entire process from distribution to administration?*	- Monitoring all stages of distribution, storage, and data collection. - Improving the cold chain to ensure vaccine efficacy. - Leveraging technology for more efficient management of vaccination data and distribution flows.
Vaccinal Pathways	*- How to design automated and more efficient vaccination pathways?* *- How to improve training for the stakeholders involved?*	- Structuring pathways to automate recalls and reduce the need for active calls. - Engaging and coordinating all stakeholders (specialists, GPs, pharmacists). - Creating an integrated network to improve accessibility and administration of vaccinations.

for COVID doses as an opportunity to suggest other vaccinations that should be administered". "*The role of a reference nurse becomes important, to whom a series of activities and interventions, including active calling, can be entrusted*". To avoid data privacy problems and to take advantage of every singular situation we need to "*Include consent for active calling in every informed consent form and on every suitable occasion*" and "*Pharmacies can be integrated into the information network. A pop-up on the pharmacy software could display information about vulnerable patients. This way, the pharmacist can guide vulnerable patients and provide information on booking the vaccines they need*" and "*The general practitioner could be equipped with a system that, when prescribing a medication to a vulnerable patient, provides information on the vaccines that the patient should receive*". Additionally, "*a vaccination clinic could be set up near the specialist clinics*" and "*Develop a more effective coordination network between Specialists, GPs, Pharmacies, and the Department of Prevention*".

LOGISTIC MANAGEMENT CATEGORY

The vaccine management was discussed in each step "*From distribution and storage logistics to data collection*", by reflecting on all the positive and critical aspects of the current management.

VACCINAL PATHWAYS CATEGORY

The vaccine pathways category considers "*Avoid active calling, but structure a pathway that allows vaccinations to proceed automatically. To achieve this, training involving all stakeholders is needed*" and "*It is not necessary to increase vaccination points, but it is essential to create a network (specialists, GPs, paediatricians, SISP operators, pharmacists, etc.)*" and "*Implement a more effective coordination network between Specialists, GPs, Pharmacies, and the Department of Prevention*".

Discussion

The present study explored strategies to enhance immunization coverage among clinically vulnerable individuals in the Apulia Region, using innovative methods such as WoCa [11], to reach a consensus among key healthcare stakeholders. The results highlighted the importance of a collaborative and multi-professional approach, such as the WoCa method, to identify several shared actionable recommendations, for increasing vaccination uptake among vulnerable groups.

One of the primary strategies, emerging from this study, was the crucial role of implementing active calls and engaging healthcare professionals, such as general practitioners (GPs), specialists, pharmacists and social workers (professional chambers and political representatives or trade union representatives), in delivering immunization information and services. In fact, previous studies have shown that active calls significantly improve immunization rates, particularly when accompanied by personalized follow-ups [12]. Our findings corroborate these results, suggesting that the integration of active calling systems within existing health service structures, such as electronic health records and pharmacy software, could facilitate patient outreach and streamline communication pathways.

The study also identified the need to develop an effective and integrated communication strategy to overcome vaccine hesitancy and misinformation, which have been identified as major barriers to achieving high immunization coverage [13]. A coordinated communication strategy, utilizing authoritative figures and clear, evidence-based messaging across traditional and digital media, was deemed essential to promote trust and adherence to vaccination recommendations. This finding is consistent with the recommendations of the World Health Organization (WHO) on the use of strategic communication to counter misinformation and promote vaccine confidence. Moreover, socio-health professionals, who carry out vaccination counseling with citizens, must be well trained in the field of scientific communication [14].

Additionally, the study emphasized the role of multi-disciplinary networks in improving access to vaccination services as described in the Italian Immunization Decrees. The establishment of a coordination network involving GPs, specialists, pharmacists, and the Department of Prevention was proposed as a mechanism to enhance vaccine delivery and ensure that frail patients are adequately informed and followed up. The adoption of this network model is in line with international guidelines that advocate for integrated care pathways to optimize healthcare delivery and address the needs of complex patient populations [15].

Logistics and vaccine management also emerged as critical components for improving immunization coverage. The establishment of a hub-spoke distribution system under the governance of the Department of Prevention was suggested to optimize the supply chain and ensure vaccine availability. This recommendation addresses common logistical challenges reported in the literature, such as cold chain maintenance and inventory management, which are essential for maintaining vaccine efficacy and minimizing waste [16].

Despite the strengths of the WoCa methodology, some limitations should be acknowledged. The WoCa method, while effective in fostering open dialogue and generating ideas, may not allow for an in-depth exploration of complex topics due to time constraints. Moreover, participant engagement can be influenced by individual personalities, potentially leading to an imbalance in contributions. Future studies should consider complementary methods, such as Delphi panels or semi-structured interviews, to validate findings and gain deeper insights. Additionally, this study interviewed a relatively small and homogeneous sample, future research with larger, more diverse cohorts is needed to confirm and extend these results.

Conclusion

In conclusion, this study demonstrated the effectiveness of the WoCa approach in generating consensus on strategies to enhance immunization coverage among clinically vulnerable individuals from Apulian stakeholders. The proposed strategies, which include the activation of multi-professional networks, targeted communication campaigns, and optimized logistic management, provide a solid foundation for the development of a comprehensive regional immunisation program. These findings offer valuable insights for policymakers and healthcare providers seeking to improve vaccination uptake and ensure equitable access to preventive healthcare services for vulnerable populations.

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Ethics approval and consent to participate

This study did not require ethical committee approval as it did not involve personal data or identifiable biological samples.

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.

Conflict of Interest statement

The Authors declare that they have no competing interests.

Authors' contributions

EG: contributed to the conception and design of the work, to the analysis and interpretation of data, and wrote the first draft of the manuscript. VG: contributed to the design of the work and to the study administration. FN: 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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Correspondence: Fabiana Nuccetelli, University of Salento, Campus Ecotekne. E-mail: fabiana.nuccetelli@unisalento.it.

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Health Promotion

Comparison of Photoprotection Knowledge, Attitudes, and Practices among Medical and Non-Medical Students at a Peruvian University

MARIANELLA CHAVEZ[1], PATRICIA CARREÑO[1], FABIANA FORTI[1], FRANCO ROMANI-ROMANI[1]
[1] Facultad de Medicina Humana, Universidad de Piura. Lima, Peru

Keywords

Medical students • Radiation Exposure • Health Knowledge, Attitudes, Practice • Skin cancer • Sunscreens

Summary

Introduction. *Skin cancer is one of the most prevalent malignancies worldwide, particularly in countries with high ultraviolet (UV) radiation exposure. Thus, to reduce sun exposure, the early adoption of protection behaviours is essential. In this task, future medical professionals must demonstrate competencies in skin cancer prevention. This study aimed to describe and compare photoprotection knowledge, attitudes, and practices (KAP) among medical and non-medical students.*

Methods. *A cross-sectional study was conducted at a private university in Lima, Peru, involving 624 students from five programs: medicine, industrial and systems engineering, law, psychology, and business administration. Participants were divided into two groups: medical and non-medical students. The Questionnaire on Habits, Attitudes, and Knowledge about Sun Exposure in Adolescence and Adulthood (CHACES), a validated tool to assess sun exposure and protection KAP, was used. Group comparisons were performed using Chi-squared and Mann-Whitney U tests.*

Results. *Participants' average age was 21.09 years old, with 56.1% being female. Medical students scored higher in photoprotection knowledge ($U = 35,853.5$; $p = 0.003$) and reported lower sun exposure ($U = 37,263.5$; $p = 0.028$) than non-medical students. However, no significant differences were observed in photoprotection behaviours ($p = 0.807$) or photoprotection attitudes ($p = 0.238$).*

Conclusion. *Medical students demonstrated greater knowledge and fewer sun exposure habits; however, their photoprotection behaviours did not differ significantly from non-medical students. These findings highlight the need for enhanced educational strategies for skin cancer prevention across all university programs.*

Introduction

Skin cancer is a global public health concern [1], particularly in countries with high ultraviolet (UV) radiation, such as Peru [2]. UV exposure is the primary risk factor for skin cancer, including basal cell carcinoma, the most common [3]; and melanoma, the most aggressive [4]. According to the World Health Organization (WHO), the global incidence of melanoma among adults aged 20-44 was 1.3 cases per 100,000 in 2022, corresponding to 39,126 new cases, with projections rising to 44,600 cases annually by 2025 [5]. In 2012, 75.7% of the 168,000 new melanoma cases worldwide in individuals aged ≥30 were linked to excessive UV exposure, which often begins earlier in life [6]. In Canada, 36% of melanoma cases in individuals aged 20 to 29 were attributable to UV exposure between 16 and 24 years old [7]. Furthermore, this age group also shows the highest prevalence of sunburns and sunbathing, with 53.0% of women reporting sunbathing and 35.5% of men experiencing sunburn in the past year [7]. Despite the availability of photoprotection strategies [8], skin cancer incidence continues to rise, underscoring the need for early preventive interventions [9].

University students represent a young population with varying levels of knowledge, attitudes, and practices regarding sun protection, which do not always translate into effective preventive behaviours [10-13]. Students in health-related programs, such as medicine, are expected to adopt better photoprotection practices, as their training includes education on the risks of UV exposure and the importance of prevention [14]. As future healthcare providers, medical students are expected to play a central role in patient education and the promotion of preventive behaviours at the primary care level [15-18].

Contrary to prior expectations, studies comparing medical and non-medical students have yielded inconsistent findings. In Poland, medical students demonstrated better photoprotection behaviours and attitudes, but no significant differences in knowledge were observed [19]. Similarly, a study in India found no differences in knowledge regarding sun exposure and photoprotection behaviours. Although sunscreen use was slightly higher among medical students (51.3%) than among non-medical students (41.6%), this difference was not statistically significant [20]. In contrast, a study in Malaysia reported that pharmacy students demonstrated greater knowledge, behaviours, and perceptions regarding sunscreen use than medical students [21]. In Peru, several studies have assessed

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photoprotection knowledge, attitudes and practices (KAP) among medical students [10, 22-24]; however, most present some risk bias or did not include direct comparisons with non-medical students. Limitations included non-validated instruments [10] or biased validation processes [22, 23], absence of cut-off points to categorize levels of knowledge or practices [22], and assessments restricted to first-year medical students [23]. The hypothesis of this study, grounded in social cognitive theory [25], is that medical students would exhibit better photoprotection behaviours than non-medical students due to their acquired knowledge, awareness of sun exposure risks, and greater self-efficacy in adopting protective behaviours. This research aimed to describe and compare sun protection KAP among students from different programs at a private university in Lima, offering insights to enhance educational and preventive strategies.

Materials and Methods

Study design and setting

This cross-sectional study was conducted at a private university in Lima, Peru. Lima is located along the central coast of the country, where summer UV index (UVI) range from 7 to 12, classified as high to extremely high risk for health. Data was collected between October and December 2023.

Study population

Participants included students enrolled in the second semester of the 2023 academic year, from the second to fifth years of five academic programs. They were categorized into two groups: medical students and non-medical students. The non-medical group included students from industrial and systems engineering, law, psychology, and business administration programs. Eligible students were required to be 18 years or older and provide informed consent. Those who consented but did not complete the demographic information section or the KAP-related questions were excluded.

Sample size

To accomplish our descriptive goal, sample size estimates were calculated separately for medical and non-medical students. Given a population of 259 medical students and 1,309 non-medical students, the reference percentage for wearing long-sleeved shirts and pants (60%) was derived from the Questionnaire on Habits, Attitudes, and Knowledge about Sun Exposure in Adolescence and Adulthood (CHACES) conducted to health science students in Ecuador [11]. This estimate reflects the average percentage of responses regarding photoprotection behaviours and knowledge. A 5% margin of error and a 95% confidence level resulted in sample sizes of 207 for medical students and 575 for non-medical students. The sample selection was non-probabilistic, and participation was voluntary following a detailed briefing about the study.

To assess the significantly different median scores between two independent groups, we estimated the *post hoc* statistical power for the variables sun exposure practices, photoprotection behaviours, photoprotection knowledge, and attitudes toward sun protection. The analysis was conducted using G*Power version 3.1.9.7.

Data collection tool

The CHACES questionnaire for adults validated in Spanish [26] was conducted online through SurveyMonkey platform. A pilot test with 26 students aimed to assess response time, question clarity, and internal consistency. Cronbach's α for the 10 attitude items was 0.859, indicating good reliability. However, the 10 knowledge items initially yielded a Cronbach's α of 0.334, prompting the removal of three items, which improved reliability to 0.477. For sun exposure habits and photoprotection behaviours, the existing items of the original instrument were applied.

Following the pilot test, the instrument was organized into two sections: general information and the CHACES questionnaire. The first section collected data on undergraduate program, age, gender, academic year (second to fifth) and city of origin (Lima – other Peruvian cities). The CHACES questionnaire comprised two items on skin phototype, six on sun exposure habits, six on photoprotection behaviours, ten on attitudes towards photoprotection, and seven on photoprotection knowledge.

Variables of interest

Sun exposure habits were measured through six items: three on the number of days of exposure per year with five ordinal response categories (none = 0, 1-5 days = 1, 6-30 days = 2, 31-90 days = 3, > 90 days = 4) and three on the number of hours per day (none = 0, 1-2 h/day = 1, 3-4 h/day = 2, 5-6 h/day = 3, > 6 h/day = 4). The sum of these items yielded a scale from 0 to 24.

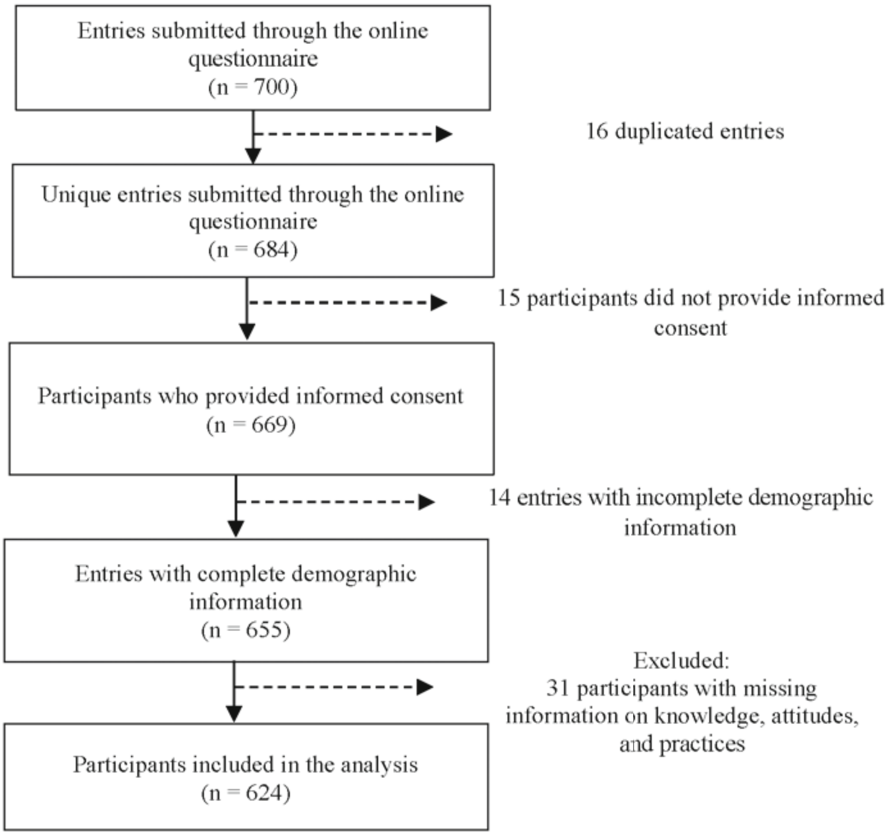
Photoprotection behaviours were evaluated using six Likert-scale items (never = 1, rarely = 2, sometimes = 3, often = 4 and always = 5), with total scores ranging from 6 to 30. Higher scores indicated better behaviours. Attitudes toward photoprotection were assessed using items with five-point Likert scale responses (strongly disagree = 1, disagree = 2, neither agree nor disagree = 3, agree = 4, strongly agree = 5). There were four reverse-scored items, with the sum of scores generating a range of 10 to 50 points. The higher the score, the better attitudes towards photoprotection. Knowledge was assessed with seven true-or-false items, with correct answers receiving a score of 1. The total knowledge score ranged from 0 to 7.

Undergraduate programs were categorized into medicine and other majors (business administration, psychology, industrial and systems engineering, and law).

Survey procedure

Permissions were obtained from each program and the survey was conducted online through SurveyMonkey platform. Participants accessed the survey using a QR code projected in classrooms and a link shared via institutional

Fig. 1. Participant Selection Flowchart.



email. Upon entering the classrooms, the study's purpose was explained and information about the process for informed consent was given. After data collection, results were exported to Excel for exploratory analysis in SPSS version 25 to identify missing or invalid data. No imputation methods were applied for missing data.

STATISTICAL ANALYSIS

Categorical variables were described using frequencies and percentages. Pearson's Chi-squared test was used with a two-tailed hypothesis to compare results between medical and non-medical students for items on sun exposure habits, photoprotection behaviours, attitudes towards photoprotection, and photoprotection knowledge. Likewise, the Mann-Whitney U test was applied to compare the scores for these discrete variables between the two groups. Further comparisons were conducted by academic year within each group using the Kruskal-Wallis test, followed by Dunn's multiple comparisons test when appropriate. Moreover, statistical analysis was performed using SPSS version 25, and GraphPad Prism 10.2.0 was used for graph generation. All statistical tests were performed with a 5% significance level.

ETHICAL CONSIDERATIONS

The study was approved by the Institutional Ethics Committee of the Universidad de Piura (Record No. 06/2023). Data were collected anonymously, and participants provided informed consent before taking part in the survey.

Results

A total of 700 students participated in the online survey. After excluding 16 duplicate entries and applying other selection criteria, the final sample consisted of 624 participants (Fig. 1). Included and excluded students were similar in terms of gender, academic year, major or residence (Tab. I).

SAMPLE CHARACTERISTICS

Industrial and systems engineering, and medical students accounted for 62.2% (n = 388) of the sample. The mean age of participants was 21.09 years, with no significant difference between medical (21.24) and non-medical students (21.02) (*p* = 0.18). Women represented 56.1% of the sample. 69.7% of participants were from Lima, with a higher percentage among non-medical students (73.7%) compared to medical students (61.0%) (*p* = 0.001) Regarding skin types, 35.7% of participants reported having Fitzpatrick skin type II. In addition, 46.5% indicated experiencing painful sunburns the day after exposure without developing a tan within a week. No significant differences were

Tab. I. Comparison of general information between included and excluded students.

Variable	Included		Excluded [a]		
	n	% [b]	n	% [b]	p-value [a]
Gender					
Male	274	43.9	11	35.5	0.356
Female	350	56.1	20	64.5	
Academic Year					
Second	138	22.1	6	19.4	0.404
Third	164	26.3	12	38.7	
Fourth	160	25.6	8	25.8	
Fifth	162	26.0	5	16.1	
Major					
Medicine	195	31.3	10	32.3	0.906
Other Majors	429	68.8	21	67.7	
Residence					
Lima	435	69.7	22	71.0	0.882
Other Peruvian Cities	189	30.3	9	29.0	

[a] Participants with incomplete responses on knowledge, attitudes, or photoprotection behaviours were excluded. [b] Percentages calculated for each column (proportion within the included or excluded group). [c] p-value corresponds to Pearson's Chi-squared test with two-tailed asymptotic estimation.

found in skin types between medical and non-medical students (Tab. II).

SCORE COMPARISON FOR KEY VARIABLES

Medical students had lower scores for sun exposure habits compared to non-medical students (median rank: 289.09 *vs* 323.14; *p* = 0.028). This comparison reached a statistical power of 37.3%. Conversely, medical students demonstrated higher scores in photoprotection knowledge (median rank: 343.14 *vs* 298.57; *p* = 0.003). The pos hoc power was 82.6%. No significant differences were observed in photoprotection behaviours (*p* = 0.807) or attitudes towards photoprotection (*p* = 0.238).

Among non-medical students, no significant differences were observed across academic years in sun exposure habits (*p* = 0.119), photoprotection behaviours (*p* = 0.793), attitudes (*p* = 0.323), or knowledge (*p* = 0.436). In contrast, significant differences were identified among medical students in sun exposure habits (*p* = 0.032) and photoprotection behaviours (*p* = 0.041) (Fig. 2).

SUN EXPOSURE HABITS AND PHOTOPROTECTION BEHAVIOURS

Medical and non-medical students did not differ significantly in specific sun exposure habits or photoprotection behaviours. Outdoor sports and leisure activities were the main sources of exposure, with 25.6% of medical students and 30.0% of non-medical students reporting more than 30 days of exposure per year. The most frequent photoprotection behaviours, reported as 'always' or 'often', were seeking shade (64.6% of medical students *vs* 51.3% of non-medical students) and using sunscreen (49.2% *vs* 57.3%). Notably, a higher proportion of non-medical students reported rarely or never avoiding midday sun compared with medical students (34.0% *vs* 28.2%, *p* = 0.044) (Tab. III).

ATTITUDES TOWARDS PHOTOPROTECTION

Medical and non-medical students showed differences in attitudes towards photoprotection. A higher percentage of non-medical students *agreed* or *strongly agreed* with the statements "I like sunbathing" (51.1% *vs* 39.0%, *p* = 0.019) and "I do not like using sunscreen" (27.0% *vs* 24.6%, *p* = 0.007). They also *agreed* or *strongly agreed* with the statement "I am concerned about spots and wrinkles from sun exposure" (74.4% *vs* 70.8%, *p* = 0.028). Additional comparisons of attitudes towards photoprotection are shown in Table IV.

PHOTOPROTECTION KNOWLEDGE

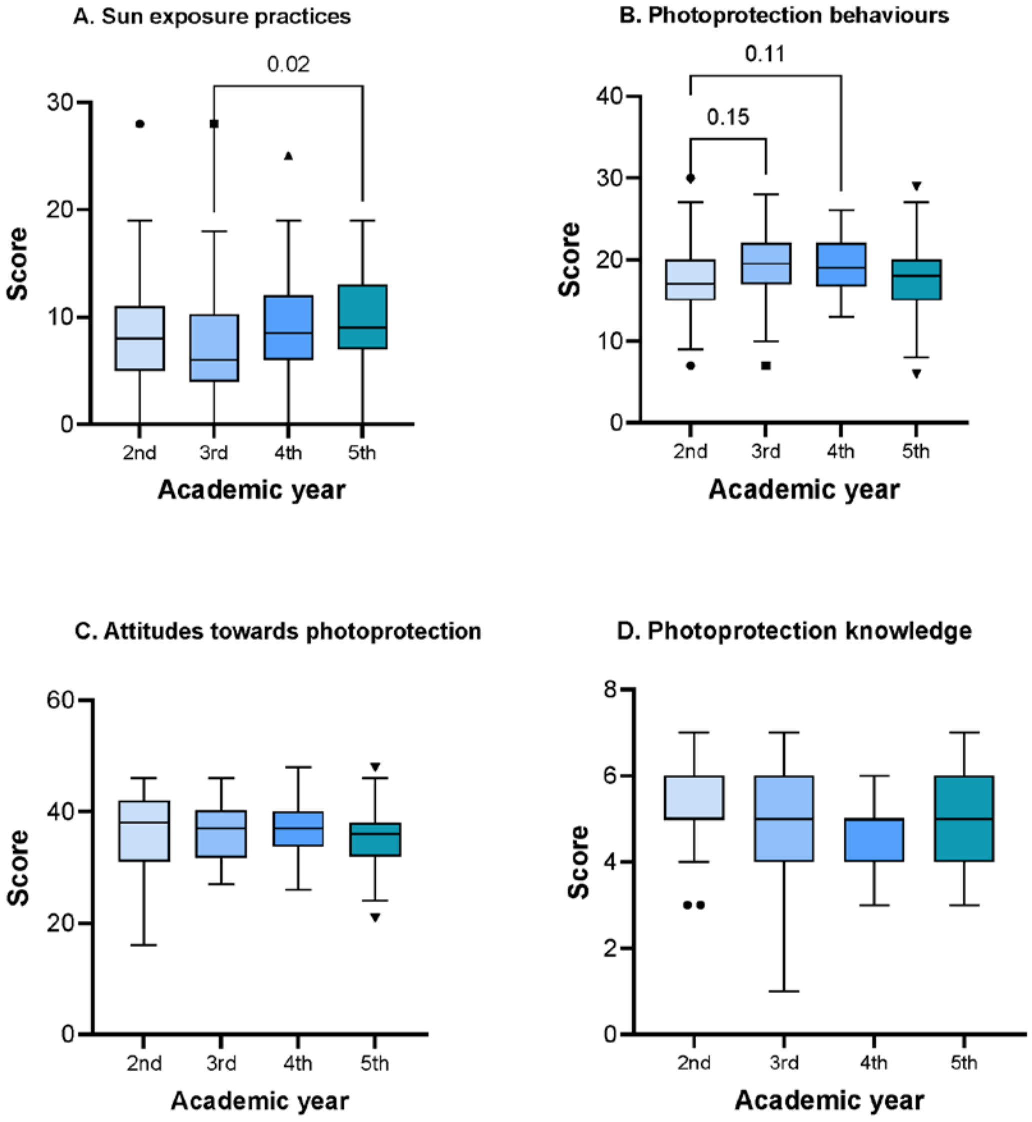
Medical students had a higher percentage of correct answers in photoprotection knowledge, achieving better results on six out of seven questions compared to non-medical students. The exception was the item regarding direct sun exposure for babies under one year old (73.8% *vs* 79.7%), although this difference was not statistically significant. A significant difference was observed in the item about using UV booths before age 30 and the increased risk of melanoma (86.7% *vs* 78.6%, *p* = 0.016) (Fig. 3). In addition, the median knowledge score in both groups was 5 correct answers, however, the interquartile ranges were 4 to 6 in medical students, and 4 to 5 in non-medical students.

Discussion

Medical students demonstrated greater knowledge of photoprotection and reported fewer sun exposure habits compared with non-medical students. However, no significant differences were observed in photoprotection behaviours or attitudes between the groups. These findings highlight persistent gaps in knowledge and sun exposure habits among university students, which appear to be influenced by their major. Providing non-medical students with more preventive information on the risks of sun exposure and skin cancer is essential to enhance awareness and preventive actions from the university setting.

These findings align with studies conducted among medical students in Turkey [27], Arab countries [28], Indonesia [29], Perú [24] which report a better understanding of the risks of sun exposure and related skin diseases among medical students. Nevertheless, despite being exposed to this information during their training, there is still a need to strengthen curriculum content on skin cancer prevention [17]. The relevance of including specific photoprotection topics in curricula is highlighted by a study showing that pharmacy students – who received specific courses on sunscreens as nutraceuticals and cosmeceuticals – demonstrated better knowledge of sunscreen use compared to medical students, who lacked such targeted instruction [21].

Fig. 2. Comparison of scores (Median and Interquartile Range) by academic year among medical students.



A. Sun exposure practices (Kruskal-Wallis H = 8.80, *p* = 0.032), B. Photoprotection behaviours (Kruskal-Wallis H = 8.25, *p* = 0.041), C. Attitudes towards photoprotection (Kruskal-Wallis H = 4.37, *p* = 0.224), D. Photoprotection knowledge (Kruskal-Wallis H = 2.53, *p* = 0.470). The bars represent Dunn's multiple comparisons test with *p*-values below 0.20.

Regarding sun protection knowledge, medical students achieved a higher percentage of correct answers on six out of seven questions compared with non-medical students. Non-medical students were more likely to correctly identify that babies under one year should avoid direct sun exposure, although the difference was not statistically significant. This finding suggests that awareness of sun exposure risks in infants is widely disseminated. A similar study in Ecuador, which applied the same research instrument, reported comparable results, with more than 59% of medical students and faculty answering correctly [11].

The only significant difference in sun protection knowledge between the two groups concerned the use of UV tanning booths before age of 30 and their association with an increased risk of melanoma, with a higher proportion of non-medical students unaware of this risk. Cultural factors may partly explain these differences [29, 30]. For instance, tanning is seen as attractive among young people in Arizona [31 and Peru [10]. In contrast, in Saudi Arabia, Almuqati et al. reported that tanning is not considered as a beauty standard, reflecting greater awareness of its harmful effects [13], a perception also common in Eastern populations [32]. Similarly, France has enforced stricter regulations on tanning booth advertising, particularly by restricting access for minor [33].

Although our findings, consistent with a study from Indonesia [29], showed higher photoprotection knowledge among medical students, prior research has been inconsistent. For instance, a study in India using a five-item knowledge questionnaire found no significant difference

Tab. II. General and skin type information of university students by major.

Variable	**Total**		**Medicine**		**Other Majors**		***p*-value** [a]
	n	**%**	**n**	**%**	**n**	**%**	
Sociodemographic Data							
Major							
Psychology	124	19.9	-	-	-	-	
Medicine	195	31.3	-	-	-	-	
Industrial and Systems Engineering	193	30.9	-	-	-	-	
Law	101	16.2	-	-	-	-	
Business Administration	11	1.8	-	-	-	-	
Age [c]							
Mean (Standard Deviation)	21.09	1.93	21.2	1.79	21.02	1.98	0.180
Gender							
Male	274	43.9	92	47.2	182	42.4	0.267
Female	350	56.1	103	52.8	247	57.6	
Academic Year							
Second	138	22.1	43	22.1	95	22.1	0.287
Third	164	26.3	46	23.6	118	27.5	
Fourth	160	25.6	46	23.6	114	26.6	
Fifth	162	26.0	60	30.8	102	23.8	
City of Origin							
Lima	435	69.7	119	61.0	316	73.7	0.001
Other Peruvian Cities	189	30.3	76	39.0	113	26.3	
Skin Type							
Fitzpatrick Skin Type							
I	82	13.1	21	10.8	61	14.2	0.411
II	223	35.7	66	33.8	157	36.6	
III	191	30.6	71	36.4	120	28	
IV	99	15.9	28	14.4	71	16.6	
V	23	3.7	7	3.6	16	3.7	
VI	6	1	2	1	4	0.9	
Skin Reaction to Sunburn							
I don't get sunburned the following day, but I develop a deep tan within a week	226	36.2	75	38.5	151	35.2	0.863
I get mildly sunburned the following day, and I develop a moderate tan within a week	79	12.7	25	12.8	54	12.6	
I get painfully sunburned the following day, and I develop a slight tan within a week	29	4.6	9	4.6	20	4.7	
I get painfully sunburned the following day, but I develop a tan after a week	290	46.5	86	44.1	204	47.6	
Sunburns							
How many times have you gotten sunburned (redness and pain) in the last year?							
None	148	23.7	58	29.7	90	21	0.065
1-2	292	46.8	92	47.2	200	46.6	
3-5	131	21	33	16.9	98	22.8	
6-10	27	4.3	5	2.6	22	5.1	
More than 10	26	4.2	7	3.6	19	4.4	

[a] The *p*-value corresponds to Pearson's Chi-squared test with two-tailed asymptotic estimation. [b] *p*-value corresponds to Student's T-test. [c] 17 missing data points.

between groups, with medical students answering a mean of 3.1 questions correctly compared to 2.9 among non-medical students [20]. In contrast, a study in Malaysia comparing final-year medical and pharmacy students with a 16-item questionnaire found that pharmacy students achieved a higher proportion of correct responses in 15 of the questions [21]. These discrepancies may be explained by differences in the questionnaires used and the characteristics of the comparison groups across studies.

In our study, both medical and non-medical students reported moderate photoprotection behaviours, mainly sunscreen use and seeking shade. Sunscreen use was reported by 49.2% of medical students and 57.3% of non-medical students, closely aligning with findings from Indonesia (50.5% *vs* 53.3%) [29]. In Malaysian, however, pharmacy students reported higher use than

Tab. III. Comparison of sun exposure habits and photoprotection behaviours by major..

Variable	Medicine		Other majors		*p*-value [a]
	n	%	n	%	
Sun exposure habits					
How many days per year are you exposed to the sun during outdoor activities?					
Swimming at the pool, beach, or other sunbathing spots.					
None	30	15.4	42	9.8	0.298
1-5	71	36.4	152	35.4	
6-30	62	31.8	150	35.0	
31-90	21	10.8	56	13.1	
More than 90	11	5.6	29	6.8	
Outdoor sports and leisure activities					
None	23	11.8	52	12.1	0.620
1-5	51	26.2	111	25.9	
6-30	71	36.4	137	31.9	
31-90	27	13.8	80	18.6	
More than 90	23	11.8	49	11.4	
Outdoor work					
None	94	48.2	177	41.3	0.530
1-5	42	21.5	110	25.6	
6-30	35	17.9	91	21.2	
31-90	16	8.2	33	7.7	
More than 90	8	4.1	18	4.2	
How many hours per day are you exposed to the sun during outdoor activities?					
Swimming at the pool, beach, or other sunbathing spots.					
None	32	16.4	66	15.4	0.938
1-2	80	41	174	40.6	
3-4	63	32.3	139	32.4	
5-6	14	7.2	39	9.1	
More than 6	6	3.1	11	2.6	
Outdoor sports and leisure activities					
None	35	17.9	58	13.5	0.487
1-2	97	49.7	231	53.8	
3-4	50	25.6	112	26.1	
5-6	7	3.6	20	4.7	
More than 6	6	3.1	8	1.9	
Outdoor work					
None	100	51.3	193	45	0.364
1-2	60	30.8	160	37.3	
3-4	28	14.4	58	13.5	
5-6	2	1	10	2.3	
More than 6	5	2.6	8	1.9	
Photoprotection behaviours					
I seek shade (***e.g.***, by using an umbrella)					
Always	39	20.0	66	15.4	0.133
Often	83	42.6	154	35.9	
Sometimes	39	20.0	111	25.9	
Rarely	22	11.3	62	14.5	
Never	12	6.2	36	8.4	
I wear sunglasses					
Always	24	12.3	54	12.6	0.894
Often	40	20.5	80	18.6	
Sometimes	35	17.9	89	20.7	
Rarely	43	22.1	99	23.1	
Never	53	27.2	107	24.9	
I wear a hat or cap					
Always	20	10.3	49	11.4	0.861
Often	41	21.0	102	23.8	

▶

Tab. III (*follows*). Comparison of sun exposure habits and photoprotection behaviours by major.

Variable	Medicine		Other majors		*p*-value [a]
	n	%	n	%	
Sometimes	50	25.6	102	23.8	0.861
Rarely	42	21.5	95	22.1	
Never	42	21.5	81	18.9	
I wear a long-sleeve T-shirt and pants					
Always	15	7.7	49	11.4	0.624
Often	49	25.1	96	22.4	
Sometimes	55	28.2	120	28.0	
Rarely	41	21.0	95	22.1	
Never	35	17.9	69	16.1	
I avoid the midday sun (12:00-16:00)					
Always	22	11.3	31	7.2	0.044
Often	47	24.1	123	28.7	
Sometimes	71	36.4	129	30.1	
Rarely	33	16.9	107	24.9	
Never	22	11.3	39	9.1	
I use sunscreen					
Always	50	25.6	118	27.5	0.223
Often	46	23.6	128	29.8	
Sometimes	54	27.7	98	22.8	
Rarely	28	14.4	62	14.5	
Never	17	8.7	23	5.4	

[a] The *p*-value corresponds to Pearson's Chi-squared test with two-tailed asymptotic estimation.

medical students (47.5% *vs* 36.6%) [21]. These results contrast with studies from India [20] and Poland [19], where medical students showed slightly higher sunscreen use than their non-medical peers.

Both groups reported a low frequency of using additional protection measures, such as hats or caps, sunglasses, and long-sleeved clothing. No significant differences were found between medical [16] and non-medical students [13]. Almuqati et al. observed that 43.1% of non-medical students wore long sleeves and 33.9% used sunglasses [13], while Seetan et al. reported that 9.4% of Jordanian medical students wore hats, 47.3% long sleeves, and 19.1% sunglasses [16]. In India, 38.8% of medical students used hats, umbrellas, or shades for sun protection, compared to 44.1% of students in other majors. Similarly, protective clothing was more frequent among non-medical students (15.3%) than medical students (8.5%), although the difference was not statistically significant [20], consistent with findings Indonesia [29] and Poland [19]. These variations may reflect cultural norms influencing clothing choices and differing levels of sun exposure across countries [13, 16].

A higher percentage of non-medical students reported sun exposure during peak hours (12:00-16:00), the period of greatest radiation. These findings contrast with studies in France [34] and Saudi Arabia [13], where students generally avoided exposure at these times. In Jordan, however, medical students showed high levels of sun exposure despite their knowledge of sun protection [16], revealing a gap between awareness and actual behaviour among both medical and non-medical students. Overall, our results indicate that outdoor sports and leisure activities were the main contributors to sun exposure, particularly among non-medical students, consistent with patterns commonly observed in young adults [35].

Significant differences emerged in three statements related to attitudes towards photoprotection. Over half of the non-medical students preferred sunbathing and expressed reluctance to use sunscreen, despite acknowledging concerns about spots and wrinkles caused by sun exposure. Such rejection of photoprotection practices has been commonly reported [10, 31, 36] and may linked to the discomfort of greasy textures or simply forgetting to apply sunscreen [37]. In contrast, medical students showed more favourable attitudes towards sunscreen use and sun avoidance, likely reflecting their understanding of photoprotection mechanisms, which facilitates greater acceptance of these practices [17]. Economic factors also influence these behaviours, as students from higher-income families or countries tend to use sun protection more consistently [36].

Photoprotection behaviours and sun exposure patterns were broadly comparable between medical and non-medical students. However, the slightly higher exposure observed among non-medical students may account for their greater prevalence of sunburn. Specifically, 22.1% of medical students reported experiencing three or more sunburns in the past year, compared with 32.3% of non-medical students. This difference is consistent with non-medical students' more favourable attitudes toward sunbathing and their less favourable attitudes toward sunscreen use.

A comparison by academic year among medical

Tab. IV. Comparisons of attitudes towards photoprotection by major.

Attitudes	Medicine		Other Majors		*p*-value [a]
	n	%	n	%	
Statement					
I like sunbathing					
Strongly agree	33	16.9	68	15.9	0.019
Agree	43	22.1	151	35.2	
Neither agree nor disagree	50	25.6	87	20.3	
Disagree	34	17.4	67	15.6	
Strongly disagree	35	17.9	56	13.1	
I like being tanned					
Strongly agree	19	9.7	37	8.6	0.776
Agree	28	14.4	77	17.9	
Neither agree nor disagree	62	31.8	132	30.8	
Disagree	39	20.0	91	21.2	
Strongly disagree	47	24.1	92	21.4	
Sunbathing makes me feel good					
Strongly agree	23	11.8	54	12.6	0.127
Agree	57	19.2	160	37.3	
Neither agree nor disagree	52	26.7	104	24.2	
Disagree	32	16.4	69	16.1	
Strongly disagree	31	15.9	42	9.8	
I do not like using sunscreen					
Strongly agree	19	9.7	16	3.7	0.007
Agree	29	14.9	100	23.3	
Neither agree nor disagree	47	24.1	87	20.3	
Disagree	54	27.7	121	28.2	
Strongly disagree	46	23.6	105	24.5	
It is worth using sunscreen					
Agree	178	91.3	396	92.3	0.192
Neither agree nor disagree	10	5.1	28	6.5	
Disagree	2	1.0	2	0.5	
Strongly disagree	5	2.6	3	0.7	
At midday, I prefer seeking shade rather than sun					
Agree	146	74.9	316	73.7	0.481
Neither agree nor disagree	31	15.9	85	19.8	
Disagree	13	6.7	20	4.7	
Strongly disagree	5	2.6	8	1.9	
I am concerned about getting sunburned					
Strongly agree	79	40.5	140	32.6	0.446
Agree	59	30.3	148	34.5	
Neither agree nor disagree	37	19	94	21.9	
Disagree	15	7.7	35	8.2	
Strongly disagree	5	2.6	12	2.8	
I am concerned about spots and wrinkles from sun exposure					
Strongly agree	94	48.2	190	44.3	0.028
Agree	44	22.6	129	30.1	
Neither agree nor disagree	43	22.1	78	18.2	
Disagree	6	3.1	26	6.1	
Strongly disagree	8	4.1	6	1.4	
I am concerned about the risk of skin cancer from sun exposure					
Strongly agree	96	49.2	223	52.0	0.919
Agree	64	32.8	134	31.2	
Neither agree nor disagree	25	12.8	55	12.8	
Disagree	5	2.6	10	2.3	
Strongly disagree	5	2.6	7	1.6	

▶

Tab. IV (*follows*). Comparisons of attitudes towards photoprotection by major.

Attitudes	Medicine		Other Majors		*p*-value [a]
	n	%	n	%	
It is easy to protect myself from the sun by wearing a hat and clothes that cover my skin					
Strongly agree	36	18.5	65	15.2	0.714
Agree	92	47.2	201	46.9	
Neither agree nor disagree	37	19.0	88	20.5	
Disagree	24	12.3	65	15.2	
Strongly disagree	6	3.1	10	2.3	

[a] The *p*-value corresponds to Pearson's Chi-squared test with two-tailed asymptotic estimation.

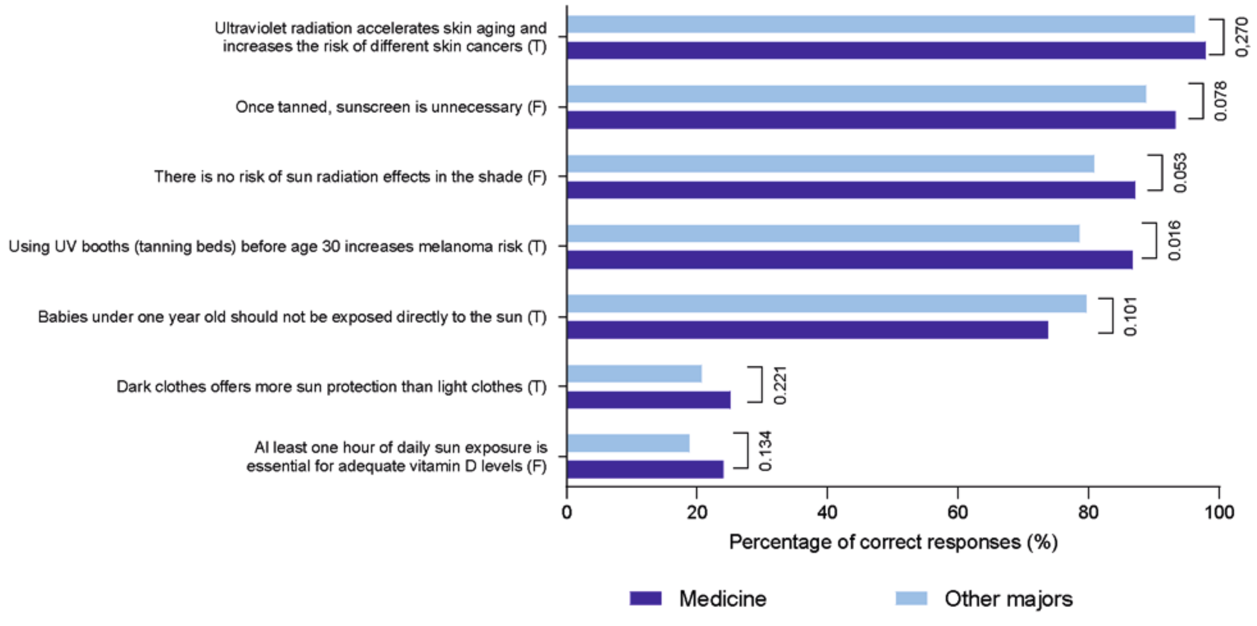
students revealed an increase in sun exposure and a decrease in photoprotection behaviours beginning in the third year. This paradox may reflect the demands of clinical rotations and coursework, which divert attention from self-care despite a certain level of photoprotection knowledge [38]. Similar findings were reported in Indonesia, where 51.7% of medical students cited forgetfulness as the main reason for not using sunscreen, compared to only 29.9% of non-medical students [29].

Attitudes and knowledge did not vary significantly across academic years in either group. Dermatology courses often provide only superficial coverage of sun exposure and cancer prevention, with less than 13 hours allocated in the first four years of medical school in countries such as Spain, England, Canada, United States [15], and Peru. As a result, medical students report low confidence in sun prevention counselling [14], with awareness of sun exposure comparable to the general population [34]. This gap also affects non-medical students, who not only lack formal education on preventing dermatological diseases related to sun exposure but also receive information from health professionals who may not be adequately trained in sun protection counselling.

This study has several limitations. First, the use of a non-probabilistic sampling method and the inability to reach the proposed sample size for non-medical students may limit representativeness. Second, the analysis focused exclusively on one health-related major (medicine), restricting the findings to this subgroup. Third, the research instrument may be subject to biases such as social desirability, recall errors, and reduced engagement due to its length. Moreover, the study did not assess additional factors that could influence behaviour, including barriers and facilitators of sun protection, beliefs about its benefits, and students' self-efficacy. Finally, the study was conducted in a single urban university in Peru, which may limit the generalizability of the results to rural settings or other cities with similar UV radiation levels.

Despite the limitations, this study used a validated

Fig. 3. Comparison of the percentage of correct responses to questions on sun protection knowledge.



The values above the brackets indicate *p*-values derived from Pearson's Chi-squared test with two-tailed asymptotic estimation. The statements are arranged by the percentage of correct answers. T indicates a correct answer as True, and F indicates a correct answer as False.

research instrument in Spanish, enabling comparability with similar studies. Moreover, by analysing differences across academic years within each group, it provides new insights into the development of sun protection capacities among medical and non-medical students.

In conclusion, medical students demonstrated greater knowledge and lower sun exposure compared to non-medical students, although no significant differences were observed in attitudes or protective behaviours. Among medical students, sun exposure and photoprotection behaviours varied across academic years, whereas no such variation was found among non-medical students. These findings reveal persistent gaps in awareness of the harmful effects of sun radiation on young adults' health and emphasize the need for strengthened photoprotection campaigns to standardize knowledge and practices across university programs.

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Conflict of Interest statement

The authors have no conflict of interests related to this study.

Authors' contributions

MC, PC, FF: Conceptualization, investigation, data curation, writing-original draft, writing-review and editing, approval of final version, and responsibility for the paper. FRR: Conceptualization, data curation, formal analysis, supervision, writing-original draft, writing-review and editing, approval of final version, and responsibility for the paper.

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Correspondence: Franco Romani-Romani, Facultad de Medicina Humana, Universidad de Piura. Lima, Peru. E-mail: franco.romani@udep.edu.pe.

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Health Technology Assessment

Mapping the social networks of key actors in the development of health technology assessment in Iran

MEYSAM BEHZADIFAR[1], SAEED SHAHABI[2], AHAD BAKHTIARI[3], SAMAD AZARI[4], BANAFSHEH DARVISHI TELI [5], MOHAMMAD YARAHMADI[6], MARIANO MARTINI [7], MASOUD BEHZADIFAR[1]
[1] Social Determinants of Health Research Center, Lorestan University of Medical Sciences, Khorramabad, Iran; [2] Health Policy Research Center, Institute of Health, Shiraz University of Medical Sciences, Shiraz, Iran; [3] Health Equity Research Center (HERC), Tehran University of Medical Sciences (TUMS), Tehran, Iran; [4] Health Management and Economics Research Center, Health Management Research Institute, Iran University of Medical Sciences, Tehran, Iran; [5] Health Management and Economics Research Center, School of Health Management and Information Sciences, Iran University of Medical Sciences, Tehran, Iran; [6] Department of Medical Parasitology and Mycology, Lorestan University of Medical Sciences, Khorramabad, Iran; [7] Department of Health Sciences, University of Genoa, Genoa, Italy

Keywords

Health Technology Assessment • Social network analysis • Iran • Stakeholder analysis • Health policy

Summary

Background. *Health Technology Assessment (HTA) is vital for evidence-based policymaking and resource allocation. In Iran, HTA development involves diverse actors with varying levels of power, influence, and support. Understanding their interactions is key to strengthening HTA processes.*

Methods. *We applied Social Network Analysis (SNA) to map relationships among 27 stakeholders identified through document review and expert interviews. Data were collected via an online questionnaire completed by 83 experts (response rate: 72.2%), assessing five dimensions: power, position, interest, influence, and support. Network metrics, including degree, closeness, betweenness, and eigenvector centrality, were analyzed using R Version 4.4.1.*

Results. *The Ministry of Health and Medical Education, Food and Drug Administration, Insurance Organizations, and Parliament were perceived as the most influential actors. The Plan and Budget Organization (degree centrality 0.34) and National Institute of Health Research (0.26) emerged as key connectors with high bridging roles. Overall, the network exhibited low density (0.13) and limited clustering (0.11), indicating sparse connectivity. Peripheral actors, such as the Chamber of Commerce, were largely disconnected from the network.*

Conclusion. *HTA development in Iran is shaped by a few central institutions, but weak connectivity and limited engagement of peripheral actors hinder collaboration. Strengthening stakeholder communication, enhancing inclusiveness, and securing sustainable funding are critical for more effective HTA implementation and evidence-informed health policy.*

Introduction

Across health systems, demand for medicines and technologies exceeds available resources, making efficient allocation essential [1]. In low- and middle-income countries (LMICs), this often requires prioritizing cost-effective interventions and protecting vulnerable populations from financial risk [2]. Transparent reimbursement processes and stakeholder engagement not only enhance public trust but also safeguard decision-makers from conflicts of interest [3].

Health Technology Assessment (HTA) has become a cornerstone of evidence-informed health policy by systematically evaluating the clinical, economic, social, and ethical implications of health technologies [4]. Its success, however, depends not only on methodological rigor but also on the dynamics of the networks of actors that influence its development and implementation [5, 6]. In Iran, HTA has gained prominence as a tool for guiding resource allocation and improving the quality of care [7]. Yet, the process is shaped by a complex web of policymakers, regulators, insurers, researchers, clinicians, and industry representatives [8]. Previous studies have examined the institutional and policy challenges of HTA in Iran, but little is known about how relationships and power structures among these actors influence its trajectory [9]. This gap is critical, as strong or weak linkages between stakeholders can determine whether HTA is effectively institutionalized and integrated into policy.

This study aims to map the social networks of key actors involved in HTA development in Iran using Social Network Analysis (SNA). Specifically, we explore the structure and connectivity of these networks, identify central and peripheral actors, and assess how dimensions of power, interest, influence, position, and support shape HTA processes. By highlighting both strengths and gaps in the stakeholder landscape, this research provides evidence to inform strategies for more inclusive, coordinated, and effective HTA implementation in Iran, with implications for other LMICs facing similar challenges.

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Methods

We used SNA, a method that explores the patterns of relationships and interactions between entities within a network [10]. SNA provides a detailed view of how these connections affect behavior, information flow, and resource distribution. Healthcare systems are intricate networks involving various participants patients, providers, institutions, and policymakers linked through referrals, communication, and collaboration [11]. Traditional approaches often focus on isolated components, potentially missing the complex and interconnected nature of these relationships. SNA allows visualization of these dynamics by mapping the connections among actors [12]. This helps identify key nodes (*e.g.,* influential organizations) and understand how information and resources circulate. It also highlights critical areas for intervention and opportunities for improved communication or resource allocation [13]. By analyzing the roles of central and peripheral actors, SNA can guide strategies to enhance coordination and efficiency across the system.

IDENTIFICATION OF KEY ACTORS

To ensure data validity, we employed multiple sources, including interviews, questionnaires, and document review. First, we examined reports, legal documents, scientific articles, and other HTA-related publications. Official sources, such as Ministry of Health reports, outputs from research institutions, and documents from international health organizations, were prioritized.

Next, we conducted in-depth interviews with 13 HTA experts to identify influential actors in HTA development and institutionalization. Participants were purposively selected using snowball sampling, ensuring diversity in gender, academic background, employment status, and executive experience. Each interview lasted 15–30 minutes and was conducted between January and March 2024 by two trained researchers (one with a PhD in health policy, the other in health economics). Interviews were carried out in person or via Skype, transcribed verbatim, and analyzed to capture the roles and relationships of different actors. Finally, we compiled a comprehensive list of actors from both document review and interviews. Duplicates were removed, and the final list included government institutions, regulatory agencies, insurers, universities, research centers, and professional associations involved in HTA policymaking, implementation, or research.

DATA COLLECTION

We created a questionnaire featuring a list of key actors. A structured questionnaire was developed for this study to assess the perspectives of key stakeholders on the development of HTA in Iran. The questionnaire consisted of five items evaluating power, position, interest, influence, and level of support. Since no validated questionnaire addressing these specific dimensions of HTA development in Iran was available, we designed a new questionnaire tailored to the study objectives. The questionnaire was developed based on a literature review and expert consultations, ensuring content validity. It was then pretested with a small group of experts to refine clarity and relevance before distribution. The final English version of the questionnaire is provided as a **Supplementary 1**. Participants were asked to score each factor on a scale from 1 to 10, with 1 representing the minimum and 10 representing the maximum. As a pilot test, the questionnaire was shared with 5 experts in the field of HTA to gather their feedback. Their expertise was used to refine the questionnaire, making any necessary corrections before finalizing it. The internal reliability of the questionnaire was assessed using Cronbach's Alpha coefficient, which yielded a value of 0.87. Additionally, we utilized triangulation and involved multiple researchers in the data analysis to enhance the robustness of our findings. A secure link to the questionnaire was emailed to 115 experts in Iran's health system who were knowledgeable about health technology assessment. Detailed instructions on how to complete the questionnaire were provided, and consent was obtained from each participant, with assurance that their responses would be kept confidential by the researchers. The questionnaires were gathered between April 2024 and June 2024.

STATISTICAL ANALYSIS

SNA metrics were used to describe both network structure and individual actors.

Network structure metrics:

- *Density* quantified the proportion of realized connections.
- *Diameter* measured the longest shortest path between two nodes, reflecting maximum distance.

Actor-level metrics:

- *Degree centrality* reflected the number of direct connections.
- *Closeness centrality* indicated how quickly a node could access others, based on average shortest path length.
- *Betweenness centrality* assessed a node's bridging role in the network.
- *Eigenvector centrality* measured prominence by weighting connections to highly central nodes.

All metrics were normalized to allow comparison across actors. Data were organized in Excel and analyzed in R (Version 4.4.1) for both calculation and visualization of network properties.

Results

Twenty-seven actors were identified during the review of documents and interviews, as follows: Ministry of Health and Medical Education (MoHME), Food and Drug Administration (FDA), Vice Presidency for Science and Technology (VPST), National Institute of Health Research (NIHR), Plan and Budget Organization

(PBO), Insurance Organizations (IO), Social Security Organization (SSO), Universities and Academic Centers (UAC), Medical Council of Iran (Organization of the Medical System) (MCI), Supreme Council of the Cultural Revolution (SCCR), Ministry of Cooperatives, Labor, and Social Welfare (MCLSW), Supreme Council of Insurance (SCI), Islamic Consultative Assembly (Parliament) (Pr), Medical Equipment Importing Companies (MEIC), Supreme Council for Health and Food Security (SCHFS), Iranian National Standards Organization (INSO), Islamic Republic of Iran Broadcasting (IRIB), Central Bank of Iran (CBI), Chamber of Commerce (CC), Non-Governmental Organizations (NGOs) Supporting Patient Rights, Medical Scientific Associations (MSA), National Tax Administration of Iran (NTAI), Ministry of Industry, Mine, and Trade (MIMT), General Inspection Organization of Iran (GIOI), Medical Equipment Manufacturers' Trade Associations (MEMTA), Private Sector (PS) and Pharmaceutical Companies (PC). After distributing the questionnaire online and evaluating the identified actors based on five items (power, position, interest, influence, and level of support) a total of 83 participants completed the survey. This resulted in a response rate of 72.17%

Influence analysis

Participants identified the Ministry of Health and Medical Education, Food and Drug Administration, Insurance Organizations, and the Islamic Consultative Assembly (Parliament) as the most influential in HTA development. Ministry of Health and Medical Education, as Iran's primary health policy authority, sets HTA agendas and ensures alignment with national priorities, coordinating across healthcare sectors. The Food and Drug Administration influences HTA by regulating and approving health technologies, shaping what is assessed and adopted. Insurance Organizations impact HTA through reimbursement decisions based on cost-effectiveness, affecting technology accessibility. Parliament influences HTA through legislation and oversight, shaping the regulatory and financial framework for HTA and aligning it with national priorities.

Interest analysis

The Ministry of Health and Medical Education, Food and Drug Administration, National Institute of Health Research, and Plan and Budget Organization showed significant interest in HTA. The Ministry of Health and Medical Education uses HTA to guide health policy and resource allocation. The Food and Drug Administration relies on HTA for evidence to regulate technologies, ensuring public safety. The National Institute of Health Research values HTA for its role in research and evidence-based healthcare improvements. The Plan and Budget Organization is interested in HTA to evaluate cost-effectiveness and manage healthcare budgets efficiently, aligning expenditures with economic goals.

Level of support analysis

The Ministry of Health and Medical Education, Insurance Organizations, Universities and Academic Centers, and Parliament provided strong support for HTA. The Ministry of Health and Medical Education supports HTA to integrate it into health policies and optimize resource use. Insurance Organizations back HTA to ensure financial sustainability and value for money in technology coverage. Universities and Academic Centers support HTA through research and training, developing the necessary methodologies and expertise. Parliament's support ensures legal and financial backing for HTA, influencing policy and resource allocation.

Position analysis

Universities and Academic Centers, the Supreme Council of the Cultural Revolution, the Islamic Consultative Assembly (Parliament), and the Central Bank of Iran held significant power in HTA development. Universities and Academic Centers generate HTA knowledge and train professionals. The Supreme Council of the Cultural Revolution influences HTA by shaping broader cultural and educational policies. Parliament holds legislative power, affecting HTA laws and funding. The Central Bank of Iran impacts HTA through its control over financial stability and government spending, indirectly affecting healthcare investment.

Power analysis

The Ministry of Health and Medical Education, Food and Drug Administration, Plan and Budget Organization, and Parliament held the most power in HTA development. The Ministry of Health and Medical Education oversees healthcare management, including HTA policies and implementation. The Food and Drug Administration controls the market entry of health technologies, affecting their assessment and use. The Plan and Budget Organization manage healthcare funding, influencing HTA resource allocation. Parliament has legislative authority, shaping HTA through laws, budget approvals, and policy oversight, aligning HTA with national priorities and public interests. **Supplementary 2** provides the ranking of the actors according to participants' opinions on five items.

SNA analysis

The calculated social network metrics, such as degree centrality, closeness centrality, betweenness centrality, eigenvector centrality, hub, and page rank, are presented in Table I. The Plan and Budget Organization (0.34) and National Institute of Health Research (0.26) exhibit the highest degree centrality, suggesting they have numerous direct interactions with other actors. The Chamber of Commerce (0.00) is isolated, with no direct connections, indicating minimal or no engagement with other actors in the network. The Plan and Budget Organization (0.55) and National Institute of Health Research (0.50) have the highest closeness centrality,

Tab. I. Social network metrics.

Actors	Degree centrality	Closeness centrality	Betweenness centrality	Eigenvector centrality	Hub	Pagerank
Ministry of Health and Medical Education (MoHME)	0.1154	0.3846	0.0146	0.3829	0.3829	0.0317
Food and Drug Administration (FDA)	0.1923	0.4098	0.1193	0.479	0.479	0.0538
Vice Presidency for Science and Technology (VPST)	0.1923	0.4464	0.0345	0.7535	0.7535	0.0485
National Institute of Health Research (NIHR)	0.2692	0.5	0.146	0.9249	0.9249	0.0676
Plan and Budget Organization (PBO)	0.3462	0.5556	0.3178	1	1	0.0895
Insurance Organizations (IO)	0.1154	0.3378	0.0245	0.143	0.143	0.0347
Social Security Organization (SSO)	0.0769	0.3676	0.0081	0.2787	0.2787	0.0229
Universities and Academic Centers (UAC)	0.1923	0.431	0.0487	0.7194	0.7194	0.0486
Medical Council of Iran (Organization of the Medical System) (MCI)	0.1154	0.4098	0.0276	0.4578	0.4578	0.0314
Supreme Council of the Cultural Revolution (SCCR)	0.1538	0.431	0.1237	0.326	0.326	0.0472
Ministry of Cooperatives, Labor, and Social Welfare (MCLSW)	0.0769	0.3846	0.018	0.2227	0.2227	0.0234
Supreme Council of Insurance (SCI)	0.0385	0.2941	0	0.1036	0.1036	0.0149
Islamic Consultative Assembly (Parliament) (Pr)	0.0385	0.3623	0	0.2162	0.2162	0.0142
Medical Equipment Importing Companies (MEIC)	0.1154	0.431	0.0709	0.3584	0.3584	0.0333
Supreme Council for Health and Food Security (SCHFS)	0.1154	0.3676	0.0372	0.1789	0.1789	0.035
Iranian National Standards Organization (INSO)	0.0385	0.3049	0	0.0705	0.0705	0.0158
Islamic Republic of Iran Broadcasting (IRIB)	0.1923	0.3968	0.1198	0.2584	0.2584	0.0572
Central Bank of Iran (CBI)	0.1154	0.4167	0.0575	0.3043	0.3043	0.033
Chamber of Commerce (CC)	0	NA	0	0	0	0.0057
Non-Governmental Organizations (NGOs) Supporting Patient Rights	0.1538	0.3623	0.0321	0.364	0.364	0.042
Medical Scientific Associations (MSA)	0.0769	0.3846	0	0.4162	0.4162	0.0224
National Tax Administration of Iran (NTAI)	0.1538	0.463	0.1159	0.3662	0.3662	0.0426
Ministry of Industry, Mine, and Trade (MIMT)	0.1154	0.3623	0.0328	0.2279	0.2279	0.0332
General Inspection Organization of Iran (GIOI)	0.2308	0.5	0.1272	0.8062	0.8062	0.0587
Medical Equipment Manufacturers' Trade Associations (MEMTA)	0.1154	0.3906	0.044	0.2112	0.2112	0.0332
Private Sector (PS)	0.1538	0.3906	0.0458	0.224	0.224	0.0439
Pharmaceutical Companies (PC)	0.0385	0.2874	0	0.0559	0.0559	0.0155

indicating they are well-positioned to quickly access information or influence throughout the network. The Supreme Council of Insurance (0.29) and Iranian National Standards Organization (0.30) have lower values, suggesting they are less central and may face longer paths to interact with other actors. The Plan and Budget Organization (0.31) and National Institute of Health Research (0.14) exhibit the highest betweenness centrality, indicating they play significant roles in bridging different parts of the network. The Supreme Council of Insurance (0.00) and Iranian National Standards Organization (0.00) have zero betweenness centrality, implying they do not act as intermediaries or bridges between other actors. The Plan and Budget Organization (1.00), National Institute of Health Research (0.92), and Vice Presidency for Science and Technology (0.75) have the highest eigenvector centrality, suggesting they are not only well-connected but also linked to other influential actors. The Chamber of Commerce (0.00) has no influence as it is isolated in the network. The Plan and Budget Organization (0.08), National Institute of Health Research (0.06), and Vice Presidency for Science and Technology (0.04) are prominent hubs, reflecting their central role in the network's structure. The Chamber of Commerce (0.00) has the lowest hub score, reinforcing its isolation and minimal influence. The Plan and Budget Organization (0.08) and National Institute of Health Research (0.06) show the highest PageRank scores, indicating they are central to the network's power structure. The Chamber of Commerce (0.00), with the lowest PageRank score, underscores its minimal impact and influence.

Additionally, network and node-level metrics, including nodes, edges, density, diameter, and other related measures, are detailed in Table II.

Tab. II. Network and node-level metrics, including nodes, edges, density, clustering coefficient, degree, and connectivity measures.

	Value
Nodes	27
Edges	46
Density	0.13
Average Clustering Coefficient	0.11
Average Degree	3.40
Number of Triangles	7
Diameter	6
Average Path Length	2.56

The network, comprising 27 nodes and 46 edges, exhibits a density of 0.13, signifying a sparse structure with limited connectivity relative to all possible edges. The average clustering coefficient of 0.11 reflects a low tendency for nodes to form tight clusters. With an average degree of 3.4074, nodes have a moderate number of connections. The presence of 7 triangles indicates some local interconnectedness. The network's diameter of 6 and average path length of 2.56 suggest that, despite its sparsity, the network maintains relatively short paths between nodes, making it moderately efficient in terms of connectivity and information flow.

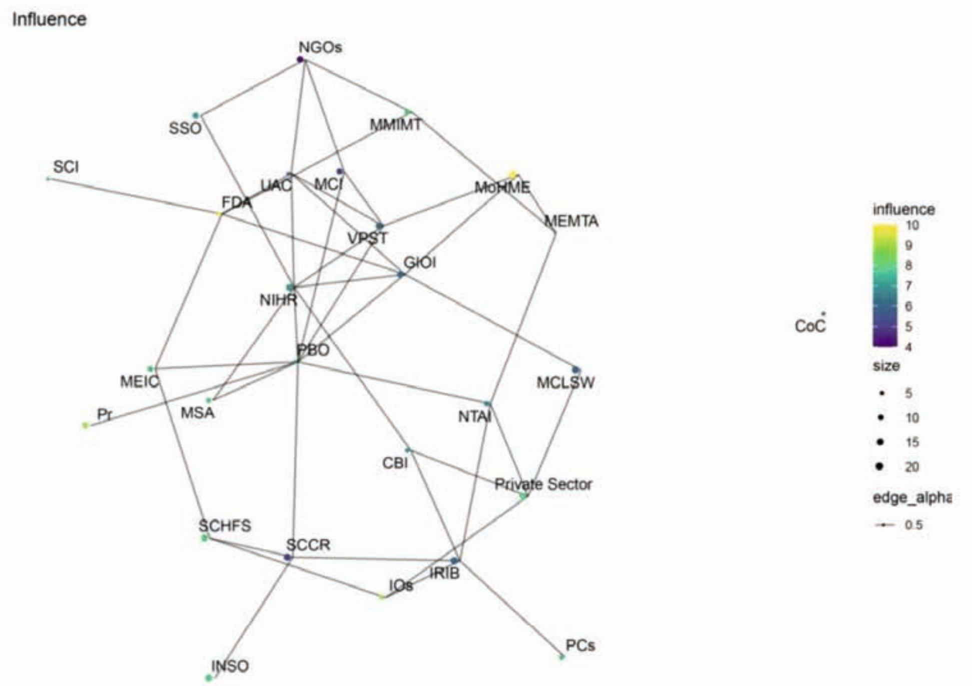
Figures 1-5 illustrate the network maps depicting the influence, interest, level of support, position, and power of the stakeholders involved in the development of HTA in Iran. Table III and Figure 6 present the ranking of actors involved in the development of health innovation, based on five items assessed by the participants. Based on composite scores, the top five actors ranked as follows: Ministry of Health and Medical Education, Food and Drug Administration, Islamic Consultative Assembly (Parliament), Insurance Organizations, and the Supreme Council of Insurance.

Discussion

This study mapped the social networks of key actors involved in HTA development in Iran, offering insights into influence, power, support, and connectivity. By applying SNA, we identified central institutions, highlighted gaps in communication, and revealed how power imbalances shape the HTA landscape.

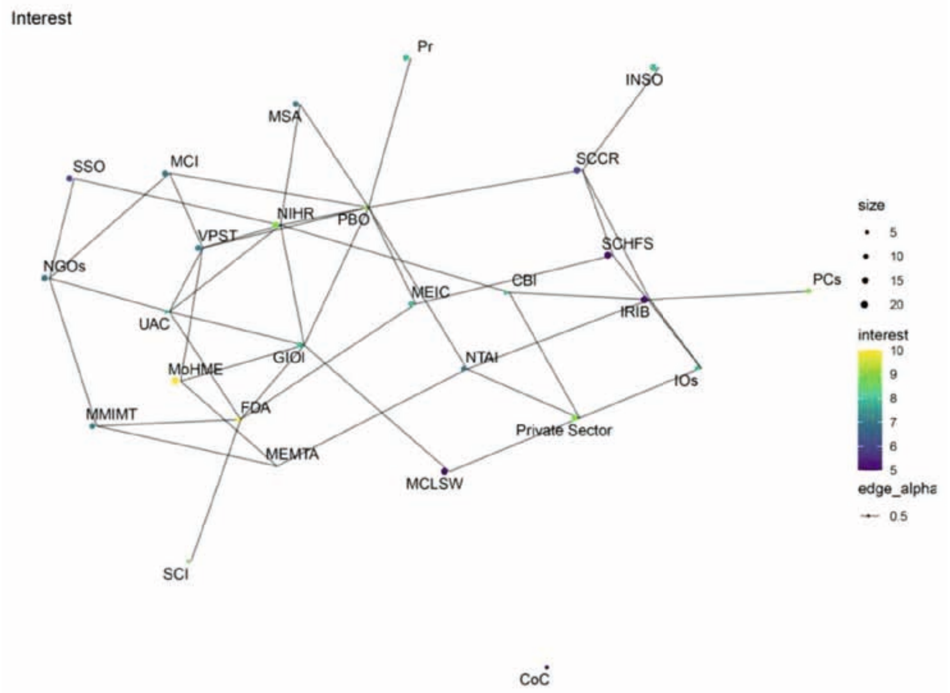
Our analysis showed that the MoHME, FDA, Insurance Organizations, and Parliament are perceived as the most influential actors. This finding is consistent with their formal roles in health policy: MoHME sets the agenda,

Fig. 1. Network map based on the influence of stakeholders in the development of HTA in Iran.



Ministry of Health and Medical Education (MoHME), Food and Drug Administration (FDA), Vice Presidency for Science and Technology (VPST), National Institute of Health Research (NIHR), Plan and Budget Organization (PBO), Insurance Organizations (IOs), Social Security Organization (SSO), Universities and Academic Centers (UAC), Medical Council of Iran (MCI), Supreme Council of the Cultural Revolution (SCCR), Ministry of Cooperatives, Labor, and Social Welfare (MCLSW), Supreme Council of Insurance (SCI), Islamic Consultative Assembly (Parliament) (Pr), Medical Equipment Importing Companies (MEIC), Supreme Council for Health and Food Security (SCHFS), Iranian National Standards Organization (INSO), Islamic Republic of Iran Broadcasting (IRIB), Central Bank of Iran (CBI), Chamber of Commerce (CoC), Non-Governmental Organizations (NGOs) Supporting Patient Rights, Medical Scientific Associations (MSA), National Tax Administration of Iran (NTAI), Ministry of Industry, Mine, and Trade (MIMT), General Inspection Organization of Iran (GIOI), Medical Equipment Manufacturers' Trade Associations (MEMTA), Private Sector (PS), Pharmaceutical Companies (PCs).

Fig. 2. Network map based on the interest of stakeholders in the development of HTA in Iran.



Ministry of Health and Medical Education (MoHME), Food and Drug Administration (FDA), Vice Presidency for Science and Technology (VPST), National Institute of Health Research (NIHR), Plan and Budget Organization (PBO), Insurance Organizations (IOs), Social Security Organization (SSO), Universities and Academic Centers (UAC), Medical Council of Iran (MCI), Supreme Council of the Cultural Revolution (SCCR), Ministry of Cooperatives, Labor, and Social Welfare (MCLSW), Supreme Council of Insurance (SCI), Islamic Consultative Assembly (Parliament) (Pr), Medical Equipment Importing Companies (MEIC), Supreme Council for Health and Food Security (SCHFS), Iranian National Standards Organization (INSO), Islamic Republic of Iran Broadcasting (IRIB), Central Bank of Iran (CBI), Chamber of Commerce (CoC), Non-Governmental Organizations (NGOs) Supporting Patient Rights, Medical Scientific Associations (MSA), National Tax Administration of Iran (NTAI), Ministry of Industry, Mine, and Trade (MIMT), General Inspection Organization of Iran (GIOI), Medical Equipment Manufacturers' Trade Associations (MEMTA), Private Sector (PS), Pharmaceutical Companies (PCs).

FDA regulates technology entry, insurers determine reimbursement, and Parliament shapes the legislative and financial framework. The dominance of these actors reflects similar patterns observed in other countries, where ministries of health and regulatory bodies are pivotal in HTA implementation [14, 15].

Insurance Organizations' strong influence aligns with experiences in countries such as Germany, the UK, and Canada, where reimbursement decisions are tightly linked to HTA findings [16–18]. In these settings, HTA outcomes directly affect technology adoption, underscoring the financial gatekeeping role of insurers. Similarly, in France and Australia, insurance organizations actively shape HTA policy to ensure technologies are both clinically valuable and financially sustainable [19, 20]. Our results suggest that Iranian insurers, though influential, must further institutionalize evidence-based reimbursement practices to maximize their impact.

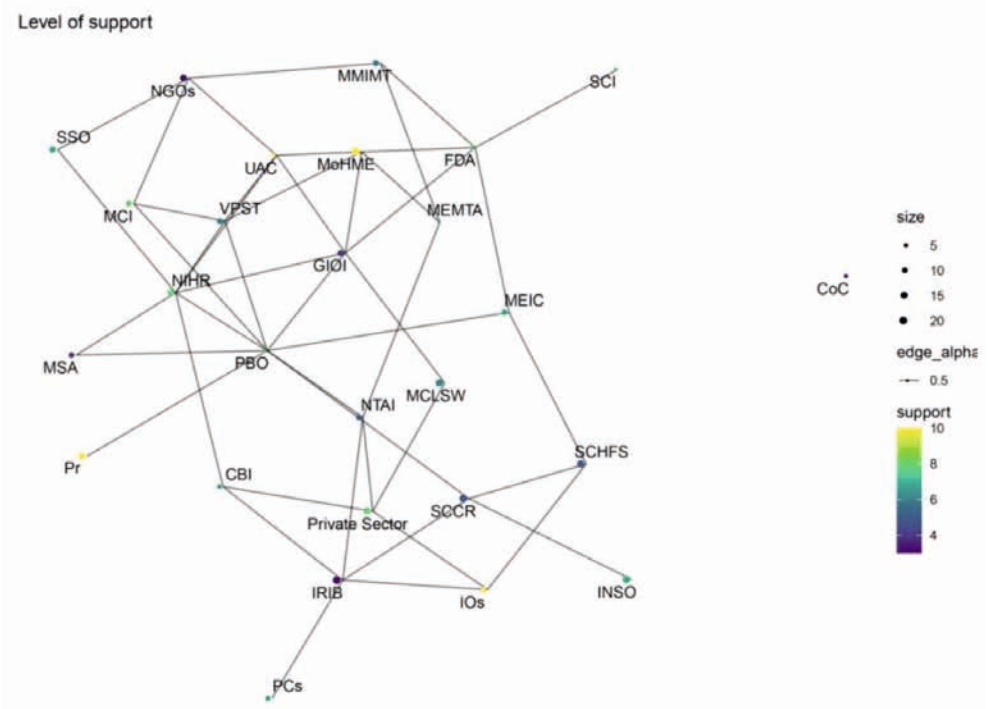
Universities, the NIHR, and the Vice Presidency for Science and Technology were also identified as strong supporters of HTA. Their contribution to training, research, and evidence generation highlights the importance of scientific capacity in sustaining HTA. Internationally, bodies such as the UK's NIHR or HITAP in Thailand play similar roles, bridging research and policymaking [21–25]. Iran's universities and research centers are well positioned to strengthen HTA through methodological innovation and capacity building.

The network analysis revealed a sparse structure, with low density (0.13) and clustering coefficient (0.11). This indicates weak collaboration across actors and limited subgroup formation, which can slow down the circulation of evidence and reduce policy coherence. Despite this, the relatively short average path length (2.56) suggests that information can still travel efficiently when connections exist. However, reliance on a few central actors, such as the PBO and NIHR, poses risks of bottlenecks. Strengthening ties among peripheral actors could improve resilience and inclusiveness [26, 27].

The isolation of the Chamber of Commerce and limited engagement of the private sector suggest that industry perspectives are underrepresented in Iran's HTA network. While private sector involvement must be carefully managed to avoid conflicts of interest, structured engagement could improve alignment between innovation, regulation, and patient needs [28, 29].

The power analysis highlighted MoHME, FDA, PBO, and Parliament as highly authoritative, reflecting their control over policy, regulation, finance, and legislation. Yet, such concentration of power also risks imbalances and conflicting priorities—for example,

Fig. 3. Network map based on the level of support of stakeholders in the development of HTA in Iran.



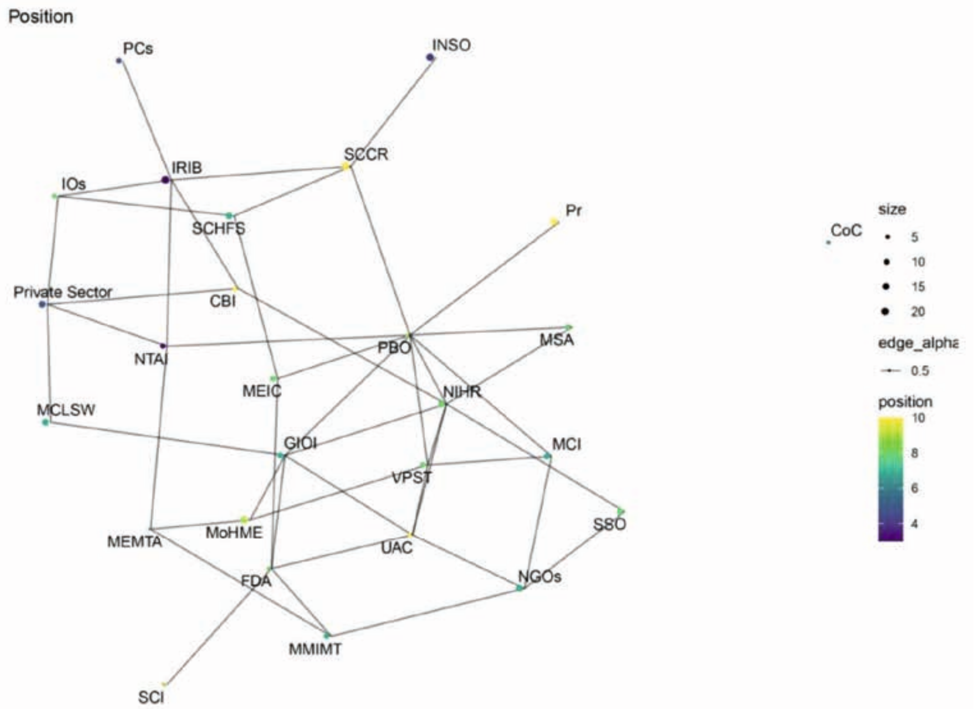
Ministry of Health and Medical Education (MoHME), Food and Drug Administration (FDA), Vice Presidency for Science and Technology (VPST), National Institute of Health Research (NIHR), Plan and Budget Organization (PBO), Insurance Organizations (IOs), Social Security Organization (SSO), Universities and Academic Centers (UAC), Medical Council of Iran (MCI), Supreme Council of the Cultural Revolution (SCCR), Ministry of Cooperatives, Labor, and Social Welfare (MCLSW), Supreme Council of Insurance (SCI), Islamic Consultative Assembly (Parliament) (Pr), Medical Equipment Importing Companies (MEIC), Supreme Council for Health and Food Security (SCHFS), Iranian National Standards Organization (INSO), Islamic Republic of Iran Broadcasting (IRIB), Central Bank of Iran (CBI), Chamber of Commerce (CoC), Non-Governmental Organizations (NGOs) Supporting Patient Rights, Medical Scientific Associations (MSA), National Tax Administration of Iran (NTAI), Ministry of Industry, Mine, and Trade (MIMT), General Inspection Organization of Iran (GIOI), Medical Equipment Manufacturers' Trade Associations (MEMTA), Private Sector (PS), Pharmaceutical Companies (PCs).

between cost containment (PBO) and technology adoption (FDA). Managing these tensions requires transparent processes, clear role definitions, and mechanisms for accountability. Our findings have implications beyond Iran. Many LMICs face similar challenges of fragmented networks, dominance of a few actors, and limited integration of peripheral stakeholders. Strengthening communication channels, fostering inclusive stakeholder forums, and building stable funding mechanisms are strategies that can enhance HTA institutionalization across diverse contexts. Finally, the study highlights a central tension: while Iran has strong institutional anchors for HTA, weak connectivity and lack of collaboration limit its effectiveness. Addressing these gaps will require deliberate efforts to foster dialogue, integrate peripheral actors, and align interests across sectors. By doing so, HTA can move from being a policy tool concentrated within a few institutions to a system-wide mechanism for evidence-informed decision-making.

LIMITATION

This study provides valuable insights into the social networks of key actors in HTA development in Iran, but several limitations should be considered. First, the identification of actors relied on interviews, questionnaires, and document review, which may introduce selection bias. Although purposive and snowball sampling helped capture diverse perspectives, less visible but potentially influential stakeholders may have been overlooked. Second, the study relied on self-reported data, which carries risks of response bias. Participants' assessments of their own or others' power, influence, or support may not fully reflect actual dynamics. Social desirability bias may also have led some respondents to overstate their contributions. Third, the cross-sectional nature of the analysis captures a snapshot of the HTA landscape at one point in time. Given the dynamic nature of health policy, relationships and influence among actors may evolve, meaning our findings may not represent longer-term trends. Future studies using longitudinal SNA could better capture these shifts. Fourth, while SNA is a powerful tool, it cannot fully capture informal networks, hidden alliances, or qualitative aspects such as trust and personal relationships, which can significantly affect HTA processes. Our reliance on quantitative centrality metrics may therefore miss some nuances. Fifth, the study primarily focused on formal institutions and organizations. The roles of individual clinicians,

Fig. 4. Network map based on the position of stakeholders in the development of HTA in Iran.



Ministry of Health and Medical Education (MoHME), Food and Drug Administration (FDA), Vice Presidency for Science and Technology (VPST), National Institute of Health Research (NIHR), Plan and Budget Organization (PBO), Insurance Organizations (IOs), Social Security Organization (SSO), Universities and Academic Centers (UAC), Medical Council of Iran (MCI), Supreme Council of the Cultural Revolution (SCCR), Ministry of Cooperatives, Labor, and Social Welfare (MCLSW), Supreme Council of Insurance (SCI), Islamic Consultative Assembly (Parliament) (Pr), Medical Equipment Importing Companies (MEIC), Supreme Council for Health and Food Security (SCHFS), Iranian National Standards Organization (INSO), Islamic Republic of Iran Broadcasting (IRIB), Central Bank of Iran (CBI), Chamber of Commerce (CoC), Non-Governmental Organizations (NGOs) Supporting Patient Rights, Medical Scientific Associations (MSA), National Tax Administration of Iran (NTAI), Ministry of Industry, Mine, and Trade (MIMT), General Inspection Organization of Iran (GIOI), Medical Equipment Manufacturers' Trade Associations (MEMTA), Private Sector (PS), Pharmaceutical Companies (PCs).

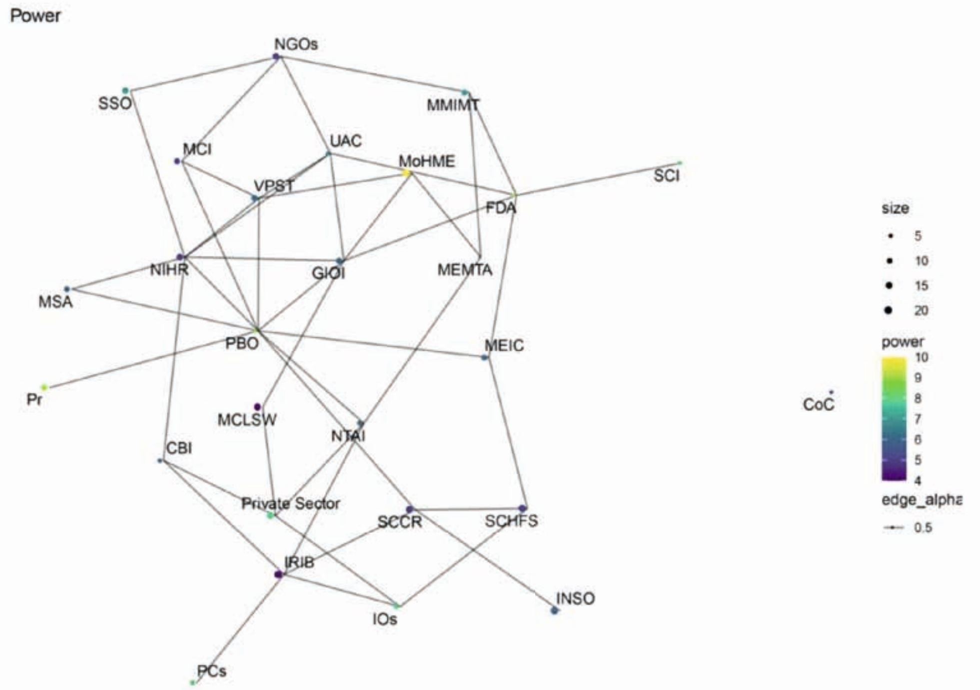
patients, and grassroots groups were not examined in depth, despite their potential influence on HTA adoption and legitimacy. Expanding future research to include these actors would provide a more comprehensive picture. Finally, the context-specific focus on Iran limits the generalizability of the findings. While the results may offer lessons for other low- and middle-income countries, differences in political structures, health systems, and cultural contexts should be considered when applying these insights elsewhere.

POLICY RECOMMENDATIONS

Based on the findings of this study, several policy recommendations are proposed to strengthen the development and implementation of HTA in Iran.

1. **Strengthen Central Coordination and Leadership**
   - Clarify and reinforce the role of the Ministry of Health and Medical Education (MoHME) as the lead agency for HTA, ensuring alignment with national health priorities and cross-sectoral coordination.
   - Establish a dedicated HTA body under MoHME to centralize activities, reduce fragmentation, and provide a unified framework for assessments.
2. **Improve Communication and Collaboration Among Stakeholders**
   - Facilitate structured and regular dialogue through formal forums or working groups that bring together MoHME, FDA, insurers, Parliament, and other actors. This directly addresses the observed low network density (0.13).
   - Develop joint initiatives and collaborative projects that promote shared goals, enhance information exchange, and optimize resource use.
3. **Enhance Stakeholder Engagement and Inclusiveness**
   - Actively involve peripheral and currently disconnected actors, such as the Chamber of Commerce and private sector, in advisory committees and working groups. Their inclusion could reduce network fragmentation and improve policy coherence.
   - Expand networks by including patient advocacy groups, professional associations, and NGOs to ensure diverse perspectives are considered in HTA processes.
4. **Strengthen the Evidence Base and Methodologies**
   - Invest in universities and research institutions to support HTA-related research, methodology development, and training.
   - Improve national data infrastructure to ensure access to

Fig. 5. Network map based on the power of stakeholders in the development of HTA in Iran.



Ministry of Health and Medical Education (MoHME), Food and Drug Administration (FDA), Vice Presidency for Science and Technology (VPST), National Institute of Health Research (NIHR), Plan and Budget Organization (PBO), Insurance Organizations (IOs), Social Security Organization (SSO), Universities and Academic Centers (UAC), Medical Council of Iran (MCI), Supreme Council of the Cultural Revolution (SCCR), Ministry of Cooperatives, Labor, and Social Welfare (MCLSW), Supreme Council of Insurance (SCI), Islamic Consultative Assembly (Parliament) (Pr), Medical Equipment Importing Companies (MEIC), Supreme Council for Health and Food Security (SCHFS), Iranian National Standards Organization (INSO), Islamic Republic of Iran Broadcasting (IRIB), Central Bank of Iran (CBI), Chamber of Commerce (CoC), Non-Governmental Organizations (NGOs) Supporting Patient Rights, Medical Scientific Associations (MSA), National Tax Administration of Iran (NTAI), Ministry of Industry, Mine, and Trade (MIMT), General Inspection Organization of Iran (GIOI), Medical Equipment Manufacturers' Trade Associations (MEMTA), Private Sector (PS), Pharmaceutical Companies (PCs).

reliable clinical, economic, and patient outcome data, thereby reducing reliance on fragmented information.

5. **Ensure Sustainable Funding and Resource Allocation**

- Secure stable, long-term funding streams to avoid over-reliance on short-term or project-based financing. Sustainable resources will support institutional capacity, staff training, and continuous HTA activities.
- Establish transparent mechanisms for resource allocation to maximize the impact of limited budgets.

6. **Enhance Transparency and Accountability**

- Implement clear guidelines and processes for HTA decision-making, including transparent criteria for prioritization.
- Introduce monitoring and evaluation systems (e.g., regular audits, performance reviews) to ensure accountability and improve trust in HTA decisions.

7. **Foster Innovation and Continuous Improvement**

- Encourage methodological innovation, such as integrating horizon scanning and digital health assessments, to keep HTA relevant in a rapidly changing environment.
- Create feedback loops for continuous learning, ensuring stakeholder input is systematically used to refine HTA processes.

Priority should be given to building stronger central coordination, enhancing communication between key actors, and securing sustainable funding. Medium-term efforts should focus on inclusiveness, capacity building, and data infrastructure, while long-term strategies should foster innovation and adaptability. By following these steps, Iran can move toward a more integrated, transparent, and effective HTA system.

Conclusion

This study explored the social networks and influence dynamics among key actors involved in HTA development in Iran. Using SNA, we mapped relationships, power structures, and support mechanisms, revealing that MoHME, FDA, Insurance Organizations, and Parliament occupy central positions, while institutions such as the Plan and Budget Organization and NIHR act as key connectors. Despite these strong anchors, the overall network was sparse, with low density and limited clustering, indicating weak collaboration and underutilization of peripheral actors. This fragmentation constrains the effectiveness of HTA and limits its integration into broader health policy. To strengthen

Tab. III. Ranking of actors involved in the development of HTA, based on five items with composite score.

Name of actors	Composite score	Rank
Ministry of Health and Medical Education (MoHME)	1.63	1
Food and Drug Administration (FDA)	1.22	2
Vice Presidency for Science and Technology (VPST)	1.20	3
National Institute of Health Research (NIHR)	0.88	4
Plan and Budget Organization (PBO)	0.79	5
Insurance Organizations (IO)	0.78	6
Social Security Organization (SSO)	0.55	7
Universities and Academic Centers (UAC)	0.39	8
Medical Council of Iran (Organization of the Medical System) (MCI)	0.29	9
Supreme Council of the Cultural Revolution (SCCR)	0.28	10
Ministry of Cooperatives, Labor, and Social Welfare (MCLSW)	0.22	11
Supreme Council of Insurance (SCI)	0.19	12
Islamic Consultative Assembly (Parliament) (Pr)	0.01	13
Medical Equipment Importing Companies (MEIC)	-0.07	14
Supreme Council for Health and Food Security (SCHFS)	-0.16	15
Iranian National Standards Organization (INSO)	-0.19	16
Islamic Republic of Iran Broadcasting (IRIB)	-0.20	17
Central Bank of Iran (CBI)	-0.29	18
Chamber of Commerce (CC)	-0.44	19
Non-Governmental Organizations (NGOs) Supporting Patient Rights	-0.46	20
Medical Scientific Associations (MSA)	-0.57	21
National Tax Administration of Iran (NTAI)	-0.60	22
Ministry of Industry, Mine, and Trade (MIMT)	-0.75	23
General Inspection Organization of Iran (GIOI)	-0.90	24
Medical Equipment Manufacturers' Trade Associations (MEMTA)	-1.06	25
Private Sector (PS)	-1.16	26
Pharmaceutical Companies (PC)	-1.59	27

HTA in Iran, strategies should prioritize improving communication between actors, engaging peripheral stakeholders, and ensuring stable funding mechanisms. Enhancing inclusiveness and transparency will also help balance existing power asymmetries and increase accountability. Looking ahead, longitudinal studies could track how these networks evolve over time, while comparative research across low- and middle-income countries may provide lessons for building more resilient and inclusive HTA systems. By addressing gaps in connectivity and coordination, Iran can move toward an HTA framework that is not only evidence-based but also collaborative, transparent, and responsive to national health priorities.

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Ethics approval and consent to participate

The study was approved by the ethical committee at Lorestan University of Medical Sciences (IR.LUMS.REC.1402.310). All participants were informed about the study objectives and procedures before participation. Written informed consent was obtained from each study participant before key informant interviews. Verbal informed consent was obtained from all participants before initiating the study. The study procedures and methods were conducted following the ethical principles and guidance of the World Medical Association Declaration of Helsinki. No waiver of consent was applied, and all participants provided informed consent before participation.

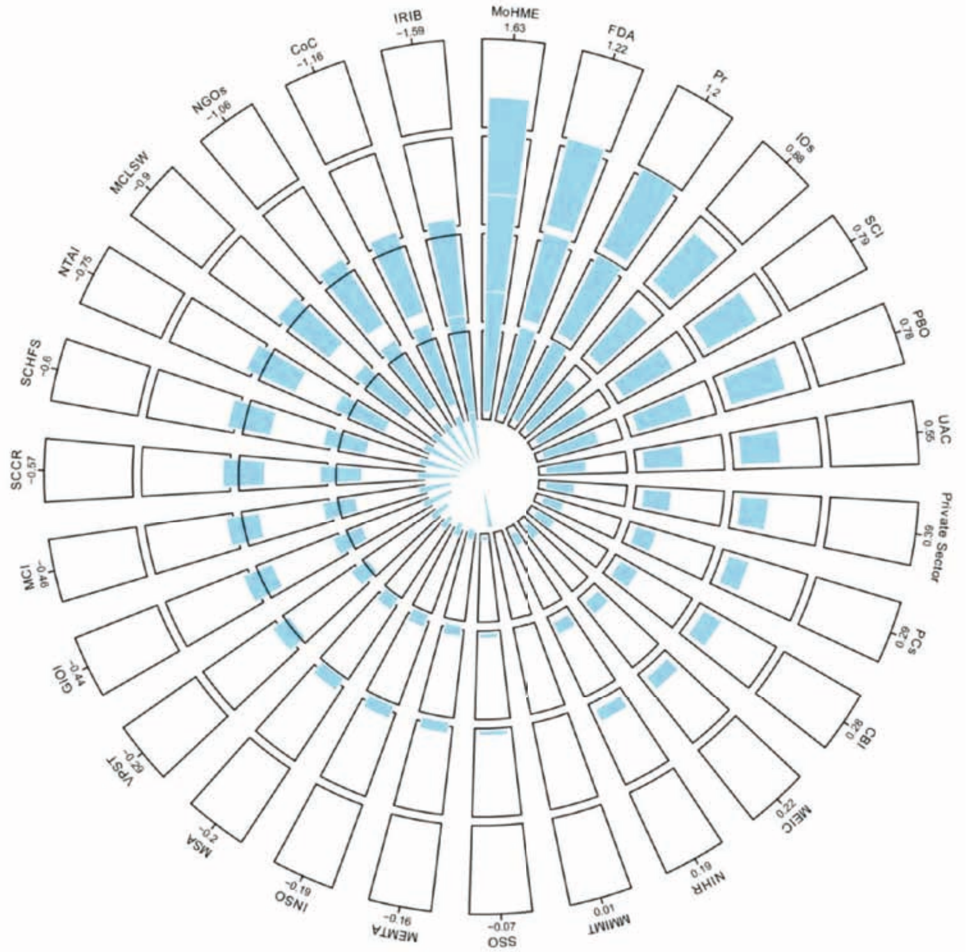
Consent for publication

Not applicable.

Availability of data and materials

The datasets generated and/or analysed during the current study are not publicly available due but are available from the corresponding author on reasonable request.

Fig. 6. Ranking of actors involved in the development of HTA, based on five items.



Conflict of Interest statement

The authors declare that they have no competing interests.

Authors' contributions

MaB, MY, SA, MM, and AB contributed to the development of the idea for this article. MeB, AB, SS, MaB and BDT partook in the acquisition and analysis of data. All co-authors joined them in critically interpreting and discussing the data. MaB, SS, MM, BDT, and MM wrote sub-sections of this article and provided input into further sub-sections of the article, along with MaB, MeB, MM, AB, SA, MY and SS. All authors have critically revised content, have approved the submitted version of this article, and are accountable for the accuracy or integrity of any part of the work.

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Correspondence: Masoud Behzadifar, Social Determinants of Health Research Center, Lorestan University of Medical Sciences, Khorramabad, Iran. E-mail: masoudbehzadifar@gmail.com, behzadifar@lums.ac.ir.

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Supplementary material

Tab. S1. Questionnaire for data collection.

Questionnaire on the Role of Stakeholders in Health Technology Assessment (HTA) Development in Iran
Introduction: This questionnaire aims to assess the role of various organizations in the development of Health Technology Assessment (HTA) in Iran. Please evaluate each actor based on their power, position, interest, influence, and level of support in HTA development. Your responses will be used for research purposes only and will remain confidential.
Section 1: Participant Information.
What is your professional role? ☐ Health policymaker ☐ Researcher/academic ☐ Healthcare provider (physician, nurse, etc.) ☐ Government official ☐ Insurance professional ☐ Industry representative (pharmaceuticals, medical devices, etc.) ☐ Other (please specify): __________ **Which sector do you primarily work in?** ☐ Public sector ☐ Private sector ☐ Non-governmental organization (NGO) ☐ Academia **Years of experience in health policy or related fields:** ☐ Less than 5 years ☐ 5-10 years ☐ 11-20 years ☐ More than 20 years
Section 2: Assessment of Key Stakeholders in HTA Development.
Please rate the following stakeholders on a **10-point scale** based on their power, position, interest, influence, and level of support in HTA development in Iran.

Tab. S2. Ranking of actors based on participants' evaluations of power, position, interest, influence, and support in HTA development.

Actors	Power	Position	Interest	Influence	Level of support
Ministry of Health and Medical Education (MoHME)					
Food and Drug Administration (FDA)					
Vice Presidency for Science and Technology (VPST)					
National Institute of Health Research (NIHR)					
Plan and Budget Organization (PBO)					
Insurance Organizations (IO)					
Social Security Organization (SSO)					
Universities and Academic Centers (UAC)					
Medical Council of Iran (Organization of the Medical System) (MCI)					
Supreme Council of the Cultural Revolution (SCCR)					
Ministry of Cooperatives, Labor, and Social Welfare (MCLSW)					
Supreme Council of Insurance (SCI)					
Islamic Consultative Assembly (Parliament) (Pr)					
Medical Equipment Importing Companies (MEIC)					
Supreme Council for Health and Food Security (SCHFS)					
Iranian National Standards Organization (INSO)					
Islamic Republic of Iran Broadcasting (IRIB)					
Central Bank of Iran (CBI)					
Chamber of Commerce (CC)					
Non-Governmental Organizations (NGOs) Supporting Patient Rights					
Medical Scientific Associations (MSA)					
National Tax Administration of Iran (NTAI)					
Ministry of Industry, Mine, and Trade (MIMT)					
General Inspection Organization of Iran (GIOI)					
Medical Equipment Manufacturers' Trade Associations (MEMTA)					
Private Sector (PS)					
Pharmaceutical Companies (PC)					

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OPEN ACCESS

Challenges of using artificial intelligence in Iran's health system: a qualitative study

MEYSAM BEHZADIFAR[1], SAMAD AZARI[2], NEGIN SAJEDIMEHR[1], AFSHIN AALIPOUR[1], MARYAM NEMATKHAH[1],
BANAFSHEH DARVISHI TELI[3], MARIANO MARTINI[4], MOHAMMAD YARAHMADI[5], MASOUD BEHZADIFAR[1]
[1] Social Determinants of Health Research Center, Lorestan University of Medical Sciences, Khorramabad, Iran; [2] Hospital Management Research Center, Health Management Research Institute, Iran University of Medical Sciences, Tehran, Iran; [3] Health Management and Economics Research Center, School of Health Management and Information Sciences, Iran University of Medical Sciences, Tehran, Iran; [4] Department of Health Sciences, University of Genoa, Genoa, Italy; [5] Department of Medical Parasitology and Mycology, Lorestan University of Medical Sciences, Khorramabad, Iran

Keywords

Artificial Intelligence • Healthcare • Iran • Health Policy • Ethical Issues • Qualitative Study

Summary

Background. *Artificial intelligence (AI) is transforming healthcare globally, enhancing diagnostics, treatment, and efficiency. However, low- and middle-income countries (LMICs) like Iran face significant barriers to AI integration. Iran's health system, challenged by an aging population, increasing non-communicable diseases, and limited resources, could benefit from AI-driven, patient-centered care. Yet, its adoption remains limited. Understanding the barriers to AI implementation is critical for informed policymaking.*

Methods. *This qualitative study involved semi-structured interviews with 15 stakeholders from healthcare management, policymaking, and AI sectors in Iran, conducted between January and April 2025. Participants were selected purposively to represent government, academia, healthcare, and technology. Data were analyzed thematically using Braun and Clarke's framework. Rigor was ensured through member checking, triangulation, and adherence to qualitative research standards.*

Results. *Five major barriers to AI adoption emerged: (1) organizational and structural limitations, including poor infrastructure and fragmented governance; (2) legal and policy challenges, marked by regulatory gaps and ethical concerns; (3) data-related issues such as low data quality, lack of standardization, and security risks; (4) shortage of skilled professionals and limited training opportunities; and (5) challenges in integrating AI into policymaking, including concerns about losing human oversight in decision-making.*

Conclusion. *AI implementation in Iran's health system faces complex and interrelated challenges. Addressing these requires a coordinated strategy focused on legal reform, infrastructure investment, capacity building, and cultural adaptation. Balancing technological innovation with ethical and human-centered care is essential for successful and sustainable integration.*

INTRODUCTION

Artificial intelligence (AI) has emerged as a transformative force in healthcare, revolutionizing diagnostic accuracy, treatment planning, and operational efficiency [1]. AI-driven technologies, such as machine learning algorithms and natural language processing, are increasingly being integrated into health systems worldwide. These advancements have demonstrated significant potential in improving patient outcomes, optimizing resource allocation, and reducing medical errors [2]. However, while AI adoption in healthcare is progressing rapidly in high-income countries, its implementation in low- and middle-income countries (LMICs), including Iran, faces substantial challenges [3].

Iran's health system is a mixed public-private model, with the Ministry of Health and Medical Education (MoHME) serving as the central authority responsible for policymaking, regulation, financing, and service delivery [4, 5]. The system is characterized by a strong public sector presence, especially in primary and secondary care, alongside a growing role for private healthcare providers. Healthcare services are delivered through a tiered structure, including health houses, rural and urban health centers, and hospitals [5-7]. The Iranian health system is under increasing pressure due to a growing elderly population, the rising burden of non-communicable diseases, and the need for more efficient healthcare delivery [4]. Traditional healthcare models often struggle to meet these demands, resulting in inefficiencies in resource allocation, workforce shortages, and delays in patient care [5]. AI offers a promising solution to these challenges by enhancing diagnostic accuracy, optimizing treatment plans, and improving hospital management systems. By adopting AI-powered tools, Iran's healthcare system can transition toward more data-driven and patient-centered care, ultimately improving health outcomes and operational efficiency [6].

Despite its potential, the adoption of AI in Iran's healthcare system remains in its nascent stages. While some healthcare institutions have begun exploring digital health solutions, broader integration of AI-based technologies in clinical practice, medical research, and health administration is still lacking [7]. AI can

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support healthcare professionals in decision-making, facilitate early disease detection, and streamline hospital workflows. Furthermore, AI-driven predictive analytics can assist policymakers in allocating resources more effectively, ensuring equitable healthcare access for all citizens [8]. As Iran's health system evolves, understanding the feasibility and implications of AI adoption is critical for maximizing its benefits and ensuring sustainable implementation [9, 10].

Despite the growing global interest in AI applications in healthcare, limited research has examined the contextual and systemic challenges of AI adoption in LMICs, particularly in Iran. Most existing studies focus on high-income settings, where infrastructure, policy frameworks, and resources differ significantly. This study addresses this gap by exploring the specific barriers to AI implementation from the perspective of diverse stakeholders within Iran's health system. By doing so, it contributes context-specific evidence to inform national strategies and guide responsible AI integration in similar LMIC contexts.

Methods

Study Design

This study utilized a qualitative descriptive research design, conducting in-depth semi-structured interviews to investigate the challenges associated with implementing AI in Iran's health system. Thematic analysis was employed to systematically analyze the data and identify key themes. The research followed the Consolidated Criteria for Reporting Qualitative Research (COREQ) checklist to improve methodological transparency and rigor (Tab. S1) [11]. This design was chosen to offer a thorough understanding of participants' perspectives and to reveal underlying themes pertinent to the adoption of AI in healthcare.

Participant Selection

Purposive sampling was employed to recruit participants with expertise in healthcare management, policy-making, and AI applications in Iran. The inclusion criteria were: (a) professionals with a minimum of five years of experience in health policy, management, or clinical practice; (b) direct involvement in decision-making related to digital health or AI; and (c) representation from various sectors, including government agencies, academic institutions, healthcare providers, and technology developers. A total of 15 individuals were interviewed. Invitations were sent through email and phone, outlining the study's objectives and the participation process. Some individuals declined due to time limitations, unfamiliarity with AI, or concerns regarding the sensitivity of the topic. Despite these challenges, the final sample comprised professionals from diverse backgrounds, ensuring a thorough exploration of AI-related issues within Iran's health system.

Interviewer Characteristics and Relationship with Participants

The interviews were carried out by two authors, each with a doctoral degree in health policy and significant experience in qualitative research. This expertise allowed for a structured and knowledgeable approach to data collection, helping to reduce bias. There were no pre-existing relationships between the interviewers and the participants before the study. Participants were made aware of the study's purpose and the interviewers' professional backgrounds to build rapport and promote open communication.

Setting

Data collection took place in various settings, including participants' workplaces, academic institutions, and healthcare facilities. To accommodate participants' schedules and geographical constraints, interviews were conducted both in person and via video calls.

Data Collection

A semi-structured interview guide (Tab. S2) was created following an extensive literature review and consultations with experts. The guide was pilot-tested with three professionals to confirm its clarity and relevance. Each interview lasted between 45 and 60 minutes and was audio-recorded with the participants' consent. Field notes were also taken to document non-verbal cues and contextual details. Data collection persisted until thematic saturation was reached, ensuring that no new significant information was identified.

Study Duration

Interviews were conducted between January 2025 and April 2025. The entire process, including participant recruitment, data collection, and analysis, was completed within this timeframe.

Data Analysis

Thematic analysis was carried out using Braun and Clarke's six-step framework: (a) becoming familiar with the data through multiple readings, (b) systematically generating initial codes, (c) identifying possible themes, (d) refining and reviewing those themes, (e) defining and naming the final themes, and (f) integrating the themes into a cohesive report. Two authors performed coding iteratively, addressing any discrepancies through discussions with a third researcher. Feedback from participants was included to validate the findings. MAXQDA Version 10 software was utilized to aid in the systematic organization and interpretation of the qualitative data.

Trustworthiness and Rigor

To establish credibility and dependability, the research utilized various methods: (a) member-checking, which involved sharing initial results with participants for their confirmation; (b) extended involvement of researchers in the subject matter to facilitate thorough analysis; (c)

Tab. I. Characteristics of study participants.

ID	Sex	Age	Work Experience	Specialty	Type of Activity	Interview Format
1	Male	45	17	Policy maker	Public / Government	Virtual
2	Female	39	14	Researcher	Public / Government	Virtual
3	Male	42	16	Physician	Private	In-person
4	Female	40	15	Insurance manager	Public / Government	Virtual
5	Male	41	15	Associate Professor of Health Economics	Public / Government	Virtual
6	Male	46	20	Insurance manager	Private	Virtual
7	Male	39	13	Pharmacist	Public / Government	In-person
8	Female	42	17	Researcher	Public / Government	In-person
9	Male	55	24	Associate Professor of Health Policy	Public / Government	In-person
10	Male	60	27	Medical specialist	Public / Government	In-person
11	Female	32	11	Hospital manager	Public / Government	Virtual
12	Male	40	16	Physician	Public / Government	Virtual
13	Male	37	12	Professor of Public Health	Public / Government	In-person
14	Male	41	16	Researcher	Public / Government	Virtual
15	Female	36	10	Pharmacist	Private	Virtual

triangulation of data sources and researchers to reduce bias; (d) incorporation of direct quotes from participants to boost authenticity; and (e) choosing participants from a range of professional backgrounds to enhance the applicability of the findings.

ETHICAL CONSIDERATIONS

The study was approved by the Ethics Committee of Lorestan University of Medical Sciences (IR.LUMS.REC.1404.112). Informed consent was obtained from all participants before the interviews, ensuring voluntary participation and confidentiality. Data were anonymized to protect participant identities, and all ethical guidelines for conducting qualitative research were strictly followed.

Results

The study included 15 participants, comprising 10 males and 5 females, with a mean age of 46.29 ± 5.71 years and an average work experience of 14.16 ± 7.38 years. Of the total interviews, 11 were conducted virtually, while 4 took place in person. Table I presents a summary of participant characteristics, including their roles, years of experience, and sectors.

This qualitative study explored the challenges associated with integrating AI into health policymaking in Iran through in-depth interviews. The analysis revealed five overarching themes: organizational and structural barriers, legal and policy constraints, data and information-related issues, skill and human resource challenges, and challenges associated with integrating AI into policymaking. Figure 1 presents the identified themes and subthemes. Each theme encompasses distinct sub-themes that encapsulate participants' perspectives on the specific impediments encountered in this context.

THEME 1: ORGANIZATIONAL AND STRUCTURAL BARRIERS

Participants consistently identified organizational and structural impediments as critical obstacles to the effective adoption of AI in health policymaking. This theme is subdivided into three key areas: lack of technical infrastructure, absence of coherent planning and management, and resistance to change.

Interviewees frequently cited inadequate technical resources as a fundamental barrier to AI implementation. They emphasized the scarcity of modern hardware, software, and reliable internet connectivity.

Some participants pointed out that:

> *"Our current equipment is outdated, and we lack consistent access to the tools required for AI deployment. Even basic connectivity issues undermine our efforts. For AI to be viable in this sector, substantial investments in foundational infrastructure are essential to support its functionality."* (Participants 2, 8, 9)

Participants underscored the lack of a unified strategy and poor inter-organizational coordination as significant hurdles.

It was emphasized that:

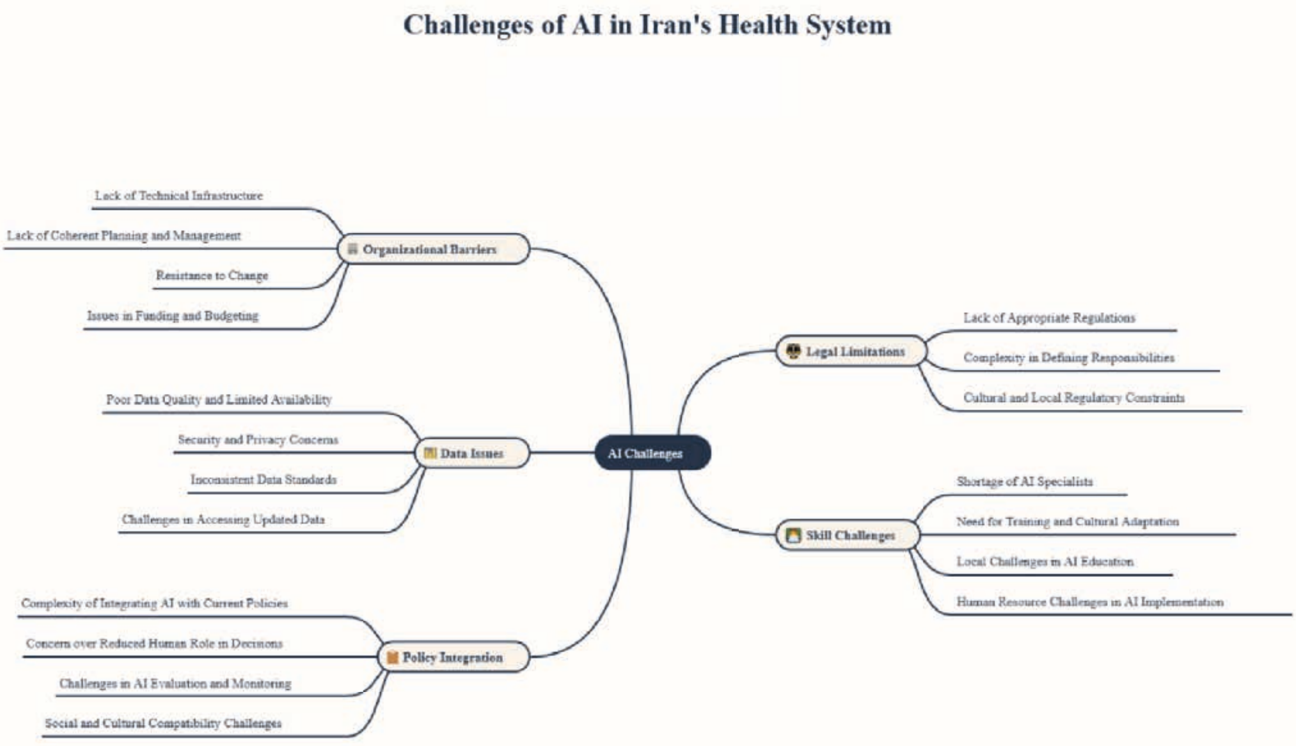
> *"There's no overarching plan for AI integration in our health system. Organizations work in isolation, leading to inefficiencies and redundancy. We need a centralized framework that defines AI's role and ensures alignment across the sector to maximize its potential."* (Participants 3, 5, 13).

Many participants noted a pervasive reluctance to embrace technological innovation at both individual and institutional levels.

A concern raised was that:

> *"A cultural aversion to change is evident, particularly among administrators who fear job displacement or misunderstand AI's purpose. This resistance stifles progress, as it hinders project initiation and staff engagement."* (Participants 1, 6, 11).

Fig. 1. Key themes and subthemes identified in the study.



THEME 2: LEGAL AND POLICY CONSTRAINTS

The absence of a supportive legal and policy framework emerged as a substantial barrier to AI adoption. This theme is characterized by two sub-themes: lack of appropriate regulations and complexity in assigning responsibilities.

Participants highlighted the absence of clear guidelines and regulatory support as a deterrent to AI use.

It was pointed out that:

> *"Without policies that promote and safeguard AI applications, health officials hesitate to proceed. Ethical and legal uncertainties further complicate adoption. Comprehensive legislation is needed to define permissible boundaries and foster confidence in AI initiatives."* (Participants 4, 7, 12)

Uncertainty surrounding accountability for AI-driven outcomes was a recurring concern.

A suggestion made was that:

> *"Determining liability when AI influences decisions is challenging. Leaders are wary of potential legal or ethical fallout, especially without clear directives. This ambiguity positions AI as a risk rather than a resource, slowing its uptake."* (Participants 2, 9, 14).

Challenges related to data availability, quality, and security were identified as pivotal constraints, encompassing two sub-themes: low-quality data and data limitations and security and privacy concerns.

Participants emphasized that fragmented and unreliable datasets impede AI's effectiveness.

It was argued that:

> *"Our data is inconsistent and poorly organized, drawn from disparate sources without standardization. This lack of robust, unified data restricts AI's ability to deliver meaningful insights for health policy."* (Participants 5, 8, 10).

Concerns about safeguarding sensitive health information were widely expressed.

A key point raised was that:

> *"The risk of data breaches or misuse looms large, given the sensitivity of health records. Stronger security measures and public assurances are prerequisites for building trust in AI applications within healthcare."* (Participants 1, 4, 9).

THEME 4: SKILL AND HUMAN RESOURCE CHALLENGES

The limited availability of qualified personnel and the need for enhanced training were prominent issues, divided into shortage of skilled AI professionals and need for training and cultural awareness.

Participants pointed to a dearth of experts proficient in both AI and healthcare.

It was mentioned that:

> *"We lack individuals with the dual expertise needed to bridge technology and health systems. Specialized training programs are scarce, forcing us to temper our expectations for AI implementation."* (Participants 6, 12, 13).

The necessity for education to bridge knowledge gaps and promote AI acceptance was evident.

Another point highlighted was that:

> *"Digital literacy among health administrators is limited, fueling skepticism about AI. Targeted training initiatives are critical to demystify the technology and position it as an asset rather than a threat."* (Participants 7, 10, 15).

THEME 5: CHALLENGES RELATED TO INTEGRATING AI INTO POLICYMAKING

Participants identified difficulties in embedding AI within existing policymaking structures, reflected in two sub-themes: complexity of integrating AI with existing policies and concerns over reducing human judgment in decision-making.

Adapting AI to align with established health policy frameworks proved challenging.

It was noted that:

> *"Our traditional policymaking processes aren't designed for AI integration, requiring significant restructuring. This overhaul demands time and readiness that many stakeholders lack."* (Participants 3, 5, 8).

Ethical apprehensions about diminishing human oversight were frequently raised.

A major concern was that:

> *"While AI offers efficiency, it lacks the nuanced understanding of human needs. Striking a balance between technological precision and compassionate decision-making remains a key struggle."* (Participants 2, 13, 14).

Discussion

This study explored the challenges of integrating AI into health policymaking in Iran, revealing five overarching themes: organizational and structural barriers, legal and policy constraints, data and information-related issues, skill and human resource challenges, and difficulties in integrating AI into policymaking. These findings align with and expand upon existing literature on AI adoption in healthcare, particularly in LMICs, while also highlighting unique contextual factors specific to Iran.

ORGANIZATIONAL AND STRUCTURAL BARRIERS

The lack of technical infrastructure, poor planning, and resistance to change emerged as significant barriers to AI adoption in Iran's health system. These findings are consistent with studies from other LMICs, such as India and Nigeria, where inadequate infrastructure and fragmented governance structures have similarly hindered AI implementation [12, 13]. However, Iran's challenges are exacerbated by economic sanctions, which restrict access to advanced technologies and funding. The resistance to change observed in this study is also reflective of broader cultural and institutional inertia, a phenomenon noted in other healthcare systems undergoing digital transformation [14]. Addressing these barriers will require substantial investments in infrastructure, coupled with efforts to foster a culture of innovation and adaptability.

LEGAL AND POLICY CONSTRAINTS

The absence of a supportive legal and policy framework was a recurring concern among participants. This finding echoes studies from countries like Brazil and South Africa, where the lack of clear regulations has slowed AI adoption in healthcare [15, 16]. In Iran, the situation is further complicated by ethical uncertainties and the complexity of assigning accountability for AI-driven decisions. These challenges underscore the need for comprehensive legislation that addresses both the technical and ethical dimensions of AI, as seen in the European Union's AI Act, which provides a regulatory framework for AI applications in healthcare [17].

DATA AND INFORMATION-RELATED ISSUES

Participants highlighted the poor quality of data and concerns about data security as major impediments to AI integration. Similar issues have been reported in other LMICs, where fragmented health information systems and limited data standardization hinder AI's potential [18]. In Iran, the lack of centralized data repositories and inconsistent data collection practices further exacerbate these challenges. Additionally, concerns about data privacy reflect global apprehensions about the misuse of health data, particularly in the absence of robust cybersecurity measures [19]. Addressing these issues will require investments in data infrastructure, standardized protocols, and public awareness campaigns to build trust in AI systems.

SKILL AND HUMAN RESOURCE CHALLENGES

The shortage of skilled AI professionals and the need for training were identified as critical barriers. This finding aligns with studies from countries like Kenya and Bangladesh, where a lack of interdisciplinary expertise has limited AI adoption [20, 21]. In Iran, the scarcity of professionals with dual expertise in AI and healthcare is compounded by limited access to specialized training programs. This highlights the urgent need for educational initiatives that bridge the gap between technology and healthcare, as well as efforts to promote digital literacy among healthcare administrators.

CHALLENGES IN INTEGRATING AI INTO POLICYMAKING

Participants expressed concerns about the complexity of integrating AI with existing policies and the potential reduction of human judgment in decision-making. These findings resonate with studies from high-income countries, where the ethical implications of AI-driven decision-making have sparked debates about the balance between efficiency and human compassion [22]. In Iran, the tension between technological precision and the human touch in healthcare is particularly pronounced, reflecting broader cultural values that prioritize personalized care. Addressing these concerns will require a nuanced approach that leverages AI's strengths while preserving the human element in healthcare decision-making.

IMPLICATIONS FOR POLICY AND PRACTICE

The findings of this study highlight critical areas where strategic action is needed to facilitate the successful integration of artificial intelligence into Iran's healthcare system. Policymakers, healthcare administrators, and technology stakeholders must collaborate to address the identified barriers through targeted interventions. First, developing robust legal and regulatory frameworks is essential. This involves creating clear policies that define the scope, accountability, and ethical boundaries of AI applications in healthcare. Establishing a dedicated regulatory body to oversee AI implementation can ensure compliance with data privacy standards and ethical guidelines. Pilot testing localized ethical frameworks in select healthcare settings can help strike a balance between AI-driven efficiency and the necessity of human oversight, particularly in sensitive areas such as diagnostics and treatment planning. Second, a significant investment in digital infrastructure is required to support AI technologies. Modernizing data systems with secure cloud storage, high-speed internet, and interoperable platforms will provide the foundation for effective AI deployment. Standardizing data collection and management practices across institutions will improve data quality and usability for AI applications. Creating centralized national health data repositories can address current fragmentation and enable more comprehensive AI-driven analyses.

Building human capacity is another critical priority. Interdisciplinary training programs that combine AI, healthcare, and ethics should be introduced in academic and professional development curricula. Upskilling current healthcare professionals through workshops and certification programs can enhance AI literacy and practical application skills. Additionally, attracting global AI expertise through incentives such as grants or partnerships with international organizations can help bridge existing knowledge gaps. Fostering collaboration across sectors is equally important. Public-private partnerships can facilitate the co-development of AI solutions tailored to Iran's specific healthcare challenges, such as managing non-communicable diseases or optimizing resource allocation. Addressing cultural resistance to AI adoption requires targeted awareness campaigns that emphasize AI's role as a supportive tool rather than a replacement for human judgment. Starting with small-scale pilot projects in low-risk areas, such as administrative workflows, can demonstrate AI's value and build confidence among stakeholders. Integrating AI into health policymaking processes can enhance decision-making and resource allocation. Forming multidisciplinary task forces within the Ministry of Health and Medical Education (MoHME) can ensure AI considerations are embedded in policy design and evaluation. Using AI-driven simulations to model policy impacts can provide policymakers with dynamic, data-informed insights. Maintaining transparency in AI applications, such as through explainable AI systems, will be crucial for sustaining trust among healthcare providers and patients. Addressing economic and geopolitical constraints requires innovative approaches. Supporting domestic AI innovation through funding and regulatory sandboxes can mitigate challenges posed by limited access to international technologies. Seeking partnerships with global health organizations for funding and technical support can further bolster Iran's AI capabilities in healthcare.

LIMITATIONS

While this study provides valuable insights into the challenges of AI adoption in Iran's health system, it has several limitations. First, the sample size of 15 participants, though sufficient for qualitative research, may limit the generalizability of the findings. Second, the study focused on the perspectives of healthcare professionals, policymakers, and AI experts, potentially overlooking the views of patients and the general public. Future research should explore these perspectives to provide a more comprehensive understanding of AI adoption in healthcare. Third, the study was conducted in Iran, and while the findings may be relevant to other LMICs, the unique socio-political and economic context of Iran may limit their transferability. Finally, the study relied on self-reported data, which may be subject to social desirability bias.

Conclusion

This study reveals five major barriers to AI integration in Iran's healthcare system: organizational and structural fragmentation, legal and regulatory gaps, data quality and governance issues, a shortage of skilled professionals, and challenges to embedding AI into existing policymaking processes. These interconnected challenges point to the need for a comprehensive, multi-sectoral strategy that includes investment in digital infrastructure, the development of clear legal and ethical frameworks, improved data systems, and targeted capacity-building programs. Additionally, integrating AI into health policymaking requires fostering a culture that supports innovation while maintaining human oversight and ethical accountability. Policymakers should draw on international experiences while adapting strategies to Iran's specific needs and constraints. Future research should develop and test context-sensitive interventions to support responsible, equitable, and sustainable AI implementation in the Iranian health system.

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Ethics approval and consent to participate

The Research Ethics Committee of Lorestan University of Medical Sciences provided ethical approval for this study (IR.LUMS.REC.1404.112) previously. All methods were performed according to the relevant guidelines and regulations, such as the Declaration of Helsinki. Informed consent for participating in this study was obtained from all the participants before the interview sessions.

Consent for publication

Not applicable.

Availability of data and materials

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

Conflict of Interest statement

The authors declare that they have no competing interests.

Authors' contributions

Me.B, Ma.B, MM and SA contributed to the conception and design of the study. Ma.B, MY, MN, AA, MM and SA conducted the interviews, and MM, NS, and Me.B were co-moderators. Ma.B, MM and SA conducted most of the analysis, which and Me.B discussed regularly. Ma.B, BD, and AB wrote the initial draft, and M.M, and S.A contributed to manuscript revisions. MM, MY, and Ma.B: editing. All authors read and confirmed the final manuscript.

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Correspondence: Masoud Behzadifar, Social Determinants of Health Research Center, Lorestan University of Medical Sciences, Khorramabad, Iran. E-mail: masoudbehzadifar@gmail.com; behzadifar@lums.ac.ir.

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Supplementary material

Tab. S1. Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist.

Item No	Guide Questions/Description	Reported on Page
Domain 1: Research team and reflexivity		
Personal Characteristics		
1. Interviewer/ facilitator	Which author/s conducted the interview or focus group?	Method
2. Credentials	What were the researcher's credentials? ***e.g.***, PhD, MD	Method
3. Occupation	What was their occupation at the time of the study?	Method
4. Gender	Was the researcher male or female?	Method
5. Experience and training	What experience or training did the researcher have?	Method
Relationship with participants		
6. Relationship established	Was a relationship established prior to study commencement?	Method
7. Participant knowledge of the interviewer	What did the participants know about the researcher? ***e.g.***, personal goals, reasons for doing the research?	Method
8. Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? ***e.g.***, Bias, assumptions, reasons and interests in the research topic	Method
Domain 2: study design		
Theoretical framework		
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? ***e.g.***, grounded theory, discourse analysis, ethnography, phenomenology, content analysis	Method
Participant selection		
10. Sampling	How were participants selected? ***e.g.***, purposive, convenience, consecutive, snowball	Method
11. Method of approach	How were participants approached? ***e.g.***, face-to-face, telephone, mail, email	Method
12. Sample size	How many participants were in the study?	Method
13. Non-participation Setting	How many people refaused to participate or dropped out? Reasons?	Method
14. Setting of data collection	Where was the data collected? ***e.g.***, home, clinic, workplace	Method
15. Presence of nonparticipants	Was anyone else present besides the participants and researchers?	Method
16. Description of sample	What are the important characteristics of the sample? ***e.g.***, demographic data, date	Method
Data collection		
17. Interview guide	Were questions, prompts, and guides provided by the authors? Was it pilot tested?	Method
18. Repeat interviews	Were repeat interviews carried out? If yes, how many?	Method
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	Method
20. Field notes	Were field notes made during and/or after the interview or focus group?	Method
21. Duration	What was the duration of the interviews or focus group?	Method
22. Data saturation	Was data saturation discussed?	Method
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	Method
Data analysis		
24. Number of data coders	How many data coders coded the data?	Method
25. Description of the coding tree	Did the authors provide a description of the coding tree?	Method
26. Derivation of themes	Were themes identified in advance or derived from the data?	Method
27. Software	What software, if applicable, was used to manage the data?	Method
28. Participant checking	Did participants provide feedback on the findings?	Method
Reporting		
29. Quotations presented	Were participant quotations presented to illustrate the themes/ findings? Was each quotation identified? ***e.g.***, participant number	Results
30. Data and findings consistent	Was there consistency between the data presented and the findings?	Results
31. Clarity of major themes	Were major themes clearly presented in the findings?	Results
32. Clarity of minor themes	Is there a description of diverse cases or a discussion of minor themes?	Results

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. International Journal for Quality in Health Care 2007;19:349-57.

Tab. S2. Interview Guide.

Title of Research:
Challenges of Utilizing Artificial Intelligence in the Health System of Iran: A Qualitative Study
Dear Participant's You are invited to participate in this interview. The purpose of this research is to explore the challenges and opportunities associated with the use of artificial intelligence (AI) in the health system of Iran. Your insights and experiences in this field are invaluable and will greatly contribute to a better understanding of this topic.
General Information: **Interviewer Name:** **Date:** **Time:** **Location:**
Privacy: All information collected during this interview will be kept anonymous and confidential. Participants may choose not to answer any questions at any time.
Interview Questions: **1. Background and Experience** Please describe your role and experience in the health system of Iran. Do you have any experience with the use of artificial intelligence in the health system?
2. Familiarity with Artificial Intelligence In your opinion, what role can artificial intelligence play in improving health services? Are you familiar with any AI technologies currently present in the health system of Iran?
3. Challenges **Technological Challenges:** What technological challenges do you see in implementing artificial intelligence in the health system? Are you facing any infrastructural or hardware issues? **Human Challenges:** What challenges exist regarding human resources (such as training and skills)? Do health system employees have any resistance towards artificial intelligence? If yes, what are the reasons? **Legal and Ethical Challenges:** Are you concerned about the legal and ethical aspects of using artificial intelligence in the health system? What laws should be established for the use of AI in health?
4. Opportunities In your opinion, what opportunities exist for the use of artificial intelligence in the health system? What initiatives or projects do you know of in this field?
5. Recommendations and Future Perspectives What recommendations do you have for improving the use of artificial intelligence in the health system? How do you envision the future of artificial intelligence use in Iran's health system? Thank you for participating in this interview and sharing your insights and experiences. If you have any additional comments or questions, we would be happy to hear them.

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INFECTIOUS DISEASE

Combating Infectious Diseases in Low-Resource Communities: Socioeconomic, Environmental, Climate Change and Gender-Based Strategies

IDRIS ZUBAIRU SADIQ[1]
[1] Department of Biochemistry, Faculty of Life Sciences, Ahmadu Bello University, Zaria-Nigeria

Keywords

Infectious diseases • Socioeconomic factors • Environmental health determinants • Climate change • Poverty

Summary

Infectious diseases continue to pose a significant challenge to global health, particularly within resource-limited communities, where socioeconomic and environmental health determinants amplify their prevalence and impact. This letter to editor examines comprehensive strategies aimed at alleviating the burden of communicable diseases by addressing essential factors such as water, sanitation, and hygiene (WASH), housing conditions, climate change, gender equity, sociocultural influences, and poverty. Common infectious diseases such as tuberculosis, malaria, HIV/AIDS, cholera, and dengue fever are significantly influenced by poor sanitation, inadequate housing, climate change, and gender disparities. Key interventions, including enhancing access to clean water, promoting sufficient sanitation, improving housing quality, and fostering climate resilience, are identified as vital measures to prevent disease transmission. Moreover, empowering women through equitable healthcare and education, implementing culturally responsive health campaigns, and engaging community members in preventive actions are distinctly highlighted. Strategies for poverty alleviation, encompassing economic development and social protection initiatives, play a crucial role in breaking the cycle of disease and poverty. This letter highlights the need for a multidisciplinary strategy and cross-sector collaboration to tackle the complex relations of these health determinants, promoting health equity and improving the well-being of vulnerable populations.

Dear Editor,

Communicable diseases continue to adversely impact resource-constrained communities, presenting a significant global health challenge. This persistent issue is linked to a complex of overlapping determinants of health, including the availability of safe drinking water and basic sanitation, housing conditions, climate change risks, gender inequity, sociocultural factors, and poverty [1]. Safe drinking water, sanitation, and hygiene (WASH) is crucial for health and well-being [2]. Ensuring access to safe drinking water and adequate sanitation is fundamental to preventing the spread of infectious diseases (Tab. I). Installing water purification systems, sewage treatment facilities, and the promotion of hygiene practices can significantly reduce disease transmission in vulnerable communities [3].

Poor housing conditions, such as overcrowding and inadequate ventilation, facilitate the spread of communicable diseases. Initiatives to improve housing quality, provide adequate living space, and ensure proper ventilation can mitigate the risk of disease outbreaks. Research shows that infectious disease transmission can be reduced by improving housing conditions, including timely and adequate repairs and maintenance, and creating an environment that supports healthy behaviors [4]. Despite the low quality of evidence, the direction and consistency of effects indicate that housing is an important risk factor for malaria. Investment in such research and housing programs should be considered a natural component of malaria control efforts and a close complement to Integrated Vector Management and WASH as part of long-term, sustainable development [5]. A study found that unacceptable housing conditions in Indian urban slums significantly negatively impact the health of residents, particularly under-five children [6].

Climate change exacerbates the spread of infectious diseases by altering the habitats of vectors such as mosquitoes and increasing the frequency of extreme weather events. Climate resilience strategies, including early warning systems and environmental management, are crucial in mitigating these impacts. Addressing climate change is crucial for preventing the spread of infectious diseases, as highlighted in various research papers. Climate change influences the epidemiology of diseases through factors like changes in climatic variables, vector patterns, and pathogen adaptation [7]. The impact of climate change on infectious diseases, especially in Asia, is significant due to increasing temperatures, changes in rainfall, and alterations in vector ecology [8]. Climate change has a profound impact on the spread of infectious diseases endemic to Africa for example Ebola, malaria, dengue fever, and cholera are largely due to the continent's varied ecosystems [9]. Effective strategies to combat this global health crisis include utilizing

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Tab. I. Infectious diseases, Socioeconomic and Environmental Determinants of health.

Disease	Causes	Water & Sanitation	Housing Conditions	Climate Change	Gender Equity	Sociocultural Factors
Tuberculosis	• Mycobacterium tuberculosis • Overcrowding • Poor ventilation	Improved sanitation	Adequate ventilation	Climate resilience	Gender-sensitive care	Culturally tailored education
Malaria	• Plasmodium parasites • Stagnant water • Mosquito bites	Mosquito control	Improved housing	Vector control programs	Mosquito net access	Community prevention efforts
HIV/AIDS	• HIV • Unsafe sex • Contaminated needles	Safe water access	Safe living conditions	Climate-resilient care	Gender-sensitive interventions	Culturally sensitive education
Cholera	• Vibrio cholera • Contaminated water • Poor hygiene	Safe drinking water	Sanitary living conditions	Rapid outbreak response	Equal access to health info	Community health education
Dengue Fever	• Dengue virus • Mosquito bites	Eliminate stagnant water	Protective housing	Early warning systems	Equal access to preventive care	Community awareness campaigns
Influenza	• Influenza virus • Airborne transmission • Seasonal variations	Clean water access	Well-ventilated homes	Climate-adaptive healthcare	Gender-sensitive health services	Health education
Hepatitis A	• Hepatitis A virus • Contaminated food/water • Poor sanitation	Improved sanitation	Hygienic living conditions	Disaster preparedness	Gender equity in health access	Public health education
Hepatitis B	• Hepatitis B virus • Bloodborne • Unsafe medical procedures	Safe water access	Safe housing	Resilient healthcare facilities	Equitable access to vaccines	Awareness campaigns
Measles	• Measles virus • Lack of vaccination	Safe water supply	Clean living conditions	Immunization programs	Gender-equitable healthcare	Community-based vaccination drives
Mumps	• Mumps virus • Direct contact • Respiratory droplets	Clean water access	Hygienic housing	Climate-adaptive healthcare	Equitable access to vaccines	Public health awareness
Rubella	• Rubella virus • Inadequate vaccination	Safe drinking water	Sanitary living conditions	Climate resilience	Gender-sensitive vaccination	Health education campaigns
Polio	• Poliovirus • Contaminated food/water	Improved sanitation	Hygienic living environments	Climate-resilient health systems	Gender equity in health services	Community vaccination campaigns
Typhoid Fever	• Salmonella Typhi • Contaminated food • Poor sanitation	Safe water access	Hygienic housing	Disaster preparedness	Equal access to healthcare	Community health education
Leptospirosis	• Leptospira bacteria • Contaminated water	Clean water access	Improved housing	Flood management	Gender-sensitive interventions	Public health education
Schistosomiasis	• Schistosoma parasites • Contaminated water contact	Safe water supply	Hygienic living conditions	Environmental management	Gender-sensitive healthcare	Community awareness campaigns
Zika Virus	• Zika virus • Mosquito bites • Tropical climate	Mosquito control	Protective housing	Vector control programs	Equitable access to preventive care	Community education
Yellow Fever	• Yellow fever virus • Mosquito bites	Eliminate stagnant water	Protective housing	Early warning systems	Equal access to vaccination	Community awareness campaigns
Ebola	• Ebola virus • Contact with infected fluids	Safe drinking water	Isolation facilities	Disaster preparedness	Gender-sensitive interventions	Public health education
SARS	• SARS coronavirus • Airborne transmission • Close contact	Improved sanitation	Safe housing	Climate-resilient healthcare	Equitable access to healthcare	Public health awareness
MERS	• MERS coronavirus • Camel contact • Respiratory droplets	Safe water access	Safe housing	Climate resilience	Gender-sensitive health services	Public health education

vaccines and vaccination as a mitigation measure against climate change-related health effects [10]. Collaborative efforts, strategic intersectoral partnerships, and the implementation of adaptation and mitigation measures are essential to address the complex interactions between climate change and infectious diseases.

Gender inequity can hinder access to healthcare and education, disproportionately affecting women and girls. Empowering women through education, economic opportunities, and equitable healthcare access is vital in reducing the burden of infectious diseases (Tab. I). Gender disparities affect vulnerability, exposure risk, treatment, and response to emerging infectious diseases like SARS-CoV-2, highlight the need for inclusive epidemic and pandemic plans that address all sex and gender factors [11]. Gender inequities persist in various fields, including Infectious Diseases, with barriers such as gender bias, work-life balance challenges, and differences in negotiation strategies hindering women's academic advancement in medicine. Recognizing the impact of gender inequity during infectious disease outbreaks is crucial, particularly in regions such as Africa, where women often face a disproportionate burden. To ensure effective prevention and management, it is essential to adopt interdisciplinary approaches that account for gender-based differences in disease causes and patterns, enhancing patient care and guiding meaningful healthcare reforms.

Sociocultural practices and beliefs can influence health behaviors and disease outcomes. Culturally sensitive health education campaigns and community engagement initiatives are essential in promoting preventive measures and encouraging timely healthcare seeking behavior. Sociocultural factors play a crucial role in preventing infectious diseases by influencing transmission dynamics and shaping public health interventions. Research highlights the importance of considering cultural factors, social norms, and social support in disease spread [12]. Additionally, the involvement of families and cultural approaches are vital in controlling and preventing diseases like Covid-19, emphasizing the importance of gender, education, marriage, and occupation in prevention efforts [13].

Poverty is a critical determinant of health, limiting access to nutritious food, healthcare, and clean-living environments. Comprehensive poverty alleviation strategies, including economic development, social protection programs, and improved access to healthcare services, are necessary to break the cycle of disease and poverty [14]. Infectious diseases, including COVID-19, HIV/AIDS, acute hepatitis, dengue, rabies, and Ebola, disproportionately affect needy communities due to poor living conditions and lack of access to healthcare, clean water, and sanitation [15] (Tab. I). Urban populations in low- and middle-income countries face increase exposure to vector-borne diseases due to factors like poverty, mobility, and climate change, necessitating evidence-based interventions and public health policies to address these threats effectively [16]. Through addressing poverty through improved access to resources, healthcare, and sanitation, the burden of infectious diseases can be significantly reduced, leading to better health outcomes and overall well-being for vulnerable populations.

Conclusion

Addressing the global burden of infectious diseases requires a holistic approach that tackles the socioeconomic and environmental determinants of health. Investing in water and sanitation infrastructure, improving housing conditions, addressing climate change, promoting gender equity, recognizing sociocultural factors, and alleviating poverty can make significant strides towards reducing the impact of communicable diseases on resource-constrained communities.

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Correspondence: Idris Zubairu Sadiq, Department of Biochemistry, Faculty of Life Sciences, Ahmadu Bello University, Zaria-Nigeria. E-mail: idrisubalarabe2010@gmail.com.

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INFECTIOUS DISEASE

Pneumococcal Vaccination of Adults in Italy: What Strategies?

ELVIRA MASSARO[1], GIOVANNI GABUTTI[2]
[1] ASL3 Healthcare System of the Liguria Region, Genoa, Italy; [2] Italian Society of Hygiene, Preventive Medicine, and Public Health (SItI), Cogorno (Ge), Italy; Adult Immunization Board (AIB)

Keywords

Pneumococcal Vaccination • *Streptococcus pneumoniae* • Invasive Pneumococcal Disease • Epidemiological Surveillance

Summary

S. pneumoniae has been classified by the World Health Organization (WHO) as one of the 12 priority pathogens with the greatest global health impact. Although many individuals (approximately 20–30% of adults and nearly 40–50% of children) may carry the bacterium asymptomatically, certain groups are considered at higher risk of disease (non-invasive illnesses and invasive diseases). These include young children, the elderly and individuals who are immunocompromised or affected by pre-existing medical conditions.

Italian surveillance data show a significant increase in Invasive Pneumococcal Disease (IPD) incidence in 2023 in comparison with 2021 and 2022, rising from 0.84 cases per 100,000 population in 2021 to 3.02 in 2023. The highest rates were observed in children under 1 year of age [10.41/100,000 (2023)] and in adults aged 65 and over (7.45/100,000 in 2023 compared with 2.11 in 2021 and 4.49 in 2022).

Surveillance systems and epidemiological studies on the global distribution of the different pneumococcal serotypes associated with disease continue to be essential to determining which serotypes to include in new vaccines, in order to produce preparations capable of preventing an increasing number of cases, hospitalizations, sequelae and deaths.

A milestone in pneumococcal vaccination was the development of conjugate vaccines (PCVs), which started in the 2000s. The first PCV, which covered seven serotypes (PCV7: 4, 6B, 9V, 14, 18C, 19F, and 23F), was introduced in Italy in 2005 for the pediatric population. The introduction of this vaccination strategy leading to a significant reduction in disease among children and an overall decline in the pneumococcal disease burden across all age-groups. However, an increase in disease caused by serotypes not included in PCV7 was observed. This phenomenon, named serotype replacement, led to the development of higher-valency conjugate vaccines. In 2010, the 13-valent pneumococcal vaccine (PCV13) and 10-valent pneumococcal vaccine (PCV10) were approved. However, the phenomenon of serotype replacement continued to be observed, and consequently, the need for broader-spectrum vaccines remained a public health priority.

In 2021 and 2022 PCV15 (serotypes: 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F and 33F) and PCV20 (serotypes: 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F and 33F) were authorized for immunization in individuals aged ≥18 years, respectively. In March 2025, the use of a new 21-valent pneumococcal vaccine was approved (serotypes: 3, 6A, 7F, 19A, 22F, 33F, 8, 10A, 11A, 12F, 9N, 17F, 20, 15A, 15C, 16F, 23A, 23B, 24F, 31 and 35B) and it included some serotypes particularly aggressive or emerging.

Maximizing the effectiveness of a vaccination program in combating diseases related to S. pneumoniae is based on the integration of three key elements: epidemiological need, immunological need and vaccine compliance.

From an epidemiological perspective, the 2023 specific data analysis reveals that, out of 1,783 cases, 734 involved individuals over the age of 64 (41.2%). The estimated global coverage with the PCV20 vaccine would be 63.6%, while with the PCV21 vaccine it would be 76.4%. The specific analysis of the most recent available data (1st half of 2024) reveals that a total of 1,152 cases were reported, 58.4% of which occurred in individuals over 64. If only the data referring to subjects over the age of 64 are analyzed, the estimated coverage becomes 72.1% for PCV20 and 79.2% for PCV21.

From an immunological standpoint, the vaccine of choice should induce an immune response that is at least non-inferior to the comparator, and ideally, more robust and long-lasting.

Regarding compliance, all possible strategies must be activated in order to raise public awareness of the risks of pneumococcal disease and the benefits of vaccination, so as to increase coverage rates.

A thorough analysis of epidemiological and clinical data, combined with an assessment of the economic and social impact, is crucial to guiding vaccination policies and supporting efficient decision-making in order to protect the health of the entire population.

Introduction

Streptococcus pneumoniae (*S. pneumoniae*), a Gram-positive bacterium, causes a wide spectrum of diseases, ranging from non-invasive illnesses such as bronchitis, non-bacteremic pneumonia, sinusitis and otitis media, to invasive diseases, including bacteremia, septicemia, osteomyelitis, pneumonia and meningitis [1].

S. pneumoniae is able to colonize the nasopharynx, resulting in a carrier state, which involves approximately 20–30% of adults and nearly 40–50% of children [2].

Among its essential structural components, phosphorylcholine – part of the bacterial cell wall – plays a key role in the colonization of the upper respiratory tract, owing to its ability to bind specific receptors on human epithelial cells [3, 4].

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Under normal conditions, colonization does not progress to clinically apparent disease. Progression to invasive disease requires the local activation of proinflammatory mediators, such as interleukin-1 (IL-1) and tumor necrosis factor (TNF) [5]. This inflammatory response induces both quantitative and qualitative changes in the receptors present on epithelial and endothelial cells. Choline in the bacterial cell wall has a high affinity for the platelet-activating factor receptor, whose expression is increased during inflammation [6]. Interaction with this receptor facilitates bacterial internalization and promotes transcellular passage across epithelial and vascular barriers, allowing *S. pneumoniae* to invade deeper tissues [7].

Another key factor in the pathogenesis of pneumococcal disease is pneumolysin, a cytotoxin capable of forming pores in eukaryotic cell membranes and interfering with complement activation, thereby contributing to immune evasion and tissue damage [6, 7].

Although many individuals may carry the bacterium asymptomatically, certain groups are considered at higher risk of disease. These include young children, the elderly and individuals who are immunocompromised or affected by pre-existing medical conditions. Among these, diabetes mellitus, chronic lung disease, liver disease, chronic kidney disease and sickle cell anemia are major risk factors. Recent studies have also identified additional predisposing conditions, such as sarcoidosis, inflammatory polyarthropathies, systemic connective tissue diseases and various neurological disorders, highlighting the complexity of individual susceptibility profiles [8]. Furthermore, concurrent viral infections can predispose individuals to invasive pneumococcal disease [9]. Other contextual and behavioral factors – such as the winter season, tobacco smoking and chronic alcohol consumption – also constitute risk factors for the development of invasive pneumococcal disease [8].

To date, the polysaccharide capsule surrounding the cell wall is widely recognized as the main virulence factor of *S. pneumoniae*. The structural composition of the capsule enables the bacterium to evade opsonization and phagocytosis [10]. Analysis of the capsule's polysaccharides has led to the identification of over 100 different *S. pneumoniae* serotypes. However, it is important to note that only a subset of these serotypes is responsible for the majority of invasive clinical cases [11]. Disease-causing serotypes differ not only in their structural characteristics but also in their associated disease severity, lethality, invasiveness, antibiotic susceptibility and distribution across age-groups and geographic regions [12, 13].

The Burden of *Streptococcus pneumoniae* Disease in Adults: A Major Public Health Concern

Despite significant progress in diagnostic and therapeutic pathways, infections caused by *S. pneumoniae* remain associated with high morbidity and mortality rates, particularly among vulnerable populations such as children, the elderly and individuals with compromised immune systems [14]. Indeed, *S. pneumoniae* has been classified by the World Health Organization (WHO) as one of the 12 priority pathogens with the greatest global health impact [3].

In 2021, *S. pneumoniae* was responsible for the majority of lower respiratory tract infection (LRTI)-related cases and deaths (excluding SARS-CoV-2), with an estimated 97 million cases and 505,000 deaths globally. Of these, the largest number occurred in children under the age of 5 years, and in adults over 70 years old [15, 16].

According to data from the European Centre for Disease Prevention and Control (ECDC), in 2022 the incidence rate of invasive pneumococcal disease (IPD) in Europe was 5.11 cases per 100,000 population, with the highest rates being observed in individuals over 64 years of age and in children under 4 years (13.42 and 12.49 cases per 100,000 population, respectively). Clinically, the most common presentations were bacteremic pneumonia (41.2%) and septicemia (37.7%), followed by meningitis (13.8%). Overall case fatality rates were 17.1% among those over 65 and 10.9% among individuals aged 45–64 [17].

Italian surveillance data show a significant increase in IPD incidence in 2023 in comparison with 2021 and 2022, rising from 0.84 cases per 100,000 population in 2021 (500 cases) to 3.02 in 2023 (1,783 cases). The highest rates were observed in children under 1 year of age [10.41/100,000 (2023), exceeding the pre-pandemic value of 6.50 in 2019] and in adults aged 65 and over (7.45/100,000 in 2023 compared with 2.11 in 2021 and 4.49 in 2022). This increase was probably attributable, at least in part, to improved diagnostic techniques and growing awareness of IPD in Public Health Surveillance. Most notifications occurred during the winter months, confirming the established seasonal pattern. The most frequently reported clinical manifestations were sepsis and bacteremia (37–55% of cases), followed by pneumonia associated with sepsis/bacteremia (25-36%) and meningitis, with or without sepsis/bacteremia (18-25%) [15]. The interim report for the first six months of 2024 cited a total of 1,152 IPD cases, 673 of which occurred in individuals over 64 years of age [18].

S. pneumoniae infections, especially in the elderly, are often responsible for a large number of community-acquired pneumonia (CAP) cases, making them the leading cause of hospital admissions among individuals aged > 65 years – approximately 2,000 admissions per 100,000 per year in the developed countries [19]. Moreover, beyond the disease burden directly caused by the infection, pneumococcal CAP in the elderly is frequently complicated by cardiovascular events, which further increase its clinical, economic and social impact [14, 20, 21].

In high-income countries, *S. pneumoniae* remains responsible for up to 50% of CAP cases, with in-hospital mortality reaching as high as 40% among older adults [22].

In Italy, CAP has a significant clinical and economic impact, with a hospitalization rate of 31.8% among adults, and *S. pneumoniae* remains the main etiological agent [23]. A large study conducted in four Italian regions between 2017 and 2020 found that, among 1,155 individuals aged ≥ 65 years hospitalized for CAP, 13.1% had an infection caused by *S. pneumoniae*. The most frequently detected serotypes were: 3 (2.0%), 8 (1.7%), 22F (0.8%), 11A (0.7%) and 9N (0.6%). Moreover, the study showed that highly invasive serotypes (1, 5, 7F and 8) accounted for 2.1% of cases. Serotypes included in the conjugate vaccines PCV15 and PCV20 were present in 4.4% and 7.5%, respectively, of CAP cases [24].

Serotype 3 plays a significant role in clinical manifestations and is associated with more severe disease [22, 25]. In recent years, this serotype has become one of the most commonly identified causes of interstitial lung disease in most Western countries [24, 26]. Its increased circulation is probably due to several factors: the current conjugate pneumococcal vaccines (PCVs) for adults appear to have limited efficacy against this serotype, whose polysaccharide capsule is thicker and lacks a covalent bond to the peptidoglycan layer. This characteristic renders the capsule more resistant to immune attack, as it reduces opsonophagocytic killing, thereby facilitating persistence and transmission.

Surveillance Systems: The Importance of Continuous Monitoring

Communicable diseases continue to constitute a public health priority, owing to their significant clinical, economic and epidemiological impact. In this context, epidemiological and laboratory surveillance plays a central role, as it allows the systematic and integrated collection of essential data that can guide public health decision-making, support efforts to combat respiratory infections and aid the development of new vaccines. It also plays a key role in both global and local health security. By definition, infectious disease surveillance involves the continuous and systematic collection of information regarding the distribution of diseases and associated risk factors, as well as the analysis of temporal, spatial and demographic trends, with the aim of informing effective prevention and control measures [27].

Recently, the World Health Organization (WHO), through the publication of the *Global Strategy on Comprehensive Vaccine-Preventable Disease Surveillance (2021–2030)*, has emphasized the need to develop more comprehensive and integrated national and regional surveillance systems capable of monitoring the full spectrum of the infectious diseases that are most relevant in various geographical contexts. This integrated approach not only supports efforts to achieve the elimination and eradication goals set out in the *Immunization Agenda 2030*, but also constitutes an essential tool for strengthening vaccination programs [28].

In the United States, following the release of the report *Addressing Emerging Infectious Disease Threats: A Prevention Strategy for the United States* [29], the Emerging Infections Program (EIP) was established a network of state health departments coordinated by the Centers for Disease Control and Prevention (CDC). The aim of this network is to detect emerging pathogens, conduct research based on laboratory and epidemiological data, and implement projects supporting public health protection and prevention efforts [30].

In 1995, the Active Bacterial Core Surveillance (ABCs) system was launched – a surveillance network created under the CDC's EIP to monitor and estimate the burden of invasive bacterial infections of public health relevance [31]. Initially composed of four sites (California, Connecticut, Oregon and Minnesota), the ABCs network expanded in 2003 to include Georgia, Maryland, New York, Tennessee, Colorado and New Mexico, thus comprising a total of 10 sites. The network ensures case monitoring through the systematic verification of clinical and laboratory data in collaboration with the CDC, state health departments and universities [32].

The need to establish an active surveillance network arose alongside the development of the 13-valent PCV, as it was crucial to have a system capable of determining baseline IPD rates, monitoring circulating serotypes and assessing vaccine effectiveness. Indeed, evidence gathered through the ABCs network revealed a significant reduction in IPD incidence in children, due to the introduction of the 7-valent PCV (PCV7), as well as in adults, due to herd protection. However, it also showed an increase in cases caused by *S. pneumoniae* serotypes not included in the commercial vaccines [31].

In Europe, the first *S. pneumoniae* surveillance systems date back to the 1990s, when the growing availability of vaccines – initially polysaccharide-based and later conjugate vaccines – highlighted the need for standardized data on disease incidence and serotype distribution, in order to measure vaccine impact and guide immunization strategies. With the introduction of the PCV7 conjugate vaccine, several European countries established dedicated surveillance systems or strengthened existing ones.

The ECDC implemented the TESSy surveillance, which was designed for the collection, analysis and sharing of epidemiological data across the European Union and the European Economic Area. This system integrates demographic, clinical and laboratory data, enabling time-trend analyses of cases and comparisons between member states, with the aims of monitoring incidence, evaluating the impact of vaccination programs, identifying emerging trends and supporting evidence-based policy decisions.

In Italy, a surveillance system for Invasive Bacterial Diseases (MIB), coordinated by the Istituto Superiore di Sanità (ISS), has been in place since 2007. The aim of this surveillance is to monitor the temporal and spatial trends of these diseases, describe the frequency of cases by pathogen (*Neisseria meningitidis*, *S. pneumoniae* and *Haemophilus influenzae*) and serotype, and estimate the proportion of cases preventable through vaccination, in order to improve prevention and control strategies [15].

Pneumococcal Vaccines: Epidemiological Evolution, Serotype Variation and New Opportunities

Surveillance systems and epidemiological studies on the global distribution of the different pneumococcal serotypes associated with disease continue to be essential to determining which serotypes to include in new vaccines, in order to produce preparations capable of preventing an increasing number of cases, hospitalizations, sequelae and deaths [33].

The development of the first generation of pneumococcal polysaccharide vaccines using purified capsular polysaccharides dates back to the 1950s. The non-conjugate polysaccharide vaccines elicit a short-lived immune response, with a significant decline in immunity 6–24 months after vaccination. Indeed, these vaccines primarily induce a B cell-mediated immune response without involving T cells [34-36].

The first second-generation pneumococcal polysaccharide vaccine was the 14-valent PPSV14, licensed in the United States in 1977. It was later superseded by PPSV23, which contains the serotypes most commonly associated with invasive pneumococcal disease (1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19A, 19F, 20, 22F, 23F and 33F) [35]. PPSV23 is indicated for active immunization from 2 years of age, is administered in a single dose and is used sequentially after a conjugate vaccine, with revaccination being possible after five years [37].

A milestone in pneumococcal vaccination was the development of conjugate vaccines (PCVs), which started in the 2000s. These vaccines are based on mechanisms similar to those of conjugated Hib vaccines, which used carrier proteins such as diphtheria toxoid (PRP-D), meningococcal outer membrane protein (PRP-OMP) and tetanus toxoid (PRP-T) [34]. The covalent conjugation of capsular polysaccharides with a carrier protein has been shown to elicit a T cell–dependent adaptive immune response and induce B memory cells, resulting in immunological memory. This antigenic shift renders these vaccines much more immunogenic in both adults and infants [38, 39].

The first PCV, which covered seven serotypes (PCV7: 4, 6B, 9V, 14, 18C, 19F, and 23F), was introduced in the United States in 2000 and in Europe in 2001. In Italy, vaccination with PCV7 was included in the National Immunization Prevention Plan (PNPV) in 2005 for the pediatric population [40].

The introduction of pediatric vaccination with PCV7 effectively generated long-lasting immunity in vaccinated infants and reduced nasopharyngeal carriage of the seven most virulent *S. pneumoniae* serotypes – leading to a significant reduction in disease among children and an overall decline in the pneumococcal disease burden across all age-groups [39, 41, 42].

In parallel with the reduction in IPD cases caused by vaccine-targeted serotypes, however, an increase in disease caused by serotypes not included in PCV7 was observed [43]. This phenomenon, named serotype replacement, *i.e.* a relative increase in cases of disease due to serotypes not included in the commercially available vaccine, led to the development of higher-valency conjugate vaccines. In 2010, the 13-valent pneumococcal conjugate vaccine (PCV13) was approved. In addition to the serotypes in PCV7, it covers serotypes 1, 3, 5, 6A, 7F and 19A. Initially indicated only for children, it was later approved for adults over 50 years of age [44]. Around the same time, a 10-valent conjugate vaccine was also approved for the pediatric population [45].

In high-income countries, the introduction of PCV10 and PCV13 conjugate vaccines has led to two significant trends: on one hand, a considerable decrease in invasive and non-invasive disease caused by vaccine-included serotypes; on the other, the phenomenon of serotype replacement [35]. This epidemiological phenomenon has generated the need to develop conjugate vaccines that contain an ever-greater number of serotypes, in order to broaden protection against pneumococcal disease.

In 2021, the European Medicines Agency (EMA) authorized PCV15, a conjugated and adsorbed polysaccharide vaccine containing the serotypes: 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F and 33F. Initially used for the active immunization of adults aged ≥18 years, in October 2022 it was also authorized for use in individuals from six weeks of age. For those over 18 years, a single dose is administered, and it is important to note that the product's Summary of Product Characteristics (SmPC) indicates co-administration with the seasonal quadrivalent (inactivated, split virion) influenza vaccine, thus providing an important contribution to vaccination strategies [46].

In February 2022, in Europe (in May 2022 in Italy), the 20-valent conjugated adsorbed vaccine (serotypes: 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F and 33F) was authorized for immunization in individuals aged ≥18 years. Later, PCV20 also obtained authorization for pediatric use (March 2024) according to a 3 + 1 schedule. In adults and the elderly, PCV20 may be co-administered with the seasonal influenza vaccine [47].

The systematic review by Teixeira et al. examined 118 studies published between 2010 and 2022 in 33 European countries, and showed that the serotypes covered only by PCV20 (8, 10A, 11A, 12F, 15B, 22F and 33F) have become increasingly prevalent among adults since the introduction of PCV13, causing both invasive and non-invasive pneumococcal disease [12].

A recent cost-effectiveness study used a Markov model to evaluate the implementation of PCV20 in the Italian adult vaccination strategy. Assuming vaccination of 100% of cohorts aged 65 to 74 years, immunization with PCV20, in comparison with PCV13, proved to be dominant (lower cost and a better health outcome), yielding an estimated reduction of 1,208 deaths; 1,171 cases of bacteremia (excluding meningitis); 227 cases of meningitis; 9,845 hospitalized cases of non-bacteremic pneumonia, and 21,058 non-hospitalized cases; the total gain was of 6,581.6 life-years and 4,734.0 QALYs (Quality Adjusted Life Year). Comparison with PCV15 showed an ICER (Incremental Cost-Effectiveness Ratio) of €66 per life-year gained and €91 per QALY. The authors concluded that vaccination of the elderly population with PCV20 was a sustainable and efficient investment [48].

In March 2025, in Europe and subsequently in Italy (May 2025), the use of a new 21-valent pneumococcal conjugate polysaccharide vaccine, conjugated to the CRM197 carrier protein, was approved [49]. The vaccine protects against 21 serotypes (3, 6A, 7F, 19A, 22F, 33F, 8, 10A, 11A, 12F, 9N, 17F, 20, 15A, 15C, 16F, 23A, 23B, 24F, 31 and 35B), some of which are particularly aggressive or emerging. Administered in a single dose, it is indicated for active immunization against invasive disease and pulmonary infection caused by *S. pneumoniae* in individuals aged 18 years or older.

Clinical trials conducted in adults have evaluated its effectiveness against invasive pneumococcal disease and pulmonary infection, as well as its immunogenicity. The double-blind, randomized STRIDE 3 trial included pneumococcal vaccine-naïve adults aged 18 years and older, with or without stable chronic medical conditions [50]. Participants were divided into two cohorts: the first included individuals aged 50 and older, who were randomized 1:1 to receive either PCV21 or PCV20. The second cohort comprised participants aged 18 to 49 years, randomized 2:1.

Serotype-specific opsonophagocytic activity (OPA) and IgG responses were measured on Day 1 and Day 30 post-vaccination. PCV21 displayed non-inferior OPA levels in comparison with PCV20 for the ten shared serotypes and met superiority criteria for 10 of the 11 serotypes included only in PCV21 (with the exception of serotype 15C). Although superiority was not reached for 15C, robust immune responses were observed. Additionally, PCV21 elicited a cross-reactive immune response to serotype 15B, probably due to structural similarity between 15B and 15C. PCV21 was generally well tolerated, with a safety profile similar to PCV20, and showed a greater response toward serotypes 3 and 8. Furthermore, the most commonly reported adverse events were mild and short-lasting (less than 3 days) pain at the injection site and headache [50].

In another Phase III randomized controlled trial (STRIDE-6), the safety, tolerability and immunogenicity of the PCV21 were evaluated in adults aged 50 years and older. The study included 717 previously vaccinated adults, who were divided into three cohorts on the basis of their prior vaccination history:

Cohort 1: individuals previously vaccinated with PPSV23, randomized 2:1 to receive PCV21 or PCV15.

Cohort 2: individuals previously vaccinated with PCV13, randomized 2:1 to receive PCV21 or PPSV23.

Cohort 3: individuals with mixed vaccination history received open-label PCV21.

Immunogenicity was assessed 30 days post-vaccination in terms of geometric mean titers (GMTs) of OPA and geometric mean concentrations (GMCs) of IgG for all serotypes included in V116. Safety was monitored by recording the proportion of participants reporting adverse events.

PCV21 was found to be immunogenic against all 21 serotypes included, with immune responses generally comparable to those elicited by the other vaccines used in the study. Thirty days after vaccination, OPA GMTs against shared serotypes were generally similar between PCV21 and PCV15 (Cohort 1), and between PCV15 and PPSV23 (Cohort 2). The most frequently reported adverse events were injection site pain and fatigue, usually mild to moderate in intensity and lasting no longer than 3 days [51].

It is also noteworthy that PCV21 includes emerging and hard-to-control serotypes, including 9N, 15C, 16F, 17F, 20A, 23A, 23B, 24F, 31 and 35B. Notably, serotype 15C is capable of eliciting a cross-reactive immune response against the deOAc15B polysaccharide, owing to structural similarity, thereby providing protection against serotype 15B.

Table I provides a summary of the evolution of pneumococcal vaccines.

Figure 1 illustrates the evolution of third-generation pneumococcal vaccines.

Pneumococcal Vaccination of Adults in Italy: Where Do We Stand?

Recent demographic projections for Italy indicate an ongoing transition marked by progressive population aging. Indeed, it is estimated that, by 2050, individuals aged 65 and over will constitute 34.6% of the total population, compared with the current 24.3% [52]. In this context, it is clear that Public Health must pay particular attention to this population group, in order to implement vaccination programs capable of reducing the disease burden due to preventable infectious illnesses.

With regard to invasive pneumococcal disease (IPD) in Italy, among adults over the age of 64, the incidence increased in 2023, reaching 7.45 cases per 100,000 inhabitants, compared with 2.11 in 2021 and 4.49 in 2022 [15].

Pneumococcal vaccination with conjugate vaccines for adults and the elderly began to be offered in 2015 in certain Italian Regions, with a gradual rollout. The 2017-2019 PNPV recommended free pneumococcal vaccination for all individuals aged ≥65 years; this consisted of the administration of PCV13, followed, after at least two months, by a dose of 23-valent polysaccharide vaccine (PPSV23) in a sequential schedule. Vaccination was also recommended for all individuals at higher risk of severe pneumococcal infections and complications due to specific clinical conditions or chronic comorbidities [53].

The 2023–2025 PNPV reinforces previous

Tab. I. Pneumococcal vaccines: the evolution.

FIRST GENERATION
1911: whole-cell vaccine
1930: vaccine serotypes combined with live attenuated bacteria
Mid-1930s: multivalent vaccines containing partially purified capsular material
Late 1940s: multivalent polysaccharide vaccines
Early 1950s: first generation of pneumococcal polysaccharide vaccines introduced into the market
SECOND GENERATION
Unconjugated polysaccharide vaccines
1977: 14-valent vaccine approved in the USA
1983: 23-valent vaccine (1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 11F, 14, 15B, 17F, 18C, 19A, 19F, 20, 22F, 23F) approved in the USA
Conjugated polysaccharide vaccines
2000: 7-valent vaccine (PCV-7) (4, 6B, 9V, 14, 18C, 19F, 23F) approved in the USA and shortly afterwards in Europe (2001)
THIRD GENERATION
Conjugated polysaccharide vaccines with expanded antigenic coverage
2009-2010: approval of the 10-valent vaccine (1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F, 23F) and the 13-valent vaccine (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 23F)
December 2021 (European approval) - March 2021 (Italian approval): 15-valent vaccine (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F and 33F) approved for adults ≥ 18 years.
February 2022 (European approval) - May 2022 (Italian approval): 20-valent vaccine for individuals ≥18 years.
March 2025 (European approval) - May 2025 (Italian approval): 21-valent vaccine (3, 6A, 7F, 19A, 22F, 33F, 8, 10A, 11A, 12F, 9N, 17F, 20, 15A, 15C, 16F, 23A, 23B, 24F, 31 and 35B) approved for individuals aged ≥ 18 years.

Fig. 1. Evolution of third-generation pneumococcal vaccine.

* For PCV21, a cross-reactive immune response was observed *versus* serotype 15B; this was elicited by serotype 15C, which is structurally similar to serotype 15B.

recommendations, reaffirming the need to ensure free pneumococcal vaccination for the cohort of 65-year-olds and for frail patients of any age [54]. It should be noted that the right to free vaccination is maintained for life.

Regarding at-risk adults and older individuals, vaccination with a single dose of PCV is recommended starting from the cohort of 65-year-olds. The offer should eventually be supplemented with a sequential vaccination schedule (PCV/PPSV) depending on the type of PCV used.

For these categories, a minimum coverage target of 75% and an optimal target of 95% has been established, in line with the standards already defined for other adult vaccinations. The stated objective is to harmonize vaccination uptake across the country, reduce regional inequalities and ensure adequate protection for the most vulnerable segments of the population [54].

A cross-sectional study conducted as part of the OBVIOUS project and published in 2024 analyzed pneumococcal vaccination coverage in Italy and the barriers limiting uptake. Conducted in 2022 on a representative sample of adults, the survey revealed that coverage among high-risk adults remained unsatisfactory: only 39.5% of eligible individuals had been vaccinated, with even lower rates among those aged ≥65 years (33.7%). Slightly higher rates were recorded among patients with chronic conditions such as diabetes, cardiovascular or respiratory diseases, but coverage still fell well below the ≥75% target set by the national program [55].

Another retrospective study, published in 2024 and conducted in the Province of Viterbo (Lazio Region, Italy), investigated the rate of completion of the sequential pneumococcal vaccination schedule among 65-year-olds. Coverage was extremely low, with only 2.32% of individuals completing the schedule within two years of turning 65, reaching a peak of just 3.27% in 2020 [56].

Finally, a study conducted during the 2023–2024 vaccination season at the geriatric outpatient clinic of the University of Palermo involved 76 frail elderly patients, who were primarily affected by cognitive or endocrine disorders such as diabetes and osteoporosis. The aim was to assess the feasibility and impact of a proactive vaccination strategy by directly offering influenza and pneumococcal vaccines at the clinic. Vaccination coverage proved encouraging: 46.05% of patients received only the pneumococcal vaccine, 28.95% received both vaccines (influenza + pneumococcus), and 25% received only the influenza vaccine [57].

However, it is important to note that the available data on pneumococcal vaccination coverage in adults and the elderly come only from local or regional studies, making it difficult to assess whether the coverage targets set by the PNPV and the Essential Levels of Care (LEA) have been achieved.

Key Elements for Choosing the Best Vaccination Strategy

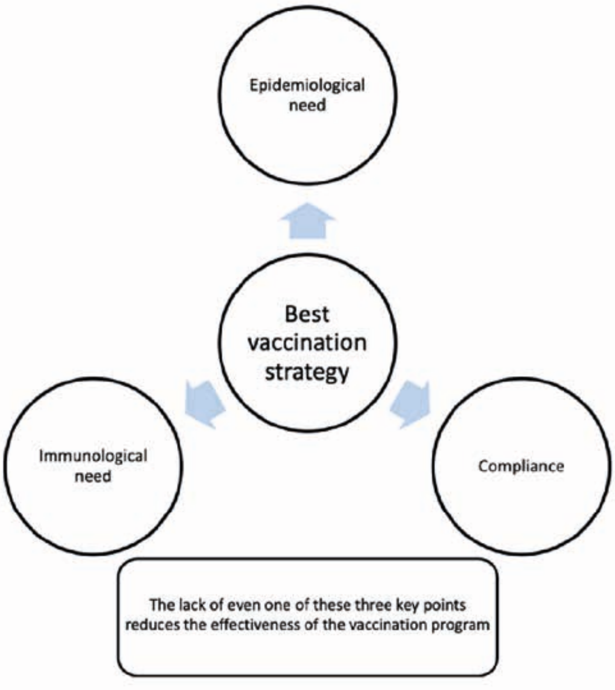
Maximizing the effectiveness of a vaccination program in combating diseases related to *S. pneumoniae* is based on the integration of three key elements (Fig. 2):

- Epidemiological need,
- Immunological need,
- Vaccine compliance.

EPIDEMIOLOGICAL NEED

The concept of epidemiological need is fundamental to defining vaccination strategies, as it is linked to ensuring that a vaccine effectively addresses the needs of a given population at a specific point in time, taking into account continuously evolving demographic characteristics. In the case of pneumococcus, the high antigenic variability (over 100 serotypes identified), the dynamics of serotype replacement induced by the selective pressures of conjugate vaccines, and the heterogeneity of the population groups affected require continuous surveillance and regular updating of preventive strategies [11-13, 58]. Over the years, serotype replacement has profoundly changed the epidemiology of IPD and CAP, particularly in the adult and elderly populations [58].

Fig. 2. Key elements for choosing the best vaccination strategy.



In the United States, after the introduction of PCV13, the incidence of IPD cases caused by vaccine serotypes in adults sharply decreased, displaying a 70% reduction in those aged ≥65 years. However, since 2014, no further reductions have been recorded, and during the 2018–2020 period, serotypes covered by PCV20 and PCV21 accounted for 54% and 85% of IPD cases in the elderly, respectively. In Canada, the most prevalent serotype among individuals aged ≥65 years in 2022 was serotype 3 (13.3%), followed by 22F (9.9%) and 9N (6.7%), with PCV20 coverage at 58.5% [59].

According to data from the ECDC, in 2022, cases due to serotypes not included in PCV13 showed higher incidence rates in individuals aged >64 years and children under 4 years old than in other population groups, with rates of 4.32 and 4.66 per 100,000 inhabitants, respectively [17]. In recent years, European epidemiological surveillance has revealed that certain serotypes continue to play a predominant role in causing invasive disease and CAP [12]. In particular, serotype 3 remains one of the main causes of IPD and CAP in adults and the elderly [60].

Data from various European and North American contexts report a considerable portion of cases caused by serotype 3 (between 12% and 19%) in subjects aged over 50 [12]. A systematic review analyzed data from primary studies conducted between 1984 and 2020 in order to gather information on the distribution of serotypes involved in pneumococcal pneumonia in adults and the elderly, while also considering the vaccination strategies in place during the studies. In all the publications, serotype 3 was the most common (11.9% of total isolates), with a growing percentage with increasing age (18.9% in those over 50). The authors reported that the prevalence of serotype 3 remained high even after the introduction of PCV10/PCV13 vaccination [60].

The persistence of this serotype, even though it was included in earlier-generation conjugate vaccines (PCV13), may be explained by its particular ability to evade the antibody response, a feature which contributes to its greater invasiveness and clinical severity, with significantly higher fatality rates than those of other serotypes [61].

At the same time, serotypes 22F and 33F have shown increasing epidemiological importance, emerging as frequent causes of invasive disease in adults. Indeed, a 2023 systematic review documented that serotype 22F accounted for approximately 6-7% of IPD cases not covered by PCV13 in adults, ranking among the most common serotypes alongside 8, 12F and 19A [62]. These findings are consistent with observations from European surveillance systems, which confirm the rising incidence of 22F and, to a lesser extent, 33F as causal agents of IPD in individuals aged ≥65 years [62].

In Italy, the ISS reported that in 2023, 58% of IPD cases

Tab. II. Serotypes identified in cases of invasive pneumococcal disease reported to the Italian MIB surveillance system that are common to both PCV20 and PCV21 vaccines [15, 18].

Serotype	2021	2022	2023	2024 (1st semester)	Total
3	41	171	336	183	731
6A	1	3	3	4	11
7F	2	5	8	7	22
8	52	137	191	118	498
10A	9	18	31	13	71
11A	8	18	29	13	68
12F	3	1	10	16	30
15B*	5	6	14	14	39
19A	11	43	57	42	153
22F	5	13	51	74	143
33F	0	4	9	9	22
Total	137	419	739	493	**1788**

* Serotype included in PCV20. For PCV21, a cross-reactive immune response was observed; this was elicited by serotype 15C, which is structurally similar to serotype 15B.

Tab. III. Serotypes identified in cases of invasive pneumococcal disease reported to the Italian MIB surveillance system that are exclusive to PCV20 [15, 18].

Serotype	2021	2022	2023	2024 (1st semester)	Total
1	4	2	8	7	21
4	2	2	8	6	18
5	1	1	1	0	3
6B	1	4	3	0	8
9V	1	1	3	1	6
14	5	15	17	22	59
18C	0	0	2	3	5
19F	7	21	34	18	80
23F	0	2	6	7	15
Total	21	48	82	64	**215**

Tab. IV. Serotypes identified in cases of invasive pneumococcal disease reported to the Italian MIB surveillance system that are exclusive to PCV21 [15, 18].

Serotypes	2021	2022	2023	2024 (1st semester)	Total
9N	7	21	42	19	89
15A	8	13	30	9	60
15C	1	1	11	16	19
16F	2	3	3	5	13
17F	1	6	8	1	16
20	5	4	9	9	27
23A	13	22	30	31	96
23B	7	24	29	15	75
24F	1	10	22	6	39
31	2	8	13	19	42
35B	0	3	11	3	17
Total	47	115	208	123	**493**

were covered by PCV20, compared with only 40% covered by PCV13. Among subjects aged ≥65, serotype 8 was the most frequent (15% of isolates), followed by 3, 22F and 33F. This indicates a mismatch between the vaccine used and the actual burden of disease [15].

An analysis of the data from the Surveillance System for Invasive Bacterial Diseases for the period 2021–2024 (first half) reveals the most frequently detected serotypes and allows us to compare them with recent conjugate vaccine formulations currently available for the adult/elderly population (PCV20 and PCV21).

Table II lists the *S. pneumoniae* serotypes detected by invasive bacterial disease surveillance in Italy during 2021–2024 (first half) [15, 18] that are common to both PCV20 and PCV21 vaccines.

As shown in Table II, a significant proportion of cases could potentially be prevented through the use of one of the latest-generation vaccines.

Surveillance data from 2021–2024 (first half) prompt further considerations.

Tables III and IV report the cases that could potentially be prevented by the exclusive use of PCV20 and PCV21, respectively.

As shown in Table IV, the new PCV21 vaccine has been specifically developed to include emerging serotypes of significant epidemiological and clinical relevance.

The 2023 specific analysis reveals that, out of 1,783 cases, 734 involved individuals over the age of 64 (41.2%). The estimated coverage with the PCV20 vaccine would be 63.6%, while with the PCV21 vaccine it would be 76.4%.

The specific analysis of the most recent available data on invasive disease cases (1st half of 2024) reveals that a total of 1,152 cases were reported, 58.4% of which occurred in individuals over 64. If only the data referring to subjects over the age of 64 are analyzed, the estimated coverage becomes 72.1% for PCV20 and 79.2% for PCV21.

The epidemiological need is conditioned not only by the age of the population but also by its vulnerability. Patients with immunodeficiencies, asplenia, HIV, or those who have undergone solid organ or hematopoietic transplants have a risk of invasive pneumococcal disease (IPD) that is 5 to 20 times higher than that of the general population [63]. Indeed, 30-day mortality in cases of pneumococcal bacteremia among immunocompromised patients can exceed 25%, as opposed to 10–15% in the general population [64]. The 2023-2025 National Immunization Plan (PNPV) therefore explicitly includes vulnerable individuals among the priority groups for vaccination, regardless of age, setting a minimum coverage target of 75% [54]. This measure addresses a clear epidemiological need to protect the groups at highest risk, in whom the expected benefit is greatest in terms of reducing hospitalizations and mortality. In summary, the persistence of serotype 3 and the emergence of new serotypes highlight the importance of ongoing epidemiological surveillance and the continuous updating of vaccination strategies. The inclusion of emerging serotypes in next-generation vaccines is a crucial step in further reducing the burden of pneumococcal disease among adults and the elderly – populations that are particularly vulnerable to this disease and its complications.

IMMUNOLOGICAL NEED

Immunogenicity constitutes the second pillar underpinning efforts to achieve "better protection". The vaccine of choice must induce an antibody response that is at least non-inferior to that of the reference comparator, thereby ensuring a comparable or superior efficacy profile across the age-groups and risk categories targeted by the vaccination program.

PCVs (pneumococcal conjugate vaccines) were developed to overcome the limitations of purified capsular polysaccharides, which elicit a T-cell–independent immune response that is poorly effective in young children and incapable of generating immunological memory [65]. The addition of a protein carrier (*e.g.,* CRM197, a non-toxic mutant of diphtheria toxin) converts the polysaccharide antigen into a T-cell–dependent immunogen that is capable of stimulating helper T cells, generating memory B cells and ensuring a stronger anamnestic response. This mechanism enhances long-lasting protection and reduces nasopharyngeal carriage, leading to herd immunity [66].

The introduction of PCV13 in children, and later also in the adult/elderly population, marked a turning point. However, as cases of IPD caused by vaccine-included serotypes declined, an increase in disease caused by non-vaccine serotypes was observed.

Another phenomenon emerged during the PCV13 vaccination campaigns; protection against serotype 3 proved to be suboptimal, with immunity waning over time. Several studies have documented lower antibody titers and lesser clinical effectiveness against this serotype, which remains a leading cause of CAP and invasive pneumococcal disease (IPD) in adults [24]. These findings have highlighted two critical aspects of immunogenicity; it must be evaluated not only in quantitative terms (antibody titers), but also in qualitative terms (opsonophagocytic activity and duration of protection).

The main correlate of protection against IPD is OPA (opsonophagocytic activity), which measures the ability of antibodies to mediate phagocytosis and bacterial killing. OPA titers ≥1:8 are generally considered protective, although the exact threshold may vary by serotype [67]. Capsular IgG antibodies (measured by enzyme-linked immunosorbent assay - ELISA) are useful, but not always predictive of protection. For example, serotype 3 can induce high IgG levels with low opsonophagocytic activity, which explains the suboptimal protection observed [68].

The two most recent conjugate vaccines currently available for the adult/elderly population (PCV21 and PCV20) meet the non-inferiority criteria for shared serotypes (*vs*. PCV13) and display superiority for the additional ones — reinforcing the rationale for their adoption. It should be noted, however, that in the non-inferiority study of PCV20 vs PPSV23, PCV20 did not meet the non-inferiority criterion for serotype 8 [47].

COMPLIANCE NEED

The parameter associated with adherence to the vaccination program plays a crucial role.

To achieve a significant public health benefit, it is essential to reach and maintain vaccination coverage levels in line with the targets set by the National Immunization Plan, *i.e.* 75% or higher in adults and the elderly.

With regard to pneumococcal vaccination, "compliance" goes beyond individual adherence to recommendations: it is a key element of Public Health. Indeed, it reflects the system's ability to translate epidemiological needs and the immunological potential of vaccines into real, sufficiently high coverage rates capable of generating a collective impact. Compliance is therefore not only a responsibility of individual citizens but also of health institutions, which must ensure that vaccination pathways are accessible, free of charge and actively promoted.

In this context, strategic planning must include multiple actions implemented through a multidimensional approach. Desirable measures include:

- Integrating vaccination pathways into both primary care and specialist care settings;
- Strengthening the active role of general practitioners and medical specialists;
- Launching information campaigns to raise public awareness of pneumococcal risks and the benefits of vaccination, also by enlisting the support of patient associations;
- Enhancing training programs for healthcare professionals;
- Improving digital systems for tracking vaccination coverage.

In summary, adequate professional training, proper public awareness, efficient local health service organization, and continuous monitoring of coverage rates are key means of ensuring broad and equitable protection.

These efforts will help reduce the clinical, social and economic burden of pneumococcal diseases, especially in the context of Italy's aging population.

Conclusions

Infections caused by *Streptococcus pneumoniae* constitute a significant public health challenge both globally and locally, as they are associated with a substantial burden of morbidity and mortality in the general population – particularly among young children and the elderly.

Patients over the age of 65 are especially vulnerable to pneumococcal diseases, owing to age-related changes in the immune system and a higher prevalence of chronic conditions. Therefore, they are a primary target for vaccination programs.

The emergence of serotypes that are poorly covered by current vaccines, combined with the significant incidence and severity of disease, calls for a reassessment of the adequacy of existing vaccination strategies, especially in adults. A dynamic vaccination strategy is required – one that can adapt to serotype replacement, a phenomenon driven by the very vaccination campaigns themselves [69].

From an epidemiological perspective, it is essential that the vaccine of choice provides broad and optimal protection against the serotypes most responsible for disease in the target population, in alignment with surveillance data.

From an immunological standpoint, the vaccine chioce should induce an immune response that is at least non-inferior to the comparator, and ideally, more robust and long-lasting.

Regarding compliance, all possible strategies must be activated in order to raise public awareness of the risks of pneumococcal disease and the benefits of vaccination, so as to increase coverage rates.

The absence of even one of the three above-mentioned pillars – epidemiological need, immunological strength and compliance – reduces the overall impact of the vaccination strategy and may have consequences both on the incidence of pneumococcal diseases and on the associated economic and social burden.

A thorough analysis of epidemiological and clinical data, combined with an assessment of the economic and social impact, is crucial to guiding vaccination policies and supporting efficient decision-making in order to protect the health of the entire population. An additional factor that makes the strengthening of vaccination campaigns even more urgent is the fight against antimicrobial resistance. Indeed, a major contributor to the significant burden of pneumococcal disease is growing resistance to the commonly used antibiotic therapies – such as beta-lactams and macrolides – with resistance rates exceeding 20% in Southern Europe [70-72].

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Conflict of Interest statement

The authors declare that they have no conflicts of interest in relation to this manuscript.

Authors' contributions

The authors contributed equally to the entire drafting of the manuscript.

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Correspondence: Elvira Massaro, MD, ASL3 Healthcare System of the Liguria Region, Genoa, Italy. E-mail: elvira.massaro@edu.unige.it.

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Infectious disease

High prevalence and associated factors of *Mycoplasma pneumoniae* infection in children aged from 2 to 59 months with atypical pneumonia from June 2023 to May 2024

KIEU DUNG LE[1], MINH MANH TO[1], VAN NGHIEM DANG[1], VAN THUAN HOANG[1]
[1] Thai Binh University of Medicine and Pharmacy, Hung Yen, Vietnam

Keywords

Atypical pneumonia • *M. pneumoniae* • Risk factors

Summary

Objectives. *To identify the prevalence of Mycoplasma pneumoniae infection and association with age and gender among children aged from 2 to 59 months, hospitalized with atypical pneumonia in Vietnam from June 2023 to May 2024.*
Methods. *A retrospective descriptive study was performed using data collected from the electronic medical records. M. pneumoniae infection was determined by the IgM serology test.*
Results. *1,296 patients aged from 2 to 59 months hospitalized with atypical pneumonia were included. The majority of patients were aged 12 months or older, with only 3.6% of cases being under 12 months of age. Male patients accounted for 58.7% of the cases. Prevalence of M. pneumoniae infection was 47.3%. Compared to children under 12 months of age, those aged 12 to under 36 months had a 10 times higher risk of M. pneumoniae infection, with OR = 9.44, 95% CI = [2.90-30.77]. Compared to children under 12 months of age, those aged 36 months to under 5 years had a 20 times higher risk of M. pneumoniae infection, with OR = 20.19, 95% CI = [6.20-65.69]. Compared to female children, male children had nearly twice the lower risk of M. pneumoniae infection, with OR = 0.62, 95% CI = [0.50-0.78].*
Conclusion. *Our study provides additional evidence on the role of M. pneumoniae in atypical pneumonia in children aged from 2 to 59 months, while also highlighting significant risk factors for M. pneumoniae infection.*

Introduction

Atypical pneumonia is a common condition, particularly in children, and plays a significant role in contributing to the burden of illness and mortality, especially in developing countries like Vietnam [1, 2]. The disease not only affects children health, but also poses the risk of leading to serious complications if not diagnosed and treated in a timely manner [1]. Children, with their underdeveloped immune systems, are a vulnerable group to various pathogens, among which atypical pneumonia is one of the leading threats.

Mycoplasma pneumoniae is considered one of the most common and concerning pathogens of atypical pneumonia [3]. *M. pneumoniae* is a small bacterium with no cell wall and a simple structure, but it has the ability to cause complex and diverse clinical manifestations. This creates significant challenges in diagnosis as the clinical symptoms are often non-specific and can easily be mistaken for other respiratory diseases. Furthermore, due to its lack of a cell wall, *M. pneumoniae* is not affected by many antibiotics commonly used to treat pneumonia, further complicating disease management and treatment [3].

In Vietnam, although pneumonia is a serious public health issue, the specific epidemiological situation related to *M. pneumoniae* in children has not been extensively studied [1, 4]. Currently, data on infection rates and specific risk factors for *M. pneumoniae* infection remain quite limited. This highlights an urgent need for more detailed research to clarify the risk factors associated with *M. pneumoniae* infection.

Identifying these risk factors is not only scientifically valuable but also highly practical. It helps improve early diagnostic capabilities, thereby enhancing treatment efficacy and reducing the risk of dangerous complications. Furthermore, recognizing risk factors plays a crucial role in establishing prevention strategies, especially for high-risk children. This will contribute to reducing the incidence and mortality from pneumonia, thereby improving the quality of pediatric healthcare in Vietnam.

Therefore, this study was conducted to identify the prevalence and risk factors of *M. pneumoniae* infection in children aged from 2 to 59 months with atypical pneumonia from June 2023 to May 2024 in Thai Binh, a densely populated province with a young population structure in Vietnam. The findings will help provide essential information for the development of medical interventions aimed at reducing the burden of pneumonia-related diseases in children.

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Methods

STUDY DESIGN AND POPULATION

This was a retrospective descriptive study conducted on all patients aged from 2 to 59 months, hospitalized for atypical pneumonia at the Thai Binh Pediatric Hospitalfrom June 1, 2023, to May 31, 2024, located in Thai Binh province, before merging provinces and cities in Vietnam.

Thai Binh is a predominantly rural region in northern Vietnam. This province has a population of approximately 1.9 million, with a population density of around 1,100 persons per square kilometer. Most of population live in rural areas and 15.5% of the population aged from 0 to 9 years [5].

Atypical pneumonia was clinically diagnosed when children presented with pneumonia along with the following suggestive clinical symptoms: a high and persistent fever > 39-40°C, cough, sputum production, dyspnea, tachypnea, hypoxia, extrapulmonary manifestations such as pleuritis, hepatosplenomegaly, or myocarditis. Chest x-ray findings in atypical pneumonia include patchy infiltrates, sometimes bilateral in distribution, and interstitial patterns.

M. pneumoniae infection was determined by serological testing, as molecular testing for *M. pneumoniae* was not available at the hospital. The serum samples were quantitatively analyzed for IgM antibodies against *M. pneumoniae* using the Virion/Serion ELISA kit (GmbH Germany, catalog number ESR127M). The antibody levels were expressed in units per milliliter (U/ml). According to the manufacturer's guidelines, the interpretation criteria for *M. pneumoniae* IgM were as follows: positive (> 17 U/ml), negative (< 13 U/ml), and borderline (13-17 U/ml). All ELISA assays were carried out strictly following the instructions provided by the manufacturer.

DATA COLLECTION

Data were extracted from the electronic medical records of hospital in Microsoft Excel format, including socio-demographic characteristics, clinical findings and laboratory testing. We then filtered out duplicate data, which included pediatric patients who underwent serological testing multiple times during the same treatment period. To eliminate duplication, we relied on the patient unique identification (for all subsequent hospitalizations if any). If a child underwent multiple tests during a single treatment period, we used the result from the most recent positive test (in cases where all tests were positive or where there were both positive and negative results) or the earliest negative result (in cases where all results were negative). If the child was hospitalized several times, data were collected corresponding to each separate treatment period.

DATA ANALYSIS

After data cleaning, R (version 4.5.0) software for was used for statistical analysis. Age was categorized into the following groups: 2 to < 12 months, 12 to < 36 months, and 36 to < 60 months. Qualitative variables were presented as counts and percentages. The primary variable was the proportion of children with pneumonia and positive for IgM anti-*M. pneumoniae*. The Chi-squared test was used to assess differences in proportions. Logistic regression was used to evaluate the association between age and gender with *M. pneumoniae* infection. The results were presented and OR and 95% CI. Statistical significance was defined as $p < 0.05$.

Results

A total of 1296 children aged from 2 to 59 months were eligible and included. The Figure 1 showed the distribution of patients with and without *M. pneumoniae* over the period time of study (Fig. 1). Time analysis showed no sustained increase or decrease in *M. pneumoniae*–associated atypical pneumonia over the study year. A monthly logistic-regression model that treated calendar time as a continuous index showed no evidence of a monotonic trend in *M. pneumoniae* IgM positivity (OR = 0.99, 95% CI 0.96-1.03; $p = 0.70$). Weekly analyses also confirmed the absence of a linear trend. Only two spline components reached nominal significance ($p < 0.05$), indicating modest, non-monotonic week-to-week fluctuations. However, the terminal spline coefficient was not significant ($p = 0.46$), suggesting a return to baseline levels.

Most children (1249, 96.4%) with atypical pneumonia were aged 12 months and older, of whom 46.7% (605/1296) were aged 12-36 months and 49.7% (644/1296) were aged 36-59 months. Only 47 (3.6%) of children were under 12 months. Male gender accounted for 58.7% (761/1296), with a male/female sex ratio of 1.4 (Tab. I).

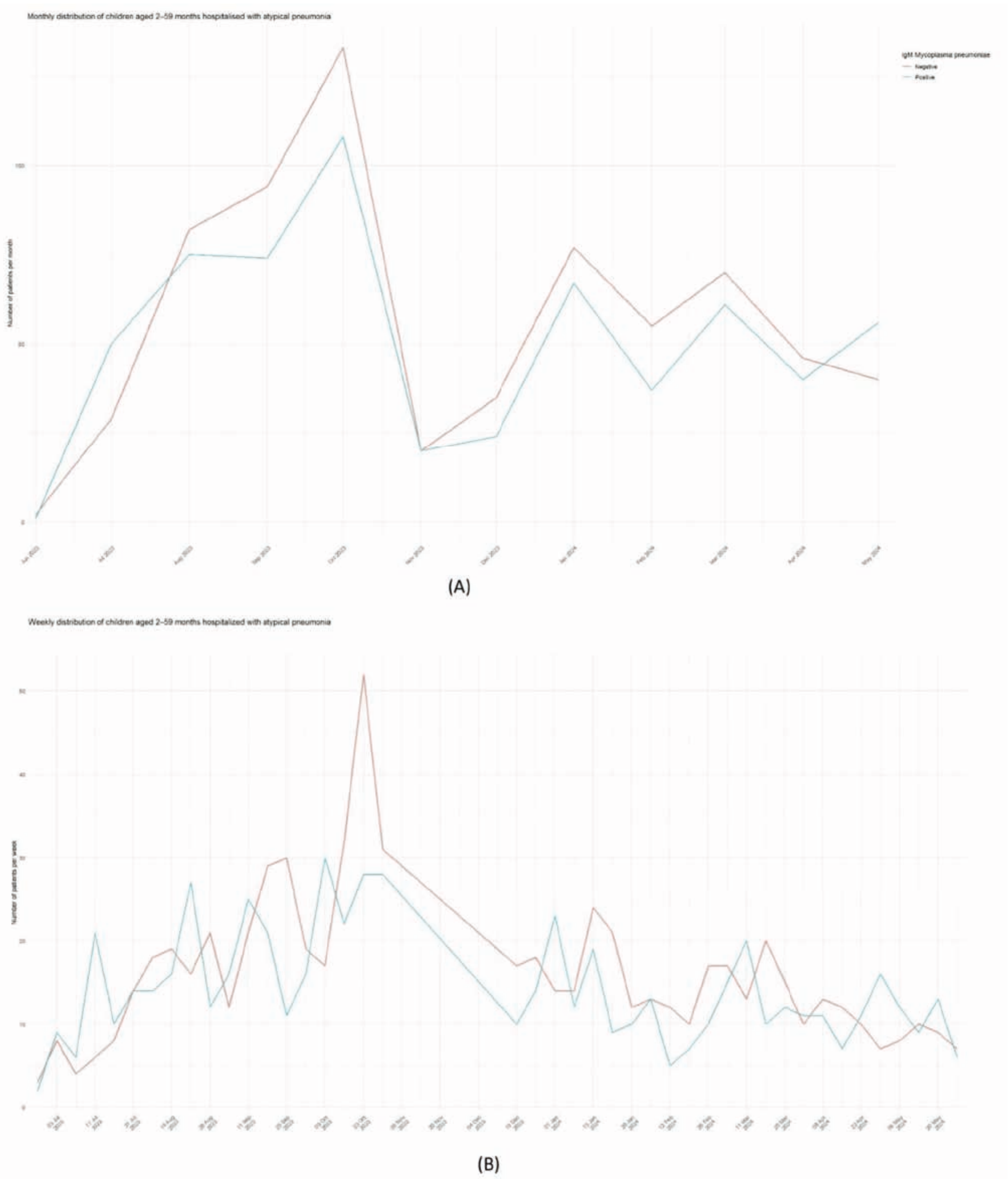
613 children (47.3%) with atypical pneumonia were infected with *M. pneumoniae*.

Compared to children aged from 2 to < 12 months, children aged 12 to under 36 months have a 10 times higher risk of *M. pneumoniae* infection, with OR = 9.44, 95% CI = [2.90-30.77]. Children aged 36 months to under 5 years have a 20 times higher risk of *M. pneumoniae* infection, with OR = 20.19, 95% CI = [6.20-65.69]. Compared to female children, male children have nearly twice the lower risk of *M. pneumoniae* infection, with OR = 0.62, 95% CI = [0.50-0.78] (Tab. I).

Discussion

Our study found that *M. pneumoniae* is a common cause of atypical pneumonia in children aged from 2 to 59 months in Thai Binh from June 2023 to May 2024, with the infection rate of *M. pneumoniae* accounting for 47.3% of cases. This high rate reflects the prevalence of *M. pneumoniae* in the pediatric population and is higher than previous studies in Vietnam and other Southeast Asian countries [1, 2, 5].

Fig. 1. Monthly (A) and weekly (B) distribution of children aged from 2 to 59 months, hospitalized with atypical pneumonia in Thai Binh from June 2023 to May 2024.



Previous studies in Vietnam have reported *M. pneumoniae* infection rates generally below 20%, which is significantly lower than our findings [1, 6] *Chlamydophila pneumoniae*, and *Legionella pneumophila* are increasingly recognized as important causes of community acquired pneumonia (CAP. Notably, in a study by Tran et al., conducted at the same location as our study, the *M. pneumoniae* infection rate was only 3.2% [7]. This discrepancy may be explained by the fact that their study focused on children with pneumonia in general, while ours specifically investigated children with atypical pneumonia. Moreover, previous studies

Tab. I. Associated factors of ***Mycoplasma pneumoniae*** pneumonia in children aged 2 to 59 months from June 2023 to May 2024.

Associated factors	IgM *M. pneumoniae* negative	IgM *M. pneumoniae* positive	OR [95% CI]	*p*-value
	n (%)	n (%)		
Age				
2 - < 12 months	44 (6.4)	3 (0.5)	Reference	
12 - < 36 months	368 (53.9)	237 (38.7)	9.44 [2.90-30.77]	0.0001
36 - 59 months	271 39.7)	373 (60.8)	20.19 [6.20-65.69]	0.0001
Gender				
Female	245 (35.9)	290 (47.3)	Reference	
Male	438 (64.1)	323 (52.7)	0.62 [0.50-0.78]	0.0001

have commonly used PCR testing to diagnose *M. pneumoniae*, whereas in Thai Binh, this method is not available for routine diagnosis. Therefore, we relied on serological test results, which likely explains the higher infection rate observed in our study.

Studies in Southeast Asian countries have reported *M. pneumoniae* infection rates in children with atypical pneumonia ranging from 3% to 26% [1, 2, 6-8]. These figures highlight *M. pneumoniae* as a common and important pathogen to be considered in the diagnosis and treatment of pneumonia in children, not only in Vietnam but across the geographical area.

The clinical significance of this finding is important, as *M. pneumoniae* is often not detected by conventional microbiological diagnostic methods, leading to missed or delayed diagnoses [3]. This can result in inappropriate treatment, prolonged illness, and increased risk of complications. Therefore, the use of accurate diagnostic methods such as PCR for the detection of *M. pneumoniae* should be encouraged, especially in healthcare settings where this technology is available [9].

Additionally, understanding the role of *M. pneumoniae* in atypical pneumonia can help improve antibiotic treatment guidelines, reduce antibiotic resistance, and improve treatment outcomes. The use of specific antibiotics such as macrolides, which are highly effective in treating *M. pneumoniae*, should be prioritized in suspected or confirmed cases of this infection [10].

A noteworthy finding in this study series is the age and gender distribution of *M. pneumoniae* infection rates. Children aged of 12 months or older were at higher risk of *M. pneumoniae* infection than those aged from 2 to 12 months. This could be explained by the development of the immune system and greater environmental exposure as children grow older, creating favorable conditions for *M. pneumoniae* infection. Previous studies have also shown that older children tend to be more frequently infected with *M. pneumoniae*, which aligns with our results [1, 10, 11].

In addition, our study found that male gender had a lower risk of *M. pneumoniae* infection compared to girls. This is a notable finding, as previous studies have generally not reported a significant gender difference in *M. pneumoniae* infection rates [1, 10, 11]. It could be explaned that behavioral, physiological, and exposure differences to risk factors may contribute to this variation, but further research is needed to better understand the biological mechanisms underlying this gender discrepancy.

Our study has several limitations. First, despite its relatively large sample size, this is a monocentric retrospective study, which limits the generalizability of the results to other regions of Vietnam. Second, by enrolling only hospitalized children with clinically suspected atypical pneumonia, we may have introduced selection bias, omitting milder outpatient cases and episodes of typical bacterial pneumonia. Third, routine multiplex PCR testing for respiratory pathogens was not available in our hospital. Consequently, potential viral or bacterial co-infections which are common in pediatric pneumonia could not be assessed and are likely under-represented in our dataset.

In conclusion, despite several limitations, our study provides additional evidence on the role of *M. pneumoniae* with high prevalence in atypical pneumonia in children aged from 2 to 59 months and highlights important risk factors such as age and gender. These findings can assist clinicians in identifying high-risk children for *M. pneumoniae* infection, thereby improving diagnostic and treatment strategies, and contributing to the reduction of disease incidence and healthcare burden in the community.

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Ethical approval

The protocol was approved by Thai Binh University of

Medicine and Pharmacy (approval date: 04 February 2025; reference number: SV.2025.02). The study was performed according to the good clinical practices recommended by the Declaration of Helsinki and its amendments. This was a retrospective study, informed consent was waived.

Availability of data and materials

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

Conflict of Interest statement

The authors declare that they have no conflict of interest.

Authors' contributions (Use CRediT terms)

Conceptualization: VTH. Data curation: MMT, KDL, VND. Formal analysis: MMT, VTH. Investigation: MMT, KDL, VND, VTH. Methodology: MMT, VTH. Software: VTH. Validation: MMT, KDL, VND, VTH. Visualization: MMT, VTH. Writing - original draft: MMT, VTH. Writing - review & editing: MMT, KDL, VND, VTH. KDL and MMT contributed equally to this work.

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Correspondence: Van Thuan Hoang, Thai Binh University of Medicine and Pharmacy, 373 Ly Bon Street, Tran Lam Ward, 410000 Hung Yen, Vietnam. E-mail: thuanytb36c@gmail.com

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OPEN ACCESS

INFECTIOUS DISEASE

Knowledge, attitudes, and practices (KAP) of the Philippine general public towards human mpox (hMPX): a cross-sectional study

MELANNIE GRACE TENDIDO[1], BEATRIZ MARIE ARAJA[1], PAMELAH JOY CONCEPCION[1], GAZELLE LOVE DELA CRUZ[1],
DANILO DIEGO IPAPO[1], ALEXIS MARIE MINA[1], MARIE LOUISE ONDIS[1], MARIA ALEXANDRA PANGILINAN[1],
MAPHEL ANGELICA PASAO[1], NERISSA MICHELLE SANCHEZ[1], ROSEANNE MAE TANIAJURA[1],
JANELLA ANGELIQUE VARIAS[1], MICHAEL VAN HAUTE[1]
[1] De La Salle Medical and Health Sciences Institute-College of Medicine, Dasmariñas City, Cavite, Philippines

Keywords

Human mpox • hMPX • Knowledge attitudes practices • General public • Philippines

Summary

Introduction. *In the Philippines, research on knowledge, attitudes, and practices (KAP) regarding human mpox (hMPX) remains limited, despite rising case numbers. With vaccines unavailable locally, enhancing community awareness and promoting non-pharmaceutical interventions are crucial for reducing transmission risks.*

Methods. *This cross-sectional study utilized an anonymized online data collection tool to explore the general public's hMPX KAP and their relationships, and identify sociodemographic groups linked to low hMPX knowledge; 502 respondents were included in the analysis.*

Results. *Knowledge levels were evenly distributed across low, moderate, and high categories. Higher knowledge was associated with being female ($\beta = 0.130$, $p = 0.004$), higher educational attainment ($\beta = 0.134$, $p = 0.006$), and smaller household size ($\beta = -0.098$, $p = 0.028$). Knowledge was not significantly associated with perceived disease susceptibility or severity, but strongly predicted perceived effectiveness of preventive measures. Perceived effectiveness, in turn, consistently emerged as the strongest predictor of preventive practices. Full mediation of the effect of knowledge by perceived effectiveness was observed with protective sexual practices and avoiding crowded places, but only partial with hand hygiene and fomite/high-touch surface disinfection.*

Conclusion. *This study highlights the complex interplay between knowledge, attitudes, and practices in shaping public health behavior toward hMPX in the Philippines. Significant knowledge gaps and the mediating role of attitudes in influencing preventive practices underscore the need for targeted, stigma-free health communication strategies. Strengthening public understanding and perception through tailored interventions will be critical in mitigating hMPX transmission.*

Introduction

Human mpox (hMPX), formerly called monkeypox, is a reemerging viral zoonotic infection caused by an enveloped double-stranded DNA orthopoxvirus (family Poxviridae) related to variola (causing smallpox) and vaccinia (used in smallpox vaccine) [1]. It has two main clades: clade I, associated with more severe disease in central and east Africa, with subclade Ia causing traditional outbreaks and subclade Ib emerging during the 2023 Democratic Republic of Congo outbreak that has since spread beyond Africa [2, 3]; and clade II, a less virulent lineage from west Africa that lacks several genes present in clade I [2]. The 2022 global outbreak – driven by subclade IIb, a newer variant of clade II [3] – was initially recognized in Europe, with the first cases detected in the United Kingdom [4]. From there, it rapidly spread to all six World Health Organization regions, prompting the declaration of a public health emergency of international concern in July 2022 [5]. In the Philippines, the first hMPX case was detected that same month [6, 7]. Since then, 911 confirmed hMPX cases (with 1 death) were reported, including both imported and locally acquired infections, none of which have an established epidemiological link [8, 9]. Despite the rise in cases, the Philippine government did not declare a national public health emergency.

The majority of identified hMPX cases were among men who have sex with men (MSM), leading to the hypothesis that the virus spreads primarily through close contact during sexual activity within these networks (though not exclusively) [10, 11], and notably not linked to recent travel to endemic areas or close contact with known hMPX cases [4]. Most diagnosed cases reported high-risk sexual behavior as potential risk factors. But while many initial cases during the outbreak were linked to close contact within sexual activity, anyone in the general population who has direct skin-to-skin contact with an infected person or contaminated fomites, or lives with someone who has hMPX, is also at risk [12].

When hMPX gained international attention in mid-2022, it coincided with already strained COVID-19 responses. Although Southeast Asian countries have made progress in health preparedness, persistent challenges such as poor governance, weak surveillance,

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limited laboratory capacity, disrupted supply chains, and low community engagement from inadequate funding could hinder the hMPX response should the situation get worse [13]. Such therefore warrants a thorough understanding of prevention and control measures on the part of the citizens. COVID-19 public health campaigns have already increased awareness of infectious diseases, making people more attentive to threats like hMPX. [14]. Greater familiarity with symptoms, transmission, and hygiene was expected to raise baseline knowledge of hMPX. However, pooled prevalences of good levels of knowledge about hMPX are reported at only 33% (95% CI: 22%, 45%) and 26% (95% CI: 17.8%, 34.2%) in two systematic reviews and meta-analyses [15, 16], with participants that included healthcare professionals, university students, and individuals from the general population. Additionally, country-based subgroup analysis showed Philippines having the lowest prevalence of good knowledge levels (5%; 95% CI: 3%, 7%) [15], though only one study was available [17]. Key factors influencing knowledge levels include education, accessibility to health information, and previous outbreaks in the region. Public health campaigns and access to accurate information have improved understanding in some areas, but misinformation remains a challenge [18]. Misinformation and stigmatized language have fueled hMPX-related stigma [19], with studies showing that incorrect social media narratives, biased news framing, and misconceptions in healthcare lead to harmful stereotypes [20-22]. Media portrayals inadvertently stigmatized entire regions – first China for COVID-19 and then Africa for hMPX – and have falsely associated hMPX with LGBTQ+ individuals, particularly MSM [21]. The knowledge gap stemming from misconceptions and stigmatization could potentially complicate public health responses by exacerbating existing barriers to healthcare access, resulting in reduced testing and case underreporting [23, 24]. Moreover, existing health communication efforts may not adequately reach all segments of the population, highlighting the need for tailored interventions. Thus, assessment of knowledge, attitudes, and practices (KAP) surrounding hMPX in the general public is critical for effective public health responses.

In the Philippine setting, KAP among the general public remains inadequately explored despite increasing hMPX prevalence. While hMPX vaccines effectively prevent infection and reduce symptom severity [25], they are not yet legally available and approved by the Philippine Food and Drug Administration (FDA) [7, 26], stressing the importance of improving community awareness and engagement in non-pharmaceutical interventions (NPI) to reduce transmission risk. However, to effectively promote and maintain preventive behaviors through NPIs, it is essential to understand how social, cognitive, and psychological factors influence these behaviors [27]. While various statistical models and approaches exist in analyzing KAP research, a model that integrates mediation might be a better approach when incorporating these factors. Mediation analysis is a statistical approach used to understand the mechanism through which an independent variable (knowledge) influences a dependent variable (practices) via a mediator variable (attitudes) [28]. In addition to direct effects of knowledge on practices, mediation analysis helps identify indirect effects where the influence of knowledge on behavior operates through attitudes. It also helps provide a clearer understanding of how interventions might work by targeting not just knowledge but also shaping attitudes to influence behavior. In this study, we aimed to describe the level of knowledge, attitudes, and practices of a sample of the Philippine general population towards hMPX and the recent outbreaks, and investigate how hMPX knowledge influences practices and whether this relationship is mediated by attitudes. By identifying mediators, public health efforts can focus not just on improving knowledge but also on addressing barriers to behavior change, such as negative perceptions or fear. Additionally, we aimed to identify sociodemographic groups associated with low levels of knowledge regarding hMPX. From the public health perspective, identifying these groups is vital for designing effective interventions that help improve outbreak control, reduce stigma and misinformation, and create equitable, impactful strategies to manage the disease.

Methods

STUDY DESIGN

This is a cross-sectional study that was conducted from April 2023 to June 2023 using an anonymized online data collection tool. Ethics approval of the study (reference number: CMERC 2022-CM-001) was granted by the College of Medicine Ethics Review Committee of the De La Salle Medical and Health Sciences Institute (DLSMHSI) in accordance with the institution's ethical guidelines for observational studies.

STUDY PARTICIPANTS

By the start of 2023, there were 85.16 million internet users in the Philippines, 84.45 million of whom were social media users [29]. While this number equated to only 73.1% internet penetration, a total of 168.3 million cellular mobile connections were active, surpassing the total population by 144.5% [29]. Considering this, we opted to leverage social media to facilitate data collection and engagement. GO Philippines (http://www.gophilippines.org) is a community-driven social enterprise designed to promote the implementation of a smart-nation program. This initiative aims to deliver essential services, including education, healthcare, finance, employment, technology, and other critical sectors, through an integrated e-commerce platform, with the goal of enhancing Filipino citizens' quality of life while fostering Philippine economic growth and development. GO Cavite is a localized initiative under the broader umbrella of GO Philippines, focusing specifically on the province of Cavite, where our base institution (DLSMHSI) is located. While GO Cavite does not have an official website, a Facebook® page (https://www.facebook.com/gocavite) and a Facebook® community page (https://www.facebook.com/groups/gocavitecommunity) exist, both bearing the same name, with approximately 1.2 million and 390,000 followers, respectively, by the time of this writing. Given the large number of followers of both online platforms, we anticipate that their sociodemographic characteristics are representative of and have similar distributions as those of the Philippine general public at large.

MINIMUM SAMPLE SIZE COMPUTATION

G*Power version 3.1 (Universität Düsseldorf) [30, 31] was used to compute the minimum sample size requirement. We employed multiple linear regression (fixed model, R^2 deviation from zero) as basis on the premise that a set of predictors collectively explains a significant amount of variance in knowledge about hMPX. Of the studies included in both aforementioned meta-analyses, only 3 studies [32-34] treated knowledge as a quantitative continuous dependent variable using multiple linear regression analysis. Of these 3 studies, only one [32] reported the adjusted coefficient of determination (adj. $R^2 = 0.055$) of the linear regression model. This translates to an effect size f^2 of 0.058. Using this f^2, assuming an α of 0.05 and a power ($1 - \beta$) of 0.80, and fixing the maximum number of predictors at 18 (10 sociodemographic variables, 1 variable representing knowledge level, and 7 variables for attitudes), the calculated minimum sample size requirement is 362.

DATA COLLECTION TOOL

We employed an anonymized online data collection tool composed of two parts. The first part contains questions pertaining to respondents' sociodemographic characteristics (age, sex, citizenship, socioeconomic status, educational attainment, employment status, area of residence, household size, religion, sexual orientation, and medical comorbidities). The second part consists of three sections that respectively measure their knowledge, attitudes, and practices regarding hMPX.

Knowledge was assessed using a 17-item questionnaire that was drafted under supervision, so it reflects current general information on hMPX (basic epidemiology, mode of transmission, clinical manifestations, treatment, and preventive measures) [35, 36]. These questions are answerable by "Yes," "No," or "I don't know." Knowledge scores were determined by awarding one point for each correct response, and a total score was calculated, with higher scores reflecting greater knowledge about hMPX.

For the section on attitudes regarding hMPX, we constructed questions assessing perceptions on disease susceptibility ("What do you think is your risk of contracting hMPX?") and severity ("How sick/unwell do you think you would get if you get infected with hMPX?"), and effectiveness of preventive measures (avoiding close skin-to-skin contact with individuals who have characteristic hMPX rash, avoiding contact with animals thought to transmit hMPX, avoiding contact with fomites, handwashing or hand sanitation, vaccination against hMPX) in reducing transmission risk based on the risk perception attitude framework [37]. Responses were rated using a Likert-type scale ranging from 1 to 5 (for susceptibility: 1 = extremely unlikely, 2 = unlikely, 3 = neither likely nor unlikely, 4 = likely, 5 = extremely likely; for severity: 1 = very low, 2 = low, 3 = neither high nor low, 4 = high, 5 = very high; for prevention effectiveness: 1 = strongly disagree, 2 = disagree, 3 = neither agree nor disagree, 4 = agree, 5 = strongly agree).

Practices on preventive behavior were assessed using questions inquiring how often the respondents observe proper hand hygiene, avoiding crowded places/large gatherings, disinfecting fomites/high-touch surfaces, and protective sexual practices. As with attitudes, responses were rated using a 5-point Likert-type scale (1 = never, 2 = rarely, 3 = sometimes, 4 = often, 5 = always).

The data collection tool underwent content validation by three infectious disease specialists, all unaffiliated with our institution to maintain objectivity. The questions were edited accordingly based on their comments and recommendations. Pretesting was then carried out by administering the edited tool to a separate sample of 10 people to provide feedback on question clarity and redundancy. Based on their feedback, with guidance by someone with expertise on questionnaire construction, the questions were further reviewed and edited for contextual sensitivity and appropriateness of language. The Cronbach's alpha, measured to assess internal consistency, was 0.84, indicating that the tool has good reliability for measuring the intended construct.

PARTICIPANT RECRUITMENT

We contacted and collaborated with the administrators of the GO Cavite Facebook® profile page and community page to seek permission for linking our study on these platforms, and to request their assistance in advertising the study to facilitate target population outreach and study participation. After the appropriate arrangements have been made between the researchers and the administrators, study advertisements were posted by the latter in the newsfeeds of both GO Cavite online platforms, effectively extending the participation invitation to all its online followers/members. These advertisements/posts show the Google Forms™ uniform resource locator (URL) that interested participants can click on. Participation was on a voluntary basis. To ensure data privacy, we edited the Google Forms™ settings so that only respondents with Gmail® accounts can gain access to the online data collection tool. Before proceeding to the data collection tool itself, the respondents were first introduced to the informed consent page containing a brief overview and explanation of the study objective and procedures, as well as its potential risks, benefits, and impacts. It likewise stressed the voluntary and non-coercive nature of the study, with the assurance that anonymity is maintained at all times in accordance with data privacy laws in effect. They are then presented the option to tick a box corresponding to giving their informed consent if they understand the study-related information and are willing to participate. Ticking the box allows them to proceed to the data collection tool, otherwise they are redirected to an exit page and are excluded from the study accordingly. Additionally, respondents were excluded if they were less than 18 years of age, had missing data, do not have Filipino citizenship or are not physically residing in the Philippines at the time of recruitment. Each included respondent was assigned a unique numeric code for the purpose of anonymization. The informed consent and the data collection tool were made available in both English and Filipino languages. No incentives were offered for participation.

Statistical Analysis

All statistical analyses were performed using Stata version 17 (StataCorp, College Station, TX). Basic descriptive statistics were computed for all variables. Categorical variables were reported using frequencies and percentages, while quantitative variables were reported as mean and standard deviation. For purpose of describing the respondents' knowledge level, knowledge scores were treated as both categorical, using modified Bloom's cutoff points (high for scores >80%, moderate for scores from 60% to 80%, and low for scores <60%) [38], and quantitative continuous. Responses to attitudes and practices were treated as quantitative continuous. Multiple linear regression analyses were performed regressing knowledge, attitudes, and practices on respondent sociodemographic characteristics. Mediation analysis was performed using the *medsem* package of Stata [39], which generates estimates of effect sizes in the form of coefficients to judge the magnitude of the direct effect of knowledge on practices, and the total indirect effect as mediated through attitudes. To maintain model parsimony and avoid overfitting, a single composite score to quantify the perceived effectiveness of preventive measures in reducing hMPX transmission risk (under attitudes) was used in the mediation analysis, and was obtained by summing the scores for avoiding close skin-to-skin contact, avoiding contact with animals thought to transmit hMPX, avoiding contact with fomites, handwashing or hand sanitation, and vaccination against hMPX (total = 25). We referred to Zhao, Lynch and Chen's approach (with Monte Carlo resampling) [40] for inferential testing for indirect effects instead of the Baron and Kenny ordinary least squares regression-based approach. The parallel multiple mediator model [41] was used, wherein the indirect effects of the individual perceptions listed under attitudes (the designated mediators) were estimated with the constraint that no mediator is modeled as influencing another mediator (*i.e.*, there are no unidirectional arrows linking any mediator to any other mediator). Bias-corrected 95% confidence intervals (95% CI) were calculated for all estimates. Results were considered statistically significant if $p < 0.05$.

Results

Sociodemographic information

A total of 502 individuals were included in the final analysis (Tab. I). The average age of the respondents was 26.06 years (SD = 9.17); most were female (67.13%), identifying as heterosexual (87.05%), urban residents (72.71%), and college-educated (89.44%). Household size was typically 4 to 6 members (64.54%). Employment and medical comorbidity status were nearly evenly distributed.

Knowledge, attitudes, and practices regarding hMPX

Knowledge scores were evenly distributed across low (32.67%; 95% CI 28.57%, 36.77%), moderate (32.27%; 95% CI 28.18%, 36.36%), and high (35.06%; 95% CI 30.89%, 39.23%), with a mean score of 11.46 (SD = 3.76). Respondents were generally aware of symptomatology and skin-to-skin transmission, but knowledge gaps remained regarding animal reservoirs, sexual transmission, and case fatality rates (Tab. II). Fewer than half (48.80%) were aware that vaccines exist, although not yet licensed locally.

Perceptions of susceptibility were generally low (mean score = 2.16, SD = 1.07) while disease severity was perceived as moderate (mean score = 3.06, SD = 1.12) (Tab. III). Preventive measures were widely perceived as effective, particularly hand hygiene and vaccination. Preventive practices were variably adopted, with hand hygiene most frequently reported (mean score = 4.63, SD = 0.68) and avoidance of crowded places least practiced (mean score = 3.84, SD = 1.09).

Sociodemographic determinants of knowledge

Multiple regression analysis (Tab. IV) showed higher knowledge among females ($\beta = 0.130$, $p = 0.004$) and those with higher education ($\beta = 0.134$, $p = 0.006$), while larger household size predicted lower knowledge ($\beta = -0.098$, $p = 0.028$). No significant associations were observed with income, residence, religion, orientation, or comorbidities.

Effect of knowledge on attitudes

Knowledge was not associated with perceived susceptibility or severity (Tab. V). However, higher knowledge significantly predicted stronger beliefs in the effectiveness of preventive measures (Tab. VI), including avoiding skin-to-skin contact ($\beta = 0.175$, $p < 0.001$), avoiding contact with animals ($\beta = 0.224$, $p < 0.001$), avoiding contact with fomites ($\beta = 0.253$, $p < 0.001$), practicing hand hygiene ($\beta = 0.251$, $p < 0.001$), and vaccination against hMPX ($\beta = 0.183$, $p < 0.001$).

Tab. I. Respondents' sociodemographic characteristics

Sociodemographic characteristic	Total (n = 502)	
	n	%
Sex		
Male	165	32.87%
Female	337	67.13%
Age		
18-24 years	337	67.13%
25-34 years	105	20.92%
35-44 years	20	3.98%
45-54 years	26	5.18%
55-64 years	14	2.79%
Educational attainment		
High school	53	10.56%
College/Bachelor level[a]	400	79.68%
Masters/Graduate school level[b]	49	9.76%
Monthly household income		
Less than Php 10000	121	24.10%
Php 10000 to Php 29999	120	23.90%
Php 30000 to Php 49999	81	16.14%
Php 50000 to Php 79999	50	9.96%
Php 80000 and above	130	25.90%
Currently employed		
No[c]	265	52.79%
Yes	237	47.21%
Residence		
Rural	137	27.29%
Urban	365	72.71%
Household size		
1–3 people	124	24.70%
4–6 people	324	64.54%
≥7 people	54	10.76%
Religious affiliation		
Not affiliated	7	1.39%
Affiliated	495	98.61%
Orientation		
Heterosexual	437	87.05%
LGBTQIA+	65	12.95%
Comorbidities		
No	262	52.19%
Yes[d]	240	47.81%

[a] Includes those who are currently attending college and those who left college before completing their degree. [b] Includes those who are currently attending graduate school and those who left graduate school before completing their degree. [c] Includes non-working students and retirees. [d] Comorbidities include allergy/atopy, bronchial asthma, gout, diabetes mellitus, hypertension, cardiovascular disease, hyperthyroidism, cancer, hematologic disorders, neurological disorders, orthopedic disorders, and psychiatric disorders. One respondent may have more than one comorbidity.

Effect of knowledge and attitudes on practices

Perceived effectiveness of preventive measures emerged as the strongest predictor of preventive practices (Tab. VII). It was positively associated with protective sexual practices (β = 0.567, p < 0.001), crowd avoidance (β = 0.190, p < 0.001), hand hygiene (β = 0.302, p < 0.001), and disinfection behaviors (β = 0.190, p < 0.001). Knowledge directly influenced hand hygiene (β = 0.119, p = 0.007) and disinfection practices (β = 0.107, p < 0.021), but not protective sexual practices or crowd avoidance. Perceived susceptibility and severity have not shown statistically significant direct effects on practices.

Relationships between knowledge, attitudes, and practices

Mediation analysis (Tabs. VIII, IX) confirmed that perceived effectiveness of preventive measures fully mediated the effect of knowledge on preventive sexual practices and crowd avoidance, and partially mediated its effect on hand hygiene and disinfection practices. No significant mediation was observed through perceived susceptibility or severity.

Discussion

Our study investigated the knowledge, attitudes, and practices related to hMPX among Filipino adults using a cross-sectional design and online recruitment via social media platforms. By leveraging the digital reach of GO Cavite, an online community with substantial public engagement, we were able to access a substantial and diverse sample of the Philippine general population. Against the backdrop of a global reemergence of orthopoxviruses and limited vaccine access in low- and middle-income countries, including the Philippines, understanding the public's KAP is crucial for informing NPIs, mitigating stigma, and guiding targeted public health responses.

Our findings showed that knowledge levels were evenly distributed across low, moderate, and high categories, reflecting patterns seen internationally during early hMPX outbreaks [32–34]. Respondents were familiar with symptoms and skin-to-skin transmission but less informed about animal reservoirs, sexual transmission, similarities to smallpox, and vaccine availability. Incomplete understanding of key transmission routes and vaccine access can translate to underestimated risk perception, causing individuals to ignore health guidance or forgo protective behaviors, especially if they don't see themselves as vulnerable [42]. Despite widespread internet access, information on hMPX may not have been sufficiently targeted in the Philippines, limiting public awareness of zoonotic diseases [43]. While this is expected given the disease's relatively low domestic profile, this highlights persistent weaknesses in adaptive health literacy (specifically the ability to rapidly absorb and act on information in a fast-moving outbreak landscape) [44] and the tendency toward "alert fatigue," where new health threats are downplayed after prolonged exposure to crises like COVID-19 [45].

Awareness of hMPX vaccine availability was low (48.80%), even though such vaccines are not yet FDA-approved in the Philippines. Such knowledge gaps may foster hesitancy and weaken readiness for future vaccination programs [46]. In a country where vaccine confidence remains fragile following the Dengvaxia controversy, which led to mistrust and declining immunization rates [47, 48], transparent and evidence-based communication is essential. In light of this prior experience, careful introduction of hMPX vaccines, once available, will be critical to avoid repeating past failures in public trust.

Tab. II. Responses to knowledge items.

Statement	Total (*n* = 502)					
	Answered correctly		Answered incorrectly		Answered 'do not know'	
	n	%	*n*	%	*n*	%
1. hMPX is a disease caused by a viral infection.	466	92.83%	11	2.19%	25	4.98%
2. The main clinical symptoms of hMPX are fever, headache, muscle aches, fatigue, and vesicular rashes.	435	86.65%	9	1.79%	58	11.55%
3. Currently, a vaccine against hMPX exists, however, it is not yet licensed for use in the Philippines.	245	48.80%	69	13.75%	188	37.45%
4. Not everyone who contracts hMPX will develop severe disease. Those who have underlying comorbidities, immune deficiencies, or in the extremes of age may be at higher risk of more serious complications and death.	353	70.32%	50	9.96%	99	19.72%
5. Contact with wild animals or exposure to their bodily fluids would pose higher risk of hMPX infection.	269	53.59%	96	19.12%	137	27.29%
6. The hMPX virus spreads via person-to-person through skin-to-skin or close contact with someone who has the characteristic vesicular rash.	428	85.26%	20	3.98%	54	10.76%
7. Ordinary citizens can prevent hMPX infection by avoiding contact with wild animals or exposure to their bodily fluids.	325	64.74%	52	10.36%	125	24.90%
8. Ordinary citizens can prevent hMPX spread by avoiding skin-to-skin contact with people who have suspected or confirmed hMPX.	454	90.44%	9	1.79%	39	7.77%
9. Smallpox and hMPX have similar signs and symptoms.	279	55.58%	57	11.35%	166	33.07%
10. Contact with open blisters/lesions increase the risk of hMPX transmission.	357	71.12%	29	5.78%	116	23.11%
11. hPMX is acquired only by men who have sex with men (MSM).	362	72.11%	34	6.77%	106	21.11%
12. hPMX can be transmitted during sexual contact.	278	55.38%	61	12.15%	163	32.47%
13. Currently, the global case fatality rate of hMPX is higher than 10%.	59	11.75%	141	28.09%	302	60.16%
14. hMPX infection cannot be confirmed by symptoms alone. A laboratory test (***i.e.***, polymerase chain reaction, PCR) using fluid sample from an open blister is needed for confirmation.	352	70.12%	52	10.36%	98	19.52%
15. The characteristic blisters/vesicles of hMPX are typically found over the face, chest, hands and feet.	411	81.87%	9	1.79%	82	16.33%
16. The blisters/vesicles caused by hMPX may also be seen in the groin, genitals and/or anus if spread through sexual contact.	321	63.94%	16	3.19%	165	32.87%
17. Individuals who contracted hPMX should quarantine themselves for 21 days.	360	71.71%	7	1.39%	135	26.89%

Tab. III. Responses of knowledge, attitudes, and practices.

Variable	Range	Mean	SD
Knowledge score	0-17	11.46	3.76
Attitudes			
Perceived susceptibility	1-5	2.16	1.07
Perceived severity	1-5	3.06	1.12
Perceived effectiveness of preventive measures	1-25	22.48	3.30
Avoiding close skin-to-skin contact with individuals who have characteristic hMPX rash.	1-5	4.37	0.94
Avoiding contact with animals thought to transmit hMPX.	1-5	4.41	0.93
Avoiding contact with fomites.	1-5	4.36	0.94
Handwashing or hand sanitation.	1-5	4.74	0.71
Vaccination against hMPX.	1-5	4.61	0.84
Practices			
Protective sexual practices.	1-5	4.55	0.92
Avoiding crowded places/large gatherings.	1-5	3.84	1.09
Proper hand hygiene.	1-5	4.63	0.68
Disinfecting fomites/high-touch surfaces.	1-5	4.44	0.89

Sociodemographic factors played a significant role in knowledge levels. Knowledge was significantly higher among women and those with higher education, consistent with patterns in prior infectious disease KAP studies on emerging infectious diseases, including COVID-19 [49]. Urban respondents also showed greater awareness, likely reflecting better access to information and services, as seen during COVID-19 [50]. These findings suggest that rural populations may remain underserved in health communication, underscoring the need for tailored outreach.

Most respondents perceived low personal susceptibility to hMPX despite ongoing global and local transmission, reflecting a disconnect between awareness of disease spread and perceived risk, likely due to limited local case numbers. In the health belief model, low perceived risk reduces motivation for preventive behavior [51]. Perceived disease severity was rated as moderate, possibly reflecting media portrayals of hMPX as largely self-limiting, despite its potential for serious outcomes in vulnerable groups.

Interestingly, despite only moderate knowledge, respondents generally viewed preventive measures as effective, and such attitudes were strongly linked with practice, suggesting that trust in health messaging (possibly reinforced by pandemic experience) may

Tab. IV. Multiple regression analysis of knowledge score on sociodemographic characteristics.

Sociodemographic characteristic	*B*	Std. error	*β*	*t*	*p*-value
(Intercept)	10.092	1.858	–	5.43	< 0.001
Sex[a]	1.039	0.358	0.130	2.90	0.004
Age	-0.361	0.197	-0.095	-1.83	0.067
Educational attainment	1.115	0.405	0.134	2.75	0.006
Monthly household income	0.156	0.112	0.063	1.39	0.166
Currently employed[b]	-0.190	0.372	-0.025	-0.51	0.610
Residence[c]	0.212	0.376	0.025	0.56	0.574
Household size	-0.633	0.286	-0.098	-2.21	0.028
Religious affiliation[d]	0.355	1.429	0.011	0.25	0.804
Orientation[e]	-0.629	0.502	-0.056	-1.25	0.210
Comorbidities[f]	0.077	0.334	0.010	0.23	0.818

$F_{(10,\,491)} = 2.72$, $p = 0.003$; adjusted $R^2 = 0.033$. [a] Male: 0, Female: 1. [b] No: 0, Yes: 1. [c] Rural: 0, Urban: 1. [d] Not affiliated: 0, Affiliated: 1. [e] Heterosexual: 0, LGBTQIA+: 1. [f] No: 0, Yes: 1

Tab. V. Multiple regression analysis of perceived hMPX susceptibility and severity on knowledge score, controlling for sociodemographic characteristics.

Variable	Perceived disease susceptibility[a]			Perceived disease severity[b]		
	B	*β*	*p*-value	*B*	*β*	*p*-value
(Intercept)	3.096	-	<0.001	3.484	-	<0.001
Sex[c]	0.024	0.011	0.817	-0.085	-0.036	0.431
Age	-0.051	-0.047	0.368	-0.140	-0.123	0.019
Educational attainment	-0.164	-0.069	0.163	-0.177	-0.071	0.150
Monthly household income	-0.073	-0.105	0.024	0.014	0.019	0.686
Currently employed[d]	0.140	0.065	0.193	0.093	0.042	0.402
Residence[e]	-0.057	-0.024	0.597	-0.007	-0.003	0.951
Household size	-0.025	-0.014	0.759	-0.060	-0.031	0.487
Religious affiliation[f]	-0.181	-0.020	0.661	-0.272	-0.029	0.525
Orientation[g]	0.067	0.021	0.643	0.337	0.101	0.026
Comorbidities[h]	0.037	0.017	0.701	0.133	0.059	0.185
Knowledge score	-0.020	-0.070	0.124	0.005	0.018	0.694

[a] $F_{(11,\,490)} = 1.50$, $p = 0.128$; adjusted $R^2 = 0.011$. [b] $F_{(11,\,490)} = 1.95$, $p = 0.031$; adjusted $R^2 = 0.021$. [c] Male: 0, Female: 1. [d] No: 0, Yes: 1. [e] Rural: 0, Urban: 1. [f] Not affiliated: 0, Affiliated: 1. [g] Heterosexual: 0, LGBTQIA+: 1. [h] No: 0, Yes: 1

drive compliance. However, this seeming paradox raises some questions. Is the public intuitively pro-prevention even without granular understanding? Or do favorable attitudes reflect a generic trust in health messaging, conditioned by recent pandemic experiences? If the latter, this trust is a valuable asset, but it requires careful stewardship by public institutions and communicators to prevent erosion through misinformation or apathy [52]. Nevertheless, recognizing the effectiveness of preventive measures, even when rooted in trust, does not guarantee consistent adoption. In our study, hand hygiene was practiced most consistently, while avoidance of crowded settings was least common, reflecting both habit-formation during COVID-19 and practical limitations in daily life [53, 54]. This highlights the complex nature of health behavior, which is shaped not only by knowledge and rational appraisal but also by contextual factors such as risk perception, social norms, behavioral feasibility, and emotional responses [55]. Earlier evidence that only 5% of Filipinos demonstrated good hMPX knowledge [29, 31] emphasizes the need for comprehensive education campaigns. Additionally, stigma may further hinder care-seeking, echoing challenges historically seen in HIV/AIDS and COVID-19 responses [34–36], particularly when they intersect with existing social inequalities. Given limited vaccine access and weak health infrastructure, accurate and inclusive communication is essential. Campaigns must avoid reinforcing stereotypes, instead engaging communities through culturally appropriate, stigma-free strategies [56].

Mediation analysis offers a nuanced understanding of how knowledge influences preventive health behaviors, suggesting that this relationship is not solely direct but substantially mediated by attitudinal factors, particularly the perceived effectiveness of preventive measures. This finding aligns with well-established health behavior change models that stress knowledge alone is insufficient for behavior change unless accompanied by affective and cognitive appraisal processes (*e.g.,* perceived relevance, utility, and personal control) [57]. Belief in the efficacy of specific health behaviors emerged as the key intermediary between knowledge and action, emphasizing the importance of public health interventions that go beyond simple information dissemination. Interpretation of this knowledge is shaped by individual beliefs, perceived feasibility, and trust in the source, and this determines whether

Tab. VI. Multiple regression analysis of perceived effectiveness of preventive measures on knowledge score, controlling for sociodemographic characteristics.

Variable	Avoiding skin-to-skin contact[a]			Avoiding contact with infected animals[b]			Avoiding contact with fomites[c]			Handwashing or hand sanitation[d]			Vaccination against hMPX[e]		
	B	β	*p*-value	*B*	β	*p*-value	*B*	β	*p*-value	*B*	β	*p*-value	*B*	β	*p*-value
(Intercept)	3.506	-	< 0.001	4.098	-	< 0.001	4.466	-	< 0.001	4.212	-	< 0.001	4.133	-	< 0.001
Sex[f]	0.111	0.056	0.221	0.149	0.076	0.092	0.085	0.042	0.340	0.139	0.092	0.038	0.102	0.057	0.203
Age	0.021	0.023	0.666	-0.057	-0.061	0.237	-0.097	-0.102	0.047	-0.005	-0.007	0.891	-0.121	-0.142	0.006
Educational attainment	0.036	0.017	0.726	0.028	0.014	0.780	-0.134	-0.064	0.182	-0.076	-0.048	0.317	-0.060	-0.032	0.509
Monthly household income	0.005	0.009	0.850	-0.017	-0.027	0.545	-0.033	-0.053	0.238	-0.003	-0.007	0.879	0.002	0.004	0.924
Currently employed[g]	0.016	0.008	0.864	0.093	0.050	0.304	0.102	0.054	0.266	0.020	0.014	0.771	-0.006	-0.003	0.945
Residence[h]	0.116	0.055	0.221	0.050	0.024	0.587	-0.117	-0.056	0.205	-0.081	-0.051	0.247	0.012	0.007	0.883
Household size	-0.001	-0.001	0.991	0.038	0.024	0.587	-0.038	-0.023	0.597	-0.017	-0.014	0.745	-0.021	-0.015	0.742
Religious affiliation[i]	-0.083	-0.010	0.818	-0.494	-0.063	0.157	-0.287	-0.036	0.414	-0.054	-0.009	0.838	0.141	0.020	0.657
Orientation[j]	0.144	0.052	0.253	-0.022	-0.008	0.858	0.024	0.009	0.843	0.136	0.064	0.145	0.109	0.044	0.329
Comorbidities[k]	-0.003	-0.002	0.970	0.050	0.027	0.544	-0.035	-0.019	0.668	0.077	0.054	0.216	0.014	0.008	0.848
Knowledge score	0.044	0.175	< 0.001	0.055	0.224	< 0.001	0.064	0.253	< 0.001	0.047	0.251	< 0.001	0.041	0.183	< 0.001

[a] $F_{(11, 490)} = 1.97$, $p = 0.030$; adjusted $R^2 = 0.021$. [b] $F_{(11, 490)} = 3.24$, $p = <0.001$; adjusted $R^2 = 0.047$. [c] $F_{(11, 490)} = 4.41$, $p = <0.001$; adjusted $R^2 = 0.070$. [d] $F_{(11, 490)} = 4.23$, $p = < 0.001$; adjusted $R^2 = 0.066$. [e] $F_{(11, 490)} = 3.23$, $p = <0.001$; adjusted $R^2 = 0.047$. [f] Male: 0, Female: 1. [g] No: 0, Yes: 1. [h] Rural: 0, Urban: 1. [i] Not affiliated: 0, Affiliated: 1. [j] Heterosexual: 0, LGBTQIA+: 1. [k] No: 0, Yes: 1

Tab. VII. Multiple regression analysis of practice of preventive behaviors on knowledge and attitudes, controlling for sociodemographic characteristics.

Variable	Protective sexual practices[a]			Avoiding crowded places/ large gatherings[b]			Proper hand hygiene[c]			Disinfecting fomites/high-touch surfaces[d]		
	B	β	*p*-value	*B*	β	*p*-value	*B*	β	*p*-value	*B*	β	*p*-value
(Intercept)	0.436	-	0.346	1.262	-	0.052	2.190	-	< 0.001	2.628	-	< 0.001
Sex[e]	0.045	0.023	0.547	0.159	0.069	0.126	0.182	0.127	0.003	0.168	0.089	0.048
Age	0.014	0.015	0.724	-0.053	-0.048	0.352	-0.003	-0.004	0.935	0.063	0.070	0.175
Educational attainment	0.028	0.014	0.736	0.186	0.077	0.112	0.038	0.025	0.584	0.021	0.011	0.824
Monthly household income	-0.002	-0.003	0.945	-0.002	-0.003	0.945	0.013	0.029	0.502	-0.020	-0.034	0.460
Currently employed[f]	-0.016	-0.009	0.832	0.027	0.013	0.797	0.057	0.042	0.368	0.063	0.036	0.466
Residence[g]	0.055	0.027	0.472	0.084	0.034	0.437	-0.083	-0.054	0.194	-0.026	-0.013	0.768
Household size	0.047	0.030	0.425	-0.090	-0.048	0.275	-0.007	-0.006	0.881	-0.040	-0.026	0.554
Religious affiliation[h]	0.180	0.023	0.537	0.730	0.079	0.075	0.481	0.083	0.047	0.251	0.033	0.451
Orientation[i]	0.213	0.078	0.039	-0.094	-0.029	0.515	0.169	0.084	0.048	0.096	0.036	0.415
Comorbidities[j]	0.071	0.038	0.302	-0.174	-0.080	0.070	0.002	0.001	0.972	-0.066	-0.037	0.398
Knowledge score	0.003	0.012	0.765	0.017	0.059	0.209	0.022	0.119	0.007	0.025	0.107	0.021
Perceived susceptibility	-0.057	-0.067	0.105	0.051	0.050	0.302	0.002	0.004	0.935	-0.053	-0.064	0.190
Perceived severity	-0.005	-0.006	0.876	0.013	0.013	0.789	-0.018	-0.030	0.523	0.010	0.013	0.796
Perceived effectiveness of preventive measures	0.158	0.567	<0.001	0.063	0.190	< 0.001	0.062	0.302	< 0.001	0.051	0.190	< 0.001

[a] $F_{(14, 487)} = 2.41$, $p = <0.001$; adjusted $R^2 = 0.327$. [b] $F_{(14, 487)} = 2.06$, $p = 0.002$; adjusted $R^2 = 0.053$. [c] $F_{(14, 487)} = 4.47$, $p = <0.001$; adjusted $R^2 = 0.155$. [d] $F_{(14, 487)} = 2.50$, $p = <0.001$; adjusted $R^2 = 0.064$. [e] Male: 0, Female: 1. [f] No: 0, Yes: 1. [g] Rural: 0, Urban: 1. [h] Not affiliated: 0, Affiliated: 1. [i] Heterosexual: 0, LGBTQIA+: 1. [j] No: 0, Yes: 1

people translate awareness into action [42, 58]. Health communication strategies can be designed to cultivate positive attitudes and enhance perceived efficacy by demonstrating both the importance of individual actions and their broader societal impact. Central to this process is fostering a sense of agency while addressing the emotional or contextual barriers that may impede action. If unaddressed, misinformation and stigma can distort

Tab. VIII. Indirect effects of knowledge on practices mediated by attitudes.

Practices (dependent variable)	Attitudes (mediator)	Estimate	Bias-corrected 95% CI	*p*-value[a]	% mediation
Protective sexual practices	Perceived susceptibility	0.002	0.000, 0.004	0.216	
	Perceived severity	0.000	-0.001, 0.001	0.997	
	Perceived effectiveness of preventive measures	0.040	0.028, 0.054	< 0.001	94.5%[b]
Avoiding crowded places/large gatherings	Perceived susceptibility	-0.001	-0.005, 0.001	0.399	
	Perceived severity	0.000	-0.001, 0.001	0.998	
	Perceived effectiveness of preventive measures	0.016	0.008, 0.026	< 0.001	40.2%[b]
Proper hand hygiene	Perceived susceptibility	0.000	-0.002, 0.002	0.938	
	Perceived severity	0.000	-0.001, 0.001	0.916	
	Perceived effectiveness of preventive measures	0.016	0.010, 0.023	< 0.001	40.9%[c]
Disinfecting fomites/high-touch surfaces	Perceived susceptibility	0.001	-0.001, 0.004	0.367	
	Perceived severity	0.000	-0.001, 0.001	0.980	
	Perceived effectiveness of preventive measures	0.013	0.007, 0.021	< 0.001	33.2%[c]

[a] If not statistically significant, no mediation via attitudes. [b] Indirect-only (full) mediation (*i.e.*, knowledge -> practice effect not statistically significant; see Tab. IX). [c] Complementary (partial) mediation (*i.e.*, knowledge -> practice effect also statistically significant; see Tab. IX)

Tab. IX. Direct effects of knowledge on practices

Practices	Estimate	Bias-corrected 95% CI	*p*-value
Protective sexual practices	0.002	–0.016, 0.021	0.802
Avoiding crowded places/large gatherings	0.024	–0.002, 0.050	0.069
Proper hand hygiene	0.024	0.008, 0.039	0.002
Disinfecting fomites/high-touch surfaces	0.027	0.006, 0.048	0.012

attitudes and blunt behavioral responses, undermining otherwise effective campaigns [37, 38].

Our use of a parallel multiple mediator model [41] with composite attitude scores provided a robust representation of psychological mechanisms while avoiding overfitting. Our survey instrument also demonstrated strong internal consistency (Cronbach's alpha = 0.84). These methodological strengths enhance the credibility of the findings and suggest the robustness of the proposed mechanism across diverse population subgroups. Our study also showed the potential for methodological innovation in participant recruitment. Although convenience sampling has limitations, collaborating with GO Cavite demonstrated how digital communities can support public health research. Overall, our findings highlight a model where knowledge and attitudes jointly shape practice, emphasizing the need for interventions that build both information and affective engagement to sustain preventive behavior [59].

Several limitations must be acknowledged. First, the cross-sectional nature of the study prevents inference of causal relationships. While mediation analysis offers insight into potential causal pathways, temporality cannot be firmly established without longitudinal data. Second, although we aimed for broad coverage by recruiting through social media, our sampling method was non-probabilistic and subject to self-selection bias. The use of an online, convenience sample may limit generalizability, particularly to older adults, rural residents, or those without internet access. Similarly, individuals more concerned about health or more digitally literate may have been more likely to participate, potentially skewing knowledge and attitude estimates. Additionally, self-reported data are subject to social desirability bias, particularly with regard to attitudes and practices. Nonetheless, we believe the large and active follower base of GO Cavite likely captures a demographically diverse subset of the public, and our sociodemographic profiling confirmed variation across key variables. Third, while our tool was available in both English and Filipino, we cannot rule out interpretation variability across different literacy levels. Despite pretesting, certain items, particularly those addressing complex epidemiological concepts, may have posed cognitive demands for some respondents. Future research should explore mixed-method approaches or in-person interviews to clarify nuanced public beliefs and address such limitations.

Conclusion

Our study underscores the complex nature of public health behavior in response to emerging infectious diseases like hMPX. Knowledge levels among the Philippine general population are variable, with significant gaps in areas critical for risk assessment and prevention. Attitudes play a crucial mediating role in translating knowledge into preventive practices, highlighting the importance of designing interventions that target both cognitive understanding and affective appraisal. Addressing these knowledge and attitudinal gaps through tailored, stigma-free public health messaging will be essential in mitigating the risk of hMPX transmission in the Philippines, particularly in light of vaccine unavailability and the potential for localized outbreaks. Further research should explore longitudinal changes in KAP and investigate the effectiveness of specific educational strategies in altering health behaviors.

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Conflicts of interest statement

The authors declare no conflicts of interest.

Authors' contributions

All authors made substantial contributions to the different aspects of this study. Conceptualization: DI, MT, NS, MP, RT, JV, GD, AM, MADP, PC, BMA, MLO. Methodology: NS, MP, RT. Validation: MVH. Project administration: DI, MT, NS, MP, RT, JV, GD, AM, MADP, PC, BMA, MLO. Investigation: DI, MT, NS, MP, RT, JV, GD, AM, MADP, PC, BMA, MLO. Visualization: AM. Supervision: MVH, DI, MT. Data curation: MVH. Formal analysis: MVH, NS. Writing, original draft: MVH. Writing, review and editing: MVH, DI, MT, NS, MP, RT, JV, GD, AM, MADP, PC, BMA, MLO.

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Correspondence: Michael Van Haute, De La Salle Medical and Health Sciences Institute - College of Medicine, Mangubat Avenue, Dasmariñas City, Cavite, Philippines 4114. Email: michael.q.vanhaute@gmail.com

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Nosocomial infections

Monitoring Surgical Site Infections: Insights from an Italian Teaching Hospital

GIOVANNI GUARDUCCI[1,2], GIULIANA FABBRI[2], MARCO TISEO[2], NICCOLÒ BOLOGNESI[2], CINZIA RAVAIOLI[2], LUCA LAVAZZA[3], PAOLA ANTONIOLI[2]
[1] Post Graduate School of Public Health, University of Siena, Italy; [2] Healthcare Management, University Hospital Trust of Ferrara, Italy; [3] Hospital Network Coordination, Local Health Authority of Ferrara, Italy

Keywords

Healthcare-Associated Infections • Infection Control • Surgical Site Infection • Surveillance • Patient Safety

Summary

Background. *Surgical Site Infections (SSIs) are among one of the most frequent and costly healthcare-associated infections (HAIs), leading to increased patient morbidity, prolonged hospital stays, and higher healthcare costs. Surveillance programs are essential for detecting, monitoring, and preve nting SSIs. However, the implementation and effectiveness of these programs varies across healthcare facilities. This study aims to provide effective data gathered from SSI trend assessment at Ferrara Teaching Hospital to improve surveillance systems.*

Materials and methods. *A retrospective study was conducted on data collected between 2020 to 2023 from the SIChER surveillance system and Hospital Discharge Cards at Ferrara Teaching Hospital. The analysis examined infection rates across various surgical procedures, applying two primary indicators: SSI Percentage by Category and Incidence Density of Hospital-Onset SSIs. Statistical analyses were performed using STATA software.*

Results. *An average of 5,158 surgical procedures were executed annually between 2020 to 2023, and SIChER-monitored procedures steadily increased during this period, reaching 80.7% coverage in 2023. The highest infection rates were recorded in colon surgery, while cardiac surgery consistently recorded no infections. The overall incidence density of hospital-onset SSIs was 0.18 per 1,000 follow-up days, with significant variations across surgical categories. The accuracy of HDCs in documenting SSIs improved over time, achieving a 97.2% match in 2023.*

Conclusion. *The study highlights an increasing trend in SSI surveillance coverage and accuracy, demonstrating the effectiveness of the SIChER system in monitoring infections. However, variations in infection rates among different procedures suggest the need for targeted strategies, particularly for high-risk surgeries such as colorectal and orthopaedic procedures.*

Introduction

Healthcare-associated infections (HAIs) caused by bacteria, viruses, or other pathogens represent one of the most common adverse events associated with medical care. They can occur across all healthcare settings, including inpatient facilities, outpatient clinics, and long-term residential care facilities. HAI transmission can result from both endogenous mechanisms and exogenous events, the latter being the most frequent. In hospital settings, it is estimated that approximately 5-15% of hospitalized patients develop at least one HAI during their stay [1]. Therefore, HAIs represent a significant public health issue as they generate heightened costs, reduce quality of life, and increase the risk of morbidity and mortality [2, 3].

According to the Centers for Disease Control and Prevention (CDC), HAIs are classified into several categories, including central line-associated bloodstream infections, catheter-associated urinary tract infections, surgical site infections (SSIs), ventilator-associated pneumonias, non-ventilator-associated nosocomial pneumonias, gastrointestinal infections, other primary bloodstream infections not associated with central lines, and urinary tract infections not associated with catheters [4]. Among these groups, SSIs are the most frequent and the most costly. An estimated 0.5%-3% of patients undergoing surgery develop such infections, leading to extended hospital stays of approximately 7-11 additional days, increased emergency department visits, and a higher risk of hospital readmission [5-7].

However, the actual frequency of SSIs is likely underestimated since roughly 50% occur after patient discharge [8]. Currently there is no international scientific standard for post-discharge SSI surveillance [9]. Common methods for identifying surgical wound infections after hospital discharge include direct observation by healthcare personnel, telephone follow-up interviews, patient-reported questionnaires, and outpatient follow-up visits [10]. Due to the lack of standardized post-discharge surveillance, SSIs are often overlooked [11, 12].

With the growing demand for healthcare services, early diagnosis of SSIs has become critical to enabling timely and effective treatment, accelerating patient recovery [10, 13]. Evidence suggests that SSI surveillance in hospital settings can reduce infection rates by increasing awareness and attention among

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healthcare professionals and promoting best practices - although this focus is not universally shared among all practitioners today [14, 15]. Surveillance is widely considered a key component of infection prevention and control programs [16, 17]. To date, there is no single, "correct", or universally accepted methodology for designing or implementing surveillance systems [16, 18]. However, some minimum criteria have been identified to ensure quality surveillance, such as a written plan clearly indicating objectives, targets and elements of the surveillance process, consistent application of surveillance methods, coherent surveillance elements, adequate human resources and information technology services, and evaluation strategies. Furthermore, for a successful surveillance program, there should be a robust data validation process to ensure that the data is accurate and reliable [16, 18, 19].

In this context, the development of surveillance and monitoring systems capable of providing comprehensive, timely, and accurate information regarding SSIs is essential to effectively address this important issue. These systems can be considered an integral part of programs aimed at promoting the quality of healthcare [20].

This study aims to monitor SSI trends at the Ferrara Teaching Hospital, with the objective of providing useful data to improve surveillance systems and contribute to reducing the incidence of this phenomenon.

Material and methods

STUDY DESIGN, DATA COLLECTION AND SETTING

A retrospective study was conducted on data from 2020 to 2023, collected from both surgical site infection surveillance of the Emilia-Romagna Region, called "SIChER", and the Hospital Discharge Cards (HDCs) of the Ferrara Teaching Hospital. The SIChER system aims to collect information on every surgical procedure and calculates infection rates taking into account: the volume of activity within each specific operational unit, each patient's intrinsic risk factors, and the risk associated with the type of surgical procedure [21].

Ferrara Teaching Hospital is the primary hospital serving the city of Ferrara, acting as a high-specialty referral hub for provincial healthcare and acute care management. Healthcare services are distributed across 41 Units and grouped into 9 clinical departments. The hospital is equipped with 660 regular inpatient beds, 21 Day Hospital beds, 30 Day Surgery beds, and extensive diagnostic facilities. The hospital includes 139 outpatient clinics and houses 23 operating rooms, 4 Day Surgery rooms, and a delivery suite. Each year, the Ferrara Teaching Hospital performs an average of 2.2 million outpatient procedures, 27,010 inpatient admissions (excluding healthy newborns), and 6,717 Day Hospital/Day Surgery admissions [22].

ANALYSIS

From the "SIChER" surgical site infection (SSI) surveillance data, the total number of procedures performed, the number of SSIs, and the number of follow-up days (postoperative inpatient days with a documented discharge date) were extracted. The surgical procedures were classified according to the US National Healthcare Safety Network (NHSH) classification system [17, 23]. The procedures included in the surveillance were only those necessary to obtain sufficient data to reach statistically valid conclusions (Tab. I), as outlined in the Technical Document from the Italian National Institute of Health titled *National Surveillance of Surgical Site Infections (SNICH2) and Prevention Indicators in Hospitals* [24]. Coronary artery bypass grafting procedures (CABG, CBGB, and CBGC) were not included as they are not procedures performed at the hospital under study.

From this data, the following two indicators were calculated [24, 25]:

- SSIs Percentage by Category: This indicator provides a picture of the proportion of infections related to a specific surgical procedure, but this is heavily influenced by the intensity of post-discharge surveillance, which considerably varies among hospitals and countries.

The formula is:

Infections in category X/Procedures in category X*100

- Incidence Density of Hospital-Onset SSIs: This indicator considers only infections detected within the hospital setting. Although it does not provide a complete epidemiological picture, such as for procedures with a short postoperative hospital stay, it is independent of post-discharge surveillance practices and adjusts for variations in postoperative inpatient stay duration. As such, this indicator may be the most reliable for inter-hospital or network-wide comparisons.

The formula is:

Infections in category X/Follow-up days in category X *1000

For both indicators, "X" denotes a specific NHSH category. The descriptive data analysis and calculation of indicators were performed using the STATA software.

Results

Table II presents the number of SIChER procedures performed, coverage of monitored procedures, and the total, partial and no match concordance with the Hospital Discharge Cards (HDCs) between the years 2020–2023. The average number of SIChER procedures performed at the Ferrara Teaching Hospital over the period of study was 5,751.3 ± 261.2, with the highest value (6,087) in 2023 and the lowest (5,375) in 2020. The coverage of monitored procedures was at least 75% each year, reaching a maximum of 80.7% in 2023.

SIChER concordance with the HDCs showed a continuous improvement trend that reached 97.2% in 2023, while the partial and no match percentages decreased accordingly over the period studied.

An improving trend in SICHeR coverage was observed

Tab. I. Type of Surgical Procedure under Surveillance by the Italian National Institute of Health.

NHSN	Description	ICD-9-CM codes inclued in the caterogy
COLO	Colon Surgery (Incision, resection, or anastomosis of the large intestine; includes large-small and small-large intestinal anastomoses, Laparoscopic removal of the large intestine, Enterotomy and Intestinal anastomosis)	45.00-45.03, 45.15, 45.26, 45.31-45.34, 45.4, 45.41, 45.49, 45.50-45.52, 45.4, 45.41, 45.49, 45.50-45.52, 45.61-45.63, 45.7-45.95, 46.0, 46.03, 46.04, 46.1-46.14, 46.20-46.24, 46.31, 46.39, 46.4, 46.41, 46.43, 45.5, 46.51, 46.52, 46.7-46.76, 46.9-46.94
REC	Rectal surgery	48.25, 48.35, 48.40, 48.42, 48.43, 48.49, 48.5-48.59, 48.6-48.69, 48.74
CHOL	Cholecystectomy (includes laparoscopic procedures)	51.0, 51.03, 51.04, 51.13, 51.2-51.24
HPRO	Hip arthoplasty	00.70-00.73, 00.85-00.87, 81.51-81,53
KPRO	Knee arthoplasty	00.80-00.84, 81.54-81.55
LAM	Laminectomy (Exploration or decompression of the spinal cord through removal or incision of vertebral structures)	03.0-03.09, 80.50, 80.51, 80.59, 84.60-84.69
CSEC	Cesarean Section	74.0-74.2, 74.4, 74.9-74.99
CARD	Cardiac surgery	35.00-35.04, 35.06, 35.08, 35.10-35.14, 35.20-35.28, 35.31-35.35, 35.39, 35.42, 35.50, 35.51, 35.53, 35.54, 35.60-35.63, 35.70-35.73, 35.81-35.84, 35.91-35.95, 35.98-35.99, 37.10-37.12, 37.31-37.33, 37.35-37.37, 37.41, 37.49, 37.60
CABG	Coronary Bypass, Unspecified	36.1-36.2
CBGB	Coronary Bypass with Thoracic and Donor Site Incision (thoracic procedure for revascularization of the heart; includes the procedure to obtain a suitable vein from a donor site for the bypass)	36.10-36.14, 36.19
CBGC	Coronary Bypass with Thoracic Incision Only (thoracic procedure for direct heart revascularization using, for example, the internal mammary artery)	36.15-36.17, 36.2

Tab. II. SICHeR procedures performed, their match in HDCs and their coverage, Ferrara Teaching Hospital years from 2020 to 2023.

	Year			
	2020	2021	2022	2023
SICHeR procedures performed	5.375	5.866	5.677	6.087
Match in HDCs	95,60%	96,60%	96,70%	97,20%
Partial Match in HDCs	1,20%	1,40%	0,90%	0,50%
Not in HDCs	3,20%	2,60%	2,40%	2,30%
Total SICHeR coverage	75,30%	79,80%	78,10%	80,70%
CARD	50,00%	100,00%	18,20%	31,80%
CHOL	83,40%	92,20%	94,70%	88,30%
COLO	71,10%	80,90%	82,90%	84,70%
CSEC	96,70%	98,80%	98,80%	90,00%
HPRO	95,30%	98,50%	90,20%	90,40%
KPRO	100,00%	100,00%	91,70%	93,80%
LAM	84,10%	93,20%	84,70%	90,40%
REC	83,10%	90,00%	84,70%	75,60%

for COLO procedures over the study period, while higher coverage was observed only in the last year, in 2023, for LAM and CHOL procedures. Nonetheless, the coverage of these three procedures stayed consistently above the hospital's average, except for COLO in 2020. Despite a downward trend, CSEC, HPRO, and KPRO procedures consistently stayed above the hospital's average. REC coverage showed initial improvement but worsened in the final two years, falling below the hospital average in 2023. CARD procedures showed a fluctuating trend, peaking at (100%) in 2021 and dropping to a minimum of (18.2%) in 2022.

Table III presents the number of surgeries performed, the number of SSIs and the follow-up days in the Ferrara Teaching Hospital from 2020 to 2023. Over the study period, the average number of surgeries was 5,158.75 ± 247.40, while those monitored were 1,560.25 ± 63.09. The majority were CSEC, followed by CHOL, COLO, HPRO, LAM, REC, KPRO, and CARD. Unlike the total volume of surgeries, the ones monitored increased over the first three years of the study before stabilizing in the final year, while the proportion demonstrated a fluctuating trend.

The average number of SSIs was 57.75 ± 18.08, however, this dropped to 15.5 ± 5.07 for monitored procedures. The ratio of SSIs in monitored procedures ranged from approximately 20% (2020) to 33% (2022). The most commonly occurring SSIs were observed in COLO, CSEC, and HPRO procedures, while sporadic cases were detected in some study years for CHOL, KPRO, LAM, and REC procedures. No SSIs were reported for the CARD subgroup for the entire period.

The average number of follow-up days were 98,385.5 ± 4,410.19, of which 31,891 ± 2,756.40 were attributable to monitored procedures with a maximum value of 34,114 days in 2022. The overall trend increased for all surgeries performed in the hospital during the first three years and declined in the final year. The highest number of follow-up days was recorded for HPRO, followed by CHOL, COLO, LAM, CSEC, REC, KPRO, and CARD.

Tab. III. Number of surgeries performed, of SSIs and of follow-up days, Ferrara Teaching Hospital years from 2020 to 2023.

Procedure	Year											
	Surgeries				SSIs				Follow-up days			
	2020	2021	2022	2023	2020	2021	2022	2023	2020	2021	2022	2023
CARD	1	1	2	4	0	0	0	0	31	11	45	96
CHOL	254	317	410	422	0	3	0	0	4.162	4.607	6.738	6.481
COLO	257	266	266	278	4	8	3	10	4.419	4.412	5.115	4.803
CSEC	443	428	415	362	2	5	4	3	6.258	2.271	2.579	1.974
HPRO	255	251	236	202	3	2	4	1	12.367	11.738	12.700	12.755
KPRO	16	11	11	14	0	0	1	0	1.042	756	795	856
LAM	203	192	222	252	0	0	2	3	3.051	3.023	4.902	5.129
REC	59	62	61	68	0	2	0	2	945	1.095	1.240	1.168
Total studied	1.488	1.528	1.623	1.602	9	20	14	19	32.275	27.913	34.114	33.262
Total	4.852	5.258	5.092	5.433	43	78	42	68	92.588	97.429	102.475	101.050
Ratio	30,67%	29,06%	31,87%	29,49%	20,93%	25,64%	33,33%	27,94%	34,86%	28,65%	33,29%	32,92%

Table IV presents the SSIs Percentage by Category and Incidence Density of Hospital-Onset SSIs recorded at the Ferrara Teaching Hospital. The average infection rate was 0.31 ± 0.27%, with a maximum value of 1.48% in 2021 and a minimum of 0.82% in 2022. Among the surgical categories, above hospital average values were observed only for COLO procedures, while CHOL procedures remained below the average value. CARD procedures consistently showed zero infection rates. SSI rates that were above the hospital average were observed in the following procedures/years: CSEC in 2022, HPRO in 2020 and 2022, KPRO and LAM in 2022, and REC in 2021 and 2023.

The average density of SSIs was 0.18 ± 0.10. COLO procedures always showed higher than the hospital average, while HPRO and CHOL remained consistently below it. CARD procedures showed zero. Values above the hospital average were observed in 2021 for CSEC and REC, in 2022 for CSEC and KPRO, and in 2023 for CSEC and REC.

Discussion

Surveillance of surgical site infections (SSIs) plays a key role in reducing infection rates, facilitates infection trend identification, informs prevention strategies, and supports the evaluation the intervention effectiveness [26]. Therefore, all Italian regions should continuously improve the surveillance strategies aimed at predicting, preventing and controlling nosocomial infections in all healthcare institutions [26-29]. In fact, the purpose of this study aimed at monitoring surgical site infection (SSIs) trends is to provide useful data so that surveillance systems for these types of infections can be improved.

Data analysis was conducted based on reports collected through the SICHeR surveillance system of surgical site infections in the Region of Emilia-Romagna. The results show a steadily increasing coverage of procedures during the study period, reaching just over 80% in the final year, exceeding the overall regional average [30]. However, this positive trend is not confirmed across all procedures included in the study. In particular, an opposite trend is observed in hip arthroplasty procedures, and in caesarean sections [31], which show a significant decrease in coverage (-6.7%). SSIs in these cases unfortunately represent one of the leading adverse events for these procedures [31, 32]. Furthermore, given the low volume of cardiac procedures minor fluctuations in surveillance coverage can produce disproportionately large percentage variations, reflecting the statistical instability associated with small sample sizes.

The SICHeR system was applied to almost all of the Hospital Discharge Records (HDCs) over the period of this study. Although there is room for improvement, this result should be positively regarded since proper HDC compilation ensures alignment between clinical, processing, and administrative data. HDCs represent the most comprehensive source of information regarding a patient's hospital stay, and serve as a tool for "evaluation, monitoring, and strengthening" of care, particularly for "complex" patients - such as those treated for conditions related to an infection [33].

In recent years, an increase in surgical activity has been observed, both overall and for certain procedures included in the study, such as cholecystectomy and spinal surgeries. For the former, no notable increase in SSIs was observed ("only" 3 cases in 2021); while for the latter an increasing trend in the development of SSIs over the last two years is shown. Despite an increase in cholecystectomy procedures, there is not a rise in surgical site infections. This could be attributed to the reorganization of operating room practices, which not only increased the volume of procedures but also reduced their duration. It is well-known that the longer the cholecystectomy procedure is, the higher the risk factor is for developing infection [34].

In colon surgery two indicators exceeded the hospital average. This could be due to a higher prevalence of laparotomic compared to laparoscopic techniques, since latter is associated with significantly lower infection incidence compared to open surgery [35]. Prevention

Tab. IV. SSIs Percentage by Category and Incidence Density of Hospital-Onset SSIs, Ferrara Teaching Hospital years from 2020 to 2023.

Procedure	Year							
	SSIs Percentage by Category				Incidence Density of Hospital-Onset SSIs			
	2020	2021	2022	2023	2020	2021	2022	2023
CARD	0	0	0	0	0	0	0	0
CHOL	0	0,95	0	0	0	0,65	0	0
COLO	1,56	3,01	1,13	3,6	0,91	1,81	0,59	2,08
CSEC	0,45	1,17	0,96	0,83	0,32	2,2	1,55	1,52
HPRO	1,18	0,8	1,69	0,5	0,24	0,17	0,31	0,08
KPRO	0	0	9,09	0	0	0	1,26	0
LAM	0	0	0,9	1,19	0	0	0,41	0,58
REC	0	3,23	0	2,94	0	1,83	0	1,71
Total studied	0,6	1,31	0,86	1,19	0,28	0,72	0,41	0,57
Total	0,89	1,48	0,82	1,25	0,46	0,8	0,41	0,67

of SSIs in this context should be addressed through comprehensive perioperative improvement bundles, complemented by continuous monitoring and evaluation process [36]. In recent years, SSIs following hip replacement surgery have significantly increased [37], unlike the findings of our study, which do not identify an upward trend for this type of procedure. The multifactorial nature of SSIs [38-42] highlights the need for effective interventions across multiple stages of surgical care. These efforts must involve all stakeholders and, when necessary, patients as well. Interactive quality improvement tools such as Clinical Audits are particularly effective in identifying shortcomings and guiding quality improvement initiatives [43].

LIMITATIONS

Despite providing valuable insights into the surveillance of surgical site infections, this study presents certain limitations. First, it analyses only local data without the ability to compare similar settings, which limits how generalized the findings are in all contexts. Second, the data is not stratified by patient type, making it impossible to identify patients at higher risk of developing SSIs. Finally, since the data is categorized by type of procedure rather than by Operational Unit (OU), it is not possible to identify specific OUs at higher risk of SSI prevalence.

Conclusion

This study aimed to monitor the trends of SSIs at the Ferrara Teaching Hospital, with the goal of improving surveillance systems and contributing to the reduction of this phenomenon. The results demonstrate steady progress in the coverage of SIChER-monitored procedures, reaching over 80% in 2023, surpassing the regional average. However, this trend was not consistent across all procedures. While infections related to colon surgery remained above the hospital average, the absence of significant increases in SSIs for cholecystectomy procedures highlights the potential impact of improved operating room practices, such as reduced procedure times. In addition, the results emphasize the importance of accurate Hospital Discharge Record (HDC) documentation, which ensures strong correlations between clinical, administrative, and surveillance data. This makes HDCs a fundamental tool for monitoring and improving patient care.

Ultimately, these findings provide valuable insights for improving SSIs monitoring and emphasize the importance of evidence-based, coordinated interventions to address this healthcare challenge.

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None.

Conflict of Interest statement

The Authors declare that there is no conflict of interest.

Authors' contribution

Conceptualization: GG, PA; Methodology: GG, GF, PA; formal analysis: GG; Data Curation: PA; Writing, original draft preparation: GG, MT, PA; Writing, review and editing: GG, GF, NB, CR, LL, PA; Visualization: GG; Supervision: GF, LL, PA; Project administration: PA. All authors approved the final version of the manuscript.

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Correspondence: Giovanni Guarducci, Post Graduate School of Public Health, University of Siena, Via Aldo Moro 2, 53100 Siena, Italy. E-mail: giovanni.guarducc@student.unisi.it

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NON COMMUNICABLE DISEASES

Final Heights in Patients with Congenital Adrenal Hyperplasia: a Retrospective Cohort Study

ELAHE RAFIEI[1], FARZANE ROUHANI[1], EMAD BAYAT[2], ZOHRE MOEINI[1], NAVID DEHNAVI[3]
[1] Department of Pediatrics, Aliasghar Children's Hospital, School of Medicine, Iran University of Medical Sciences, Tehran, Iran;
[2] Department of General Surgery, School of Medicine, Iran University of Medical Sciences, Tehran Iran;
[3] Department of Biology Education, Farhangian University, Tehran Iran

Keywords

Final heights • Congenital Adrenal Hyperplasia • Salt wasting • Simple-virilizing

Summary

Introduction. *Congenital adrenal hyperplasia (CAH) attributed to 21-OHD is one of the most common genetic endocrine disorders that occurs due to the disruption and defects in the steroidogenic enzymes involved in the production of cortisol. The current study aims to assess the final height of patients with classic CAH forms in Iran.*

Methods. *The retrospective cohort study was conducted on 30 patients (determined using the previous studies by the sample size formula to compare two means) studies with classic type CAH who were followed up and treated in the endocrinology clinic of Ali Asghar Hospital during the 2000-2022 years. The history of the patients at the time of diagnosis was extracted from the patient's files and recorded in the checklist. All data was analyzed using IBM SPSS Statistics version 22 software.*

Results. *In the simple virilizing (SV) group, the target and final height for females was 162 and 159.2 cm, and for males were 173 and 171 cm. In the salt-wasting (SW) group, the target and final height for females was 164 and 163.2 cm, and for males were 171.7 and 173.1 cm. There was a significant and reverse correlation between the mean age at the time of diagnosis and the Final Height percentile among all cases (r: -0.55, p: 0.02) and the SW group (r: -0.75, p: 0.002). A positive and significant correlation was seen between the bone age advanced and final height percentile in the SV group (r: 0.04, p: 0.03). The final height percentile increased significantly with an increase in the Duration of treatment regardless of CAH type (r: -0.67, p: 0.009). Also, there was a positive and significant correlation between hydrocortisone dose and final height percentile in the SV group (r: 0.24, p: 0.04).*

Conclusion. *The results of the present study showed that early diagnosis of the disease at a young age, lower bone age of patients, preventing the increase of obesity in children with CAH, and receiving appropriate drugs with standard doses can play an effective role in increasing the final height of CAH patients.*

Introduction

Controlling the production of enzymes in the body is the responsibility of genes, and each person has a pair of genes to create the enzyme that produces cortisol. People with congenital adrenal hyperplasia (CAH) have a pair of defective genes, which do not function properly, resulting in a deficiency of the 21-hydroxylase enzyme [1]. CAH represents an important public health concern as the most common autosomal recessive disorder, with significant impacts on growth, development and quality of life [2, 3]. Early diagnosis and proper management not only prevent acute complications like adrenal crises but also substantially improve quality of life through optimized growth and sexual development [4].

The treatment of patients with CAH is the use of steroid drugs throughout life. Although current treatments cannot restore the body's cortisol levels to normal, studies are underway to develop new formulations of hydrocortisone. A decrease in cortisol causes an increase in adrenocorticotropic hormone (ACTH) and adrenal gland hyperplasia, and the precursors of enzymes increase [5]. The most common enzyme defect that causes this disease is 21-hydroxylase enzyme deficiency, which is seen in 90% of patients, followed by 11-beta-hydroxylase deficiency [6, 7]. As a result of the deficiency of the enzymes mentioned above, the increase of cortisol precursors and its conversion to androgens in female fetuses causes virilizing and various degrees of genital ambiguity. Also, it manifests as false precocious puberty in boys [8]. Virilizing varies from a slight enlargement of the clitoris to a completely masculine appearance of the genitals. On the other hand, aldosterone deficiency causes salt excretion from types of 21-hydroxylase deficiency [2, 9]. Depending on the type of enzyme deficiency, different manifestations and symptoms of the disease and laboratory symptoms occur, the most common manifestations of which are salt wasting, simple masculinization, and false precocious puberty [10]. The problem of these patients is mainly due to late diagnosis and difficulties during treatment. If diagnosed late, many patients with adrenal crises die [10]. Classic CAH disease, if not treated, can cause a salt imbalance in the body and result in dehydration, blood pressure drop, vomiting, shock, and even death. Also, this disease can cause problems in the child's growth and development [3]. One of

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the treatment methods used in patients with CAH is the use of steroids. However, its use causes excessive production of androgens in sufferers and as a result, disrupts the growth of organs [11-13]. If the disease is not well controlled, the height growth rate will increase in the early years of life, but eventually, with the premature closure of the growth plates, the final height will remain short. If the steroid prescribed to the patient is high, height growth will be low at first, and weight growth will increase [14]. According to recent studies, there are conflicting reports of the final height of CAH patients indicating short stature or normal height. Patients with CAH are in a state of hyperandrogenism due to the disease itself, and due to the treatment of the disease, they are in a state of hypercortisolism for the rest of their lives, which can cause short stature. On the other hand, the age of onset of puberty and advanced bone age lead to premature puberty, which can affect the final height. Considering the subject's importance, the current study aims to assess the final height of patients with classic congenital adrenal hyperplasia that includes the salt-wasting (SW) and the non-salt wasting/simple virilizing (SV) forms. Our study provides crucial information on final height outcomes in Iranian CAH patients, addressing a gap in developing country populations where newborn screening is not universal. These findings will help optimize treatment protocols and counseling for families affected by this chronic condition.

Materials and methods

The retrospective cohort study was conducted on 30 patients with classic type CAH who were followed up and treated in the endocrinology clinic of Ali Asghar Hospital during the 2000-2022 years.

Eligibility criteria

Patients with bone age more than 14 years in girls and more than 16 years in boys and classic CAH with 21-hydroxylase deficiency who have been monitored in the endocrinology clinic center since the diagnosis of the disease until reaching the final height, also patients treated with hydrocortisone alone were included. Patients who suffer from other types of CAH, treated with Growth Hormone, GnRh, aromatase inhibitors, or other drugs, taking other drugs that affect growth, such as immunosuppressants were excluded.

Data collection

The history of the patients at the time of diagnosis and the required demographic information (including gender, age at the time of diagnosis, weight, and height at the time of diagnosis) were extracted from the patient's files and recorded in the checklist. Finally, the effect of different factors such as hydroxyprogesterone level, hydrocortisone, and duration of treatment on the final height of the patients was assessed.

Sample size

Using previous studies [15] and comparing the average height of children with their parents, taking into account the average height of children with CAH equal to 159 ± 2 and the average height of parents equal to 154.6 ± 4 and a 95% confidence interval and using the following formula and taking into account the possibility of attrition the sample size of 30 people was calculated.

$$n = \frac{\left(Z_{۱-\frac{\alpha}{۲}}+Z_{۱-\beta}\right)^{۲}(\delta_{۱}^{۲}+\delta_{۲}^{۲})}{(\mu_{۱}-\mu_{۲})^{۲}}$$

In the mentioned formula $Z_{1\text{-}a/2}$ and $Z_{1\text{-}B}$ were considered 1.96 and 0.84 respectively.

Data analysis

The Shapiro-Wilk test has been performed to evaluate the sample distribution before the mean and standard deviation can be used. Quantitative and Qualitative data were reported as mean ± SD (Due to normal distribution of data) and numbers and percentages respectively. The association between quantitative variables such as height and age with the type of CAH was assessed using the t-test. Also, the correlation between quantitative variables was assessed using the Pearson or Spearman correlation test (In normal and normal and non-normal data). The p-value less than 0.05 was considered a significant level. The data was analyzed using IBM SPSS Statistics version 22 software.

Results

Patient's characteristics at the time of diagnosis

In the current study, 14 patients with SW and 14 with SV were studied (two cases excluded due to incomplete data and this attrition was considered in calculated sample size). The average age of patients in SW and SV at this time was 1.88 and 101 months respectively ($p = 0.04$). Regarding the BMI, the average in SW and SV were 18.85 ± 4.53 and 19.02 (3.74) respectively ($p = 0.77$). In comparing the mean of height, this mean in SW and SV was 52.2 cm ± 40.00 and 126.46 cm ± 22.30 respectively ($p = 0.60$). Considering the mean of weight, this mean in SW and SV was 3.62 kg ± 18.71 and 37.86 kg ± 9.98 respectively ($p = 0.60$). More details about the patient's features at the time of diagnosis were shown in Table I.

Characteristics of CAH patients at the time of study

The average age of patients in SW and SV at this time was 18.5 ± 3.61 and 16.79 ± 1.81 respectively ($p = 0.35$). The average BMI in SW and SV were 23.01 ± 1.98 and 23.96 ± 2.50 respectively ($p = 0.67$). In comparing the mean of Hydrocortisone dose (mg|m^{2}), this mean in SW and SV were 12.32 ± 4.10 and 11.96 ± 5.11 respectively

Tab. I. Characteristics of CAH patients at the time of diagnosis.

Variables	Males			Females			Total		
	Salt wasting	Simple virilizing	*p*	Salt wasting	Simple virilizing	*p*	Salt wasting	Simple virilizing	*p*
	N = 6	N = 1		N = 8	N = 13		N = 14	N = 14	
Average age of first visit (Month)	2	132	-	1.8	99	0.05	1.88	101	0.04
BMI mean at diagnosis (percentile)	67.3 ± 40.94	68.9	-	63.22 ± 32.51	72.55 ± 23.02	0.55	65.00 ± 34.91	72.2 ± 22.94	0.73
BMI mean at diagnose (kg/m2)	20.50 ± 4.93	23.46	-	17.61 ± 4.08	18.67 ± 3.66	0.41	18.85 ± 4.53	19.02 ± 3.74	0.77
Height mean at diagnosis (percentile)	84.50 ± 17.80	85.77	-	78.79 ± 26.48	76.95 ± 19.42	0.8	81.24 ± 22.54	77.58 ± 18.80	0.05
Weight mean at diagnosis (kg)	30.58 ± 21.87	46	-	3.65 ± 16.37	37.21 ± 9.54	0.16	3.62 ± 18.71	37.86 ± 9.98	0.60
Weight mean at diagnosis (Percentile)	54.67 ± 36.59	87.07	-	55.18 ± 28.70	69.06 ± 26.07	0.55	54.82 ± 31.09	70.35 ± 25.51	0.58
Height means at diagnosis (cm)	52.2 ± 43.95	140	-	52 ± 39.75	125.42 ± 22.85	0.55	52.2 ± 40.00	126.46 ± 22.30	0.60
Bone Age mean at diagnosis (Z.score)	-	1.2	-	-	1.40 ± 0.81	0.27	-	1.39 ± 0.78	_
Predicted mean Adult Height at diagnosis (cm)	_	166.4	-	-	152.9	_	-	152.91 ± 6.02	_
Bone age advanced*	0	4	-	0	3.8	0.65	0	3.81	0.03

* Difference between chronological age and bone age.

(*p* = 0.73). The mean of 17 OH Progesterone levels (nmol/dl) in SW and SV were 12.40 ± 16.13 and 18.04 ± 16.35 respectively (*p* = 0.08). In comparing the mean of the duration of treatment (Year), this mean in SW and SV were 18.34 ± 5.17 and 8.37 ± 3.56 respectively (*p* = 0.87). More details are shown in Table II.

Comparison of target, predicted, and final height of CAH patients.

As shown in Table III, the mean of the final height means percentile in SW and SV were 33.7 and 25.3 respectively (*p* = 0.21). Also, after receiving the treatment in both studied groups, the final height was close to the target height. In the SV group, the target and final height for females was 162 and 159.2 cm, and for males were 173 and 171 cm. In the SW group, the target and final height for females was 164 and 163.2 cm, and for males were 171.7 and 173.1 cm. More information is shown in Figure 1 and 2.

The correlation between different variables with the final height of patients

There was a significant and reverse correlation between the mean age at the time of diagnosis and the Final Height percentile (r: -0.55, *p* = 0.02). Also, a similar correlation was seen between the mentioned variables in the SW group (r: -0.75, *p* = 0.002). There was a significant and reverse correlation between the mean BMI at the time of diagnosis and the final height percentile in the SW group (r: -0.55, *p* = 0.02). Regarding the correlation between bone age mean at the time of diagnosis year and with final height percentile, there was a significant and reverse correlation between the mentioned variables in the SV group (r: -0.33, *p* = 0.04). A positive and significant correlation was seen between the bone age advanced and final height percentile in the SV group (r: 0.04, *p* = 0.03). There was a reverse and significant correlation between the mean BMI percentile at the time of study and the final height percentile in the SV group (r: -0.67, *p* = 0.009). The final height percentile increased significantly with an increase in the Duration of treatment regardless of CAH type (r: -0.67, *p* = 0.009). Also, there was a positive and significant correlation between hydrocortisone dose and final height percentile in the SV group (r: 0.24, *p* = 0.04). It means with an increase in hydrocortisone dose the final height percentile will be increased (Tab. IV).

Tab. II. Characteristics of CAH patients at the time of study

Variables	Males			Females			Total		
	Salt wasting N = 6	Simple virilizing N = 1	*p*	Salt wasting N = 8	Simple virilizing N = 13	*p*	Salt wasting N = 14	Simple virilizing N = 14	*p*
Current average age (years)	18 ± 2.97	17	-	18.88 ± 4.19	16.77 ± 1.88	0.41	18.5 ± 3.61	16.79 ± 1.81	0.35
The average duration of treatment (Year)	6.06 ± 18	6	-	18.68 ± 4.60	8.52 ± 3.57	0.55	18.34 ± 5.17	8.37 ± 3.56	0.87
The average age of menarche	-	-	-	10.88 ± 0.79	10.85 ± 1.16	0.86	-	-	-
BMI mean at study (kg/m^2)	23.70 ± 1.97	24.50	-	22.49 ± 1.95	23.92 ± 2.60	0.60	23.01 ± 1.98	23.96 ± 2.50	0.67
BMI mean at study (kg/m^2)_ (Percentile)	69.83 ± 21.66	82.40	-	65.54 ± 23.64	75.35 ± 13.40	0.47	67.38 ± 22.05	75.85 ± 13.01	0.38
Bone Age mean at diagnosis advanced (year)	_	2	-	_	2.08 ± 1.19	_	_	2.07 ± 1.14	_
Hydrocortisone dose mean (mg/m^2)	11.25 ± 3.79	15	-	13.13 ± 4.38	11.73 ± 5.24	0.46	12.32 ± 4.10	11.96 ± 5.11	0.73
Hydrocortisone dose mean (mg/m^2)	11.25 ± 3.79	15	-	13.13 ± 4.38	11.73 ± 5.24	0.46	12.32 ± 4.10	11.96 ± 5.11	0.73
17 OH Progesterone level mean (nmol/dl)	21.67 ± 22.20	7.80	-	5.45 ± 1.50	17.01 ± 18.60	0.003	12.40 ± 16.13	18.04 ± 16.35	0.08

Tab. III. Comparison of target, predicted, and final height of patients.

Variable	Male			Female			Total		
	Salt wasting N = 6	Simple virilizing N = 1	*p*	Salt wasting N = 8	Simple virilizing N = 13	*p*	Salt wating N = 14	Simple virilizing N = 14	*p*
Final height mean (cm)	173.1	171	_	163.2	159.2	0.02	_	_	_
Final height mean (percentile)	40	30	_	29	25	0.01	33.7	25.3	0.21
Predict adult height at diagnosis	_	166.4	_	_	152.9	0.03	_	_	_
Predict adult height at diagnosis (percentile)	_	8	_	_	10	_	_	9.8	_
Target height mean (cm)	171.7	173	_	164	162	0.04	-	-	_
Target height mean (percentile)	40	43	_	53	51	0.04	47	50	_
Advance height	_	4.6	_	6.3	_	_	_	_	_

Discussion

Congenital adrenal hyperplasia (CAH) attributed to 21-OHD is one of the most common genetic endocrine disorders that occurs due to the disruption and defects in the steroidogenic enzymes involved in the production of cortisol. This disorder is diagnosed with the reduction of cortisol feedback and the increase in the secretion of adrenocorticotropic hormone (ACTH) from the pituitary gland and subsequent Adrenal hyperplasia. The most common treatment in all forms of CAH is corticosteroid replacement therapy [16, 17]. Implementation of CAH newborn screening enabled early diagnosis of patients with 21-OHD and consequently prevented Stunting as well as early puberty in children [18, 19]. the current study aims to assess the final height of patients with classic congenital adrenal hyperplasia that includes SW and SV forms in Iran.

The current study was conducted on 30 patients with CAH, and the two main groups were SV (14 people)

Tab. IV. Correlation between different variables with the final height of patients.

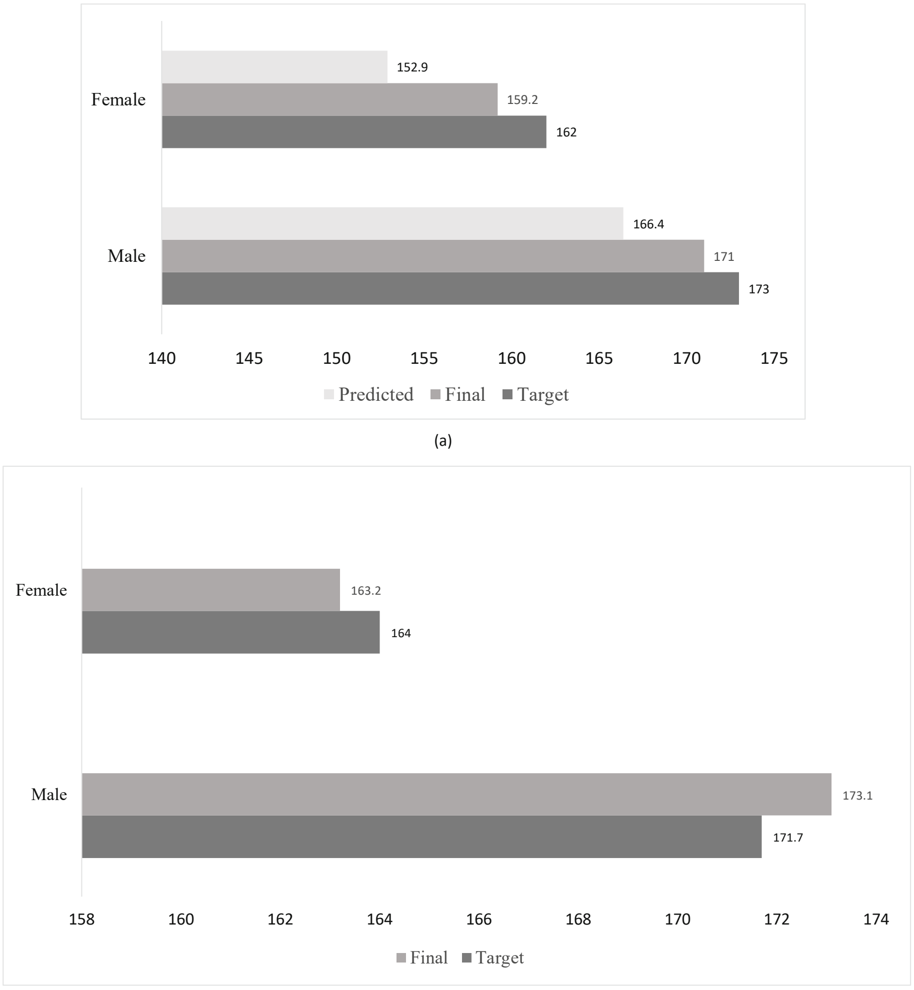
Variables	Group	r (Final Height)	*p*	r (Final Height Percentile)	*p*
Age at diagnosis (months)	Total	-0.059	0.05	-0.558**	0.02
	Salt wasting	-0.089	0.04	-0.759**	0.002
	Simple virilizing	-0.061	0.837	-0.113	0.700
BMI at diagnosis (kg/m²), Percentile	Total	-0.079	0.690	-0.339	0.078
	Salt wasting	-0.319	0.266	-0.647*	0.012
	Simple virilizing	0.153	0.601	0.143	0.625
BMI at study (kg/m²), Percentile	Total	0.107	0.588	-0.275	0.157
	Salt wasting	-0.216	0.459	-0.768**	0.001
	Simple virilizing	0.272	0.346	0.285	0.323
Bone age at diagnosis (years)	Total	–	–	–	–
	Salt wasting	0.369	0.043	-0.336	0.045
Bone age Z-score at diagnosis	Total	–	–	–	–
	Salt wasting	0.04	0.275	0.04	0.244
Bone age advanced	Salt wasting	0.049*	0.038	0.043	0.037
Predicted adult height at diagnosis (cm)	Total	0.271	0.164	-0.216	0.270
	Salt wasting	–	–	–	–
	Simple virilizing	0.017	0.955	0.024	0.934
Height at diagnosis (cm), Percentile	Total	0.118	0.549	0.040	0.842
	Salt wasting	-0.161	0.835	0.232	0.910
	Simple virilizing	0.056	0.045	0.042	0.056
BMI at study, Percentile	Total	-0.29	0.12	-0.458*	0.014
	Salt wasting	-0.046	0.875	-0.183	0.532
	Simple virilizing	-0.639*	0.014	-0.670**	0.009
Target height Z-score	Total	0.059	0.767	0.244	0.210
	Salt wasting	0.172	0.556	0.488	0.076
	Simple virilizing	-0.073	0.805	0.015	0.958
Duration of treatment (years)	Total	-0.050	0.801	0.457*	0.015
	Salt wasting	0.089	0.762	0.759**	0.002
	Simple virilizing	-0.115	0.695	-0.061	0.836
Hydrocortisone dose (mg/m²)	Total	0.022	0.011	0.010	0.059
	Salt wasting	0.055	0.051	0.244	0.020
	Simple virilizing	0.183	0.032	0.244	0.040
17-OH Progesterone (nmol/dl)	Total	-0.277	0.054	-0.697**	0.040
	Salt wasting	0.219	0.451	-0.775**	0.001
	Simple virilizing	-0.496	0.061	-0.519	0.057

* Refer to $p<0.05$ and ** $p < 0.01$.

and SW (14 people). The results of the present study showed that the target and final height in both types of disorders are very close in both women and men, which indicates the effectiveness of treatment in preventing Stunting in these people. Some studies have suggested general screening to diagnose CAH, especially the SW type, during infancy. Due to the length of the various stages of the test, the diagnosis may be delayed and lead to severe clinical symptoms in the patient [15]. It must be considered, that despite recent advances in treating CAH, several important questions about patient growth and final height remain unknown. Most of the studies conducted in this field [18, 20, 21], and of them have indicated that the final height is shorter than the target height. The results of a meta-analysis indicated that the average final height was higher than the reported values. However, these values were still lower than the average height of the entire population [22]. The results of another study showed that the final height of CAH patients is lower than the average value of the population and also lower than expected [23, 24].

Regarding the effectiveness of treatment methods, the results of the current study indicate a significant and reverse correlation between the mean age at the time of diagnosis and the final height percentile. Also, a similar correlation was seen between the mentioned variables in salt wasting group. These findings mean that the delay in the diagnosis of CAH can lead to a worsening of the prognosis of the disease. Studies have shown that early diagnosis of CA and good treatment compliance have a positive effect on the final height of patients [22, 23, 25]. Hargitai et al showed that short stature, especially in infancy, is usually associated with poor steroid treatment [26]. Another study in this field showed that timely treatment with GnRH can play an important role in improving the final height of patients and reducing

Fig. 1. Comparison of final, target, and predicted height of cases in Simple virilizing(a) and salt-wasting group (b).



(a)

(b)

the difference from the target height [27]. Alternative treatments such as the use of growth hormone associated with puberty inhibitors, in addition to the anti-estrogen effect, have been effective in improving the prognosis of height in these patients [28-31]. The observed inverse relationship between the final height and the age of the patients indicates that it is possible to reach the desired height in younger patients, and with better treatment of childhood CAH, normal growth can be expected [32]. The results of the present study showed that the final height of cases in the SV group was lower than in Salt-wasting individuals. These results are consistent with the results of a similar study [33, 34].

Our results showed a significant and reverse correlation between the mean BMI at the time of diagnosis and the final height percentile in the SW and SV groups. The BMI status in congenital adrenal hyperplasia cases was assessed in previous studies [35]. The results of these studies have shown that children with CAH are prone to obesity, which can affect their growth.

According to our results, bone age mean at the time of diagnosis showed a significant and reverse correlation with final height in the SV group. The bone age advanced and final height had a positive and significant correlation in the SV group. These findings mean that an increase in bone age advance can lead to an increase in final height. Using the above findings, it can be concluded that the lower bone age at the time of disease diagnosis, can be led to more effective treatment methods and the improved final height.

The current study results showed that the final height percentile increased significantly with an increase in the duration of treatment regardless of CAH type. Our finding indicates a positive and significant correlation between hydrocortisone dose and final height percentile in the SV group. It means with an increase in hydrocortisone dose the final height percentile will be increased. Contrary to our results, Wisniewski et al showed that treatment with hydrocortisone did not have a significant association with height outcomes among children without classic CAH [36]. In the treatment process of CAH, providing conditions for the natural secretion of ACTH in the treatment of CAH to, control the excessive secretion of adrenal androgens, and replace steroids that the adrenal gland is unable to synthesize has an important role that must be considered(20). In general, prescribing excessive doses of drugs in these patients should be avoided. Treatment with insufficient doses of hydrocortisone leads to an increase in androgens and the aggravation of bone age progression and loss of growth potential. On the other hand, too much glucocorticoid reduces the environmental effects of growth hormone, with a direct impact on bones, it directly causes a reduction in bone growth [37, 38]. Therefore, the dose of corticosteroid used can suppress adrenal androgens and minimize the negative effects of long-term steroid treatment. Therefore, if the patient receives unacceptable doses, for example, more or less than the required level, it may lead to a shortening of the final height [6]. The results of this study have significant applications for healthcare systems, particularly in developing countries where universal newborn screening for CAH is not yet implemented. Our findings demonstrate that early diagnosis and proper treatment initiation can substantially prevent growth and developmental complications in affected individuals. These outcomes may encourage health policymakers to expand nationwide newborn screening programs for early CAH detection. Furthermore, the positive impact of optimized treatment on patients' height outcomes underscores the need for standardized treatment protocol training for physicians and healthcare providers.

The significant correlation between treatment duration and improved growth outcomes highlights the crucial importance of regular long-term follow-up care for CAH patients. These findings can inform the development of more comprehensive care programs for CAH patients, ultimately leading to improved quality of life and reduced economic burden on healthcare systems. The study particularly emphasizes the need for specialized endocrine clinics and multidisciplinary care teams in resource-limited settings to achieve optimal patient outcomes. The current study had some limitations: a relatively small sample size (N = 28), though adequately powered for primary outcomes; a single-center design that may limit generalizability of the results; a lack of data on socioeconomic factors that could influence treatment adherence, and, finally, a retrospective design dependent on the quality of records.

Conclusion

The results of the present study showed that early diagnosis of the disease at a young age, lower bone age of patients, preventing the increase of obesity in children with CAH, and receiving appropriate drugs with standard doses can play an effective role in increasing the final height of CAH patients. Therefore, developing screening programs for the timely detection of these disorders can play a very important role in the height growth of these children and improving their quality of life in both classic types. First, implementing newborn screening programs is crucial for the early detection of CAH. Second, regular growth monitoring and bone age assessments should become standard components of care. Third, glucocorticoid dosing requires careful balancing between androgen suppression and growth preservation. These measures can significantly improve height outcomes and quality of life for CAH patients, particularly in resource-limited settings.

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Data availability

The datasets generated and analyzed during the current study are available from the corresponding author upon reasonable request.

Conflicts of interest statement

We declare no conflict of interest.

Authors' contributions

ER and FR: Concept, Methodology, Data collection, writing. EB, ZM, ND: Proof Reading, Formatting, Data collection, and writing.

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Correspondence: Farzane Rouhani, Department of Pediatrics, Aliasghar Children's Hospital, School of Medicine, Iran University of Medical Sciences, Tehran, Iran. E-mail: Rohani.F.Prof@gmail.com.

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Non communicable diseases

Assessment of "Quality of Life" of Parents and Siblings of Intellectually Disabled Children residing at one of Metropolitan cities at Western India

SAHIL RAJESH SOLANKI[1], RUJUL PANKAJBHAI SHUKLA[2], VIRAL R DAVE[3]
[1] Department of Community Medicine, GCS Medical College, Ahmedabad; [2] Department of Community Medicine, Ananya College of Medicine & Research, Kalol, Gandhinagar; [3] Department of Community Medicine, GCS Medical College, Ahmedabad

Keywords

Columbia Impairment Scale-Youth version • Intellectually disabled • National Institute of Mental health Disability Impact Scale • Quality of Life

Summary

Introduction. *Intellectual disability is a permanent disability and raising such a child may lead to varied physical, social, emotional response from caregivers. Data of Quality of life of family members of such children is underexplored.*

Objectives. *To measure quality of life of family members of intellectually disabled children.*

Methodology. *A cross-sectional study was conducted involving seven functional special schools in Ahmedabad. Out of 382 eligible children, 253 parents (Category A) and 195 siblings (Category B) were included. Data were collected using a pre-tested, semi-structured questionnaire. Quality of life for parents was assessed using the National Institute of Mental Health Disability Impact Scale, while siblings were evaluated using the Columbia Impairment Scale (Youth Version).*

Results. *Among Category A participants, the most negatively affected domains were social life (77.1%), physical care (65.2%) and embarrassment (60.5%). Positive effects included better family relationships and increased empathy. Among siblings, 80.5% exhibited functional impairment (score >16), with common problems related to emotional well-being, behaviour and peer interactions. Age, education, and employment status significantly influenced impairment scores.*

Conclusion. *Parents and siblings of children with ID experience considerable negative impacts on their quality of life. These findings highlight the need for targeted psychosocial and support interventions to address the challenges faced by these families.*

Introduction

Intellectual disability is a condition characterized by significant limitations in both intellectual functioning and adaptive behaviour that originates before the age of 22 [1]. Even in present times birth of a child with intellectual disabilities is considered unwelcome event [2]. Parents suffer from guilt, grief, shock and bitterness [3]. Parents of such children are usually underprepared for role and responsibilities as parents. They have to make changes in their lifestyle, restrictions are imposed on their social life, they have less time for themselves, their leisure and recreational activity get compromised [4]. This causes stress which leads to psychological morbidity and disturbance in marital harmony [5]. The impact is not only on parents but also on other family members including siblings. As per census 2011, a total of 2.68 crore persons in India are living with disabilities, amongst which 15 lakh comprise of intellectual disability [6]. In Gujarat, 66393 people are living with intellectual disability [6]. A recent meta-analysis of ID studies among children and adolescents showed a summary prevalence of 2% (range 1-3%) in India [7]. No specific data is available for number of children every year detected with Intellectual disability. The present study was undertaken to explicitly find the demands and challenges faced by the parents and siblings of children with intellectual disability. Studies conducted in India & other international countries which evaluate the quality of life of parents of intellectually disabled children are available however studies regarding quality of life of siblings of such children in India or any other countries are unexplored.

Objectives

To measure quality of life among family members of intellectually disabled children
To find determinants affecting quality of life of the study participants.

Methodology

A cross-sectional study was started after seeking permission from Institutional Ethics Committee. List of special schools for intellectually disabled children situated in Ahmedabad was prepared. Out of 11 schools list obtained, 7 schools were functional at the time of

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the study. Remaining schools informed to have closed due to lack of student enrolment. Functional schools were contacted and data of total number of students enrolled in each school was obtained. From the obtained data, 382 students were enrolled. Parents and siblings were considered as family members for the current study. All 382 children were included in the sampling frame. Per child, parents included in the interview were either father or mother, who-so-ever was available of the selected child; both were not included in the study. Socio-demographic details of spouse were asked to the study participants. In case of divorce, last known socio-demographic details of spouse which was provided by the study participants were considered in the result. If a selected child had more than one sibling, than elder most sibling was interviewed. Not more than one sibling per selected child was interviewed. Permission from head of each school was obtained before start of study. In-person interview was carried out by study investigators on priorly fixed days at venue like school premises, home or work place whichever was convenient to family members using pre-tested semi-structured questionnaire. Before the initiation of the study, validation of questionnaire was done as questionnaire was also translated to the local language. Amongst 20 family members of Intellectually disabled children, pilot study was conducted. Validation was checked through applying Cronbach alpha which was found to be reliable ($\alpha = 0.76$). These 20 family members included in pilot study were later included in the final study and their second interview after validation of questionnaire was carried out. During the course of data collection if contact with parent or sibling was not established for interview, second attempt to interview was made as per convenience. Before interviewing siblings, parents' permission was obtained.

Out of 382 participants, contact with parents of 102 participants could not be established with multiple attempts and 27 refused to provide consent to participate in the study. Final sample size in the study which was analyzed was 253. Amongst 253 participants, 216 participants had siblings in which 195 were interviewed as remaining were not eligible to participate in the study. Questions regarding socio-demographic profile of family like type of family, total family members, age of parents, marital status of parents of affected child, total family income, education and occupation of parents of affected child, details of siblings of intellectually disabled child were asked.

For assessing quality of life of parents of affected child, National Institute of Mental Health Disability Impact Scale [8] was used. It is pre-validated questionnaire [9-11]. It has 11 areas of impact; within each area further questions are present. Each question needs to be responded in either of three ways: not affected- score 0, somewhat affected- score 1 and lot of affected- score 2. Higher the score in 10 areas, greater is the negative impact. Higher the score in area 11, greater is the positive impact. From maximum possible score in 10 areas, score with more than 50% were considered as negative impact while in 11th area, score with less than 50% of maximum possible score was considered as negative impact.

For assessing quality of life of siblings, Columbia Impairment Scale (CIS) Youth Version was used [12]. It is 13 question pre-validated [13, 14] scale which categorizes problem of siblings from No problem- Score 0, Some problem- Score1 to 3, Very Bad problem- Score 4 and Not Applicable / Don't know- Score 5. Functional impairment was considered if total score was above 16.

Data entry was done in MS Excel. Analysis was done using MS Excel and Statistical Package for Social Science (SPSS) Version 20. Heat map was created to explain spearman correlation analysis. In heat map RED suggest Weak/ Negative correlation, GREEN suggest strong Positive correlation and YELLOW suggest Moderate correlation. In current manuscript Parents are addressed as Category A participants and Siblings as Category B participants.

INCLUSION & EXCLUSION CRITERIA

Inclusion criteria

Parents and siblings having child with intellectual disability and they are their main caregiver and those giving consent. Age of Siblings should be 18 years or above at the date of interview.

Exclusion criteria

Parents and siblings not living and not main carer of intellectually disabled child, parents and siblings reporting of having mental illness at time of interview, those parent or sibling who couldn't be contacted and those not giving consent.

Results

A total of 253 parents of the selected participants were interviewed. Amongst the selected children, 224 (88.5%) were male and 29 (11.5%) were female. Age of disabled children was 16.33 + 2.655 with minimum age 11 and maximum age 21. By religion, 200 (79.1%) were Hindu, 36 (14.2%) were Muslim while 17 (6.7%) were Christian. Chronological order of the affected child amongst total children of Category A participants was first child in 101 (39.9%), second in 82 (32.4%), third in 35 (13.8%) & fourth in 35 (13.8%) participants.

CATEGORY A COMPONENT

Socio-demographic detail of the Category A participants is given in Table I. Amongst interviewed, 220 (87.0%) were male and 33 (13.0%) were female.

Mothers who were currently homemaker by occupation, 29 (14.9%) were working in the past before the diagnosis of the child with intellectual disability. Amongst all participants, 37 (14.6%) had no children other than the affected child. Number of siblings elder to affected child were one in case of 82 (38.0%), two in 35 (16.2%) and three in 35 (16.2%) participants. One sibling younger to the affected child was in 64 (29.6%) participants. Age of siblings was 27.62 + 7.911. Current level of education

Tab. I. Socio-demographic details of the Category A participants (n=253).

Variable	Subcategory	Frequency (%)
Type of Family	Nuclear	185 (73.1%)
	3-generation	58 (22.9%)
	Joint	10 (4.0%)
Age of Father (in completed years)	<50	23 (9.1%)
	51-60	195 (77.1%)
	>60	35 (13.8%)
Age of Mother (in completed years)	<50	23 (9.1%)
	51-60	201 (79.4%)
	>60	29 (11.5%)
Education of Father	Secondary	72 (28.5%)
	Higher Secondary	35 (13.8%)
	Graduate	81 (32.0%)
	Post graduate	65 (25.7%)
Education of Mother	Primary	35 (13.8%)
	Secondary	72 (28.5%)
	Higher Secondary	53 (20.9%)
	Graduate	93 (36.8%)
Occupation of Father	Business	64 (25.3%)
	Private job	95 (37.5%)
	Government job	65 (25.7%)
	Retired	29 (11.5%)
Occupation of Mother	Business	29 (11.5%)
	Government job	29 (11.5%)
	Home maker	195 (77.1%)
Currently marital status	Married	224 (88.5%)
	Divorced	31 (11.5%)

of siblings was Primary in 6 (2.8%), Secondary in 58 (26.9%), Higher secondary in 23 (10.6%) & Graduate or above in 129 (59.7%) participants.

Cause of intellectual disability was identified by the parents amongst 116 (45.8%) participants. Amongst reasons identified delayed conception was in 55 (47.4%) participants, followed by birth injury in 13 (11.2%), lack of oxygen damaging brain due to breach delivery in 19 (16.4%) & head injury in 29 (25.0%) participants. Other disabilities in addition to intellectual disability were reported by 29 (11.5%) participants. Among disabilities, flat feet were reported by 23 (79.3%) & inability to speak by 6 (20.7%) participants. None of the intellectually disabled children had any family members with history of intellectual disability.

Quality life of Category A participants assessed using NIMH Disability Impact Scale is given in Table II. Maximum negative impact on caregivers was on Social aspect followed by Physical care, Embarrassment & Sibling effect. In positive impact area, maximum score was obtained in Better relationship with family members & More Empathy.

Heat map of Spearman's rank Correlations amongst various domains of NIMH disability impairment scale is given in Table III.

As per Table III, Strong positive correlation was obtained between physical care & health component, social & specific thoughts component, physical care & social component and financial & positive impact component. Weak or no correlation was obtained between sibling effect & relationship component. Negative correlation was obtained between financial & sibling effect component, embarrassment & sibling effect component and sibling effect & positive impact component.

Tab. II. Assessment of Quality of Life of Category A participants using NIMH Disability Impact Scale (n = 253).

Areas	Maximum possible score	Mean score	Number of participants having negative impact (%)
1. Physical Care	16	7.64 + 5.11	165 (65.2%)
2. Health	10	4.33 + 1.633	130 (51.4%)
3. Career	8	2.10 + 1.853	35 (13.8%)
4. Support	12	3.77 + 2.188	60 (23.7%)
5. Financial	10	4.40 + 2.252	107 (42.3%)
6. Social	6	3.82 + 1.449	195 (77.1%)
7. Embarrassment / Ridicule	8	3.75 + 1.832	153 (60.5%)
8. Relationship	12	4.72 + 3.178	37 (14.6%)
9. Sibling effect (n = 216)	14	6.06 + 5.445	128 (59.3%)
10. Specific Thoughts	8	1.88 + 1.491	58 (22.9%)
11. Positive impact	12	8.04 + 1.777	94 (37.2%)

Regression analysis was applied between sociodemographic variables of Category A participants (independent variable) and score of NIMH Disability Impairment Scale. All independent variables demonstrated a statistically significant association with the dependent variable ($p < 0.001$ for all).

Category B Component

A total of 195 siblings of selected intellectually disabled were interviewed. Mean age of study participants was 22.76 + 3.464. Demographic details of the participants along with its association to total score obtained in Columbia Impairment Scale Youth version (CIS-Y) are given in Table IV.

Quality life of category B participants assessed using Columbia Impairment Scale Youth version (CIS-Y) is given in Table V. Functional impairment (total score- > 16) was observed amongst 157 (80.5%) category B participants while absence of impairment (total score- < 16) was observed amongst only 18 (19.5%) category B participants. Linear regression was applied between various socio-demographic variables of Category B participants (independent) and score obtained in CIS-Y scale (dependent). Statistically significant regression was obtained between current age of Category-B participants (B = -0.827; $p \leq 0.001$), current status of education (B = -4.827; $p \leq 0.001$), current status of income (B = -1.448; $p = 0.05$) & relation to affected sibling (B = -3.308; $p = 0.002$) and score obtained in CIS-Y scale.

Tab. III. Correlation* between domains of NIMH Disability Impairment Scale (n=253).

NIMH Disability Impairment Scale	1	2	3	4	5	6	7	8	9	10	11
1. Physical Care	1	0.902	0.393	0.526	0.128	0.819	0.09	0.403	0.771	0.819	0.134
2. Health	0.902	1	0.298	0.31	0.123	0.798	-0.029	0.365	0.588	0.754	0.138
3. Career	0.393	0.298	1	0.688	0.279	0.614	0.713	0.511	0.271	0.709	0.376
4. Support	0.526	0.31	0.688	1	0.206	0.629	0.673	0.749	0.2	0.603	0.337
5. Financial	0.128	0.123	0.279	0.206	1	0.373	0.482	0.673	-0.016	0.098	0.844
6. Social	0.819	0.798	0.614	0.629	0.373	1	0.263	0.709	0.623	0.855	0.293
7. Embarrassment	0.09	-0.029	0.713	0.673	0.482	0.263	1	0.536	-0.162	0.39	0.777
8. Relationship	0.403	0.365	0.511	0.749	0.673	0.709	0.536	1	0.017	0.385	0.578
9. Sibling effect	0.771	0.588	0.271	0.2	-0.016	0.623	-0.162	0.017	1	0.702	-0.139
10. Specific Thoughts	0.819	0.754	0.709	0.603	0.098	0.855	0.39	0.385	0.702	1	0.247
11. Positive impact	0.134	0.138	0.376	0.337	0.844	0.293	0.777	0.578	-0.139	0.247	1

* Pearson Correlation value.

Tab. IV. Demographic details of Category B participants and their association to score obtained in CIS-Y (n = 195).

Variable	**Sub-category**	**Frequency (%)**	**Chi-square test (*p*-value)**
Age (in completed years)	<21	76 (39.0%)	**30.143** **(< 0.001)**
	>21	119 (61.0%)	
Gender	Male	165 (84.6%)	0.180 (0.672)
	Female	30 (15.4%)	
Education (last completed)	Secondary (9-10 std)	28 (14.4%)	**111.484** **(< 0.001)**
	Higher Secondary (11-12 std)	58 (29.7%)	
	Graduate or above	109 (55.9%)	
Current status of income	Student	96 (49.2%)	**109.747** **(< 0.001)**
	Unemployed	41 (21.0%)	
	Employed	58 (29.8%)	
Your relation to Affected sibling	Participant younger in age	76 (39.0%)	**30.143** **(< 0.001)**
	Participant elder in age	119 (61.0%)	

Tab. V. Quality of life of Category B participants based on CIS-Y scale (n = 195).

Variable	**Mean score**	**Number of participants identified with problem (%)**
Problem of getting into trouble	1.95 + 1.114	87 (44.6%)
Problem in getting along mother/mother figure	1.44 + 0.806	19 (9.7%)
Problem in getting along with your father/father figure	2.07 + 0.806	70 (35.9%)
Problem of feeling unhappy or sad	2.39 + 0.660	109 (55.9%)
Problem with your behavior at school or at your job	2.27 + 0.990	88 (45.1%)
Problem with having fun	1.35 + 0.652	137 (69.3%)
Problem getting along with adults other than your mother and/or your father	2.26 + 1.218	47 (24.1%)
Problem with feeling nervous or afraid	1.47 + 1.076	96 (49.2%)
Problem in getting along with your sister(s) and/or brother(s)	2.30 + 0.776	96 (49.2%)
Problem in getting along with other kids your age	1.23 + 0.996	19 (9.7%)
Problem getting involved in activities like sports or hobbies	1.35 + 1.011	39 (20.0%)
Problem with your school work OR doing your job	1.75 + 0.819	28 (14.4%)
Problem with your behavior at home	1.30 + 0.776	19 (9.7%)
Overall score	23.12 + 6.267	157 (80.5%)

Discussion

Current study included parents & siblings of intellectually disabled children. In the present study male children were higher than female which is similar to a study done at Delhi [4] where male: female children ratio was 3:1. Amongst the parents interviewed in the present study, 87% were males while a recent study at Anand district in Gujarat state [15], India showed almost equal number of male and female participants which could be attributed to better sex ratio in Anand district as compared to the location of present study.

Majority of the children belonged to Hindu family in this study (79.1%) which is nearer to the studies done in Odisha state (86.7%) [16] and a study done in North India (74.2%) [17]. This may be due to majority religion being Hindu in India. Majority of mothers in the present study (79.4%) belonged to 51-60 years age group while a South Indian study[18] which included only mothers showed that 70% mothers were 30-41 years old. This difference is probably due to variations in the age distribution and age at first birth in female populations of the two locations. Around two thirds of the children belonged to nuclear family (73.1%) in the current study which is close to a study done in Hyderabad City in Telangana state (68%) [19]. The reason for this maybe schools giving admission to especially abled children are located in urban areas where the study is conducted are having nuclear families more. Most of the parents (88.5%) were married which is nearer to the result from a study done in the country of Saudi Arabia [20] where 83% parents were married.

The chronological order of the affected child among his/her siblings was most commonly first (39.9%) and second (32.4%) in the present study. This result is similar to a study done at Vizianagaram in Andhra Pradesh state [21] where first order child (42.8%) were affected more. This may be due to current scenario of late marriage leading to delay in undergoing first pregnancy preference amongst educated population in India. A study done in the country of Saudi Arabia[20] showed that third and higher order children were more affected (54.7%) as compared to first and second order. This difference may be due to difference in geographical and reproductive preference amongst populations of India and Saudi Arabia.

The present study revealed that 65.2% of the parents were facing difficulty with respect to physical care requirements of mentally retarded children which is somewhat near to the result from Vizianagaram [21] where 52.2% parents faced difficulty in physical care domain. When it comes to social restrictions, 77.1% parents responded with a negative impact while 60.5% parents had negative impact in Embarrassment domain. Similar studies conducted at Vizianagaram [21] and Raipur [22] showed much lower impact in social restrictions (31.7% & 23.2% resp.) and Embarrassment domains (26.7% & 21.6% resp.). This difference may be due to socio cultural differences across different states of India and difference in the sample size and time duration during which studies are conducted. Less negative effect was seen on areas like Career, Relationship, Support, Specific thoughts & Finance. Negative correlation was obtained between Embarrassment & Health, Sibling effect & Financial, Sibling effect & Embarrassment, Sibling effect & Positive impact.

As per Table III, Strong positive correlation between Physical care & health component suggest caregivers who report physical caregiving burden & also experience more health-related issues. Correlation between social & specific thoughts component suggest care-givers who report higher social burden are more likely to have distressing specific thoughts. Correlation between physical care & social component indicates physical caregiving stress strongly affecting social functioning. And correlation between financial & positive impact component surprisingly suggests resilience or coping mechanism established by parents to combat financial challenges. Weak or no correlation was obtained between sibling effect & relationship component suggesting the sibling's burden doesn't directly influence caregiver's relationship perception. Negative correlation was obtained between embarrassment/positive impact & sibling effect component, suggesting that embarrassment and perceived positive impact are inversely related to sibling effects.

In the domain effect on sibling due to getting less time, 59.3% parents reported of having negative impact in the current study which is nearer to an observation of 54% in a study done at Anand [23].

Sibling Component analysis showed that males (84.6%) were more than females which is different as compared to a study done in United States of America [24] which showed 52.2% female siblings. This may be due to difference in sex ratio and gender demographics between India and America. More than half of the siblings had completed graduate (55.9%) level of education. The possible reason for this can be parent's investment in educating their apparently healthy child so that they may be able to support their dependant disabled sibling in all possible ways in future. Out of total siblings, 61% were elder in relation to the intellectually disabled child which is near to the observation of 56.4% in the study done at USA [24].

Columbia Impairment Scale youth version showed a mean score of 23.12 + 6.267 among siblings of affected child. Functional impairment (total score- >16) was observed amongst 157 (80.5%) siblings. Age, education, current status of income and relation to affected sibling had statistical association with score obtained in CIS-Y. The overall regression model was statistically significant, and several predictors were found to be significantly associated with the total score of CIS-Y. Participant's age (B =-0.827, p <.001) and education level (B = -4.827, p < .001) were both significantly and negatively associated with the total score, indicating that higher age and education were associated with lower scores. Current income status also showed a marginally significant negative relationship (B =-1.448, p =.050). In addition, the variable indicating whether the affected sibling was elder or younger than the respondent was significantly associated with the total score (B = -3.308, p = .002), suggesting that sibling age relation has a meaningful impact.

Limitations

Present study had a cross-sectional study design due to which follow up of parents and siblings of intellectually disabled children was not possible. The pattern of change in their quality of life during various stages of raising intellectually disabled child could not be observed. The study was limited to the parents and siblings of intellectually disabled children in Ahmedabad, India hence the results could not be generalized. Various determinants of parents and siblings like addiction, complications during pregnancy and childbirth, malnutrition, neglect or abuse were not asked.

Recommendations

A multicentric study involving parents and siblings of intellectually disabled children from diverse cultural and socioeconomic background, geographical locations across India needs to be conducted for a more generalizable result. A Longitudinal study design with a qualitative component as well as adding more determinants can further aid in shedding more light in this area of research.

Conclusion

This study highlights the considerable impact that intellectual disability in children has on the quality of life of their family members, particularly parents and siblings. Using standardized and validated tools, it was found that a significant proportion of parents experienced negative effects, especially in social life, physical care responsibilities and emotional burden such as embarrassment and sibling-related stress. Siblings, too, were notably affected, with over 80% demonstrating functional impairments in emotional well-being, social relationships, and daily functioning. Sociodemographic determinants such as age, educational attainment and employment status were found to be significantly associated with the extent of impairment, particularly among siblings. These findings fulfil both objectives of the study—measuring quality of life among family members and identifying key determinants influencing it.

The results underline the urgent need for structured psychosocial support, counselling services and inclusive policies aimed at enhancing coping mechanisms and resilience among families of children with intellectual disabilities. Focused interventions can play a crucial role in improving the well-being of not just the affected individuals, but their entire household ecosystem.

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Conflict of Interest statement

Authors fully disclose there is NO any existing or potential conflicts of interest of a financial, personal or any other nature that could affect or bias their research.

Authors' contributions

SRS: data collection, writing-original draft & writing-review. RPS: conceptualization, review of literature, methodology, study design, data collection, data entry & analysis, writing-original draft, writing-review & editing. VRD: methodology, study design, writing-original draft, writing-review, editing.

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Correspondence: Rujul Pankajbhai Shukla, B-502 Vandematram Fabula, Behind Nirma University, Chharodi, Ahmedabad 382481. E-mail: rujulpshukla90@gmail.com.

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Attitude and Practices Towards Breast Cancer Among Undergraduate Female Pharmacy Students in Pakistan

NUMAIRA QASIM[1], AHMED UMER SOHAIB[1*], RUKSANA ASHRUF[2], HEBATALLAH AHMED MOHAMED MOUSTAFA[3]
[1] Department of Pharmaceutical Sciences, Faculty of Pharmacy, Superior University, Lahore, Pakistan;
[2] Clinical Pharmacy and Pharmacy Practice Unit, Faculty of Pharmacy, AIMST University, Bedong, Kedah, Malaysia;
[3] Clinical Pharmacy and Pharmacy Practice Department, Faculty of Pharmacy, Badr University in Cairo, Cairo, Egypt

Keywords

Attitude • Breast Cancer • Practice • CBE • BSE

Summary

Background. *Lack of knowledge, attitude and perception towards breast cancer still a major public health issue disease in many developed and under-developed countries including Pakistan. In 2024 in Pakistan, one in every 8 females is affected by Breast Cancer.*

Objective. *To determine the awareness, attitude, and practices of Pharmacy (Pharm-D) students towards Breast Cancer (BC) and their correlation with participants' age and level of study.*

Methodology. *A cross-sectional study was conducted on 401 female students of Pharmacy from December 2023 to March 2024, using a self-administered questionnaire assessing awareness, attitude, and practices towards BC. For sample size calculation, Raosoft® online sample size calculator with a 5.0% margin of error and a 95.0% confidence interval was used. The respondents were sampled via convenience sampling.*

Results. *Our sample included 401 participants. The majority gained knowledge about BC from the media (69.8%). About 73.4% of participants did not participate in breast self-examination (BSE), and about 41.3% of them believed they were not at risk. About 92.6% of participants didn't undergo clinical breast examination (CBE). Nearly half of the participants (44.9%) agreed that BC is more common in older women. About four-fifths of the respondents (79.3%) agreed that regular examination can reduce the risk of BC.*

Conclusion. *The practice of BSE by the Pharm.D students is lagging. There were notable gaps in CBE by pharmacy students due to the belief that breast cancer predominantly affects older women. Therefore, it is important to make future pharmacists aware of practicing BSE and CBE regularly.*

Introduction

Malignant tumors or cancerous growths are the leading cause of mortality among women worldwide, with breast cancer (BC) as the primary cause. BC is uncontrolled growth of abnormal cells in the breast, leading to the formation of tumors [1]. The majority of BCs are histologically adenocarcinoma, with most classified as infiltrating duct carcinomas [2]. Both global and local data show that BC accounts for approximately one-third of all cancers among the female gender [3].

There are known risk factors of BC such as older age, lifestyle, family history, and smoking, however, these do not apply to every patient with breast cancer [4]**.** In addition, hereditary elements, such as changes or mutations in the BC susceptibility genes BRCA1 and BRCA2 may lead to the development of BC [5].

BC is a progressive disease, which can progress from a small lesion into a fatal disease, hence early detection and treatment lead to favorable outcomes, reducing its mortality and morbidity. The relatively higher survival rate of BC at a young age can justify the value of early disease diagnosis. However, poverty has been a dilemma in Pakistan, where government spending on healthcare is somewhat limited. Middle-income countries like Pakistan need awareness campaigns to prevent delays in the diagnosis of BC [6].

Screening for BC is effective because many patients remain asymptomatic until they reach an advanced stage. Screening methods include the detection of a palpable breast or axillary mass, pain, skin changes, nipple discharge, or asymmetric changes by breast self-examination (BSE) performed by the individual, clinical breast examination (CBE) performed by the healthcare provider, or by imaging using mammography or ultrasound [7].

Awareness of BC symptoms, screening methods, and risk factors can decrease mortality and morbidity. Studies conducted all over Pakistan showed that both educated and uneducated females suffer from a lack of the necessary knowledge, misperceptions, poor behaviors, and wrong beliefs about BC. Because BC programs and screening services differ widely among countries according to healthcare systems, health literacy, and socioeconomic characteristics, the results of attitude and practice studies are specific to each country or even region [8].

This study aimed to determine the awareness, attitudes and practices of female students (Pharm. D) regarding BC. We also investigated their correlation with participants' age and level of study.

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Material and Methods

STUDY DESIGN AND SAMPLE SIZE CALCULATION

A cross-sectional study was conducted among female university students studying Doctor of Pharmacy (Pharm. D) at Bahauddin Zakariya University, Multan, Pakistan to investigate their awareness, attitude, and practices toward BC. The study was conducted from December 2023 to March 2024. The ethical committee of the Department of Pharmacy Practice, Bahauddin Zakariya University, Multan, Pakistan approved this research. An anonymous self-administered questionnaire (printed) was distributed to the enrolled female pharmacy students of Bahauddin Zakariya University, Multan. For sample size calculation, we used the Raosoft® online sample size calculator [9] with a 5.0% margin of error and a 95.0% confidence interval. The minimum required sample size of (377) was increased to (401) for stronger and more reliable evident data. The respondents were sampled via convenience sampling.

INCLUSION CRITERIA

Undergraduate female students studying Doctor of Pharmacy (Pharm-D) and aged between 18 to 28 years, at Bahauddin Zakariya University, Multan, Pakistan, (who provided consent to participate and were not under any sort of stress or influence that may cause any sort of change in their response towards questionnaire) were included in our study.

EXCLUSION CRITERIA

Female students who were not pharmacy undergraduates and not enrolled at Bahauddin Zakariya University, Multan, Pakistan were excluded from our study.

Data Collection Tool: Questionnaire

A self-administered questionnaire exploring awareness, attitude, and practices towards BC, was developed from a review of previous related journal articles and the draft was reviewed by two field experts, who are Pharmacy Practice lecturers. The questionnaire utilized a mixed-scale (combined-scale) methodology, incorporating various questions (nominal, ordinal, and Likert) to collect comprehensive information. The questionnaire consists of four sections, namely sociodemographic, knowledge, attitude and practice. The sociodemographic section included the participants' age, marital status, level of study, and family history of BC. The awareness section comprised of four questions, while the attitude and practice sections comprised of three questions each pertaining to BC.

A mixed-scale methodology was employed for this questionnaire, whereby nominal scales such as the dichotomous 'Yes' or 'No' options were utilized for factual items, while ordinal scales such as Likert scales were used in assessing attitude and perception-related questions. This approach was employed to comprehensively evaluate the participants' awareness, attitude, and practices related to BC. Simple English was used for the questionnaire to ensure it was comprehensible for the participants.

A pilot study was then conducted with 33 participants to assess the clarity (via face validation) and internal consistency (via Cronbach alpha). The participants provided positive feedback in terms of ease of comprehension and response difficulty. Only minor refinements were made to enhance the clarity. Cronbach's alpha was calculated at 0.727, indicating that the questionnaire had acceptable internal consistency and reliability, and was suitable for the main study.

STATISTICAL ANALYSIS

The required data was collected and entered IBM SPSS® Statistics for Windows (version 25.0 SPSS Inc. Chicago, IL, USA). Pearson's Chi-Square test was used for analysis. The p-value of <0.05 was considered statistically significant.

Result

DEMOGRAPHICS OF RESPONDENTS

Our study included 401 female Pharm. D students within the age group of 18 to 28 years. In terms of the participants' marital status, most participants were unmarried (n = 392, 97.7%), aged between 18 to 21 years old (n = 335, 83.5%) and were studying in the 1st year of Pharm. -D (n = 98, 24.4%) (Tab. I).

AWARENESS OF BC

Most of the participants (n=288, 71.8%) gained awareness about BC through the media. Nearly half of the participants (44.6%) agreed that BC is more common in older women. Regarding whether BC is a curable disease, about three-quarters of the participants (75.8%) believed it was curable, while the rest disagreed (11.7%) and some were unsure (12.5%) about it. When the participants were asked if they considered BC as a public health issue, 85.8% of them agreed. (Tab. II).

ATTITUDE TOWARD BC

About (92.6%) of participants had never had a breast examination by any doctor. About four-fifths of the respondents (79.3%) agreed that regular examination can reduce the risk of breast cancer. Interestingly, a

Tab. I. Participants' Demographics.

Variables	Categories	N (%)
Age	18-21 years	335 (83.5%)
	22-25 years	63 (15.7%)
	26-28 years	3 (0.7%)
Marital Status	Single	392 (97.7%)
	Married	9 (2.2%)
Study Year	1st	98 (24.4%)
	2nd	62 (15.5%)
	3rd	82 (20.5%)
	4th	80 (19.9%)
	5th	79 (19.7%)

Tab. II. Awareness of Breast Cancer among Pharmacy students.

Responses	Frequency N (n=401)	Percentage %
What is your main source of knowledge about BC?		
Media	288	71.8
From family member	52	13.0
From hospital	31	7.7
From a friend	26	6.4
No information	4	0.9
Do you believe that BC occurrence is common in old age?		
Agree	179	44.6
Disagree	140	34.9
Neutral	82	20.4
Do you think BC is a public health issue?		
Yes	344	85.8
No	34	8.5
Don't know	23	5.7
Do you perceive BC as a curable disease?		
Yes	304	75.8
No	47	11.7
Don't know	50	12.5

small proportion of the participants (5.2%) perceived themselves at a higher risk for developing BC, while nearly the same number of respondents believed they were not at risk (41.3%) or were unsure about it (40.8%) (Tab. III).

Practices towards BC

Majority of the participants in our study (74.3%) revealed that they did not take part in BSE while about a quarter of participants claimed to have practiced BSE. When asked about the reasons for not practicing BSE regularly, most of them think they do not have any problem (79.0%), while the rest do not think they should do so. When asked about reasons for not having done so, nearly 70% of the participants responded, "no need for it", 18.0% of them selected being "too young to participate", and only 5.2% selected "concern about extra time" (Tab. IV).

Correlation between Age with Respondent's Demographics and Breast Cancer Awareness

The findings for age vs. demographic factors (marital status and education) were the only statistically significant. Regarding age vs. the various aspects of awareness and practice towards BC, all pairs were found to be non-statistically significant with a p-value greater than 0.05 (Tab. V).

Discussion

The findings from our study indicated that most of the participants have heard about BC through the media (78.1%), in line with a previous study [10]. Other sources of information about BC reported previously included the internet, BC campaigns, friends and relatives, and healthcare professionals [11]. This highlights that BC-related information is accessible through various sources, however, the accuracy and reliability of these sources may vary. This raises the need for evidence-based health educational resources to be disseminated via social media and other easily accessible platforms. The present study found that most of the participants (44.9%) agreed that BC is common among old-age

Tab. III. Attitude towards Breast Cancer Examination.

Responses	Frequency N (n = 401)	Percentage %
Would you see the doctor for any breast complaints?		
Agree	314	78.3
Disagree	71	17.7
Neutral	16	4.0
Do you think that regular examinations can reduce the occurrence of BC?		
Agree	318	79.3
Disagree	61	5.4
Neutral	22	15.2
Do you perceive yourself at risk for developing BC?		
Not at risk	165	41.2
Lower risk	52	12.9
Higher risk	21	5.2
Don't know	163	40.6

Tab. IV. Practices towards Breast Cancer.

Responses	Frequency N (n=401)	Percentage %
Do you practice BSE?		
Yes	103	25.8
No	298	74.3
What is the reason you don't practice BSE? BSE regularly?		
I don't have any problem	317	79.0
I don't think I should	84	21.0
Did you visit any doctor for clinical breast examination? pr(CBE)?		
Yes	15	7.4
No	386	92.6
If not, then why?		
No need for it	269	67.1
Too young to participate	72	18.0
Concern about extra money	26	6.5
Concern about extra time	21	5.2
Already did it	13	3.2

Tab. V. Comparison of age with demographics and attitude and practices towards breast cancer.

Section	Variable vs age factor	p-value
Sociodemographic	Age vs year of study	0.032*
	Age vs marital status	0.000*
Awareness	Age vs source of information about BC	0.529
	Age vs BC occurs more in older women	0.462
	Age vs is it a public health issue	0.286
	Age vs is BC is a curable disease	0.225
Attitude	Age vs preference to seek help from doctor	0.745
	Age vs regular examination of breast in females can reduce occurrence of such disease	0.674
	Age vs risk of developing BC	0.412
Practice	Age vs practice BSE	0.103
	Age vs not practicing BSE	0.051
	Age vs examination by doctor	0.732
	Age vs reasons for not getting examined by doctor	0.249

BC: breast cancer, BSE: breast self-examination. * p-value < 0.05.

females, similar to previous studies conducted in Saudi Arabia by Dandask KF et al [12]. Moreover, two-thirds of our participants perceived BC as a curable disease, aligning with a review by Hong and Xu. However, the stage at which BC is diagnosed plays a crucial role in its curability, emphasizing the need for timely screening. This highlights the importance of BC reporting and health campaigns in Pakistan. Half of the participants in a study carried out in Saudi Arabia were pessimistic about the curability of BC, while only 35.7% of women in an Indian survey considered it to be curable [13].

Most pharmacy students surveyed in this study (78.3%) reported they would visit a physician for any possible breast complaint. On the other hand, a higher percentage of Pakistani females (94.7%) reported they would see a physician in case of a breast mass and only 1.9% of them would go for homeopathy or other alternative medicine modalities. A very similar percentage (77.8%) was reported in a previous study in India where only 6.1% of them said they would seek traditional healers instead [14]. This implies that the participants demonstrate a strong level of trust in healthcare professionals and evidence-based medicine when it comes to medical matters.

About 79.3% of participants thought that regular examination can reduce the occurrence of BC, in line with a previous study conducted in most of the participants reported that early diagnosis promotes early treatment (79.0%) and decreases mortality rates (77.5%) [15]. A survey in Gaza showed that women there believe that early detection of BC increases survival [16]. Such consistent trends across different populations show a generally positive perspective on timely screening and its role in minimizing BC-related burden.

Most of our participants (79.3%) believed that regular examinations could reduce the chances of developing BC. This implies that most women in this study perceived that deaths and sufferings caused by BC are preventable through awareness and timely detection. Specially designed educational material on the early warning signs of BC and BC screening can be used to improve their awareness and attitudes, which in turn could encourage more females participating in regular BSE.

A lot of our participants (41.2%) felt that they were not at risk of developing BC. Family history of BC was found to significantly increase the level of BC awareness and performing BSE and CBE. Since BC diagnosed at a later stage possibly due to lack of awareness, may lead to a poorer prognosis, educational programs should be tailored according to age, healthcare access, socioeconomic status, and health literacy of the target population. Increasing awareness and promoting appropriate behaviors related to BC can help reduce the stage of malignancy upon presentation, improve the quality of life, and increase survival.

Most of the participants do not practice BSE regularly because they think they do not have any problems (79.0%), which is in contrast to the findings of a two-center study conducted in Pakistan and the United Kingdom [17]. Only 25.8% the female Pharm. D students reported practicing BSE, close to the rate of females performing BSE reported previously in another study in Pakistan (21.8%) [18]. In contrast, other surveys in Pakistan [19] and Iraq [20]18 (4 revealed a higher percentage with 46.0% and 48.3% of females performing BSE, respectively. Similarly, a cross-sectional study conducted in two universities in Iraq found that 90.9% of participants had heard about BSE, and 48.3% practiced it [21]. A study in India reported a lower rate of practicing BSE (12.1%) [22]. Another study in Iran reported that 12.9% of females reported practicing BSE regularly, while 50.6% of them reported an occasional practice [23]. Because BSE is a simple, non-invasive practice that takes only a few minutes, can be performed by females at home, and does not require a visit to the clinic, it is a good screening choice for developing countries, including Pakistan. Since BSE is a free screening method, it is suitable to be performed by all Pakistani females including those in the low-income households. These individuals represent nearly 37.0% of the population who live below the poverty line and those who are at risk of poverty (52.0%) [24]. This highlights the need for targeted interventional programs to bridge the gap in BSE practices among women of lower socioeconomic groups.

Only 7.4% of our respondents reported they had CBE. Slightly higher rates of CBE (12.7-14.0%) were reported in previous studies in Pakistan [25]. On the other hand, a much higher percentage of women reported going for CBE in Iran (44.3%) [26] and UAE (49.4%) [27]. This disparity may be due to the difference in healthcare systems among different countries.

Interestingly, Iran's healthcare system has shown notable progress through initiatives such as IraPEN. It is a localized adaptation of WHO's Package of Essential Non-Communicable Disease Interventions, which has strengthened early detection, including BC screening [28] [29]. Contrastingly, Pakistan's healthcare system has yet to have such a system and also faces challenges such as limited public health funding [30].

The much higher rate of CBE among women in Iran and UAE may stem from greater awareness of BC risks, stronger health education initiatives, and better access to CBE services. In contrast, the lower rates observed in the present study may be influenced by their younger age. This gap could be tackled by incorporating relevant health information on CBE into their academic curriculum.

Reasons for not going for CBE in our study were reporting "no need for it" (67.1% of participants), thinking they are "too young to participate" (18.0% of the participants), and concerns about either money (6.5%) or time (5.2%). Although numerous studies have explored BC awareness, attitude, and practices, those were mainly conducted on general populations and in diverse settings. The present findings focused on a specific demographic, the female Pharm. D students, who are future healthcare professionals. These baseline insights can assist in assessing their understanding regarding BC and its screening practices, which would help in the development of educational interventions and public health strategies in ensuring they are well prepared to educate patients and the public regarding BC and the importance of early screening.

Conclusion

This study highlights that participants have a general awareness regarding BC and a good attitude towards the same. However, the practice of BSE by these students is lagging. We identified notable gaps in CBE by Pharm. D students due to the belief that BC predominantly affects older women, and they do not need it at present. Therefore, it is necessary to make future pharmacists aware of the importance of regular BSE and CBE practices. Researchers and policymakers should focus on enhancing educational efforts about BC in universities, which could potentially help reduce its incidence in Pakistan and globally.

Limitations

There are a few limitations in our study. Firstly, given that it is a cross-sectional study, the temporal relationship between variables cannot be ensured. Secondly, we only recruited participants from Multan, specifically, female Pharm. D students enrolled at Bahauddin Zakariya University. This limits the study's external validity to all female Pharm. D students. We also used convenience sampling for recruiting participants, which may have added some bias to our findings.

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Conflict of Interest statement

The authors declare no conflict of interest.

Authors' contributions

NQ: Conceptualization, investigation, and writing the original draft. AUS: Data curation, formal analysis, and software. RA: Writing review and editing. HAMM: revised the manuscript

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Correspondence: Ahmed Umer Sohaib, Department of Pharmaceutical Sciences, Faculty of Pharmacy, Superior University, 17-KM Raiwind Road, Lahore, Pakistan. E-mail: iamsohaib22@gmail.com.

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Non communicable diseases

Why do middle-aged adults use or avoid health services? A study of social and demographic determinants

SEYED ABBAS HOSEINALIPOUR[1], MARYAM FARHADIAN[2,3], AKRAM KARIMI-SHAHANJARINI[1,4]
[1] Department of Public Health, School of Public Health, Hamadan University of Medical Sciences, Hamadan, Iran;
[2] Department of Biostatistics, School of Public Health, University of Medical Sciences, Hamadan, Iran;
[3] Research Center for Health Sciences, Institute of Health Sciences and Technologies, Hamadan University of Medical Sciences, Hamadan, Iran; [4] Social Determinants of Health Research Center, Institute of Health Sciences and Technologies, Hamadan University of Medical Sciences, Hamadan, Iran

Keywords

Healthcare utilization • Middle-aged adults • Social determinants • Health access barriers • Iran

Summary

Introduction. *Middle-aged adults experience distinctive health issues, yet underutilize preventive care despite Iran's strong primary healthcare (PHC) system. This research investigates social and demographic determinants of healthcare services utilization among middle-aged adults in Qom, Iran, to inform the development of targeted community-based screening initiatives.*

Methods. *A cross-sectional study was conducted in underprivileged suburbs of Qom (June-September 2024) among 697 adults aged 30–59, randomly sampled by cluster sampling. Awareness of available services, utilization, and satisfaction with PHC service information were collected via phone interviews. Multivariate logistic regression identified predictors of service utilization.*

Results. *Only 11.8% (n = 82) of the participants were aware of middle-aged health services, and 24.2% (n = 169) had utilized them in the past year. Women had at least one PHC visit 2.5 times more than men (35.3% vs 13.9%, p < 0.001), and utilization increased with age (31.1% among 50–59-year-olds vs. 19.6% in 30-39 years-old, p = 0.023).The strongest predictor was awareness: aware adults had 22.4-fold higher odds of use (95% CI: 11.60-43.29, p < 0.001). Dissatisfaction (by 7.7% of users) was linked to gaps in staff communication (38%), overcrowding (38%), and perceived incompetence (30%) (multiple responses permitted). Work and education were not independently associated with service use after adjustment, suggesting indirect impacts.*

Conclusion. *PHC utilization among middle-aged population is handicapped by low awareness and gender/age disparities. Interventions should prioritize health literacy programs, staff training to improve patient-provider communication, and systemic modifications to reduce overcrowding. Increased outreach to men and younger adults is necessary to ensure equitable preventive care.*

Introduction

Middle age is a critical health transitional phase, often marked by the onset of non-communicable disease (NCD) risk factors and other health-related changes. At this stage, people often confront challenges such as declining health, shifting social roles and heightened awareness of mortality – manifested in fears of loss of autonomy, loss of autonomy, increased fatigue, reduced libido, and cognitive decline [1]. These transitions highlight the importance of proactive healthcare engagement to mitigate long-term health risks. According to the 2016 Iranian National Population and Housing Census, middle-aged adults constitute 42% of the population [2].

The concept of Primary Health Care (PHC) was first developed at the 1978 International Conference on Primary Health Care in Alma-Ata. Aims to tackle essential health issues among communities, PHC ensure basic delivers essential preventive, curative, and rehabilitative care. It is a solution that continues to ensure improvement in the health of communities globally, including Iran. Strengthening the PHC system is emphasized as the most inclusive, effective, and efficient approach to achieving health for all [3]. The accessibility and affordability of healthcare have become primary objectives for achieving universal health coverage [4]. However, the imbalance in resource distribution between primary and secondary healthcare facilities, coupled with policies that resulted in unrestricted access to higher-level services like clinics and hospitals, has led to a bypass of primary care centers. This poses significant challenges to global health access, exacerbates the unequal distribution of medical resources, and hinders access to and continuity of essential healthcare.

The global burden of non-communicable diseases (NCDs) makes this issue even more significant. Each year, these diseases kill 41 million people worldwide, accounting for 74% of global mortality. According to WHO's 2021 report, 15 million of these deaths occur among individuals aged 30 to 69 [5]. The mortality rate from diabetes and cerebrovascular diseases is significantly associated with decreased

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access to healthcare services [6]. Consequently, many countries are implementing routine preventive care for this age group, focusing on risk assessment, brief recommendations, and referrals for necessary measures [7]. In Iran, a health service program for women aged 45-60 years was initially designed because menopause was prioritized in the National Disease Burden Report [8]. The program was initially pilot-implemented in four selected universities of medical sciences (Shahid Beheshti, Iran, Mazandaran, and Shiraz) with various geographical and demographic situations. Subsequently, because of the April 2014 Health Transformation Plan [8, 9], the program's coverage was increased. The emphasis was given to healthy promotion for the entire middle-aged population (30-59 year-old men and women). The integrated care is presently in practice nationwide to promote healthy longevity and reduce premature death through risk factor control and disease prevention through an overall package of care.

This comprehensive health package includes a wide range of services including prevention lifestyle consultation, free vitamin D supplements, mental and behavioral health screening, infectious diseases testing (HIV, STIs, hepatitis, tuberculosis), chronic disease screening (diabetes, hypertension, cardiovascular risks), gender-specific care, and occupational risk assessments [10]. According to national policy, the necessary human resources and infrastructure to offer these services are established in the PHC network.

Despite the launch of this program, studies show that middle-aged Iranians underutilize primary healthcare. For example, a recent national study found that only 13.7% of women aged 30-59 had mammographic screening [11]. Utilization is a critical factor in evaluating the strength of healthcare systems. Many factors influence the utilization of healthcare services, independent of the need for care. Some of these factors are modifiable across population groups, while others are due to biological or environmental differences between groups, such as disproportionate residence in polluted environments, access to healthy food and adequate housing, and education related to the effective use of healthcare services. Other factors related to access differences include health insurance coverage, the income required to receive services, ease of service provision, and discriminatory practices by service providers [12].

Iranian research demonstrates that there exists a group of barriers causing the low utilization of primary healthcare services in middle-aged individuals [13, 14]. These barriers are structural and logistic in nature, *i.e.*, occupation, lack of time, and distance from health centers, and service quality problems like poor staff communication skills and lack of confidence in their technical competence. Widespread self-medication is another significant factor involved. Given the importance of preventive services among middle-aged individuals and the novelty of this age group's program in Iran's primary care system, understanding the utilization patterns of health services and their determining factors is crucial for health sector planning. Therefore, this study was conducted to determine the prevalence and identify the factors associated with preventive care reception and service utilization among middle-aged adults in the city of Qom, Iran.

Methods

This cross-sectional study was conducted in disadvantaged areas of Qom city, the capital of Qom Province, Iran from June to September 2024. Qom Province, located approximately 125 kilometers south of Tehran, has a population of 1.3 million; with 70% falling within the working-age group (15-64 years). Middle-aged individuals (30-59 years) represent a significant proportion of this group, highlighting the importance of addressing their healthcare needs. According to the unpublished national report on Health Indicators of Middle-Aged Adults in Iran, Qom Province has a poor status in terms of access to and utilization of healthcare services [15].

Middle-aged individuals residing in underserved areas of Qom were selected using random cluster sampling, with health centers serving as the clusters. Clusters were selected proportionally based on the population size served by each of the 14 comprehensive health centers covered by the Integrated Health System (SIB).

The sample size was calculated assuming a 50% prevalence of healthcare service utilization ($p = 0.5$) to maximize variability, with a 95% confidence level, a 5% margin of error, a 10% non-response rate, and a Design Effect of 1.5. This yielded an estimated sample size of 697 participants. We made contact with 697 individuals who met were eligible according to our study criteria. The non-response rate was around 10% ($n = 70$) of individuals who could not be contacted or refused to participate. To manage this and reach the target sample size, these 70 non-respondents were substituted by additional eligible adults from our sampling frame. Unfortunately, we were unable to obtain individual-level demographic data for each specific non-respondent adult to perform a rigorous individual - level bias analysis. However, as a check on possible bias, we contrasted the end sample distribution among our 14 health centers with the original proportional distribution in our designed cluster sampling design. We found no systematic differences, suggesting that the non-response did not have a significant impact on the geographic or center-based composition of our sample.

The following measures were used:

- Awareness of the middle-aged service package: Awareness was evaluated by asking participants, 'Are you aware of the middle-aged service package provided at comprehensive health centers?' If participants answered 'yes,' they were further asked to name three services offered for middle-aged adults at the health centers. Only those who correctly named at least three services were considered as having true awareness and were coded as ‘yes.’

- Utilization of services in the past year: Participants were asked, “In the past year, have you visited a comprehensive health center to receive services such as blood pressure measurement, nutritional counseling, or similar services?”.
- Satisfaction with services received: Participants who utilized services were asked, “How satisfied are you with the services you received at the comprehensive health center?”.

Reasons for dissatisfaction: Dissatisfied participants were asked, “What are the reasons for your dissatisfaction with the services received?” They could select more than one reason from the following options: a) Lack of scientific expertise among staff, b) Services were often delivered too hastily or with too little attention to detail, c) Overcrowding at the center and long waiting times, d) Inappropriate behavior by staff, e) Limited services provided, focusing only on trivial or non-specialized cases.

Verbal informed consent was obtained from all participants prior to the administration of each phone interview. This approach was utilized since obtaining written consent was not practical in a phone-based study. Researchers read a scripted consent statement describing the study purpose, procedures, risks, benefits, and freedom to withdraw at any time. Verbal confirmation of consent to participate was received from the participants. This process was approved by the *ethics committee* of Hamadan University of Medical (IR.UMSHA.REC.1403.047).

Data were analyzed using SPSS software. In the first step, descriptive statistics were calculated, and the chi-square test of independence was performed, stratified by the categories of health care utilization (utilized health care vs did not utilize health care). In the second step, multivariate logistic regression analysis was conducted to identify the potential determinants of health care utilization among middle-aged adults. A p-value of less than 0.05 was considered statistically significant.

Results

A total of 697 middle-aged adults (males 51.6%; females 48.4%) were investigated. Average age was 41.7 ± 8.6 years old. The results of the study revealed that only 82 (11.8%) middle-aged participants were aware of the availability of specific middle-aged services at healthcare centers. Of the 697 participants, 169 (24.2%) utilized health care services in the past year.

Among the 169 participants who had used preventive healthcare services in the past year, 92.3% (156 individuals) expressed satisfaction with the services they received. Of the 7.7% who reported dissatisfaction, 38% attributed it to communication barriers between healthcare providers and participants, 38% to the staff’s lack of adequate attention to individuals, 38% to overcrowding at the center, and 30% to the lack of professional competence among the staff. As detailed in Table I, Chi-square tests revealed significant associations between healthcare service use and all demographics investigated ($p < 0.05$ for all). Women reported 2.5 times higher utilization rates than men (35.3 vs 13.9%; $\chi^2 = 43.49$, $p < 0.001$). A gradient by age was observed, with highest use in the 50-59-year age group (31.1%) compared to younger age groups (19.6% for 30-39 year-olds; $\chi^2 = 7.57$, $p = 0.023$). Married participants utilized services more than the unmarried (25.0 vs 11.9%), and unemployed participants utilized services much more than employed ones (34.7 vs 14.6%). Participants with lower educational attainment were more likely to use the services (29% among illiterate individuals vs 14% among those with a university degree). The strongest difference appeared in the awareness of services: those who awarded available services utilized them with an 80.5% rate while that was only 16.7% among those who were not aware ($\chi^2 = 160.03$, $p < 0.001$).

The results of the multivariate logistic regression analysis are presented in Table II. This analysis revealed service awareness as the most robust independent predictor of healthcare utilization. Participants who were awarded of available health services were 22.4 times more likely to utilize healthcare compared to those who not aware (adjusted OR = 22.41, 95% CI: 11.60-43.29, $p < 0.001$). The model confirmed the age-dependent use pattern observed in univariate analyses, with 50–59 year-old adults maintaining significantly higher odds of service utilization compared to the 30-39-year reference group (aOR = 1.93, 95% CI: 1.08-3.45, $p = 0.02$). Male gender had a significant association with 2.02-fold increased odds (95% CI: 0.80-4.74), although this was not statistically significant ($p = 0.10$). Similarly, insured participants also had marginally non-significant 83% greater odds of utilization (aOR = 1.83, 95% CI: 0.99-3.37, $p = 0.053$). Surprisingly, neither education nor employment status retained statistical significance in the fully adjusted model, indicating these factors may not have an independent influence on healthcare utilization after controlling for awareness and demographic characteristics. The regression model results complement the univariate analyses in providing more nuanced insights into the independent effects of each predictor.

While initial results from the Chi-square test (Tab. I) indicated statistically significant associations between each of the independent variables and health care utilization, additional analysis with multiple logistic regressions (Tab. II) found only two variables – health service awareness and age group – to be significant predictors of health service utilization. These findings indicate that factors such as insurance coverage, employment status, and education level may affect health-seeking behavior indirectly or in conjunction with other determinants instead of being direct drivers.

Tab. I. Bivariate Associations between Sociodemographic Characteristics and Preventive Health Care Utilization Based on Chi-Square Tests (n = 697).

Variables	Total	Middle-aged adults(N=697)			
		Utilized health care	Did not utilize health care	X^2	*p*
Sex					
Female	337	119 (35.3%)	218 (64.7%)	43.49	< 0.001***
Male	360	50 (13.9%)	310 (86.1%)		
Age					
30-39	286	56 (19.6%)	230(80.4%)	7.57	0.023*
40-49	250	63(25.2%)	187 (74.8%)		
50-59	161	50 (31.1%)	111 (68.9%)		
Marital status					
Married	655	164 (25.0%)	491 (75.0%)	3.70	0.054
Unmarried	42	5 (11.9%)	37 (88.1%)		
Educational level					
Illiterate	72	21(29.2%)	51(70.8%)	11.93	0.008**
Less than a high school diploma	361	102 (28.3%)	259 (71.7%)		
High school diploma	157	3119.7%)	126 (80.3%)		
University education	107	15 (14.0%)	92 (86.0%)		
Employment status					
Employed	363	53 (14.6%)	310 (85.4%)	38.37	< 0.001***
Unemployed	334	116 (34.7%)	218 (65.3%)		
Health insurance coverage					
Yes	559	149 (26.7%)	410 (73.3%)	8.91	< 0.01**
No	138	20 (14.5%)	118 (85.5%)		
Awareness of middle-aged health services					
Yes	82	66 (80.5%)	16 (19.5%)	160.03	< 0.001***
No	615	103 (16.7%)	512 (83.3%)		

Discussion

This study provides critical insights into the utilization patterns of primary healthcare services among middle-aged adults in Qom, Iran. The findings reveal that only 11.8% of participants were aware of the middle-aged service package, and merely 24.2% had utilized these services in the past year. These low levels of awareness and utilization mean that preventive care among middle-aged adults is not sufficiently high to be able to make a noticeable difference in health outcomes. This trend is consistent with a body of evidence from across Iran, showing low uptake of preventive services. For instance, the MAHCP study showed that more than 27.3% of middle-aged adults were not undergoing routine health screening [14]. This pattern is also reinforced by studies aimed at individual screenings: Enjezab [16], Salabat et al. [17] and Nikkhoo et al. [11] reported low cancer screening rates (less than 30%) among Iranian adults. Such consistent underuse in a range of studies and settings suggests systemic barriers at multiple levels, including restricted public awareness, cultural preferences for curative over preventive care, and structural barriers to seeking care. International comparisons also help to highlight these challenges. In China, for example, many patients do not use primary care centers but opt for higher-level facilities, reflecting a lack of trust and awareness in primary care [18], similar to the Iranian context.

In contrast, studies from some countries like Bhutan, reported a 71.4% utilization rate of preventive services [19]. These disparities underscore the importance of tailored strategies to improve healthcare engagement among middle-aged populations, particularly given the unique pressures they face, such as competing work and family responsibilities and the rising burden of chronic conditions [20, 21].

The low awareness and utilization rates underscore the need for targeted interventions to improve outreach and education, particularly among men and younger age groups, who exhibited lower engagement with services. This suggests Iran's health system may lack effective communication strategies, a gap also observed in bypassing studies where poor awareness of local services drives patients to distant facilities [22]. This aligns with studies in other developing countries, where awareness, health literacy, and socioeconomic status are major determinants of preventive service use [12, 23].

Although univariate analyses revealed utilization was associated with gender, age, employment, and education, multivariate models confirmed only age and awareness as independent predictors. This implies that socioeconomic characteristics (*e.g.,* employment) affect utilization indirectly – for instance, by restricting exposure to health information or influencing perceived need for care. These patterns are seen globally, where healthcare-seeking behavior is influenced by age, gender, and socioeconomic status, but their effects could be moderated by awareness and access [23, 24].

Tab. II. Logistic Regression Analysis of Predictors for Utilization of Preventive Health Care among Middle-aged Adults (n = 670).

Variable	B (SE)	Adjusted OR [95% CI]	*p*-value
Sex (Ref:Female)			0.10
Male	0.70 (0.43)	2.02 (0,80-4.74)	
Age (Ref: 30-39)			
40-49	0.47 (0.25)	1.61 (0.94-2.67)	0.63
50-59	0.66 (0.29)	1.93 (1.08-3.45)	0.02*
Marital status (Ref: Married)			
Single	-0.65 (0.55)	0.51 (0.17-1.53)	0.23
Educational level (Ref: Illiterate)			
Less than a high school diploma	0.24 (0.35)	1.27 (0.63-2.57)	0.50
High school diploma	-0.24 (0.42)	0.78 (0.34-1.81)	0.57
University education	-0.91 (0.51)	0.40 (0.14-1.01)	0.07
Employment status (Ref: Unemployed)			
Employed	-0.38 (0.43)	0.68 (0.29-1.59)	0.37
Health insurance coverage (Ref: Uninsured)			
Insured	0.60 (0.31)	1.83 (0.99-3.37)	0.53
Awareness of middle-aged health services (Ref: No awareness)			
Aware	3.11 (0.33)	22.41 (11.60-43.29)	< 0.001***

The gender disparity (2.5× higher use among women) parallels patterns in settings where cultural and social norms shape healthcare-seeking behaviors [25]. Although Rao and Sheffel [25] found that females are more likely than males to bypass local providers. In Iran, qualitative research indicates that middle-aged men face specific barriers, including time constraints, sociocultural expectations, and limited flexibility in service provision [13]. Addressing these issues requires not only making services more convenient and accessible via male-friendly policies such as extended working hours outside of clinics' regular working hours and men's health clinics but also improving the empowerment of healthcare workers and the work environment and equipment in comprehensive health centers. Specially targeted education and outreach that targets men's views on health and preventive care must also be conducted. The issue is with low utilization of preventive services among men because it can result in late diagnosis of chronic illnesses.

This research discovered that preventive services were utilized by adults in the 50-59 age brackets twice as frequently as for adults in the 30-39 range. This inequality can likely be explained by a combination of factors, foremost of which are the increased load of age-related morbidity and chronic illness, demanding more regular medical interaction. At the same time, this trend is also possibly a reflection of the effectiveness of focused public health outreach efforts. Most healthcare systems have special screening recommendations and awareness campaigns targeted at adults in this age range, urging attendance at preventive measures like cancer screening and cardiovascular risk factor assessment. Nevertheless, the association of age and healthcare use seems more intricate among older adults. While there is some evidence of lower use of primary care services by elderly individuals – perhaps an effect of access barriers in the form of mobility issues, transportation issues, or cost constraints [21, 26, 27] – others, including Liu et al. [28] and a recent study by Smith et al. [26], reported higher attendance at targeted preventive screenings, diagnostic procedures, and vaccinations by elderly individuals. This disagreement is perhaps due to heterogeneity in the type of services measured. Older individuals may underutilize routine primary care visits [such as regular checkups] while actively participating in important preventive measures that they perceive will have a direct impact on their lifespan.

The differences seen would also be due to systemic and cultural reasons. In systems where insurance benefits rise with age, preventive care utilization is greater in older individuals. Where primary care is referral- or copay-based, logistical and cost barriers may deter routine check-ups without screening exempt from coverage. Therefore, the higher utilization rate in the age group of 50-59 is most likely the result of an interaction between biological need, systemic targeting, and evolving health attitudes.

While insurance coverage and employment status were related to utilization on univariate analysis, they were no longer significant after adjustment, indicating that structural barriers and health system navigation may be more important than financial access alone.

Participants cited several primary deterrents to care-seeking. These included barriers rooted in their perceptions of care, such as the perceived lack of attentiveness on the part of staff and a perceived deficiency of professional competence. They also cited more objective structural and communication barriers, including communication issues with providers, severe overcrowding, and long waiting times. This is a critical distinction; the initial set of issues could potentially be tackled with interventions like patient-provider communication enhancement and trust building, but the latter requires system-wide change in clinic management, personnel, and infrastructure. These results are consistent with international evidence, highlighting the universality of such barriers across health care systems. Research in Saudi Arabia and Korea, for example, illustrates that dissatisfaction often arises from perceived disrespect, discrimination, or inadequate engagement during clinical encounters, subsequently decreasing the likelihood of healthcare utilization [27, 29]. Beyond interpersonal issues, structural inefficiencies – such as overcrowding, rushed consultations, and excessive wait times – pose yet another set of barriers. These organizational failing have been well-documented in resource-poor settings such as Bangladesh and Nepal, where systemic limitations compound patient frustration and deter timely care-seeking [30, 31]. Importantly, perceived quality of care plays a central role. Patients' trust in healthcare systems diminishes when providers are viewed as lacking technical skill or professionalism, a phenomenon seen across diverse geographic and economic contexts [30, 32]. Finally, macro-level issues – including resource constraints, infrastructural shortcoming, and limited availability of services – serve to further entrench cycles of dissatisfaction and underutilization [30-32].

One of the main strengths of this study is its robust sampling approach within a population with unmet needs. Nevertheless, several limitations should be mentioned. First, the cross-sectional design limits causal inference. Second, the use of self-reported data may pose recall and social desirability biases. Third, the application of phone survey method could have been prone to sampling bias since it can potentially underrepresent individuals who do not own phones, are less comfortable with phone interviews, or who do not like responding to unfamiliar numbers and may limit our generalizability of our findings. Finally, given that the research was conducted in Qom, the results may not be fully generalizable to all other socio-cultural contexts in Iran

Conclusion

This study highlights the critical need for multifaceted interventions to enhance primary healthcare utilization among middle-aged adults in Iran. Based on our results, we recommend the adoption of the following specific strategies:

- To enhance awareness: Initiate public health education campaigns targeting middle-aged adults, focusing on the importance of preventive care. The campaigns should particularly target men, who had significantly lower utilization rates of use, through media they access most frequently.
- To improve communication: Develop and mandate training modules for healthcare providers in patient-centered communication and effective counseling skills. This is necessary for building trust and for patients to return for follow-up and preventive care.
- To overcome structural barriers: Policy efforts need to focus on expanding health insurance coverage to restrict financial barriers. Furthermore, clinic hours need to be rearranged to more easily accommodate workers overcoming the access gap observed for working adults.

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Conflicts of interest statement

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper. No potential conflicts of interest exist.

Authors' contributions

ABH: Conceptualization, Methodology, Writing original draft. MF: Methodology, Formal analysis, writing. AKS: Conceptualization, Methodology, Funding acquisition, Supervision, Writing.

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Correspondence: Akram Karimi- Shahanjarini, School of Public Health, Hamadan University of Medical Sciences, Shaheed Fahmideh Ave. Hamadan. E-mail: karimi.a@umsha.ac.ir.

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NON COMMUNICABLE DISEASES

Social and Behavioral Determinants of Dental Care Utilization among Homeless Pregnant Women in the United States

DINA ABDO[1], SANJA AVRAMOVIC[1], JANUSZ WOJTUSIAK[1], PANAGIOTA KITSANTAS[1]
[1] Department of Health Administration and Policy, College of Public Health, George Mason University

Key words

Homeless women • Pregnant women • Dental health • Dental preventive care • Dental care utilization

Summary

Introduction. *Despite modest research on oral healthcare during pregnancy, there is a dearth of evidence describing dental care among pregnant women experiencing homelessness. The purpose of this study was to examine associations between dental care utilization and social and behavioral determinants of health among United States (US) pregnant women who experienced homelessness relative to those who did not.*

Methods. *This was a cross-sectional study that used data from the 2012-2018 Pregnancy Risk Assessment Monitoring System (PRAMS). The sample consisted of 5,939 homeless and 209,942 non-homeless women. Bivariable and multivariable analyses were conducted to determine associations between dental health-related measures and social and behavioral determinants of health based on whether a woman experienced homelessness 12 months prior to birth.*

Results. *In this sample, 41.2% of homeless women saw a dentist for a problem while this was true for only 19.1% of women who were not homeless. Approximately 36.4% of women who experienced homelessness did not have their teeth cleaned before pregnancy compared to 25.7% of women who were not homeless. Lack of preventive care, smoking, older age, and experiencing multiple stressors during pregnancy were positively associated with seeing a dentist during pregnancy for both groups of women.*

Conclusion. *The results indicate the need for healthcare providers and policy officials to develop targeted interventions and policies to ensure that dental care is readily accessible for all pregnant women and especially those who are homeless.*

Introduction

It is estimated that only 22-34% of pregnant women in the United States (US) visit a dentist during their pregnancy, and when a problem occurs, only 50% seek dental care [1]. These rates are even lower depending on race/ethnicity, education, and income [2]. Recent research evidence shows that socioeconomic disparities in oral health care exist among disadvantaged pregnant women with extensive dental problems during pregnancy and postpartum [2]. Low socioeconomic status, poor mental health, homeless or at risk of homelessness, substance abuse, and incarceration can have adverse effects on oral health and access to quality dental care among pregnant women. Homeless women in particular tend to have low levels of knowledge about best practices for good oral health and have a higher likelihood of not being able to receive preventive services or curative treatment [3].

Limited research, however, exists on oral healthcare utilization among women who have experienced homelessness around the time of pregnancy. Since pregnancy is a critical period for health behavior change, especially for oral health, more research is needed to shed some light on factors that influence dental care utilization and oral health in women who have experienced homelessness around the time of pregnancy. Information generated from such studies can be used for targeted intervention and prevention programs. The purpose of this study was to examine associations between dental care utilization and social and behavioral determinants of health among US pregnant women who experienced homelessness relative to those who did not.

Methods

DATA SOURCE

The Pregnancy Risk Assessment Monitoring System (PRAMS) is conducted by the Centers for Disease Control and Prevention (CDC) Division of Reproductive Health. PRAMS collects data on pregnant women related to their pregnancy experiences, birth outcomes, and the postpartum period. The CDC and states are using PRAMS to monitor changes in maternal and child health indicators and to measure progress toward improving the health of mothers and their children [4].

In the present study, PRAMS data from 2012-2018 were used. The sample included 215,881 observations with 5,939 (2.75%) of the sample being homeless 12 months prior to giving birth and 209,942 (97.2%) of the sample not being homeless. The homeless women within the study were identified based on the following PRAMS

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question: "During the 12 months before your new baby was born, I was homeless or had to sleep outside, in a car, or in a shelter."

Measures

The outcome variable dental care utilization during pregnancy was measured using the survey question "During your most recent pregnancy did you see a dentist for a problem?" The independent measures selected for this study were categorized into social determinants of health, dental health, and behavioral determinants. Social determinants of health measures were selected based on previous research and included the following: Maternal age, marital status, race/ethnicity, education, and the use of services from the Women, Infants, and Children (WIC) during pregnancy [5]. The dental health variables were pre-pregnancy teeth cleaned, the importance of caring for teeth and gums, and access to dental insurance.

The behavioral determinants measures included drinking during pregnancy, smoking during pregnancy, medical risk factors, number of prenatal visits, and number of stressors.

Marital status was composed of married and not married. Race/ethnicity included non- Hispanic white, non-Hispanic black, non-Hispanic other, and Hispanic women. Education included three categories, ≤11 years of education, 12 years/high school and ≥13 years of education. WIC participation during pregnancy was recoded as no or yes. Pre-pregnancy teeth cleaning was assessed based on the question "Twelve months before pregnancy did you get your teeth cleaned?". In addition, the importance of caring for gums and teeth was assessed based on the question "During your most recent pregnancy were there problems with gums and teeth?", and access to dental insurance was coded as yes or no. Drinking and smoking during pregnancy were coded as yes or no. Medical risk factors (*e.g.,* gestational diabetes, hypertension, etc.) were coded as yes or no, and the number of prenatal visits included three categories, < = 8 visits, 9-11 visits, and 12 or more visits. The number of stressors variable was comprised of three levels, namely no stressors, 1-2 stressors, and 3 or more stressors.

Data Analysis

Descriptive statistics were used to evaluate the sample characteristics and dental care utilization in pregnant homeless and non-homeless women. Analyses using the chi-squared test were conducted to determine if there are any statistically significant associations between dental care utilization and each of the independent variables across the two groups of women. Logistic regression analyses were conducted to evaluate the association of homeless pregnant women's social determinants of health, dental health, and behavioral determinants with dental care utilization. These analyses were also conducted for those who were not homeless. The statistical analyses were conducted using STATA, version 17 [6] and findings at $p < 0.05$ were considered to be statistically significant. All of the analyses were weighted to account for the complex survey design of PRAMS.

Results

Table I illustrates the distribution of characteristics of women based on whether they experienced homelessness 12 months prior to giving birth. In this sample, 41.2% of women who were homeless saw a dentist for a problem while this was true for only 19.1% of women who were not homeless. Approximately 36.0% of women who experienced homelessness did not have their teeth cleaned before pregnancy compared to 25.7% of women who were not homeless. A large portion (48.2%) of 25–34-year-old women experienced homelessness. The importance of caring for teeth/gums was higher among non-homeless women (77.3% versus 70.9%).

Approximately, 59.9% of the homeless women and 65.5% of the non-homeless had dental insurance.

A high proportion of homeless women were non-Hispanic white (43.3%), non-Hispanic black (32.9%), and about 26.1% of women who were homeless only had high school education or less. Similarly, a high proportion of women who were not homeless were non-Hispanic white (61.7%). Over 61.1% of women who were homeless utilized WIC during their pregnancy. A slightly larger number of homeless women (22.6%) reported medical risk factors during pregnancy compared to their non-homeless counterparts (19.3%). Homeless women were also less likely to have at least 12 prenatal visits (36.1%) relative to the non-homeless group (52.1%) and were more likely to report smoking during pregnancy. In this sample, over 92.2% of homeless women reported 3 or more stressors while only 26.3% of the non-homeless women reported a such number of stressors.

Associations between sample characteristics and seeing a dentist for a problem during pregnancy among homeless and non-homeless women are displayed in Table II. Significant associations emerged for both groups between seeing a dentist for a problem and dental insurance, race/ethnicity, marital status, WIC services, and stressors. Lack of pre-pregnancy teeth cleaning was significantly associated with seeing a dentist for a problem, and it was particularly more evident among the homeless group of women (64.6%) compared to the group who did not experience homelessness (22.2%). Similarly, 34.9% of homeless women who were Hispanic saw a dentist for a problem during their pregnancy while only 18.3% of non-homeless Hispanic women visited their dentist for a problem. Among homeless women with 3 or more stressors, 42.3% saw a dentist for a problem while 28.8% of non-homeless women with 3 or more stressors saw a dentist for a problem.

Logistic regression analysis was conducted to evaluate the factors that influence dental care (seeing a dentist for a problem) separately for homeless and non-homeless women during pregnancy (Tab. III). Homeless women who did not have their teeth cleaned had 1.39

Tab. I. Sample Characteristics based on Experiencing Homelessness 12 Months Prior to Birth.

	Experienced homelessness 12 months prior to birth n = 5,939 Unweighted n (Weighted %)	Did not experience homelessness 12 months prior to birth n = 209,942 Unweighted n (Weighted %)
See dentist for problem		
No	2,928 (58.8)	147,064 (80.9)
Yes	2,091 (41.2)	36,580 (19.1)
Pre-pregnancy teeth cleaned		
No	2,313 (36.4)	59,636 (25.7)
Yes	1,482 (24.8)	79,949 (37.0)
Unknown	2,144 (38.8)	70,357 (37.3)
Important to care for teeth/gums		
No	842 (13.3)	21,262 (9.57)
Yes	4,197 (70.9)	164,329 (77.3)
Unknown	900 (15.7)	24,351 (13.1)
Dental insurance		
No	1,457 (22.4)	45,900 (20.4)
Yes	3,481 (59.9)	137,577 (65.5)
Unknown	1,001 (17.7)	26,465 (14.1)
Maternal age		
Less than 24 years old	2,511 (42.7)	54,453 (24.5)
25-34 years old	2,864 (48.2)	119,999 (58.4)
More than 35 years of age	563 (9.11)	35,486 (17.1)
Married		
Not Married	4,578 (78.2)	82,093 (37.1)
Married	1,329 (21.8)	127,266 (62.9)
Ethnicity/race		
Non-Hispanic White	1,871 (43.3)	102,610 (61.7)
Non-Hispanic Black	2,117 (32.9)	35,959 (13.4)
Non-Hispanic Other	941 (8.35)	31,535 (9.36)
Hispanic	804 (15.4)	34,242 (15.5)
Maternal education		
≤ 11 Years of Education	1,522 (26.1)	27,787 (12.4)
12 years/High School	2,226 (38.8)	50,877 (23.7)
≥ 13 years	2,098 (35.1)	128,932 (63.9)
WIC* services during pregnancy		
No	1,157 (19.2)	97,690 (47.8)
Yes	3,600 (61.1)	79,165 (33.8)
Unknown	1,182 (19.6)	33,087 (18.4)
Drinking during pregnancy		
Yes	264 (4.45)	9,908 (4.87)
No	3,496 (56.2)	129,202 (57.6)
Unknown	2,179 (39.4)	70,832 (37.5)
Smoking during pregnancy		
Yes	2,162 (35.1)	20,542 (8.77)
No	3,679 (64.9)	187,492 (91.2)
Medical risk factors		
No	4,297 (77.4)	157,573 (80.7)
Yes	1,573 (22.6)	50,331 (19.3)
Number of prenatal visits		
≤8	2,175 (35.8)	42,297 (16.9)
9-11	1,598 (28.1)	62,420 (31)
12+	1,883 (36.1)	98,095 (52.1)
Number of stressors		
No Stressors	N/A**	63,194 (31.5)
1-2	450 (7.76)	88,256 (42.2)
3 or more	5,489 (92.2)	58,492 (26.3)

* Women, Infants, and Children (WIC). ** N/A - no value for the group.

(95% CI: 1.08,1.79) times higher odds of seeing a dentist for a problem compared to women who had their teeth cleaned before their pregnancy. Homeless women between the ages of 25 and 34 years old were also more likely (OR = 1.47 95% CI: 1.18,1.85) to have seen a dentist for a problem compared to women who were less than 24 years old. Utilization of WIC services during pregnancy was significantly associated with a higher likelihood of seeing a dentist for a dental issue (OR = 1.45, 95% CI: 1.11, 1.89) among women who experienced homelessness. Women who smoked and were homeless during their pregnancy had 1.35 (95% CI: 1.07, 1.70) times higher odds of seeing a dentist for a problem. Homeless women who reported 3 or more stressors in their lives had higher odds (OR = 1.98, 95% CI: 1.31, 3.01) of seeing a dentist for a problem relative to those with 1-2 stressors.

Non-homeless women who did not have their teeth cleaned had 1.05 (95% CI: 1.00, 1.10) higher odds of seeing a dentist for a problem compared to women who had their teeth cleaned before their pregnancy. Non-homeless women between the ages of 25 and 34 years old were more likely (OR = 1.22, 95% CI: 1.15,1.28) to have seen a dentist compared to women who were less than 24 years old. Compared to married women, those who were not married were also more likely to see a dentist. Women who were black and non-homeless were also more likely (OR = 1.08, 95% CI: 1.01,1.15) to have seen a dentist for a problem compared to non-Hispanic white women. However, Hispanic women had lower odds of seeing a dentist for a problem (OR = 0.83, 95% CI: 0.78, 0.88) relative to white women. In addition, lower levels of education were associated with a higher likelihood of seeing a dentist for a problem in this group of women. Similarly, to homeless women, non-homeless women who utilized WIC during their pregnancy also had higher odds (OR = 1.67, 95% CI:1.59, 1.76) of seeing a dentist for a problem during their pregnancy compared to women who did not have WIC.

Women who were smokers and non-homeless during their pregnancy had higher odds of (OR = 1.97, 95% CI 1.85, 2.10) seeing a dentist for a problem as well as

►

Tab. II. Associations between Sample Characteristics and Seeing a Dentist for a Problem During Pregnancy based on Experiencing Homelessness 12 Months Prior to Birth.

	Experienced homelessness 12 months prior to birth			**Did not experience homelessness 12 months prior to birth**		
	Saw dentist for a problem			**Saw dentist for a problem**		
	Yes Weighted %	**No Weighted %**	***p*-value**	**Yes Weighted %**	**No Weighted %**	***p*-value**
Pre-pregnancy teeth cleaned			0.000			0.000
No	64.6	54.3		22.2	77.8	
Yes	35.4	45.7		17.2	82.8	
Unknown	40.5	59.5		18.5	81.5	
Important to care for teeth/gums			0.324			0.539
No	38.6	61.4		19.3	80.7	
Yes	41.7	58.3		19.0	81.0	
Unknown	44.4	55.6		36.1	63.9	
Dental insurance			0.070			0.000
No	44.7	55.3		20.6	79.4	
Yes	40.0	60.0		18.5	81.5	
Unknown	39.0	61.0		23.1	76.9	
Maternal age			0.002			0.000
Less than 24 years old	37.3	62.7		22.1	77.9	
25-34 years old	45.5	54.5		18.5	81.5	
More than 35 years of age	36.8	63.2		16.6	83.4	
Married			0.111			0.000
Not Married	42.1	57.9		24.9	75.1	
Married	37.8	62.2		15.6	84.4	
Ethnicity/race			0.019			0.000
Non-Hispanic White	44.6	55.4		18.1	81.9	
Non-Hispanic Black	39.4	60.6		24.0	76.0	
Non-Hispanic Other	41.8	58.2		20.0	80.0	
Hispanic	34.9	65.1		18.3	81.7	
Maternal education			0.349			0.0000
≤11 Years of Education	41.5	58.5		24.6	75.4	
12 years/High School	43.2	56.8		24.6	75.4	
≥13 years	39.2	60.8		15.9	84.1	
WIC* services during pregnancy			0.023			0.0000
No	35.4	64.6		14.0	86.0	
Yes	42.5	57.5		26.4	73.6	
Unknown	45.5	54.5		18.9	81.1	
Drinking during pregnancy			0.565			0.0000
Yes	36.7	63.3		17.1	82.9	
No	41.9	58.1		19.5	80.5	
Unknown	40.6	59.4		18.5	81.5	
Smoking during pregnancy			0.0000			0.0000
Yes	48.5	51.5		37.8	62.2	
No	37.3	62.7		17.2	82.8	
Medical risk factors			0.2445			0.0000
Yes	43.7	56.3		21.0	79.0	
No	40.5	59.5		18.6	81.4	
Number of prenatal visits			0.4531			0.0000
≤8	41.3	58.7		21.7	78.3	
9-11	42.0	58.0		19.3	80.7	
12+	38.5	61.5		18.0	82.0	
Number of stressors						0.0000
No Stressors	N/A**	N/A**		13.7	86.3	
1-2	27.9	72.1		16.9	83.1	
3 or more	42.3	57.7		28.8	71.2	

* Women, Infants, and Children (WIC) services. ** N/A because homelessness was a stressor.

Tab. III. Logistic Regression Results for Factors Associated with Dental Care (Seeing a Dentist for a Problem) among Women who Experienced Homelessness 12 Months Prior to Birth and Women who did not Experience Homelessness.

	Experienced homelessness 12 months prior to birth		**Did not experience homelessness 12 months prior to birth**	
	Saw dentist for a problem OR (95% CI)	***p*-value**	**Saw dentist for a problem OR (95% CI)**	***p*-value**
Pre-pregnancy teeth cleaned				
No	**1.39 (1.08, 1.79)**	0.009	**1.05 (1.00, 1.10)**	0.043
Yes	Reference		Reference	
Unknown	0.92 (0.36, 2.34)	0.875	1.09 (0.89, 1.34)	0.369
Important to care for teeth/gums				
No	0.85 (0.64, 1.13)	0.271	**0.85 (0.80, 0.91)**	0.000
Yes	Reference		Reference	
Unknown	0.92 (0.22,3.95)	0.919	**2.22 (1.47, 3.33)**	0.000
Dental insurance				
No	1.08 (0.85, 1.37)	0.508	1.02 (0.98, 1.07)	0.251
Yes	Reference		Reference	
Unknown	1.12 (0.51, 2.44)	0.771	0.96 (0.79, 1.16)	0.680
Maternal age				
Less than 24 years old	Reference		Reference	
25-34 years old	**1.47 (1.18, 1.85)**	0.001	**1.22 (1.15, 1.28)**	0.000
More than 35 years of age	0.98 (0.65, 1.46)	0.914	**1.19 (1.11, 1.27)**	0.000
Married				
Not Married	1.06 (0.84, 1.39)	0.525	**1.13 (1.08, 1.19)**	0.000
Married	Reference		Reference	
Ethnicity/race				
Non-Hispanic White	Reference		Reference	
Non-Hispanic Black	0.82 (0.63, 1.06)	0.163	**1.08 (1.01, 1.15)**	0.010
Non-Hispanic Other	0.93 (0.66, 1.29)	0.669	**1.14 (1.07, 1.21)**	0.000
Hispanic	0.75 (0.54, 1.02)	0.072	**0.83 (0.78, 0.88)**	0.000
Maternal education				
≤11 Years of Education	1.12 (0.84, 1.48)	0.424	**1.29 (1.21, 1.38)**	0.000
12 years/High School	1.10 (0.86, 1.40)	0.427	**1.27 (1.21, 1.34)**	0.000
≥13 years of education	Reference		Reference	
WIC* services during pregnancy				
No	Reference		Reference	
Yes	**1.45 (1.11, 1.89)**	0.006	**1.67 (1.59, 1.76)**	0.000
Unknown	**1.76 (1.10, 2.80)**	0.017	**1.22 (1.12, 1.33)**	0.000
Drinking during pregnancy				
No	Reference		Reference	
Yes	0.955 (0.61, 1.50)	0.843	0.98 (0.91, 1.08)	0.793
Unknown	1.14 (0.46, 2.83)	0.775	0.95 (0.78, 1.17)	0.690
Smoking during pregnancy				
Yes	**1.35 (1.07, 1.70)**	0.011	**1.97 (1.85, 2.10)**	0.000
No	Reference		Reference	
Medical risk factors				
No	Reference		Reference	
Yes	1.11 (0.87, 1.41)	0.366	**1.08 (1.03, 1.13)**	0.000
Number of prenatal visits				
≤8	Reference		Reference	
9-11	1.05 (0.81,1.36)	0.699	0.98 (0.93,1.03)	0.549
12+	0.89 (0.70,1.14)	0.360	**0.94 (0.89, 0.99)**	0.028
Number of stressors				
No Stressors	No value		**0.82 (0.78, 0.86)**	0.000
1-2	Reference		Reference	
3 or more	**1.98 (1.31, 3.01)**	0.001	**1.60 (1.53, 1.68)**	0.000

* Women, Infants, and Children (WIC) services.

those who reported medical risk factors (OR = 1.08, 95% CI: 1.03, 1.13) compared to women who were nonsmokers and those with no medical problems, respectively. Non-homeless women who completed 12 or more prenatal visits had a lower likelihood of seeing a dentist (OR = 0.94, 95% CI: 0.89, 0.99) compared to those with at most 8 prenatal visits. Non-homeless women who reported at least 3 or more stressors had higher odds of seeing a dentist for a problem than those with 1-2 stressors.

However, no stressors were associated with a lower likelihood (OR = 0.82, 95% CI: 0.78, 0.86) of seeing a dentist.

Discussion

The findings of this study show that 41.2% of women who experienced homelessness saw a dentist for a problem and 36.4% had not had a pre-pregnancy teeth cleaning compared to the 19.1% of non-homeless women who saw a dentist for a problem and 25.7% who had their teeth cleaned. These results indicate that women's dental care utilization was higher among women who experienced homelessness 12 months prior to birth primarily for treatment rather than prevention. Overall, prevention-related services such as cleaning teeth were low for both groups but more evident among homeless women. Although research shows that pregnant women use dental services less frequently than the general population [7], underserved populations such as homeless women have difficulty accessing oral health services [3]. Most pregnant women do not receive the oral care they need during pregnancy, and homeless pregnant women in particular are less likely to receive proper oral care [8]. This is due to poor access to dental health insurance or difficulty paying for oral health services and may explain the findings of higher utilization of dental care for dental issues among homeless in this sample. Targeted intervention and prevention programs for this high-risk subpopulation of pregnant women are needed to improve access to oral healthcare and especially preventive services. Patient care education is important for homeless women for proper self-care and for awareness of resources and eligible dental services through government programs such as Medicaid.

In addition, non-homeless women who did not find it important to care for teeth/gums had lower odds of seeing a dentist for a problem than those who did. This was also true for homeless women, although it was not a statistically significant finding in the logistic regression analyses. Lack of interest in oral health and knowledge of adverse health outcomes can increase the risk of poor oral health. In addition, older women were more likely to see a dentist for a problem relative to their younger counterparts. This could be the result of developing more dental issues because the prevalence of cavities is twice as high in older adults [9]. In addition, previous research shows that race can impact the odds of an individual not having a dental visit [10]. In the present study, non-homeless Hispanic women were less likely to see a dentist for a problem compared to white women, and this could be due to a lack of dental insurance, knowledge or value of oral health during pregnancy, fear and safety concerns, as well as lack of prenatal oral health counseling [11]. However, black and Other racial/ethnic groups had a higher likelihood of seeing a dentist for a problem relative to white women. Potential racial/ethnic disparities in dental care and outcomes present a public health challenge that requires multifaceted approaches for this population.

Positive associations were also found between receiving WIC services, higher number of life stressors, smoking and seeing a dentist for a dental issue. Receiving WIC services during pregnancy, low educational levels, and seeking dental services for problems during pregnancy has been reported in previous research studies [10]. Socioeconomic factors such as limited income and education may predispose women to additional life stressors, placing homeless women at particularly high risk for delayed or forgone preventive dental care (McGeough et al. 2020) which in turn may lead to serious dental health issues that may force them to seek care when the issue becomes unbearable. Life stressors such as those faced by women who may experience homelessness around the time of pregnancy may delay critical medical and dental care that could lead to adverse birth outcomes. Stressors can also influence the use of smoking which known to negatively impact oral health.

LIMITATIONS

This study has several limitations. Since the PRAMs survey is sent to mothers 2-9 months after delivery, questions about dental care utilization or oral health before pregnancy are prone to recall bias [12]. Recall bias and self-reported data may lead to misclassification errors and biased results. The reasons for a dental visit were not included and thus there is no way to differentiate between women visiting a dentist for a routine preventive visit or an emergency procedure [12]. PRAMS data do not contain specific measures that specify the exact time or frequency a mother was homeless. This may have excluded certain women who suffered from homelessness during short periods of time and may have not been reported leading to potential underestimation of homelessness in this population.

Conclusion

The findings of this study highlighted several factors that may affect dental health utilization among homeless and non-homeless women. Lack of preventive care such as cleaning one's teeth, smoking, older age, and experiencing multiple stressors were positively associated with seeing a dentist during pregnancy for both groups of women. The results indicate the need for healthcare providers and policy officials to develop targeted interventions and policies, respectively, to ensure that dental care is readily accessible for all pregnant women especially those who are homeless. Efforts among healthcare practitioners to educate pregnant women, and in particular those who are experiencing homelessness, about preventive dental care services are crucial. In addition, it is imperative for state and federal funding to create accessible dental treatment centers for homeless women. Collaboration between homeless centers and dental clinics within communities to provide dental services to homeless pregnant populations may increase access to preventive services and necessary treatment. Evidence-based programs that provide dental healthcare services tailored for homeless women who are pregnant are needed as well. Understanding the complex needs of different populations of pregnant women is necessary for building accessible and equitable dental healthcare services as well as creating training materials and programs for dental care providers who may service these populations.

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Conflict of Interest statement

The authors declare that they have no competing interests.

Authors' contributions

All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by DA, PK, SA, JW. The first draft of the manuscript was written by DA and finalized by PK. All authors read and approved the final manuscript.

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Correspondence: Panagiota Kitsantas, Department of Health Administration and Policy, College of Public Health, George Mason University, 4400 University Drive, MS 1J3, Fairfax, VA 22030. E-mail: pkitsant@gmu.edu

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HEALTH CARE MANAGEMENT

Breaking the Stalemate: How Italy's Non-Medical Health Professions Are Trapped by Redundant Roles and Ineffective Degrees

ROBERTO TEDESCHI[1]
[1] Independent Researcher, Bologna, Italy

Keywords

Non-medical health professions • Educational Inefficacy • Healthcare Harmonization

Dear Editor,

I would like to bring to your attention an issue that significantly impacts non-medical health professions in Italy, a situation further complicated by the recent recognition of osteopathy as a new health profession. Currently, the Italian healthcare system acknowledges 20 non-medical health professions: nurse, pediatric nurse, midwife, physiotherapist, speech therapist, podiatrist, therapist in neuro and psychomotor therapy of developmental age, psychiatric rehabilitation technician, occupational therapist, professional educator, medical radiology technician, biomedical laboratory technician, orthopedic technician, audiometry technician, hearing aid technician, dental hygienist, dietitian, neurophysiopathology technician, cardiovascular and perfusion technician, and, most recently, osteopath [1].

This multiplicity of professional roles, instead of enriching the healthcare system, often leads to overlapping competencies and operational inefficiencies. The abundance of these roles not only creates confusion and redundancy but also weakens the potential for any individual profession to progress and gain recognition within the healthcare hierarchy.

One of the critical issues at play here is the limited impact of advanced educational degrees, particularly the master's degree, which in theory, should signify a substantial leap in a professional's education and career trajectory. However, within the Italian context, this academic title fails to offer any tangible advantage over a three-year bachelor's degree. Professionals who complete a master's degree often find themselves with the same operational skills and job opportunities as those with only a bachelor's degree, with no access to roles of greater responsibility or advanced specialization [2].

Compounding this problem is the proliferation of university master's programs, which promise advanced specializations and skills but rarely translate into meaningful professional progress. These postgraduate programs are often marketed as opportunities for differentiation, but in practice, they offer little recognition or advancement within healthcare institutions or the job market. Consequently, many professionals accumulate titles that do not lead to real career progression, resulting in frustration and a sense of professional stagnation.

Adding to these challenges is the reluctance of the medical profession to grant greater autonomy and operational freedom to non-medical health professionals, even when they have completed advanced training programs. This resistance stems from a historical hierarchical division between doctors and other health professions, where doctors often maintain strict control over all clinical decisions, even in areas where other professionals could operate autonomously due to their specialized training. This attitude not only stifles the recognition of the competencies of non-medical health professionals but also contradicts the primary objective of any healthcare system: the well-being of the patient [3, 4].

Moreover, this resistance and lack of professional advancement opportunities contribute to the declining appeal of certain health professions, such as nursing, while leaving other lesser-known professions struggling to attract new entrants. Economic factors also play a crucial role, as these professions become less financially viable for aspiring healthcare workers, leading to workforce shortages in critical areas.

At the European level, there has been little effort to standardize or unify training pathways for non-medical health professions. This lack of harmonization is starkly evident when comparing the scope of practice across countries. For instance, in the United Kingdom, physiotherapists can perform acupuncture, prescribe medications, and order diagnostic tests, thanks to additional years of study and advanced competencies. In contrast, their Italian counterparts remain confined to a much narrower scope of practice, highlighting the disparity in professional development and autonomy within the European Union [5, 6].

The introduction of new health professions such as osteopathy, along with the proliferation of advanced academic titles, underscores the inherent contradictions in the Italian healthcare system. To truly improve our system, it is essential to reduce the overlaps between professions, reform the advanced education system, and promote greater autonomy for non-medical health professionals. Only by addressing these issues can we ensure that every healthcare worker can fully express their competencies, ultimatl keeping the patient at the center of care.

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Authors' contributions

Author have accepted responsibility for the entire content of this manuscript and approved its submission.

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Correspondence: Roberto Tedeschi, Independent Researcher, Bologna, Italy. E-mail: roberto.tedeschi82@gmail.com.

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OPEN ACCESS J PREV MED HYG 2025; 66: E420-E420

EDITORIAL

Response to the letter "Breaking the Stalemate: How Italy's Non-Medical Health Professions Are Trapped by Redundant Roles and Ineffective Degrees"

ROBERTO GASPARINI[1]
[1] Editor of Journal of Preventive Medicine and Hygiene

I am writing in response to the recent letter expressing concerns over the recognition of osteopathy and the perceived proliferation of non-medical health professions in Italy. While I appreciate the effort to highlight challenges within the healthcare system, I respectfully disagree with the view that the diversity of these roles leads to confusion, inefficiency or stagnation.

On the contrary, the acknowledgment of 21 non-medical health professions represents a long-overdue recognition of the complexity of patient care. Today's healthcare demands interdisciplinary collaboration, not a hierarchical or overly centralized system. Each profession brings unique expertise that contributes to comprehensive, patient-centered care.

Rather than creating overlap, the differentiation of roles allows professionals to focus on specific domains, improving efficiency and outcomes. The competencies of a physiotherapist differ significantly from those of an occupational therapist, a speech-language pathologist, or a podiatrist – as is appropriate, given the distinct roles and scopes of practice associated with each profession. These distinctions are essential, not problematic. The idea that fewer, broader roles would lead to more effective care is, in my view, an oversimplification of the nuanced needs of modern medicine.

The criticism of master's degrees and postgraduate specialization also warrants reconsideration. While it is true that structural reforms are needed to better align education with clinical career pathways, master's programs are not useless. They offer professionals opportunities to deepen their knowledge, pursue research, and refine advanced competencies. The impact of this training may not always be immediately visible in job titles or pay scales, but it contributes significantly to care quality, innovation, and professional identity.

Furthermore, the medical profession's supervisory role is not inherently oppressive or outdated – it ensures safety, consistency, and accountability in clinical decision-making. However, collaboration is increasing, and Italy is gradually moving toward models that allow more autonomy for highly trained professionals, especially in community and chronic care settings. Autonomy and safety are not mutually exclusive – they must evolve together.

Rather than resisting the introduction of new professions, we should celebrate the system's capacity to adapt to emerging evidence and patient needs.

The broader concern should not be the number of professional categories, but rather how well the system integrates them. Better coordination, clearer scopes of practice, and shared protocols can prevent inefficiencies without sacrificing specialization. Additionally, salary structures and career pathways should be reviewed—but not at the expense of academic progress or role diversity.

Finally, regarding European harmonization, it's true that Italy has room for improvement. But it's also important to recognize that each country adapts health professions to its legal, cultural, and clinical landscape. Uniformity should not come at the expense of national context or patient trust.

In summary, the future of Italian healthcare lies in enhancing interdisciplinary collaboration, not simplifying it. The growing diversity of non-medical health professions, including newer fields like osteopathy, represents not a limitation but a valuable strength within the healthcare landscape. With thoughtful reform, these professions can thrive, innovate, and most importantly, deliver the best possible care to patients.

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Correspondence: Roberto Gasparini, Editor of Journal of Preventive Medicine and Hygiene. E-mail: roberto.gasparini3@gmail.com.

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J PREV MED HYG 2025; 66: E421-E427

OPEN ACCESS

Health Care Managment

A Field Report from War-Torn Remote Villages in South-Eastern Ukraine: Enhancing Healthcare Access Through a Community-Oriented Primary Care Model

DARIO LUPICA SPAGNOLO[1], ELEONORA COLPO[1], MARCO PERETTI[1], ALESSANDRO MANNO[1], VIOREL IESANU[1],
SAMUELE CIRNIGLIARO[1], DAFINA SHTEFAN[1], GABRIELA BIANCHI[1], ELISA DE CHECCHI[1], DANIELE GIACOMINI[1],
ALESSANDRO LAMBERTI-CASTRONUOVO[1]
[1] EMERGENCY NGO ETS, Milan, Italy

Keywords

EMERGENCY NGO • Community Health Workers • Ukraine • Community oriented primary care • Continuity of care

Summary

The ongoing conflict in Ukraine has severely disrupted healthcare infrastructure, displaced medical personnel and restricted access to care, prompting an unprecedented international support. Since October 2023, the non-governmental organization EMERGENCY has conducted a field assessment to identify critical barriers to healthcare delivery in remote villages of Donetsk to inform an effective intervention. The assessment revealed that many health needs, particularly those related to chronic diseases and mental health, were pre-existing but had been exacerbated by the war, resulting in a secondary surge of unmet needs in rural communities facing growing barriers to basic care. In response, a Community Health Worker (CHW)-led intervention was developed to bridge gaps between communities and health services. Locally recruited CHWs conduct door-to-door assessments, monitor treatment adherence for chronic diseases, address mental health needs, arrange home-based care for bedridden individuals, deliver health education sessions, and facilitate timely referrals in close collaboration with nurse-led clinics. To strengthen resilience, CHWs are trained in basic emergency and disaster preparedness, including life support skills, improving community-level readiness for health emergencies. To address sustainability challenges, the intervention is integrated into Ukraine's primary care network, and provides CHWs with ongoing training and compensation through regular contracts. Aligned with national health priorities and the Health Cluster's strategy, the model targets marginalized groups, engages communities, and strengthens local health systems, ensuring efficient use of resources and continuity of care. This report outlines a scalable, context-sensitive approach to enhancing healthcare access in conflict settings, with relevance for other humanitarian contexts.

Introduction

Since Russia's full-scale invasion of Ukraine in February 2022, the war has caused significant human losses, with over 12,000 civilians, including around 600 children, killed by February 2025, [1] and almost 4 million people internally displaced (IDPs) [2]. Around 6 million remain in violence-affected areas, with another 6 million having fled the country, and an estimated 14.6 million requiring humanitarian assistance in 2024 [3].

Healthcare access in South-Eastern Ukraine has been severely compromised by insecurity, displacement of civilians and healthcare workers (HCWs), and disrupted supply chains [4]. Attacks on health facilities further threaten access. Since the escalation, 2,184 episodes have been reported, resulting in 204 deaths, 696 injuries, and major service disruptions [5].

In Donetsk oblast, 46% of health facilities are non- or partially functional, over half are damaged, and 50% report equipment losses [6].

International aid has mobilized on an unprecedented scale, making Ukraine the largest recipient of assistance from any single country in a year [7]. By November 2024, 645 organizations had reached 8 million people with shelter, food, water and sanitation, and healthcare [8].

In October 2023, the international non-governmental organization (NGO) EMERGENCY, [8] building on prior support [9] for Ukrainian refugees in Moldova, launched a needs and assets assessment in Donetsk (Fig. 1), twenty months after the full-scale invasion. The assessment aimed to identify needs and resources in affected areas providing an evidence base for effective assistance. While there is extensive literature on health system disruptions in conflict, little is documented on concrete models of health delivery during protracted war, particularly in Ukraine. International humanitarian actors increasingly emphasize the importance of holistic, person-centred approaches through multisectoral integrated strategies as essential to reach the invisibles and the most vulnerable [5], who continue to bear the brunt of war-related health system breakdowns. To address this gap, an interdisciplinary assessment was undertaken, informed by the Multi-Sector Initial Rapid Assessment (MIRA) framework [10], commonly used in humanitarian contexts, to capture evolving health needs and service availability nearly two years into the conflict. This report presents the findings and outlines a strategic response relevant to similar humanitarian contexts.

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Fig. 1. Surveyed area during the assessment: Donetsk oblast, Kramatorsk raion.

Methods

The assessment was conducted by an interdisciplinary team, comprising a coordinator, two HCWs, a logistician, and a cultural mediator, all with prior experience in humanitarian assessments. The MIRA framework was used [10]. Typically employed in sudden-onset disasters, it was adapted to evaluate emerging health needs nearly two years into the war, enabling timely input for strategic planning and decision-making.

Four main data sources were used:

1. Document review: reports from national authorities and international organizations (*e.g.*, Health Cluster Bulletins [5, 11]; Health Context and Response Update [12]) were systematically reviewed to contextualize facility-level findings and triangulate local perspectives with secondary data;
2. Facility inspections: visual inspections were conducted in the main secondary hospitals and primary care facilities across the oblast (see map in Fig. 1); a structured MIRA-checklist was used to record functionality of infrastructure, availability of medicines and equipment, staffing, and referral capacity;
3. Key informant consultations: semi-structured consultations were carried out with representatives from each clinic and three members of local health department;
4. Community perspectives: interviews were conducted with 19 community representatives and local residents across 10 settlements, purposively selected to reflect both urban and rural contexts as well as areas of high and low accessibility. A brief interview guide was used, focusing on perceived barriers to care, priority health needs, and coping strategies.

Notes from facility inspections, consultations, and community interviews were collated and synthesized thematically. An initial set of categories was derived from the domains of the MIRA framework (e.g., service availability, access barriers), and emergent themes were added inductively from the data. Findings from the different sources were then triangulated to identify convergent issues and cross-validate emerging priorities. Results are presented according to the MIRA domains that guided the assessment.

The study was conducted according to the principles enunciated in the Declaration of Helsinki, and approved by the Independent Institutional Review Board of EMERGENCY NGO (Protocol 7/2025, May 2025).

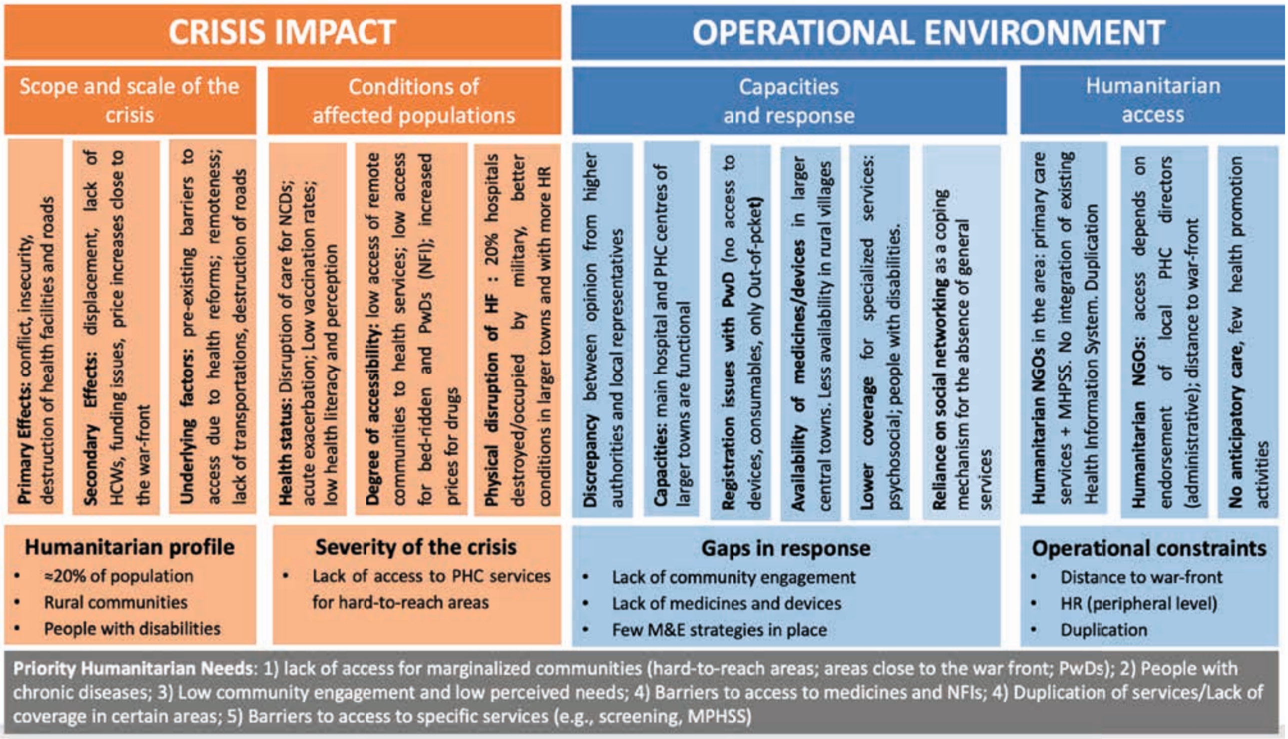
Results

The assessment results are organized according to the MIRA framework, [10] with a visual summary presented in Figure 2.

Crisis impact

The war has caused extensive destruction of facilities and roads, displaced civilians and HCWs, and severely

Fig. 2. MIRA framework.



limited transportation in the surveyed area. Larger cities show relative resilience, with hospitals and primary care facilities often appearing well-maintained, some even freshly painted. However, patients' waiting areas are often empty.

In contrast, smaller villages and rural frontline communities face greater hardships. Many local nurses cannot access their health facilities, as many are occupied by military forces. Remaining health posts are rudimentary, poorly equipped, or relocated to administrative buildings. Village populations have declined dramatically, with 25-50% of residents fleeing, and even higher percentages in active combat zones. Those left behind are predominantly elderly individuals and persons with disabilities (PwDs), who represent approximately 60% of the population. A sense of abandonment is palpable as residents urge humanitarians 'not to forget them'. They struggle with basic tasks, and face major barriers in reaching healthcare or obtaining medications. Since the war began, many rural pharmacies have closed, and those still operating often charge higher prices. These challenges are not entirely new, as they stem in part from an incomplete health reform program initiated in 2010 and intended for completion by 2020. This reform closed health facilities in small villages unless supported by local administrations. [13] The war has worsened these long-standing barriers, compounding limited access with staffing shortages, higher medication costs, reduced financial resources, disrupted transport, deteriorating infrastructure, and insecurity. [14]

CONDITIONS OF AFFECTED POPULATIONS

Before the war, Ukraine already faced significant health challenges, including an aging population, [15] a high prevalence of non-communicable diseases, particularly cardiovascular conditions, [16] and elevated burdens of HIV and tuberculosis (TB) [17, 18]. Low health literacy contributed to low immunization rates, especially among children [19-22]. The war has severely disrupted access to medications, diagnostic services, and preventive care, worsening health outcomes for older adults, PwDs, individuals with chronic conditions, and IDPs [23]. Hospital directors reported that the breakdown of the primary care's gatekeeping function and the disrupted continuity of treatment for chronic illnesses have led to more frequent and severe exacerbations at hospitals. Additionally, HIV and TB case-finding, diagnosis and treatment continuity have also been interrupted in many surveyed areas, potentially leaving several cases undiagnosed and untreated [24]. Mental health disorders have surged, yet services remain limited, and stigma persists [25]. In surveyed rural areas, no basic mental health service was available. Some local NGOs offered online consultations, but these efforts are undermined by inadequate spaces, unreliable internet connectivity and difficulties in using digital tools at the community level. Among those affected by the war, an estimated 22% experience conditions ranging from mild anxiety or depression to psychosis, while nearly one in ten lives with a moderate or severe mental health condition [26].

OPERATIONAL ENVIRONMENT: CAPACITIES AND RESPONSE

A clear discrepancy emerged between statements from high-level authorities and the accounts of village leaders and local health staff regarding the situation in peripheral areas. As the team moved closer to the front lines, it became evident that several needs remain unmet at the community level, despite significant humanitarian funding and response efforts since the war's onset. Many front-line areas are critically underserved, with interviewees reporting that around 50% of residents in hard-to-reach locations cannot access even the most basic service. Community-based healthcare is largely absent, restricting care to those able to travel, sometimes up to 20 kilometers, on unpaved road to health facilities. Consequently, these communities remain disengaged, with persistently low perceived health needs. Additionally, no immunization program is available in these areas, increasing the risk of vaccine-preventable disease outbreaks. The departure of skilled birth attendants has created significant gaps in maternal health services. However, few women of childbearing age remain in these communities. Instead, older adults, PwDs, and those in isolated villages are often left without adequate support. IDPs often face administrative barriers and may not register in their new locations, limiting their access to basic care, including essential medications and routine vaccinations.

OPERATIONAL ENVIRONMENT: HUMANITARIAN ACCESS

The ongoing war has created a precarious security environment, placing both staff and beneficiaries at risk and disrupting vital supply lines. This has deterred many international NGOs from operating near the frontline. EMERGENCY NGO maintains a 25 km safety buffer zone to allow time for evacuation if hostilities escalate. Access is further hampered by poor road conditions, long distances between villages, and heavy winter snowfall, which can isolate entire communities. Humanitarian operations also depend on local authority endorsement. These authorities function within a structured national health system with their own priorities, making negotiation and collaboration essential for uninterrupted aid delivery. Additional challenges include bureaucratic hurdles, such as visa and registration requirements, which can delay operations and increase complexity. It was also difficult to ascertain the number and capacity of humanitarian actors in rural areas, complicating coordination, and often resulting in service gaps or duplication. Despite these challenges, national and few international NGOs remain active in these areas. Some deliver medications to remote communities, while others provide basic care services through mobile teams. However, NGO health records are generally not integrated into Ukraine's national system, causing treatments provided in remote areas to go unrecorded in patient histories.

Discussion

The assessment revealed that while primary care centers in Donetsk's larger cities remain functional and well-staffed, remote villages are disproportionately affected. Services in these areas declined following national health reform, and the ongoing war has further eroded access. Older adults, PwDs, and rural residents face significant barriers to care, especially for chronic conditions like hypertension and diabetes. Mental health needs are often unmet, and disrupted screening efforts have raised the risk of undiagnosed cases of HIV and TB, and other infectious diseases. These findings align with earlier reports on the topic [26, 27].

To address these challenges, EMERGENCY launched an intervention to improve access to public primary care in war-affected villages, with a focus on vulnerable groups. The project is rooted in a community-based model that brings services closer to people through a network of trained local actors and flexible service delivery mechanisms. The organization also supports local HCWs with essential equipment, and implements semi-mobile clinics to better serve these remote communities. Community Health Workers (CHWs), recruited locally, play a central role. They conduct door-to-door health assessments, monitor adherence to chronic disease treatments, address mental health needs, arrange home-based care for bedridden individuals, and facilitate referrals. CHWs also provide health education, informal counseling, and guidance on hygiene and disaster preparedness. Their ongoing training, formal contracts, and compensation are key to ensure service quality and long-term sustainability.

Integrated into Ukraine's primary care system, CHWs collaborate with nurse-led clinics to organize screenings, distribute medicines and non-food-items, and ensure that only urgent cases are referred to higher-level care. A robust data system tracks intervention impact, including: (1) case management and follow-up outcomes; (2) CHW's effectiveness in reconnecting individuals to care; and (3) referral patterns and avoidable hospitalizations.

This approach builds on existing evidence of CHW effectiveness in peacetime [28, 29], conflict [30-32], and post-conflict settings [33]. By leveraging local trust and social networks, CHWs advocate for vulnerable populations and improve access to care, [34] ultimately enhancing both physical and mental well-being in remote communities that might otherwise remain isolated due to conflict and insufficient infrastructure. This approach aligns with the principles of Community-Oriented Primary Care, conceptualized in South Africa in the 1960s, which blends primary care and public health strategies through an anticipatory approach [35, 36]. Extensive evidence affirms that a CHW-led model of care is low-cost, scalable, and effective in settings where conflict hampers formal services [37, 38]. The intervention also aligns with Health Cluster's priorities [12], targeting marginalized groups, engaging local actors, and integrating with existing health systems to ensure sustainability and avoid parallel systems.

Implementing such a model amid conflict carries inherent challenges. Security concerns may limit access to communities, while displacement may weaken the trust required for effective service delivery [39]. Logistical barriers, including disrupted communication and resource shortages, further reduce CHWs' capacity. In many settings, CHWs lack formal recognition, compensation, and training, all factors that contribute to low motivation and high attrition rates [39]. To mitigate this, the intervention ensures CHWs receive transportation support, ongoing training, and formal contracts with fair compensation. Sustainability remains a concern. CHWs are not yet fully embedded in Ukraine's health system, raising questions about long-term integration. Still, their training allows for future adaptation, and some organizations are advocating for their permanent inclusion globally [40].

This report highlights the potential of CHWs to strengthen community-based healthcare in conflict settings, offering critical insights for designing resilient interventions. By involving local stakeholders in program design, the intervention promotes ownership and long-term sustainability [41,42]. This community-centered approach ensures continuity of care, lowers barriers to access, and actively engages war-affected villages in co-managing their health. It also aligns with broader efforts to 'build back better'. By prioritizing primary care, Ukraine can restore and enhance its healthcare system, leveraging the central role of CHWs to ensure resilience and equity in future health services [43].

STRENGTHS AND LIMITATIONS

This report offers firsthand insights from areas near the frontline, collected by a multidisciplinary team. It gives voice to affected communities, and documents their experience during the war. Conducted in a priority zone designated by the regional health authority, the assessment allowed for focused, context-specific data collection. While valuable, the findings reflect local conditions at the time and are not generalizable to other regions.

Conclusion

The ongoing war and resulting health challenges make Donetsk an appropriate setting for a robust primary care intervention. Strengthening access to essential services, supporting chronic disease management, and promoting early detection of infectious diseases can improve population health and autonomy. Anchored in collaboration with the public health system and driven by CHWs, this model offers a scalable, sustainable framework for similar interventions in conflict-affected settings.

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Conflict of Interest statement

None.

Authors' contributions

DLS and EC contributed equally to the conceptualization, data collection, and initial drafting of the report. MP provided clinical oversight and contributed to critical report revisions. AM and GB supported data acquisition and contributed to contextual analysis. VI, SC, DS, and DG contributed to field coordination, stakeholder engagement and manuscript editing. ED. participated in data organization and contributed to reviewing and editing the report. ALC led the overall report design, supervised the assessment process, and contributed to data interpretation, writing, and final approval of the submitted version. All authors have substantially contributed to the work, revised it, approved the final version, and agreed to be accountable for all aspects of the work.

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Correspondence: Alessandro Lamberti-Castronuovo, Primary Health Care Focal Point - Medical Coordination Unit - EMERGENCY NGO ETS. Via Santa Croce, 19, 28100 Milan Italy. E-mail: alessandro.lamberti@emergency.it.

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HEALTH CARE MANAGEMENT

Achieving Health Equity in Decentralized Healthcare: An Innovative Approach to Preventive Care in Southern Italy

GIOVANNA LIGUORI[1], RACHELE MARIA RUSSO[1], VIVIANA BALENA[1], MARIA TERESA MONTAGNA[2], ANTONIO DI LORENZO[3], FRANCESCO TRIGGIANO[3], OSVALDA DE GIGLIO[3], PIETRO PASQUALE[4], MICHELE FERNANDO PANUNZIO[1]
[1] Local Health Authority, Foggia, Italy; [2] Formerly University of Bari Aldo Moro, Bari, Italy;
[3] Interdisciplinary Department of Medicine, Hygiene Unit, University of Bari Aldo Moro, Bari, Italy;
[4] Veterinary Epidemiological Observatory of the Apulia Region - I.Z.S of Apulia and Basilicata, Department of Health Promotion and Wellness (P.P.), Bari, Italy

Keywords

Healthcare Disparities; Environmental Health; Vaccination Coverage; Chronic Disease Management; Predictive Analytics in Healthcare

Summary

This contribution focuses on the Italian Ministry of Health's Decree No. 77 of 23 May 2022, aimed at standardizing preventive healthcare nationwide. The implementation of Ministerial Decree 77 represents a crucial step in strengthening preventive care in Italy, by redefining community-based healthcare models and promoting proactive, population-centered interventions. It highlights regional disparities in healthcare access and explores innovative approaches, including Regulation 13/2023 of the Apulia Region (Southern Italy), to improve health outcomes.

In this context the comparison of healthcare management systems of northern and southern Italy, particularly on vaccination rates, chronic disease management and the integration of environmental health is relevant.

It examines the Apulian regulatory model, emphasizing environmental determinants such as air quality monitoring and predictive analytics to mitigate climate-related health risks.

The Apulia model led to significant health improvements, including a 25% reduction in waterborne diseases and a 12% reduction in heatwave-related hospitalizations. Multidisciplinary collaboration and community engagement enhanced policy effectiveness and public confidence.

This work underscores the importance of balancing national health guidelines with regional autonomy to address health inequalities. The Apulia model demonstrates the need for integrating environmental health factors and offers a replicable framework to improve health equity and resilience. Recommendations include strengthening administrative capacity, fostering inter-regional collaboration, and promoting innovative regional healthcare approaches.

Introduction

Regional health inequalities are a critical challenge in decentralized healthcare systems. In this type of organization, uneven resource allocation, infrastructure variability and inconsistent policy implementation often lead to inequitable health outcomes [1, 2]. In Italy, although the Ministry of Health provides national guidelines and basic principles for healthcare, the Regions and Autonomous Provinces are granted a degree of independent healthcare management.

Ministerial Decree No. 77 of 23 May 2022 (MD 77/22) [3] introduced a national regulatory framework defining models and standards for the development of territorial support in the National Health Service and setting reference parameters for human resources and strategic objectives. The implementation of Ministerial Decree 77 represents a crucial step in strengthening preventive care in Italy, by redefining community-based healthcare models and promoting proactive, population-centered interventions. Despite this initiative, the implementation of the decree has highlighted significant contrasts between the northern and southern regions of the country. Northern regions, such as Lombardy and Veneto, with advanced digital infrastructure, robust financial resources and efficient administrative frameworks, contrast sharply with southern regions, including Calabria and Sicily, which face challenges related to poor logistics, insufficient funding and widespread inefficiencies at the administrative level. Such disparities are evident in critical areas such as immunization coverage, chronic disease management and environmental health, and hinder the improvement of healthcare services.

In the context of these broader challenges, Apulia is a notable exception. Apulia is a region in south-eastern Italy, extending along the Adriatic and Ionian coasts, with a population of approximately 4

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million. It features a mix of urban and rural areas, a high proportion of elderly residents, and several socioeconomically deprived communities, making it a key setting for addressing health inequalities and implementing population-based healthcare strategies. Since the implementation of Regional Regulation No. 13 of 19 December 2023 [4], Apulia has adopted a proactive approach to integrating environmental health determinants into its public health framework. This innovative model incorporates air quality monitoring, water safety inspections and predictive analysis into healthcare strategies, in line with global frameworks such as the World Health Organization (WHO) Health in All Policies (HiAP) initiative [5]. In addition, Apulia has promoted multidisciplinary collaboration among health professionals, environmental scientists and local authorities, drawing inspiration from approaches used in other countries [6].

The Apulian approach emphasizes community engagement, involving citizens in participatory forums and designing culturally tailored educational campaigns in line with recommendations from several authors [7,8]. Despite being at an early stage, these initiatives have already shown positive impacts: since their implementation, cases of waterborne diseases and heatwave-related hospital admissions have significantly decreased in the Apulian territory, demonstrating the potential of context-specific and community-led solutions to address health inequalities and improve health outcomes.

This work has two main objectives: i) to analyze regional disparities in the implementation of MD 77/22; ii) to evaluate the Apulian Regional Regulation 13/2023 as a case study of how environmental health integration and community-based approaches can address systemic challenges. The authors also explore how decentralized health systems can balance the need for national standardization with the benefits of more fruitful regional adaptability.

Regional disparities in the implementation of Ministerial Decree 77/2022

The implementation of MD 77/22 in Italy has revealed significant regional disparities, particularly between northern and southern regions. Differences in resources and access to healthcare reflect different levels of health infrastructure, administrative capacity and resource allocation across the country. Therefore, the standardization of health policies in a decentralized system such as the Italian one may influence the outcomes of the implementation of the Decree.

Northen Regions (Lombardy and Veneto)

Among the northern regions of Italy, Lombardy (Italy), around 10 million inhabitants, and Veneto (Italy), 4,854,000 inhabitants, selected as the two most populous and economically advanced regions in northern Italy, have well-developed and efficient health infrastructures, which play a key role in the implementation of health policies and initiatives. These regions have often exceeded national targets in various health-related areas. Their vaccination programs have been particularly successful, with coverage rates of over 90% [9].

This efficiency highlights the strength of these regions' healthcare systems in monitoring public health trends and responding rapidly to emerging health threats. In addition, both Lombardy and Veneto have demonstrated a strong commitment to integrating environmental health into their health systems: increasing air quality monitoring infrastructure demonstrates their proactive approach to environmental risk management. These regions are now number one in the Italian health system.

Southern Regions (Calabria and Sicily)

Instead, the southern Italian regions continue to face significant obstacles to the full implementation of MD 77/22. Calabria (Italy, population: 1.850 million) and Sicily (Italy, population: 4.785 million) face persistent health service challenges, especially in rural areas where inequalities are more pronounced.

Several studies have highlighted substantial disparities in chronic disease management and healthcare access between Northern and Southern Italy. Southern regions exhibit significantly lower per-capita health expenditure and experience higher rates of unmet healthcare needs, largely due to cost barriers and limited local infrastructure – factors that translate into substantially reduced access compared with Northern regions [10].

This disparity highlights structural inequalities: insufficient healthcare personnel, inadequate facilities and poor funding hinder the development and expansion of health services in southern Regions, disproportionately affecting vulnerable populations as reported in other study [11].

Apulia's Innovative Model: Regulation No. 13 of 19 December 2023

Apulia is a notable exception to the trend observed in southern Italy, with its innovative approach "Regulation No. 13 of 19 December 2023" (Definition of models and standards for the development of territorial assistance) [4].

This regulation is an example of a forward-looking model for integrating environmental health determinants into public health strategies. It provides:

1. Environmental health integration: Apulia has effectively integrated environmental health concerns into its preventive strategies. For example, air quality monitoring and water safety inspections have been increased by 40%, contributing to a 25% reduction in

reported waterborne diseases. In addition, the Region addressed climate-related health risks by using predictive analysis to reduce heat-related hospital admissions by 12%;
2. Multidisciplinary cooperation: Apulia's success can also be attributed to its emphasis on multidisciplinary collaboration. Partnerships between health professionals, environmental scientists and local authorities have enabled a comprehensive response to public health challenges, in line with successful international models such as the German federal initiatives to integrate environmental health;
3. Community engagement: Apulia has prioritized community engagement by incorporating participatory forums, educational campaigns, and stakeholder consultations into its public health planning. This approach has doubled public participation in health planning processes and led to a 20% improvement in compliance with health advisories, demonstrating the value of citizen engagement in improving public health outcomes.

Recommendations for Addressing Regional Disparities

To effectively address the regional disparities in the implementation of MD 77/22, the following policy recommendations are proposed:

1. *Strengthening administrative capacity*: Investment in administrative capacity is essential to improve coordination and operational efficiency, especially in underperforming regions. Areas for investment should include human resources, training and digitalization. Training should focus on key areas such as epidemiological surveillance, prevention and management of chronic diseases, and effective resource allocation. By strengthening the administrative foundations, regions will be better equipped to implement health policies, ensure timely interventions and improve health outcomes;
2. *Institutionalize multidisciplinary cooperation*: Establishing formalized frameworks for interaction between different sectors, such as health, environmental science and local government, is essential to foster innovation and address complex health challenges. One such approach could be the creation of regional health-environment committees that work to integrate climate resilience strategies into health planning. These committees could serve as platforms for sharing expertise and coordinating efforts across sectors, ensuring that public health strategies are holistic and responsive to environmental factors that influence health outcomes;
3. *Improve community engagement*: Public health initiatives should prioritize community engagement through participatory models that seek to incorporate local feedback and culturally appropriate outreach strategies. Involving communities in the design and implementation of health interventions ensures that programs are more relevant to local needs. Particularly in regions vulnerable to climate-related health risks, health education campaigns are essential to raise awareness and encourage preventive health behaviours. Community involvement can promote fundamental and lasting changes in people's lifestyles;
4. *Incentivize Innovative Models*: To encourage the replication and dissemination of effective healthcare practices, financial and operational incentives should be introduced for regions that adopt innovative models, such as Apulia's Regulation 13/2023. These incentives would motivate regions to implement successful strategies and help standardize best practice across the country. The incorporation of environmental health considerations into public health policies, as demonstrated by Apulia, could serve as a model for other regions, fostering a cohesive national approach to healthcare that integrates both health and environmental determinants;
5. *Develop robust monitoring and evaluation systems*: The development of transparent and region-specific monitoring and evaluation systems is essential to ensure accountability and improve health service delivery. These systems should be designed to assess progress towards national and regional health targets, identify areas where inequalities persist and where interventions are most needed. Regular performance reviews and evaluations will help to monitor the effectiveness of policies implemented and promote continuous improvement in health services. The establishment of such systems is essential to maintain attention to health equity and ensure that the benefits of the Decree are distributed evenly across regions.

By implementing these recommendations, Italy can reduce regional inequalities, optimize health care and promote a more equitable and effective health system, in line with the objectives of MD 77/22.

Conclusions and Future Directions

Significant regional disparities have emerged since the implementation of MD 77/22. Northern regions, particularly Lombardy and Veneto, have shown strong performance on key health indicators, reflecting the benefits of consolidated health infrastructure, sustained financial investment and administrative efficiency. In contrast, southern regions, including Calabria and Sicily, face significant challenges: vaccination coverage, chronic disease management services and investments in health infrastructure. With Regulation 13/2023, Apulia emerged as a notable exception, offering an innovative and effective model to address systemic gaps. Through effective multidisciplinary collaboration between health professionals, environmental experts and local authorities, has integrated environmental health into the public health framework, focusing on monitoring air and water quality and proactively managing climate change risks. This approach is in line with global frameworks, such as the WHO's Health in All Policies (HiAP) and the UN's Sustainable Development Goals (SDGs). Following successful international models, it has led to significant improvements, including a 25% reduction in waterborne diseases and a 12% reduction in heatwave-related hospital admissions. In addition, Apulia's commitment to community engagement through educational campaigns and participatory forums led to a 20% increase in public participation in health planning and improved compliance with health advisories. Unexpectedly, our study also found that integrating environmental determinants, supported by predictive analytics, not only helped address immediate health risks, but also built long-term resilience to climate-related challenges. These findings highlight the potential of community-led strategies to build trust, align public policies with local needs, and promote sustainable health improvements. The authors are aware of some limitations and weaknesses of this study: variability in data quality across regions, limited long-term evaluations of interventions provided for in Apulia by Regulation 13/2023, and difficulties in establishing causal relationships between policy implementation and health outcomes. These limitations should be addressed in future research exploring standardized frameworks for multidisciplinary and interdisciplinary collaboration. However, the observed differences and successes points to several strategies that can be considered for future development: strengthening administrative capacity; investing in staff, training and digital infrastructure; improvement of health education campaigns and evaluation of the long-term results of integrating preventive health care with environmental hygiene policies. By addressing these challenges, Italy and other decentralized systems can move closer to achieving equitable access to preventive care and strengthening resilience to emerging health risks. Apulia, with its innovative model, shows how the integration of environmental health and community engagement can fill systemic gaps and lead to improvements in health and, consequently, lifestyles. There is also a need for more comprehensive data collection and monitoring systems that can assess both the qualitative and quantitative aspects of policy implementation to reduce inequality. Finally, given the growing challenges posed by climate change, more research is needed to assess how public health systems can not only better integrate climate resilience into their strategies but also be better prepared to respond to future health crises. Thanks to health literacy, it is now possible to improve people's ability to understand and use health information, to make healthy choices and to participate actively in local health systems [12-14].

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Conflict of Interest statement

The authors declare no conflicts of interest.

Authors' contributions

Conceptualization, MFP, GL, RMR and VB; formal analysis, MFP, GL, MRR and VB; writing-original draft preparation, MTM, MFP, GL, RMR and VB; writing-review and editing, MTM, MFP, GL, RMR, ADL, FT and VB; supervision, MTM, MFP, and ODG. All authors have read and agreed to the published version of the manuscript.

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Correspondence: Giovanna Liguori, Local Health Authority, Foggia, 71121, Italy. E-mail: Giovanna.liguori@aslfg.it; Maria Teresa Montagna, Department of Biomedical Sciences and Human Oncology, University of Bari Aldo Moro, Piazza Umberto I, 70121, Bari, Italy. E-mail: mariateresa.montagna@uniba.it.

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HISTORY OF MEDICINE AND ETHICS

1985: Forty years ago, the world opened its eyes to AIDS. History of the early years of the HIV epidemic

DAVIDE ORSINI[1], MARIANO MARTINI[2,3,4]
[1] University Museum System of Siena, History of Medicine, University of Siena, Siena, Italy;
[2] Department of Health Sciences, University of Genoa, Italy;
[3] Interuniversity Research Center on Influenza and Other Transmissible Infections (CIRI-IT), Genoa, Italy;
[4] UNESCO Chair "Anthropology of Health - Biosphere and Healing System", University of Genoa, Genova, Italy

Key words

1985 • History of Infectious Diseases • HIV • AIDS • Public Health • Hygiene • Epidemic

Summary

At the end of 1980, Michael Gottlieb, a researcher at the University of California, was conducting a clinical study on deficiencies of the immune system when he heard of the case of a young man with a rare form of pneumonia due to Pneumocystis carinii (now known as Pneumocystis jirovecii), a protozoon that usually affects only people with a weakened immune system [1]. In the following months, Gottlieb discovered further cases of patients with Pneumocystis carinii pneumonia, oral candidiasis and a very low level of T lymphocytes. All were male and active homosexuals [2]. In reality the infection had already manifested itself in previous years but had always been mistaken for something else [3].

HIV probably originated from a virus found in chimpanzees and began infecting humans in the first half of the 20th century. It probably emerged when members of the Bantu tribe, who lived in the forests of central Africa, consumed chimpanzee meat infected with a virus called simian immunodeficiency virus (SIV). This may have caused a so-called spillover from chimpanzees to humans [4, 5].

Introduction

The first confirmed case of HIV positivity dates back to 1959; a blood sample taken from a man from Léopoldville (now Kinshasa, in the Democratic Republic of Congo), when analysed 30 years later, was found to contain antibodies to HIV-1 [6]. The virus began to circulate, reaching Haiti in the mid-1960s [7] and arriving in the United States in 1969, about 12 years before the disease was discovered in 1981, as reported by the evolutionary biologist Michael Worobey of the University of Arizona [8].

On June 5, 1981, the Morbidity and Mortality Weekly Report (MMWR), a weekly epidemiological digest for the United States published by the Centers for the Disease Control and Prevention (CDC), reported five unexplained cases of *Pneumocystis carinii* pneumonia in previously healthy individuals at three Los Angeles hospitals.

"The diagnosis of Pneumocystis pneumonia was confirmed for all 5 patients antemortem by closed or open lung biopsy. The patients did not know each other and had no known common contacts or knowledge of sexual partners who had had similar illnesses. Two of the 5 reported having frequent homosexual contacts with various partners. All 5 reported using inhalant drugs, and 1 reported parenteral drug abuse. […] The fact that these patients were all homosexuals suggests an association between some aspect of a homosexual lifestyle or disease acquired through sexual contact and Pneumocystis pneumonia in this population." [9]

In the general public's view, this connection inextricably linked the contagion to stigmatized, transgressive behavior and the disease immediately became a potentially discriminatory condition [10].

In the following months, a New York dermatologist, Alvin E. Friedman-Kien, reported to the CDC several cases of patients suffering from a rare tumor of the blood vessels, Kaposi's sarcoma. "Between June 1, 1981, and May 28, 1982, the CDC received reports of 355 cases of Kaposi's sarcoma (KS) and/or serious opportunistic infections (OI), especially *Pneumocystis carinii* pneumonia (PCP), occurring in previously healthy persons between 15 and 60 years of age. Of the 355, 281 (79%) were homosexual (or bisexual) men, 41 (12%) were heterosexual men, 20 (6%) were men of unknown sexual orientation, and 13 (4%) were heterosexual women." [11]

The *Centers for Disease Control and Prevention* set up a task force specifically dedicated to research on Kaposi's sarcoma and other opportunistic infections. The most widely accredited hypothesis was that the disease only affected homosexuals, as the New York Times headlined on July 3, 1981: "Rare cancer seen in 41 homosexuals". At this point, the term "gay cancer" entered the public lexicon. This led to the categorization of Gay-Related Immune Deficiency – GRID, and the identification of specific risk categories such as homosexuals, heroin users and hemophiliacs [12].

Although the modes of transmission and contagion were unclear, the hypothesis that the disease had a viral origin was beginning to gain sway among researchers. In

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August 1982, during a conference sponsored by the Food and Drug Administration (FDA), the term "acquired immunodeficiency syndrome" (AIDS) was coined to describe the terminal clinical stage of HIV infection. This term indicated a syndrome of non-hereditary origin, acquired through a still-unknown transmission mechanism, which resulted in deficiency of the immune system.

However, only when so-called heterosexual people began dying of AIDS did the global perception of the disease begin to change. It also transpired that the initial involvement of the gay community was fortuitous, though society did not change its negative view of those affected by the disease. Indeed, it was difficult, if not impossible, to separate AIDS and homosexuality in the mind of the public at that time.

Meanwhile, from a research perspective, in May 1983 the French virologist Luc Montagnier (1932-2022) and Françoise Barré Sinoussi (b. 1947) (Fig. 1-2) at the Pasteur Institute in Paris isolated a new virus that was suspected of being the agent responsible for the transmission of the disease. Having been sent to the CDC in Atlanta, the virus was analyzed and named LAV (Lymphadenopathy-Associated Virus) [13] but was renamed HIV (human immunodeficiency virus) three years later. Luc Montagnier and the Françoise Barré Sinoussi therefore announced in the scientific journal "Science" their discovery of the virus that causes AIDS (acquired immunodeficiency syndrome). It was a retrovirus, a type of virus with RNA as genetic material, rather than the usual DNA [14].

A year later, on April 22, 1984, the CDC publicly stated that the French LAV virus had been definitively identified as the cause of AIDS by researchers at the Pasteur Institute.

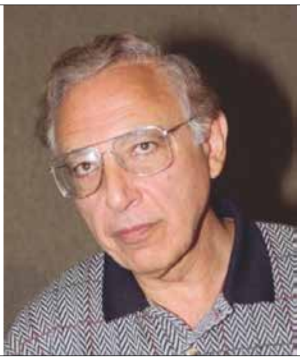
The following day, however, Health and Human Services announced that Robert Gallo (b. 1937) (Fig. 3), the director of the *National Cancer Institute's Laboratory of Tumor Cell Biology,* had isolated from AIDS patients a virus that was a candidate for causing the disease, calling it HTLV-III (Human T-cell leukemia virus type III) [15,16,17,18], the first human retrovirus ever discovered.

Thus began a scientific and legal battle between the two prestigious research institutes, both of which claimed credit for the discovery. Finally, in 2008, Luc Montagnier and Françoise Barré-Sinoussi, researchers at the Pasteur Institute in Paris, were awarded the Nobel Prize for Medicine "for their discovery of human immunodeficiency virus" [19].

Fig. 1. Luc Montagnier (1932-2022) - (Public Domain - Wikipedia commons).

Fig. 2. Françoise Barré-Sinoussi (born in 1947) - (Public Domain - Wikipedia commons).

Fig. 3. Robert Gallo (b. 1937) - (Public Domain - Wikipedia commons).



Stigmatization of people with HIV: from the ignorance of the 1980s to today's U=U equation

In 1985, exactly 40 years ago, public awareness began to change, as it emerged that a disease which for some years had afflicted subjects who engaged in risky behaviors linked to the sexual sphere and the use of drugs also affected other categories.

On July 25, 1985, the American actor Rock Hudson (1925-1990) was hospitalized after collapsing in Paris, where he had gone for experimental treatment at the American Hospital and the Pasteur Institute. He instructed his staff to issue a press release officially announcing that he had AIDS, a diagnosis that he had received a year earlier, on June 5, 1984.

Hudson had never revealed his homosexuality, which was known to only a few. Even when the signs of AIDS began to show, he denied his illness for more than a year, claiming variously to be suffering from anemia, anorexia nervosa and liver cancer. Indeed, Hollywood's

Fig. 4. Rock Hudson, pictured with Elizabeth Taylor in *Giant*, 1956 (Public Domain - Wikipedia commons).

film industry would never have allowed the news to come out, as it would have destroyed the virile image with which the public, especially women, identified the actor (Fig. 4).

Hudson's revelation of his illness, and subsequently of his homosexuality, marked a turning point in the public's perception of the AIDS epidemic. The case became a worldwide media sensation and had an immediate impact on the visibility of AIDS, while a wave of panic spread everywhere. The hospital where the actor was hospitalized immediately emptied, owing to fear of contagion. Moreover, when Hudson wanted to return to the United States, no airline would accept him as a passenger; indeed, his entourage was forced to book an entire flight just for him.

With the panic surrounding a disease that was little known and incurable at the time, prejudice against HIV-infected subjects was rife, a prejudice that was to last for years. Even the widespread media campaigns of the 1980s and 1990s failed to eliminate the stigma attached to AIDS patients, though they did increase public awareness of risky behaviors.

Today, the main problem is no longer the virus itself, but the people around HIV sufferers, who often have narrow-minded and judgemental attitudes. Over the last 40 years, science has made enormous progress, and AIDS can now be considered a chronic disease. Indeed, specific antiretroviral therapies (ART) are able to reduce the viral load to undetectable levels (plasma HIV-RNA < 200 copies/mL).

Thus, the risk that an HIV-positive subject on antiretroviral therapy with stably suppressed viremia can transmit the virus through unprotected sexual intercourse is zero, as stated by the World Health Organization: "People living with HIV who are taking ART and have an undetectable viral load will not transmit HIV to their sexual partners" [20].

Society's acceptance of the equation U=U ("undetectable=untransmittable") could be an important factor in reducing the stigma that has plagued HIV carriers for decades. It could also put an end to the internalization of the social stigma that has often caused these people to consider themselves potential spreaders of the virus. On November 12, 2019, the *"Italian Consensus Conference on UequalsU"* was held at the Ministry of Health in Rome, marking a historic step for Italy too. The leading Italian scientific communities involved in research into HIV, together with other associations and communities, officially recognized the validity of the U=U principle.

Despite that, "a new global study presented this week at the 13th IAS Conference on HIV Science in Kigali (IAS 2025) has revealed that 50 countries around the world continue to enforce HIV-related travel and residence restrictions, in clear violation of international human rights principles. The data, shared by the HIV Justice Network through its new platform *Positive Destinations*, highlights the persistence of discriminatory laws and policies that prevent people living with HIV from freely travelling, working, studying, or settling in many parts of the world" [21, 22].

"These restrictions, rooted in stigma and outdated public health thinking, obstruct access to healthcare, employment, education, and family unity - said Edwin J Bernard, HIV Justice Network's Executive Director." [22]

The epidemic spreads among heterosexuals, drug users and hemophiliacs

In 1985, the epidemic entered its "third phase". After the first, "hidden", phase in the 1960s and 1970s, and the second phase in the early 1980s, when the disease spread almost exclusively among homosexuals, the epidemic exploded in the mid-1980s among drug addicts in central and southern Europe, the United States, India and many other regions of Asia and Africa. Indeed, while most AIDS cases were reported among homosexual and bisexual men, the infection was beginning to spread to heterosexuals and intravenous drug users.

That same year, the World Health Organization began collecting systematic data on AIDS cases, recording 5,967 cases of AIDS, the final stage of the disease when the immune system is severely compromised. However, this figure represents only diagnosed and reported cases; realistically, the actual number of people infected with HIV was much higher.

Again in 1985, epidemiologists began to hypothesize that the disease could also be spread through blood products, with serious implications for hemophiliacs, who periodically received concentrates produced from large batches (pools) of plasma, much of which had been collected in the late 1970s and early 1980s, before the first cases of AIDS had even been detected.

An emblematic case was that of Ryan White (1971-1990), a boy from Indiana who contracted HIV following a blood transfusion [23].

Ryan suffered from hemophilia A, a condition that prevents blood from clotting and is characterized by frequent bleeding. For this reason, he regularly underwent blood transfusions. In 1984, when he was only 13 years old, he was hospitalized with pneumonia. During routine tests, he was found to be HIV-positive.

Fig. 5. President Barack Obama signs the Ryan White HIV/AIDS Treatment Extension Act of 2009. (Public Domain - Wikipedia commons).

Ryan had been infected during one of the many blood transfusions he was forced to undergo in order to survive. On July 27, 1985, he was denied entry to school. His family's legal battle to protect his right to attend school brought the issue of AIDS into the national spotlight. The boy fought this stigma with uncommon courage. He chose to speak out publicly about the need for AIDS education, becoming a veritable living emblem of the fight against the disease and the stigma associated with it.

Despite the fact that doctors had given Ryan only six months to live, he survived until 1990, participating in numerous fundraising events for AIDS research, supported by various music and entertainment celebrities, including Elton John and Michael Jackson. His testimony was crucial to making people understand that AIDS was not a disease that affected only homosexuals.

In 1990, shortly after Ryan's death, the U.S. Congress passed the Ryan White Care Act to support care for people with AIDS who do not have adequate health insurance or other resources (Fig. 5).

In March 1985, perhaps also in the wake of the Ryan White case, the US Food and Drug Administration authorized the first blood test, the Enzyme-Linked Immunosorbent Assay (ELISA), which indicates the presence of specific antibodies that the immune system creates after contact with the HIV virus. American blood banks then began to test the batches of blood in their possession.

In the same year, Europe also adopted these control practices, introducing specific HIV tests and improving transfusion safety. Unfortunately, however, effective tests for detecting HIV in blood did not immediately become available in all European countries. In Italy, on 17 July 1985, the General Directorate of the Public Health Service issued a circular urging that every unit of donated blood be tested for the presence of anti-LAV/HTLV-III antibodies, in the same way as the HIV viruses had initially been identified [24]. Nevertheless, determination of the presence of the HIV virus in the blood units collected became mandatory only through Law no. 531 of 29 December 1987 [25].

The First International Conference on AIDS

In 1985, the first International Conference on Acquired Immunodeficiency Syndrome (AIDS) was also held; from April 15 to 17, over 3,000 participants from 50 countries gathered in Atlanta. This provided an opportunity to discuss the clinical progression of the disease, the modes of virus transmission, epidemiological trends, and HIV testing. The conference was followed by a meeting organized by the World Health Organization on April 18 and 19, during which participants reviewed the information presented at the conference and assessed its international health implications. Evidence of this work can be found in its *Memorandum* [26]. This document initially provides a significant overview of the situation of the syndrome since its recognition in 1981.

"Since the first recognition of the acquired immunodeficiency syndrome (AIDS) in 1981, nearly 11,000 cases have been reported, mainly from the industrial countries. More than 80% of cases recorded to date have been reported from the USA. AIDS presents a major health problem in Haiti, and the reported incidence of the disease is increasing in Brazil and Canada. While six countries in Europe (Denmark, France, Federal Republic of Germany, Netherlands, Switzerland and the United Kingdom) have reported increasing numbers of cases since 1981, there have been relatively few cases from countries in Asia and the Western Pacific region (except Australia). Recent information indicates that AIDS may be a serious public health problem in tropical Africa; estimated incidence rates in some central African cities are comparable to those in New York or San Francisco, and cases have been identified in residents or migrants from over a dozen African countries." [26]

The passage regarding the social groups affected by the disease is interesting: "In North America, Europe, and Australia, homosexual men account for at least 70% of the total of detected AIDS cases. The disease has also been noted in intravenous drug abusers, hemophiliacs, recipients of blood transfusion, and the heterosexual partners or infants of patients or members of groups at increased risk of infection. Studies undertaken in Haiti and central Africa and among emigrants from these countries show that the disease is occurring mainly in the heterosexual population. Heterosexual contact in these populations is a major risk factor for transmission of infection." [26]

But the most important part is certainly the passage concerning recommendations, information, and health education, which are considered essential to stemming the ever-increasing spread of the virus.

"Control measures for AIDS will differ from country to country, but the most promising means of limiting the spread of LAV/HTLV-III infection is through education aimed at altering the behavior and practices of certain individuals. Information about the disease, probable routes of transmission, and ways to reduce the risk of infection should be widely disseminated in the community and to groups at increased risk of infection. This information should be presented so that it can be easily understood. The public should be informed that there is no evidence of spread by the airborne route, by casual social contacts with infected persons (even within households), and by food, or to health care workers who are not in the high-risk group." [26]

While the various groups at high risk of infection are still mentioned, the document stresses that although "the highest prevalence of infection and disease in some countries is among homosexual or bisexual men, in others heterosexual transmission is equally or more important" [26].

The most noteworthy recommendations are:

- the use of condoms, although the document states that "The use of condoms may prevent the spread of infection", but adds that "this has not yet been documented";
- advice to infected women not to become pregnant "because this may exacerbate the disease, and infection may spread to the fetus or infant" [26].

In this regard, on December 6 CDC published a Morbidity and Mortality Weekly Report with recommendations on preventing mother-to-child transmission of HIV. They include: delaying pregnancy until more is known about the risks of transmission and avoiding breastfeeding [27].

At the international level, the *Memorandum* of the meeting organized by the World Health Organization on 18 and 19 April 1985 highlights some interventions to be undertaken worldwide: "establish a network of collaborating centers with special expertise in the field; coordinate global surveillance of AIDS; assist in the development of an effective vaccine; encourage and assist in periodic serological studies in countries where AIDS has yet to be recognized, and ensure the collection of comparable data and representative selections of sera" [26].

In addition, each country was urged to carry out specific interventions, the first and most fundamental being that of providing information: "inform the public that LAV/HTLV-III infection is acquired through heterosexual and homosexual intercourse, sharing of needles by intravenous drug abusers, transfusion of contaminated blood and blood products, transmission from mothers to their babies, and probably through repeated use of needles and other non-sterile instruments that pierce the skin or mucous membranes. Information should be provided about the risk of LAV/HTLV-III infection and AIDS, especially to those men and women who may be at increased risk because of multiple sexual partners". And again, "ensure that health care workers are informed about AIDS and LAV/HTLV-II infection, the modes of transmission and clinical spectrum, the available programs of management, including psychosocial support, and the methods for prevention and control" [26].

Each country was also to assess the risk that AIDS constitutes for its population, establish specific diagnostic methods, screen potential blood and plasma donors for the presence of antibodies against the virus, and provide potential donors of organs, blood, sperm or other human material with precise information on AIDS. Finally, it was deemed essential for each country to refer HIV-positive individuals for medical evaluation: "[…] develops guidelines for the total care of AIDS patients and for handling specimens from them in hospital and other settings. These guidelines should be similar to those which are in use for the care of patients with hepatitis B. And lastly, develops codes of good laboratory practice to protect staff against the risk of infection" [26].

The 1985 AIDS Conference in Atlanta therefore marked a turning point in the global approach to preventing and managing the epidemic. It constituted a crucial step in the fight against the disease, highlighted the importance of information and education, helped to raise public awareness of AIDS, and sought to reduce the stigma and promote solidarity with those affected by the disease.

In the same year, on August 31, the Pentagon announced that, starting on October 1, all new military recruits would be tested for the infection. On September 17, the U.S. President Ronald Reagan (1911-2004) publicly mentioned AIDS for the first time, calling it "a top priority" [28].

And on October 2, the U.S. Congress allocated nearly $190 million to AIDS research.

Nevertheless, the public's attitude towards AIDS patients did not change. Indeed, on October 25, the New York State Board of Public Health authorized local health officials to close "gay bathhouses, bars, clubs, and other places where "high-risk sexual activity takes place." Moreover, 1985 ended with a Los Angeles Times poll on December 19, which revealed that a majority of Americans favored quarantine for people with AIDS [28].

Stigma has accompanied AIDS since its first manifestations [29] and absurdly, "ending the AIDS epidemic by 2030 will require addressing stigma more systematically and on a larger scale than current efforts" [30].

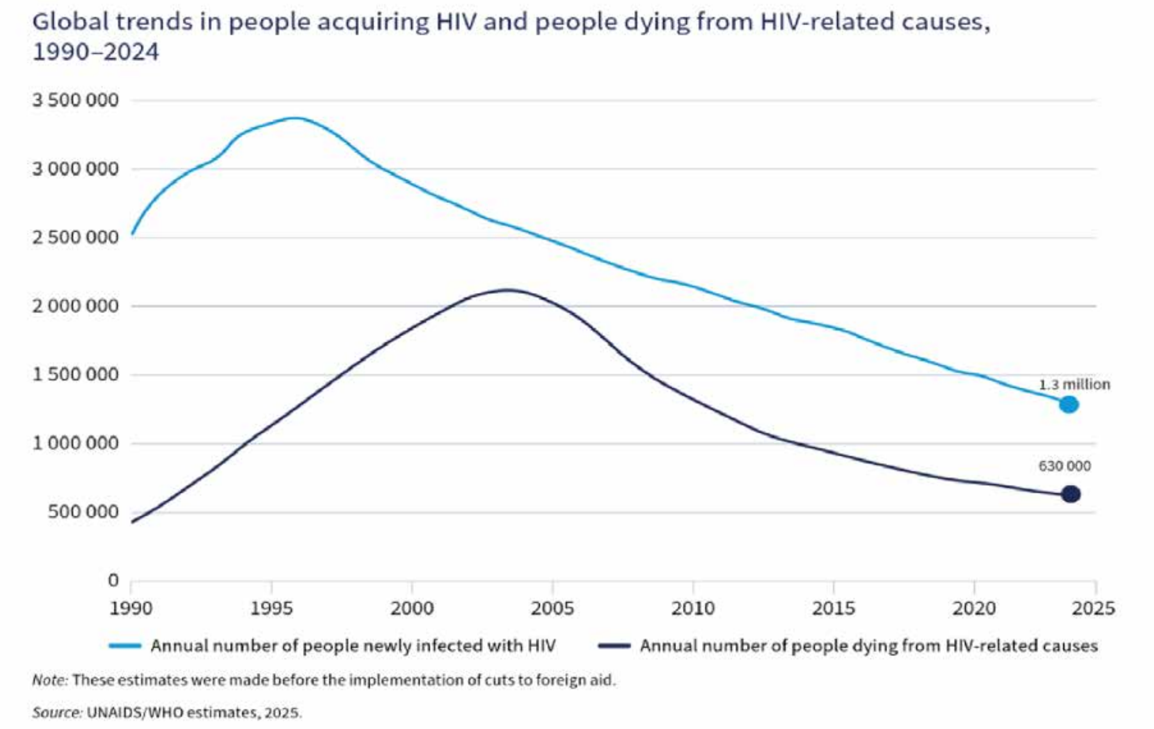
"The problem of human immunodeficiency virus (HIV) /acquired immunodeficiency syndrome (AIDS) is increasingly complex, including not only health-related concerns but also rampant stigma and discrimination, further exacerbating the health and social conditions of the affected individuals" [31].

A look at current data and the possibilities of new drugs

We can conclude this article by highlighting some significant data on the disease and its spread in the 40 years since 1985, which, as mentioned above, was a fundamental turning point in the history of AIDS.

Since the epidemic started, 91.4 million [73.4 million–116.4 million] people have been infected with HIV, and 44.1 million [37.6 million–53.4 million] have died from AIDS-related illnesses [32]. Approximately 40.8 million [37.0–45.6 million] people were living with HIV at the end of 2024; of these, 1.4 million were children under the age of 15 years. In 2024, 1.3

Fig. 6. Global trends in people acquiring HIV and people dying from HIV-related causes, 1990–2024 (source: UNAIDS/WHO estimates, 2025).



Note: These estimates were made before the implementation of cuts to foreign aid.

Source: UNAIDS/WHO estimates, 2025.

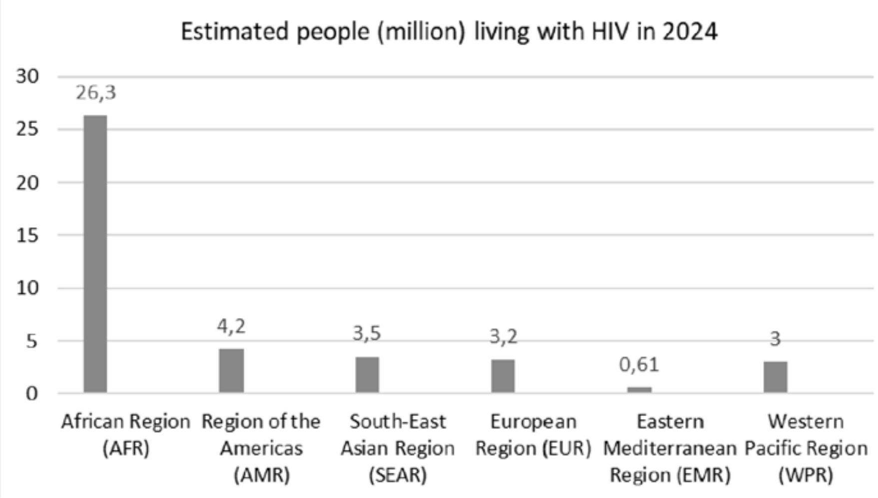
million [1.0–1.7 million] people acquired HIV and 630,000 [490,000-820,000] died from HIV-related causes globally; of these, 75,000 were children under the age of 15 years [33]. Since 2010, the number of people acquiring HIV has declined by 40%, from 2.2 million [1.7-2.8 million] [32] (Fig. 6).

It should be pointed out that, thanks to information campaigns and the introduction of specific drugs, in particular antiretroviral drugs in 1997, "since 2010, the number of people acquiring HIV has been reduced by 40%, from 2.2 million [1.7–2.8 million] and HIV-related deaths have been reduced by 54%, from 1.4 million [1.1 million–1.8 million]" [32]. The figure below shows the estimated number of HIV-positive subjects in 2024 in the various WHO Regions (Fig. 7).

Although the trend observed offers hope for a solution to the HIV epidemic, the numbers of new diagnoses oblige us to remain vigilant.

The UnAIDS Global AIDS Report 2024, "The Urgency of Now: AIDS at a Crossroads", highlights significant progress in some regions, especially sub-Saharan Africa, where new HIV infections have decreased by 56 percent

Fig. 7. Estimated people (million) living with HIV in 2024 (source: UNAIDS/WHO estimates, 2025).



since 2010, thanks to effective prevention, education, and treatment programs.

However, “three regions are experiencing rising numbers of new HIV infections: eastern Europe and central Asia, Latin America, and the Middle East and North Africa. For the first time in the history of the HIV pandemic, more new infections are occurring outside sub-Saharan Africa than in sub-Saharan Africa” [34].

In this regard last August 26th the Centre for Health Protection (CHP) of the Department of Health (DH) announced that a total of 180 new cases of Human Immunodeficiency Virus (HIV) infection and 47 new cases of Acquired Immunodeficiency Syndrome (AIDS) were reported in the first half of 2025 in Hong Kong [35].

The occurrence of such situations highlights the lack of adequate prevention in these regions and underscores the importance of a global, coordinated response tailored to specific local situations.

Careful vigilance is also needed to address an international funding crisis for HIV research, communication, and prevention efforts. “Discontinuation of international financial support for HIV has potential to jeopardise decades of steady yearon-year progress in reducing new HIV infections and deaths, especially in sub-Saharan Africa. Even under optimal mitigation scenarios, stopping large-scale funding could unravel 10–15 years of progress within a few years [...]. In the worst-case scenario, if PEPFAR funding were ceased entirely and no equivalent mechanism replaced it, surges in HIV incidence could potentially undo nearly all progress achieved since 2000” [36].

Further hope is engendered by a drug that was presented only a few months ago, and which offers a promising option for pre-exposure prophylaxis (PrEP). Indeed, on June 18, 2025, the Food and Drug Administration approved a twice-yearly injection that provided a near-perfect shield against HIV infection in clinical trials [37].

The new drug, based on the molecule Lenacapavir, seems to be able to effectively contribute to putting an end to the epidemic on a global scale: a possibility that comes at a time when sexually transmitted diseases such as AIDS are increasing dangerously among young people.

“This milestone follows promising 2024 results from the PURPOSE 1 and PURPOSE 2 trials, which demonstrated the safety and efficacy of lenacapavir across diverse populations and settings. Administered just twice a year, lenacapavir offers sustained protection and adds to the growing range of HIV prevention options”. [37]

In the introduction to the guidelines for injectable lenacapavir, which the World Health Organization published last July 14, there is a passage that concludes this article well: “To end HIV as an epidemic, focus is needed on a comprehensive approach that includes combination HIV prevention. This includes biomedical options such as HIV testing, preexposure prophylaxis (PrEP), post-exposure prophylaxis (PEP), voluntary medical male circumcision and condom promotion. Rapid, wider access to PrEP and its effective use could significantly reduce the number of new HIV infections, especially among key populations and people in areas where HIV incidence is high” [38].

For this to happen, what is needed is significant funding, clear decisions by governments, and a further concerted effort by all to fight HIV alongside those affected by it.

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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

DO: conceived the study; DO & MM: designed the study; drafted the manuscript; performed a search of the literature; revised the manuscript; conceptualization and methodology; investigation and data curation; original draft preparation; review; editing. All authors have read and approved the latest version of the paper for publication.

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Correspondence: Davide Orsini, via Pier Andrea Mattioli, 4/B 53100 Siena Italy (IT). E-mail: davide.orsini@unisi.it

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